

Trade journal for all aspects of pharmaceutical law

Official organ of the German Pharmaceutical Law Day

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In cooperation with the Research
Center for Pharmaceutical Law at
Philipps University of Marburg

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Essays

Dr. Marco Stief, LL. M.*

EU pharmaceutical package: Background, current status, and prospects

The pharmaceutical strategy announced by the European Commission in November 2020 and presented on April 26, 2023 as a reform of general EU pharmaceutical legislation² cleared a decisive hurdle on December 11, 2025: the Council and the European Parliament reached a provisional political agreement in trilogue on the so-called pharmaceutical package (directive and regulation).³ The agreement is still subject to formal approval by both institutions.

legislator and will only become legally effective upon publication in the Official Journal.

The new regulation will amend or replace Directive 2001/83/EC⁴ and Regulations No. 726/2004/EC⁵, No. 141/2000/EC⁶ on orphan medicinal products, and No. 1901/2006/EC⁷ (medicinal products for paediatric use).⁸ The most significant reform in 20 years aims to promote innovation, improve security of supply, strengthen competitiveness, and facilitate access to medicines in the EU.⁹

* The author is a lawyer and partner in the Munich office of Maiwald, where he heads the legal department, www.maiwald.eu.

- 1 See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions of November 25, 2020, COM (2020) 761 final, available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A52020DC0761>, last accessed on January 12, 2026. See also the European Commission press release of November 25, 2020, available at https://ec.europa.eu/commission/presscorner/detail/de/ip_20_2173, last accessed on January 12, 2026.
- 2 See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions of April 26, 2023, COM(2023) 190 final, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023DC0190&qid=1767716662121>, last accessed on January 12, 2026. See also the European Commission press release of April 26, 2023, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_1843, last accessed on January 12, 2026.
- 3 See press release from the European Commission dated 11. 12 December 2025, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_25_3015, last accessed on 12. 1. 2026.

- 4 Directive 2001/83/EC of the European Parliament and of the Council of November 6, 2001, on the creation of a Community index for medicinal products for human use (OJ 2001 L 311, 67).
- 5 Regulation (EC) No. 726/2004 of the European Parliament and of the Council of March 31, 2004, laying down Union procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, 1).
- 6 Regulation (EC) No. 141/2000 of the European Parliament and of the Council of December 16, 1999, on orphan medicinal products (OJ 2000 L 18, 1).
- 7 Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of December 12, 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directives 2001/20/EC and 2001/83/EC and Regulation (EC) No. 726/2004 (OJ 2006 L 378, 1).
- 8 See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions of April 26, 2023, COM (2023) 190 final, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023DC0190&qid=1767716662121>, last accessed on January 12, 2026.

The key points communicated publicly to date reveal, above all, the duration of regulatory document and market protection, which was particularly controversial in the trilogue: eight years of document protection are planned, accompanied by one year of market protection. Under certain conditions, this market protection can be extended for a further year.¹⁰ In addition, the publications to date contain only brief statements on the availability and security of supply of medicinal products, the design of the "Bolar" exception, and measures and incentive mechanisms in connection with antimicrobial resistance.¹¹

The key points currently published already allow for a reliable assessment of the significant political changes in direction compared to the Commission's draft. However, a final detailed assessment will have to wait until the final consolidated text of the law has been completed following legal review and formal adoption.

The following section first discusses the background to the EU pharmaceutical package, then critically examines the most important changes, and finally provides an international assessment, including a possible impact analysis of the pharmaceutical package.

I. Background to the EU pharmaceutical package

Pharmaceutical regulation at the EU level has developed continuously since the 1960s and today represents a complex, largely harmonized legal framework. The starting point was Directive 65/65/EEC¹³, which was introduced in 1965 in response to the thalidomide scandal¹⁴ and initiated a Community marketing authorization procedure for medicinal products. This was followed by the first systematization of the requirements for the quality, safety, and efficacy of medicinal products

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The last major reform of pharmaceutical law came into force in 2004.¹⁶ The European Union strengthened centralised authorisation by the EMA, improved drug safety through extended reporting requirements and systematic monitoring, shortened authorisation periods and specified the various forms of market exclusivity as an incentive for innovation.

Almost 20 years later the COVID-19 pandemic in particular has exposed structural weaknesses: a comprehensive supply of medicines could not be reliably guaranteed in the event of a crisis. This was due to the fact that a significant proportion of active ingredient and drug production (mainly for ^{cost reasons}) had been relocated to Asia, particularly India. If global supply chains are disrupted, this leads directly to supply bottlenecks and in extreme cases to supply shortages.

In November 2020, the Commission announced

- 9 European Council, Council of the European Union, The "medicines package": new EU rules for medicines, as of December 12, 2025, available at <https://www.consilium.europa.eu/en/policies/pharma-pack/>, last accessed on January 12, 2026.
- 10 See press release from the European Council and the Council of the European Union dated December 11, 2025, available at <https://www.consilium.europa.eu/de/press/press-releases/2025/12/11/pharma-package-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>, last accessed on January 12, 2026.
- 11 See press release from the European Council and the Council of the European Union dated December 11, 2025, available at <https://www.consilium.europa.eu/de/press/press-releases/2025/12/11/pharma-package-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>, last accessed on January 12, 2026.
- 12 Detailed comparison of the current legal situation with the preliminary Commission drafts S. Stief/Grabow, Quo vadis Arzneimittelrecht — ein Überblick zur Überarbeitung der EU-Arzneimittelvorschriften (Quo vadis pharmaceutical law — an overview of the revision of EU pharmaceutical regulations), PharmR 2023, 317.
- 13 Council Directive 65/65/EEC of January 26, 1965, on the approximation of provisions laid down by law, regulation, or administrative action relating to proprietary medicinal products (OJ 1965 No. 22, 369), repealed since December 17, 2001 by Directive 2001/83/EC (OJ 2001 L 311, 67).

- 14 At that time, only registration was required for drug approval. Clinical trials or special testing procedures were not necessary. The administration of the sleeping pill and sedative thalidomide to pregnant women led to severe malformations in thousands of children. Contergan was withdrawn from the market in 1961. The scandal led to stricter approval regulations internationally. See the information webpage of the Contergan manufacturer Grünenthal <https://www.contergan-skandal.de/de-de/der-contergan-skandal/>, last accessed on January 12, 2026.
- 15 See the BfArM article on the thalidomide scandal at: https://www.bfarm.de/EN/BfArM/Organisation/History/_node.html?utm_source=chatgpt.com, last accessed on January 12, 2026.
- 16 Regulation (EC) No. 726/2004 of the European Parliament and of the Council of March 31, 2004, laying down Union procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, 1).
- 17 The Commission also addresses Russia's war of aggression against Ukraine and rising inflation rates, see Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions of April 26, 2023, COM (2023) 190 final, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023DC0190&qid=1767716662121>, last accessed on January 12, 2026.
- 18 Detailed biased statement on current problems in the supply of medicines from the perspective of generic drug companies, Pro Generika e.V., On the 2021 federal election: What politicians should do now, as of September 2021, available at <https://www.progenerika.de/news/corona-pandemie-das-sollte-politik-jetzt-tun/>, last accessed on January 12, 2026.
- 19 See Laschet, Generika: So riskant ist die Abhängigkeit von Asien (Generic drugs: The risks of dependence on Asia), hautnah dermatologie 2021, p. 14 f., available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC7970747/#:~:text=These%20permissions%20are%20granted%20for,19%20as%20a%20global%20pandemic.&text=Almost%20two%20thirds%20of%20the%203,788,only%20up%20to%20%C3%BCnf%20approvals.&text=It%20was%20a%20trivial%20medical%20device,mainly%20patent-free%20medicines>, last accessed on January 12, 2026, p. Pro Generika e. V., Global Chain Reaction, available at: <https://www.progenerika.de/lieferketten/>, last accessed on January 12, 2026.

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to present a new pharmaceutical strategy.²¹ This "Pharmaceutical Strategy for Europe"²² aims at a far-reaching reform of the legal framework in order to ensure the resilience of the supply of medicines and to secure Europe's competitiveness in the future compared to its major competitors from the US and China.²³

The proposals have since been debated in the ordinary legislative procedure. The European Commission adopted the proposed regulation and directive on

April 26, 2023,²⁴ whereupon the European Parliament adopted its position in April 2024. In June 2025, the Council agreed on a general approach as a negotiating mandate.²⁵ On this basis, the Commission, Parliament, and

Council in the subsequent trilogue negotiations on December 11, 2025.

II. Objectives of the EU legislator

The pharmaceutical package essentially pursues four objectives:

1. Firstly, it aims to ensure faster and fairer access to affordable, effective, and safe medicines across the EU.

2. Secondly, the package aims to significantly strengthen security of supply in crisis situations and to establish more robust response mechanisms. The shortcomings revealed by the COVID-19 pandemic are to be addressed with concrete, practical instruments.

3. Thirdly, the focus is on promoting innovation and competitiveness, in particular through regulatory modernization and procedural simplification. This is intended to make the EU more attractive as a location for research, development, and manufacturing and to secure its international competitiveness. In addition, targeted incentive and reward mechanisms are intended to boost innovations that are less attractive economically but relevant to supply. Meeting unmet medical needs and closing supply gaps is particularly necessary in pediatrics, orphan drugs, and the field of antimicrobial resistance (AMR).

4. Fourthly, the environmental compatibility of medicinal products should be improved and, at the same time, the emergence and spread of antimicrobial resistance should be combated more effectively.

²⁰ See European Commission, Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorization and supervision of medicinal products for human use, establishing rules for the European Medicines Agency, amending Regulation (EC) No. 1394/2007 and Regulation (EU) No. 536/2014, and repealing Regulation (EC) No. 726/2004 and Regulation (EC) No. 141/2000 (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 of 26 April 2023, COM(2023) 193 final, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0193&qid=1767716188984>, last accessed on January 12, 2026.

²¹ See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions of November 25, 2020, COM (2020) 761 final, available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A52020DC0761>, last accessed on January 12, 2026. See also the European Commission press release of November 25, 2020, available at https://ec.europa.eu/commission/presscorner/detail/de/ip_20_2173, last accessed on January 12, 2026.

²² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions of November 25, 2020, COM (2020) 761 final, available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A52020DC0761>, last accessed on January 12, 2026.

²³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions of November 25, 2020, COM (2020) 761 final, available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A52020DC0761>, last accessed on January 12, 2026.

²⁴ See European Commission, Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorization and supervision of medicinal products for human use, establishing rules for the European Medicines Agency, amending Regulation (EC) No. 1394/2007 and Regulation (EU) No. 536/2014, and repealing Regulation (EC) No. 726/2004 and Regulation (EC) No. 141/2000 (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 of 26 April 2023, COM(2023) 193 final, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0193&qid=1767716188984>, last accessed on January 12, 2026.

²⁵ See press release from the European Council and the Council of the European Union dated June 4, 2025, available at <https://www.consilium.europa.eu/de/press/press-releases/2025/06/04/pharma-package-council-agrees-its-position-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/#:~:text=The%20pharmaceutical%20package,enforcement%20of environmental regulations,> last accessed on January 12, 2026; see also European Council, Council of the European Union, The "Pharmaceutical Package": new EU rules for medicines, as of December 12, 2025, available at <https://www.consilium.europa.eu/en/policies/pharma-pack/>, last accessed on January 12, 2026.

²⁶ See press release from the European Commission dated 11. 12. 2025, available at: https://ec.europa.eu/commission/presscorner/detail/de/ip_25_3015, last accessed on

12. 1. 2026, cf. press release of the European Council and the Council of the European Union dated 11. 12. 2025, available at <https://www.consilium.europa.eu/de/press/press-releases/2025/12/11/pharma-package-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>, last accessed on January 12, 2026.

²⁷ See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions of April 26, 2023, COM (2023) 190 final, p. 10, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023DC0190&qid=1767716662121>, last accessed on January 12, 2026.

²⁸ See European Council, Council of the European Union, The "Medicines Package": new EU rules for medicines, as of December 12, 2025, available at <https://www.consilium.europa.eu/en/policies/pharma-pack/>, last accessed on January 12, 2026.

²⁹ See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions of April 26, 2023, available at: <https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52023DC0190>, last accessed on January 12, 2026. The manufacture, use, and improper disposal of pharmaceutical residues contaminate soil and water, posing a threat to the environment and public health. Studies have shown that antimicrobials, for example, can be found in water sources. disposal of pharmaceutical residues contaminate soil and water, thereby posing a risk to the environment and public health. Studies have shown that antimicrobial agents can be detected in water sources, for example, which can promote antimicrobial resistance, cf. European Council, Council of the European Union, The "Pharmaceutical Package": new EU regulations for medicinal products, as of December 12, 2025, available at <https://www.consilium.europa.eu/en/policies/pharma-pack/>, last accessed on January 12, 2026.

The general, overarching objective of the pharmaceutical package is to ensure a high level of public health. In addition, harmonization of the internal market should make it easier for authorities to exercise greater control and supervision of medicinal products.

Although the pharmaceutical strategy is understood as a "holistic response to the current challenges facing pharmaceutical policy"³¹, in which legislative and non-legislative measures work together towards an overarching goal, the reform proposal also highlights the limits of the EU legislator's powers. Therefore, issues that fall outside the scope of EU law cannot be covered by the regulation. These include, in particular, global pharmaceutical developments and national decisions on pricing and reimbursement.

Despite the Union's fundamental regulatory competence, certain topics are deliberately not addressed. For reasons of efficiency and in the interests of ensuring that the package is targeted, regulations on the advertising of medicinal products, falsified medicinal products, and homeopathic and traditional herbal medicinal products in particular are not included in the reform proposal.³²

III. Critical examination of important regulations

1. Shortening of market exclusivity?

The Commission's proposal to reduce the term of basic document protection from eight to six years³³

³⁰ See European Commission, Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorization and supervision of medicinal products for human use, establishing rules for the European Medicines Agency, amending Regulation (EC) No. 1394/2007 and Regulation (EU) No. 536/2014 and repealing Regulation (EC) No. 726/2004, Regulation (EC) No. 141/2000 and Regulation (EC) No. 1901/2006 of 26 April 2023, COM (2023) 193 final, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0193&qid=1767716188984>, last accessed on January 12, 2026.

³¹ European Commission, Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorization and supervision of medicinal products for human use, establishing rules for the European Medicines Agency, amending Regulation (EC) No. 1394/2007 and Regulation (EU) No. 536/2014 and repealing Regulation (EC) No. 726/2004, Regulation (EC) No. 141/2000 and Regulation (EC) No. 1901/2006 of 26 April 2023, COM (2023) 193 final, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0193&qid=1767716188984>, last accessed on January 12, 2026.

³² See European Commission, Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorization and supervision of medicinal products for human use, establishing rules for the European Medicines Agency, amending Regulation (EC) No. 1394/2007 and Regulation (EU) No. 536/2014 and repealing Regulation (EC) No. 726/2004, Regulation (EC) No. 141/2000 and Regulation (EC) No. 1901/2006 of 26 April 2023, COM (2023) 193 final, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0193&qid=1767716188984>, last accessed on January 12, 2026.

received the most attention in public debate, but was ultimately unsuccessful.

Since the 1960s, and particularly as a result of the thalidomide scandal, regulatory requirements for quality, efficacy, and safety have increased significantly. Clinical development is therefore now the most cost- and time-intensive stage in the "life cycle" of a drug. Clinical phases I to III regularly account for the largest share of costs, often amounting to around 44% of research and development expenditure.³⁴ At the same time, development times and failure rates remain high: it takes around 12–13 years from the first synthesis to market approval, and on average only one to two out of 10,000 substances investigated actually reach the market.³⁵ Depending on the methodology and data basis, the total (capitalized) development costs of a newly approved drug vary greatly. A frequently cited estimate is around US\$2.8 billion, including the costs of failed projects and capital costs.³⁶ Against this background, intellectual property rights, in particular patents and supplementary protection certificates, as well as regulatory documentation and market protection, serve as economic compensation. They are intended to provide a period of time in which the considerable investment in development can be recouped.³⁷

³³ See European Commission, Proposal for a Directive of the European Parliament and of the Council on the establishment of a Union code relating to medicinal products for human use and repealing Directive 2001/83/EC and Directive 2009/35/EC, April 26, 2023, COM(2023) 192 final, available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52023_PC0192, last accessed on January 12, 2026. For more details, see Stief/Grabow, Quo vadis Arzneimittelrecht — ein Überblick zur Überarbeitung der EU-Arzneimittelvorschriften (Quo vadis pharmaceutical law — an overview of the revision of EU pharmaceutical regulations), PharmR 2023, 317, (319 f.).

³⁴ Federal Association of the Pharmaceutical Industry, Pharma Data 2024, p. 23, available at <https://www.bpi.de/index.php?eID=dumpFile&t=f&f=81021&token=c94916c479598c5343e03f0f9ab7cebb46f9d64a>, last accessed on January 12, 2026.

³⁵ These and other statistics on the German pharmaceutical industry are available at https://pharma-fakten.de/die-branche/#:~:text=Die%20Pharmabranche%20in%20Deutschland%20*%20research%20&percent%20of%20industry%20turnover%20in%20research%20and%20development, last accessed on January 12, 2026.

³⁶ Federal Association of the Pharmaceutical Industry, Pharma Data 2024, p. 24, available at <https://www.bpi.de/index.php?eID=dumpFile&t=f&f=81021&token=c94916c479598c5343e03f0f9ab7cebb46f9d64a>, last accessed on January 12, 2026. Other sources even estimate between 4 and 6 billion US dollars, cf. Buntz, R&D World, How much does the pharma industry spend on R&D anyway? Probably more than you thought, October 25, 2024, available at <https://www.rdworldonline.com/how-much-does-the-pharma-industry-spend-on-rd-anyway-probably-more-than-you-thought/>, last accessed on January 12, 2026.

³⁷ German pharmaceutical companies reinvest 16% of industry revenue in research and development, making them the leaders in Germany, cf. Pharma Fakten, The pharmaceutical industry in Germany, available at https://pharma-fakten.de/die-branche/#:~:text=The%20pharmaceutical%20industry%20in%20Germany%20*%20Research%20&percent%20of%20industry%20revenue%20in%20research%20and%20development, last accessed on January 12, 2026.

In addition to protecting research-based drug manufacturers in a competitive environment, the EU is also pursuing the goal of providing patients across Europe with better access to affordable medicines. To this end, the market entry of gene therapies and biosimilars in particular is to be accelerated, thereby further increasing their market share. The share of these products has already risen significantly in recent years, and this trend is now to be supported and reinforced by regulatory measures.

For healthcare systems, more intense competition from generics and biosimilars typically means lower prices and thus noticeable savings. At the same time, lower prices improve access to medicines — whether to the original therapy or to its generic or biosimilar alternative. These goals are fundamentally welcome. However, the legitimate interests of research-based pharmaceutical companies, which are already under considerable strain due to high development risks, long development and approval times, strict regulatory requirements, and increasing cost and price pressure, must not be overlooked. A balanced legal framework must therefore promote cost efficiency and security of supply without structurally weakening the incentives for investment and innovation in pharmaceutical research.

To date, document protection has been structured as follows:

The basic data protection period is eight years and begins with the granting of the first marketing authorization for the reference medicinal product. During this period subsequent applicants may not refer to the preclinical and clinical data submitted by the originator in an abbreviated marketing authorization procedure. Since, by definition, generic and biosimilar manufacturers do not conduct their own complete clinical efficacy and safety studies on the active ingredient, there is generally no realistic route to approval during the eight-year data protection period. Accordingly, in practice, it is unlikely that an application for approval of a generic or biosimilar will be submitted during this period.

Under the current EU system, the eight-year data protection period is followed by a period of indication-independent market protection.

market exclusivity ("market protection"/"marketing protection") of two years ("8 + 2" system). After eight years, generic and biosimilar companies may submit an abbreviated marketing authorization application based on the preclinical and clinical data of the reference medicinal product. The application can be reviewed at this stage and approval can also be granted. However, the actual marketing of the product remains prohibited until ten years after the initial approval of the reference medicinal product.

38 Stief/Grabow, Quo vadis Arzneimittelrecht — ein Überblick zur Überarbeitung der EU-Arzneimittelvorschriften (Quo vadis pharmaceutical law — an overview of the revision of EU pharmaceutical regulations), PharmR 2023, 317 (318).

39 Stief/Grabow, Quo vadis Arzneimittelrecht — an overview of the revision of EU pharmaceutical regulations, PharmR 2023, 317 (318).

40 The legal basis is Article 14(11) of Regulation (EC) No. 726/2004 (OJ 2004 L 136, 1).

If, within the first eight years after initial approval, a further (new) indication is approved that offers a "significant clinical benefit" over existing therapies, this market protection can be extended by an additional year ("8 + 2 + 1"). This results in a maximum regulatory protection period of 11 years under EU/EEA law.

During the reform negotiations, models were initially discussed that would combine a reduction in basic document protection with a bundle of extension options. This would have reduced basic protection, but at the same time, the effective total protection period could have been increased again if the respective requirements were met.

As a result of the trilogue negotiations, the European Council, Parliament, and Commission instead agreed to maintain the eight-year market exclusivity and further limited the extension options⁴¹ by reducing marketing protection to one year. This can be extended by a further year if additional innovation and supply-related criteria are met, resulting in a maximum period of 10 years.⁴²

Whether the reduction in market protection will actually lead to earlier launches of generics and biosimilars in practice will only become clear once it has been implemented. In purely mathematical terms, the reduction from two years to one could bring forward the earliest possible market entry by up to twelve months. However, this effect will only be realized if generic or biosimilar companies submit their applications immediately after the eight-year data protection period expires and the approval process is completed within this one year.

This is precisely where practical doubts arise: although the regulatory "active" evaluation period in the centralized procedure formally lasts up to 210 days, in reality, queries, "clock stops," and downstream steps often significantly prolong the procedure, with 12 to 18 months between submission and approval decision not being uncommon.⁴³ Against this background, the reduction in market protection in many cases threatens to remain merely a change "on paper," at least where the procedures are not sufficiently streamlined or where additional requests for information are to be expected. Conversely, the reform may

41 See press release of the European Council and the Council of the European Union of December 11, 2025, available at <https://www.consilium.europa.eu/de/press/press-releases/2025/12/11/pharmapackage-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>, last accessed on January 12, 2026.

42 See press release from the European Council and the Council of the European Union dated December 11, 2025, available at <https://www.consilium.europa.eu/de/press/press-releases/2025/12/11/pharmapackage-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>, last accessed on January 12, 2026. See also Hachmeister/Kohoutek, Report from Brussels, PharmR 2026, 76 (78).

43 See European Commission, Authorization procedures — The centralized procedure, available at https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/authorisation-procedures-centralised-procedure_en?utm.com, last accessed on January 12, 2026.

This will result in real time savings where preparations are made early and the (extended) Bolar exemption provides legal certainty for the "Day 1" setup.

During the legislative process, there was broad consensus between the Commission, the Council, and the Parliament to introduce independent, one-time regulatory document and data protection for four years for "repurposed" medicinal products.⁴⁴ This new protection favors medicinal products based on an already known (and regularly already approved) active substance, but which are further developed for a new therapeutic indication not yet approved in the European Union. The prerequisite is that additional, appropriate non-clinical or clinical studies are submitted that demonstrate a significant clinical benefit of the new indication. In addition, exclusivity is only granted once per medicinal product and is subject to further formal criteria.⁴⁵

2. Data exclusivity vouchers

In order to stimulate the development of urgently needed antibiotics and tackle the problem of antimicrobial resistance (AMR), the new EU pharmaceutical package introduces for the first time the instrument of a transferable data exclusivity voucher.⁴⁶ The voucher is intended to create incentives for research and development in an area that is structurally characterized by market failure due to low expected sales.⁴⁷ The core of the mechanism is that, pursuant to Article 40 of the draft regulation, the voucher gives its holder the opportunity to obtain a one-year extension of data exclusivity for an authorized medicinal product.⁴⁸

The granting of the voucher is subject to strict formal requirements, Article 40(1), (3) and (4) of the Regulation

Draft. In addition, it should only be considered for human medicinal products that qualify as "priority antimicrobial agents," i.e., those that are expected to have significant clinical benefits in terms of AMR and are specifically targeted against resistant pathogens. The assessment is based, among other things, on prioritization systems such as the WHO pathogen lists, Art. 40 (3) of the draft regulation. In addition, the concept provides for a quantitative limit on the number of vouchers available in order to control the budgetary impact and concentrate the instrument on a few particularly relevant innovations.

Of particular dogmatic and political significance is the one-time transferability of the voucher to another marketing authorization holder, Art. 40 (3) of the draft regulation. This creates an exclusivity right which, unlike traditional data exclusivity, is not necessarily tied to the product whose development is to be incentivized.⁵² It is precisely this construction that forms the core of the controversy: the economic value of the voucher is structurally measured by the market value of the "target drug" whose exclusivity is being extended. This can lead to considerable additional costs because the market entry of generics or biosimilars is delayed and monopolistic price levels are perpetuated.⁵³

Against this backdrop, limiting mechanisms have been introduced or discussed in the legislative process. Of particular note is especially the so-called

"blockbuster clause": According to the political agreement, the voucher cannot be used for drugs with annual gross sales in the EU of more than EUR 490 million (based on a multi-year reference period). This provision aims to limit the budgetary risks of the instrument and prevent costs from spiraling out of control by extending the exclusivity of particularly high-revenue products.

Furthermore, the model in Article 42(1) and (2) of the draft regulation provides for grounds for expiry and revocation. According to Article 42 of the draft regulation, the voucher expires either upon redemption (Commission decision pursuant to Article 47 of the draft regulation) or if it is not used within five years of issuance. It may also be revoked prior to transfer if a Union-wide application for

⁴⁴ European Commission, Proposal for a Directive of the European Parliament and of the Council on the establishment of a Union code relating to medicinal products for human use and repealing Directive 2001/83/EC and Directive 2009/35/EC, April 26, 2023, COM(2023) 192 final, Art. 84, available at: <https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX:52023PC0192>, last accessed on January 12, 2026.

⁴⁵ See European Commission, Proposal for a Directive of the European Parliament and of the Council on the establishment of a Union code relating to medicinal products for human use and on the repeal Directive 2001/83/EC and Directive 2009/35/EC, April 26, 2023, COM(2023) 192 final, Art. 84, available at: <https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX:52023PC0192>, last accessed on January 12, 2026.

⁴⁶ See European Commission, Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorization and supervision of medicinal products for human use, establishing rules for the European Medicines Agency, amending Regulation (EC) No. 1394/2007 and Regulation (EU) No. 536/2014 and repealing Regulation (EC) No. 726/2004, Regulation (EC) No. 141/2000 and Regulation (EC) No. 1901/2006 of 26 April 2023, COM (2023) 193 final, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0193&qid=1767716188984>, last accessed on January 12, 2026, see Stief/Tsakiliotis, Transferable data exclusivity vouchers — A regulatory incentive to combat the AMR crisis?, pharminD 2024, 1125, for details.

⁴⁷ See recital 77 of the draft regulation.

⁴⁸ See recital 79 of the draft regulation.

⁴⁹ See WHO, WHO publishes list of bacteria for which new antibiotics are urgently needed, press release dated February 27, 2017, available at: <https://www.who.int/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed>, last accessed on January 12, 2026.

⁵⁰ See Recital 80 of the proposed regulation; for more details, see Stief/Tsakiliotis, Transferable Data Exclusivity Vouchers — A Regulatory Incentive to Combat the AMR Crisis?, pharminD 2024, 1125 (1128 f).

⁵¹ See Recital 79 of the Draft Regulation.

⁵² See Recital 82 of the Draft Regulation.

⁵³ Stief/Tsakiliotis, Transferable Data exclusivity vouchers — A regulatory incentive to combat the AMR crisis?, pharminD 2024, 1125 (1129 f).

⁵⁴ See press release from the European Council and the Council of the European Union dated December 11, 2025, available at <https://www.consilium.europa.eu/de/press/press-releases/2025/12/11/pharmapackage-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>, last accessed on January 12, 2026.

Delivery/procurement/purchase of the priority antimicrobial agent is not fulfilled (para. 2 in conjunction with Art. 40 para. 4 lit. a VO-E), so that the reward remains linked to the actual supply.

3. Future of the Roche Bolar privilege

The so-called Roche-Bolar exception is a patent law barrier that privileges actions that serve exclusively to obtain drug approvals. It allows generic and biosimilar manufacturers to carry out the testing, examination, and submission activities necessary for approval and market entry preparations even before the patent or supplementary protection rights expire. This can enable immediate market entry ("Day 1") after the expiry of the property right without the preparatory activities necessary for this being classified as patent infringement.⁵⁶ The aim of the exception is to stimulate market competition as quickly as possible through rapid market entry after the expiry of monopoly rights in order to reduce prices and strengthen economic approaches to

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In practice, the Roche-Bolar exception is often equated with the general experimental privilege. Under certain conditions, this privilege allows experimental activities on patented inventions, in particular for research purposes or to gain new knowledge.⁵⁸ The Bolar exception, on the other hand, privileges studies, trials, and other preparatory acts insofar as they serve directly and exclusively to fulfill pharmaceutical law requirements, namely the preparation and implementation of an approval procedure.

The Roche-Bolar exemption, which is based on Article 10(6) of Directive 2001/83/EC under EU law, has not yet been implemented uniformly by the Member States. The scope and conditions of the privileged acts differ considerably in some cases,⁵⁹

This leads to legal uncertainty in practice and encourages strategic location decisions ("forum shopping"), particularly when preparing for the cross-border market entry of generics and biosimilars. Particularly in the run-up to "Day 1" market entry, diverging national interpretations can lead to differing risk profiles with regard to injunctive relief and damages claims arising from intellectual property rights.

The pharmaceutical package therefore aims to define the scope and conditions of the exception more clearly and coherently across the EU. The pharmaceutical package takes up the Roche-Bolar exception and clarifies its wording in order to more clearly outline the scope of privileged preparatory measures. The extension of the scope to the submission of bids in public procurement procedures initiated by the Council has been retained.

As a result of the trilogue negotiations, the Bolar exception was expressly extended to activities related to marketing authorization, health technology assessment, pricing and reimbursement procedures, and participation in public tenders, with actual distribution remaining strictly linked to the expiry of patent and SPC protection.

An actual concretization of the exception would have far-reaching consequences. Actions that are now expressly privileged have often served as a basis for preliminary injunctions due to alleged (imminent) patent infringements. The clarification will make these "pre-launch" injunctions significantly more difficult. In the context of the UPC, this is likely to raise the threshold for issuing preliminary injunctions noticeably, because preparatory acts covered by Bolar protection regularly lack the probability of an infringement.

Whether original drug manufacturers can also invoke the Bolar exception remains open. While Parliament focused solely on the applicability of obtaining a marketing authorization, the Commission explicitly referred to generic, biosimilar, and (bio)hybrid products, and the Council referred to them "in particular."⁶⁴ It is also unclear to what extent the exception applies to marketing authorization applications outside the EU.

⁵⁵ For details on the Bolar exemption, see *Stief*, The European Research and Bolar Exemptions – Background, Status Quo and a Look at the Agreement on a Unified Patent Court (UPCA) and the EU Commission's New Draft Directive for the Reform of Pharmaceutical Legislation, GRUR Int. 2024, 824; *Stief*, Pharmaceutical Patents: Exceptions to Patent Protection — Experimental Privilege, Bolar Exemption, SPC Waiver, and Compulsory License, PharmR 2024, 641.

⁵⁶ BT-Drs. 15/5316, 1, 31.

⁵⁷ See also *Stief/Grabow*, Quo vadis Arzneimittelrecht — ein Überblick zur Überarbeitung der EU-Arzneimittelvorschriften (Where is pharmaceutical law headed — an overview of the revision of EU pharmaceutical regulations), PharmR 2023, 317 (319).

⁵⁸ On the experimental privilege: *Stief*, Pharmaceutical Patents: Exceptions to Patent Protection — Experimental Privilege, Bolar Exemption, SPC Waiver, and Compulsory License, PharmR 2024, 641 (642); *Stief*, The European Research and Bolar Exemptions — Background, Status Quo and a Look at the Agreement on a Unified Patent Court (UPCA) and the EU Commission's New Draft Directive for the Reform of Pharmaceutical Legislation, GRUR Int. 2024, 824 (824).

⁵⁹ For more details, see *Stief*, Pharmaceutical Patents: Exceptions to Patent Protection — Trial Privilege, Bolar Exemption, SPC Waiver, and Compulsory License, PharmR 2024, 641 (642); *Stief*, The European Research and Bolar Exemptions – Background, Status Quo and a Look at the Agreement on a Unified Patent Court (UPCA) and the EU Commission's New Draft Directive for the Reform of Pharmaceutical Legislation, GRUR Int. 2024, 824 (828).

⁶⁰ For details, see *Stief*, Infringement of Pharmaceutical Patents — Legal consequences and passive legitimacy, PharmR 2024, 685.

⁶¹ See press release from the European Council and the Council of the European Union dated December 11, 2025, available at <https://www.consilium.europa.eu/de/press/press-releases/2025/12/11/pharmapackage-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>, last accessed on January 12, 2026.

⁶² See press release from the European Council and the Council of the European Union dated December 11, 2025, available at <https://www.consilium.europa.eu/de/press/press-releases/2025/12/11/pharmapackage-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>, last accessed on January 12, 2026.

⁶³ For further information on this topic, see: *Cordery/Mumby*, The new Bolar provisions and their potential impact on the European PI landscape, Kluwer Patent Blog, April 16, 2025, available at <https://legal-blogs.wolterskluwer.com/patent-blog/the-new-bolar-provisions-and-their-potential-impact-on-european-pi-landscape/>, last accessed on January 12, 2026.

The Parliament's proposal, which prevailed in the trilogue negotiations, emphasizes that patent protection must not influence approval, HTA, and reimbursement (so-called patent linkage).⁶⁵ In contrast to the US, the EU classifies patent linkage⁶⁶ as anti-competitive and therefore illegal, as it can systematically delay the market entry of generics through costly patent disputes. The consequences in the form of higher drug prices are borne by patients.

The changes to the Roche-Bolar privilege make it easier for European generic drug companies to prepare their drug approvals before the original manufacturer's market exclusivity expires. This allows market entries to be better prepared immediately after the expiry of property rights, which strengthens competition, promotes innovation incentives in the value-added segment, and facilitates patient access to affordable medicines. Consequently, it is hardly surprising that statutory health insurance funds in particular support this proposal.

Opponents criticize that an excessive extension of the Roche-Bolar privilege would effectively devalue document protection. Original manufacturers in particular fear that generic drug companies could use the concessions as an incentive for "launch at risk," i.e., bringing products to market before the patent protection expires. This would increase legal uncertainty and could willingness to invest originators

⁶⁸ The concern is therefore less about a formal abolition of property rights than about a de facto erosion of these rights due to the early market availability of generic products.

It should also be noted that the relevant provisions are still contained in a directive and therefore require implementation by the Member States. The EU legislator emphasizes the goal of harmonization and the uniform scope of the exception throughout the EU. Whether this will actually achieve a coherent framework for application or whether the divergences observed to date will simply continue at a new regulatory level remains a key open question of the reform.

4. Availability of medicinal products

With regard to the availability of medicinal products, the agreement reached by the EU institutions resulted in the retention of Article 56a of the new legislative package proposed by the Council. This allows EU countries to oblige companies to supply sufficient quantities of protected medicinal products and to ensure that supply needs are met. Protective measures have also been put in place to prevent Article 56a from being used as an opportunity for parallel trade.

IV. International classification of the EU pharmaceutical package

The EU pharmaceutical package is being watched not only nationally but also globally. The decisions made by legislators are decisive for the location strategies of leading pharmaceutical companies and thus crucial for Europe's competitiveness.

Europe has noticeably lost its former position as a leading innovation hub in drug development in recent years. According to the indicators used by the Commission, the share of new drugs "originating" in the Union is now only about one-fifth.⁷⁰ This contrasts with continued outstanding academic performance: in the field of life sciences/medicine, Europe has a very high publication density in international comparison. The findings therefore suggest that the problem is less one of knowledge than of translation and location. Political and economic framework conditions, including administrative complexity, fragmentation of the study landscape

- ⁶⁴ See *European Parliament*, Parliament takes a stand on EU pharmaceutical reform, Press release from 10. 4. 2024, available at: <https://www.europarl.europa.eu/news/de/press-room/20240408IPR20308/parlament-positioniert-sich-zur-eu-arzneimittelreform?utm.com>, last accessed on 12 January 2026; cf. European Council, Council of the European Commission, "Pharmaceutical package": Council adopts position on new rules for a fairer and more competitive EU pharmaceutical sector, press release dated 4. June 2025, available at: <https://www.consilium.europa.eu/en/press/press-releases/2025/06/04/pharma-package-council-agrees-its-position-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/?utm.com>, last accessed on January 12, 2026.
- ⁶⁵ Pecak/Blindzellner/Haas, Drug supply in the EU: Status and outlook from the perspective of the statutory health insurance system, *ÄrzteZeitung* 2025, available at <https://www.aerztezeitung.de/Kooperationen/Arzneimittelversorgung-in-der-EU-Status-und-Ausblick-aus-Sicht-der-GKV-458922.html>, last accessed on January 12, 2026.
- ⁶⁶ Under patent linkage, approval to market a generic drug is contingent on the patent status of the original product, cf. Ehlich/Zumstein, FAQs on China's Patent Linkage System, Maiwald Blog, Oct. 18, 2021, available at <https://www.maiwald.eu/de/maiwald-blog/faqs-on-chinas-patent-linkage-system/>, last accessed on Jan. 12, 2026; *Medicines for Europe*, Why Clarification & Harmonization of the Bolar Exemption and an Explicit Prohibition of Patent Linkage Is Needed in the European Union, Oct. 20, 2023, available at <https://www.medicinesforeurope.com/wp-content/uploads/2023/10/Updated-Medicines-for-Europe-Bolar-Patent-Linkage-Paper-20-Oct-2023-1.pdf>, last accessed on January 12, 2026.
- ⁶⁷ Pecak/Blindzellner/Haas, Drug supply in the EU: Status and outlook from the perspective of the statutory health insurance system, *ÄrzteZeitung* 2025, available at <https://www.aerztezeitung.de/Kooperationen/Arzneimittelversorgung-in-der-EU-Status-und-Ausblick-aus-Sicht-der-GKV-458922.html>, last accessed on January 12, 2026.

- ⁶⁸ Association of Research-Based Pharmaceutical Companies, Statement on the reform of EU pharmaceutical law, 2023, p. 9, available at <https://vfa.de/de/gesundheits-versorgung/eu-pharma-paket/eu-schadetsforschung>, last accessed on January 12, 2026.
- ⁶⁹ See press release from the European Council and the Council of the European Union dated December 11, 2025, available at <https://www.consilium.europa.eu/de/press/press-releases/2025/12/11/pharma-package-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>, last accessed on January 12, 2026.
- ⁷⁰ Moll, EU Competitiveness: Mind the gap between rhetoric and reality, 2023, available at <https://efpia.eu/news-events/the-efpia-view/blog-articles/eu-competitiveness-mind-the-gap-between-rhetoric-and-reality/>, last accessed on January 12, 2026.

and financing risks reduce the attractiveness of conducting clinical trials in the EU. As a result, study activity is shifting to a significant extent to other jurisdictions. The US and China in particular show a significantly higher number of clinical trials in relevant comparative studies.⁷¹ This underscores the regulatory conflict of objectives in the pharmaceutical package: on the one hand, access and cost efficiency are to be strengthened, while on the other hand, the framework conditions must be balanced so that investment in clinical development and market approval in the EU does not erode further.

Nevertheless, the European Union remains the second largest pharmaceutical market worldwide after the US. The pharmaceutical and life sciences industry is one of the most productive and research-intensive sectors in Europe, with significant added value, a high employment impact, and central importance for innovation and supply sovereignty.

In the industry-led impact assessment, reference is made to a model calculation carried out by Charles River Associates (CRA)⁷³ to argue that the changes to innovation incentives originally proposed by the Commission (particularly in the area of regulatory data protection) could significantly impair the EU's attractiveness as a location for pharmaceutical research and development. In this regard, EFPIA refers to projections according to which, if the trend data observed between 2015 and 2020 continues, the number of people employed in pharmaceutical research and development in Europe could halve by 2030 and company-financed research and development investment could decline by around EUR 15 billion per year.⁷⁴ Reference is also made to public statements by company management that research and development activities could increasingly be shifted to the US and Asia, also against the backdrop of global location incentives. However, the significance of these forecasts depends largely on the assumptions inherent in the model (trend extrapolation/CAGR, delimitation of the effects considered). An independent, comprehensive

official competition impact assessment in the sense of a "competitiveness check."

In international location comparisons, the US and—increasingly—China are often presented as jurisdictions with procedural and ecosystemic advantages in drug development. In the US, a uniform, nationwide approval process at the FDA opens up access to a single, very large sales market. In addition, there are several legally and administratively established programs for accelerated development and testing (in particular Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review), which can facilitate earlier market approval or earlier patient access in cases of serious diseases and unmet medical needs. China has also significantly modernized and accelerated its regulatory procedures in recent years, for example through priority reviews with shortened review periods and its own "expedited pathways" (including a Chinese breakthrough therapy system).⁷⁵

In contrast, the EU also has a "single application" model with its centralized procedure: a single application to the EMA leads to an EU-wide marketing authorization following scientific evaluation and a Commission decision. The disadvantages of the EU discussed in the context of location competition are therefore seen less in the existence of a centralized approval path and more in the subsequent fragmentation (especially pricing and reimbursement decisions), multi-layered administrative requirements, and barriers to clinical translation and cooperation between academic research and industry. Although the Commission's reform approach addresses procedural streamlining and red tape in specific areas, structural location factors of this kind have not yet been the focus of the pharmaceutical package, which primarily addresses the regulatory framework for medicinal products, incentive mechanisms, and security of supply instruments.

It remains to be seen to what extent EU legislators will actually be able to achieve their own goals with the pharmaceutical package.

⁷¹ Pharma Facts, EU Pharma Package: Europe's competitiveness at risk, 2023, available at <https://pharma-fakten.de/news/eu-pharma-paket-wettbewerbsfaehigkeit-europas-in-gefahr/>, last accessed on January 12, 2026.

⁷² See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions of April 26, 2023, COM (2023) 190 final, p. 8, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023DC0190&qid=1767716662121>, last accessed on January 12, 2026.

⁷³ Charles River Associates, Impact of the General Pharmaceutical Legislation on Europe's innovation ecosystem and biotechnology companies, January 2024, p. 3 f., available at: <https://www.europabio.org/wp-content/uploads/2024/01/STUDY-FINAL-CRA-EuropaBio-The-impact-of-the-EUs-GPL-on-the-biotech-innovation-ecosystem.pdf?utm.com>, last accessed on January 12, 2026.

⁷⁴ See Pharma Facts, EU Pharma Package: Europe's competitiveness at risk, 2023, available at <https://pharma-fakten.de/news/eu-pharma-paket-wettbewerbsfaehigkeit-eu-ropas-in-gefahr/>, last accessed on January 12, 2026.

⁷⁵ See National Medical Products Administration, Measures facilitate approval of 48 first-in-class innovative drugs, press release dated March 21, 2025, available at: https://eng-lish.nmpa.gov.cn/2025-03/21/c_1080286.htm?utm.com, last accessed on January 12, 2026; see also Liu/Zhang/et al. a., Evolution of drug regulations and regulatory innovation for anticancer drugs in China, *Acta Pharm Sin B* 2022, p. 4365 ff., available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC9764065/?utm.com>, last accessed on January 12, 2026.

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Compliance update: German and EU antitrust law in the pharmaceutical sector

I. Introduction

In his report on the "The Future of EU Competitiveness" identifies the pharmaceutical sector as an important factor for the European economy.¹ The report was commissioned by the European Commission ("Commission") and formed the basis of its "Competitive Compass," which it published in January 2025.² Anyone who does not believe that lax antitrust enforcement will automatically produce internationally successful "European champions" will therefore not be surprised that the Commission and national antitrust authorities have been closely monitoring compliance with antitrust rules in the pharmaceutical sector for many years.

This is also reflected in the Commission's reports from 2024³ and 2019⁴ on the enforcement of antitrust and merger control rules in the pharmaceutical sector. In addition to "classic" price agreements, the reports refer to pharmaceutical-specific antitrust violations such as "pay-for-delay" agreements or patent extension measures and misleading information about competing products.

The Commission's Zoetis decision represents a novelty in the field of pharmaceutical antitrust law: for the first time, the decision concerned a so-called "killer acquisition" which, in the Commission's view, violated antitrust regulations.

From a compliance perspective, general antitrust developments and trends, such as antitrust violations in the HR sector, are also relevant.

This article summarizes recent decisions by antitrust authorities in the field of (veterinary) pharmaceuticals and provides an overview of general antitrust developments and trends that are relevant for pharmaceutical companies. The article also deals with practical tips for avoiding antitrust violations (compliance management systems, dawn raids, etc.).

II. Current decisions in the field of (veterinary) drugs

Various recent decisions in the field of (veterinary) pharmaceuticals provide pharmaceutical companies with important guidelines for behavior that complies with antitrust law.

