

European Commission proposes transferable data exclusivity vouchers to tackle the antimicrobial resistance crisis

Sponsored by



Marco Stief August 14, 2023



Marco Stief of Maiwald considers a regulatory proposal designed to promote antimicrobial R&D and address the ineffectiveness of patent protection, but points out that the proposal lacks clarity and there might be a high price to pay

To effectively combat the antimicrobial resistance (AMR) crisis and promote antimicrobial innovation, the European Commission proposes, in the articles of Chapter III of the new [Regulation on the reform of the EU pharmaceutical legislation](#) (the Draft Regulation), the creation of a transferable data exclusivity voucher as a regulatory incentive for the development of 'priority' antimicrobials.

According to Article 40 (2) of the Draft Regulation, which was published in April 2023, the voucher shall grant its holder an additional year's data protection for an authorised medicinal product.

This article explains the background of the regulation and the substantive conditions for granting the voucher, as well as the provisions governing the transfer and effect of the voucher.



It is expected that data exclusivity vouchers will become a strong focus of pharmaceutical patent strategies and will have particular relevance in pharmaceutical R&D. In practical terms, the voucher would extend the regulatory data protection of a blockbuster drug to compensate for investments in antimicrobial R&D, generally not a very profitable field of innovation.

Nevertheless, this measure remains controversial: the price to be paid for vouchers by national healthcare systems can be too high.

The ‘silent pandemic’

AMR, also known as the ‘silent pandemic’, is responsible for an estimated 33,000 deaths per year in the EU and imposes high costs on healthcare systems. Resistance of microbes to antibiotics can be due to the natural characteristics of certain organisms or the result of genetic mutations that have arisen through natural evolution or horizontal gene transfer, allowing the transfer of resistance between different bacterial species.

Investment in R&D of novel antimicrobials is urgently needed to effectively address AMR. However, the high public health demand does not correspond to the current supply in the pharmaceutical industry (see Recital 77 of the Draft Regulation), due to technical aspects of R&D in the antimicrobial field, and the lack of effective regulatory incentives and public health measures to curb the overuse of antibiotics, often referred to as market failure.

Furthermore, the ineffectiveness of patent protection per se regarding this field of innovation is a factor to be noted. The incentives of patent protection can, in fact, exacerbate the problem. A patent does not guarantee its holder a return on investment, but only a market opportunity to achieve it, which can only be realised if the sales volume during the lifetime of the patent meets profit expectations.

The pressure to generate sales, and thus profits, during the limited protection period of the patent can thus lead to a careless use of antibiotics, which exacerbates the problem of increasing resistance and runs counter to the political and public health goals of maintaining the effectiveness of the antimicrobial agent. For this reason, what is needed are regulatory solutions that essentially aim at decoupling return on investment from the sales volume of antibiotics.

‘Priority antimicrobial agent’ within the meaning of the Draft Regulation

The granting of the voucher is at the discretion of the European Commission and is linked to the formal and material requirements of Article 40 (1), (3) and (4) of the Draft Regulation.

The voucher model is only intended to reward breakthrough innovations in the field of antimicrobial agents (see Recital 80 of the Draft Regulation). It can therefore only be granted in relation to medicinal products for human use that constitute a ‘priority antimicrobial’ within the meaning of Article 40 (3) of the Draft Regulation; i.e., if preclinical and clinical data demonstrate a significant benefit in terms of AMR and it has at least one of the following characteristics:

- It represents a new class of antimicrobials;
- Its mechanism of action is distinctly different from that of any authorised antimicrobial in the EU; and/or
- It contains an active substance not previously authorised in a medicinal product in the EU that addresses a multi-drug-resistant infection or a serious or life-threatening infection.

Article 40 (3) of the Draft Regulation further specifies that in the scientific assessment of the above criteria and in the case of antibiotics, the European Medicines Agency shall consider the “WHO [World Health Organization] priority pathogens list for R&D of new antibiotics” or an equivalent list drawn up at EU level. The WHO priority list, in the development of which scientists from the German Centre for Infection Research at the University of Tübingen were substantially involved, categorises pathogens into three priority levels.