1. First *hardcore* cartel involving an active pharmaceutical ingredient

In October 2023, the Commission imposed its first fine for price fixing and quota allocation in relation to an active pharmaceutical ingredient.

The total amount of the fine imposed on Alkaloids of Australia, Alkaloids Corporation, Boehringer, Linnea, and Transo-Pharm

was EUR 13.4 million in total.⁵ A sixth company, C2 PHARMA, was granted full immunity from fines because it had informed the Commission about the cartel under the leniency program. Transo-Pharm also received a 50% reduction in the fine under the leniency program, and Linnea received at least a 30% reduction.⁶ All six of the above-mentioned companies admitted to the cartel, and the proceedings were concluded with a settlement, which resulted in a further 10% reduction in the fines for the companies concerned.⁷

In July 2025, the Commission finally also imposed a fine on the company Alchem

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- 1 Report by former Italian Prime Minister and former President of the European Central Bank *Mario Draghi* on the future of the European Union's (EU) competitiveness, published on September 9, 2024, Part B, p. 187 ff.
- 2 Available at: https://commission.europa.eu/topics/competitiveness/competitiveness-compass_en.
- 3 Report from the Commission to the Council and the European Parliament dated January 26, 2024, Current state of enforcement of competition law in the pharmaceutical sector (2018–2022), COM(2024) 36 final, available at: <https://data.consilium.europa.eu/doc/document/ST-5983-2024-INIT/en/pdf>; *Burholt/Zölck*, Report of the European Commission on the enforcement of competition law in the pharmaceutical sector, PharmR 2024, 201 ff.
- 4 Report from the Commission to the Council and the European Parliament of January 28, 2019, Enforcement of competition law in the pharmaceutical sector (2009–2017), COM (2019) 17 final, available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/execsumm_en.pdf; *Burholt*, Report of the European Commission on antitrust and merger control decision-making practice in the pharmaceutical sector, PharmR 2019, 95 ff.
- 5 *European Commission*, press release dated October 19, 2023, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5104; Summary of the Commission's decision of October 19, 2023, in proceedings under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement, Ref. C/2024/6961 final, available at: https://eur-lex.europa.eu/legal-content/DE/TXT/HTML/?uri=OJ:C_202406961.
- 6 *European Commission*, press release dated October 19, 2023, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5104; Summary of the Commission's decision of October 19, 2023, in a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement, Ref. C/2024/6961 final, available at: https://eur-lex.europa.eu/legal-content/DE/TXT/HTML/?uri=OJ:C_202406961.
- 7 *European Commission*, press release dated October 19, 2023, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5104; Summary of the Commission's decision of October 19, 2023, in a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement, Ref. C/2024/6961 final, available at: https://eur-lex.europa.eu/legal-content/DE/TXT/HTML/?uri=OJ:C_202406961.

amounting to EUR 489,000. Alchem had decided against a settlement with the Commission.⁸

The Commission accused the companies of fixing minimum prices, allocating quotas, and exchanging sensitive business information relating to N-butylscopolamine bromide, a starting material for the manufacture of *Buscopan* and generic drugs for the treatment of abdominal cramps.⁹

The agreement on minimum sales prices and the allocation of quotas violate German and EU antitrust law pursuant to Section 1 GWB and Article 101(1) TFEU. Like customer and territory agreements, they constitute particularly serious horizontal restrictions known as "hardcore antitrust violations" and are regularly punished with heavy fines. The exchange of competitively sensitive information between competitors also generally violates German and EU antitrust law pursuant to Section 1 GWB and Article 101(1) TFEU.

2. "Pay-for-delay" agreements

The issue of pay-for-delay agreements continues to be a focus of antitrust decision-making in the pharmaceutical sector. Pay-for-delay agreements refer to agreements in the pharmaceutical sector whereby an original manufacturer (patent holder) grants a generic manufacturer a financial or economic advantage in order to delay the market entry of its cheaper generic product. Pay-for-delay agreements generally violate both German and EU antitrust law and, in some cases, German and EU market abuse law.

The first case of "pay for delay" agreements being punished under antitrust law was the Commission's *Lundbeck* decision.¹⁰ The Commission imposed a fine of EUR 93.8 million on the Danish pharmaceutical manufacturer *Lundbeck* and further fines totaling EUR 52.2 million on various generic manufacturers. This decision was upheld by the ECJ in 2021.¹¹

Further fines were imposed in the area of "pay-for-delay." In 2014, the Commission imposed fines totaling EUR 428 million on *Servier* and five other generic drug manufacturers, including *Lupin* and *Krka*, a total of EUR 428 million in fines.¹² The "pay-for-delay" allegation in the *Servier* case was based on various settlements relating to patents on the active ingredient perindopril and corresponding manufacturing technologies.¹³ The active ingredient perindopril, developed by *Servier*, is used to treat cardiovascular diseases such as high blood pressure.¹⁴ After the patents for perindopril expired in the 2000s, *Servier* applied for further patents in connection with the active ingredient.

— for example, for the technology used to manufacture perindopril, which was registered in 2004 in favor of *Servier*.¹⁵ In patent disputes with various generic drug manufacturers, *Servier* concluded several settlement agreements in which *Servier* undertook to make payments and the generic drug manufacturers agreed to enter the market at a later date in return.¹⁶ The Commission considered this to be both a violation of the EU antitrust prohibition under Article 101(1) TFEU and an abuse

of a dominant position under Article 102 TFEU.¹⁷

In its judgment of July 27, 2024, the ECJ upheld the Commission's decision in the *Servier* case with regard to a violation of the EU antitrust ban.¹⁸ Patent settlements in which generic manufacturers agree not to enter the market and not to challenge the patent in return for payment constitute, in the view of the ECJ, an intentional restriction of competition within the meaning of the EU antitrust prohibition. With regard to the Commission's finding of abuse of a dominant position under Article 102 TFEU, the ECJ objected to the market definition applied by the General Court¹⁹ and referred the case back to the General Court for reconsideration. This decision is still pending.

In its judgment of October 23, 2025, the ECJ (as previously the General Court) also upheld the Commission's decision in *Teva/Cephalon*.²⁰ In 2020, the Commission had imposed a fine of EUR 60.5 million on the pharmaceutical companies *Teva* and *Cephalon*.²¹ In the Commission's view, *Teva* and *Cephalon* had agreed to delay the market launch of a lower-priced generic version of *Cephalon*'s drug for sleep disorders (modafinil) by several years after the expiry of *Cephalon*'s main patents. This agreement was concluded well before *Teva*'s acquisition of *Cephalon*.

- 8 European Commission, press release dated July 4, 2025, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_25_1721; Summary of the Commission's decision of October 19, 2023 in a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement, Ref. C/2024/6961 final, available at: https://eur-lex.europa.eu/legal-content/DE/TXT/HTML/?uri=OJ:C_202406961.
- 9 European Commission, press release dated October 19, 2023, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5104; Summary of the Commission's decision of October 19, 2023, in a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement, Ref. C/2024/6961 final, available at: https://eur-lex.europa.eu/legal-content/DE/TXT/HTML/?uri=OJ:C_202406961.
- 10 European Commission, press release dated June 19, 2013, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_13_563. ECJ, judgment of March 25, 2021, Ref.: C-591/16 P — *Lundbeck*.
- 11 ECJ, judgment of March 25, 2021, Ref.: C-591/16 P — *Lundbeck*.
- 12 European Commission, Decision of July 9, 2024 in Case COMP/AT. 39612, *Perindopril (Servier)*.
- 13 European Commission, Decision of July 9, 2024 in Case COMP/AT. 39612, *Perindopril (Servier)*.
- 14 European Commission, Decision of July 9, 2024 in the matter of COMP/AT. 39612, *Perindopril (Servier)*, para. 1 et seq., 11 et seq.
- 15 ECJ, Press Release No. 107/24, available at: <https://curia.europa.eu/jcms/upload/docs/application/pdf/2024-06/cp240107en.pdf>.
- 16 European Commission, Decision of July 9, 2024 in Case COMP/AT. 39612, *Perindopril (Servier)*.
- 17 Summary of the Commission's decision in ECJ, judgment of June 27, 2024, Ref.: C-176/19 P, ECLI:EU:C:2024:549, para. 26 et seq. and ECJ, judgment of June 27, 2024, ref.: C-201/19 P, ECLI:EU:C:2024:552, para. 40 et seq.
- 18 ECJ, judgment of June 27, 2024, Case C-176/19 P et al. — *Servier*.
- 19 CFI, judgment of December 12, 2018, Case T-691/14 — *Servier*.
- 20 ECJ, judgment of October 23, 2025, Case C 2/24 P
- 21 European Commission, press release of November 26, 2011, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2220.

For pharmaceutical manufacturers, the above-mentioned decisions mean that any dispute resolution agreements between patent holders and generic drug manufacturers must still be carefully reviewed under antitrust law for any possible appearance of a "pay for delay" agreement.

3. Patent extension measures and discrediting/misleading information

In addition to hardcore cartels, information exchange, and In recent years, the Commission has increasingly focused on antitrust violations resulting from patent extension measures and discrediting and/or misleading information in relation to "pay-for-delay" agreements.

In October 2024, the Commission imposed a fine of EUR 462.6 million on *Teva* for (abusive) patent extension measures and the dissemination of discrediting or misleading information.²² The background to this was *Teva's* conduct in several markets for glatiramer acetate, a drug for multiple sclerosis that *Teva* markets under the name *Copaxone*.²³ The Commission accused *Teva* of abusing the patent system and patent procedures by filing several unsuccessful partial patent applications and strategically withdrawing them before a decision was made by the European Patent Office.²⁴ In the Commission's view, this strategy prevented the creation of precedents favorable to generic manufacturers, thereby delaying their entry into the market.²⁵ Secondly, according to the Commission's investigations, *Teva* carried out targeted campaigns aimed at denying the equivalence of competing generics. These measures included the dissemination of misleading information intended to undermine the confidence of doctors and patients in the efficacy and safety of generic drugs.²⁶ In the Commission's view, these practices constituted a violation of the EU prohibition on abuse of market power under Article 102 TFEU.²⁷ Depending on the Member State, the alleged infringements lasted for a period of four to nine years and, according to the Commission, prevented a reduction in list prices and savings in the public health sector.²⁸ The Commission's *Teva* decision is not yet final; *Teva* filed a lawsuit with the General Court in January 2025.²⁹

In September 2025, the Commission also carried out unannounced inspections (known as dawn raids) at the premises of a company in the vaccine industry.³⁰ The Commission suspects that the company under investigation may have violated the prohibition on abuse of market power under Article 102 TFEU. In particular, according to its own statements, the Commission is investigating "possible exclusionary practices by the company that could amount to anti-competitive disparagement measures."

Pharmaceutical companies should critically review their current patent strategies, particularly with regard to the filing of partial patents, and carefully analyze possible antitrust risks.

Drug manufacturers should also ensure that their communication and marketing strategies relating to competing products are objective and factually accurate and do not contain any misleading or reputation-damaging statements.

4. "Killer acquisitions" in the context of antitrust and abuse of market power

So-called *killer acquisitions* have been the focus of the Commission and national antitrust authorities for some time. *Killer acquisitions* in the pharmaceutical sector refer to the purchase of innovative, competing pipeline products with the aim or consequence of discontinuing overlapping drug R&D projects — which ultimately reduces innovation competition in the affected markets. In Germany, the 9th amendment to the GWB in 2017 introduced the so-called transaction value threshold (see Section 35 (1a) GWB), according to which certain mergers can be reviewed by the Federal Cartel Office under merger control law even if they fall below the turnover-based thresholds of Section 35 (1) GWB. According to the ECJ ruling in 2023 in the case of

22 European Commission, press release dated October 31, 2024: available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_5581.

23 Summary of the Commission's decision of October 31, 2024, in proceedings under Article 102 of the Treaty on the Functioning of the European Union (TFEU) (Case AT. 40588 — *Teva Copaxone*), para. 10, available at: https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=OJ:C_202501680.

24 Summary of the Commission's decision of 31. 10. 2024 in a proceeding under Article 102 of the Treaty on the Functioning of the European Union (TFEU) (Case AT. 40588 — *Teva Copaxone*), para. 13 et seq., available at: https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=OJ:C_202501680.

25 Summary of the Commission's decision of October 31, 2024, in a proceeding under Article 102 of the Treaty on the Functioning of the European Union (TFEU) (Case AT. 40588 — *Teva Copaxone*), para. 14, available at: https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=OJ:C_202501680.

26 Summary of the Commission's decision of October 31, 2024, in proceedings under Article 102 of the Treaty on the Functioning of the European Union (TFEU) (Case AT. 40588 — *Teva Copaxone*), paragraph 16, available at: https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=OJ:C_202501680.

27 Summary of the Commission's decision of 31. 10. 2024 in a proceeding under Article 102 of the Treaty on the Functioning of the European Union (TFEU) (Case AT. 40588 — *Teva Copaxone*), para. 1, available at: https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=OJ:C_202501680.

28 European Commission, press release dated October 31, 2024, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_5581.

29 Case T-19/25.

30 European Commission, press release dated September 30, 2025, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_25_2255.

31 For various definitions of so-called "killer acquisitions," see also: "Online expert workshop — DG Competition study on 'killer acquisitions' in the pharma sector" on April 10, 2025, available at: https://competition-policy.ec.europa.eu/about/reaching-out/online-expert-workshop-killer-acquisitions_en.

*Towercast*³² Transactions may also be subject to review by the Commission or national competition authorities even if they do not meet the European or national merger control thresholds and have not been referred to the Commission under Article 22 of the Merger Regulation. With its decision, the ECJ allows for an *ex post* review of transactions against the EU prohibition on abuse of market power under Article 102 TFEU.

On this basis, on November 6, 2025, the French competition authority imposed a fine of just under EUR 4.7 million on *Doctolib* for abuse of a dominant market position in connection with the acquisition of a competitor (despite the absence of merger control notification requirements). From the perspective of the French competition authority, *Doctolib*'s acquisition of its competitor *MonDocteur* in 2018 was, among other things, aimed at closing off the market for online doctor's appointments.

In March 2024, the Commission also initiated proceedings for the first time concerning the discontinuation of the development of pipeline products: The Commission is investigating whether the animal health company *Zoetis* abused its alleged dominant position in relation to its veterinary medicine *Librela* (Art. 102 TFEU).³³ The background to the proceedings is that *Zoetis* markets *Librela*, the first and only monoclonal antibody drug approved for dogs with osteoarthritis in Europe.³⁴ At the same time as developing *Librela*, *Zoetis* acquired another painkiller for the same indications that was in the final stages of development and was to be marketed by another company in the EEA.³⁵ The allegation is that *Zoetis* closed off the market by discontinuing the development of the alternative drug and refusing to transfer the alternative drug to another company.³⁶

It remains to be seen whether the Commission's suspicions will be confirmed in the course of its investigations. Overall, however, it is to be expected that the Commission and national antitrust authorities will in future take a closer look at antitrust violations in connection with the discontinuation of pipeline products in the pharmaceutical sector.

Pharmaceutical companies should therefore carefully review R&D agreements, license agreements, and M&A activities for compliance with German and EU antitrust law before concluding them.

III. Other current trends in antitrust law

In addition to the decisions specifically issued in the pharmaceutical sector, other current developments are also relevant for drug manufacturers. These trends must be taken into account both in antitrust guidelines and in the context of antitrust compliance management systems.

1. Antitrust violations in the HR sector

An important general trend is antitrust violations in the HR sector. Companies have long been

no longer compete with each other solely at the product level, but also compete for (skilled) workers. There is no antitrust exemption for the area of human resources. Although there is an exception to the antitrust prohibition for legally permissible collective bargaining agreements³⁷, this exception only applies if the agreement actually falls within the scope of collective labor law in terms of its content and parties.³⁸

Antitrust risks exist primarily in the following agreements between companies (as well as a corresponding exchange of information):

- **No-hire** agreements: Companies agree not to hire each other's employees if they apply for a job with the participating companies.
- **No poach** agreements: Companies agree not to actively poach each other's employees.
- **Wage fixing** agreements.

In June 2025, the Commission imposed fines totaling EUR 329 million on *Delivery Hero* and *Glovo*, two large food delivery companies. Among other things, the two companies are alleged to have agreed not to poach each other's employees.

When asked whether the Federal Cartel Office was investigating antitrust violations in the talent market, Andreas Mundt, President of the Federal Cartel Office, said in an interview with *Global Competition Review* on January 3, 2025, that it was "a bit of a miracle" that, given the many proceedings in the field of human resources in other jurisdictions, there had not yet been such a case in Germany. It is probably only a matter of time before this changes and the Federal Cartel Office takes up such a case.

³² *ECJ*, judgment of March 16, 2023, Case C-449/21 — *Towercast*.

³³ *European Commission*, press release of March 26, 2024, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_1687.

³⁴ *European Commission*, press release dated March 26, 2024, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_1687.

³⁵ *European Commission*, press release dated March 26, 2024, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_1687.

³⁶ *European Commission*, press release dated March 26, 2024, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_1687.

³⁷ This has been established case law at European level since ECJ Al-bany, 1999. In its ruling, the ECJ stated that collective agreements between organizations representing employers and employees "inevitably have certain restrictive effects on competition" (*ECJ* Al-bany, 1999, para. 59 ff.).

³⁸ For details, see *Zimmer* in: Immenga/Mestmäcker, *Competition Law*, 7th ed. 2025, para. 175 ff. with further references.

³⁹ See press release dated June 2, 2025, available at: https://germany.representation.ec.europa.eu/news/kartell-fur-online-essenslieferung-329-millionen-euro-geldbusse-fur-delivery-hero-und-glovo-2025-06-02_de.

⁴⁰ *Andreas Mundt* in: Q&A with Andreas Mundt, interview conducted by Janith Aranze, published on January 3, 2025, in *Global Competition Review*.

2. Restriction of parallel trade

Another (long-term) trend is restrictions on parallel trade. Any restrictions on parallel trade (export bans, quotas, etc.) must therefore be carefully examined under antitrust law. The Commission's determination to punish anti-competitive restrictions on parallel trade is demonstrated by the following two decisions outside the pharmaceutical sector:

First, in 2024, the Commission imposed fines totaling EUR 5.7 million on the fashion house *Pierre Cardin* and its largest licensee, *Ahlers*.⁴² Between 2008 and 2021, the companies had entered into anti-competitive agreements and coordinated their behavior in order to protect *Ahlers* from competition in its license territories in the European Economic Area (EEA).⁴³ Specifically, they prevented other *Pierre Cardin* licensees and their customers from selling *Pierre Cardin* brand clothing online or offline outside their license territories or to retailers with a low-price strategy.⁴⁴ From the Commission's point of view, the aim was to ensure absolute territorial protection for *Ahlers* and to artificially divide up the internal market.

Secondly, in 2024, the Commission imposed a fine of EUR 337.5 million on *Mondelez* for obstructing cross-border trade in chocolate, biscuits, and coffee from 2006 to 2020.⁴⁵ In the Commission's view, *Mondelez* used anti-competitive agreements and concerted practices to prevent wholesalers and retailers from selling cross-border without authorization, and used its market power to stop deliveries to low-price countries and prevent imports into more expensive markets.⁴⁶ The Commission considered this to be a harmful partitioning of the internal market, which led to higher consumer prices.⁴⁷

In the pharmaceutical sector, unilateral quota systems in particular can be a means of adequately countering the economic risks of parallel trade in a manner that complies with antitrust law. In *Le'los v. GlaxoSmithKline*, the ECJ clarified that unilateral quotas may violate the prohibition on abuse of a dominant market position under Article 102 TFEU (or, in Germany, Sections 18 et seq. GWB) if the company imposing the quotas holds a dominant market position.⁴⁸ However, in the view of the ECJ, even a dominant company must have the possibility of taking "reasonable measures commensurate with the need to protect its own commercial interests."⁴⁹ This may be relevant, for example, in the case of "abnormal" order quantities.⁵⁰

Whether the criteria established by the ECJ are met must always be examined on a case-by-case basis.

3. Excessive pricing (abuse of high prices)

In recent years, both the Commission and various national antitrust authorities have been looking into what they consider to be abusive overpricing by pharmaceutical manufacturers. In 2021, for example, the Commission declared the commitments offered by the pharmaceutical company *Aspen* to be legally binding in order to address concerns about excessively high prices for six off-patent cancer drugs.

commitments offered by the pharmaceutical company *Aspen* legally binding in order to address concerns about excessively high prices for six off-patent cancer drugs.⁵¹ According to the Commission's investigation, *Aspen* had gradually increased prices in many European countries by several hundred percent after acquiring the products. A review of *Aspen's* earnings data conducted by the Commission revealed that, following the price increases, the company consistently generated profits from the sale of these drugs in Europe that were very high both in absolute terms and in comparison to the earnings of similar companies in the industry.

The Commission was unable to find any legitimate justification for *Aspen's* consistently high profits in its investigation, especially since *Aspen's* medicines have been off-patent for 50 years. When national authorities attempted to resist the price increases, *Aspen* also threatened to delist its products, according to the Commission.

In its preliminary assessment, the Commission classified *Aspen's* pricing and conduct as abusive within the meaning of Article 102 TFEU. *Aspen* therefore committed to the Commission to significantly reduce the prices of the six cancer drugs in question.

As far as can be seen, there is as yet no case law from the Federal Cartel Office in the area of *excessive pricing* by pharmaceutical manufacturers. Insofar as drug manufacturers in Germany still have any leeway from a regulatory perspective, they should always critically review any price increases. This applies in particular to the marketing of older products without significant investment and/or R&D/development costs.

41 See *Kallmayer/Schwarz/Förtsch* in: Stief/Bromm, *Vertrags-handbuch Pharma und Life Sciences* (Contract Handbook for Pharmaceuticals and Life Sciences), 2nd edition, 2021, Chapter 6. I. B. 3.

42 *European Commission*, press release dated November 28, 2024, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_6104.

43 *European Commission*, press release dated November 28, 2024, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_6104.

44 *European Commission*, press release dated November 28, 2024, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_6104.

45 *European Commission*, press release dated May 23, 2024, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_2727.

46 *European Commission*, press release dated May 23, 2024, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_2727.

47 *European Commission*, press release dated May 23, 2024, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_2727.

48 *ECJ*, judgment of September 16, 2008, C-468/06 to C-478/06, *Lelos v. GSK*, ECLI:EU:C:2008:504, para. 69f, 77.

49 *ECJ*, judgment of September 16, 2008, C-468/06 to C-478/06, *Lelos v. GSK*, ECLI:EU:C:2008:504, para. 69 et seq.

50 *ECJ*, judgment of 16 September 2008, C-468/06 to C-478/06, *Lelos v. GSK*, ECLI:EU:C:2008:504, para. 76 et seq.

51 See summary of the Commission's decision of February 10, 2021 (AT. 40394 — *ASPEN*), available at: [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021AT40394\(02\)](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021AT40394(02)).

IV. Avoiding antitrust violations

In order to avoid heavy fines, time-consuming proceedings with antitrust authorities, civil lawsuits for antitrust damages, loss of reputation, and other negative consequences of antitrust violations, pharmaceutical manufacturers should have an effective antitrust compliance management system (CMS) in place.

1. Compliance management systems (CMS)

Effective compliance management systems can both prevent antitrust violations and detect them in a timely manner.

One of the most important preventive measures is a risk analysis of the company under antitrust law. Companies should be aware of the markets in which they operate, how these markets are defined under German and EU antitrust law, and what market shares and market positions they have in these markets. This ensures compliance with the applicable antitrust regulations. If, for example, a company has a dominant market position, this has an impact on, among other things, the company's pricing and discounting policies. If market shares exceed certain thresholds, this may affect the applicability of block exemption regulations, for example in the case of exclusivity agreements with suppliers or customers.

It is also important to analyze which associations the company is active in and which employees are involved in the association's work.

Finally, regular and targeted training of employees is essential. Both employee training and antitrust guidelines/manuals, etc. must also be regularly adapted to new developments in antitrust law, such as antitrust risks in the area of human resources.

2. Dawn raids

After the "corona dip," there has been an increase in antitrust searches (so-called dawn raids).⁵² In times of digitalization and home offices, however, the nature of searches has changed: The clear focus is now on e-searches, i.e., the search of email accounts, hard drives, networks, servers, clouds, central and local sharepoints, and a wide variety of end devices (some of which are used for both professional and private purposes ("dual use")).

What may be searched during a dawn raid is regulated for the Commission in Art. 20 of Regulation 1/2003⁵³ and for the Federal Cartel Office in Section 59b of the German Act Against Restraints of Competition (GWB). In its explanatory notes, the Commission expressly states:

"The auditors may search the company's IT infrastructure (e.g., cloud services, servers, desktop computers, laptops, tablets, and other mobile devices) and any data carriers (e.g., external storage media, backup tapes, USB sticks, CD-ROMs, DVDs). This also applies to private devices and data carriers found on site that are used for professional purposes."(54)

*and data carriers found on site that are used for professional purposes."*⁵⁴

If evidence is "removed" or destroyed during a search, this can result in heavy fines. For example, in its decision of June 24, 2024, the Commission imposed a fine of EUR 15.9 million on International Flavors & Fragrances Inc. and International Flavors & Fragrances IFF France SAS because a senior employee deleted WhatsApp messages during an antitrust investigation in which he had communicated with competitors.⁵⁵

Even in home offices, searches may be conducted on suspicion of antitrust violations. In an accompanying working document to the 2022 Commission report, the Commission analyzes how the COVID-19 pandemic has changed working habits. This has implications for where potential evidence of antitrust violations can be found.⁵⁶ For the first time in many years, the Commission has therefore exercised its power to search not only the employer's business premises but also the private homes of individuals.⁵⁷ The Federal Cartel Office also searched a total of eight private homes in 2024.⁵⁸

Dawn raid guidelines must be adapted to these developments (focus on e-searches, home offices) and employees must be prepared for "emergencies" through targeted training. The IT department must be trained and aware of its responsibilities in the event of a search by antitrust authorities.

V. Conclusion

The pharmaceutical sector remains the focus of antitrust authorities. Compliance management systems must be continuously updated and adapted to new antitrust developments and risk areas, such as antitrust violations in the HR sector. Dawn raid guidelines must also be reviewed to ensure they are up to date (e-searches, home office) and

⁵² See, for example, the Federal Cartel Office's annual report on important proceedings, data, and facts for 2023 and early 2024, available at: https://www.bundeskartellamt.de/SharedDocs/Publikation/DE/Jahresbericht/Jahresbericht_2023_24.html.

⁵³ Council Regulation (EC) No. 1/2003 of December 16, 2002, on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ No. L 1 of January 4, 2023, p. 1.

⁵⁴ Guidance on Commission inspections under Article 20(4) of Council Regulation (EC) No. 1/2003.

⁵⁵ *European Commission*, press release dated June 24, 2024, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_3435; *European Commission*, Decision of June 24, 2024, in case AT. 40882 — IFF.

⁵⁶ *European Commission*, Accompanying document to the Report on Competition Policy 2022, COM(2023) 184 final, point 1.3.

⁵⁷ *European Commission*, Accompanying document to the Report on Competition Policy 2022, COM(2023) 184 final, point 1.3.

⁵⁸ See Annual Report 2024/2025 of the Federal Cartel Office, available at: https://www.bundeskartellamt.de/SharedDocs/Publikation/DE/Jahresbericht/Jahresbericht_2024_25.pdf?__blob=publicationFile&v=7.

Employees (especially IT staff) should be trained accordingly. In light of the extensive activities of the antitrust authorities, it makes sense to analyze your own antitrust risks (once again) and, based on this analysis, take appropriate antitrust compliance measures. The associated costs are negligible compared to the costs incurred by an antitrust violation.

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Supply concepts of umbilical cord blood and umbilical cord tissue banks — Framework for advertising to the general public in light of Section 10 (1) HWG*

I. Introduction

The advanced development of stem cell therapies in modern medicine has been accompanied by the increasing establishment of public and commercial umbilical cord blood and umbilical cord tissue banks in Germany and the European Union.¹ The supply concepts of umbilical cord blood and umbilical cord tissue banks aim to obtain the stem cells contained in the umbilical cord blood and umbilical cord tissue at the time of a child's birth in order to use them in medical care due to their hematopoietic and mesenchymal properties.²

Specifically, umbilical cord blood is collected by puncturing the umbilical cord vein after the umbilical cord of a newborn has been cut in order to remove the remaining blood. In addition, a section of the umbilical cord itself is secured as biological material.

The stem cells contained in umbilical cord blood and umbilical cord tissue are then enriched using chemical and physical processes prior to cryopreservation. The enriched umbilical cord blood and processed umbilical cord tissue are deep-frozen after the addition of a cryoprotectant.

If needed for therapeutic purposes, the umbilical cord blood can be thawed and then prepared and used for stem cell therapy in the form of a hematopoietic stem cell transplant. Hematopoietic stem cell transplantation is a widely used standard treatment in the vast majority of European Union member states and is covered by statutory health insurance for around 80 diseases in the fields of hematology, oncology, metabolic disorders, and immunodeficiencies.

The stem cells required for hematopoietic stem cell transplantation can be obtained from bone marrow, mobilized peripheral blood, or umbilical cord blood.⁴ In contrast, the use of stem cells from umbilical cord tissue requires further processing to obtain mesenchymal stem cells.

and has not yet been established as a standard therapy. Nevertheless, mesenchymal stem cells are increasingly being used globally

— including within the European Union — increasingly being used, mostly in clinical trials or other experimental treatment approaches, such as compassionate use programs or hospital exemption procedures.

Against this backdrop, the extraction of stem cells from umbilical cord blood and umbilical cord tissue opens up a wide range of current therapeutic options, some of which are still in the clinical research phase.⁵ The diverse applications of such stem cells with high proliferation potential in state-of-the-art therapies are therefore sometimes even regarded as a *turning point in medicine*, offering hope for treating currently incurable diseases.⁶

However, preserving such options for prospective therapy requires a decision by the mother or guardian long before the actual treatment is needed.

* This article is based on a request from practice.

1 *Bien' /Vermeulen/Ba, czek et al.* (2024) 8:59 *European Journal of Midwifery*, 5; Market Data Forecast, Europe cord blood banking services market growth 2024—2033, available at: <https://www.marketdataforecast.com/market-reports/europe-cord-blood-banking-services-market> (last accessed on December 12, 2025).

2 *Bien' /Vermeulen/Ba, czek et al.* (2024) 8:59 *European Journal of Midwifery*, 5.

3 *Schlenke/Cassens/Sibrowski*, in: Kiefel, *Transfusion Medicine and Immunohematology*, 4th ed. 2011, 261 (263).

4 See, for example, *Snowden/Sa'nchez-Ortega/Corbacioglu et al.* (2022) 57: 1217—1239.

5 *Bien' /Vermeulen/Ba, czek et al.* (2024) 8:59 *European Journal of Midwifery*, 5. Stem cells from umbilical cord blood are already being used to treat lymphatic and hematopoietic diseases (such as sickle cell anemia). In the current guidelines for the treatment of cerebral palsy, the use of umbilical cord blood is considered to be evidence-based and effective, whereas mesenchymal stem cells are considered a potentially promising option worth trying as a therapy, see, for example, *Novak/Morgan/Fahey et al.* (2020) 20:3 *Current Neurology and Neuroscience Reports*.

6 *Bien' /Vermeulen/Ba, czek et al.* (2024) 8:59 *European Journal of Midwifery*, 5.

The rights of the child require that umbilical cord blood and umbilical cord tissue be collected and stored at the time of birth. The necessary basis for an informed decision about the prospects and burdens to be weighed in connection with the planned collection of umbilical cord blood and umbilical cord tissue is — in addition to the factual information and advice provided by the doctor or midwife — is that pregnant women and future parents are aware of the existing care concepts of umbilical cord blood and umbilical cord tissue banks. However, they are often not sufficiently informed about the care concepts and possible subsequent therapy options.

Since the market for umbilical cord blood and umbilical cord tissue processing and application is still in its development phase and, in terms of demand, (probably still) limited awareness, the question arises for the actors involved in the supply chain from a multifaceted perspective as to the legal limits within which corresponding supply concepts and the opening up of subsequent therapy options may be advertised to interested parties. A look at legal practice shows, however, that the fundamental question of the admissibility under therapeutic products advertising law of advertising for umbilical cord blood and umbilical cord tissue, as well as subsequent therapy options, has only been addressed in isolated cases to date.

This neglect seems unsatisfactory, given that this is a field of research and therapy that, despite some unresolved issues, is already at an advanced stage of development. In addition, this could open up potentially far-reaching and novel treatment options for which there are currently no or only very limited therapeutic alternatives.

Against this background, the legal issues arising in connection with the collection and processing as well as the advertising and marketing of umbilical cord blood and umbilical cord tissue will be addressed below. First, the regulatory classification of umbilical cord blood and umbilical cord tissue must be clarified (see section II below). Building on this, the follow-up question of whether and to what extent interested parties may be informed and advertised about the possibilities of collecting and storing umbilical cord blood and umbilical cord tissue, as well as the possibilities of treating (potentially) future diseases with stem cell therapy, will be addressed (see section III below). Finally, a conclusion will be drawn (see section IV below).

II. Regulatory classification of umbilical cord blood and umbilical cord tissue

1. Classification of umbilical cord blood under therapeutic products advertising law by case law

1.1 On the specific issue of the regulatory classification of umbilical cord blood and umbilical cord tissue, there are only isolated decisions in case law

, but these have not adequately addressed the legal issues that need to be considered.

1.2 The decision of the Leipzig Regional Court of

December 10, 2010 (Ref.: — 04HK O 4388/09 —) was essentially the question of the admissibility of representations made by an operator of an umbilical cord blood bank for the collection and storage of stem cells from umbilical cord blood for future therapeutic purposes and a resulting violation of the prohibition on public advertising under Section 10(1) of the German Act on Advertising in the Field of Healthcare (Heilmittelwerbegesetz, "HWG"). At the time, the representations at issue in the proceedings were also challenged on the grounds of an alleged violation of the prohibition of misleading advertising pursuant to Section 3 HWG, on the basis that there was insufficient scientific evidence of the therapeutic effect of the subsequent autologous therapy.

1.3 As a result, the 4th Chamber for Commercial Matters of the Leipzig Regional Court ruled that the advertising of a prescription drug was inadmissible under Section 10 (1) HWG, pointing out that the website advertised "*the umbilical cord blood itself as a functional drug and no longer merely a precursor*."⁸ Although umbilical cord blood itself is not subject to prescription, — the prohibition in Section 10 (1) HWG still applies, since when advertising umbilical cord blood itself, "*inevitably [...] the end product is also being advertised*."⁹

1.4 The classification and assessment of the legal opinion found by the Leipzig Regional Court with regard to the prohibition of advertising to the general public under Section 10 (1) HWG essentially depends on the regulatory product characteristics of umbilical cord blood and the blood preparations obtained from it through further processing steps. Based on this, the follow-up question arises as to whether the legal assumption of the

4th Chamber of the Leipzig Regional Court is actually tenable, according to which the prohibition of advertising to the general public under

Section 10 (1) HWG already applies in factual terms if a substance taken from the body itself is not yet subject to the definition of a medicinal product — and to prescription requirements — but the further intended use of this substance cannot be meaningfully described without at the same time referring to a preparation that can potentially be obtained from it, which — as an end product — is itself subject to prescription.

1.5 This applies to blood preparations derived from umbilical cord blood, particularly in view of the fact that years can pass between the time of application and the collection of umbilical cord blood, through to the preparation and application of a ready-to-use blood preparation, whereby

7 Bien'/Vermeulen/Ba, czech et al. (2024) 8:59 European Journal of Midwifery, 5.

8 LG Leipzig, judgment of December 10, 2010 — 04HK O 4388/09, juris para. 46.

9 LG Leipzig, judgment of 10 December 2010 — 04HK O 4388/09, juris para. 46.

the actual necessity of use as a blood preparation — for an autologous or allogeneic stem cell donation — is not even finally determined at the time of application and collection.

1.6 Unfortunately, none of this was taken up in the appeal proceedings by the 14th Senate of the Dresden Higher Regional Court in its ruling of July 19, 2011 (Ref.: — 14 U 87/ 11 —). Instead, the inadmissibility of the specific representation challenged was based on a violation of the general prohibition of misleading advertising under Section 5 (1) No. 1 of the Unfair Competition Act ("UWG"), which is why it was left open whether a violation of the prohibition of advertising to the general public under Section 10 (1) HWG was also to be assumed. In the opinion of the Dresden Higher Regional Court, the therapeutic possibilities pursued with umbilical cord blood were not presented in a sufficiently objective and factual manner in the contested representations, so that the relevant public was misled about the prospects of success of a treatment.¹⁰ Against this background, the fundamental question of whether and, if so, under what conditions the advertising of umbilical cord blood (and umbilical cord tissue) may constitute a violation of the prohibition on advertising to the general public under Section 10 (1) HWG was not further discussed.

2. Distinction under pharmaceutical law between functional medicinal products and mere precursors

2.1 In the absence of a supreme court ruling on the question of whether umbilical cord blood and umbilical cord tissue are in fact functional medicinal products within the meaning of Section 2 (1) of the German Medicinal Products Act (Arzneimittelgesetz, "AMG") or rather as a precursor, this question must be examined below. The guiding criteria for the assessment are (i) the recognizability of the medicinal purpose as the starting point for consideration and (ii) the necessity of essential processing steps as a decisive evaluation criterion.

2.2 Recognizability of the medicinal purpose as the starting point for consideration

2.2.1 For a product to be considered a medicinal product, Section 2 (1) sentence 2 no. 2 AMG requires a medicinal purpose to be specified in the wording "*for the purpose of [...]*".¹¹ For reasons of drug safety and consumer protection, the intended purpose must be determined objectively on the basis of the general understanding of the market.¹²

2.2.2 In its earlier case law, the Federal Administrative Court therefore based its distinction between medicinal products and mere precursors—with regard to functional medicinal products—on the stage of production at which it is possible to determine and recognize an intended use.¹³ According to this understanding, it was sufficient for classification as a functional medicinal product that a substance was intended for medicinal purposes when it was manufactured. In contrast, it was irrelevant for classification as a medicinal product if a chemical-physical process took place during further processing, as a result of which...

a completely new substance is created, which is ultimately used in or on the human body.¹⁴

2.2.3 An example of this earlier decision-making practice can be found in the ruling of the Federal Administrative Court on the assessment of so-called marker kits, which are enriched with a radioactive substance, administered intravenously, and used for imaging organs. At the time, the Federal Administrative Court considered it appropriate to classify the marking kits as medicinal products on the grounds that "*the manufacturer of such dry substances [...] requires a medicinal product manufacturing license in accordance with Section 13 (1) AMG and is subject to the special manufacturing responsibility pursuant to § 19 AMG and is subject to strict liability under § 84 AMG*".¹⁵

2.2.4 However, the line of argumentation taken shows that, in this specific case, the regulatory classification as a medicinal product was guided less by legal and systematic requirements and more by considerations of protection. Ultimately, the Federal Administrative Court accepted the classification as a medicinal product in the context of an impact assessment in order to trigger the application of the regulations on manufacturing responsibility and strict liability, which were considered appropriate and necessary. In a dogmatically questionable manner, a legal consequence was not derived from the existence of a factual requirement, but rather, conversely, a desired legal consequence was used to infer a factual requirement necessary for this purpose.

2.2.5 Apart from the dogmatic weakness of this approach, it does not appear convincing from a protection perspective, at least with regard to the regulatory classification of umbilical cord blood and umbilical cord tissue examined in this article. This is because the life cycle of umbilical cord blood and umbilical cord tissue is regulated by Directive 2002/98/EC of the European Parliament and of the Council of January 27, 2003, setting standards of quality and safety for the collection, testing, processing, storage, and distribution of umbilical cord blood and umbilical cord tissue.

10 Higher Regional Court of Dresden, judgment of July 19, 2011 — 14 U 87/11, juris para. 17 ff.

11 Müller, in: Kügel/Müller/Hofmann Arzneimittelgesetz (German Medicines Act),

3. Edition 2022, AMG, Section 2, margin note 111; Rehmann, Arzneimittelgesetz (German Medicines Act), 5th edition 2020, AMG, Section 2, margin note 2; see also Wesser, in: Kloesel/Cyran, Arzneimittelrecht, 138th edition, 2022, AMG, Section 2, margin note 48; Brixius, in: Bergmann/Pauge/Steinmeyer, Gesamtes Medizinrecht, 4th edition, 2024, AMG, Section 2, margin note 3.

12 BayVGH, decision of August 23, 1982 — 11 CS 82 A. 1343, Sander, Entscheidungsband zum Arzneimittelrecht, as of July 2013, § 2 AMG No. 7, p. 3; Müller, in: Kügel/Müller/Hofmann Arzneimittelgesetz, 3rd ed. 2022, AMG, § 2 Rn. 112, 114; Rehmann, Arzneimittelgesetz (German Medicines Act), 5th edition, 2020, AMG, Section 2, margin note 2; see also Wesser, in: Kloesel/Cyran, Arzneimittelrecht (Medicines Law), 138th edition, 2022, AMG, Section 2, margin note 49; Brixius, in: Bergmann/Pauge/Steinmeyer, Gesamtes Medizinrecht (Complete Medical Law), 4th ed. 2024, AMG, § 2 margin note 3.

13 BVerwG, judgment of November 29, 1984 — 3 C 6/84, juris margin note 25 (available here available); See also BGH, decision of November 6, 2007 — 1 StR 302/07, juris margin note 6; explanatory note on this BVerwG, judgment of March 3, 2011 — 3 C 8/10, juris para. 17.

14 Federal Administrative Court, judgment of November 29, 1984 — 3 C 6/84 —, juris para. 25; Federal Administrative Court, judgment of March 3, 2011 — 3 C 8/10, juris para. 17.

15 BVerwG, judgment of November 29, 1984 — 3 C 6/84, juris para. 25.

collection, storage, and distribution of human blood and blood components ("Directive 2002/98/EC"), Directive 2004/23/EC of the European Parliament and of the Council of March 31, 2004 setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells ("Directive 2004/23/EC") and the provisions implementing these directives in the German Transfusion Act ("TFG") and the German Organ and Tissue Donation and Transfer Act ("TPG") and Sections 20b and 20c of the German Medicines Act ("AMG").

2.3 Necessity of essential processing steps as a decisive evaluation criterion

2.3.1 In the period that followed, the Federal Administrative Court became aware of the dogmatic weakness of its initially advocated more far-reaching approach, with the result that the case law was corrected accordingly.¹⁶ Since then, the decisive criterion for distinguishing between medicinal products and intermediate products has been whether an overall assessment of the manufacturing process leads to the conclusion that significant processing and/or preparation steps are still required before the final product is ready for sale.

2.3.2 From a legal perspective, this was correctly justified by the Federal Administrative Court on the grounds that, in addition to the provisions on medicinal products, the legislator has also created regulations for active substances, intermediate products, and starting materials.¹⁸ This means that the law already makes a distinction that precludes any product in a multi-stage manufacturing process from being classified as a medicinal product solely because a medicinal use becomes apparent at a later stage.¹⁹ This is also reflected, for example, in the provision of Section 13(1)(1) and (3) AMG, which differentiates between the manufacture of medicinal products and other substances of human origin intended for the manufacture of medicinal products with regard to the manufacturing authorization.²⁰ Furthermore, unlike food law, for example, pharmaceutical law lacks an explicit provision stipulating that the "precursors of a product" are subject to the regulations applicable to the "end product."²¹

2.3.3 The recent ruling by the Federal Administrative Court thus appropriately reflects the distinction made in pharmaceutical law between medicinal products and precursors by using the necessity of further essential processing steps as the decisive criterion for differentiation.²² According to the now established case law of the Federal Administrative Court, processing or preparation of the product is essential if according to common opinion it characterizes the manufacturing process or is of particular importance for the product's readiness for use. For example, the facts underlying the decision of the Federal Administrative Court of August 17, 2017 — 3 C 18/15 concerned the import and subsequent processing of leeches, whereby — also in view of the time component of the 32-week quarantine — both the sorting out of unsuitable leeches and the quarantine and monitoring processes were classified as essential processing steps in the context of an assessment of the manufacturing process.

of unsuitable leeches and the quarantine and monitoring processes were classified as essential processing steps in the context of an assessment of the manufacturing process.²⁴

2.4 Umbilical cord blood and umbilical cord tissue as mere preliminary products

2.4.1 Based on this established case law of the Federal Administrative Court, umbilical cord blood and umbilical cord tissue are to be classified as mere precursors of the end product still to be manufactured. This is because an overall assessment of the comprehensive manufacturing process leads to the conclusion that umbilical cord blood and umbilical cord tissue require further — essential — processing steps and are therefore intended for further processing into a medicinal product.

2.4.2 When umbilical cord blood and tissue are collected, these substances taken from the human body are not yet intended (or suitable) for immediate medicinal use. Instead, after collection, the umbilical cord tissue undergoes further essential production steps, including quality and viability tests, preparation and cryopreservation if necessary²⁵ and final quality controls, before it can be used as a medicinal product. In the case of umbilical cord tissue, even more extensive processes are required in order to isolate functional cells, propagate them, test their efficacy, and prepare them in a suitable dosage and dosage form as a medicinal product.

3. Classification of umbilical cord blood and umbilical cord tissue as presentation medicinal products due to reference to the end product?

3.1 The 4th Chamber of the Leipzig Regional Court recognized the necessity of further essential processing steps, but ultimately disregarded this fact. In this context, the court pointed out that the representations at issue in the proceedings did not refer solely to the umbilical cord blood itself, but also, "necessarily," to the "end product" produced in the course of the further processing process.

- 16 *BVerwG*, judgment of August 17, 2017 — 3 C 18/15, juris para. 25; *BVerwG*, judgment of March 3, 2011 — 3 C 8/10, juris para. 18. See also *OVG Lüneburg*, judgment of October 24, 2002 — 11 LC 207/02, juris para. 38.
- 17 *Federal Administrative Court*, judgment of August 17, 2017 — 3 C 18/15, juris para. 25, 27.
- 18 *Federal Administrative Court*, judgment of March 3, 2011 — 3 C 8/10, juris para. 18.
- 19 *Federal Administrative Court*, judgment of March 3, 2011 — 3 C 8/10, juris para. 18.
- 20 See also *Wesser*, in: Kloesel/Cyran Arzneimittelrecht Kommentar, 138. Akt.-Lief. 2022, AMG, Art. 2 para. 22.
- 21 See also *BayVGH*, decision of August 23, 1982 — 11 CS 82 A. 1343; *Sander*, Decision Volume on Medicinal Products Law, as of July 2013, Section 2 AMG No. 7, p. 3.
- 22 *Federal Administrative Court*, judgment of March 3, 2011 — 3 C 8/10, juris para. 18. See also *OVG Lüneburg*, judgment of October 24, 2002 — 11 LC 207/02, juris para. 38.
- 23 *BVerwG*, judgment of August 17, 2017 — 3 C 18/15, juris para. 27.
- 24 *BVerwG*, judgment of August 17, 2017 — 3 C 18/15, juris para. 28.
- 25 *Hasskarl/Hasskarl/Ostertag*, PharmR 2002, 81 (84).

This constructive approach has been interpreted in the literature to mean that the Leipzig Regional Court assumed that the product in question was a presentation drug, even though it had been incorrectly labeled as a functional drug.

3.2 However, this interpretation is not convincing. The legal concept of a presentation drug is designed to cover not only actual drugs but also so-called apparent drugs under the regulatory term "drug" in order to ensure comprehensive protection of consumers from potentially harmful or toxic products that could be used instead of suitable remedies.²⁸ The legal concept of a presentation drug covers cases in which a product that objectively has no medicinal properties is falsely attributed such properties.²⁹ Although these circumstances always constitute a violation of the prohibition of misleading advertising under the law on the advertising of medicinal products, national and European legislators wanted to put a stop to such practices in general by not only prohibiting misleading claims about effects under the regulations on the advertising of medicinal products, but also by prohibiting the use of misleading packaging and packaging inserts. However, national and European legislators wanted to put a stop to such practices in general by not only prohibiting misleading claims about effects under the regulations governing the advertising of medicinal products, but also by consistently subjecting such "quasi-medicinal products" to the regime of medicinal product law in general.

3.3 These considerations make it clear that the legal concept of a presentation drug is unsuitable for the regulatory classification and treatment of umbilical cord blood and umbilical cord tissue. On the one hand, it is not necessary to close any gaps in protection, as umbilical cord blood and umbilical cord tissue cannot (and should not) be used in any form on the human body as precursors and are already subject to a comprehensive framework of special legislation. On the other hand, given that the respective end products as functional medicinal products are themselves subject to the regime of pharmaceutical law, there is no apparent need for increased protection that could require and justify the classification of the precursors as presentation medicinal products.

3.4 The regulatory classification of umbilical cord blood and umbilical cord tissue as presentation drugs would therefore only be considered if the umbilical cord blood and umbilical cord tissue were presented in a form that would give the false impression that they could be used directly as drugs. However, such a scenario—which is completely unrealistic—was not the basis for the decision of the Leipzig Regional Court and therefore does not need to be discussed further below.

4. Reference object of the advertisement as a reference point for classification under therapeutic products advertising law

4.1 The legal question to be answered by the 4th Commercial Chamber of the Leipzig Regional Court must therefore be understood correctly as meaning that a distinction must be made according to the respective reference object of the information and advertising. Insofar as representations refer (only) to umbilical cord blood and umbilical cord tissue

In view of the regulatory classification outlined above as precursors that still require further significant processing steps, advertising as such does not constitute factual advertising for (prescription) drugs.

4.2 The situation may be different if the respective end products are discussed, with which the relevant therapeutic possibilities are exhausted in each case. These may initially be products that are classified as medicinal products for regulatory purposes, in which case this classification should then be made correctly not on the basis of the legal concept of a presentation medicinal product, but on the basis of the concept of a functional medicinal product.

4.3 Against this background, the question therefore arises as to whether the threshold for the prohibition of advertising to the general public pursuant to Section 10 (1) HWG is actually already exceeded if a presentation on umbilical cord blood and umbilical cord tissue also refers to the opening of treatment options pursued with the collection of umbilical cord blood and umbilical cord tissue. This has not been further substantiated by the Leipzig Regional Court, but has simply been assumed on the basis that the description of the intended use of the preliminary products "necessarily" also has to refer to the "end products."

4.4 Whether the strict and far-reaching interpretation of the prohibition of advertising to the general public pursuant to Section 10 (1) HWG advocated by the Leipzig Regional Court is actually compatible with the protective purposes of the provision has not been further addressed by case law. This central question will therefore be examined in more detail below.

III. Legal framework of the ban on advertising to the general public under Section 10(1) HWG

1. Regulatory content and normative purposes

1.1 Ban on advertising to the general public

1.1.1 Section 10(1) HWG establishes a ban on advertising prescription drugs to the general public. These drugs may only be advertised to doctors, dentists, veterinarians, pharmacists, and persons who are authorized to trade in these drugs.

1.1.2 Advertising for prescription drugs is therefore only permitted to — in comparison to

26 *LG Leipzig*, judgment of December 10, 2010 — 04HK O 4388/09, juris para. 46.

27 *Higher Regional Court of Dresden*, judgment of June 28, 2011 — 14 U 87/11 PharmR 2012, 149 (152) with note by *Ruhl/Strobel*.

28 *ECJ*, judgment of November 15, 2007 — C-319/05, juris para. 43; *Federal Administrative Court*, judgment of March 3, 2011 — 3 C 8/10, juris margin note 21; *Müller*, in: *Kügel/Müller/Hofmann Arzneimittelgesetz (German Medicines Act)*, 3rd ed. 2022, AMG, § 2 para. 20; *Wesser*, in: *Kloesel/Cyran, Arzneimittelrecht (Medicines Law)*, 138th ed. 2022, AMG, § 2 para. 48a; *Platzmann*, in: *Prütting, Medical Law*, 6th ed. 2022, AMG, § 2 margin note 3a; *Stephan*, in: *Fuhrmann/Klein/Fleischfresser, Drug Law*, 3rd ed. 2020, § 2, margin note 85.

29 *Wesser*, in: *Kloesel/Cyran, Arzneimittelrecht*, 138th ed. 2022, AMG, Section 2 margin note 35.

the legal definition of specialist circles contained in Section 2 HWG — restricted specialist audience and therefore not permissible for other audiences.³⁰ The ban on advertising to the general public finds its basis in European law in Article 88(b) of Directive 2001/83/EC of the European Parliament and of the Council of

6. 11. 2001 establishing a Community code relating to medicinal products for human use ("**Directive 2001/83/EC**").

1.2 Limiting the risks of self-medication

1.2.1 The prevailing opinion traditionally sees the purpose of Section 10 HWG as limiting the risks of self-medication.

³¹However, this is contradictory insofar as genuine self-medication with prescription drugs is already effectively ruled out by the statutory prescription requirement. The risk of self-medication with prescription drugs can therefore only exist to a very limited extent from the outset, for example, if already prescribed drugs are kept in the "home medicine cabinet" and can then be used without prior consultation with a doctor.³² However, this circumstance is taken into account in healthcare practice by the fact that the prescription of prescription drugs must be based on the safe and proper use of the drug in accordance with its approval and on the specific need. Targeted and excessive

"stockpiling," which could result in further potential dangers in the form of improper self-medication, is therefore already counteracted by law in other ways.

1.3 Protection of the relationship of trust between doctor and patient

1.3.1 The weaknesses of a justification of Section 10 (1) HWG based on limiting the dangers of self-medication are now recognized in case law and literature. Against this background, a shift in emphasis is needed.

Pursuit of the protective purpose of Section 10 (1) HWG to be drawing attention to the fact that the physician, who has freedom and responsibility in the choice of therapy, as well as the relationship of trust between the physician and the patient, must be protected from advertising-induced prescriptions and disturbances. According to this understanding, the protective purpose of the prohibition under Section 10(1) HWG is therefore to ensure that the physician's consultation and prescription activities are not influenced by advertising.

1.3.2 However, this protective purpose is also hardly convincing. This is because it is one of the tasks of the physician responsible for therapy to consider and discuss all possible treatment options with the patient. The idea that this must be a one-sided communication from the physician to the patient hardly corresponds to the model of a mature and informed patient and has long been outdated by the Internet age and the information available there.

1.3.3 The supposed goal of doctors providing advice and prescribing medication without being influenced by advertising is not realized without restriction by the legislature itself, which—rightly—allows advertising for prescription drugs to be directed at professional circles. However, if the legislature does not consider it justified and necessary to "protect" doctors themselves from advertising influence for prescription drugs, it is not entirely clear why something else should apply with regard to the fact that patients could be prompted by such advertising for prescription drugs to discuss their importance and usefulness with their doctor in the event of treatment.

1.4 Fiscal protection

1.4.1 Against this background, there are many indications that maintaining the ban on advertising prescription drugs to the general public is primarily aimed at protecting the financial stability of the statutory health insurance system from advertising-induced prescription pressure.³⁴ In this respect, too, however, it should be possible and reasonable for a physician to discuss the medical appropriateness of a prescription in dialogue with the patient. From a legal perspective, the protection of fiscal interests is not one of the protective purposes pursued by the provisions of the law on the advertising of medicinal products. Rather, the protection of the financial stability of the statutory health insurance system must be ensured — solely — by the relevant provisions of social security law.

1.4.2 Even if the different protective and target orientations of the ban on advertising prescription drugs to the general public are not readily comprehensible against the backdrop of the model of an intelligent, critical, and informed average consumer in the Internet age, in which numerous — and, moreover, largely unchecked information on prescription drugs is available "at the click of a mouse," they must nevertheless be taken as a basis for assessment as long as the legislature adheres to them.³⁵

30 Reese, BeckOK HWG, 15th edition, as of October 1, 2025, § 10 Rn. 77; Mand, in: Prütting, Medizinrecht, 6th ed. 2022, HWG, Section 10 margin note 1.

31 BVerfG, decision not to accept case of April 30, 2004 — 1 BvR 2334/03, juris margin note 11; OLG Hamburg, PharmR 2007, 294, 297; Reese, BeckOK HWG, 15th edition, as of October 1, 2025, § 10 para. 21; Mand, in: Prütting, Medical Law, 6th edition 2022, HWG, § 10 margin note 2.

32 Whether such (exceptional) circumstances alone can actually constitute a justification for a general advertising ban seems doubtful, but this issue will not be discussed in depth here. See also Reese, BeckOK HWG, 15th edition, as of October 1, 2025, Section 10 margin note 21; Reese, FS Sander, p. 289.

33 Mand, in: Prütting, Medizinrecht, 6th ed. 2022, HWG, § 10 margin note 5; margin note 103; Zimmerman, in: Fuhrmann/Klein/Fleischfresser, Arzneimittelrecht, 3rd ed. 2020, § 28 margin note 103; critical Reese, BeckOK HWG, 15th edition, as of October 1, 2025, § 10 margin note 22–24.

34 Reese, BeckOK HWG, 15th edition, as of October 1, 2025, § 10 margin note 25; Mand, in: Prütting, Medical Law, 6th edition 2022, HWG, § 10 margin note 5.

35 Critical on this point Reese, BeckOK HWG, 15th edition, as of 1. 10. 2025, § 10 margin note 23.

2. Necessity of an interpretation in conformity with (EU) fundamental rights

2.1 Against the background of the concerns outlined above, however, legal practice in recent years has increasingly recognized that a blanket and schematic application of the prohibition under Section 10(1) HWG is not permissible. In addition to the exceptions in Section 1 (5) to (8) HWG, normative starting points for this arise from a restrictive interpretation of the term "product-specific sales promotion" to be considered in each individual case, which also takes into account the aspect of an interpretation of advertising regulations that complies with (EU) fundamental rights.³⁶ The criterion for such a restrictive interpretation in conformity with (EU) fundamental rights must be, in each individual case, whether the advertising in question poses at least abstract potential risks which, according to the regulatory purposes of the norm outlined above, are to be counteracted by legislation.

2.2 The Federal Court of Justice is now increasingly taking these aspects into account in its interpretation and application of abstract endangerment offenses under the law on advertising for medicinal products.³⁷ It is true that it is in the nature and function of an abstract offense that it should apply with regard to a presumed abstract danger of the acts covered, without there actually having to be a concrete danger to legal interests in individual cases. Nevertheless, the Federal Court of Justice recognizes that advertising bans, as measures restricting fundamental rights, do not constitute and must not pursue a legislative end in themselves. Therefore, if, in individual cases, there is no reason to fear the existence of such an abstract danger in view of special and atypical circumstances that distinguish the conduct in question from the standard case established by law, the advertising ban must be set aside in the context of a restrictive and protective interpretation.

3. Right to medical self-expression

3.1 The necessity of an interpretation that complies with (EU) fundamental rights and of a restrictive interpretation of the prohibition under the law on advertising for medicinal products in § 11 (1) HWG is also recognized by the highest court rulings, particularly with regard to the doctor's right to self-presentation, which is enshrined in constitutional law in Art. 12 (1) of the Basic Law ("GG").

3.2 In its ruling of October 9, 2003 (Ref.: — I ZR 167/01 —) on the assessment under competition law of the practice areas listed by a dentist on his website, the Federal Court of Justice fundamentally clarified that *"in addition to the advertising effect based on his services and reputation, the doctor cannot be denied, within certain limits, announcements of an advertising nature"* and that he *"remains free, in principle, to draw attention to his services in an appropriate manner and to satisfy an existing interest in information that has been brought to his attention."*⁽³⁹⁾

3.3 In its decision not to accept the case on April 30, 2004 (Ref.: — 1 BvR 2334/03 —), the Federal Constitutional Court held that the significance and scope of the doctor's right to self-presentation, which is enshrined in Article 12(1) of the Basic Law, must be taken into account in the interpretation of the content and scope of the ban on advertising to the general public under Section 10(1) of the German Medicines Advertising Act (HWG). With regard to the presentation of a physician on his website, which is the subject of the proceedings, stating that he offers a "biological facelift" with the prescription-only active ingredient botulinum toxin (Botox), the Federal Constitutional Court expressly emphasized that, in view of the fact that *"the doctor would be prevented from providing a meaningful description of the treatment he offers"* if advertising with the single-ingredient product (Botox) were prohibited, *the courts must address the question of whether [...] the right to self-expression outweighs the legislative purpose of Section 10 (1) HWG.*⁴⁰ In this interpretation, particular consideration should be given to whether (i) the advertising in question is carried out on a passive presentation platform, which means that it is not imposed on the general public unprepared; and (ii) the risk of self-medication is (rather) low.⁴¹

3.4 With regard to the presentation of umbilical cord blood and umbilical cord tissue, as well as the prescription-only end products that can be obtained from them, to target audiences, doctors cannot be prevented from referring to these (preliminary) products in advertising in order to adequately describe their range of services and treatments. This is because, in view of the special circumstances surrounding stem cell therapy, it would not be possible to describe the range of services and treatments without referring to umbilical cord blood and umbilical cord tissue as preliminary products and the prescription-only end products that can be obtained from them. In addition, stem cell therapy essentially consists of the use of end products obtained from umbilical cord blood and umbilical cord tissue. An overly strict interpretation and application of the ban on advertising to the general public in Section 10(1) HWG would therefore lead to the completely inappropriate and disproportionate result that doctors would be unable to meaningfully describe the content of the treatment to be performed. Since there is not even any abstract potential risk to the recipients of the advertising, the prohibition in Section 10 (1) HWG must be considered to be behind the ver-

³⁶ Reese, BeckOK HWG, 15th edition, as of October 1, 2025, Section 10, margin note 27; see also Mand, in: Prütting, Medizinrecht, 6th edition, 2022, HWG, Section 10, margin note 9

³⁷ BGH, judgment of March 1, 2007 — I ZR 51/04, juris margin note 19; BGH, judgment of January 18, 2012 — I ZR 83/11, juris margin note 18; Reese, BeckOK HWG, 15th edition, as of October 1, 2025, Section 11 margin note 63 et seq.

³⁸ Reese, BeckOK HWG, 15th edition, as of October 1, 2025, § 11 para. 64.

³⁹ Federal Court of Justice, judgment of October 9, 2003 — I ZR 167/01, juris para. 36; see also previously Federal Court of Justice, judgment of June 8, 2000 — I ZR 269/97, juris para. 24 on the "legitimate need to present one's own range of services to interested parties."

⁴⁰ BVerfG, decision not to accept case of April 30, 2004 — 1 BvR 2334/03, juris para. 14 f.

⁴¹ BVerfG, decision not to accept case of April 30, 2004 — 1 BvR 2334/03, juris para. 15.

constitutionally guaranteed right to medical self-expression.

3.5 This leads to the following interim finding: The advertising of umbilical cord blood and umbilical cord tissue as precursor products does not, in principle, violate Section 10 (1) HWG, as they are neither functional nor presentation drugs. Furthermore, in view of the constitutionally guaranteed right to medical self-expression, the promotion by doctors of prescription-only end products obtained from these precursors does not, in principle, constitute a violation of the prohibition on advertising to the general public under the law on the advertising of medicinal products.

3.6 Against this background, the central question for advertising by umbilical cord blood and umbilical cord tissue banks is whether the legal opinion represented by the 4th Chamber of Commerce of the Leipzig Regional Court, according to which the mere reference to the subsequent use of umbilical cord blood and umbilical cord tissue for the manufacture of prescription-only end products is sufficient to trigger the prohibition under Section 10(1) HWG.

4. Consequences for advertising by umbilical cord blood and umbilical cord tissue banks

4.1 However, the following considerations show that this is not objectively the case. Ultimately, none of the protective purposes of Section 10(1) HWG are affected in a legally significant way by factual information about the possibilities of the subsequent manufacture and use of stem cell therapies.

4.2 No abstract risk of self-medication

4.2.1 This applies first and foremost to the primary protective purpose of preventing potentially dangerous self-medication. Self-treatment is not a concern from the outset with regard to the intended purpose of umbilical cord blood and umbilical cord tissue as mere precursors of medicinal products still to be manufactured.

4.2.2 Furthermore, the risk of self-medication with prescription end products is ruled out because, at the time of application, the possibility of collecting umbilical cord blood and umbilical cord tissue as end products does not yet exist and therefore cannot be used for self-medication at this stage, even in rare exceptional cases.

4.2.3 Finally, the entire process, from the collection of umbilical cord blood and umbilical cord tissue to the processing into the end product and the application of the stem cell preparation, is subject to close regulatory and medical control. Against this background, there is not even the slightest abstract risk of self-medication, which is why there is no apparent reason for a ban that could justify the application of Section 10 (1) HWG.

4.2.4 According to the restrictive interpretation of abstract offenses of endangerment under the law on advertising for medicinal products required by the case law of the Federal Court of Justice

, the application of the prohibition in Section 10 (1) HWG cannot be based on the risk of self-medication.

4.3 No impairment of the relationship of trust between doctor and patient

4.3.1 The application of the ban on advertising to the general public under Section 10(1) of the German Medicines Advertising Act (HWG) cannot be justified on the grounds of protecting the independence of therapy and prescription decisions or safeguarding the relationship of trust between doctor and patient. The decisive factor in this respect is also that the physician's treatment decision regarding the prescription and use of the prescription-only end product cannot be influenced in an inappropriate manner, even in abstract terms, by the — upstream — advertising of umbilical cord tissue and umbilical cord blood. While it may be conceivable in principle that a patient addressed by advertising for prescription-only drugs that are immediately available and applicable may ask their treating physician to prescribe them, this scenario cannot occur *per se* in the case of advertising for umbilical cord blood and umbilical cord tissue.

4.3.2 At the time of advertising the collection of umbilical cord blood and umbilical cord tissue, there is no situation requiring treatment in which a physician responsible for therapy could come under any kind of pressure to prescribe a prescription drug for the patient's potential subsequent treatment. The only decision that is subject to advertising influence is the decision to collect the umbilical cord blood and umbilical cord tissue itself. However, since these preliminary products do not fall under the definition of a prescription drug, the protective purpose of Section 10 (1) HWG is not affected in this respect either.

4.3.3 The only theoretical possibility in which a patient could be prompted by an advertisement for potentially available treatment options involving prescription drugs to immediately consider such treatment and discuss it with their doctor is the scenario in which umbilical cord blood or umbilical cord tissue has already been collected from the addressee prior to the advertising. However, even in such a case, there can be no assumption of an abstract risk in the sense of an improper influence on the relationship of trust between the doctor and the patient. This is because the decision to collect umbilical cord blood and umbilical cord tissue has already been made in the past in these cases and can no longer be influenced retrospectively by the advertising.

4.3.4 Since the collection in the past was carried out prospectively with a view to the possibility of later treatment with prescription drugs that were yet to be obtained from it at the time, there is also no danger that patients could be motivated to undergo such treatment for the first time as a result of advertising. Rather, these patients are already undergoing

medical treatment, during which the possibility of drug therapy based on umbilical cord blood or umbilical cord tissue specifically collected for this purpose is to be discussed. There is also no evidence to suggest that advertising for umbilical cord blood and umbilical cord tissue that refers to the possibility of subsequent treatment with prescription drugs could have an inappropriate influence on the relationship of trust between doctor and patient.

4.3.5 With the restrictive interpretation of the abstract danger elements of the law on advertising for medicinal products required by the Federal Court of Justice, the application of the prohibition in Section 10 (1) HWG cannot therefore be based on the danger of an inappropriate influence on the relationship of trust between doctor and patient.

4.4 *No abstract risk of a fiscal burden on the statutory health insurance system*

4.4.1 Finally, fiscal considerations, insofar as they may be relevant to the interpretation of Section 10 (1) HWG, do not justify a different view. Even if a benefit in kind or assumption of costs by the health insurance funds in the statutory health insurance system occurs in individual cases, the fiscal protection provided by Section 10 (1) HWG would not be affected in view of the lack of a causal and attributive connection between the original advertisement for the collection and storage of umbilical cord blood and umbilical cord tissue and the subsequent prescription.

4.4.2 This is because advertising that took place a significant period of time before can no longer influence the doctor's decision to prescribe the prescription-only end product, especially since the advertising may initially only have influenced the decision to collect umbilical cord blood and umbilical cord tissue.

4.4.3 In this respect, too, there is therefore not even an abstract threat to the financial stability of the statutory health insurance system to be feared, so that, according to the standards of the highest court jurisdiction on the interpretation of abstract threats under the law on the advertising of medicinal products, the prohibition in Section 10 (1) HWG cannot be applied in this respect either.

IV. Conclusion

1. The prohibition of advertising to the general public under Section 10 (1) HWG does not, in principle, preclude advertising presentations by the various actors involved in the supply chain that describe the entire cycle from the collection of umbilical cord blood and umbilical cord tissue as preliminary products through further processing into end products to the therapeutic options, in accordance with an interpretation that is consistent with fundamental rights and also takes into account the protective purposes of the regulation.

2. The reference point for the assessment under therapeutic products advertising law is the object of the advertising. A violation of the prohibition in Section 10 (1) HWG due to the advertising of umbilical cord blood and umbilical cord tissue is ruled out from the outset due to the lack of regulatory classification of these precursors as (prescription-only) medicinal products.

classification of these preliminary products as (prescription) medicinal products.

3. With regard to the presentation of the end product obtained from umbilical cord blood and umbilical cord tissue, doctors cannot be prevented from referring to these in advertising in order to adequately describe their range of services and treatments. The prohibition under Section 10(1) HWG takes a back seat to the constitutionally guaranteed right to medical self-presentation.

4. Taking into account the protective purposes of the provision in Section 10 (1) HWG and (EU) fundamental, it can also be assumed that providers of care concepts may, in principle, advertise the objectives pursued with the collection and storage of umbilical cord blood and umbilical cord tissue for the manufacture of prescription drugs for potential future therapeutic applications. This is because, given the restrictive interpretation of the abstract offense of endangering the public prohibited by Section 10(1) HWG required by the highest court ruling of the Federal Court of Justice, a reason for prohibition cannot be assumed in view of the risk of endangering the protective purposes of the norm, which has not even been substantiated in abstract terms.

5. Legally relevant gaps in protection are not created by such a restrictive interpretation of the ban on advertising to the general public in Section 10(1) HWG that is in conformity with fundamental rights. This is because umbilical cord blood and umbilical cord tissue are already subject to strict regulation as preliminary products. Furthermore, patients who are considering drug therapy are already receiving comprehensive medical care. Insofar as advertising should contain misleading or scientifically unproven claims about efficacy, any specific dangers resulting from this can be sufficiently prevented and countered by the prohibitions on misleading advertising under the law on the advertising of medicinal products and the law on unfair competition pursuant to Sections 3 HWG and 5 UWG. Against this background, there is no need or justification for an "excessive" application of the ban on advertising to the general public under Section 10 (1) HWG.

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Distinction between medical devices and medicinal products — Distortion of European law through repeated application of questionable basic assumptions

A commentary on the ruling of the Federal Administrative Court (BVerwG) of July 30, 2025 — 3 C 7.24

The availability of safe and effective healthcare products requires legal certainty for manufacturers and pharmaceutical companies. For years, the distinction between medical devices and medicinal products has been based on the fundamental assumption that official drug approval guarantees a higher level of protection for patients and users than the CE marking of medical devices on a declaratory basis. This basic assumption is reflected in a large number of administrative procedures based on decisions by authorities, which in turn were issued under the provisions of Directive 93/42/EEC on medical devices (MDD). With the entry into force of Regulation (EU) 2017/745 on medical devices (MDR), the requirements for material medical devices have been increased to such an extent that MDR-compliant products can now be assumed to offer a level of protection comparable to that of medicinal products. This is because material medical devices such as nasal sprays or hydrogels are now subject to at least risk class IIa in accordance with Annex VIII, Rule 21 MDR. Unlike previously under risk class I, manufacturers are no longer allowed to carry out the conformity assessment procedure themselves. For medical devices in class IIa and above, this is carried out by a notified body. Distortions in European law arise when current administrative court rulings apply standards that may have been plausible under old EU law but are contrary to the intention of the current legal framework. Both the reference to judgments issued under the repealed MDD and the subjective interpretation of earlier case law without considering the context of the respective proceedings carry the great risk that current case law will lead to objectively untenable results and thus legal certainty will not be guaranteed. As an example, this commentary analyzes the ruling of the Federal Administrative Court (BVerwG) of July 30, 2025, in case 3 C 7.24, with a particular focus on the relevance of so-called presentation drugs for demarcation issues and the different forms of rationality in normative legal interpretation and scientific logic.

I. Introduction

The purpose of European law with regard to

Medical devices and medicines are guaranteed safety standards for all citizens, enabling innovation and ensuring a fair, functioning internal market. Regulation (EU) 2017/745 on medical devices (MDR)¹ and Directive 2001/83/EC on medicinal products for human use (MPD)² are the underlying current legal norms that impose comparable safety and efficacy requirements on both product groups.

the safety of products before they are allowed to be placed on the market. With regard to medical devices consisting of substances or combinations of substances, the MDR has closed regulatory gaps that, under the superseded Directive 93/42/EEC on medical devices (MDD)³, regularly led to pharmaceutical law being given priority with regard to the required level of protection for patients and other users. In this respect, safety and efficacy are no longer in question when distinguishing between material medical devices and medicinal products, but are equally prerequisites for MDR-compliant CE marking of medical devices and MPD-compliant approval of medicinal products.

A distortion of European law arises when interpretations by authorities and administrative courts regarding the distinction between medical devices and medicinal products are derived from decisions based on regulatory principles that are no longer valid. The fact that administrative law focuses more on the correct interpretation of the law, taking into account the arguments presented, without re-examining the validity of the underlying assumptions *per se*, leads to judgments that are contrary to the spirit and purpose of European law, particularly in cases that were decided by the authorities under the provisions of the MDD.

The ruling of the Federal Administrative Court (BVerwG) of July 30, 2025, in case 3 C 7.24⁴ is another example of such a distortion. Legal certainty and the feasible applicability of the relevant legal norms are fundamental prerequisites for manufacturers of medical devices and pharmaceutical companies to develop innovative healthcare products and make them available to patients and users.

The following assessment of the Federal Administrative Court ruling of

July 30, 2025, does not explicitly deal with the correct regulatory classification of the product in question itself, but rather with the relevance of so-called presentation drugs pursuant to Art. 1 (2a) MPD for demarcation issues and the limits of normative legal interpretation through the negation of scientific logic. Contrary to the statements of the Federal Administrative Court in the present ruling, the relevance of the

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1 <https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:02017R0745-20250110>.

2 <https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:02001L0083-20250101>.

3 <https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:01993L0042-20071011>.

4 <https://www.bverwg.de/300725U3C7.24.0>.

Presentation drugs cannot be derived from the case law of the European Court of Justice (ECJ) and have been questioned elsewhere by the Federal Administrative Court itself. The reversal of the burden of proof to demonstrate the non-existence of a medicinal effect of material medical devices also calls into question confidence in objective case law.

II. Background

The starting point for the present Federal Administrative Court ruling was a decision by the Federal Institute for Drugs and Medical Devices (BfArM) dated January 16, 2014, according to which the product in question fulfilled both the requirements for a functional drug in accordance with Section 2 (1, No. 2 b) of the German Medicines Act (AMG)⁵ and was also a presentation drug in accordance with Section 2 (1, No. 2 a) AMG. The AMG transposes the definitions of medicinal products in the MPD into national law with identical wording. This assessment was shared by the Administrative Court of Cologne (VG Köln) and confirmed by the Higher Administrative Court of Münster (OVG Münster) in its ruling of September 26, 2019.

In the appeal proceedings, the plaintiff then argued that the presentation drugs were not relevant for distinguishing between medical devices and medicinal products and that the Higher Administrative Court of Münster had imposed the burden of proof on it to demonstrate the non-pharmacological effect.

Before the proceedings were reopened, the BfArM referred to the ECJ ruling of January 19, 2023, on the request for a preliminary ruling (C-495/21 and C-496/21) and the resulting ruling of the Federal Administrative Court (BVerwG) of September 14, 2023 (3 C 2.23). The fact that both judgments contain the distortions addressed at the outset (MPJ, issue 2, 2023, 153–155/MPJ, issue 2, 2024, 110–118)^{6,7} and that the Federal Administrative Court itself expressed a completely different opinion in its referral decision to the ECJ of May 20, 2021⁸ was not given due consideration by either the BfArM or the Federal Administrative Court in the present case.

III. Legal basis

The legal basis on which the BfArM bases its jurisdiction (see judgment of the Federal Administrative Court of July 30, 2025 — 3 C 7.24 (margin note 8) appears questionable. The BfArM is not responsible for market surveillance of medical devices; this is the responsibility of the supervisory authorities of the federal states. In the event of differing opinions on the regulatory status of CE-marked medical devices, the supervisory authorities under the MDD had the option of applying the procedure set out in Section 13 (3, No. 2) of the Medical Devices Act (MPG)⁹:

(3) *The competent higher federal authority decides at the request of a competent authority or the manufacturer the manufacturer*

2. *the distinction between medical devices and other products* ...

(emphasis added by the author)

On the other hand, a request by a supervisory authority to determine the approval requirement for a drug in accordance with Section 21.4 AMG already presupposes that the

the product in question is a medicinal product:

(4) *The competent federal authority shall also decide, irrespective of an application for authorization pursuant to paragraph 3 or an application for approval pursuant to Section 21a (1) or Section 42 (2), upon request by a competent state authority, on the authorization requirement for a medicinal product, the approval requirement for a tissue preparation, or the approval requirement for a clinical trial. The competent state authority shall attach a reasoned opinion on the classification of the medicinal product or clinical trial to the application.*

(Emphasis added by the author)

It is not surprising that the licensing requirement was regularly affirmed in this case, as medicinal products are generally subject to licensing. Rather, what should be questioned is the acceptance by the judiciary of the application of incorrect legal norms, which, in view of the question of demarcation that actually needs to be clarified, carries the risk of bias.

1. Relevance of presentation drugs

As confirmed by the Federal Administrative Court itself, the decisive criterion for distinguishing between medical devices and medicinal products is the main mode of action of the product (para. 18). If the intended medical purpose is not achieved through pharmacological, immunological, or metabolic effects (PIM), the product is a medical device within the meaning of Art. 2 (1) MDR. If, on the other hand, there is a PIM effect, the product in question is to be classified as a functional medicinal product within the meaning of Art. 1 (2b) MPD. The particular relevance of the mode of action as a distinguishing criterion is expressly in line with Art. 1 (6b) MDR:

Accordingly, the MDR does not apply to

medicinal products within the meaning of Article 1(2) of Directive 2001/83/EC. In deciding *whether a product falls within the scope of Directive 2001/83/EC or this Regulation, the main mode of action of the product shall be taken into account.*

(Emphasis added by the author)

With its comments on presentation medicines, however, the Federal Administrative Court repeats the arguments already made by in the judgments of ECJ of 19 January 2023 and the Federal Administrative Court ruling of 14 September 2023 have led to distorted interpretations. Due to the similar definitions of presentation drugs and medical devices with regard to the treatment, alleviation, or prevention of diseases, these characteristics cannot be used as a distinguishing criterion *per se*. Otherwise,

5 https://www.gesetze-im-internet.de/amg_1976/ (The European Court of Justice, judgment of January 19, 2023—a missed opportunity!).

6 Commentary on the ECJ ruling of January 19, 2023 — a missed opportunity!

7 Distinction between medicinal products and medical devices — relevance of the Federal Administrative Court, judgment of September 14, 2023: Claritas in ambiguitas — limits of administrative law with regard to the distinction between medicinal products and material medical devices.

8 <https://www.bverwg.de/200521B3C19.19.0> (The German Federal Administrative Court's ruling on the classification of medical devices).

9 <https://www.buzer.de/gesetz/3284/a46065.htm>.

All material medical devices are also presentation drugs, even if their effect is proven not to be based on PIM.

The fact that this is not intended is already made clear in Recital 7 of Amending Directive 2004/27, which revised the definitions of medicinal products and implemented the distinction between presentation and functional medicinal products in European law:

... If a product clearly falls under the definition of other product groups, in particular foodstuffs, food supplements, medical devices, biocides, or cosmetic products, this Directive should not apply. ...

(Emphasis added by the author)

The implementation of specific requirements for medicinal devices in the MDR, e.g., with regard to (i) adsorption, distribution, metabolism, and excretion (ADME, Annex I (12.2) MDR), (ii) the introduction of a special classification rule (Annex VIII, Rule 21 MDR) and (iii) special conformity assessment procedures involving a notified body (Annex IX (5.4) MDR) are rather evidence that material medical devices are expressly desired.

Regularly equating material medical devices with presentation drugs seems more like an *argumentum ad baculum*, whereby a drug classification is to be enforced contrary to scientific and regulatory logic.

The statement by the Federal Administrative Court that the ECJ ruled in its judgment of January 19, 2023, that a product marketed as a medical device can also be a presentation drug (para. 12) is simply incorrect. The ECJ did not formulate this in such clear terms at any point in its judgment. Rather, the ECJ stated that it is up to the national courts to assess in each individual case whether the conditions for the definition of the term "promotional drug" within the meaning of Directive 2001/83, as amended by Directive 2007/47, are met if the main mode of action of a product has not been scientifically established.

Also questionable is the Federal Administrative Court's interpretation that the ECJ's failure to address the interpretation of the term "pharmacological effect" made it clear that this is not relevant for the affirmation of a presentation drug as distinct from a medical device (para. 14).

To its credit, the Federal Administrative Court may be said to have created unnecessary scope for misguided interpretations in several respects with its ruling of January 19, 2023.

The first question referred to the ECJ was:

Can the intended main effect of a substance be pharmacological within the meaning of Article 1(2)(a) of Directive 93/42 even if it is not based on a receptor-mediated mode of action and the substance is not absorbed by the human body but remains on the surface of, for example, mucous membranes and reacts there? In such a case, what criteria should be used to distinguish between pharmacological

and non-pharmacological, in particular physical-chemical, agents?

(Emphasis added by the author)

The first sub-question in itself has nothing to do with the distinction between presentation medicines and material medical devices, nor does it have anything to do with the applicability of the rule of doubt pursuant to Art. 2 (2) MPD. In response to this closed sub-question, a clear yes or no based on a plausible scientific justification would have been desirable.

The open second sub-question would then logically have been answered with reference to the legal norms applicable to pharmacological and non-pharmacological products, namely the MPD and MDR.

In this respect, any comments on presentation medicines and the rule of doubt are not suitable for answering the actual question, which is why the ECJ's statement "In view of the answers to questions 2 to 4, there is no need to answer the first question" cannot be reinterpreted in the sense of the BVerwG's interpretation.

In response to Reference 4, the ECJ correctly determined that the rule of doubt pursuant to Art. 2 (2) MPD applies to presentation medicines and functional medicines, as the legal norm does not distinguish between the two definitions of medicines at this point. However, the finding in the same judgment that, in the absence of scientific evidence of efficacy, the product can be neither a medical device nor a functional medicinal product *effectively* suspends the rule of doubt for classification decisions:

If there is doubt about the absence of a PIM effect, this logically means that a PIM effect is suspected. In case of doubt, the product is therefore a functional medicinal product. Consequently, at the meeting of the Medical Devices Coordination Group (MDCG) on April 4, 2022, the EU Commission summarized as a harmonized clarification of the member states that presentation drugs are irrelevant for the distinction between medical devices and drugs (*MP by presentation is irrelevant for borderline*). The dilemma arising from the ECJ ruling, which was most likely issued in ignorance of the above MDCG interpretation, is now that, in case of doubt, the product is a functional medicinal product but, without scientific evidence of a PIM effect, it cannot be classified as such!

However, there is usually no doubt that the product in question is intended to be used for the treatment, alleviation, or prevention of diseases. However, this is not reserved for presentation drugs, but is also covered by the definition of medical devices. Ultimately, promotional drugs have been included in drug law primarily with regard to health claims made about food and cosmetics, which are not permitted to have any medical purpose.

The resulting regulatory gap will predictably be the subject of future requests for a preliminary ruling to the ECJ. In view of objectively reliable case law, it will be important that the correctness of the basic assumptions on which preliminary decisions were made is sufficiently addressed in the pleadings of the lower courts in order to counteract the limitations of administrative law.^{6,7}

The real core problem in distinguishing between medical devices and medicinal products remains the lack of a scientifically plausible legal definition for PIM, without which the ECJ obviously does not see itself in a position to make a legally binding interpretation of the distinction.

2. Reversal of the burden of proof

In connection with the reversal of the burden of proof, a toxic situation arises for material medical devices, which in turn clearly contradicts the intention of the MDR: the manufacturer of a product in question is required to prove, on the basis of PIM definitions that are scientifically questionable and legally non-binding *per se*, that an unintended and scientifically unproven PIM effect does not actually exist.

Such conclusive proof of the non-existence of a PIM effect is impossible from a scientific point of view. Not being able to prove something is not proof of non-existence, but at best a statement that nothing has been found.

The absurdity of the reversal of the burden of proof is illustrated by Bertrand Russell's example of the teapot in space:

One *cannot prove* that there is no teapot orbiting the sun in space between Earth and Mars that is so small that it cannot be found with telescopes — *one simply has no reason to assume this*.¹⁰

(Emphasis added by the author)

Rather, it is a fundamental scientific principle that whoever makes a claim must prove it.

This insight is also reflected in earlier interpretations by the ECJ itself. In its judgment of January 15, 2009, in Case C-140/07, the ECJ states:

a) ECJ interpretation of the burden of proof

Article 1(2b) of the MPD must be interpreted as meaning that a product

... cannot be regarded as *a medicinal product* within the meaning of this provision *if*, due to its composition—including the dosage of its active ingredients—and *when used as intended*, it *cannot restore, correct, or influence physiological functions in a significant way through a pharmacological, immunological, or metabolic effect*.

(Emphasis added by the author)

In deriving this interpretation, the ECJ clearly assigns the burden of proof to the authority that suspects a medicinal effect (paras. 41/42 of the judgment of January 15, 2009):

[41] It follows that products containing a physiologically active substance *cannot be systematically classified as functional medicines without the competent authorities examining each product with the necessary care on a case-by-case basis*, taking into account *in particular its pharmacological, immunological, or metabolic properties* as determined by the current state of scientific knowledge.

[42] In this context, it should be noted that *the criterion of suitability for restoring, correcting, or influencing physiological functions must not lead to products being classified as functional medicines which, although they have an effect on the human body, have no significant physiological effects and therefore do not really influence its functional conditions*.

(Emphasis added by the author)

b) PIM definitions according to MDCG 2022-5

The fact that—especially with the current PIM definitions—a physiological interaction cannot be ruled out for almost every substance does not change the fact that only a significant restoration, correction, or influence of physiological functions depending on the dosage justifies classification as a functional drug. The burden of proof lies with the party making the claim.

The MDCG 2022-5 guideline, which is not legally binding *per se*, was rejected by Germany in the MDCG, particularly with regard to the inadequate PIM definitions. The explanatory statement¹¹ states, among other things:

This forces the manufacturer to *prove the absence of a pharmacological effect* when justifying the classification as a medical device, *which is not possible with the given definition*.

(Emphasis added by the author)

In this respect, the ECJ ruling of January 19, 2023 cannot be a definitive basis for interpretations of demarcation. Rather, the ECJ itself must be measured against the feasibility of its case law, which will predictably be the subject of future requests for a preliminary ruling.

If the Federal Administrative Court bases its decision on this standard (para. 15) without further questioning the basic assumptions and on the basis of the questionable interpretation of the ECJ ruling, the reasoning behind the ruling may not raise any concerns from a purely administrative law perspective (para. 16) and may also be a decision that does not violate federal law (para. 17). However, it still misses the point and purpose of European law. When deciding whether the product should be classified as a presentation drug, if the question is based purely on the disease reference, the expectations of the average informed consumer, the requirement to sell only in pharmacies, interactions, or side effects

¹⁰ https://de.wikipedia.org/wiki/Russells_Teekanne.

¹¹ <https://ec.europa.eu/transparency/expert-groups-register/core/api/front/document/95312/download> (see embedded PDF).

is set aside, then what is inherent in product classification is excluded, namely that these are characteristics that are not reserved for medicinal products and therefore do not constitute a distinguishing criterion from material medical devices. The fact that material medical devices may also be subject to pharmacy exclusivity and do not automatically "become" medicinal products as a result of this fact and taking into account the perception of the general consumer does not require further discussion. There is unlikely to be a general assumption that only medicinal products can be purchased in pharmacies. Furthermore, the consumer image created by the ECJ and the other courts involved does not seem to correspond to the current situation and is therefore likely to be outdated. If, on the basis of incorrect assumptions in this regard, a demarcation decision leads to the classification of a product in question as a medicinal product, it is formally correct that such a medicinal product is not subject to

Section 2 (3) No. 7 AMG is excluded, but this does not make the demarcation decision correct.

c) Referral order of the Federal Administrative Court in case 3 C 19/19

It remains astonishing that the Federal Administrative Court once again completely disregards the arguments it itself set out in the order for reference in case 3 C 19/19 of May 20, 2021¹² as the correct basic assumptions and does not use the mode of action referred to in para. 18 as the decisive demarcation criterion. In the order for reference, the Federal Administrative Court had argued, among other things, as follows:

(18) ... This argues against the sequence of examination found to be correct by the court of appeal, which always first classifies products marketed as medicinal products as (presentation) medicinal products. Recital 7 of Directive 2004/27/EC does not suggest anything else: it too assumes the equal coexistence of different regulatory systems.

(23) ... A product could therefore be classified as a medical device even if its non-pharmacological effect cannot be positively determined.

(25) Since medical devices made of materials ... are also intended to alleviate, prevent, or treat diseases, there is no difference between medical devices and medicinal products in terms of their therapeutic purpose. ... There are therefore doubts as to whether a product marketed by the manufacturer ... as a Class I medical device can already be regarded as a medicinal product within the meaning of Article 1(2)(a) of Directive 2001/83/EC if, according to its presentation, it is intended to cure or alleviate diseases but no specific medicinal effect is claimed for this purpose.

(26) ... Contrary to the opinion of the Court of Appeals, the average consumer who reads the information on the product packaging will therefore consider a preparation that is explicitly marketed as a medical device to be a drug.

CE marking is not "without significance." In principle It cannot be assumed that a

an average, knowledgeable consumer will consider a preparation explicitly offered as a medical device to be a medicinal product.

(27) In any case, a reference to a therapeutic purpose should not be sufficient to justify such assumptions if the product is not advertised as having specific medicinal effects. ... With such information, the manufacturer does not give the impression that the product is a medicinal product, but rather indicates <the manufacturer> indicates the legally prescribed purpose of a medical device.

(28) Even the reference to "interactions" and "undesirable effects" should not allow the conclusion that the product is being presented as a specific medicinal product. ... However, the information required for the labeling of medical devices pursuant to No. 13.3 of Annex I to Directive 93/42/EEC also includes special instructions for use (letter j) and warnings and/or instructions on precautions to be taken (letter k).

(29) ... Because exclusive distribution through pharmacies is not reserved for medicinal products, but is also intended for certain medical devices ...

(31) ... It would therefore also be conceivable to limit the priority rule to functional medicinal products within the meaning of Article 1(2)(b) of Directive 2001/83/EC.

(32) ... in cases where no pharmacological effect of the substance has been established, there is no reason for priority to be given to pharmaceutical law ... However, if the product falls under the definition ... of a medical device ... this <consumer> protection can also be provided under the legal provisions applicable to this product. These regulations are likely to be more relevant to the actual properties of the product than those of pharmaceutical law. The application of pharmaceutical law could therefore prove to be a disproportionate restriction on the free movement of goods (emphasis added by the author)

Finally, the repeated demand for a reversal of the burden of proof also leaves open the question of the rule of law: the principle of *ultra posse nemo obligatur*, which is regularly applied by the Federal Constitutional Court (BVG) on the basis of the principle of the rule of law, according to which a legal obligation to perform an impossible act cannot exist (cf. § 275 (1) of the German Civil Code), or, in administrative law terms, that the addressee of a norm cannot be required to behave in a manner that is impossible for them, should also be taken into account when scientific logic refutes the feasibility of the normative interpretation of the law. The way would already be open, as the administrative courts consistently assume in their case law that "the law cannot lawfully require a person to behave in a manner that is impossible for them" (cf. OVG Münster, decision of September 27, 2010 — 1 E 940/10, BeckRS 2010, 145745 marginal no. 8).

3. Level of protection

In the grounds for its judgment of January 19, 2023, the ECJ did not consider the above argument

¹² <https://openjur.de/u/2374676.ppdf>

further, but rather focuses on the level of consumer protection:

(39) This approach is also supported by the general structure of Directive 93/42, which does not provide for the same level of consumer protection as Directive 2001/83. This deviation is justified by the negative requirement for medical devices under Article 1(2)(a) of Directive 93/42, according to which the principal intended action is not achieved by pharmacological or immunological means or by metabolic action. The presumption that these products are less dangerous justifies the marketing of goods on a declaratory basis, in contrast to the legal regulation applicable to functional or presentation medicinal products, for which prior authorization is required for marketing pursuant to Article 6 of Directive 2001/83.

(Emphasis added by the author)

The ECJ mentions that by 2023, the MDR will have long since replaced the MDD and that basic safety and performance requirements (GSPR) equivalent to those for human medicinal products will now apply to substantive medical devices, and that with the new classification rule in accordance with Annex VIII, Rule 21 MDR, the involvement of a notified body in the conformity assessment procedures for the vast majority of material medical devices is now mandatory, the ECJ does not mention this at all.

In view of the history of the cases at hand, which were decided under the old law, the MDD, this may have been legally correct, but a corresponding clarification would nevertheless have been desirable for future demarcation decisions. The new legal framework of the MDR offers at least a comparable level of protection for substantive medical devices and medicinal products, and the purely declaratory basis for medical devices in risk class I has *de facto* been completely eliminated. This is because, due to the high classification required under Annex VIII, Rule 21 MDR for material medical devices that were classified as risk class I under the MDD, such as nasal sprays or hydrogels, there is no longer any "self-certification" by the manufacturer, but rather a review and certification of the product by a notified body. The regular surveillance audits of manufacturers by notified bodies, which in turn are subject to significantly higher qualification requirements by drug regulatory authorities, lead to significantly better detection of any non-conformities, both in terms of the products and the manufacturers' quality management processes.

4. Pharmacological effect

A further distortion of the intention of European law arises from the Federal Administrative Court's comments on pharmacological effects. On the one hand, the ECJ ruling of November 6, 2012, in case C-308/11 is not cited in the correct context, and on the other hand, the ECJ ruling of March 13, 2025, in case C-589/23 is not examined in relation to the underlying issue:

The starting point of Case C-308/11 was whether the pharmacological effect of a substance (in this case chlorhexidine) only leads to classification as a humanif the effect relates to human cells or tissues, or whether classification as a human medicinal product also applies if the effect is directed against pathogenic germs in the human body. The latter was confirmed by the ECJ without the ECJ addressing the definition of PIM effects itself. In any case, the ECJ did not state in its decision at the time that any interaction with body components is covered by the PIM definitions of the MEDDEV 2.1/3, rev. 3¹³ guideline valid at the time.

If the Federal Administrative Court then derives confirmation of the misinterpretation of the ECJ ruling from 2012 from the ECJ ruling on D-mannose in case C-589/23, the Federal Administrative Court overlooks the fact that the competitive inhibition of FIM proteins on the cell surface of bacteria by D-mannose or cranberry PAC, which inhibits binding to the glycocalyx of the urinary tract, already constituted a pharmacological effect according to MEDDEV 2.1/3, rev. 3. Whether this occurs through covalent bonds, hydrogen bonds, or van der Waals forces is irrelevant. The principle of specific binding of D-mannose or cranberry PAC to bacterial FIM proteins, accompanied by competitive inhibition, is the main reason for assuming a pharmacological effect. And this is not only based on legally non-binding guidelines, but in particular on fundamental pharmacological theory and scientific understanding of molecular biological processes.

At best, the Federal Administrative Court can be credited here with the fact that the ECJ also failed to make this distinction and thus lacked the necessary clarity in this regard. What is difficult in this context is the uncritical adoption by the ECJ of the statements in MDCG Guideline 2022-05, rev. 1¹⁴, which could lead to further distorted interpretations of European law. The ECJ emphasizes that MDCG 2022-5, rev. 1 is intended to clarify and define in more detail the definition of the term "pharmacological agents" in MEDDEV 2.1/3, rev. 3. However, the ECJ does not examine whether MDCG 2022-5 has actually achieved this objective. The fact that only 9 of 27 Member States agreed to the publication of MDCG 2022-5, thus failing to meet the quorum required for publication under EU law, raises the question of whether the non-legally binding guideline actually reflects the harmonized understanding of the Member States. In addition, the objections explicitly published in the MDCG minutes of the meeting on October 24-25, 2022¹⁴ by Germany and Italy with regard to the insufficient PIM definitions should be reason enough not to apply the ECJ ruling in case C-589/23 to any unspecific interactions.

¹³ https://www.medical-device-regulation.eu/wp-content/uploads/2019/05/2_1_3_rev_3-12_2009_en.pdf.

¹⁴ https://health.ec.europa.eu/document/download/b5a27717-229f-4d7a-97b1-e1c7d819e579_en?filename=mdcg_2022-5_en.pdf.

The transfer of substances to human cells and tissues, pathogenic germs, or even other components of the human body.

In the absence of more detailed background information, it is not possible or appropriate to assess the extent to which the sodium drops considered in the present case have a pharmacological effect. Nevertheless, doubts remain insofar as a certain cell-damaging effect of the preparation and the denaturation derived from this by the BfArM (marginal numbers 26/27) do not necessarily lead to automatic classification as a human medicinal product. For example, the Manual on Borderline & Classification, Version 1.22 (May 2019)¹⁵ contains an entry on alum hemostatic sticks, which are classified as medical devices due to their astringent properties, i.e., the precipitation of proteins on the surface layer of the skin, which in turn contracts the tissue and thus stops bleeding, due to the absence of a PIM effect.

IV. Conclusion

With regard to the deficiency in the evidence presented by the court of fact, which was rejected by the Federal Administrative Court, questions remain unanswered, at least with regard to the failure to observe the laws of logic, in particular with regard to the reversal of the burden of proof, and the interpretations of presentation drugs argued elsewhere by the Federal Administrative Court itself. The same applies to the repetition of the assumptions regarding the promotion of health protection

through drug approval procedures. These basic assumptions are not tenable for MDR-compliant material medical devices and should not further limit the development of innovative material medical devices at the expense of patients, manufacturers, and Germany/Europe as a location for innovation.

The social responsibility of all economic actors lies in ensuring the availability of safe and effective healthcare products for patients. Decisions on the distinction between medical devices and medicinal products must now be made on the basis of current legislation, given that the MDR and MPD offer a comparable level of protection. Historical decisions must be reviewed to determine the extent to which they still meet today's standards or whether they would be decided differently today. Just as the tail does not wag the dog, the interpretation of legal texts should not contradict their intention.

15 https://health.ec.europa.eu/system/files/2020-08/md_borderline_manual_05_2019_en_0.pdf.

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Case law

1 Admissibility of advertising measures by a Dutch mail-order pharmacy (coupon advertising II)

Directive (EC) 83/2001 Art. 86, 87 III; ZPO §§ 293, 945; AMG §§ 73 II No. 1a, 78 I; UWG § 3a

If the trial court bases its decision on a party's submission concerning foreign law on the grounds that this submission was not contested by the other party, without conducting its own investigations to verify this submission, this constitutes a violation of the obligation under Section 293 of the German Code of Civil Procedure (ZPO) to investigate foreign law ex officio.

The provision of Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 1, letter a HWG, which permits promotional gifts and allowances in exceptional cases if they are granted in a specific amount or in an amount to be calculated in a specific manner, does not cover the advertising of a range of bonus amounts to be determined in each individual case (in this case: at least EUR 2.50 and up to EUR 20 per prescription).

The exception in Section 7 (1) sentence 1, clause 2, no. 2, subclause 1, letter a HWG does not allow a pharmacy to offer a monetary amount or a percentage discount for the subsequent purchase of additional products, including non-prescription drugs, in return for submitting a prescription for prescription drugs.

purchase of additional products, including non-prescription drugs.

BGH, judgment of November 6, 2025 — I ZR 182/22

Facts of the case: 1 The plaintiff is a Dutch mail-order pharmacy that delivers non-prescription and prescription drugs to end customers in Germany by mail order.

2 The defendant is the professional association of pharmacists in the district of North Rhine.

3 Since 2012, the plaintiff has been advertising various discount campaigns in which customers were promised an advantage in the form of a cash discount, a voucher to be redeemed when purchasing another medication, a hotel voucher, or an annual membership with the ADAC when purchasing prescription drugs. The defendant considers these advertising measures to be a violation of the price fixing regulations for prescription drugs under pharmaceutical law and therefore obtained—insofar as relevant to the appeal proceedings—the following five preliminary injunctions against the plaintiff between 2013 and 2015, each of which was duly enforced.

4 On May 8, 2013, the defendant obtained a preliminary injunction from the Regional Court of Cologne (Ref. 84 O 90/13), which was enforced on May 14, 2013, against an advertisement by the plaintiff with the statement

Send in your prescription — take part and secure a bonus of up to €20! D. M. values comprehensive advice. Support

us in this and take part in the medication check. We will thank you for your help with a cash bonus. You will receive at least €2.50 and up to €20 per prescription. (...),

whereby the amount of the promised bonus depends on the complexity of the illness or the price of the prescription medication (for example, a €2.50 bonus for sending in a prescription for a hormonal contraceptive, between €2.50 and €20 for sending in a prescription for medication to treat serious chronic illnesses such as Parkinson's disease). This preliminary injunction was lifted by the Regional Court of Cologne in its ruling of

March 22, 2017, due to changed circumstances in view of the ECJ ruling in the case of "Deutsche Parkinson Vereinigung" (ECJ, ruling of October 19, 2016 — C-148/15, GRUR 2016, 1312

= WRP 2017, 36).

5 On September 26, 2013, the defendant obtained a preliminary injunction from the Regional Court of Cologne (Ref. 84 O 220/13), which was enforced on October 2, 2013, against an advertisement by the plaintiff with the statement

Refer friends now & collect free overnight stays! (...)

For each friend referred: 1 hotel voucher worth approximately 150 euros* + 5 euro voucher for your friend! (...)

As soon as your friend submits a prescription or orders over-the-counter products with a total value of at least 20 euros. (...)

Each referred friend will also receive a \$5 voucher to order over-the-counter medications, health, and care products.

as well as another referral with the details

Refer a friend now and receive a free ADAC membership for the first year* (...)

For every friend you refer, we will thank you with a classic ADAC membership (free of charge in the first year instead of EUR 44.50) or a discounted ADAC Plus membership in the first year (only EUR 35.00 in the first year instead of EUR 79.50) (...)

As soon as your friend submits a prescription or orders over-the-counter products with a total value of at least EUR 20. (...)

Each referred friend will also receive a EUR 5 voucher to order over-the-counter medicines, health, and care products.

6 On November 5, 2013, the defendant obtained a preliminary injunction from the Regional Court of Cologne (Ref. 84 O 256/13), which was enforced on January 21, 2014, against an advertisement by the plaintiff with the following information

Send in your prescription now! (...) Unfortunately, we cannot spare you the trip to the mailbox. But to compensate for your travel expenses by bus and train, new customers will receive €10 from us, which will be deducted from the invoice amount immediately upon submission of the prescription.

whereby the discount was advertised for orders of prescription drugs with a minimum order value of EUR 50. This preliminary injunction Verfügung was lifted by the Regional Court Cologne with judgment of March 22, 2017, due to changed circumstances with regard to the ruling of the ECJ in the "Deutsche Parkinson Vereinigung" case.

7 On November 4, 2014, the defendant obtained a preliminary injunction from the Regional Court of Cologne (Ref. 84 O 208/14), which was enforced on December 30, 2014, against an advertisement by the plaintiff containing the information

10 EUR voucher for your prescription

for a subsequent order of non-prescription products. This preliminary injunction Verfügung was lifted by the Regional Court Cologne with judgment of

March 22, 2017, due to changed circumstances with regard to the ruling of the ECJ in the "Deutsche Parkinson Vereinigung" case.

8 On September 29, 2015, the defendant obtained a preliminary injunction from the Regional Court of Cologne (Ref. 81 O 82/15), which was enforced on May 26, 2016, for an advertisement by the plaintiff containing the following information

5 euro voucher for your next prescription order,

with the aforementioned amount to be deducted directly from the invoice amount. This preliminary injunction was overturned by the Regional Court of Cologne in a final judgment dated March 21, 2017.

9 In the course of the enforcement of some of the preliminary injunctions, high administrative fines were imposed on the plaintiff at the defendant's request.

10 The plaintiff is claiming damages from the defendant on the grounds that the preliminary injunctions were unjustified from the outset. This is because the ECJ ruled in the case of "Deutsche Parkinson Vereinigung" (ECJ, GRUR 2016, 1312) that the price fixing for the dispensing of prescription-only human medicines provided for in the German Medicines Act violates the free movement of goods (Art. 34 TFEU) because it has a greater impact on the sale of prescription drugs by pharmacies located in other Member States than on the sale of such drugs by pharmacies located in Germany.

11 The Regional Court dismissed the action. On appeal, the plaintiff expanded its claim and — insofar as relevant to the appeal proceedings — requested that

1. order the defendant to pay the plaintiff damages for the period up to and including September 30, 2016, in the amount of at least EUR 18,476,648.12 plus interest at a rate of nine percentage points above the base rate since October 3, 2015;

2. to declare that the defendant is obliged to compensate the plaintiff for all further damages exceeding the minimum damages specified in claim 1, which the plaintiff incurred up to and including December 31, 2016, as a result of the enforcement of the preliminary injunctions issued by the Regional Court of Cologne under file numbers 84 O 90/13, 84 O 220/13, 84 O 221/13, 84 O 222/13, 84 O 223/13, 84 O 224/13, 84 O 225/13, 84 O 226/13, 84 O 227 2016 as a result of the enforcement of the preliminary injunctions of the Regional Court of Cologne under file numbers 84 O 90/13, 84 O 220/13, 84 O 256/13, 84 O 208/14, and 81 O 82/15.

12 The Court of Appeal amended the Regional Court's judgment on the plaintiff's appeal by way of a fundamental and partial judgment, declared claim 1 to be justified on its merits and upheld claim 2 to the extent described above (Higher Regional Court of Düsseldorf, judgment of March 3, 2022 — 20 U 86/19, juris). With its appeal, which was allowed by the Court of Appeal and which the plaintiff is seeking to have dismissed, the defendant is pursuing its request for the complete dismissal of the action.

13 The Senate referred the matter to the ECJ by order of July 13, 2023 (GRUR 2023, 1318 = WRP 2023, 1198 — Gutscheinwerbung I) for a preliminary ruling on the interpretation of Directive 2001/83/EC on the Community code relating to medicinal products for human use:

1. Is advertising for the purchase of prescription medicines from a pharmacy's entire range of products subject to the provisions on advertising for medicinal products in Directive 2001/83/EC (Titles VIII and VIIIa, Articles 86 to 100)?

2. If the answer to question 1 is in the affirmative:

Is it compatible with the provisions of Title VIII and, in particular, with Article 87(3) of Directive 2001/83/EC if a national provision (in this case: Section 7(1) sentence 1, second half-sentence, no. 2, first part of the sentence, letter a HWG) is interpreted as prohibiting the advertising of the entire range of prescription-only medicinal products of a mail-order pharmacy established in another Member State with promotional gifts in the form of vouchers for a sum of money or a percentage discount on the subsequent purchase of further products?

3. Furthermore, if the answer to question 1 is in the affirmative:

Is it consistent with the provisions of Title VIII and, in particular, with Article 87(3) of Directive 2001/83/EC if a national provision (in this case: Section 7(1) sentence 1, second half-sentence, no. 2, first part of the sentence, letter a HWG) is interpreted as permitting advertising for the entire range of prescription-only medicines offered by a mail-order pharmacy established in another Member State with promotional gifts in the form of direct price reductions and payments?

14 The ECJ answered this question in its judgment of February 27, 2025 (C-517/23, GRUR 2025, 424 = WRP 2025, 583 — Apothekerkammer Nordrhein):

1. Article 86(1) of Directive 2001/83/EC of the European Parliament and of the Council of November 6, 2001 establishing a Community code relating to medicinal products for human use, as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, must be interpreted as meaning that

— Promotional campaigns for the purchase of unspecified prescription drugs in the form of discounts and payments do not fall under the term "advertising for drugs" within the meaning of this provision,

— whereas promotional campaigns for the purchase of unspecified prescription drugs using promotional gifts in the form of vouchers for the subsequent purchase of non-prescription drugs do fall within that concept.

2. Art. 34 TFEU and Art. 3(4)(a) of Directive 2000/31/EC of the European Parliament and of the Council of

June 8, 2000, on certain legal aspects of information society services, in particular electronic commerce ("Directive on electronic commerce") must be interpreted as not precluding national legislation which, for reasons of consumer protection, prohibits an advertising campaign offering customers of a pharmacy established in another Member State a cash reward for sending in their prescriptions and participating in a "medicine check" without the exact amount of that reward being apparent.

3. Article 87(3) of Directive 2001/83/EC, as amended by Directive 2011/62/EU, must be interpreted as not precluding national legislation which prohibits promotional campaigns for the purchase of unspecified prescription medicines using promotional gifts in the form of vouchers for a specific amount of money or a percentage discount on the subsequent purchase of other products, such as non-prescription medicines.

Reasons: 15 A. The Court of Appeal considered claim 1 to be well-founded on its merits and claim 2 to be well-founded with regard to the aforementioned preliminary injunctions, stating the following:

16 The defendant owes the plaintiff the compensation claimed in claim 1 for the damage caused by the enforcement of the preliminary injunctions, which were unjustified from the outset.

17 The plaintiff's claim for damages pursuant to

Section 945 of the German Code of Civil Procedure (ZPO) is not precluded by the fact that the defendant, in its role as the self-governing body of pharmacists in the North Rhine region, performs sovereign tasks in the form of a public corporation and, in this function, acts in a sovereign manner towards its members, even if it does not exercise supervision over the pharmacies in the district. In relation to the plaintiff, the

defendant did not choose to proceed by means of administrative action under public law or to involve the supervisory authorities, but instead brought the matter before the civil courts. It must also adhere to this approach with regard to any liability for damages arising from the enforcement of the preliminary injunctions.

18 The preliminary injunctions proved to be unjustified from the outset.

19 By distributing medicines from the Netherlands to end customers in Germany, the plaintiff did not violate Section 73 (1) sentence 1 no. 1a sentence 3 AMG. The plaintiff operates a pharmacy under Dutch law. There is also a standard comparable to that in Germany for the mail-order trade in medicinal products from the Netherlands, insofar as mail-order pharmacies—such as the plaintiff in the present case—also operate a brick-and-mortar pharmacy.

20 The preliminary injunctions are also not justified on the grounds of a violation of Section 7 (1) HWG by the plaintiff. The plaintiff's advertising campaigns are covered by the exception provision of Section 7 (1) sentence 1 no. 2 letter a HWG; there is no violation of the law on drug prices.

21 The fixed drug prices provided for in Section 78 (1) sentence 4 AMG (old version) are, as the ECJ has ruled, not applicable to the plaintiff based in the Netherlands due to a violation of the free movement of goods (Articles 34 and 36 TFEU). The cases to be assessed in the present case are to be assessed in the same way as the case underlying the ECJ ruling, which concerned a discount campaign in the form of a

"prescription bonus" of EUR 2.50, a further bonus

i. H. of 0.5% of the value of the goods, and a voucher worth EUR 5 for the first order. The ECJ ruling does not only apply between the parties to the legal dispute at that time, but is generally binding; it also applies retroactively to the date of enforcement of the preliminary injunctions.

22 There is no need to refer the matter back to the ECJ to clarify whether fixed drug prices are necessary to ensure a comprehensive and uniform supply of prescription drugs.

23 The claim asserted by the plaintiff in claim 1 is not ready for decision with regard to the amount of damages. However, the damage is highly probable, so that the issuance of an interim judgment is justified. In any case, with regard to privately insured persons who have to pre-finance the purchase price of a drug and who are also particularly price-sensitive due to the price-suppressing lump sums under subsidy law or insurance contract allowances, there is much to suggest that damage has been incurred.

24 Claim 2 is successful insofar as it is relevant to the appeal. The necessary interest in a declaratory judgment exists because the plaintiff is not yet able to definitively quantify the damage it has suffered and there is a risk of the statute of limitations expiring. The claim is also well-founded

justified because the preliminary injunctions proved to be unjustified from the outset.

25 B. The defendant's appeal is successful. According to the correct opinion of the court of appeal, the plaintiff's claim for damages under § 945 ZPO (see B I below) is not precluded by the fact that the defendant is a public-law corporation (see B II below) and that the preliminary injunctions issued do not prove to be justified from the outset from the point of view of a violation of § 4 No. 11 UWG (Unfair Competition Act) in conjunction with the fixed drug prices provided for in § 78 (1) sentences 1 and 4 AMG (Medicines Act) in the contested offer of premiums and vouchers (see B III below). However, the appeal successfully challenges the assessment of the Court of Appeal that the plaintiff did not violate the prohibition on transfer stipulated in Section 73 (1) sentence 1 No. 1a AMG, so that a claim for damages under Section 945 ZPO is not excluded on the basis of the obligation to refrain from such a violation (see B IV below). The Court of Appeal's assessment under the law on the advertising of medicinal products also does not stand up to legal review in all respects (see B V below).

26 I. According to Section 945 Case 1 of the German Code of Civil Procedure (ZPO), a party that has obtained an injunction that was unjustified from the outset is obliged to compensate the opposing party for any damage incurred as a result of its enforcement. The provision of Section 945 ZPO is based on the legal principle that enforcement based on an enforcement order that is not yet final is carried out at the creditor's risk (Federal Court of Justice, judgment of November 19, 2015 — I ZR 109/14, GRUR 2016, 720 [juris para. 11] = WRP 2016, 854 — Hot Sox, with further references).

27 The claim under Section 945 of the German Code of Civil Procedure (ZPO) is ruled out, on the one hand, if the preliminary injunction proves to have been justified from the outset, i.e., if it was issued correctly. On the other hand, this claim does not exist if the party affected by the enforcement of an unjustified injunction is in any case obliged under substantive law to refrain from the conduct prohibited by the preliminary injunction. In the latter case, there is in any event no damage to be compensated under § 945 ZPO (Federal Court of Justice, judgment of July 20, 2006 — IX ZR 94/03, BGHZ 168, 352 [juris para. 27]; Federal Court of Justice, GRUR 2016, 720 [juris para. 38] — Hot Sox, each with further references).

Therefore, in the damages proceedings, the question arises as to whether the final revocation of preliminary injunctions has binding effect in the subsequent main proceedings (most recently in favor of this view, Federal Court of Justice, judgment

v. March 26, 1992 — IX ZR 108/91, NJW 1992, 2297 [juris para. 14]; dissenting opinion

MünchKomm.ZPO/Drescher, 7th ed.,

§ 945 margin note 16; Braun in Musielak/Voit, ZPO, 22nd ed., § 945 margin note 5; Bruns in Stein/Jonas, ZPO, 23rd ed., § 945 marginal no. 26), generally not (cf. BGH, GRUR 2016, 720 [juris marginal no. 38] — Hot Sox, with further references; Teplitzky/Sender, Competition Law Claims and Proceedings, 13th ed., chap. 36 margin note 21 with further references).

28 II. As the Court of Appeal correctly stated, the fact that the defendant is a public corporation does not preclude the application of § 945 ZPO in the case in dispute.

29 If a legal entity under public law acts in a manner subject to civil law and civil procedure law, it must accept the application of civil law and civil procedure law consequences. Thus, a legal entity under public law that can be held liable under unfair competition law for its business activities must accept the application of civil procedural rules on coercive measures (see BGH, judgment of March 12, 2020 — I ZR 126/18, BGHZ 225, 59 [juris para. 82 to 84] — WarnWetter-App, with further references). The defendant has decided to assert claims under unfair competition law by way of civil proceedings for a preliminary injunction and must therefore accept the application of Section 945 of the German Code of Civil Procedure (ZPO) associated with this type of claim.

30 III. The appeal unsuccessfully challenges the assessment of the Court of Appeal that the preliminary injunctions issued were not justified from the outset from the point of view of a violation of § 4 No. 11 UWG (old version) in conjunction with the fixed drug prices provided for in § 78 (1) sentences 1 and 4 AMG.

31 1. The Court of Appeal rightly assumed that the fixed price for medicinal products may not be applied to the detriment of the plaintiff insofar as the setting of uniform selling prices provided for in Section 78 (1) sentence 4 AMG (old version) proves to be an absolute prohibition of price competition and, as such, has a greater impact on the plaintiff — a pharmacy established in a Member State other than the Federal Republic of Germany — than on pharmacies established in German territory, because this constitutes a barrier to market access that infringes Article 34 TFEU (see ECJ, GRUR 2016, 1312 [juris para. 26 et seq.] — German Parkinson's Association; ECJ, Judgment of July 15, 2021 — C-190/20, GRUR 2021, 1325 [juris para. 40 to 44] = WRP 2021, 1277 — DocMorris; Federal Court of Justice, Judgment of November 18, 2021 — I ZR 214/18, GRUR 2022, 391 [juris para. 65] = WRP 2022, 434 — Gewinnspielwerbung II).

32 2. For a renewed referral to the ECJ to clarify whether the fixed drug prices provided for in Section 78(1) sentence 4 AMG (old version) are necessary to ensure the required comprehensive and uniform supply of drugs to the population and to safeguard the financial equilibrium of the statutory health insurance system (see Federal Court of Justice, judgment of November 24, 2016 — I ZR 163/15, GRUR 2017, 635 [juris para. 49] = WRP 2017, 694 — Freunde werben Freunde), there is no reason to do so. According to the findings of the Court of Appeal, a request for information addressed to the Federal Government by the Munich Higher Regional Court in 2018 remained unanswered until the decision in the appeal instance. The defendant did not present any evidence that a further request for information would be promising. No further clarification of the economic, statistical, and health policy data underlying the provision in Section 78 (1) sentence 4 AMG, which has since expired, is to be expected (see also BGH, judgment of July 17, 2025 — I ZR 74/

24, GRUR 2025, 1404 [juris paras. 52 to 60] = WRP 2025, 1159 — Arzneimittel-Check).

33 IV. The appeal successfully challenges the assessment of the Court of Appeal that the plaintiff did not violate the prohibition on transfer stipulated in Section 73 (1) sentence 1 no. 1a AMG, so that a claim for damages under Section 945 ZPO is not excluded on the grounds of the obligation to cease and desist resulting from such a violation.

34 1. According to Section 73 (1) sentence 1 no. 1a AMG in the version since

According to the version of the law that remains unchanged as of May 31, 2011, approved medicinal products may only be shipped to end consumers in Germany if they are sent by a pharmacy in a member state of the European Union or another signatory state to the Agreement on the European Economic Area in accordance with German regulations on mail order or electronic commerce and the pharmacy is authorized to engage in mail order business in accordance with its national law, insofar as it corresponds to German pharmacy law with regard to the regulations on mail order business, or in accordance with the German Pharmacy Act. According to Section 73 (1) sentence 3 AMG, the Federal Ministry publishes at regular intervals an updated overview of the Member States of the European Union and the other signatory states to the Agreement on the European Economic Area in which safety standards comparable to German law exist for mail order and electronic commerce in medicinal products.

35 The ban on importation regulated in Section 73 (1) sentence 1 no. 1a AMG constitutes a market conduct regulation

i. S. v. Section 4 No. 11 UWG in the version applicable at the time the preliminary injunctions were issued (now:

§ 3a UWG) (see Federal Court of Justice, judgment of December 20, 2007 — I ZR 205/04, GRUR 2008, 275 [juris para. 20] = WRP 2008,

356 — Mail order business with medicinal products).

36 2. The Court of Appeal assumed that the plaintiff had not violated the prohibition on transport and stated:

37 The plaintiff operates a pharmacy under Dutch law, as demonstrated by the submission of extracts from the Dutch pharmacy register and a letter from the competent Dutch supervisory authority. The plaintiff argued that Dutch law only requires a notification obligation for the operation of a pharmacy and does not require an operating license. The plaintiff further argued that, pursuant to Article 61 of the Dutch Pharmacy Act, a pharmacy is required to appoint a pharmacist who is registered in the register of established pharmacists for the location of the pharmacy. According to the plaintiff's further submission, the Dutch Health and Youth Care Inspectorate maintains the pharmacy register and updates it every 14 days. The defendant did not substantiate any objection to this submission.

38 Insofar as the plaintiff, according to the defendant's unsubstantiated and disputed submission, operates a so-called "border pharmacy" that exclusively supplies medicines to persons living in another European Union member state,

and Dutch law stipulates that the permissibility of operating such a pharmacy is governed by the regulations of the Member State in which the patient lives, there is no evidence to suggest that the plaintiff requires a license or declaration from the German supervisory authorities to operate its brick-and-mortar pharmacy in the Netherlands.

39 As can be seen from a report by the "Inspectie voor de Gezondheidszorg" dated April 8, 2016, the plaintiff is authorized under Dutch law to engage in mail-order sales of medicinal products. According to the announcement by the Federal Ministry of Health dated

5. 7. In 2011, there was a standard comparable to that in Germany for the mail-order sale of medicinal products from the Netherlands, insofar as mail-order pharmacies also operated a brick-and-mortar pharmacy.

40 3. The Court of Appeal correctly assumed that the announcement pursuant to Section 73 (1) sentence 3 AMG is binding on the courts insofar as it establishes that, at the time of its publication, certain Member States of the European Union had safety standards comparable to German law for mail-order and electronic trade in medicinal products, subject to certain conditions. for mail order and electronic trade in medicinal products (BGH, GRUR 2008, 275 [juris para. 30] — Mail order trade in medicinal products).

41 The appeal does not challenge the finding of the Court of Appeal that the Federal Ministry of Health announced on July 5, 2011, that comparability exists in the Netherlands for medicinal products intended for use on or in the human body, insofar as mail-order pharmacies also maintain a brick-and-mortar pharmacy. Because, according to the announcement, the finding of comparability depends on the operation of a brick-and-mortar pharmacy, the response to the appeal unsuccessfully argues that the plaintiff is authorized to engage in mail-order business even if it does not operate a brick-and-mortar pharmacy.

42 The Court of Appeal further correctly held that the question of operating a brick-and-mortar pharmacy must be assessed in accordance with the requirements applicable in the Netherlands, because the announcement by the Federal Ministry of Health is based on a comparison of the legal requirements for mail order business in the Member States of the European Union and in the other contracting states of the European Economic Area, which takes into account the respective national characteristics (see BGH, GRUR 2008, 275 [juris para. 30]), taking into account the respective national particularities (see BGH, GRUR 2008, 275 [juris para. 30] — Mail order trade in medicinal products).

43 4. However, the appeal successfully argues that the court of appeal violated § 293 ZPO by insufficiently determining the requirements for operating a brick-and-mortar pharmacy under Dutch law.

44 a) According to § 293 ZPO, the law applicable in another state only requires proof insofar as it is unknown to the court (sentence 1); when determining these legal norms, the court is not limited to the evidence provided by the parties and is also authorized to use other sources of information and to take the necessary steps for such use.

(sentence 2). However, these possibilities do not in principle release the trial court from its obligation to investigate ex officio the provisions of the applicable foreign law that are relevant to the decision of the case (BGH, decision of

6. 10. 2016 — I ZB 13/15, NJW-RR 2017, 313 [juris para. 66]; decision of 9 February 2017 — V ZB 166/15, NZG 2017, 546 [juris para. 7]; judgment of 25 June 2019 — X ZR 166/18, NJW 2019, 3375 [juris para. 23]). How the trial court obtains this knowledge is at its discretion. However, the investigation of foreign law must not be limited to consulting legal sources, but must also take into account the specific form of the law in foreign legal practice, in particular foreign case law. The trial court is required to investigate the law as a whole, as it has developed in doctrine and case law. In doing so, it must exhaust the sources of knowledge available to it (established case law; see only BGH, judgment of January 14, 2014 — II ZR 192/13, NJW 2014, 1244 [juris para. 15]; judgment of September 10, 2015 — IX ZR 304/13, WM 2015, 2248 [juris para. 15]). Because foreign legal norms are not facts but legal principles, there is no burden of proof on the parties (BGH, decision of December 12, 2007 — XII ZB 240/05, NJW-RR 2008, 586 [juris para. 37]; decision v. May 17, 2018 — IX ZB 26/17, WM 2018, 1316 [juris para. 19]).

45 In this regard, the court of appeal merely examines whether the trial court exercised its discretion without legal error, in particular whether it sufficiently exhausted the available sources of information, taking into account the circumstances of the individual case (Federal Court of Justice, decision of April 30, 2013—VII ZB 22/12, WM 2013, 1225 [juris para. 39]; BGH, NJW 2014, 1244 [juris para. 15]; BGH, judgment of March 18, 2020 — IV ZR 62/19, NJW-RR 2020, 802 [juris para. 23]; on Appeal cf. Decision of February 20, 2025 — I ZB 26/24, GRUR 2025, 848 [juris para. 51] = WRP 2025, 471 — Fernbus in Belgium).

46 b) Subsequently, the Court of Appeal exercised its discretion incorrectly when determining the requirements for operating a brick-and-mortar pharmacy under Dutch law.

47 The Court of Appeal based its interpretation of Dutch law solely on the plaintiff's submission that there is no requirement for a license to operate a pharmacy in the Netherlands, but only a notification requirement, and that Article 61 of the Dutch Pharmacy Act requires a pharmacy to appoint a pharmacist who is registered in the register of established pharmacists for the location of the pharmacy. The Court of Appeal based its decision on this submission on the grounds that the defendant had not substantively contested it. In doing so, the Court of Appeal applied the principles of the burden of proof and presentation in the determination of foreign law in a legally erroneous manner, instead of — as required by Section 293 of the German Code of Civil Procedure (ZPO) generally requires the court to conduct its own investigations to verify this submission. Insofar as it is based on the content of the letters from official bodies submitted by the plaintiff, the reasoning of the Court of Appeal does not indicate that these letters explain the requirements of Dutch

for the operation of a brick-and-mortar pharmacy. The Court of Appeal also erred in law in considering the question raised by the defendant as to whether a Dutch "Grensapotheek" is subject to special legal requirements to be irrelevant according to the principles of the burden of proof and presentation.

48 V. The Court of Appeal's assessment that the preliminary injunctions were unjustified from the outset under Section 7 HWG only partially stands up to legal review, namely with regard to the preliminary injunctions of

November 5, 2013 (Ref. 84 O 256/13) and September 29, 2015 (Ref. 81 O 82/15). The preliminary injunctions of May 8, 2013 (Ref. 84 O 90/13), September 26, 2013 (Ref.

84 O 220/13) and November 4, 2014 (Ref. 84 O 208/14)

, on the other hand, prove to have been justified from the outset, so that

§ 945 ZPO.

49 1. According to Section 7 (1) sentence 1, first half-sentence, HWG, it is inadmissible to offer, announce, or grant gifts and other promotional items (goods or services) or to accept them as a member of the professional community, unless one of the exceptions regulated by law in Section 7 (1) sentence 1, second half-sentence, HWG applies. The following are exempt from the prohibition

— What is considered here alone — low-value trifles (Section 7 (1) sentence 1, clause 2, no. 1, clause 1, case 2 HWG) and gifts or promotional items in a specific monetary amount or calculated in a specific manner (Section 7 (1) sentence 1, clause 2, no. 2, clause 1, letter a HWG). However, in both exceptions, gifts or other promotional items for medicinal products remain inadmissible if they are granted in contravention of the price regulations based on the Medicinal Products Act — or the Fifth Book of the Social Code (as amended on December 15, 2020) — apply (Section 7 (1) sentence 1 clause 2 no. 1 clause 1 case 2 HWG). 2020) (Section 7 (1) sentence 1, clause 2, no. 1 half-sentence 2, Section 7 (1) sentence 1 half-sentence 2 no. 2 part-sentence 2 HWG).

50 2. The Court of Appeal correctly assumed that the general prohibition on offering, announcing, and granting promotional gifts, as regulated in Section 7 (1) sentence 1 HWG, constitutes a market conduct regulation within the meaning of Section 4 No. 11 UWG (old version) (now: Section 3a UWG) because it serves to protect the health of consumers. By extensively curbing value advertising in the field of medicinal products, it is intended to counter the abstract risk that consumers will be unduly influenced by the prospect of promotional gifts when deciding whether and, if so, which medicinal products to use (established case law; see only BGH, GRUR 2022, 391 [juris para. 26] — Gewinnspielwerbung II, with further references).

51 3. The Court of Appeal was right to consider the advertising measures challenged as product-related and thus falling within the scope of the German Law on the Advertising of Medicinal Products.

52 a) Only product-related advertising (product and sales advertising) is included in the scope of this Act, and not general company advertising (corporate and image advertising), which generally promotes the reputation and performance of the company without reference to specific medicinal products

the reputation and performance of the company in general. The answer to the question decisive for the applicability of the German Advertising of Medicines Act, namely whether the advertising to be assessed is sales or company advertising, depends largely on whether, based on the overall appearance of the advertising, the focus is on the presentation of the company or on the promotion of specific or at least identifiable products. Even advertising for the entire range of goods offered by a pharmacy can be product-related. There is no convincing reason to accept the incentive of value advertising, which is considered fundamentally undesirable by the legislator in the area of advertising for medicinal products, precisely when this form of advertising is used for a particularly large number of medicinal products (established case law; see only BGH, GRUR 2022, 391 [juris para. 35] — Gewinnspielwerbung II, with further references).

53 b) The Court of Appeal rightly assumed that the contested advertising measures were aimed either at the entire range of prescription drugs or even at the plaintiff's entire product range and were therefore product-related. Contrary to the opinion expressed by the plaintiff in the appeal proceedings, this is not merely company-related advertising that does not fall within the scope of the German Law on the Advertising of Medicinal Products. According to the case law of the ECJ, advertising by a pharmacy for the purchase of prescription drugs, which is intended solely to influence the decision in favor of the pharmacy where a customer already purchases prescription drugs, does not constitute advertising for medicinal products within the meaning of Directive 2001/83/EC, but rather advertising for the pharmacy that is not covered by that directive (ECJ, GRUR 2025, 424 [juris 34 to 37] — Apothekerkammer Nordrhein, with further references). However, this does not mean that such advertising does not fall within the scope of the German Advertising of Medicines Act (Heilmittelwerbegesetz, HWG). The counter-exception for (price-controlled) prescription drugs regulated in Section 7 HWG clearly shows that the HWG also covers advertising for prescription drugs. Although the counter-exception does not apply to the shipment of prescription drugs from another EU member state, it does apply to the sale (including by mail order) within Germany. The Federal Court of Justice has already ruled that Directive 2001/83/EC and the German Advertising of Medicines Act are based on different concepts of "advertising of medicinal products" and that, unlike Directive 2001/83/EC, the German Advertising of Medicines Act also covers advertising by a pharmacy for the purchase of prescription-only medicinal products (BGH, GRUR 2022, 391 [juris para. 34 to 40] — Gewinnspielwerbung II).

54 4. The Court of Appeal was right to classify the bonuses and vouchers offered in the contested advertising measures as promotional gifts within the meaning of Section 7 (1) sentence 1 HWG.

55 The term "promotional gift" in Section 7 (1) sentence 1 HWG must be interpreted broadly in view of the purpose of the provision, which is to counteract the abstract danger of an unobjective influence arising from promotional gifts in the field of medicinal products by extensively curbing such gifts.

of any undue influence arising therefrom, must be interpreted broadly. It basically covers any monetary benefit that is not calculated from the recipient's point of view. An advertising gift therefore requires that the benefit be granted free of charge from the recipient's point of view; they must regard it as a gift (see BGH, GRUR 2022, 391 [juris para. 41] — Gewinnspielwerbung II, with further references). The premiums and vouchers to be assessed in the present case fulfill this requirement.

56 5. The bonuses and vouchers advertised in the contested advertising measures are not minor items of negligible value within the meaning of Section 7 (1) sentence 1, clause 2, no. 1, clause 1, case 2 HWG. Their value exceeds the threshold of low value for public advertising, which is EUR 1 (see BGH, judgment of July 17, 2025 — I ZR 43/24, GRUR 2025, 1416 [juris para. 45] = WRP 2025, 1154 — PAY-BACK, with further references).

57 6. Only some of these bonuses and vouchers are gifts or promotional gifts that are granted in a specific amount or in a specific manner within the meaning of Section 7 (1) sentence 1, clause 2, no. 2, clause 1, letter a HWG.

58 a) An advertising gift granted in a specific amount of money within the meaning of Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 1, letter a HWG is the donation of a specific sum of money, the amount of which cannot be doubted by the public due to its specificity (BeckOK.HWG/Doepner/Reese, 14th edition [as of May 1, 2025], Section 7 marginal number 603). This is the case, for example, with the offer of a bank credit in the amount of EUR 10 for the referral of a new customer (see BGH, GRUR 2017, 635 [juris para. 56] — friends recruit friends), an "instant bonus" that is offset against the statutory co-payment (cf. BGH, judgment of February 26, 2014 — I ZR 79/10, GRUR 2014, 593 [juris para. 2] = WRP 2014, 692 — Sofort-Bonus), the reimbursement of the purchase price for a medical device (Hamburg Higher Regional Court, GRUR-RR 2019, 486 [juris para. 33]; Cologne Higher Regional Court, WRP 2022, 368 [juris para. 62]) or a "beauty bonus" of EUR 50 to be credited towards the initial treatment with a medical device (LG Hamburg, PharmR 2011, 487 [juris para. 39]).

59 b) A "monetary amount to be calculated in a specific manner" within the meaning of Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 1, letter a HWG refers to price reductions in percentage terms or otherwise easily calculable amounts that are granted on the normal price (BGH, GRUR 2022, 391 [juris para. 48]).

— Competition advertising II; Fritzsche in Spickhoff, Medical Law, 4th edition, Section 7 HWG margin number 25; Prütting/Mand, Medical Law, 7th edition, Section 7 HWG margin number 85). Such a case exists, for example, when a discount of 10% is offered for the referral of a new customer (cf. BGH, GRUR 2017, 635 [juris margin note 56] — Freunde werben Freunde) or when offsetting a percentage co-payment for medical aids prescribed by law (cf. BGH, judgment of December 1, 2016 — I ZR 143/15, GRUR 2017, 641 [juris para. 41] = WRP 2017, 536 — Waiver of co-payment for aids).

60 c) On the other hand, advertising with a monetary advantage that is not granted in a specific or determinable amount of money but as a benefit in kind—such as consumer goods or services—does not fulfill the exception provided for in

Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 1, letter a HWG (see BGH, judgment of March 26, 2009 — I ZR 99/07, GRUR 2009, 1082 [juris para. 17] = WRP 2009, 1385

— DeguSmiles & more; BeckOK.HWG/Doepner/Reese

Ibid. § 7 margin note 601; cf. also Prütting/Mand ibid. § 7 HWG margin note 89). This also applies if the value of the benefit is stated as a specific monetary amount. This is supported first and foremost by the wording of the provision, because a benefit in kind is not a monetary amount. A further argument in favor of this is that, in the case of a benefit in kind, the advertiser could otherwise evade the scope of application of Section 7 (1) sentence 1, clause 2, no. 1, clause 1, case 2 HWG, which requires that a benefit in kind be of negligible value in order to be permissible, and benefit from the provision of Section 7 (1) sentence 1, clause 2, no. 2, clause 1, letter a HWG (cf. OLG Hamm, WRP 2022, 633 [juris para. 42]). Benefits in kind also do not fall within the scope of this exemption because, unlike monetary benefits that lead to a direct price reduction, the protective purpose of the law on advertising medicinal products is particularly relevant in this case, namely to prevent undue influence. This is because there is no objective connection with the purchase of the medicinal product and, in addition, there is an abstract risk of misleading consumers about the value of the benefit in kind.

61 In the case of a ban on benefits in kind that do not consist of discount vouchers for the subsequent purchase of further products, which are specified in terms of amount or as a percentage and are the only relevant factor in the dispute (see paras. 62 and 73 below), this is also unlikely to constitute an "absolute prohibition of price competition" within the meaning of the case law of the ECJ, which infringes Art. 34 TFEU within the meaning of the case law of the ECJ, because this only covers the prohibition of advertising with direct price reductions (see BGH, GRUR 2023, 1318 [juris para. 64] — Gutscheinerwerbung I). The Senate has already ruled on this in relation to advertising with a competition (BGH, GRUR 2022, 391 [juris para. 49 to 56] — Gewinnspielwerbung II). It is not apparent that anything else should apply to other promotional gifts which likewise do not lead solely to an immediate price reduction and whose prohibition serves to protect health because it is intended to prevent undue influence.

62 d) The question of whether the granting of discount vouchers for the subsequent purchase of further products, specified in terms of amount or as a percentage (e.g., discount voucher for the next purchase from the advertiser worth EUR 5; voucher for a 10% discount at an online marketplace), which, according to the above, are also considered non-cash benefits, falls under the exception in Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 1, letter a HWG, is not answered uniformly in case law and literature. In the opinion of the Senate, which has not yet taken a position on this issue, (see case law references in BGH,

GRUR 2023, 1318 [juris Rn. 35] — Gutscheinerwerbung I), this is not the case.

63 aa) It is partly assumed that a cash discount within the meaning of this provision is only one that reduces the price of the advertised remedy (rejecting a cash discount in the case of a shopping voucher for an online marketplace OLG Cologne, WRP 2016, 1388; Brixius in Bülow/Ring/Artz/Brixius, HWG, 6th edition, Section 7, margin note 282; Sosnitzer in Sosnitzer/Meisterernst (formerly Zipfel/Rathke), Food Law, as of 192. Supplementary delivery [as of March 2025], Section 7 HWG, margin note 40; Wesser, A&R 2019, 109, 113 f.). The reason for allowing cash discounts is the assumption that advertising with a price reduction does not constitute undue influence, because price competitiveness is a decisive factor in consumer decisions. This means that only discounts that affect the price of the product are privileged. Otherwise, the fundamental prohibition on benefits in § 7 (1) sentence 1 HWG would be undermined, because then any monetary advertising gift would have to be considered a permissible cash discount within the meaning of § 7 (1) sentence 1, second half-sentence, no. 2, sub-sentence 1, letter a HWG (cf. Wesser, A&R 2019, 109, 113 f.).

64 bb) According to another opinion, vouchers denominated in a monetary amount for the purchase of further products are also covered by the scope of application of Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 1, letter a HWG (OLG Bamberg, WRP 2013, 1641; BeckOK.HWG/Doepner/Reese, loc. cit. Section 7 marginal number 603c; Fritzsche in Spickhoff, loc. cit. Section 7 HWG marginal number 24).

65 cc) In the opinion of the Senate, the exception in Section 7 (1) sentence 1, clause 2, no. 2, clause 1, letter a HWG is to be interpreted as meaning that it applies only to directly effective price reductions and payments, but not to vouchers for a monetary amount or a percentage discount for the subsequent purchase of further products.

66 A restriction of the exception in

Section 7 (1) sentence 1 clause 2 no. 2 subclause 1 letter a HWG applies to direct price reductions and payments, as suggested by the wording of the provision, which requires that the benefit or promotional gift be "granted in a (...) monetary amount (...)". This wording is obviously to be understood as meaning that a sum of money is paid out or at least deducted from the invoice amount. This is not the case with a discount voucher for future purchases. Above all, however, this understanding corresponds in particular to the protective purpose of Section 7 (1) HWG, which is to counteract even the abstract risk of undue influence on the advertising target group in connection with the purchase of medicinal products. It is true that a consumer is aware of the value of a voucher for a future purchase and therefore there is no risk of misjudging the value of the promotional gift (on this motive for privileging cash discounts, see BGH, GRUR 2009, 1082 [juris para. 9 and 11] — DeguS-miles & more). However, insofar as such a discount voucher creates an incentive to purchase further medicinal products, this affects the further protective purpose of the law on the advertising of medicinal products, namely to prevent uncritical self-medication and possible damage to health.

counteract the dangerous overuse and misuse of medicinal products (for this protective purpose, see BeckOK.HWG/Doepner/Reese, loc. cit. § 7 margin note 364 f.; Prütting/Mand, loc. cit. § 7 HWG margin note 3). By classifying discount vouchers for future purchases as gifts or promotional items within the meaning of Section 7 (1) clause 2 no. 1 clause 1 case 2 HWG, which are only permissible as small items of low value, this further protective purpose is taken into account in a special way, because With regard to discount vouchers offered for the purchase of other goods from other suppliers in connection with the purchase of therapeutic products, this classification already reduces the risk of an inappropriate motivation for the initial purchase of therapeutic products. The irrelevance lies in the fact that, in contrast to permissible cash discounts, the advertisement does not promote a reduction in the price of the desired therapeutic product, but rather an advantage in the purchase of other goods that is in no way related to the purchase of the therapeutic product (BGH, GRUR 2025, 1416 [juris para. 34] — PAY-BACK; dissenting opinion BeckOK.HWG/Doepner/Reese loc. cit. § 7 Rn. 603c to 603e; Prütting/Mand loc. cit. § 7 HWG Rn. 92; Deckers, MedR 2024, 110, 111; Reese, MPR 2024, 121, 129 f.).

67 The clear distinction between cash discounts within the meaning of Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 1, letter a HWG and (other) promotional gifts within the meaning of Section 7 (1) sentence 1, clause 2, no. 1, clause 1, case 2 HWG, which (also in the form of a discount promise) is only permissible as a small gift of negligible value, also serves to ensure legal certainty (cf. BGH, GRUR 2023, 1318 [juris para. 37] — Gutscheinerwerb I).

68 Insofar as the Senate ruled with regard to an unfair inducement within the meaning of Section 1 UWG (old version) that the benefit granted in the form of a shopping voucher worth DM 10 essentially constitutes a price reduction on the purchase of goods and that the reasonable consumer recognizes this (BGH, judgment of May 22, 2003 — I ZR 8/01, GRUR 2003, 1057 [juris para. 18] = WRP 2003, 1428 — Einkaufsgutschein), this assessment is not transferable to the law on advertising of medicinal products, which — as explained — has a specific protective purpose.

69 e) Accordingly, only some of the benefits or promotional gifts at issue here are permissible under Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 1, letter a HWG because they are granted in a specific amount of money or in a specific manner.

70 aa) The gifts or promotional items that are the subject of the preliminary injunctions of May 8, 2013 (Ref. 84 O 90/13), September 26, 2013 (Ref. 84 O 220/13) and November 4, 2014 (Ref. 84 O 208/14)

71 (1) At , , with , preliminary injunction , injunction , dated May 8, 2013 (Ref. 84 O 90/13) prohibiting advertising with a bonus for participating in the plaintiff's "medicine check" of at least EUR 2.50 and up to EUR 20 per prescription, contrary to the opinion of the Court of Appeal, does not constitute the offering of a specific or specific type of

calculated amount of money within the meaning of Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 1, letter a HWG. According to the findings of the Court of Appeal, those addressed by the advertising who are interested in purchasing medicines for the treatment of serious chronic diseases are left in the dark about the absolute amount or calculation of the promised bonus, because only a range of possible bonus amounts is indicated without disclosing the calculation method intended by the plaintiff. The protective purpose of the provision is affected because the possibility that the addressees of the advertising may overestimate the amount of the bonus granted in individual cases due to the indication of a range means that there is a risk of undue influence on the addressees of the advertising.

72 This interpretation of Section 7(1) sentence 1, clause 2, no. 2, sub-clause 1, letter a of the HWG is in conformity with EU law. According to the case law of the Court of Justice, the advertising measure at issue here does not fall under the concept of advertising for medicinal products within the meaning of Article 86(1) of Directive 2001/83/EC, because advertising campaigns for the purchase of (unspecified) prescription-only medicinal products in the form of price reductions and payments are not covered by this provision (see ECJ, GRUR 2025, 424 [juris paras. 39 to 42 and 81] — Apothekerkammer Nordrhein). However, a ban on this advertising measure is compatible with Article 34 TFEU and Article 3(4)(a) of Directive 2000/31/EC in view of its inherent potential to mislead consumers (see ECJ, GRUR 2025, 424 [juris para. 61 to 81] — Apothekerkammer Nordrhein).

73 (2) The North Rhine-Westphalia Chamber of Pharmacists () with preliminary injunction injunction dated September 26, 2013 (Ref. 84 O 220/13) Prohibited advertising is also not covered by the exception in Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 1, letter a HWG. In the case in dispute, it is not relevant to the decision whether a benefit in kind—in this case, a hotel voucher or a free annual membership in the ADAC—is also not covered by this provision if its value is stated in a specific monetary amount (see already para. 60). This is because offering a discount voucher to a newly acquired customer for the subsequent purchase of over-the-counter products does not constitute a promotional gift permitted under Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 1, letter a HWG, as no direct price reductions or payments are granted.

74 This interpretation of Section 7(1) sentence 1, clause 2, no. 2, sub-clause 1, letter a of the HWG is in conformity with EU law. In view of the discount voucher promised to the newly acquired customer for the subsequent purchase of non-prescription products, the advertising measure at issue here falls under the concept of advertising for medicinal products within the meaning of Article 86(1) of Directive 2001/83/EC, according to the case law of the Court of Justice, because it promotes the purchase of non-prescription medicinal products (see ECJ, judgment of 14 January 2004, Case C-275/02, Altmann, ECR 2004, p. I-103, paragraph 36). This advertising may, contrary to Article 87(3) of Directive 2001/83/EC, lead to inappropriate and excessive use of non-prescription medicines. — Apothekerkammer Nordrhein). Contrary to Article 87(3) of Directive 2001/83/EC, such advertising may lead to the inappropriate and excessive use of non-prescription medicinal products, so that its prohibition is in line with the essential objective of protecting

public health (see ECJ, GRUR 2025, 424 [juris para. 82 to 94] — Apothekerkammer Nordrhein).

75 (3) The Federal Institute for Drugs and Medical Devices () with preliminary injunction Verfügung dated 4. 11. 2014 (Ref. 84 O 208/14) Prohibited advertising with a EUR 10 voucher for submitting a prescription for a subsequent order of non-prescription drugs and health and care products is also not permitted under Section 7 (1) sentence 1, clause 2, no. 2, clause 1, letter a HWG, because no immediate price reductions or payments are granted. For the reasons already explained above (see para. 73 et seq.), this prohibition is also in conformity with EU law.

76 (4) In the aforementioned cases, there is also the abstract risk of undue influence on the advertising recipient, which is necessary for the assumption of an advertising gift. This teleological restriction of the concept of advertising gifts applies not only to advertising aimed at specialists, but also to advertising aimed at the general public (established case law; see only BGH, judgment of February 20, 2020 — I ZR 214/18, GRUR 2020, 659 [juris para. 24] = WRP 2020, 722 — Gewinnspielwerbung I, with further references). The Court of Appeal did not expressly comment on this. However, the findings made by the Court of Appeal constitute Findings provide a sufficient basis for assessment by the Senate. In the event of a dispute, there is a risk of undue influence if, as in the aforementioned cases, vouchers for a monetary amount or a percentage discount are used to advertise the subsequent purchase of non-prescription drugs and health and care products. This affects the protective purpose of Section 7 (1) HWG, which is to counteract uncritical self-medication and the excessive and improper use of medicinal products, which may be harmful to health (see already above, para. 66).

77 bb) The appeal unsuccessfully challenges the assessment of the Court of Appeal, the preliminary injunctions of November 5, 2013 (Ref. 84 O 256/13; prohibition of a discount described as travel expense reimbursement

i. H. v. 10 EUR when submitting prescriptions to), and dated

September 29, 2015 (Ref. 81 O 82/15; prohibition of advertising with a discount of EUR 5 when ordering prescriptions) were unjustified from the outset from the perspective of Section 7 HWG.

78 (1) In both cases, these are cash discounts permitted under Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 1, letter a HWG, which directly reduce the invoice amount of the order. They do violate Section 7 (1) sentence 1, clause 2, no. 2, sub-clause 2 HWG because they were granted contrary to the price regulations that applied at the time under the German Medicines Act. The advertising concerned prescription drugs that were subject to fixed drug prices. Granting a cash discount that directly reduces the invoice amount of the order violates the fixed drug price. However, the Court of Appeals correctly assumed that this reservation regarding compliance with the fixed drug price may not be applied to the plaintiff (see above, para. 31 et seq.).

79 (2) The appeal unsuccessfully argues that the remaining amount after deduction of the co-payment or (if there is no co-payment) the entire discount amount is often offset against the price of other products from the range that are sold within the same order and which may also be non-prescription drugs. The appeal cannot succeed with this argument because it is based on a statement of facts made for the first time in the appeal, contrary to Section 559 (1) of the Code of Civil Procedure.

80 VI. There is no reason to refer the matter back to the ECJ (see ECJ, judgment of October 6, 1982 — 283/81, ECR 1982, 3415 [juris para. 21] = NJW 1983, 1257 — Cilfit et al.; judgment of October 1, 2015 — C-452/14, GRUR Int. 2015, 1152 [juris para. 43] — Doc Generici; judgment of October 6, 2021 — C-561/19, NJW 2021, 3303 [juris para. 32 et seq.] — Consorzio Italian Management and Catania Multiservizi). In the present case, there is no question relevant to the decision regarding the interpretation of EU law that has not already been clarified by the case law of the Court of Justice or cannot be answered beyond doubt. Insofar as the Senate's view that the prohibition of benefits in kind does not fall under the ECJ's concept of an "absolute prohibition of price competition" (see para. 60) could be called into question under EU law, this is irrelevant in the present case (see para. 73).

81 C. Accordingly, the contested judgment must be set aside on the basis of the defendant's appeal insofar as it was found to the detriment of the defendant. The plaintiff's appeal against the judgment of the Regional Court must be dismissed insofar as it concerns claims 1 and 2 with regard to the preliminary injunctions of May 8, 2013 (Ref. 84 O

90/13), 26 September 2013 (Ref. 84 O 220/13) and

4. 11. 2014 (Ref. 84 O 208/14) have been dismissed, because the matter is ready for decision in this respect (Section 562 (1), Section 563 (3) ZPO). Due to the decision on the preliminary injunctions of 5. 11. 2013 (Ref. 84 O 256/13) and 29 September 2015

(Ref. 81 O 82/15), as well as the costs of the appeal, the case must be referred back to the Court of Appeal for a new hearing and decision (Section 563 (1) sentence 1 ZPO). ■

2 Comirnaty has a positive risk-benefit ratio

AMG §§ 84 I 2 No. 1, No. 2, 84a I

The positive risk-benefit ratio of Comirnaty is determined by the factual effect of the European Commission's implementing decision of October 10, 2022, on the unconditional approval of the vaccine.

The decisive factor in weighing up the benefits and risks is the overall assessment of benefits and risks based on reliable scientific findings, which must therefore be proven by the claimant if necessary, whereby the degree of therapeutic efficacy correlates with the degree of tolerance of serious side effects.

There is no basis for the view that the benefit-risk ratio of the vaccine should be assessed differently depending on the batch.

Braunschweig Higher Regional Court, reference decision of October 29, 2025 — 9 U 16/25

Facts of the case: 1 The plaintiff is suing the defendant, the manufacturer of the Comirnaty vaccine, for material and immaterial damages due to alleged impairments caused by his two coronavirus vaccinations on ... 11. 2021 and ... 12. 2021, respectively, with the vaccine, and for the provision of information about the known effects, side effects, and interactions, as well as all other findings that may be relevant for the assessment of the acceptability of harmful effects, insofar as they affect panic attacks, insomnia, depressive episodes, shortness of breath, exhaustion, central pulmonary artery embolism, and pneumonia on the left side.

2 For further details of the facts and legal arguments

I. Instance and the motions filed therein, reference is made to the facts of the LG judgment (pp. 2–7 = pp. 2942–2947 LGA).

3–39

40 For further details of the parties' submissions in the second instance, reference is made to the plaintiff's statement of grounds for appeal dated February 21, 2025 (pp. 30–49 LGA) together with annexes (pp. 50–58 HA) and the defendant's response to the appeal dated June 4, 2025 (pp. 50–58 HA). 2025 (pp. 30–49 HA) together with the annexes (pp. 50–583 HA) and the defendant's response to the appeal dated June 4, 2025 (pp. 603–636 HA) together with the annexes (pp. 637–663 and pp. 665–685 HA).

Reasons: 41 The judgment of the Regional Court (pp. 2941–2956 LGA) proves to be correct, even when measured against the statements in the grounds for appeal (pp. 30–49 HA).

42 In the unanimous opinion of the Senate, the grounds for appeal are not valid.

43 The contested decision is not based on a violation of law within the meaning of Section 546 of the German Code of Civil Procedure (ZPO), nor do the facts to be taken as a basis pursuant to Section 529 (1) ZPO justify a different decision, Section 513 (1) ZPO.

44 The Regional Court rightly dismissed the action. The plaintiff cannot successfully rely on Section 84 (1) AMG. Although the scope of application of the provision is open, the requirements of Section 84 (1) sentence 2 AMG are not met (see point 1 (a)). No labeling deficiencies can be identified (see point 1 (b)). The plaintiff cannot rely on any other basis for his claim either (see point 2). Similarly, the requirements for a claim for information under Section 84a AMG are not met (see point 3). In this respect, the appeal is already inadmissible because it does not challenge all the considerations underlying the decision of the Regional Court. A referral to the ECJ is not necessary (see point 4).

45 1. The requirements set out in Section 84 (1) sentence 1 AMG for the existence of a human medicinal product subject to authorization, which was placed on the market in Germany by a pharmaceutical entrepreneur and supplied to a consumer, are met in the case of the Comirnaty vaccine developed by the defendant and placed on the market in Germany, which was administered to the plaintiff domestically and supplied to a consumer, are undisputedly met in the case of the Comirnaty vaccine developed by the defendant and marketed in Germany, which was administered to the plaintiff. Further comments are unnecessary in this regard. The dispute

only the specific requirements of the claim under Section 84 (1) sentence 2 no. 1 and no. 2 AMG are in dispute.

46 Liability for damages within the meaning of Section 84 (1) sentence 2 AMG only applies if "the medicinal product, when used as intended, has harmful effects that exceed what is acceptable according to medical science" (negative risk-benefit ratio, see lit. a) or if "the damage occurred as a result of labeling, product information, or instructions for use that did not correspond to the findings of medical science" (insufficient drug information, see lit. b). Neither of these is the case here.

47 a) The Regional Court correctly found that the Comirnaty vaccine has a positive risk-benefit ratio.

48 According to Section 84 (1) sentence 2 no. 1 AMG, the pharmaceutical company is only liable for damages if "the medicinal product, when used as intended, has harmful effects that exceed what is acceptable according to medical science." The claim of an injured party therefore presupposes a negative risk-benefit ratio of the medicinal product. The risk-benefit assessment to be carried out is of an abstract and general nature — which the plaintiff now also appears to assume (cf. BB p. 4, second paragraph = p. 33 HA: "correctly in relation to the patient population as a whole") — and refers to the entire patient group targeted by the pharmaceutical company's indication within the scope of the intended use (cf. OLG Koblenz, judgment of September 25, 2024 — 5 U 379/24, para. 34, juris; OLG Frankfurt

furt, judgment of February 19, 2025 — 23 U 13/24, para. 237, juris; Higher Regional Court of Düsseldorf, judgment of April 29, 2025 — I-4 U 172/23, para. 110, juris). The decisive factor is the overall assessment of benefits and risks in accordance with established scientific findings, which must therefore be proven by the claimant if necessary, whereby the degree of therapeutic efficacy correlates with the degree of tolerance of serious side effects (Higher Regional Court of Frankfurt, judgment of February 19, 2025 — 23 U 13/24, para. 238). If the assessment shows that the risk for a specific patient group is higher than for the entire patient population, special warnings or the inclusion of a contraindication in the drug information may be necessary. However, this does not

— regardless of whether an instruction error (§ 84 (1) sentence 2 no. 2 AMG) can be assumed — does not preclude a positive risk-benefit ratio as long as the overall benefits outweigh the risks (cf. OLG Frankfurt, judgment of February 19, 2025, loc. cit.). However, known, accepted, and expressly communicated risks are not taken into account if their severity, frequency, or incidence has not changed (see OLG Frankfurt, judgment of February 19, 2025 — 23 U 13/24, para. 239). The specifics of a specific individual case may have an impact on the overall assessment in the form of the type, severity, and statistical frequency of adverse side effects, as reported in accordance with reporting requirements; however, the risk-benefit assessment must not be based on individual circumstances (see OLG Frankfurt, judgment

v. 19. 2. 2025 — 23 U 13/24, para. 240, juris; OLG Koblenz, judgment of July 10, 2024 — 5 U 1375/23, para. 24, juris; from September 25, 2024 — 5 U 379/24, margin note 34, juris). The abstract general assessment is explained by the fact that the approval procedure always relies on anonymized studies and evaluates the results as a whole, whereas data on the individual risks in each case are not available (OLG Koblenz, judgment of September 25, 2024 — 5 U 379/24, para. 34, juris). The specifics of the individual case, on the other hand, can (only) be assessed and taken into account by the physician prescribing the drug (OLG Koblenz, loc. cit.).

49 The abstract-general approach must always be used as a basis for assessment—even in the event of an admission procedure that may not have been carried out properly or completely (see OLG Koblenz, judgment of September 18, 2024—5 U 1139/23, para. 101 et seq., juris).

50 Based on the above criteria, the risk-benefit ratio for the Comirnaty vaccine at issue in this case is to be assessed as positive. The decisive factor here is the assessment at the time of the last oral hearing, which must, however, be projected back. It must be examined whether, taking into account the pharmaceutical environment at the time, the now known harmful effects should have been accepted or not (cf. OLG Frankfurt, judgment of February 19, 2025 — 23 U 13/24, para. 241 et seq., juris). Such a consideration fits into the liability system in the event of changes in risk and does justice to the character of Section 84 AMG as a case of strict liability (cf. the accurate and detailed reasoning of the Higher Regional Court of Koblenz, judgment of July 10, 2024 — 5 U 1375/23, para. 28-32, juris). Whether the date of marketing or the date of use of the vaccine is decisive for the retroactive projection can be left open in the present case. For both possible dates, the benefit-risk ratio is assessed positively. In detail:

51 aa) The positive risk-benefit ratio of Co-mirnaty has been established on the basis of the legal effect of the European Commission's implementing decision of October 10, 2022, on the unconditional approval of the vaccine (Exhibit B3 = Exhibit Volume Defendant), which confirmed the decision of December 21, 2020 on the conditional (extraordinary) approval (see recitals (1) ff. of the decision of October 10, 2022 = p. 1 of Annex B3, Annex Volume Defendant).

52 (1) The implementing decision of the European Commission of October 10, 2022 on the unconditional approval of the vaccine states that, at the time of approval, the vaccine was safe under pharmaceutical law due to its favorable risk-benefit ratio.

53 Under EU law, the principle of presumption of legality applies to legal acts of the Union (see BVerwG, decision of July 7, 2022 — 1 WB 2/22, para. 205 et seq., juris). This means that the actions of a European institution have legal effect as long as they have not been withdrawn or declared invalid in the context of an action for annulment, a request for a preliminary ruling, or a plea of illegality (see ECJ, judgment of February 12, 2008 — C-199/06, para. 60, juris). Thus, both European and national

national authorities and courts, within the scope of their legal review, refer to the factual effect of the legal act in question, assume its legal validity, and, in principle, do not have to re-examine its legality in its entirety (see BVerwG, loc. cit.). A court called upon to decide must therefore assume that the legal act is valid as long as and to the extent that it has not been repealed and there are no serious procedural errors or deficiencies in jurisdiction that are so serious as to call into question the legal effect as a whole (nullity).

54 The scope of the effect of the facts depends on the regulatory content of the legal act and, in addition, on the findings of fact on which it is based (cf. OLG Frankfurt, Judgment of February 19, 2025 — 23 U 13/24, para. 248, juris). These include the existence of a positive risk-benefit ratio, because without this, approval would not have been possible. The assessment of the benefit-risk ratio was an essential prerequisite for both the conditional and unconditional approval of the vaccine. The conditional (exceptional) approval, which was granted for the vaccine in question on December 21, 2020, was granted in accordance with Art. 14-a (3) Regulation (EC) 726/2004 and Art. 4 (1) sentence 1 lit. 2020, requires, pursuant to Art. 14-a (3) Regulation (EC) 726/2004 and Art. 4 (1) sentence 1 lit. a) Regulation (EC) 507/2006, that "the benefit-risk ratio of the medicinal product is positive." With the conditional approval, "special obligations" were imposed on the drug manufacturer in accordance with Art. 14-a (4) of Regulation (EC) 726/2004, which, according to paragraph 5, consist of "complete ongoing studies or initiate new studies to confirm the positive benefit-risk ratio." The existence of a positive benefit-risk ratio then had to be demonstrated again in accordance with Article 14a(8) of Regulation (EC) No. 726/2004 in order to obtain a regular marketing authorization valid for five years. In its recitals, the implementing decision refers to the fact that the defendant has fulfilled the specific obligations imposed on it under the conditional authorization pursuant to Article 14a(4) of Regulation (EC) No. 726/2004 (see recital 2 = p. 1 of Annex B3, Annex Volume Defendant).

55 The factual effect also continues to apply. Neither has the unconditional authorization been amended, suspended, revoked, or otherwise withdrawn (Article 20a, sentence 2, Regulation (EC) 726/2004), nor has the use of the vaccine been suspended (Article 20(4) Regulation (EC) 726/2004). Rather, on August 30, 2023, in its assessment report on the extension of the assessment report for market authorization, it once again confirmed the positive risk-benefit ratio of the vaccine in question (see p. 35 of Annex K49 = p. 1496 LGA).

56 (2) On the other hand, the plaintiff cannot successfully argue that, pursuant to Article 15 of Regulation (EC) No. 726/2004, the civil liability of the manufacturer under national law remains unaffected by the authorization (see BB p. 3 f. = p. 32 f. HA) and that it is incompatible with Art. 19 (4) GG if he cannot challenge the official approval decision (cf. BB p. 15 = p. 44 HA; p. 86 d. S.s. v. 11. 9. 2024 = p. 495 LGA). The factual effect is neither

the civil liability of the manufacturer or the review of the marketing authorization decision by national courts.

57 The authorization granted by the European Commission pursuant to Article 3 of Regulation (EC) No. 726/2004 (see Art. 1 d. Implementing Decision dated

10. 10. 2022 = p. 2 of Annex B3, Annex Volume Defendant) is equivalent to a national authorization pursuant to Section 21 (1) sentence 1 AMG. Thus, a plaintiff may challenge the binding effect of the approval decision in civil proceedings if he substantiates which circumstances were not taken into account in the approval decision or became known subsequently that would have precluded approval (cf. OLG Koblenz, judgment of July 3, 2025 — 5 U 271/

25, para. 31, juris; Higher Regional Court of Frankfurt, judgment of February 19, 2025 — 23 U 13/24, para. 252, juris; Higher Regional Court of Munich, reference decision of November 5, 2024 — 14 U 2313/24, BeckRS 2024, 31623, para. 241). The same applies if the approval authority authority has made an error of judgment in weighing up the benefits and risks (cf. Higher Regional Court of Koblenz, judgment of July 3, 2025 — 5 U 271/25, para. 31, juris; OLG Frankfurt, judgment of February 19, 2025 — 23 U 13/24, para. 253, juris; OLG

Munich, Reference Decision of November 5, 2024 — 14 U 2313/24e, BeckRS 2024, 31623, margin note 241). The decision of the Regional Court of Halle cited in the appeal (see BB p. 3 f.

= p. 32 f. HA) disregarded this.

58 However, the plaintiff did not raise any such significant objections. For details, please refer to the following explanations under lit. cc.

59 bb) Even if the approval decision were not to be assumed to have a binding effect with regard to the positive risk-benefit ratio, the result would still be the same. Based on its own assessment and the evaluation of European and national expert committees, the Senate concludes that, according to the facts presented by the parties at the relevant time of the conclusion of the oral proceedings, projected to the time of its marketing and the vaccinations at issue, the risk-benefit ratio of the vaccine at issue is positive.

60 (1) The European Commission's marketing authorization decisions are based on the technical recommendations of the EMA, which has obtained an opinion on the risk-benefit ratio of the vaccine in accordance with Article 14a(3), (4), and (8) of Regulation (EC) No. 726/2004. Its bodies include, pursuant to Article 56(1)(a), the Committee for Medicinal Products for Human Use (CHMP), which prepares the Agency's opinions on questions relating to the evaluation of medicinal products for human use, and, pursuant to Article 56(1)(a)(aa), the Pharmacovigilance Risk Assessment Committee (PRAC). The latter makes recommendations to the CHMP and the coordination group on all matters relating to pharmacovigilance activities in relation to medicinal products for human use and risk management systems. It is also responsible for monitoring the effectiveness of these risk management systems. Both the CHMP and the PRAC are composed of a pluralistic membership. In accordance with Articles 61 and 61a of the Regulation, each Member State is represented by a member with specific expertise. In accordance with Article 61(3) of the Regulation, the members of the CHMP may be accompanied by experts

from specific scientific or technical fields.

61 The counterpart to the EMA at federal level is the PEI (short: PEI; Section 77 (2) AMG). The PEI is the lead authority in Germany responsible for the development, approval, evaluation, and monitoring of the quality, efficacy, and safety of vaccines; it is responsible in particular for recording and evaluating vaccine-induced risks and coordinating any measures to be taken (OLG Koblenz, judgment of September 25, 2024 — 5 U 379/24, para. 76, juris; OLG Frankfurt, decision of April 29, 2025 — 23 W 25/24, para. 49, juris; OLG Munich, reference decision of November 5, 2024 — 14 U 2313/24, BeckRS 2024, 31623, margin note 358).

62 In addition, it is a research institution that is intended to pool expertise on vaccine assessment, including the assessment of individually occurring adverse vaccine reactions (cf. OLG Koblenz, a. loc. cit.; OLG Frankfurt, loc. cit.; OLG Munich, aa loc. cit., margin no. 359).

63 The institutions mentioned are therefore medical-pharmaceutical and thus scientific expert bodies. Their recommendations and decisions are not based on political interests, even though the establishment of the European Medicines Agency and its bodies was based on a political decision. There was no other way to establish an institution such as the EMA that would be recognized and capable of acting in all member states (OLG Koblenz, loc. cit., para. 77; OLG Munich, loc. cit., para. 360).

64 The assessments of drug safety by the CHMP, PRAC, and PEI are equivalent to expert reviews. The legal requirements for their composition already qualify them as expert bodies; they combine conflicting scientific experiences, findings, views, and hypotheses and incorporate these into a comprehensive benefit-risk assessment (see OLG Koblenz, loc. cit., para. 78; Munich Higher Regional Court, loc. cit., para. 361). The information provided by the PEI is official information and is therefore generally suitable to replace expert opinions (see Frankfurt Higher Regional Court, loc. cit., para. 50, juris, with further references). The assessment of the experts from CHMP, PRAC, and PEI, who are not themselves in a hierarchical relationship with each other, represents the greatest possible expertise on the question to be decided here, namely the risk-benefit ratio of the vaccine at issue (see OLG Koblenz, loc. cit., para. 79, juris). They are therefore able to provide the Senate with the necessary expertise to assess the question of the benefit-risk ratio of the defendant's vaccine (see also BVerwG, loc. cit., para. 140; OLG Oldenburg, judgment of December 18, 2024 — 5 U 53/24, para. 85, juris; Higher Regional Court of Celle, decision of October 11, 2024 — 5 U 323/23, margin note 21). The adopts the following findings of the above-mentioned expert committees as the basis for its decision.

65 Based on all known and reported side effects and vaccination complications to date, both the CHMP and the PEI have concluded

that at the time of granting the standard approval for the vaccine in question on October 10, 2022, the benefit-risk ratio was positive, as was previously the case for the conditional approval decision.

66 The CHMP recommendation of October 15, 2022, underlying the EU Commission's implementing decision of October 10, 2022 (submitted as Annex B4, Annex Volume Defendant), shows that the CHMP recommendation of September 15, 2022 (submitted as Annex B4, Annex Volume Defendant) states that the CHMP recommends that the marketing authorization for the medicinal 2022, it appears that the defendant has been subject to various "specific obligations" (abbreviated to "SO") since the conditional marketing authorization of the vaccine in dispute on December 21, 2020 (cf. Art. 14a(4) Regulation (EC) 726/2004). The Committee notes that new data had been submitted for all specific obligations in a timely manner and that it was acceptable for the fulfillment of the obligations. The general conclusion on the specific obligations (section 2.3 of the report = p. 14 of Annex B4) is as follows:

"[...] The clinical safety profile and efficacy of this product are characterized as comprehensive and support a positive benefit-risk ratio. [...]"

67 In section 6.2 (= p. 33 f. of Appendix B4), the CHMP states with regard to the benefit-risk ratio that the new data had no impact on the benefit-risk ratio of the vaccine in the approved indication, but rather confirmed the positive benefit-risk ratio in the approved indication. The report further states:

"Uncertainties and limitations regarding adverse effects:

The uncertainties and limitations of adverse effects have already been discussed in other procedures. The main uncertainties concern the long-term effects and the effects on certain risk groups.

Benefit-risk assessment and discussion:

The benefits of Comirnaty in terms of protection against COVID-19 clearly outweigh the identified risks, and no new information has come to light during this extension period that would change the balance. All quality-related SVs are considered to be fulfilled. [...] Significance of favorable and unfavorable effects:

Not applicable.

Benefit-risk ratio:

Based on the cumulative evidence of favorable and unfavorable effects, the benefit-risk ratio of Comirnaty remains positive."

68 Section 7 (p. 35 of Appendix B4) states:

Based on the review of the available information on the status of compliance with the specific obligations, the benefit-risk balance for Comirnaty in the approved indication (see summary of product characteristics) remains favorable. As all specific obligations have either been fulfilled or reclassified as Category 3 studies in the RMP, there are no longer any reasons to impose conditions on the marketing authorization, and the CHMP therefore recommends granting a standard marketing authorization for Comirnaty, which is not subject to any specific obligations."

for the marketing authorization of Comirnaty, which is not subject to any specific obligations."

69 The PEI has in its opinion from 10. 10. 2022 (Exhibit B2, Defendant's Exhibit Volume), the Committee for Medicinal Products for Human Use at the EMA recommended converting the conditional marketing authorization for the Defendant's vaccine and another mRNA vaccine from a different manufacturer into an unconditional marketing authorization (see p. 1 of Exhibit B2, first paragraph). In view of the totality of the available data, the specific obligations were no longer considered decisive for the risk-benefit ratio of the vaccine products, and the conditional authorization could be converted into a standard authorization (see p. 1 of Annex B2, last paragraph). In line with this, the PEI's statement on the "suspected cases of side effects or vaccination complications following vaccination with the Omicron-adapted bivalent COVID-19 vaccines Comirnaty Original/Omicron BA. 1, Comirnaty Original/Omicron BA. 4—5 (...)" reported in Germany up to October 31, 2022, the conclusion can be drawn that the suspected cases of side effects or vaccination complications reported from Germany up to October 31, 2022 did not give rise to any new risk signals from the PEI's point of view either (see Annex K23 — last page —, Annex Volume Plaintiff).

70 The unconditional approval granted by the European Commission on October 10, 2022, in accordance with the CHMP recommendation, has not been amended, suspended, or revoked to date.

71 The assessment of the aforementioned expert committees is further supported by the assessment of STIKO, another interdisciplinary expert commission. It recommends vaccination with the defendant's (adapted) vaccine (see p. 1 of Annex B14 = p. 125 LGA). Its vaccination recommendations — which require that the benefits of the recommended vaccination outweigh the risks — are recognized as the medical standard (see BGH, decision of May 3, 2017 — XII ZB 157/16, para. 27, juris).

72 (2) Insofar as the plaintiff has objected that the European Commission pursued "predominantly its own interests" with its implementing decision of October 10, 2022, and that the EMA was merely "supposedly independent" (cf. p. 55 d. p. v. September 11, 2024 = p. 464 LGA; p. 19 f. d. Replica = p. 195 f. d. A.), he is just as unsuccessful as with his other objections of "political pressure" on the EMA and its bodies and the "right to issue instructions" at national level (cf. p. 56 f. d. S.s. v. September 11, 2024 = p. 465 f. LGA; p. 20 f. of the reply = p. 196 f. of the file).

73 The Higher Regional Court of Koblenz, with which the Senate concurs after its own critical examination, correctly stated in its judgment of September 25, 2024 — 5 U 379/24 — correctly stated in this regard:

"Contrary to the plaintiff's opinion, there can ultimately be no assumption of 'results-oriented bias' due to political pressure on the EMA and its affiliated committees (as well as on the

national authorities) with regard to their recommendations to the European Commission. It is not clear what political pressure the EMA is supposed to be under when it makes a recommendation regarding the application for approval of a medicinal product; this recommendation may be in favor of or against the Europe-wide approval of the medicinal product. Furthermore, the claim made in this context that this gives rise to a reasonable suspicion that there was no critical examination of the available studies that showed considerable doubts about the effectiveness of the defendant's vaccine or contained considerable risks associated with the active ingredients contained in the products remains without any basis. This applies both to the CHMP of the EMA and to national authorities.

Furthermore, the argument neglects the fact that the EMA has a pluralistic composition and is characterized by the very diverse backgrounds of its experts. There is therefore no evidence of stringent "leadership" of the EMA by the EU Commission, nor of the EMA being bound by its political guidelines. The plaintiff's assertions remain unsubstantiated. Nor is the EMA subordinate to the European Commission, as the plaintiff claims. Rather, the European Commission is the sole executive body of the EU, while the EMA belongs to the executive branch of the European Union, but not at any hierarchical level. Its main task is to 'provide the Union institutions and Member States with scientific opinions of the highest possible standard so that they can exercise the powers conferred on them by Union legislation in the field of medicinal products with regard to the authorization and supervision of medicinal products' (see recital No. 19 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council of March 31, 2004, laying down Union procedures for the authorization and supervision of medicinal products for human use and establishing a European Medicines Agency). The plaintiff's assertion that the EMA is subject to 'influence by the Commission in its function' is therefore completely unfounded.

In addition, in the present case, the EU Commission is likely to have had a specific interest in a particularly safe vaccine, since—as the plaintiff himself has argued—the Commission and the member states have assumed full liability for the vaccine vis-à-vis the manufacturer. In such a case, it would be absurd if the EMA, in what the plaintiff claims to be "preemptive obedience," had issued a recommendation for the approval of the vaccine in the EU with millions of applications expected, even though it was aware of its allegedly unacceptable risks.

When the agreement (APA) submitted as Exhibit K49—again only in English, although the German version is known to the court—states that the Commission recognizes that the efforts of the contracting party to develop and distribute the vaccine are ambitious "in light of significant risks and uncertainties" (under Section I. 6.7.), this does not constitute a concession to the

associated with significant risks within the meaning of Section 84 or Section 5 of the German Medicines Act (AMG). Rather, this phrase—as becomes clear a few lines later—is due to the fact that the vaccine may not be approved due to uncertainties "in the areas of research, development, and manufacturing due to technical, clinical, regulatory, or manufacturing, shipping, storage, or other problems or errors." In addition, at the time the contract was drawn up in June 2020, a comprehensive review of the vaccine had not yet taken place, so that for this reason too, the phrase quoted by the plaintiff was not intended to imply any concession that the risks of the vaccine outweighed its benefits. Finally, it cannot be established that the contract put pressure on the Commission to 'obtain' approval of the vaccine as quickly as possible, with a timetable running until August 15, 2021. On the one hand, the Commission did not have to 'obtain' approval for the vaccine from a third party, as the plaintiff attempts to suggest, since it is itself the EU body responsible for marketing authorization under pharmaceutical law. On the other hand, no time pressure can be identified in the termination clause, especially since the clause also provided for the possibility of termination by the Commission if it was unable to grant approval by August 15, 2021—i.e., around 14 months after the contract was drawn up. In view of the conditional approval already granted on December 21, 2020, it is not apparent that the provision for a termination option from August 15, 2021

(paras. 122–125, juris).

74 (3) The failure to take evidence by obtaining an expert opinion (see BB p. 14, fifth paragraph = p. 43 HA), which the plaintiff claims to be a procedural error, is not objectionable. Against the background explained above of the maximum level of expertise available in the expert committees, which replaced the expert opinion obtained, there are no indications that a (renewed) assessment by a single virologist, pharmacologist, or other scientist as an expert would be likely to lead to different findings in the present case. This is confirmed by the expert opinion submitted by the defendant from a similar case (cf. p. 14 f. and p. 20 d. Annex B16 = p. 2146 f., 2152 LGA). It would be unrealistic to assume that a single expert could have access to more sources, a larger database, and more extensive knowledge than the European expert committees, each consisting of at least

27 persons (see also OLG Koblenz, judgment of July 23, 2025 — 5 U 271/25, para. 56, juris; OLG Munich, reference decision v. 5. 11. 2024 — 14 U 2313/24e, BeckRS 2024, 31623, margin no. 367). Nor does the plaintiff argue what superior knowledge an individual expert might have. In this regard, it must be taken into account that the expert's assessment of a positive or negative risk-benefit ratio must in any case refer not to the plaintiff and his illnesses, but to the entirety of the potential patient group within the European Union (cf. OLG Koblenz, loc. cit.; OLG Munich, loc. cit., margin note 368).

75 (4) The assessment to be made by the Senate pursuant to Section 84 (1) sentence 2 no. 1 AMG is not identical to the assessment made by the EU Commission in its marketing authorization decision. However, the above-cited decisions of the expert committees, which are consistent in their positive assessment of the benefit-risk ratio, represent a significant indication in the context of the court decision, if one does not already assume a factual effect. The history of the vaccine described above, from its initial conditional approval to the granting of standard approval in the EU and approval for vaccines tailored to virus variants, which — based on constantly updated data — have not been changed, revoked or withdrawn, leads to the conclusion that the cases of side effects that became known after conditional approval did not change the positive risk-benefit assessment of the expert groups (see also OLG Koblenz, loc. cit., para. 57, juris; Munich Higher Regional Court, loc. cit., para. 372). The unanimous opinion of recognized expert committees that, at least at the time of the plaintiff's vaccinations on ... 11, 2021, and on ... 12, 2021, but also already at the time of the conditional approval of the vaccine on

The Senate concurs with the statement that on December 21, 2020, and at the later date of approval, October 10, 2022, there was a positive benefit-risk ratio.

conditional approval on October 10, 2022, the Senate concurs. Consequently, the benefit-risk ratio is positive both for the time of marketing—regardless of when between the conditional approval of the vaccine and the plaintiff's vaccinations it is to be dated—and for the time of further use. cc)

76 The plaintiff has not presented any relevant medical evidence that the aforementioned expert committees did not take into account before recommending approval or that became known after approval and would have justified a different approval decision, nor is any such evidence otherwise apparent.

In detail:

77 (1) Contrary to the plaintiff's opinion, the Regional Court dealt with the data sufficiently and with accurate considerations (cf. Regional Court, p. 10 f., under lit. (a) and (b) = p. 2950 f. LGA).

78 The data from clinical and non-clinical studies submitted by the defendant were apparently sufficient for the CHMP and the EMA to fulfill the requirements for conditional approval; just as the study data on the specific obligations following the conditional approval of the vaccine were sufficiently meaningful for the CHMP to assess the benefits of the vaccine in relation to the side effects that were apparent at that time (see also OLG Koblenz, judgment of February 12, 2025 — 5 U 738/24, para. 63 juris).

79 The Regional Court rightly points out that the CHMP involves experts from the medicines agencies of 27 EU Member States and other teams of experts from various scientific disciplines in the assessment of the benefit-risk ratio (Regional Court judgment, p. 10, last paragraph = p. 2950 LGA). The fact that the Committee for Medicinal Products for Human Use (§ 61 (1) Regulation (EC) 726/2004), consisting of 27 members — one from each EU Member State — in the

decision of September 15, 2022, on an apparent — lack of dissenting opinion (cf. Section 61(7) sentence 2 of Regulation (EC) No. 726/2004) — unanimous conclusion regarding the benefit-risk assessment, is justified in view of the combined expertise (cf. section 1(a)(bb) (2)) against significant concerns regarding the scope of the data, the significance of the studies, and the assessability or usability of the results (cf. also OLG Koblenz, loc. cit., para. 70, juris).

80 Insofar as the plaintiff continues to object that the data from the standard approval is not up to date (BB p. 4, penultimate paragraph = p. 33 HA) and that the "further approval of August 30, 2023" does not contain any new verifiable findings (cf. BB p. 4, third-to-last paragraph

= p. 33 HA), he does not provide any evidence that and why the findings of the Regional Court are incorrect. It has not provided any evidence that and why the findings of the Regional Court are inaccurate.

September 11, 2024 = p. 452 f. LGA), genotoxicity, and carcinogenicity (p. 11 of the reply, second and third paragraphs = p. 187 of the file; p. 44 of the submission dated September 11, 2024, penultimate and last paragraphs = p. 453 LGA) and the data collection periods (cf. p. 45 of the submission dated September 11, 2024 = p. 454 LGA), doubts about the methodology and reliability of the data (cf. pp. 46–52, 74 of the document dated September 11, 2024

= pp. 455–461, 483 LGA) and reports of suspected cases (cf. pp. 57–64, 67 of the decision of September 11, 2024 = pp. 466–473, 476 LGA) in its considerations and has come to the convincing conclusion that all circumstances were taken into account in the approval decision and thus also in the assessment of the benefit-risk ratio. The fact that it did not break down each individual objection in the grounds for its decision does not prove a lack of consideration (cf. § 313 (3) ZPO).

81 The Regional Court was also right not to uphold any of the objections to the assessment report of September 15, 2022 (Exhibit K38 = pp. 1142–1213 LGA). In detail:

82 (a) Insofar as the plaintiff emphasizes the lack of long-term studies as a risk reflected in the long-term consequences that have since occurred (cf. BB p. 13 et seq. = p. 42 et seq. HA), he does not succeed.

83 This circumstance was known at the time of the decision and was classified as acceptable.

84 The CHMP was aware of the lack of long-term studies. For example, the assessment report dated September 15, 2022 refers to "major uncertainties" with regard to "long-term effects" (see p. 34 — second paragraph — Annex B4, Annex Volume Defendant).

85 Nevertheless, the CHMP recommended granting a standard marketing authorization for Co-mirnaty (see p. 35 of Annex B4, under "7.").

86 The fact that no long-term studies could be conducted before the standard approval was granted is also evident from the timing of the conditional approval of the vaccine in question, only a few months after the outbreak of the pandemic in spring 2020, and is inherent in the conditional approval of a medicinal product. According to Art. 14-a (1) Regulation 726/2004, "an authorization may be granted before

comprehensive clinical data are available, provided that the benefits of the immediate availability of the medicinal product on the market outweigh the risk resulting from the fact that additional data are still required" and "in crisis situations, such medicinal products may be authorized even if complete preclinical or pharmaceutical data have not yet been submitted."

87 There is no concrete evidence or indication that the European and national institutions failed to take proven long-term effects into account in their subsequent recommendations and decisions. Suspected cases are not sufficient for this purpose (see the comments under point 1(a)(cc)(1)(f)).

88 (b) The plaintiff further argues that neither genotoxicity nor carcinogenicity studies were conducted prior to approval (p. 11 of the reply, second and third paragraphs = p. 187

of the file; p. 44 of the letter dated September 11, 2024, penultimate and last

Paragraph = p. 453 LGA), also does not lead to a negative benefit-risk ratio.

89 The lack of such studies was known prior to the vaccine's approval. This is not only evident from the reverse conclusion drawn from the data assessed by the CHMP as qualitatively and quantitatively sufficient prior to the approval recommendation of September 15, 2022 — the CHMP agreed with the MAH's view that "at this point in time, comprehensive data [...] are available that provide exhaustive information on the safety, reactogenicity, immunogenicity, and efficacy of Comirnaty" and recommended converting the conditional marketing authorization into a standard authorization (see p. 34 f. of Annex B4, Annex Volume Defendant) — but also from the first assessment report "EMA707383/2020" in the corrected version of February 19, 2021 (Annex K33, pp. 986—1125 LGA). On page 50 (= p. 1035 LGA), the absence of genotoxicity studies is explicitly described as "acceptable." The components of the vaccine formulation are lipids and RNA, which are not expected to have genotoxic potential. According to the report, this also applies to the lack of carcinogenicity studies (p. 56 of Exhibit K33 = p. 1041 LGA:

"nor carcinogenicity studies"). Nevertheless, both led to not to a negative benefit-risk assessment, but nevertheless to a recommendation for conditional approval (cf. p. 139 of Annex K33 = p. 1124 LGA: "recommends the granting of the conditional marketing authorization").

90 (c) Insofar as the plaintiff complained that it was "particularly striking" that the entire report dealt only with the risks and not with the benefits of the vaccine (p. 52 of the report dated September 11, 2024, penultimate paragraph = p. 461 LGA), this does not imply a lack of benefits.

91 The lack of comments on the benefits can be explained by the fact that the report was for the extension of the vaccine's marketing authorization. The CHMP had already assessed the benefit-risk ratio as positive before the vaccine was first (conditionally) approved on December 21, 2020. If the assessment and evaluation of the benefits does not change, then

no further explanations are required. Only newly emerging risks, the development of previously identified risks, and the relationship between the unchanged assessed benefits and the new or newly assessed risks need to be considered (see OLG Koblenz, judgment of February 12, 2025—5 U 738/24, para. 73).

In the present case, this led to the continued positive assessment of the benefit-risk ratio, as stated several times in the report:

"During the period covered by this annual extension, new data has become available. However, this data has no impact on the benefit-risk ratio of COMIRNATY in the approved indication.

The data collected as part of the specific obligations for Comirnaty during the period of this annual renewal confirm the positive benefit-risk ratio in the approved indication" (p. 32 of Annex K38 = p. 1173 LGA);

Benefit-risk assessment and discussion:

The benefits of Comirnaty in terms of protection against COVID-19 clearly outweigh the identified risks, and no new information has come to light during this renewal period that would have changed the ratio" (p. 34 of Annex K38 = p. 1175 LGA).

92 There is no evidence of an incorrect assessment based on the fact that "almost everyone will have contracted COVID-19 by 2022, whether vaccinated or unvaccinated" (p. 53 of the document dated September 11, 2024, last paragraph = p. 462 LGA).. An infection of vaccinated persons, some of whom suffered severe cases (cf. p. 52 of the document dated September 11, 2025

= p. 461 LGA), does not prove that the vaccine is ineffective. The defendant has never claimed that the vaccine in question offers (absolute) protection against infection, including against virus variants, and this is not the indication for the vaccine. In the subsequent period, adapted vaccines were developed to protect against infection with a virus variant (cf. the recommendation by the EMA for the approval of the vaccine against the Omicron XBB.1.5 variant

= Annex B1, Annex Volume Defendant). For the reasons stated above, it is also irrelevant that the CHMP assessment report does not comment on the efficacy of the vaccine in question against a variant of the virus, as the plaintiff has complained (see p. 54 of the decision of September 11, 2024 = p. 463 LGA).

93 Irrespective of this, the EU Commission was aware of the vaccine's lack of absolute efficacy in preventing infection — and, accordingly, in preventing severe disease — even before its conditional approval and accepted this. The CHMP assessment report, as amended on February 19, 2021, states as its "Conclusions on clinical efficacy" (section 2.5.4)

= p. 97 f. of Appendix K33 = p. 1082 f. LGA) that the vaccine's excellent efficacy (prevention of symptomatic COVID-19) of 95% in subjects with no evidence of previous SARS-CoV-2 infection for all relevant subgroups. Under the heading "Uncertainties and limitations about favorable effects" ("Uncertainties and limitations about favorable

effects," section 3.3, p. 132 of Appendix K33 = p. 1117 LGA), it is discussed in detail that no reliable statement can be made about the vaccine's effectiveness against severe cases of COVID-19. This also applies to the question of the vaccine's effectiveness in protecting against asymptomatic infection, its effectiveness in preventing the transmission of SARS-CoV-2 in people who become infected after vaccination, its effectiveness in protecting immunocompromised and pregnant individuals, and the duration of protection provided by the vaccine. All these uncertainties were therefore known before the conditional approval of the vaccine was granted. Nevertheless, they did not lead to the assumption of a negative benefit-risk ratio (see section 3.8 = p. 138 of Annex K33 = p. 1123 LGA: "The overall benefit/risk balance of Co-mirnaty is positive."). Rather, the CHMP recommended the conditional approval of the vaccine (see p. 139 of Annex K33, under section 4 = p. 1124 LGA: "The CHMP therefore recommends the granting of the conditional marketing authorization"). The fact that the plaintiff has generally disputed the accuracy of the underlying data (see p. 53 of the statement of 11 September 2024, penultimate paragraph = p. 462 LGA) does not provide any grounds for doubting the assessment presented. Rather, the subsequent assessment report dated September 15, 2022, also shows that the CHMP continued to take into account and accept the lack of absolute efficacy in its recommendations. The "remaining uncertainties" mainly relate to use in immunocompromised individuals, long-term efficacy and safety, and, for example, efficacy against transmission (see p. 33 of Annex K38 = p. 1174 LGA). The benefits of Comirnaty in terms of protection against COVID-19 "clearly" outweigh the identified risks (see p. 34 of Exhibit K38 = p. 1175 LGA).

94 Furthermore, there is no basis for the view that the risk-benefit ratio of the vaccine should be assessed differently depending on the batch. The plaintiff's assertion that "in Denmark, too, the risk of vaccination with BNT162b2 is ... [A] significantly dependent on the batch received at random" (see p. 42 of the judgment of September 11, 2024, second paragraph = p. 451 LGA) is not supported by the study referred to by the plaintiff. It does not provide any valid arguments against the positive risk-benefit ratio of the vaccine. The study shows that the results, which are only preliminary anyway, "should be interpreted in light of several limitations."

(e.g., that the reports also include reports based purely on suspicion) and, due to these limitations, any signals arising from reporting systems such as that of the Danish Medicines Agency cannot be used to determine any causality of the vaccine for the adverse reactions (see p. 3 of Annex K37 = p. 1141 LGA).

95 (d) Insofar as the plaintiff challenged the assessment report of September 15, 2022, arguing that it contains data from the period from April 30, 2021, to

April 29, 2022, so that, based on the date of the report, the data between April 30, 2022, and

15. 9. 2022 completely absent, he fails to recognize—as the Regional Court correctly noted—that the report merely assesses the

period for the extension of the market authorization, which, according to page 4 of the report, covers the period from 30. 4. 2021 to

April 29, 2022. Any data beyond this is therefore not relevant for this extension period (see also OLG Koblenz, judgment of February 12, 2025 — 5 U 738/24, para. 64, juris).

96 Furthermore, the sentence on page 13 (p. 1154 LGA) of the report justifies this: "In view of the inevitable vaccination of a large proportion of patients in the control arm of study C4591001, it is agreed that further follow-up is no longer meaningful for the safety and efficacy profile of Comirnaty," contrary to the plaintiff's opinion (cf. p. 45 of the document dated September 11, 2024 = p. 454 LGA).

not the conclusion that the CHMP assumed

that further findings could not lead to a different assessment. The wording does not mean that that from the period between the

30 April 2022 and 15 September 2022, no new findings can be obtained or the new findings obtained during this period are not to be included in the assessment of the benefit-risk ratio. Rather, it follows from the context of the quoted sentence that studies C4591001 and C4591007 are to be terminated prematurely and removed from the list of specific obligations. The CHMP considered this to be "acceptable" because the remaining outstanding data from those studies are not expected to provide significantly different findings (see page 13 of Annex K38 = p. 1154 LGA). This does not mean, however, that no new data should be collected in general or that they should not be taken into account in the ongoing assessment of the benefit-risk balance.

97 (e) The further objection, raised in numerous forms, that the data underlying the approval is deficient, for example in that the data is insufficient, not "clean" or accurately collected, not meaningful, not up-to-date but outdated, unusable, methodologically flawed, collected in a non-transparent manner and not verifiable on the basis of the assessment report, did not originate from independent studies or from unfinished studies, is also unfounded.

98 The plaintiff has obviously made the allegations without any basis. Instead of relying on substantiated arguments, he has merely offered "court expert opinions" as blanket evidence for most of his objections (see pp. 45, 46, 47, 49, 51 d.

See 11 September 2024 = pp. 454–456, 458, 460 LGA).

99 Since the studies are not reproduced in full in the assessment report, but rather only a summary of the numerous individual studies can be included, the individual quotations in the report do not provide any information about the overall significance of the studies or the data on which they are based. Obviously, the findings obtained from the available study data up to the date of the CHMP assessment report were sufficient for the Committee's assessment. The CHMP concluded that all specific obligations ("SO," both quality SO and clinical

SI, see p. 13 of Annex K38 = p. 1154 LGA) had been fulfilled and that the requirements of Article 14a(5) of Regulation (EC) No. 726/2004 had therefore been met. Accordingly, it recommended "the granting of a standard marketing authorization for Comirnaty, which is not subject to any specific obligations" (p. 35 of Annex K38 = p. 1176 LGA).

100 The plaintiff himself refuted the doubts raised by statements made by former employees (see p. 47 et seq. of the September 11, 2024, ruling = p. 456 et seq. LGA) by pointing out that follow-up checks had been carried out and that, therefore, irregularities had not been systematically ignored, as his submission had suggested. The mere fact that none of the sites was inspected by one of several whistleblowers does not change this. In particular, the fact that the manufacturer sponsored studies does not in itself prove that it influenced their conduct; Rather, Art. 14-a (5) of Regulation (EC) 726/2004 considers such an approach "part of the specific obligations under paragraph 4" (see also: OLG Koblenz, judgment of February 12, 2025 — 5 U 738/24, para. 71 et seq., *ju-ris*).

101 The aforementioned reasons also apply to the objection that the reporting period for the "safety-related changes to the RSI" is too short (see p. 50 of the document dated September 11, 2024 = p. 459 LGA). The plaintiff's claim made by the plaintiff remains without substance. It fails to take into account that, pursuant to Article 14 of Regulation (EC) No. 726/2004, the defendant must fulfill numerous obligations regarding pharmacovigilance even after granting unconditional marketing authorization, and that Article 14(2) of Regulation (EC) No. 726/2004 always requires a reassessment of the benefit-risk ratio (cf. OLG Koblenz, loc. cit., para. 67, *juris*).

102 (f) Nor is the plaintiff's argument convincing that the number of reported suspected cases of side effects, including deaths, and the existing "dark figure" refute the positive benefit-risk ratio of the vaccine at issue (see pp. 57-64, 67 d. S.s. v. 11. 9. 2024 = pp. 466-473, 476 LGA).

103 According to the plaintiff's own statement, all of the sources cited by him have in common that they only report suspected cases (cf. p. 63 of the document dated September 11, 2024 = p. 472 LGA: "Of course, the cases reported and retrieved from databases are only suspected cases." However, suspected cases do not prove a causal link to the vaccine. They do not make any definitive statements about the causality of the vaccination for the side effects. The EMA has clarified at the European level that the causality of the vaccination for the reporting of a side effect is not established in every case (p. 4 of the safety update of August 11, 2021, Appendix C7 = p. 199 HA) and at the national level by the PEI (p. 16 of the safety report dated December 23, 2021 = Appendix K27; p. 20 of the Safety report dated May 4, 2022 = Exhibit K25; p. 36 of the safety report dated August 19, 2021 = Exhibit K24; all in the exhibit volume of the plaintiff).

104 Furthermore, particular caution is required when dealing with reports of suspicion from private individuals, because it is not possible to verify whether they have provided the data correctly and whether the subjective perception of illness can be objectified

(see OLG Koblenz, loc. cit., para. 97, *juris*).

105 The opinions of individual scientists and doctors cited by the plaintiff are inherently individual opinions on individual aspects of the overall assessment, which, against the background of the contrary assessment of the European Medicines Agency and the European Commission based on numerous and extensive studies, are not sufficient to establish that the vaccine is "dangerous" within the meaning of Section 84 (1) sentence 2 no. 2 of the German Medicines Act (*Arzneimittelgesetz*). Contrary assessment of the European Medicines Agency and the European Commission. Individual scientists and doctors cannot question the entire spectrum of "medical science findings." Furthermore, they do not take the overall view of the positive therapeutic effects of the drug in relation to the risk (cf. Section 4 (28) in conjunction with (27) AMG) required for the benefit-risk ratio when they

— as is regularly the case — only consider individual aspects (see also: OLG Koblenz, loc. cit., para. 100).

106 Nor does a possible number of unreported cases justify a different assessment. Only the side effects that have been reported to the regulatory authorities and confirmed can be taken into account in assessing the risks of a vaccine in relation to its benefits. When authorities decide on the approval of a vaccine, any speculation about merely potential side effects, their severity, and their number is prohibited (Higher Regional Court of Koblenz, loc. cit., para. 99).

107 (g) The other objections to the conduct and duration of the approval study and the selection of participants (see p. 81 et seq. of the decision of September 11, 2024 = p. 490 et seq. LGA) do not justify an insufficient data basis or associated doubts about the assessment of the benefit-risk ratio. The Higher Regional Court of Frankfurt, with which the Senate concurs after its own critical examination, stated in its decision of April 29, 2025

— 23 W 25/24 — stated:

"In addition to the above, it should be noted that the approval was based on a structured process involving clinical trials on humans, which was based on data that the approval authority assessed as sufficient in terms of quality and quantity.

The fact that the blinding of the approval study was lifted does not justify its "termination" (insofar as this is associated with failure). The complainant has not demonstrated that the lifting of the blinding was inadmissible or that it was carried out secretly. There is no evidence that the approval study was unblinded prematurely because there were more deaths in the vaccination group than in the placebo group, nor is there any evidence to support the apparent assumption that the placebo group was obviously only dissolved because

had produced 'poor data'. The complainant has not provided any further details on this sweeping and disputed statement, meaning that her submission is insufficient.

Furthermore, there is no evidence to suggest that the study was terminated in the sense of a failure. The mere reference to the term 'early termination' (p. 101 AEI) is not sufficient for this. Insofar as this is consistent with

The term "premature termination of studies" is merely one possible translation that may suggest failure, but does not necessarily imply this, nor does it suggest it in the present case. In light of the quote cited by the complainant, only a 'premature termination' can be established, which was assessed by the Committee for Medicinal Products for Human Use as justified and acceptable. This is also supported by the fact that the respondent fulfilled the specific conditions of the conditional approval of December 21, 2020, as can be seen from recital 2 of the decision of October 10, 2022 [...].

It should be noted that the respondent's obligations did not end there. Rather, pursuant to Article 14(2) of Regulation (EC) No. 726/2004, the respondent had to fulfill essential obligations regarding pharmacovigilance even after the unconditional marketing authorization had been granted (see also OLG Koblenz judgment

of September 25, 2024 — 5 U 379/24 = BeckRS 2024, 25753

Para. 68). This is accompanied by the defendant's comprehensible argument that it would have been ethically unacceptable to knowingly expose a large placebo group to an increased risk of severe COVID-19 disease over a prolonged period during a pandemic (paras. 63-66, juris).

108 (2) Contrary to the plaintiff's view, the vaccine's uselessness does not result from the lack of protection against transmission of the virus (see p. 58

of the decision of September 11, 2024 = p. 467 LGA; p. 5 f. of the decision of

26. 9. 2024 = p. 2502 f. LGA) nor from the possible lack of or only minor therapeutic benefit (p. 11 of the complaint, second paragraph = p. 13 of the file), the need for refresher treatment (cf. p. 10 f. of the reply = p. 186 f. of the file; p. 44 of the statement of 11. 9. 2024 = p. 453

LGA) or the mere preventive effect (cf. BB

p. 5, first paragraph = p. 34 HA).

109 The failure to prevent transmission does not negate the characteristic of a protective vaccination. From

Section 2 No. 9 IfSG states that protective vaccination is about protection against a disease and not about protection against the transmission of a disease. Accordingly, the fact that protection against infection wanes over time and the risk of reinfection (especially after mutations of the virus) increases does not indicate a lack of benefit from the vaccine already administered (see OLG Frankfurt, loc. cit., para. 78, juris). Irrespective of this, the non-absolute protection and the (inherent) lack of knowledge about every aspect of the vaccine's efficacy were known to the expert committees and taken into account in the approval decision (see section 1(a)(cc)(1)).

110 The plaintiff has still not sufficiently demonstrated the alleged lack of benefit (see BB p. 4, last paragraph = p. 33 HA). The reference to the lack of mention of protection against serious illnesses in the assessment report is misguided. The plaintiff himself pointed out that the report in any case represents an overall effectiveness of 95% or 100% and a relative effectiveness of 95.3% for another purpose—the prevention of COVID-19 (see BB p. 5, first paragraph = p. 34 HA).

an overall efficacy of 95% or 100% and a relative efficacy of 95.3% (see BB p. 5, first paragraph = p. 34 HA).

111 (3) Insofar as the plaintiff continues to complain of a divergence between the approved and the administered vaccine due to different manufacturing processes (cf. BB p. 5-7 = p. 34-36 HA), he is unsuccessful.

112 The existence of a second manufacturing process does not in itself constitute a divergence between the vaccines, because the (ongoing) approval does not refer to a specific process, but to the vaccine itself (see OLG Frankfurt, judgment of February 19, 2025—23 U 13/24, para. 268, juris). The institutions involved in the approval were also aware of the two manufacturing processes. In its judgment of September 25, 2024 (5 U 379/24 = BeckRS 2024, 25753, para. 78 et seq.), the Higher Regional Court of Koblenz referred to the EMA's assessment report of February 19, 2020 and the subsequent assessment report of the CHMP in the corrected version of February 19, 2021 (submitted there as Annex K27 and here as Annex K33 = pp. 986-1125 LGA), the Higher Regional Court of Koblenz stated the following:

"Even if the EMA [...] in the 'Assessment Report of February 19, 2020' had classified the changeover of the manufacturing process from 'process 1' to 'process 2' as 'questionable' [...], this statement would in any case have been superseded by the later assessment report of the EMA's Committee for Medicinal Products for Human Use, CHMP, EMA707383/2020' in of the corrected version dated

February 19, 2021 (Appendix K27).

This assessment report does not indicate that the two different manufacturing processes are considered problematic. Rather, it describes that the two different manufacturing processes, as described by the plaintiff, are known (see p. 27 of the assessment report, "Development of Manufacturing Processes," Exhibit K27), and that the defendant's explanation of the differences between batches from the two processes is considered 'reasonable' (see p. 29). The EMA further states:

A safety risk assessment was conducted for potential process-related impurities in the active ingredient process with regard to patient safety.

The sources of contamination are adequately addressed. The safety risk assessment strategy involves comparing the theoretically worst-case concentration of contaminants—assuming they are not removed—with the calculated thresholds for safety concerns. The worst-case values for residual raw materials and reagents from the manufacturing process of the ... active ingredient were calculated to be well below the specified safety limits. This is considered acceptable. (pp. 30, 31 of the assessment report, "Development of Manufacturing Processes," Appendix K27).

And:

Residual DNA template is a process-related impurity originating from the linearized DNA template added to the in vitro transcription reaction. The residual DNA template is measured as defined in the

active ingredient specification. The content is controlled by a specification limit that is considered to be appropriately low. (p. 33, Annex K27)."

113 The Senate agrees with the statements made by the Higher Regional Court of Koblenz and, after its own examination, fully concurs with them. Furthermore, it should be noted that the report deals with the question of the comparability of the processes from various angles and concludes that both processes are comparable and that there are no significant differences between the active ingredient batches from process 1 and process 2 (see in particular p. 19 and p. 33 of Annex K33 = p. 1004, 1018 LGA: "were comparable," "no significant differences").

114 It would therefore have been incumbent on the plaintiff to demonstrate the alleged harmful divergence of the vaccines in concrete terms. However, he failed to do so. In detail:

115 (a) Insofar as he refers to the article "Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose" for his argument that a neomycin and an SV40 complex are not listed on the plasmid map submitted in the approval procedure — submitted in translation as Annex C4 (pp. 159–183 HA) in the appeal proceedings and as Annex K53 (pp. 1706–1730 LGA) in the first instance — does not indicate that the vaccine in question poses a safety risk. The methodology described in the paper — examination of expired vials of unknown origin — raises considerable doubts about the reliability of the results. The authors themselves recognized this and deemed further investigation necessary. On page 14 of the appendix, it states (= p. 172 HA):

One limitation of this study is the unknown origin of the vaccine vials examined. These vials were sent to us anonymously by mail without ice packs. It is known that RNA degrades faster than DNA, and it is possible that poor storage leads to faster degradation of RNA than DNA. RNA is a very stable molecule, but it can degrade very quickly in the presence of metals and heat or ubiquitous RNases in the background. All vaccines in this study exceeded the expiration date indicated on the vial, suggesting that further work is needed to understand the DNA-to-RNA ratios in fresh batches. The publication of these qPCR primers may be helpful in investigating additional batches with more controlled supply chains." (Emphasis added by the Senate).

116 Irrespective of this, the defendant has substantiated why SV40 sequence elements are not associated with any harmful effects (see BE p. 19 f. = p. 621 f. HA). This is consistent with the information from the PEI for medical professional circles dated

December 22, 2023 (see p. 2 f. of Annex BE04 = p. 661 f.

HA). In it, it confirmed that all batches distributed in Germany had been tested in accordance with the OMCL guidelines and approval requirements and had only been released after successful testing (see p. 4 of Annex B04, second paragraph = p. 663 HA). Plasmid DNA

Residual amounts were detectable in minimal quantities below strict limits and considered harmless (see p. 3 of Appendix B04, second paragraph = p. 662 HA: "considered harmless"). However, there is no evidence that these residual amounts are associated with side effects. On the other hand, the publications by McKernan et al. are said to lack sufficient information on whether the conditions mentioned were met, as well as information on the traceability of the methodology chosen (see p. 2 of Annex B04, first paragraph = p. 661 HA). In addition, McKernan et al. only examined four vials of the vaccine in question (p. 1 of Appendix C4 = p. 159 HA); the significance of the investigations for the billions of other vaccine doses produced is therefore questionable.

117 On February 29, 2024 (Appendix BE03 = pp. 654–659 HA), the CHMP made a similar statement regarding the integrity of the vaccine. It confirmed that the vaccine contained only SV40 sequence elements ("SV40 sequence," "no SV40 proteins"; see p. 5 of Appendix BE03, second paragraph = p. 658 HA). This does not change the risk profile of the vaccine; the SV40 sequence elements do not pose a risk to vaccinated individuals ("do not alter the overall safety profile of the vaccine and does not pose a risk to vaccinees," "Moreover, the SV40 sequence elements are not oncogenes and do not cause cancer," "no update to the provided risk assessment is needed," "there is no evidence to support a potential risk"; p. 5 of Appendix BE03, second to fourth paragraphs = p. 658 HA). The CHMP therefore continued to assess the benefit-risk balance as positive ("The benefit-risk balance of Comirnaty remains positive"; p. 5 of Appendix BE03, seventh paragraph = p. 658 HA).

118 (b) The plaintiff did not demonstrate whether the expressly "private investigations" of Prof. Dr. ..., who described the contamination (cf. BB p. 7 = p. 36 HA), met the necessary scientific standards at all, so that his assertion cannot call into question the official decision in terms of a positive risk-benefit ratio. The blanket accusation of "systematic contamination" (cf. BB p. 7, last paragraph = p. 36 HA) based on individual investigations, some of which raise considerable doubts about the reliability of the methodology, is not sufficient for this.

119 The report broadcast by MDR on December 12, 2023, also does not provide such evidence. This is all the more true because it is no longer possible to verify the views expressed therein. The report was deleted from the broadcaster's media library and removed from its website. In January 2024, MDR then published a new report that addresses rumors of vaccine batches being contaminated with DNA and explains in general terms that and why these rumors are false (see Annex B13 = pp. 361-371 LGA).

120 The publications to which he refers provide no evidence that the plaintiff in particular received a vaccine dose contaminated with foreign DNA, nor that the risk-benefit ratio of the vaccine should be assessed differently depending on the batch.

121 (c) Insofar as the plaintiff continues to refer to the general danger of contamination due to the mode of action of the vaccine and the danger of spike proteins (see BB p. 9 — first paragraph — and p. 10 — second paragraph — = p. 38, 39 HA), his argument remains unsubstantiated and contradictory with regard to the prospects of success of the appeal.

122 With regard to the spike proteins, which he claims could cause vascular damage, he argued that the authors of the essay referred to in support of his claim (Exhibit C5) themselves assumed that the amount of spike proteins contained in vaccines was not sufficient to "cause vascular damage on a large scale" (see BB p. 10, second paragraph = p. 39 HA). In the first instance, he also conceded in this context that the effects of the coronavirus vaccines had "only been investigated to a limited extent" (see p. 24, second paragraph = p. 433 LGA). Furthermore, impurities up to a certain limit are "acceptable" (BB p. 9, first paragraph = p. 38 HA); they cannot therefore always lead to harmful health effects, which is also the plaintiff's view. Furthermore, the plaintiff has left open the question of what specific effects the alleged contamination of the vaccine with foreign DNA is supposed to have had on the health of those vaccinated and speculates about "incalculable harmful events" (see BB p. 9, first paragraph = p. 38 HA). The general mode of action of spike proteins with possible consequences (cf. pp. 6-11, 23 f. of the decision of September 11, 2024 = pp. 415-420, 432 f. LGA)

does not prove that the limit values were exceeded or that side effects caused by impurities in the vaccine in question.

123 Irrespective of this, the claim of "systematic contamination" contradicts the findings of the EMA (cf. the comments under No. 1 lit. a) cc) (3) (a)).

124 (d) Insofar as the plaintiff objects that the batch testing at the PEI is limited to a visual inspection (BB p. 10, last paragraph = p. 39 HA), it is not apparent to what extent this would mean that the testing standards were not complied with and that he must therefore have been vaccinated with a vaccine from a contaminated batch. As explained, there is no evidence of general systematic contamination with foreign DNA. The essay "Batch testing as an essential pillar of the supply of safe and effective vaccines" — submitted as Annex C6 in the appeal proceedings — does not indicate a general error due to a mere visual inspection. According to page 5 of the essay (= p. 193 HA), a visual inspection is provided for. The author left open the question of whether and to what extent this can be used to determine purity with regard to the contamination alleged by the plaintiff.

125 (e) The plaintiff's further assertion that visible particles had been detected in all batches of the defendant's vaccine that were examined, meaning that no batch should have been administered (see p. 22 of the judgment of September 11, 2025, last paragraph = p. 431 LGA), was rejected by the court, as was his blanket assertion of

"systematic contamination" without substance

and is therefore unable to call into question the positive risk-benefit ratio.

126 (4) Insofar as the plaintiff claims in the grounds for appeal that until July 29, 2021, there was "Already" 244,807 cases "with suspected side effects" in 4,198 deaths and 330 million vaccine doses (BB p. 12 = p. 41 HA), he failed to take into account that, despite the authorities' apparent knowledge, according to the EMA's Public Safety Update of August 11, 2021 (Annex C7 = pp. 196-200 HA), they neither revoked nor suspended the approval. 2021 (Exhibit C7 = pp. 196-200 HA), they have neither revoked nor suspended the approval. Furthermore, his submission and the documents submitted in both instances—in particular the newly submitted studies and discussion content—only reveal suspected cases which, as explained (see section 1 lit. a) cc) (1) (f)), do not constitute reliable findings and are therefore not relevant.

127 (5) Regarding his repeated assertion that there is no evidence of a positive effect of vaccination on overall mortality, but rather the opposite is true (see BB p. 16 = p. 45 HA), the plaintiff has not presented any new aspects that call into question the assessment by the expert committees.

128 The use of individual studies — in the grounds for appeal, the study CorrelationCovid-vaccine-mortality of September 17, 2023 (Exhibit C8 = pp. 201-380 HA; Exhibit K31 = pp. 805-984 LGA) and the statistics from the lecture and discussion evening at ... on

November 12, 2024 (Appendices C9 and C10 = pp. 381-583 HA) — regarding infection mortality does not justify a different assessment of the risk-benefit ratio. As individual opinions, the findings merely represent excerpts from the state of research that was incorporated into the assessment by the regulatory authorities. The assessment by the regulatory authorities is based on an overall evaluation that takes into account not only the mortality aspect, but also the overall burden of the virus in the target population. The fact that this assessment—even ex post—is based on a sound factual basis is evidenced by the continued standard approval and subsequent confirmations of the positive risk-benefit ratio by the EMA and the PEI. The statements and batch releases were based on thorough reviews of the vaccine — the PEI expressly emphasizes this in its information letter dated December 5, 2023 (Appendix B14 = pp. 125-127). LGA) and December 22, 2023 (Exhibit B04 = pp. 660-663 HA).

129 Irrespective of this, the plaintiff's presentation already reveals limitations with regard to the reliability of the data. With regard to the study of

September 17, 2023, he stated that the "overall risk of death" from the injection of the vaccine could be "inferred from the excessive overall mortality and the synchronicity with the introduction of the vaccine" (cf. BB p. 17, second paragraph = p. 46 HA). Consequently, this concerns suspected cases based on the number of deaths after the introduction of the vaccine, but not proven deaths due to the vaccine. The same applies to the statements in the reply, which also deal with "suspected deaths" (cf. inter alia

p. 15 — last paragraph — and p. 16 — second paragraph — d. Reply = p. 191 f. d. A.). As already explained (cf.

see section 1 lit. a) cc) (1) (f)), suspected cases are not sufficient to disprove the positive risk-benefit ratio.

130 Insofar as the plaintiff has objected to methodological errors in the PEI's safety analysis (see pp. 11–17 of the reply = pp. 187–193 of the file), the objections are also unfounded. In particular, his complaint that the PEI applies the "observed versus expected method" in such a way that it can never actually produce a risk signal is not sufficient to call the approval decision into question. Even if the significance of this method may depend largely on the comparability of the underlying data — particularly with regard to cohort selection, time periods, and causes of death — the plaintiff has not specifically demonstrated that the PEI uses systematically different comparison variables ("observed" only suspected cases, "expected" all-cause mortality — cf. on this understanding of the comparative values: OLG Frankfurt, decision of April 29, 2025 — 23 W 25/24, para. 68, juris) or otherwise applied the method incorrectly.

131 (6) The objection that the approval cannot indicate a positive risk-benefit ratio because it does not go through the "applicable safety levels" and is not comparable to an otherwise usual multi-year process (cf. p. 4 f. and p. 7 d. S.s. v. 26. 9. 2024 = p. 2501 f., 2504 LGA) does not hold water. The argument ignores the fact that conditional approval is provided for by law. Consequently, not every early approval can be flawed per se. In addition, as already explained, there are extensive pharmacovigilance obligations to ensure that subsequent findings are taken into account retrospectively. However, in the present case, there are no indications to date that the approval of the vaccine — even ex post — was flawed.

132 (7) Even the alleged possible side effects in the form of neurological and neuromuscular complaints (see pp. 2–4 of the document dated September 26, 2024 = pp. 2499–2501 LGA) do not justify a different assessment.

133 The guidelines of the German Society of Neurology for diagnosis and therapy in neurology on "Neurological manifestations in COVID-19" (Exhibit K60 = pp. 2514–2650 LGA), to which

the plaintiff referred, do not prove a negative

Benefit-risk ratio. The statements made there largely concern the consequences of a COVID-19 infection and not the vaccine at issue. Insofar as they consider side effects to be possible, the benefit-risk assessment is positive. The mRNA and vector vaccines provide "a high level of protection against infection with SARS-CoV-2" and are considered to have "few side effects, apart from possible non-specific vaccine reactions in the first two days" (see p. 128 of Annex K60 = p. 2641 LGA). Vaccination is "the most effective means of containing and combating the COVID-19 pandemic." With regard to sinus and cerebral vein thrombosis, the guidelines distinguish between vector vaccines and mRNA vaccines — such as the one at issue —; for the latter, the risk is lower (see p. 128 of Annex K60 = p. 2641 LGA). In addition, the "er-

increased thrombosis rate" in relation to "spontaneous SHVT and SHVT in the course of COVID-19 disease," for which the risk is 10 times higher than with a vector vaccine (see p. 132 of Appendix K60 = p. 2645 LGA). Guillain-Barre syndrome has only been observed after vaccination with Vaxzevria, but not with the other vaccines — i.e., not with Comirnaty — (see p. 128 of Exhibit K60 = p. 2641 LGA). Consequently, it cannot be concluded from the guidelines that the neurological and neuromuscular side effects claimed by the plaintiff lead to a negative benefit-risk ratio.

134 (8) Insofar as the plaintiff also presented further publications and studies in the first instance as arguments against the positive risk-benefit ratio of the vaccine at issue, these are individual aspects which, against the background of the contrary assessments of the European Medicines Agency and the European Commission based on numerous and extensive studies, are not sufficient to support the plaintiff's claim. European Medicines Agency and the European Commission, respectively, are insufficient to substantiate his claim.

Justify the "dangerousness" of the vaccine within the meaning of Section 84 (1) sentence 2 no. 1 AMG. Individual scientists are not able to represent the entire spectrum of "medical science findings," and the overall view of the positive therapeutic effects of the drug in relation to the risk, which is required for the benefit-risk ratio, is not taken into account when considering individual aspects (see OLG Koblenz, judgment of July 23, 2025 — 5 U 271/25, para. 88,

juris). Individual cases—even those with serious side effects—are not sufficient to call into question the positive risk-benefit ratio due to the abstract, general nature of the assessment. However, this error of judgment underlies the plaintiff's argument that individual damages should not be ignored (see p. 2—penultimate paragraph—and

p. 22, second paragraph — d. S.s. v. 9. 12. 2024 =

Bl. 2820, 2840 LGA) and a positive risk-benefit ratio determined by the regulatory authorities do not release the defendant from examining the individual circumstances of the specific case (cf. p. 5 — third last paragraph — and p. 26 — penultimate paragraph — of the judgment of

December 9, 2024 = pp. 2823, 2844 LGA). He has raised the question of

whether a positive risk-benefit ratio—abstract general assessment—is confused with the question of causality between vaccination and alleged health impairment—case-by-case assessment if there is a basis for liability. His view that he does not have to question the general "safety assessment" of the vaccine, but rather demonstrate a plausible possibility of a causal link (p. 28 of the decision of December 9, 2024, penultimate paragraph = p. 2846 LGA), illustrates this.

135 b) The liability requirement of Section 84 (1) sentence 2 no. 2 AMG is also not met.

136 aa) According to this, the pharmaceutical company is liable for compensation if the damage is the result of labeling (§ 10 AMG), package insert (= package insert, § 11 AMG) or specialist information (§ 11a AMG)

. In the present case, there are no indications that any of the aforementioned product information

at the relevant time did not correspond to the state of scientific knowledge.

137 Not every remote possibility of potential side effects must be included in the product information. According to Section 84 (1) sentence 2 no. 2 AMG, "the findings of medical science" are the benchmark for what information the pharmaceutical company must include in the information carriers (labeling, instructions for use, and technical information). A serious suspicion is sufficient for this, as long as it is based on valid scientific data (see in detail OLG Koblenz, judgment of July 10, 2024 — 5 U 1375/23, juris para. 112 with further references).

138 Regardless of whether the date of marketing of the vaccine or the date of its use is to be taken as a basis, the plaintiff has not demonstrated that the product information did not correspond to the state of scientific knowledge at either of the dates mentioned.

139 The plaintiff makes a blanket assertion that, if data had been collected carefully, the defendant should have informed him of the possible side effects at the time of his vaccinations, because they occurred in the early phase of the drug's use (see BB p. 15, second paragraph = p. 44 HA). In the first instance, he also merely claimed in general terms that the defendant had been aware of the serious and even life-threatening side effects of the vaccination (p. 22 of the complaint, first paragraph = p. 24 of the file; p. 30 of the reply = p. 206

d. A.); she had become "increasingly aware [day by day] that vaccinated individuals were reporting an increase in autoimmune diseases, post-vaccination syndrome, neurological disorders, thrombosis, coronary heart disease, fatigue syndrome, and many other conditions temporally associated with the COVID-19 vaccination." (p. 25 — first paragraph — and p. 27 — penultimate paragraph — of the complaint = p. 27 of the file; p. 30 of the reply, second paragraph = p. 206 of the file); "the manufacturers of the coronavirus vaccines" had, at the time "of placing on the market" — which, however, is not explained — knew about the "dangerousness" of the vaccines (p. 16 of the judgment of September 11, 2024, third paragraph = p. 425 LGA); the "manufacturers" were obliged "already at the time of placing on the market, but at the latest when the possibility of further health risks became apparent" to label their medicinal products "appropriately," which they failed to do (see p. 16 — penultimate paragraph —, p. 68 — third-to-last paragraph — and p. 80 — last paragraph — of the judgment of September 11, 2024 = pp. 425, 477, 489 LGA); the question arises as to whether the "warnings for patients with specific pre-existing conditions may be incomplete." "and "sufficient reference was made in the instructions for use to the fact that there could be interactions between the vaccination and predisposing pre-existing conditions such as a tendency to thrombosis" (cf. p. 5 of the decision of December 9, 2024, second paragraph = p. 2823 LGA).

140 Consequently, it is not clear from the plaintiff's submission which specific side effect was not included at what point in time in which information medium—labeling, instructions for use, or specialist information—although this

would have been consistent with current medical knowledge. Nor do the objections to the approval decision itself indicate a specific point in time at which the alleged clinical pictures are said to have given rise to a serious suspicion based on valid scientific data, which was known to the defendant and which at the same time did not prompt it to amend the package inserts or the summary of product characteristics accordingly. Mere general reports of suspected cases, some of which are of unclear origin (see section 1(a)(cc)(1)(f)), do not constitute valid scientific data reflecting the "state of scientific knowledge." This also applies to the suspected cases in Annexes K43 and K44. The fact that the "current package insert" contains other possible side effects (see p. 66 of the document dated September 11, 2024, fourth paragraph = p. 475 LGA) does not allow the conclusion that the side effects also reflected the "state of scientific knowledge" at earlier points in time.

141 Another assessment does not justify the exemption from liability in the negotiated contracts (but according to the plaintiff: cf. p. 12 of the complaint, first paragraph = p. 14 of the file; p. 9 f. and p. 28 of the reply = p. 185 f., 204

of the file; p. 16 — third paragraph —, p. 68 — third paragraph —, p. 78 — third last paragraph — and p. 80 — third paragraph — of the statement of 11. 9. 2024 = pp. 425, 477, 487,

489 LGA; p. 8 of the p.p. dated September 26, 2024, first paragraph = p. 2505 LGA).

142 The exclusion of liability is also justified in light of the plaintiff's further arguments regarding the "Advance Purchase Agreement" (p. 78 f. of the S.s. v.

September 11, 2024 = p. 487 f. LGA; cf. also p. 30 f. of the judgment of

9. 12. 2024 = p. 2848 f. LGA) there is no indication that the product information was insufficient or that the risk-benefit ratio should be assessed as negative. The Munich Higher Regional Court, with which the Senate concurs after its own critical examination, correctly stated in its decision of November 5, 2024 — 14 U 2313/24

—that

"The fact that the development was particularly 'recognized' as 'challenging' or 'ambitious' is already understandable against the background that it seemed conceivable ex ante that the vaccine could subsequently possibly be 'discontinued due to uncertainties in the areas of research, development, and manufacturing due to technical, clinical, regulatory, or manufacturing, shipping, storage, or other problems or errors' — which is why the development was an economic risk for the manufacturer.

Furthermore, at the time the contract was drawn up in June 2020, a comprehensive review of the vaccine had not yet taken place, so that for this reason too, the wording cited by the plaintiff should not be taken to imply an admission that the risks of the vaccine outweigh its benefits (OLG Koblenz, loc. cit.).

Contrary to the grounds for appeal, the disclaimer (as an assumption of liability by the EU member states in K 24 Section 1 (12)) is also not otherwise suitable as evidence for the plaintiff's assumption that the defendant had "significant doubts about

the effectiveness and safety of its own vaccine at the time of K 24:

It is clearly based on the peculiarity that the risks were less easy to assess than would have been the case if there had been time to develop and test a vaccine 'at leisure' (keyword: '8 to 10 years').

2.2.5 The Commission may have been under 'time pressure'. However, this was mainly caused by the pandemic situation and the impending collapse of health systems, which had already occurred in parts of the Union.

The fact that the contract with the defendant contained a deadline for granting approval, after which the defendant (and not only the defendant) could have terminated the contract, cannot be seen as a significant contribution to the time pressure. Furthermore, time pressure is not an indication that a decision at that time or subsequently must have been wrong. Time pressure does not suggest a negative risk-benefit ratio.

Furthermore, it cannot be established that the contract put any pressure on the Commission to obtain approval for the vaccine as quickly as possible: on the one hand, the Commission did not need to obtain approval for the vaccine from a third party, but could decide on this itself. Secondly, the termination clause does not indicate any time pressure, especially since the clause also provided for the Commission to terminate the contract if approval could not be obtained by August 15, 2021—i.e., around 14 months after the contract was drawn up. In view of the conditional approval already granted on December 21, 2020, it is not apparent that the provision of a termination option from August 15, 2021, could have exerted time pressure on the Commission (OLG Koblenz, loc. cit.)." (BeckRS 2024, 31623, paras. 280-286).

143 bb) The defendant's liability under Section 84 (1) sentence 2 no. 2 AMG also fails because the plaintiff has not demonstrated that his alleged health damage was caused by the allegedly incorrect package insert or product information.

144 Liability under Section 84 (1) sentence 2 no. 2 AMG requires—unlike under no. 1, where it is only necessary to examine whether the damage to health is based on the unacceptable effect of the medicinal product—a double causality: The infringement of legal rights must be based on the use of the medicinal product and at the same time must have occurred as a result of insufficient information about the medicinal product — labeling, prescribing information, or package insert. A causal link between the incorrect information and the damage to health can only be affirmed if this damage would almost certainly have been avoided if the information had been correct. The plaintiff must demonstrate and prove that the damage would not have occurred if the prescribing information and package insert had been exhaustive and accurate (see Federal Court of Justice, judgment of January 24, 1989 — VI ZR 112/88, para. 35, juris).

145 In accordance with this requirement, the Regional Court rightly found that the plaintiff's claim both in the

lack of presentation of the product information for information purposes — outside the scope of the information sheet, which is not relevant in this respect (see also OLG Koblenz, judgment of July 23, 2025 — 5 U 271/25, para. 106, juris; OLG Düsseldorf, judgment of April 29, 2025 — I-4 U 172/23, para. 72, juris) — prior to vaccination (cf. LGU p. 13, last paragraph = p. 2953 LGA) and the lack of evidence of a conflict of decision due to the vaccination based on economic considerations (cf. LGU p. 14, second paragraph = p. 2954 LGA). The plaintiff did not sufficiently challenge these findings in his appeal. The mere assertion that a doctor would not have recommended vaccination if the instructions for use had been correct does not challenge a vaccination decision based on economic considerations. Nor does it follow that the plaintiff had actually read the instructions for use.

146 Insofar as the plaintiff claims that the doctors would not have recommended vaccination to him if they had been correctly informed (BB p. 14 = p. 43 HA), there is no evidence that the doctors who vaccinated him had even taken note of the package insert and instructions for use prior to his vaccination. Nor does his statement in the first instance indicate that he was actually aware of this. The submission was also limited to the assertion that the doctors "would not have administered the vaccination if they had been fully informed about all the risks of the vaccination or had known that numerous risks had not yet been researched" (p. 70 of the pages dated September 11, 2024, second paragraph = p. 479 LGA). Consequently, the plaintiff did not satisfy his burden of proof with regard to the use of a prescription drug that was not to be taken by the patient himself (cf. OLG Koblenz, judgment of September 18, 2024 — 5 U 1139/23, para. 165 et seq., juris; Higher Regional Court of Koblenz, judgment of July 23, 2025 — 5 U 271/25, para. 126, juris).

147 2. For the reasons stated above, the defendant is also not liable to the plaintiff on the basis of any other possible grounds for claims.

148 a) A claim under Section 823 (1) of the German Civil Code (BGB) for faulty product monitoring and under Section 826 BGB is precluded by the fact that the plaintiff has not substantiated that the product information at the relevant times was incorrect or incomplete. In this respect, it is also not apparent that the defendant, based on any knowledge it may have had—regardless of whether it can be held responsible for the federal government's vaccination campaign—should have "countered" the "obvious downplaying of the coronavirus vaccination in the media and politics." (p. 26 of the complaint, penultimate paragraph = p. 28 of the file; see also p. 28 of the complaint, first paragraph = p. 30 of the file; p. 32 of the reply = p. 208 of the file).

149 b) The plaintiff has no claim under Section 823(2) of the German Civil Code (BGB) in conjunction with Section 5 of the German Medicines Act (AMG). The existence of a questionable drug within the meaning of Section 5 (2) AMG, for which, as in Section 84 (1) AMG, the scientific unreasonableness of the harmful effects of the drug is decisive, cannot be established in the present case. Reference is made to the above statements under

point 1(a) is referred to in order to avoid repetition. c)

150 The Regional Court was right to reject a claim under Section 32 GenTG on the basis of Section 37 (1) GenTG. Irrespective of this, the vaccine against infectious diseases is not a gene therapy product (cf. point 2.1, sentence 4 of the Annex to Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products) and, pursuant to Section 2 (3) GenTG, the law is not applicable to the vaccine in question, as it is used on humans (see OLG Koblenz, judgment of July 23, 2025 — 5 U 271/25, para. 139, juris).

151 d) There is no claim under the Product Liability Act pursuant to Section 15 (1) ProdHaftG. According to this, the provisions of the Product Liability Act do not apply if, as in this case, the product in question is a medicinal product that was supplied to the consumer within the scope of the Medicinal Products Act (cf. on the conformity of the provision with the directive: OLG Koblenz, judgment of July 10, 2024 — 5 U 1375/23, paras. 165-168, juris).

152 3. The plaintiff has no right to information against the defendant under Section 84a AMG. With regard to this claim, the appeal is already inadmissible due to insufficient grounds.

153 The prerequisite for the right to information is that the user of the medicinal product presents facts and, if necessary, proves that a specific medicinal product caused the damage (see Federal Court of Justice, judgment of May 12, 2015—VI ZR 328/11, para. 12, juris). Such circumstantial evidence may include, for example There must be a (close) temporal connection between the use of the drug and the occurrence of the legal violation, comparable damage to other persons, the subsiding or recurrence of symptoms when the drug is discontinued or reused, the intake of a contaminated drug, and the exclusion of other factors capable of causing damage. In a second step, these facts must then make it plausible that the drug caused the damage to the user. The requirement that the (contributory) causation of the damage by the drug must be plausible places lower demands on the degree of conviction of the trial judge than full proof (BGH, loc. cit.). Thus, in case law, a reasonable assumption within the meaning of Section 84a (1) AMG is affirmed in any case if there is more evidence in favor of the drug causing the infringement of legal rights than against it (overwhelming probability), and is correspondingly denied if there is more evidence against the drug as the cause of the damage than in favor of it (OLG Frankfurt a. M., judgment of August 19, 2021 — 26 U 62/19, para. 67, juris).

154 The pharmaceutical company may object to the reasonable assumption that the damage was caused by a medicinal product on the grounds that the information is not required, Section 84a (1) sentence 1 clause 2 AMG. The information is required within the meaning of Section 84a (1) sentence 1 clause 2 AMG if there is a possibility that

that the requested information may serve to establish a claim for damages; however, if the requested information clearly does not strengthen the evidentiary position of the party requesting the information with regard to such a claim for damages, the requirement is not met (see BGH, loc. cit., para. 21, juris.). The prerequisite is that the objection of non-necessity is effective against the claims under both alternatives of Section 84 (1) AMG (see BGH, loc. cit., para. 22). The right to information is therefore not necessary, among other things, if it is obvious that the injured party has no claim under

Section 84 (1) AMG, or if the pharmaceutical company can already demonstrate and prove other circumstances likely to cause damage within the meaning of Section 84 (2) sentence 3 AMG when asserting its right to information (see BGH, judgment of March 26, 2013 — VI ZR 109/12, para. 9, 16 et seq., 43, juris).

155 According to this provision, a claim for information is ruled out because, according to the above statements (cf. point 1), there is no claim under Section 84 AMG.

156 Irrespective of this, the Regional Court also rightly rejected the claim for information on the grounds that the defendant invoked other circumstances likely to cause damage in the form of a leg vein thrombosis, a pulmonary artery embolism, and nicotine abuse (cf. Regional Court, p. 14 f. = p. 2954 f. LGA). It therefore based its rejection of the claim for information on several independent, self-supporting legal considerations. In such a case, the grounds for appeal must address each supporting consideration. Pursuant to Section 520 (3) sentence 2 no. 2 ZPO, the grounds for appeal must contain a description of the circumstances which, in the opinion of the appellant, constitute the violation of law and its relevance to the contested decision. Ultimately, the grounds for appeal, assuming they are valid, must be capable of undermining the basis of the contested decision (OLG Braunschweig, judgment of October 7, 2004 — 8 U 104/03; cf. BGH

NJW 2002, 682, 683). To this end, it must address all aspects address points that are capable of invalidating the considerations of the first judge that led to the outcome. The appeal must therefore explain for each independent ground why it does not support the decision (see Federal Court of Justice, decision of June 21, 2022 — VI ZB 87/21, Ls. uns para. 6; decision of 21 December 2021 — VI ZB 18/20, para. 8, juris; decision of 10. 2. 2015 — VI ZB 26/14; decision of 3. 3. 2015 — VI ZB 6/14; BGH NJW-RR 2015, 511, 512 with further references; Higher Regional Court of Braunschweig, judgment of October 7, 2004 — 8 U 104/03; See BGH NJW 2002, 682, 683). Otherwise, the appeal is inadmissible (BGH, decision of December 21, 2021 — VI ZB 18/20, para. 8, juris; February 12, 2020 — XII ZB 445/ 19, para. 14; February 11, 2020 — VI ZB 54/19, para. 6; 11. 10. 2017 — XI ZB 32/15, para. 10 = NJW-RR 2017, 365; dated November 25, 1999 — III ZB 50/99, BGHZ 143, 169, 171, judgment of 27 November 2003 — IX ZR 250/00, WM 2004, 442, decision of October 18, 2005 — VI ZB 81/04, NJW-RR 2006, 285 and of May 12, 2009 — XI ZB 21/08, juris para. 13, each with further references).

157 According to this standard, the grounds for appeal are sufficient with regard to the claim for information as an independent subject matter of the dispute alongside the claim for damages

. The plaintiff did not address the issue of other circumstances likely to cause damage in the grounds for appeal.

158 Insofar as he refers to the fact that the Bamberg Higher Regional Court, in its ruling of April 8, 2024, upheld the right to information in the version newly formulated in the grounds of appeal (cf. BB p. 3, second paragraph = p. 32 HA), he did not thereby dispute the other circumstances conducive to damage. The case decided there and the present case differ significantly in this respect. In that decision, unlike in the present case, it was undisputed that thrombosis with thrombocytopenia syndrome is recognized as a complication of vaccination, that the plaintiff suffers from it, and that the use of the vaccine was, under the circumstances of the individual case, likely to cause intestinal vein thrombosis (see OLG Bamberg, judgment of April 8, 2024

— 4 U 15/23e, para. 40, juris). This also applies to the decision of the Dresden Higher Regional Court of October 29, 2024, in which it ordered a vaccine manufacturer to provide information. There, too, the causality between the administration of the preparation by way of vaccination and the damage to health in the form of sinus vein thrombosis with thrombocytopenia was undisputed (see OLG Dresden, judgment of October 29, 2024 — 4 U 31/24, para. 34, juris).

159 The further considerations in the grounds for appeal regarding the right to information also do not refer to pre-existing conditions and nicotine abuse. The majority of the considerations regarding information relate to the fact that data on the contaminants must be available. Thus, the defendant must have access to the "documents, data, information, and reports" for reviewing the vaccine batch in question for contaminants (see BB p. 8, last paragraph = p. 37 HA). The plaintiff has an "increased interest" in the "records and documentation" relating to the manufacturing process "due to the justified suspicion of systematic contamination" (BB p. 10, first paragraph = p. 39 HA). Against the background of the contamination, the claim for information is "to be regarded as justified" (BB p. 11, first paragraph = p. 40 HA). These considerations do not concern the causality between vaccination and damage to health in the individual case in dispute, but rather considerations regarding the risk-benefit ratio.

160 With regard to the plaintiff's health, however, the grounds for appeal merely state that his health impairments were due to the harmful effects of the vaccine, which led to the "unreasonableness ruling" (BB p. 11, second paragraph = p. 40 HA). This is not sufficient to undermine the objection raised by the Regional Court regarding the lack of necessity due to other circumstances conducive to damage. He did not challenge the finding that such circumstances existed. Rather, it follows from the context of the sentence that the plaintiff is merely attempting to demonstrate the negative risk-benefit ratio on the basis of the health impairment he considers to be a consequence of the vaccination. In line with this, the grounds for appeal then go on to discuss cumulative causality exclusively in relation to the possible negative risk-benefit ratio. Insofar as the plaintiff concluded that "every

Risk which, as a result of an overall assessment together with other risks, leads to an unacceptable harmful effect, is itself an unacceptable harmful effect" (BB p. 11 f. = p. 40 f. HA), it does not have the objection of contributory causation in the first instance (cf. inter alia p. 8 of the reply, penultimate paragraph = p. 184 of the file; p. 6 of the letter dated 26. 9. 2024, third last paragraph = p. 2503 LGA; p. 24 of the reply of 9. 12. 2024, second paragraph = p. 2842 LGA), but continued to attack the assessment of the risk-benefit ratio.

161 Irrespective of this, the plaintiff did not challenge the findings that other circumstances conducive to damage existed with his objection of contributory causation. In the first instance, he only contested the pulmonary artery embolism—he had taken blood thinners for a year and was then considered cured (see p. 4 of the reply = p. 180 of the file). He did not challenge the other pre-existing conditions caused by a leg vein thrombosis and the general risks associated with nicotine abuse, at least not conclusively. Insofar as he also described the thrombosis in 2014 as "cured" in his written statement of December 9, 2024 (see p. 10, second paragraph = p. 2828 LGA), this contradicts his assertion that

"continues to suffer" from the consequences of previous illnesses and that, following a thromboembolic event, the risk of recurrence remains significantly elevated for years (cf. *ibid.*, first paragraph = p. 2828 LGA). In addition, he had suffered from thrombotic microangiopathy and a myocardial infarction, which had further deteriorated his state of health and increased the risk of health impairments in connection with the vaccination (see *loc. cit.*, first paragraph = p. 2828 LGA). He had responded to the

"specific pre-existing health conditions" that "may have contributed to the development of thrombotic events" (*ibid.*, p. 2 — second paragraph — and p. 4 — second paragraph = pp. 2820, 2822 LGA; see also p. 4, third paragraph = p. 2822 LGA: "History of severe thrombotic diseases"). The same applies to orthopedic impairments (see *ibid.*, p. 19, second paragraph

= Bl. 2837 LGA). The plaintiff has therefore not demonstrated that he was healthy prior to the vaccinations in question, but rather that he may have had pre-existing conditions that could have caused the alleged health impairments. However, if, according to the plaintiff's submission, the use of the drug was only as likely to be the cause as any other possible circumstance, there is no

"predominant" probability within the meaning of a reasonable assumption (cf. Section 84a AMG) that the vaccination caused the damage. This probability ratio is not changed by the mere possibility of the vaccination being a contributing cause. The plaintiff's submission does not show that the pre-existing conditions would not have been capable of causing the alleged health impairments per se, even without vaccination. The reference to the presumption of causality and alleged *prima facie* evidence is therefore insufficient. The presumption of causality under Section 84(2) sentence 1 AMG does not apply if another circumstance is capable of causing the damage according to the circumstances of the individual case.

(Section 84 (2) sentence 3 AMG). Due to the possibility of pre-existing conditions as the cause of the complaint, there is insufficient prima facie evidence to show that the alleged health impairments are based on the vaccination according to typical life experience (see also: OLG Koblenz, judgment of July 10, 2024 — 5 U 1375/23, para. 156, juris; OLG Koblenz, judgment of September 25, 2024 — 5 U 379/24, para. 179, juris). The plaintiff himself also recognized that the temporal connection alone is not sufficient to prove causality — in the sense of vaccination as the decisive trigger (p. 18 of the plaintiff's statement of claim dated December 9, 2024 = p. 2836 LGA) (see loc. cit., p. 17, second paragraph = p. 2835 LGA).

1624 . A referral to the ECJ on the legal question of the risk-benefit ratio is not required.

163 The legal question formulated by the plaintiff does not ultimately concern, within the meaning of Article 267(1) TFEU, "the interpretation of the Treaties" or "the validity and interpretation of acts of the institutions, bodies, offices, or agencies of the Union," but rather, in his opinion, "standard approval [...] [cannot] be a decisive criterion for the existence of a positive risk-benefit ratio" (see BB p. 15, penultimate paragraph = p. 44 HA). Irrespective of this, there is no obligation to refer the matter to the Court of Justice under Article 267(3) TFEU, as the Senate does not have the final say due to the possibility of appealing against the refusal of authorization to the Federal Court of Justice.

164 This does not result in any curtailment of legal protection for the plaintiff. As already explained (see point 1(a)(aa)(2)), despite the binding effect of the admission decision, the national courts may review it — if there are sufficient grounds for doing so in individual cases.

165 III. The rejection pursuant to Section 522 (2) sentence 1 ZPO is not precluded by the aspect of uniformity of case law within the meaning of Section 522 (2) sentence 1 no. 3 ZPO.

166 With regard to the right to information, the contrary rulings of the Higher Regional Courts of Bamberg and Dresden are not relevant to the decision. The appeal is already inadmissible in the present case. Irrespective of this, these decisions are based on special circumstances of the individual case, which are not relevant here. In the cases decided there, unlike in the present case, the causality between the administration of the preparation by way of vaccination and the damage to health was undisputed (see Higher Regional Court of Bamberg, judgment of April 8, 2024 — 4 U 15/23, para. 40, juris; OLG Dresden, judgment of October 29, 2024 — 4 U 31/24, para. 34, juris).

167 Other higher regional courts have also rejected claims for damages on the grounds of the positive risk-benefit ratio and insufficient evidence of causality in the respective individual cases (Higher Regional Court of Celle, decision of October 11, 2024 — 5 U 323/23; Higher Regional Court of Düsseldorf, judgment of April 29, 2025 — 1-4 U 172/23; Higher Regional Court of Frankfurt, judgment of February 19, 2025 — 23 U 13/24; Higher Regional Court of Frankfurt, decision of April 29, 2025 — 23 W 25/24; Higher Regional Court Koblenz, judgment of July 10, 2024 — 5 U 1375/23, dated September 18, 2024 — 5 U 1139/23, dated September 25, 2024 — 5 U 379/24, dated 18 December 2024 — 5 U 168/24, dated 12. 2. 2025 — 5 U 738/24, dated 23. 7. 2025 — 5 U 271/

25; Munich Higher Regional Court, decision of November 5, 2024 — 14 U 2313/

24, dated 10. 4. 2025 — 1 U 180/24, dated 13. 8. 2025

— 1 U 3021/24, dated August 21, 2025 — 1 U 3881/24, dated September 23, 2025 — 1 U 4159/24; Higher Regional Court of Oldenburg, judgment of

December 18, 2024 — 5 U 53/24; see also Brandenburg Higher Regional Court on the rejection of PKH for an appeal, decision of January 14, 2025 — 4 U 122/24). In contrast, in a coverage protection lawsuit, the Higher Regional Court of Karlsruhe affirmed the sufficient prospects of success of a lawsuit against a vaccine manufacturer and confirmed the judgment of the court of first instance ordering the legal expenses insurer to grant coverage protection. instance, its decision was based on the special circumstance that the coverage request dated from August 2022 and the higher court decisions only date from after that time (cf. Higher Regional Court of Karlsruhe, judgment of May 15, 2025 — 12 U 141/24, para. 66, juris). Furthermore, it referred to the difficulty of the legal issues and the lack of clarification by the highest court (see OLG Karlsruhe, loc. cit., para. 65). These aspects are decisive in a coverage lawsuit, but not for the question of whether the uniformity of case law requires a decision by the court of appeal. ■

3 Assessment of the health risks of cosmetic products (eyelash growth products)

Regulation (EC) No. 1223/2009, Art. 27; Regulation (EC) No. 1223/2009

Art. 10

When assessing the health risks of cosmetic products, proven effects or side effects of molecularly related medicinal products may be taken into account.

It is to be expected that consumers trust that cosmetic products are medically safe and may therefore use them carelessly and without caution.

A positive safety assessment within the meaning of Art. 10 of Regulation (EC) No. 1223/2009 (EU Cosmetics Regulation) does not preclude the implementation of a safeguard clause procedure pursuant to Art. 27 of Regulation (EC) No. 1223/2009.

VG Hannover, decision of November 13, 2025 — 15 B 7553/25

Facts of the case: 1 The applicant operates a large number of drugstores throughout Germany. It objects to the prohibition of the sale of a cosmetic product for promoting eyelash growth, which it sells in its stores as a distributor.

2 The product in question is the cosmetic D. of the brand E. from the manufacturer F.. The cosmetic is intended to strengthen eyelash growth and is applied to the upper lash line in a similar way to eyeliner.

3 On December 10, 2024, the food safety authority of the Tempelhof-Schöneberg district office in Berlin carried out an inspection at one of the applicant's stores. It took a sample of the cosmetic product D. from the E. brand and sent it to the Berlin-Brandenburg State Laboratory. The State Laboratory prepared an expert opinion on the product and determined that it contained 0.026 g/100 g of the substance bimatoprost methylamide (methylamino dihydroxy noralfaprostal, MDN).

4 The substance MDN is a synthetic prostaglandin analogue, a substance that is structurally related to the human tissue hormone prostaglandin. Prostaglandins form a group of substances that are produced in various organs of the body by biosynthesis from fatty acids and control numerous physiological processes by binding to specific receptors. They are particularly involved in the regulation of reproduction (e.g., induction of labor), the cardiovascular system, respiration, pain, and the ocular and sensory systems. Prostaglandin analogues are used medically to treat high intraocular pressure and open-angle glaucoma. In Germany, the prostaglandin analogues bimatoprost, tafluprost, latanoprost, and travoprost are approved for these treatments. One of the side effects of treating open-angle glaucoma patients with these active ingredients is increased eyelash growth. In the USA, bimatoprost is approved as a medication for insufficient eyelash growth (hypotrichosis of the eyelashes).

5 In its test report on cosmetic product D. dated April 17, 2025, the Berlin-Brandenburg State Laboratory concluded that the tested sample of the cosmetic product did not meet the safety requirements for cosmetic products under Article 3 of Regulation (EC) No. 1223/2009 (EU Cosmetics Regulation). It justified its decision primarily on the basis that the Federal Institute for Risk Assessment (BfR) had carried out an assessment of eyelash growth products containing prostaglandin analogues such as MDN in May 2018. Due to the high similarity of the molecular structure of MDN to that of the pharmacological agents bimatoprost, latanoprost, ta-fluprost, and travoprost, a comparable, if not identical, side effect profile could be expected. Tafluprost ethylamide may cause side effects such as eye and headaches, eye redness, irritation or inflammation, irreversible color change of the iris, effects on intraocular pressure, and changes in the fatty tissue of the eyelid. Due to the lack of clinical studies, women are also required to use contraception when using the active ingredient travoprost, as it should not be used during pregnancy. Another cause for concern is that the effectiveness of the medication may be reduced when cosmetics are used in conjunction with glaucoma therapy involving a structurally related active ingredient. The Federal Institute for Risk Assessment considered an eyelash growth product with an MDN content of 0.016 g/100 g. It concluded that, without the relevant experimental data, it could not be ruled out that even a tenfold reduction in the concentration of the active ingredient could cause side effects that are harmful to health. The BfR did not have any clinical data from which a dose could be derived at which the unwanted side effects would no longer be expected. The Berlin-Brandenburg State Laboratory also stated that the Scientific Committee on Consumer Safety (SCCS) of the European Commission had also found that the use of prostaglandin analogues in cosmetic products could pose a health risk to consumers.

6 In a letter dated May 27, 2025, the respondent sent the applicant the test report from the Berlin-Brandenburg State Laboratory with a request for comment.

7 The applicant informed the respondent that it should contact the manufacturer of the cosmetic product directly to clarify the facts of the case.

8 The applicant's legal representative, who also represents the manufacturer of the cosmetic product F., further stated in a letter dated June 6, 2025, that the manufacturer had

had the product undergo the regulatory safety assessment required under Article 10 of Regulation (EC) No. 1223/2009 on May 6, 2025. It was found that the manufacturer had fulfilled all regulatory requirements of the EU Cosmetics Regulation. The respondent did not provide evidence that the use of the cosmetic product actually posed a risk to health.

9 In a letter dated June 24, 2025, the respondent consulted the applicant on the intended issuance of a sales ban for the cosmetic product.

10 In response, the latter stated in a letter dated July 8, 2025, that MDN was not one of the substances of concern for cosmetic products that were prohibited under Article 14 of Annex II to Regulation (EC) No. 1223/2009 or only permitted under certain restrictions under Annex III. It had already fulfilled the regulatory requirements of Article 10 of Regulation (EC) No. 1223/2009. The expert opinion of the Berlin-Brandenburg State Laboratory and the statements of the SCCS were not sufficient to prove that the cosmetic product did not comply with the requirements of the Regulation. In this respect, only the safety assessment pursuant to Art. 10 is decisive. Insofar as the respondent is of the opinion that there is insufficient data to assess the safety of the product, ignorance cannot prove a health risk. Rather, these are mere speculations. However, the European Court of Justice requires that the distribution of a product must pose a real risk to the health of the population in order to justify official bans or restrictions. The manufacturer has been distributing the product on a large scale both within and outside the EU for almost ten years without any cases of health concerns arising. It submitted a further current and positive safety assessment dated July 4, 2025.

11 In a decision dated July 21, 2025, the respondent prohibited the applicant from continuing to supply the cosmetic product as long as it still contained the substance MDN as an ingredient. This included any supply of the product, whether for payment or free of charge, for distribution, consumption, or use on the Community market in the course of a commercial activity. This measure would remain in force until the SCCS assessed the concentration of MDN in cosmetic products for promoting eyelash or eyebrow growth as safe and the product in question complied with this concentration. In addition, it ordered the immediate enforcement of the measure taken and threatened the applicant with a penalty payment of EUR 5,000.00 for each case of non-compliance. The respondent cited Art. 26 of Regulation (EC) No. 1223/2009 as the legal basis for the order. In conjunction with Section 1 (1), Section 6 (1), Section 7 (7), and Section 11 NPOG. The respondent referred to the test report of the Berlin-Brandenburg State Laboratory and the assessments of the Federal Institute for Risk Assessment (BfR) and the SCCS as justification. In particular, there were considerable uncertainties and risks associated with the use of the cosmetic product in terms of reproductive and developmental toxicity, as well as local adverse effects in the eye and the skin around the eye. Warning notices or recommendations for use on the product were not sufficient to ensure safe use by consumers. Although a safeguard clause procedure pursuant to Art. 27 of Regulation (EC) 1223/2009 is a less severe measure than a preliminary sales ban, the requirements for such a procedure are not met. A risk-benefit assessment, as is possible under pharmaceutical law, is not permissible under cosmetics law. The fact that there has been no feedback from consumers regarding health damage to date may be due to the fact that they are unlikely to be able to establish a connection between the use of the product and health complaints. In justifying the order for

immediate enforcement, it stated that particular health risks to consumers could arise if the regulations for cosmetic products were not complied with. It was therefore unacceptable that such deficiencies would continue to exist until the conclusion of legal proceedings in the event of a lawsuit being filed. The applicant's interest in postponing enforcement had to take second place to the public interest in ensuring safety in the use of cosmetic products and protection against criminal offenses.

12 In an email dated July 21, 2025, the applicant informed the respondent that it had implemented the immediate sales ban at all German points of sale as well as in international trade and distance selling.

13 The applicant filed a lawsuit on July 22, 2025 (15 A 7552/25), which has not yet been decided, and filed an application for preliminary legal protection.

14 It considers the contested decision to be unlawful and argues that the applicant had already provided insufficient grounds for the order of immediate enforcement. The grounds lack reference to the individual case because they refer only in general terms to the marketing of cosmetic products and not to the specific product. Furthermore, there is no particular interest in enforcement, such as in the form of sufficiently concrete and imminent irreversible health risks. The applicant's freedom to exercise its profession is significantly restricted by the order for immediate enforcement. In addition, there is no legal basis for the specific part of the order requiring a safety assessment by the SCCS prior to placing the product on the market. Rather, Article 10 of Regulation (EC) No. 1223/2009 provides that an external safety assessor should carry out the assessment. Furthermore, the SCCS's assessment is only preliminary. In any case, a warning on the label is a less severe measure than a sales ban and should be given priority.

15 Following the court's indication, the respondent issued an amendment notice on September 22, 2025, in which it ordered that the disputed decision of July 21, 2025, is amended to the effect that the order listed therein is issued in accordance with Art. 27 of Regulation (EC) No. 1223/2009 in conjunction with Section 1 (1), Section 6 (1), Section 7 (1) and Section 11 NPOG. The time limit for the order was amended to the effect that the measure was submitted to the European Commission for assessment in accordance with Article 27 (3) of Regulation (EC) No. 1223/2009. If the Commission considers the measure to be unjustified, it will be repealed. Otherwise, the measure will remain in force indefinitely. The applicant will be informed immediately of the outcome of the Commission's assessment. Otherwise, the provisions of the contested decision remain unaffected.

16 In the main proceedings, the applicant now seeks, in addition to the annulment of the amended decision, a declaration that the decision in its original version was unlawful. It further adds that the requirements of Article 27(3) of Regulation (EC) No. 1223/2009 are also not met, as there is no justified concern of a serious risk to human health. It is not possible to predict when the EU Commission will issue a decision, which means that, despite the amendment, the applicant faces a sales ban lasting several years. Finally, a distinction must be made between prostaglandins such as tafluprost and MDN, as the substances are administered to the user's body in different ways and therefore have different effects on their organism. In particular, it is very unlikely that the small amounts of MDN to be applied to the upper lash line would actually have an effect on the uterus and embryo of pregnant users

. The SCCS's assessment of the cosmetic products is therefore flawed or incomplete.

17—19

20 For further details of the facts of the case, reference is made to the court file and the administrative proceedings of the respondent.

Reasons: 21 The application is admissible but unfounded.

22 With regard to the prohibition of sale, the application is admissible as an application for restoration of the suspensive effect of the action pursuant to Section 80 (5) sentence 1 alternative 2 VwGO. The applicant's action has no suspensive effect because the respondent has ordered the immediate enforcement of the prohibition of sale pursuant to Section 80 (2) sentence 1 no. 4 VwGO.

§ 80 (2) sentence 1 no. 4 VwGO. In view of the threat of a penalty payment, the application is admissible as an application for an order for the suspensive effect of the action pursuant to § 80 (5) sentence 1 alternative 1 VwGO, because an action against the threat of coercive measures pursuant to § 64 (4) sentence 1 NPOG has no suspensive effect.

23 However, the application is unfounded.

24 An application pursuant to Section 80 (5) sentence 1 alternative 2 VwGO is justified if the order for immediate enforcement is formally unlawful and/or, in the context of a weighing of interests, the applicant's interest in being provisionally spared from the enforcement of the measure outweighs the public interest in immediate enforcement. These conditions are not met in the present case.

25 The order for immediate enforcement with regard to the prohibition of sale proves to be formally lawful.

26 According to Section 80 (3) sentence 1 VwGO, in cases of ordering immediate enforcement within the meaning of Section 80 (2) sentence 1 no. 4 VwGO requires the special interest in the immediate enforcement of the administrative act to be justified in writing. The purpose of this requirement to state reasons is, on the one hand, to encourage the authority to carefully examine the special interest in the immediate enforcement of the administrative act, bearing in mind the exceptional nature of the enforcement order. On the other hand, the justification is intended to convey the relevant reasons for the order to the person concerned, thus enabling them to defend their legal rights. Finally, the justification provides a basis for proper judicial review as to whether the special interest justifying the enforcement order actually exists. The statement of reasons must therefore clearly indicate the specific reasons why, in the specific case, the authority gives priority to the public interest in the immediate enforcement of the administrative act over the interest of the person concerned in postponing enforcement. Accordingly, blanket, meaningless, formulaic phrases do not satisfy the requirement to state reasons. However, the authority may rely on and refer to the considerations underlying the administrative act itself if the reasons justifying the issuance of the administrative act also demonstrate the urgency of its enforcement (Nds. OVG, decision of March 19, 2002 — 11 MB 102/02 —, juris para. 18).

27 The respondent's statement of reasons satisfies these requirements. In its statement of reasons for prohibiting the sale, it has explained in a comprehensible manner what health risks it believes the eyelash growth product poses, specifically reproductive and developmental toxicity as well as local adverse effects in the eye and on the skin around the eye. In its statement of reasons, it also refers to the test report of the Berlin-Brandenburg State Laboratory dated April 17, 2025, on which the applicant had already commented in the hearing procedure. This report details possible health risks such as eye and headaches, eye redness, irritation, and inflammation, irreversible color change of the iris, effects on intraocular pressure, and changes in the fatty tissue of the eyelid, as well as harmful effects on the fetus during pregnancy. The fact that the respondent does not expressly refer to the preceding statements in the paragraph entitled "Reasons for immediate enforcement" is irrelevant. This is because the applicant must have been aware from the context of the decision that the respondent, with the statements made in this section,

"Particular health risks posed by cosmetic products" referred to the risks described above for the specific product affected by the sales ban and not to any other risks. In view of this context, the statements are not merely empty words, but it is clear that the health risks described above are the reasons why the respondent considers the enforcement of the sales ban to be particularly urgent and does not wish to wait for the conclusion of the main proceedings. Whether these reasons are valid in terms of content does not need to be examined in the context of the formal legality of the immediate enforcement. This question can only have an effect on the substantive weighing of interests (see Saxony Higher Administrative Court, decision of August 5, 2011 — 2 B 259/10 —, juris para. 7).

28 According to Section 80 (5) sentence 1 VwGO, in cases where the authority has ordered immediate enforcement pursuant to Section 80 (2) sentence 1 no. 4 VwGO, the court may restore the suspensive effect if the applicant's interest in being provisionally spared from the enforcement of a measure outweighs the public interest in immediate enforcement. This is usually the case if the contested administrative act is found to be unlawful in the summary examination that is possible and necessary in summary proceedings, because the enforcement of an unlawful administrative act is contrary to the principle of legality.

29 This is usually the case if the contested administrative act proves to be unlawful in the summary examination that is possible and necessary in summary proceedings, because there can be no public interest in the enforcement of an unlawful administrative act. If, on the other hand, the administrative act is lawful upon summary review, the interest in enforcement outweighs the applicant's interest in suspension only if there is also a special public interest in enforcing the administrative act before it becomes final. As a rule, the special public interest must go beyond the interest that justifies the administrative act itself. It only exists if the order is justified by serious concrete dangers or other serious public interests or concerns of others.

Participating party is justified, which outweigh the interest of the party concerned in postponement (see BVerfG, decision of 27 April 2005 — 1 BvR 223/05 —, juris para. 31; Nds. OVG, decision of June 29, 2016 — 11 ME 100/16 —, juris para. 19).

30 According to these principles, the order for immediate enforcement of the sales ban was materially lawful. After a summary examination of the facts and legal situation, the sales ban in the contested decision of the respondent dated July 21, 2025, as amended on

September 22, 2025, is likely to be lawful. In addition, there is a particular public interest in enforcement that goes beyond the interest that justifies the administrative act itself.

31 The legal basis for the sales ban is correctly Art. 27(1) of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of November 30, 2009, on cosmetic products, as amended on January 1, 2025, which entered into force on September 1, 2025. The sales ban is an administrative act with permanent effect because the respondent has issued a ban with a continuously updated obligation. This means that the factual and legal situation at the time of the court decision is decisive. There is nothing in substantive law to the contrary (see VG Berlin, judgment of

January 28, 2020 — 25 K 5.19 —, juris para. 25; BVerwG, judgment v. 19. 9. 2013 — BVerwG 3 C 15.12 —, juris Rn. 9).

If, in the case of products that comply with the requirements of Article 25(1), a competent authority finds or has reasonable grounds to believe that one or more cosmetic products made available on the market are likely to pose or have posed a serious risk to human health, it shall, in accordance with Article 27(1) of Regulation (EC) No. 1223/ 2009 to ensure that the cosmetic product(s) is (are) withdrawn from the market, recalled or its (their) availability is otherwise restricted.

32 The respondent was designated by the Federal Republic of Germany as the competent authority for the application of the provisions of the Regulation pursuant to Art. 34 (1) of Regulation (EC) No. 1223/2009 (current list available at: www.bvl.bund.de/kosmetikbehoerden). It heard the applicant prior to issuing the contested decision in accordance with Section 28(1) of the Administrative Procedure Act (VwVfG) and gave it the opportunity to comment.

33 The factual requirements for an order pursuant to Art. 27(1) of Regulation (EC) No. 1223/2009 are met.

34 In the case of the eyelash growth product D. of the brand E. from manufacturer F. is a cosmetic product that meets the requirements of Art. 25(1) of Regulation (EC) No. 1223/2009. The requirements specified therein for the responsible person, i.e. in particular the manufacturer of the product (Art. 4(3) sentence 1 of Regulation (EC) 1223/2009), include, among others, the good manufacturing practice referred to in Article 8 (Art. 25(1) half-sentence 2 letter a), the safety assessment referred to in Article 10 (letter b) and the restrictions referred to in Articles 14, 15 and 17 for substances.

(Letter f). It is undisputed between the parties that the manufacturer of the product in question complies with all the requirements of Article 25(1) of Regulation (EC) No. 1223/2009, and there are no indications to the contrary. In particular, F. has already obtained a positive safety assessment for the product within the meaning of Article 10 of Regulation (EC) No. 1223/2009 on several occasions in order to demonstrate the conformity of the cosmetic product with the safety requirements in Article 3.

35 There is also actual evidence of possible harmful effects of the eyelash growth product, which, according to Article 27(1) of Regulation (EC) No. 1223/2009, at least gives rise to concern that the product could pose a serious risk to human health. It is necessary, but also sufficient for such justified concern, that there are concrete doubts based on reliable scientific findings that the product does not pose a serious risk to human health and that the responsible persons cannot dispel these doubts with the help of conflicting findings. This standard also arises from the fact that cosmetic products are generally luxury products for aesthetic use and that public interest in their distribution is typically lower than, for example, in the case of food, feed, or medicinal products. This also follows from No. 9, sentence 2 of the recitals to Regulation (EC) No. 1223/2009, which stipulates that a risk-benefit assessment must not justify any risk to human health.

36 Such justified concern arises here from the test report of the Berlin-Brandenburg State Laboratory dated April 17, 2025, which in turn refers to the findings and assessments of the Federal Office for Risk Assessment (BfR) and the Scientific Committee on Consumer Safety of the EU Commission (SCCS). The Chamber considers the State Laboratory's statements to be plausible, namely that cosmetic products containing the prostaglandin analogue MDN (bimaprost methylamide) pose similar risks to medicinal products containing other prostaglandin analogues with a similar molecular structure, such as bimatoprost, tafluprost, Latanoprost and Travoprost. In the field of pharmaceutical law, the European Court of Justice has ruled that, when classifying a product as a "medicinal product" within the meaning of this provision, a national authority may determine the pharmacological properties of that product by relying on scientific knowledge about a structural analogue of that substance if no scientific studies of the substance of which the product consists are available and provided that the degree of analogy, based on an objective and scientifically sound analysis, allows the assumption that a substance present in a product in a certain concentration has the same properties as an existing substance for which the necessary studies are available (ECJ, judgment v. 13.10.2022 — C-616/20 —, juris

Rn. 38). The fact that MDN has a similar effect to other prostaglandin analogues is particularly evident because MDN is only used for cosmetic purposes because, when applied to the eye, it

increases eyelash growth, it has the same side effects as the prostaglandin analogues used as medicinal products. The fact that the desired side effects of MDN are consistent with those of bimatoprost, tafluprost, etc. suggests that there may also be similarities in terms of undesirable side effects that are harmful to health.

37 These harmful side effects of bimatoprost, tafluprost, latanoprost, and travoprost, and thus probably also of MDN, pose a serious risk to human health. Prostaglandin analogues used as medicinal eye drops lower intraocular pressure during treatment, so the structurally related MDN may also affect intraocular pressure. Intraocular pressure holds the retina in place, and in the worst case, too low intraocular pressure can lead to retinal detachment (<https://flexikon.doccheck.com/de/Au-geninnendruck>). In addition, eye redness and irritation as well as headaches are side effects of bimatoprost, tafluprost, etc., which are less serious but occur frequently. The risks posed by prostaglandin analogues to the fetus when used by pregnant women are very abstract due to a lack of clinical studies, but cannot be ruled out and are all the more serious in the event that damage actually occurs.

38 Unlike the prostaglandin analogues in prescription medical eye drops, MDN in eyelash growth products is not taken under medical supervision. There is no expert assessment of the desired effects and undesirable side effects. Instead, people who use cosmetic products regularly place blind trust in their medical safety. For this reason, the applicant's objection that no harmful effects of MDN have been reported or documented to date when used as an eyelash growth product cannot dispel the justified concern of a serious risk. There is much to suggest that people do not make a connection between the use of the product and side effects such as headaches or increased intraocular pressure and that these are therefore not known to either the manufacturer or the public.

39 The fact that users are likely to handle the eyelash growth product carelessly and recklessly also contradicts the applicant's argument that the eyelash growth product is used in a different way to other prostaglandin analogues, in that it is not dripped into the eye but applied to the upper lash line. According to No. 9, sentence 1 of the recitals of Regulation (EC) No. 1223/2009, cosmetic products should be safe under normal or reasonably foreseeable conditions of use. This means that risks arising from use that is not in accordance with the intended use but is nevertheless reasonably foreseeable must also be taken into account. Although the product packaging contains the warning

Do not apply inside the eye or on the lower lash line. However, it is doubtful whether consumers actually read this warning and, even if they do, whether they take it seriously and observe it carefully enough. Furthermore, even if the liquid is applied carefully to the upper lash line, contact with the eye itself cannot be reliably ruled out.

40 Although the eyelash growth product has a positive safety assessment pursuant to Art. 10 of Regulation (EC) No. 1223/2009, this does not preclude the implementation of a safeguard clause procedure. The fact that a positive safety assessment cannot, in principle, constitute an obstacle is already clear from the standard set out in Article 27 of Regulation (EC) No. 1223/2009 itself, which serves to close gaps in protection that may also exist in cosmetic products that meet the formal requirements of Article 25 of Regulation (EC) No. 1223/2009. The fact that a safety assessment has been carried out for the respective cosmetic product and that it has a positive safety report in accordance with Annex I is also a necessary minimum requirement for the product to be placed on the market. However, the fact that the distributor has fulfilled the requirements of Article 10 of Regulation (EC) No. 1223/2009 does not rule out the possibility that, based on other findings, there may be reason to believe that the distribution and use of a cosmetic product may pose serious risks to human health.

41 Finally, it should be noted that, according to recital 36 of Regulation (EC) No. 1223/2009, measures taken by the Commission and the Member States with regard to human health should be based on the precautionary principle. This means that in cases where, after evaluation of the available information, the possibility of harmful effects on health is identified but scientific uncertainty remains, provisional risk management measures may be taken to ensure the high level of health protection chosen in the Community until further scientific information is available for a more comprehensive risk assessment. In such circumstances, a Member State must be allowed to take protective measures in accordance with the precautionary principle without having to wait for the existence and magnitude of these risks to be clearly established. A risk assessment may not be based on purely hypothetical considerations (see ECJ, judgment of January 28, 2010 — C-333/08 —, juris para. 14, 91). However, this is not the case here.

42 Article 27(1) of Regulation (EC) No. 1223/2009 provides for the legal consequence that the competent authority shall take all appropriate provisional measures to ensure that the cosmetic product or products are withdrawn from the market, recalled, or their availability is otherwise restricted. The respondent was therefore not granted discretionary power, but only a choice of measures. The respondent exercised this discretion in accordance with its duties after a summary examination and, in particular, observed the principle of proportionality. The mere requirement to affix further warnings on the product packaging is not as effective as the sales ban, because there is no minor

There is a likelihood that consumers will either not read the warnings or underestimate the dangers described. The respondent's decision was also not disproportionate. The respondent's fear that it may take many years for the European Commission to evaluate the measure is countered by the fact that a preliminary opinion from the SCCS is already available, meaning that the Commission already has a comprehensive basis for its decision on which to build. Furthermore, the eyelash growth product is only one of over 20,000 products that the applicant sells in its stores, so the economic damage caused by the sales ban is likely to be manageable. ■

4 Revocation of license to practice as a pharmacist due to unworthiness (billing fraud)

BAPo §§ 4, 6; ECHR Art. 6 I; VwGO § 87a II, III

The authority is entitled, but not obliged, to decide on measures relating to licensing law even before the conclusion of criminal proceedings. In view of the purpose of revoking the license, which is to protect the relationship of trust between pharmacists and patients, a final criminal conviction and thus the imposition of a criminal penalty are of considerable importance.

VG Frankfurt/M., judgment of November 11, 2025 — 7 K 1774/22.F

Facts of the case: 1 The parties are in dispute over the revocation of the plaintiff's license to practice as a pharmacist.

2 The plaintiff is a licensed pharmacist and has been operating the X. pharmacy, which he took over from his brother, and the I. pharmacy since 2010. Both pharmacies are located in S. The plaintiff employs a total of around 20 people.

3 From January 2010 to December 2013, the plaintiff billed statutory health insurance companies a total of 65 times in conjunction with several patients for prescriptions without actually purchasing the prescribed medications or dispensing them to the patients. The billing was carried out through both of the plaintiff's pharmacies. The health insurance companies assumed that the claims were legitimate. The total amount of these claims amounted to at least €1,637,091.58 during the period in question. The plaintiff shared the profits with the respective patients, paying them for the prescriptions in cash or by dispensing other medications. The plaintiff thus continued the business of his brother, who had previously operated the X. pharmacy and had relinquished his own license to practice medicine as a result of criminal prosecution. The plaintiff did so as a result of threats from patients in order to protect his brother from further prosecution (p. 87 ff. of the administrative file, vol. 2).

4 In December 2013, the plaintiff terminated these transactions even before he became aware of the criminal investigations against him.

5 After the offense was uncovered, the plaintiff reached settlements with all affected statutory health insurance funds regarding compensation payments, which he fulfilled in full. He confessed from the outset of the criminal proceedings and established a compliance system in his pharmacies to prevent future billing fraud.

6 In a letter dated September 28, 2015, the defendant suspended the plaintiff's license to practice medicine pending the outcome of the investigation (p. 18 ff. of the administrative file, vol. 2). As a result, he refrained from ordering the suspension of the license to practice medicine until the time the indictment was filed (p. 20 of the administrative file, vol. 2).

7 After the public indictment was filed in 2019, the defendant again heard the plaintiff regarding the intended order to suspend his license to practice medicine (p. 43 of the administrative file, vol. 2). Following a statement by the plaintiff's representative, the defendant declared that it would refrain from issuing any orders relating to the license to practice medicine for the duration of the criminal proceedings, but expressly reserved the right to take measures relating to the license to practice medicine after the conclusion of the criminal proceedings.

8 At the beginning of June 2021, the defendant learned from the health department of the city of S. that irregularities had been found during an inspection at the X. pharmacy (p. 77 f. of the administrative file, vol. 2). There had been deficiencies in the performance of the tests as well as hygiene deficiencies (see p. 60 ff. of the electronic file). The city then revoked the plaintiff's authorization as a service provider for performing coronavirus tests by notice dated June 4, 2021, and ordered the immediate closure of the testing facility in the city area for which the plaintiff was responsible, under threat of a penalty payment (p. 64 ff. of the paper file).

9 On June 28, 2021 (Ref. N01), the Regional Court of S. sentenced the plaintiff to a total prison term of two years for fraud in 65 cases (cf. 86 ff. of the administrative file, vol. 2). The Regional Court suspended the sentence, with a probation period of three years. The Regional Court refrained from imposing a professional ban pursuant to Section 70 (1) of the German Criminal Code (StGB). The judgment became final.

10 On January 18, 2022, a random inspection was carried out at the X. pharmacy, during which the health department determined that coronavirus testing was still being offered. The pharmacy employees were then instructed to stop testing immediately. During a police inspection the following day, it was determined that testing was still being carried out. Testing was then prohibited again (p. 109 of the electronic file).

11 In a decision dated February 2, 2022, the defendant revoked the plaintiff's license to practice medicine (item 1), ordered the surrender of the license certificate and all certified copies thereof (item 2), and set fees and expenses in the amount of €351.55 (item 3) (p. 122 ff. of the administrative file, vol. 2). The defendant referred to the judgment of the regional court as justification. In addition, the defendant referred to the deficiencies in the performance of coronavirus tests that had been brought to his attention by the health department of the city of S. The plaintiff was guilty of conduct that rendered him unfit to practice as a pharmacist. Thus, the requirements of § 4 (1) sentence 1 no. 2 BapO had subsequently ceased to apply. Therefore, the license to practice should be revoked in accordance with § 6 (2) BapO. In this regard, the defendant referred in particular to the criminal energy expressed in the act, the severity of the sentence, and the financial damage incurred. The plaintiff had also exploited his position as a pharmacist to commit the offense. Due to these circumstances, the plaintiff's behavior had seriously damaged the public image of pharmacists. During a probationary period imposed by a criminal court, which was still ongoing, it could not be assumed that the plaintiff had matured to such an extent that his unworthiness had been compensated for by the character flaws that had come to light. The plaintiff also continually displays a lack of care and concern with regard to his professional duties, which raises doubts about his reliability. This is evident from the circumstances that led to the revocation of his license to perform coronavirus tests.

As a result, due to the established unworthiness, it can remain open whether the plaintiff is also unreliable.

12 In a letter from his representative dated March 1, 2022, the plaintiff lodged an appeal against the revocation of the approval (p. 140 ff. of the administrative file, vol. 2). In support of his appeal, the plaintiff first cited the time lapse between the authority's knowledge of the allegations against the plaintiff in 2015 and the decision of February 2, 2022. Since the first hearing on an intended order to suspend the license, the plaintiff had been practicing his profession with the defendant's consent. Despite the defendant's knowledge of the relevant circumstances, the license had not been revoked. During this time, the plaintiff had performed his profession without complaint.

13 On May 16, 2022, a rejection notice was issued (p. 149 ff. of the administrative file, vol. 2). This was received by the plaintiff's representative on June 1, 2022 (p. 155 of the administrative file, vol. 2). The defendant essentially justified the appeal decision on the grounds that the determination of a pharmacist's unworthiness did not require a risk assessment and that there was therefore no need to consider the risk of repetition. It was therefore irrelevant whether the plaintiff would run his pharmacy without complaint in the future. Whether a criminal court imposed a professional ban under Section 70 of the German Criminal Code (StGB) was not relevant to the revocation of the license to practice, as the professional ban depended on other conditions, including a prognosis. The long period between the authority becoming aware of the situation and the revocation decision was irrelevant. The plaintiff had always been advised that further steps could be taken with regard to his license to practice medicine. The suspension of the license to practice medicine had not been ordered in the ongoing criminal proceedings because no dangers had been identified until the conclusion of the criminal proceedings. Furthermore, there were indications that cast doubt on the plaintiff's reliability. Among other things, the plaintiff had continued the trial operation despite the prohibition.

14 The plaintiff filed a lawsuit with the Administrative Court of Darmstadt on June 20, 2022. The Administrative Court of Darmstadt referred the lawsuit to the court of jurisdiction by order of June 24, 2022.

15 The plaintiff claims that the findings of the health department regarding the deficiencies in the context of the coronavirus testing are inaccurate. The plaintiff and his employees were aware of all relevant legal provisions. He also ensured that the tests were carried out conscientiously. On the day of the inspection, the plaintiff himself was not present; rather, Mr. R. was the pharmacist on duty, so that the health department's findings regarding the plaintiff's person were not possible at all. Hygiene regulations were also complied with at all times.

16 The plaintiff is of the opinion that the defendant did not sufficiently assess the circumstances of the individual case. This constitutes an unjustified, serious interference with the freedom of occupation. The defendant wrongly failed to take into account the plaintiff's years of law-abiding behavior up to the time of the appeal decision. If the consequences of the lengthy administrative proceedings are not compensated, this would constitute a violation of Article 6(1) of the ECHR. In particular, the compensation for damages and the assistance provided by the plaintiff in clarifying the matter during his probationary period should have been taken into account. Events that occurred arbitrarily long ago could not be used to justify unworthiness, while the period that followed was ignored. In particular, a failure of the justice system, which, as in the present case, led to an unusually long duration of the criminal proceedings, could not be to the detriment of the plaintiff. The defendant did not have to wait for the criminal conviction to revoke the license, as the plaintiff had also confessed to

the defendant and the indictment had been presented to the defendant. In any case, within the framework of proportionality, priority should have been given to the measure of revoking the pharmacy operating license.

17—21

22 For further details on the facts and legal arguments, reference is made to the content of the pleadings and attachments included in the court file (up to page 116 as a paper file, then with a new ascending page number as an electronic file) and to the content of the defendant's administrative files (one Leitz folder and two binders). These were the subject of the oral hearing. For the content of the oral hearing, reference is made to the minutes of the hearing.

Reasons: 23 The decision may be made by the rapporteur, as the parties have agreed to this (Section 87a (2) and (3) VwGO).

24 The admissible action is unsuccessful on the merits.

25 The legal basis for the contested decisions is Section 6(2) in conjunction with Section 4(1) sentence 1 no. 2 BApO. This legal basis does not raise any constitutional concerns (Federal Administrative Court, decision of October 23, 2007 — 3 B 23/07 —, juris, para. 5).

26 The contested decisions were formally issued in a lawful manner.

27 Whether there is a procedural error in the form of a failure to hear the plaintiff within the meaning of § 28 (1) HVwVfG because the defendant only heard the plaintiff on an intended order to suspend the license pursuant to § 8 BApO, but not on an intended revocation of the license pursuant to § 6 (2) HVwVfG, although both measures are subject to different requirements under administrative law pursuant to § 8 BApO, but not on an intended revocation of the license to practice medicine pursuant to § 6 (2) HVwVfG, even though the two measures are based on different requirements, can be left open here. In any case, the defendant dealt with the plaintiff's objections seriously and sufficiently intensively in the context of the appeal proceedings, so that any hearing error is in any case deemed to have been remedied pursuant to § 45 (1) No. 3 HVwVfG.

28 The contested decisions are also not formally unlawful because approximately seven years passed between the authority becoming aware of the allegations against the plaintiff in 2015 and the decision in 2022. In particular, the time limit set out in Section 48(4) sentence 1 HVwVfG and Section 49(2) sentence 1 in conjunction with Section 48(4) sentence 1 HVwVfG is not applicable, even by analogy, to the cases covered by Section 6(2) BApO. Within its scope of application, it supersedes Section 6 (2) BApO the provisions of Sections 48, 49 HVwVfG. The purpose of Section 6 (2) BApO, which is to protect the health of individual patients and the relationship of trust between pharmacists and patients, leaves no room for consideration of the limitation period in Section 49 (2) sentence 1 in conjunction with Section 48 (4) sentence 1 HVwVfG, which serves to protect the trust of the person concerned (cf. § 5 (2) sentence 1 BAO: BVerwG, judgment of September 16, 1997 — 3 C 12/95 —, BVerwGE 105, 214-223, juris, para. 20 et seq.). This applies all the more so in the case of revocation on grounds of unworthiness or unreliability of the person concerned, where the circumstances justifying the revocation are to be found in the conduct of the person concerned. As a rule, there is therefore no legitimate expectation on the part of the person concerned

(see BVerwG, loc. cit., para. 22). This is also the case here.

29 The contested decisions were also issued in accordance with substantive law.

30 According to § 6 (2) BApO, the license to practice medicine must be revoked if one of the requirements under § 4 (1) sentence 1 no. 2 BApO subsequently ceases to apply. According to Section 4 (1) sentence 1 no. 2 BApO, a license to practice as a pharmacist shall only be granted if the applicant has not engaged in conduct that would render him or her unworthy or unreliable to practice the profession of pharmacist.

31 Accordingly, the defendant was right to consider the plaintiff unfit for the profession within the meaning of Section 4 (1) sentence 1 no. 2 BApO.

32 The decisive point in time for assessing unworthiness is that of the last administrative decision, in this case the appeal decision (cf. § 5 (2) BAO: BVerwG, decision of 14.1998 — 3 B 95/97 —, juris, para. 6, BVerwG, decision of August 18, 2011 — 3 B 6/11 —, juris, para. 9, BVerwG, Decision of July 31, 2019 — 3 B 7/18 —, juris, para. 15).

33 The case law of the Federal Administrative Court has clarified that the only grounds for revoking a license to practice medicine on the basis of unworthiness can be serious misconduct that is likely to permanently undermine public confidence in the profession, even if the conduct would have no consequences for the continuation of the license to practice (BVerwG, decision of August 18, 2011 — 3 B 6/11 —, juris, para. 8). Unworthiness therefore presupposes that the pharmacist's conduct has caused him to lose the reputation and trust that are indispensable for the practice of his profession. This definition links the determination of professional unworthiness to high standards, particularly with regard to the principle of proportionality. It requires serious misconduct on the part of the pharmacist which, when all circumstances are taken into account, makes his continued practice of his profession appear unacceptable at the relevant point in time (BVerwG, decision of 14 April 1998 — 3 B 95/97 —, juris, para. 11 with further references), whereby a specific minimum penalty is not decisive (BVerwG, decision of August 18, 2011 — 3 B 6/11 —, juris, para. 8). Whether such serious misconduct exists depends decisively on the circumstances of the individual case and cannot be clarified in a manner that applies across all cases (BVerwG, decision of August 18, 2011 — 3 B 6/11 —, juris, Rn. 8, cf. also BVerwG, decision of 20 September 2012 — 3 B 7/12 —, juris, Rn. 4 f.). It is not necessary for the misconduct to directly affect the relationship between the pharmacist and the patient; rather, misconduct affecting other professional duties of the pharmacist is also sufficient — depending on the severity of the offense, criminal offenses outside the professional sphere may also suffice (cf. Federal Administrative Court, decision of July 31, 2019 — 3 B 7/18 —, juris, para. 9, Bay. VGH, judgment of 8. 11. 2011 — 21 B 10.1543 —, juris, para. 34, Hess. VGH, decision of 24. 11. 2011 — 7 A 37/11.Z —, juris, para. 25 and 30).

34 Against this background, a case of billing fraud—both against statutory health insurance funds and privately insured patients—can also constitute grounds for disqualifying a pharmacist (for doctors: Federal Administrative Court, decision of

September 20, 2012 — 3 B 7/12 —, juris, para. 4 f., Hess. VGH, decision of November 24, 2011 — 7 A 37/11.Z —, juris, para. 25, Bay. VGH, judgment of June 28, 2017 — 21 B 16.2065 —, juris, Rn. 16 ff.). The professional duties of pharmacists also include proper billing of health insurance companies (see Federal Administrative Court, judgment of September 26, 2002 — 3 C 37/01 —, juris, para. 42, Bavarian Administrative Court, judgment of November 8, 2011 — 21 B 10.1543 —, juris, para. 34, Hess. VGH, decision of 24 November 2011 — 7 A 37/11.Z —, juris, para. 30).

35 In this context, the examination of the characteristic of unworthiness does not require a prognosis regarding the future dangers posed by the person concerned to the general public and patients (cf. regarding doctors: Federal Administrative Court, decision

v. 9. 1. 1991 — 3 B 75/90 —, juris, para. 3, Federal Administrative Court,

decision of November 2, 1992 — 3 B 87/92 —, juris, para. 11, BVerwG, decision of July 31, 2019 — 3 B 7/18 —, juris, para. 15, OVG Saxony-Anhalt, decision of February 19, 2024 — 1 M 5/24 —, juris, para. 22, Bavarian VGH, judgment of

August 6, 2024 — 21 B 23.726 —, juris, para. 25). Because it Even if the revocation of a license to practice due to unworthiness is a measure to avert danger and not a sanction, the revocation of the license to practice is only justified if, at the relevant time of the conclusion of the administrative proceedings, it is still necessary to avert a danger to the relationship of trust between pharmacist and patient. This is the case if the conditions for professional unworthiness are met at that point in time (BVerwG, decision of July 31, 2019 — 3 B 7/18 —, juris, para. 15). This requires an assessment of the individual case based on the scope of Article 12(1) of the Basic Law, which must also take into account any changes in circumstances that may justify a different assessment of professional unfitness (BVerfG, decision of September 8, 2017 — 1 BvR 1657/17 —, juris, para. 14, see also BVerfG, decision of August 28, 2007 — 1 BvR 1098/07 —, BVerfGK 12, 72-80, juris, para. 23).

36 If the condition of unworthiness is met, the withdrawal of the license to practice medicine, which is in any case a very serious encroachment on the freedom to choose a profession, is objectively justified regardless of any proceedings that may have been conducted by a medical disciplinary court (cf. for doctors: BVerwG, decision of 14 April 1998 — 3 B 95/97 —, juris, para. 11 with further references).

37 According to these standards, the defendant rightly assumed that the plaintiff was unfit to practice at the relevant time of the appeal decision of May 16, 2022.

38 In this regard, the plaintiff's conviction by the Regional Court of S. on June 28, 2021, and the facts underlying the conviction, i.e., the acts adjudicated and the circumstances in which they were committed, must first be taken into account. The court hearing the case may rely on the facts established by the criminal court — based on its own assessment — insofar as there are no significant indications that such findings are incorrect (cf. BVerwG, decision of August 18, 2011 — 3 B 6/11 —, juris, para. 10, OVG Lüneburg, decision of December 15, 2020 — 8 LA 80/20 —, juris, para. 8). No such indications are apparent here.

39 By committing 65 instances of billing fraud, the plaintiff violated in a particularly serious manner

his professional duties. The criminal court accordingly concluded that the plaintiff was guilty of particularly serious cases of fraud due to the commercial nature of the offense (see p. 111a of the administrative file, vol. 2). Added to this is the particularly large number of 65 individual acts over a period of around four years. From this, the defendant rightly concluded that the plaintiff had considerable criminal energy, which is reflected in the circumstances of the offense. An aggravating factor to be taken into account is that the plaintiff had seen a negative example in his brother immediately before starting his own illegal business. The plaintiff continued his brother's business, partly with the same patients and partly with new patients, even though his brother had just surrendered his license to practice medicine as a result of criminal investigations. The plaintiff must therefore have been particularly aware of the illegality of his actions and their possible consequences under licensing law when he committed the offense. Nevertheless, he decided to continue the business according to the same pattern that his brother had already practiced in the X. pharmacy. This is mitigated by the fact that, according to the findings of the Regional Court, the plaintiff also agreed to continue doing business with the patients because he hoped that this would protect his brother from further prosecution. The actions resulted in considerable damages totaling over 1.6 million euros on the part of the statutory health insurance funds and thus on the part of the insured community. The two-year prison sentence imposed by the Regional Court also reflects the significance of the plaintiff's breach of his professional duties. Ultimately, the plaintiff exploited his position as a pharmacist to commit the offense, which was only possible because of his profession. The acts were also closely related to his professional duties and took place in the form of billing statutory health insurance funds, which is a core area of the plaintiff's professional activity. The plaintiff benefits from the fact that the acts did not directly concern patient health issues, but were limited to the area of billing. However, the public perception of a pharmacist and thus also the trust of patients in the profession of pharmacist cannot be divided into administrative activities and activities affecting the health of patients. Rather, the trust of patients in a pharmacist—and in this case the plaintiff—is also shaken by the fact that the plaintiff blatantly fails to fulfill his professional duties other than those relating to health. In the present case, this is particularly evident in the corresponding press coverage of the plaintiff's criminal trial (see pp. 79 and 81 of the administrative file, vol. 2).

40 According to the above standards, the changed circumstances that may justify a different assessment of professional unworthiness must also be taken into account. These include, in particular, the plaintiff's behavior after the offense, especially his efforts to make amends and his cooperation in the criminal investigation.

41 In this regard, the plaintiff benefits from the fact that, according to the findings of the Regional Court, he had already ceased his illegal activities shortly before he himself was

criminal investigations against him. The compensation for damages sought by the plaintiff must also be taken into account in his favor. To this end, the plaintiff concluded settlements with the health insurance companies concerned (see Annexes 9, 10, and 11 on p. 14 ff. of the administrative file, vol. 3). The plaintiff also made payments in accordance with these settlements. In addition, the plaintiff set up a so-called compliance system designed to prevent future billing fraud (see Annex 1 on p. 1 ff. of the administrative file, vol. 3), which he also implemented by means of service instructions to his employees (see Annexes 2 to 5 on p. 14 ff. of the administrative file, vol. 3). The plaintiff actively cooperated in his own criminal and administrative proceedings under medical licensing law by making comprehensive confessions and assisting in the investigation—for example, by giving witness statements and reporting to the public prosecutor's office.

-in other criminal proceedings relating to billing fraud in pharmacies (see, for example, Annexes 7 and 8 on p. 10 ff. of the administrative file, vol. 3). Finally, it must be taken into account in favor of the plaintiff that approximately eight and a half years had passed between the end of the last criminal act in December 2013 and the appeal decision in May 2022, whereby the plaintiff cannot be blamed for the delays in the criminal proceedings.

42 In the overall assessment of the circumstances speaking for and against the plaintiff's unworthiness, the severity and extent of the misconduct ultimately outweigh the plaintiff's post-offense behavior and the considerable time that elapsed before the appeal decision was made. The assessment is based on the regulatory purpose of Section 6 (2) in conjunction with Section 4 (1) sentence 1 no. 2 BApO. In addition to protecting patient health, this purpose is to protect the relationship of trust between patients and pharmacists. Accordingly, the decisive factor in assessing unworthiness in the present case is whether the plaintiff's conduct is likely to permanently disrupt this relationship of trust.

43 In the opinion of the rapporteur, this can be assumed to be the case at the time of the appeal decision.

44 The combination of the considerable number of 65 particularly serious cases of billing fraud, the considerable duration of four years over which the plaintiff continued his criminal behavior, and the high damage of over €1.6 million to the insured community of the statutory health insurance funds concerned is particularly likely to seriously undermine patients' trust in the plaintiff and in the profession of pharmacist. This also applies in light of the fact that correct billing to (statutory) health insurance funds is a core obligation of pharmacists and is of particular importance in the public perception. In this context, it is necessary—without the misconduct having to become known to the public (cf. Bavarian Administrative Court, judgment of November 8, 2011

— 21 B 10.1543 —, juris, margin note 35) — it is already apparent from press reports about the plaintiff that the public took considerable offense at the plaintiff's misconduct, thus seriously damaging the relationship of trust between patients and pharmacists

(pp. 79 and 81 of the administrative file, vol. 2). The severity of the plaintiff's professional misconduct is reflected not least in the length of the prison sentence of two years imposed, which, according to the regional court's statements, was only possible by "narrowly combining" the 65 individual sentences of between two months and one year of imprisonment and thus appeared to the regional court to be "still appropriate to the offense and the degree of guilt" (p. 56 ff. of the administrative file, vol. 2).

45 On the other hand, only limited weight can be given to the plaintiff's conduct after the offense, which ultimately does not mean that the plaintiff regained his professional integrity before the administrative proceedings were concluded. The defendant rightly pointed out that the plaintiff's confession and his good behavior in general during pending criminal proceedings were significantly influenced by the proceedings themselves and, during the probationary period, by the possibility of the suspension of the sentence being revoked (see Bavarian Administrative Court, judgment of November 8, 2011 — 21 B 10.1543 —). VGH, judgment of November 8, 2011 — 21 B 10.1543 —,

juris, para. 37 with further references, Bavarian VGH, judgment of June 28, 2017

— 21 B 16.2065 —, juris, para. 25, VG Munich, judgment of October 20, 2015 — M 16 K 15.1873 —, juris, para. 23, VG Ansbach, judgment of June 14, 2024 — AN 4 K 23.219 —, juris, para. 68). The compensation paid can also only be taken into account to a limited extent in favor of the plaintiff if it is essentially limited to the fulfillment of existing civil law claims for damages (cf. Bavarian Administrative Court, judgment

, November 8, 2011 — 21 B 10.1543 —, juris, para. 37 m. w. N.). In this case, the settlements related specifically to the damage incurred and were limited to compensation for that damage. They were also clearly concluded under the influence of the pending criminal proceedings, of which the plaintiff must have been aware that a substantial prison sentence – possibly no longer eligible for probation – was to be expected and that compensation for damages would have a mitigating effect on the sentence.

46 The fact that the plaintiff ceased his illegal activities shortly before learning of the criminal proceedings against him and also assisted in other criminal proceedings does not constitute sufficiently important circumstances to arrive at a different assessment.

47 The plaintiff's objection that the proceedings had dragged on for years and that the delay was not within the plaintiff's sphere of responsibility, but that the criminal proceedings had not been adequately pursued for reasons beyond the plaintiff's control for about two and a half years, does not alter the assessment of the plaintiff as unworthy at the time of the appeal decision (see p. 69a of the paper file).

48 There are no legal objections to the defendant postponing the decision on revoking the license until the criminal proceedings have been legally concluded. The defendant was entitled to wait for the outcome of the criminal proceedings first. The Federal Pharmacists' Act allows the revocation of the license to be postponed until the conclusion of the criminal proceedings by giving the authority the option of suspending the license pursuant to § 8.

Paragraph 1 No. 1 and Paragraph 2 (Federal Administrative Court, decision of August 4, 1993 — 3 B 5/93 —, juris, margin note 5). Conversely, the authority is merely entitled, but not obliged, to decide on measures relating to the right to practice medicine even before the criminal proceedings have been concluded (cf. BVerwG, loc. cit., dissenting opinion: Schelling in: Spickhoff, 4th ed. 2022, BÄO § 5 para. 61). In light of the purpose of revoking a license to practice, which, as explained above, is, among other things, to protect the relationship of trust between pharmacists and patients, a final criminal conviction and thus the imposition of a criminal record are of considerable importance. This is because the relationship of trust between pharmacists and patients can be significantly impaired by a final conviction. The significance of a final criminal conviction for the relationship of trust between pharmacists and patients exceeds that of the mere act or the mere accusation of an act. The public attaches great importance to a conviction, not least because of the presumption of innocence under criminal law. This is exemplified by the actual reactions of the public in connection with the start of the criminal trial and the conviction of the plaintiff by the Regional Court of G. (see pp. 79 and 81 of the administrative file, vol. 2). Finally, the severity of the sentence—even though references to a blanket "minimum sentence" are prohibited—is also an essential aspect in determining unfitness for the profession under licensing law.

49 For these reasons, the fact that the plaintiff confessed to the defendant from the outset does not lead to a different conclusion. This does mean that the partial purpose of Section 8(1)(1) and (2) BApO, which is to enable the licensing authority to have recourse to the investigative powers of the criminal prosecution authorities and thus to the findings of fact of the criminal court, recedes into the background. However, even if the plaintiff confesses to the licensing authority, the licensing authority is not obliged to conclude the administrative proceedings before the end of the criminal proceedings. Rather, for the reasons stated above, the licensing authority may wait before deciding on the revocation of the license—in particular, in order to take into account the sentence imposed by the criminal court and the legal validity of the conviction in its overall assessment. However, it must then — as described — take into account all relevant facts that have occurred up to the time of the official decision.

50 The time elapsed between the last offense and the appeal decision cannot, in itself, refute the assumption that the plaintiff is unfit to practice.

51 The time interval is only one factor among others, which may be of greater or lesser importance depending on the circumstances of the case (OVG North Rhine-Westphalia, decision of January 23, 2014 — 13 A 1636/13 —, juris, para. 8, VG Munich, judgment of October 20, 2015 — M 16 K 15.1873 —, juris, para. 20, Schelling in: Spickhoff, 4th ed. 2022, BÄO § 5 para. 24, cf. also Federal Administrative Court, decision of November 15, 2012 — 3 B 36/12 —, juris, para. 7).

52 Insofar as case law is based in part on specific time limits after which it can be assumed that professional integrity has been regained (see OVG Lüneburg, decision of July 29, 2015 — 8 ME 33/15 —, juris, para. 25; there: at least eight years from the end of the last offense), even according to this case law, these are minimum periods that must be reached in any case. However, even then, it must be assessed in each individual case whether a longer period is to be assumed for the restoration of professional integrity.

53 According to these standards, the period of approximately eight and a half years between the plaintiff's last offense and the defendant's appeal decision does not lead to a different assessment of the plaintiff's professional suitability at the time of the appeal decision and thus to the illegality of the contested decisions. Rather, it can be assumed that, based on the relevant date of the decision in May 2022, a further maturing process on the part of the plaintiff was necessary. The passage of time is also of little significance here due to the criminal proceedings, which will continue until at least June 2021.

54 The plaintiff's reference to Art. 6 (1) ECHR does not help. The Regional Court of G. compensated accordingly for the excessive length of the criminal proceedings. In disputes arising from the core area of public law, however, Art. 6(1) ECHR does not apply (see BVerwG, decision of December 21, 2021 — 9 B 19/21 —, juris, para. 22, and Meyer in: Karpenstein/Mayer, 3rd ed. 2022, ECHR Art. 6 para. 13). The revocation of a pharmacist's license for the purpose of averting danger is such a dispute.

55 According to the standards outlined above, the fact that the professional court for healthcare professions at the Administrative Court of Giessen imposed a reprimand and a fine of EUR 1,000 on the plaintiff (see p. 81 ff. of the paper file) is not decisive for the court's decision. Insofar as the plaintiff wishes to infer from this that the revocation of his license to practice medicine is unlawful (p. 80 of the paper file), the rapporteur does not agree.

56 Insofar as the defendant alternatively argues that there are indications that the plaintiff is unreliable, the reporting judge can, on the basis of the already established unworthiness, leave open the question of whether the plaintiff was also unreliable within the meaning of Section 6 (2) in conjunction with

§ 4 (1) sentence 1 no. 2 var. 2 BapO at the time of the appeal decision.

57 Due to the plaintiff's unworthiness within the meaning of Section 6 (2) in conjunction with Section 4 (1) sentence 1 no. 2 var. 1 BApO at the time relevant to the decision, the defendant had to revoke the plaintiff's license to practice medicine (Section 6 (2) BApO). Contrary to the plaintiff's argument in the grounds for appeal, the defendant had no discretion.

58 The revocation is also not disproportionate. There are no constitutional concerns regarding the application of Section 6 (2) BApO to cases in which the pharmacist is guilty of conduct that has damaged the social security health system

(see BVerwG, judgment of September 26, 2002 — 3 C 37/01 —, ju-ris, para. 17 et seq.).

59 Nor was the defendant—as the plaintiff believes—required, in accordance with the principle of proportionality, to give priority to revoking the pharmacy operating license pursuant to Section 4 (2) ApoG.

60 This is because, pursuant to Section 6 (2) BApO, revocation of the pharmacy operating license can only be considered if the legal requirements for revocation of the license to practice medicine are not met, i.e., the assessment of the incriminated conduct of the person concerned does not (yet) justify the assumption of unreliability or unworthiness to practice the profession of pharmacist within the meaning of Section 4 (1) sentence 1 no. 2 BapO; for the profession of pharmacist also includes the activity as a salaried pharmacist (BVerwG, decision of October 23, 2007 — 3 B 23/07 —, juris, para. 5 with further references). However, as stated above, the defendant is rightly convinced of the unworthiness assumed the plaintiff's necessity.

61 Finally, the principle of proportionality also takes into account the possibility of applying for the reissuance of the license to practice medicine or a professional license pursuant to Section 2 (2)

§ 11 BApO (see BVerwG, decision of October 23, 2007 — 3 B 23/07 —, juris, para. 6, Bavarian Administrative Court,

judgment of November 8, 2011 — 21 B 10.1543 —, juris, para. 38, VG

Gelsenkirchen, judgment of August 25, 2022 — 18 K 3908/20 —, juris, para. 83).

62 The order to surrender the license to practice medicine under point 2 of the contested decision is correctly based on § 52 sentences 1 and 2 HVwVfG. It does not raise any legal concerns.

63 The fee of EUR 350 set out in section 3 of the contested decision (Section 1 (1), Section 2 (1) HVwKostG in conjunction with Section 1 VwKostO-HMSI in conjunction with section 1162 of the Annex to VwKostO-HMSI) and the expenses charged in the amount of EUR 1.55 (Section 9 HVwKostG) do not give rise to any legal concerns, nor does the fee of EUR 258 set for the notice of objection (Section 4 (3) sentence 1 in conjunction with Section 3 (2) HVwKostG). ■

Se cti on s

Report from Berlin



Dr. Christian Jäkel

1. Amendments to the Veterinary Medicines Act and the Pharmacy Act

On December 23, 2025, the law amending the Veterinary Medicines Act (TAMG) and the Pharmacy Act was published in the Federal Law Gazette.¹ The Federal Council had approved it at its meeting on December 19, 2025.² Pursuant to Article 57 of Regulation (EU) 2019/6 on veterinary medicinal products, Member States must submit comprehensive data on the use of antimicrobial medicinal products in animals to the European Medicines Agency (EMA) on an annual basis. Details on data collection are regulated in Delegated Regulation (EU) 2021/578 and Implementing Regulation (EU) 2022/209. The amendment to the TAMG serves to bring national regulations on the recording of antibiotic use in animals into line with EU requirements. In addition, the shipment of prescription veterinary medicinal products will be facilitated in future. The exemptions from the manufacturing authorization will be extended to the preparation, division, or modification of the packaging or presentation of human medicines. Reporting obligations within the framework of Antibiotic minimization will be de-bureaucratized starting in 2027. In the Pharmacy Act (ApoG), the mail-order license will be formally extended to human and veterinary drugs following the

continues to be prohibited. Section 28a ApoG clarifies that a license issued before January 10, 2026 is also valid as a permit for the mail-order sale of veterinary drugs subject to pharmacy-only sale in accordance with Sections 43 and 44a (2) TAMG.

2. BMG: Amendments to Annex III of the Narcotics Act

On December 23, 2025, the amendment to Annex III of the Narcotics Act (BtMG) was published in the Federal Law Gazette.³ Annex III of the BtMG contains marketable and prescribable narcotics. The active ingredient zuranolone was added. According to current scientific findings, the potential for dependence and abuse cannot be ruled out for this active ingredient.⁴ Due to their lower effect, preparations of the substance zuranolone containing a maximum of 50 mg per divided form of the active ingredient are exempt. In addition, these preparations may not contain any other substance

revision of the regulations governing the mail-order sale of veterinary drugs in the TAMG. Electronic commerce in prescription veterinary drugs will remain

150	Pharmaceuticals Act and the Pharmacy Act of December 22, 2025, Federal Law Gazette 2025 I No. 356.	Report from Brussels
2	BR-Drs. 690/25(B).	
3	Twenty-sixth Ordinance Amending Annexes to the Narcotics Act of December 19, 2025, Federal Law Gazette 2025 I No. 365.	
4	BR-Drs. 596/25.	

Annexes I to III. The active ingredient Zurano-Ion is indicated for the treatment of postpartum depression. There is a medicinal product with a Union authorization containing this active ingredient.

3. G-BA: Aut idem — Supplement to the notes on the interchangeability of dosage forms (Annex VII to the Medicinal Products Directive)

Part A of Annex VII to the Medicines Directive contains information on the interchangeability of dosage forms, taking into account their therapeutic comparability (Section 129 (1a) sentence 1 SGB V, aut idem). Medicinal products whose replacement by a medicinal product with the same active ingredient is excluded under Section 129 (1a) sentence 2 SGB V are listed in Part B of Annex VII. The relevant provisions are contained in Section 40 of the Medicinal Products Directive.

In its decision of August 21, 2025, the Joint Federal Committee (G-BA) supplemented the information on interchangeability

⁵ The amendments were published on November 4, 2025, and came into force on December 15, 2025.

Information has been added regarding the interchangeability of the dosage forms powder for solution for infusion, powder for solution for injection, powder for solution for injection/infusion⁶ of the active substance ceftriaxone for intramuscular and intravenous administration.

⁵ BAnz AT 4. 11. 2025 B5, www.bundesanzeiger.de.

⁶ The dosage forms are designated using the standard terms of the European Directorate for the Quality of Medicines (European Pharmacopoeia Commission, EDQM).

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Report from BRUSSELS



Dr. Lea Hachmeister and Elisabeth Kohoutek

1. EU Biotech Act — new achievements for clinical research

On December 16, 2025, the EU Commission presented the first part of the EU Biotech Act.¹ The aim of the legislative project is to strengthen the competitiveness of the European biotechnology sector and promote innovation along the entire value chain, from research and clinical development to financing and market access.

The first part of the Biotech Act has a clear focus on clinical research: in this area, the reform measures are aimed in particular at setting time limits for approval procedures. By the end of January 2026, a number of regulatory authorities in Europe, including the BfArM and the PEI, will participate in a pilot project called FAST-EU (Facilitating and Accelerating Strategic Trials). This is a coordinated fast-track procedure for the evaluation and approval of multinational clinical trials. The aim is to reposition Europe as an attractive location for clinical research in the international arena, thereby giving patients earlier access to innovative therapies.

With regard to clinical trials, the draft regulation provides for the following amendments, in particular to Regulation 536/2014 (CTR):

i. **Decentralization:** direct distribution of study medication to the private addresses of study participants

is to be included in the CTR. This harmonization is welcome and closes the circle with Section 47 AMG, which has already been amended in line with the Medical Research Act.

ii. **Data protection legal basis:** the draft provides for a harmonized legal basis for data processing in the context of clinical trials. In future, the uniform legal basis is to be Art. 9 (2) (i) GDPR (public interest in the area of public health). Deviating national regulations are to be excluded (cf. Art. 9 (4) GDPR). This proposal represents a considerable simplification for multinational clinical trials.

iii. **Data protection controllers:** The sponsor and the trial site should each be controllers under the GDPR. Whether they are joint controllers or individual controllers is not specified.

iv. **Secondary use:** The processing of health data from a clinical trial for further research purposes should be possible in future without renewed consent.

v. **Faster approval procedure:** Approval for multinational clinical trials under the

¹ Press release from the EU Commission dated December 16, 2025, available at: https://commission.europa.eu/news-and-media/news/commission-proposes-new-measures-improve-health-and-healthcare-sector-2025-12-16_en, last accessed on January 10, 2026.

CTR should be issued within 75 days if no additional information is required, or even within 47 days. The additional 50-day period for clinical trials with advanced therapy medicinal products (ATMPs) under the CTR would be eliminated.

vi. **Minimally invasive studies:** for so-called minimally invasive studies, in which additional diagnostic or monitoring procedures are carried out that involve only minimal additional risks or burdens for the participants, only the approval of an ethics committee will be required in future.

vii. **Combined clinical trials:** The Biotech Act introduces a single application for combined clinical trials, i.e., trials that combine a clinical trial with a drug with a performance study of an in vitro diagnostic device or with a clinical investigation of a medical device. Under current law, the sponsor must apply for separate approvals for each of these studies in accordance with the respective regulations. The new rules for combined studies are intended to eliminate these regulatory friction losses by eliminating the need to submit separate applications under CTR and MDR/IVDR.

viii. **Support for innovation:** The proposal provides for so-called regulatory sandboxes in the sense of real-world settings in which novel approaches and innovations in the field of clinical trials can be tested, such as AI-supported study designs, decentralized studies, and new methods of data collection.

In addition, the draft Biotech Act provides for the following further adjustments, among others:

i. **Supplementary protection certificates:** Companies will in future be able to obtain an additional year of patent protection for biopharmaceuticals. Currently, protection under the supplementary protection certificate (SPC) is limited to 5.5 years. However, the requirements for this are quite strict and require (i) a new active ingredient that differs "significantly" from that of an approved drug,

(ii) a "significantly different" mechanism of action with safety and efficacy at least equivalent to that of authorized medicinal products for the same disease, (iii) clinical trials to evaluate efficacy and support approval, conducted in more than two Member States, and (iv) at least one manufacturing step—excluding packaging, testing, and certification—carried out within the EU.

ii. **Use of AI, data, and digitalization:** the use of AI, high-performance computers, and data infrastructures in biotechnology is to be promoted. Among other things, trustworthy testing environments, improved data use, and support for SMEs in the use of digital technologies are planned, in accordance with the AI Regulation and existing data protection regulations.

iii. **Artificial intelligence:** the EMA is to publish guidelines on the use of advanced technologies, including AI, in the drug development lifecycle—from preclinical research, clinical development, and trials to manufacturing and post-authorization monitoring.

iv. **Biosecurity and biodefence:** in view of increasing dual-use risks, the Biotech Act provides for binding biosecurity measures. These include requirements for screening recipients of sensitive biological materials, stricter sequence screening, and the expansion of early warning and defence capabilities against biological threats.

Good approaches, but not yet final: the Biotech Act is a proposed regulation and is currently going through the regular legislative process. It is not expected to come into force before the end of 2026.

2. EU Commission proposes targeted simplification of MDR and IVDR

On December 16, 2025, the EU Commission presented a reform proposal to amend Regulation (EU) 2017/745 on medical devices (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR).² The aim is to simplify the regulations, make them faster and more effective, and further promote competitiveness, innovation, and patient safety.

Essentially, the reform proposal includes the following adjustments:

i. **Risk classification:** The risk classification rules are to be amended (Annex VIII MDR). In addition to reusable surgical instruments and accessories for active implantable medical devices, software may also be classified in a lower risk class in the future. This is because the reform proposal also covers Rule 11 of the MDR on the classification of software. Under the current version, very few software products fall under risk class I. The new version of Rule 11 initially classifies software in class I, unless higher classification criteria apply. This is a reversal of the previous logic, with class I being defined by the exclusion principle.

In future, medical device software intended to generate output that has clinical utility and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation, or alleviation of a disease or condition will generally be classified as Class I. As before, Rule 11 specifies cases in which a higher classification is applicable. For classification in Class IIa, Rule 11 specifies the use of software in "non-critical situations." Whether this criterion in particular has actually significantly expanded the scope of Class I products is questionable and remains to be seen.

If the scope of Class I is indeed expanded, this change could also have an impact on the applicability of the AI Regulation to AI-based medical device software. This is because in the

2 press release of the EU Commission dated December 16, 2025, available at: https://health.ec.europa.eu/publications/proposal-regulation-simplify-rules-medical-and-vitro-diagnostic-devices_en?prefLang=de, last accessed on January 10, 2026; Draft Regulation COM(2025) 1023 final of

December 16, 2025, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=comnat:COM_2025_1023_FIN, last accessed on January 10, 2026.

As a rule, medical devices in risk class IIa and above are subject to the AI Regulation as so-called high-risk AI.

ii. **AI-based medical devices:** The EU Commission envisages a fundamental realignment of the interaction between the AI Regulation and the regulation of medical devices. In future, medical devices and in vitro diagnostics are likely to fall within the scope of the AI Regulation only to a very limited extent. The MDR and IVDR are to be moved from Section A to Section B of Annex I of the AI Regulation as harmonization provisions. Background: Article 2(2) of the AI Regulation stipulates that high-risk AI systems covered by Section B are largely exempt from the obligations of the AI Regulation. For AI-based medical devices and in vitro diagnostics, this means that the material requirements for high-risk AI systems in particular do not have to be met. Accordingly, in future, only the MDR/IVDR would apply to medical devices and in vitro diagnostics. This would avoid duplication of regulations and overlaps between legal acts.

iii. **Person Responsible for Regulatory Compliance (PRRC):** Detailed qualification requirements are to be eliminated. For SMEs, when using an external PRRC, their availability will suffice in the future instead of a "permanent and continuous" presence (Art. 15 MDR/IVDR).

iv. **Certificate of conformity:** The previous maximum validity period of five years is to be abolished. In future, certificates of conformity issued by notified bodies will be valid indefinitely. Instead of recertification, notified bodies will carry out periodic reviews appropriate to the risk for as long as the certificate is valid (Art. 56 MDR; Art. 51 IVDR).

v. **Clinical evidence:** The concept of clinical data is to be expanded, the use of clinical data from equivalent medical devices is to be made more flexible, and the possibility of basing safety and performance exclusively on non-clinical data is to be strengthened (Art. 2 No. 48, Art. 61, Annex II and XIV MDR; Annex XIII IVDR).

vi. **Combined studies:** For combined studies involving medicinal products, medical devices, and/or in vitro diagnostic medical devices, a single application for coordinated assessment in accordance with the CTR should suffice in future (new Art. 79a MDR, new Art. 75a IVDR).

vii. **Well-established technologies:** A definition for medical devices based on well-established technologies ("well-established technology devices") is to be created. Simplified rules are to apply to these products (Art. 2 No. 72, Art. 18, Art. 32, Art. 52, Art. 53, Art. 54, Art. 55, Art. 56, Art. 57, Art. 58, Art. 59, Art. 60, Art. 61, Art. 62, Art. 63, Art. 64, Art. 65, Art. 66

(Art. 2 No. 72, Art. 18, Art. 32, Art. 52, Art. 61, Art. 86 MDR).

viii. **In-house devices:** The conditions for manufacturing and using self-developed medical devices and in vitro diagnostics in healthcare facilities should be simplified. Transfers of in-house devices to other healthcare facilities should be permitted under certain conditions. Under the IVDR, the requirement that no equivalent product be available on the market should be waived. Central laboratories for clinical trials should be covered by the exemption (Art. 5 (5) MDR/IVDR).

ix. **Regulatory sandboxes:** To promote innovation, so-called regulatory sandboxes are to be introduced. These will enable manufacturers or potential manufacturers to develop, test, validate, and, if necessary, use innovative products under real-world conditions for a certain period of time under regulatory supervision without having to meet all regulatory requirements (Art. 59b, c MDR; Art. 54b, c IVDR).

x. **Digital compliance instruments:** As part of its digitalization efforts, the draft regulation provides for the following measures in particular: (i) electronic instructions for use for patient-related tests, (ii) submission of the EU declaration of conformity, information, and documents in digital form, as well as electronic transmission of documents to notified bodies, (iii) subject to future implementing provisions, certain information on the product label may be provided in digital form (Art. 19, Art. 52b, Art. 110a MDR, Annex I and VI MDR; Art. 17, Art. 48b, Art. 103a IVDR, Annex I and VI IVDR).

The next steps: the legislative proposals to simplify the regulations on medical devices and in vitro diagnostic medical devices will now be submitted to the EU Parliament and the Council for adoption. Furthermore, ^{comments on}the draft can be submitted until the beginning of March 2026

3 Comments can be submitted on the EU Commission's website, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14808-Medical-devices-and-in-vitro-diagnostics-targeted-revision-of-EU-rules_en, last accessed on January 10, 2026.

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