The most critical group includes multi-drug-resistant bacteria, which pose a particular threat in hospitals, nursing homes, and patients whose care requires devices such as ventilators and blood catheters. These include *Acinetobacter*, *Pseudomonas* and various *Enterobacteriaceae*. They can cause serious, and often fatal, infections such as bloodstream infections and pneumonia.



The second and third tiers of the list – the high and medium priority categories – include other increasingly drug-resistant bacteria that cause more common diseases such as gonorrhoea and food poisoning from *Salmonella*.

Effect of the voucher

According to Article 41 (1), paragraph 1, a voucher may be used to extend the regulatory data protection for the priority antimicrobial product or another medicinal product authorised under this regulation by the applicant or another marketing authorisation holder by 12 months.

Article 41 (1), paragraph 2 clarifies that the voucher may only be used once and only for a single, centrally authorised medicinal product, and only if this medicinal product is within the first four years of its legal data protection. The fact that the voucher can be used for a centrally authorised medicinal product other than the priority antimicrobial is intended to decouple the return on investment from the volume of sales of the antibiotic. This aims at reducing and mitigating the economic incentives of the traditional pharmaceutical business model. Otherwise, **maximising sales profits would ultimately promote the emergence and spread of AMR due to misuse and overuse.**

The use of the voucher within the first four years of the regulatory data protection of the respective authorised medicinal product serves the purpose of predictability for the competition, **especially generic manufacturers**, which will refer to the medicinal product of the prior applicant in their marketing authorisation application after the expiry of the regulatory data protection.

Transfer of the voucher

Of particular economic interest for pharmaceutical companies active in R&D of antibiotics is the commercial transferability of the voucher as provided for in the Draft Regulation. Article 41 (3) allows the voucher to be transferred once to another marketing authorisation holder. A second purchase is explicitly prohibited.

The transferability of the voucher **should also benefit companies that do not have a particularly lucrative patent portfolio**, so that the investments in R&D of the antibiotic product can be compensated for by the income from another potentially more profitable product. This aspect is crucial for the antimicrobial market given the significant role of SMEs (see Recital 77 of **the Draft Regulation**). If the voucher is tradable, its holder can participate by way of transfer in a share of the profits generated by the sale of the medicinal product covered by the buyer's exclusivity.

To ensure that the financial reward, ultimately borne by the healthcare systems, is largely absorbed by the developer of the priority antimicrobial and not by the purchaser of the voucher, the European Commission limits the number of vouchers available on the market to ten in any 15-year period.

Final thoughts

The major advantage of the voucher model in combating the AMR crisis is the decoupling of the return on investment from the volume of sales of antibiotics to the extent that the voucher can be used for a medicinal product authorised other than the priority antibiotic. A data exclusivity voucher may prove to be particularly profitable in the industrial property portfolio of SMEs and pharmaceutical conglomerates, especially as it may reflect the value of the extension of the regulatory data protection of a highly profitable medicinal product by way of transfer.

It is expected that pharmaceutical R&D in the field of antimicrobial agents will gain in importance by creating more synergies between SMEs specialised in antimicrobial research and large corporations that can make the necessary investments and have the knowhow in manufacturing, production, and distribution. Therefore, as part of a diversified patent strategy, it is recommended that pharmaceutical R&D, especially in the antimicrobial field, be more orientated towards obtaining or transferring a data exclusivity voucher alongside other well-known industrial property rights.

However, this regulatory solution has ignited controversy among **generic and originator companies, consumer rights non-governmental organisations**, and SMEs in the field of antimicrobial R&D. One of the most important objections raised is that by extending the regulatory data protection of a blockbuster drug by one year, the voucher model will lead to high healthcare costs.



These costs will have to be borne by the healthcare systems of the member states, a fact that the European Commission is well aware of, as evidenced by Recital 81 of the Draft Regulation. In the US, for example, extending the protection of a hit patent on blockbuster drugs for up to two years at the beginning of the 21st century would have had a social cost of \$7.7 billion. This amount is significantly higher than the estimated \$400–800 million for the development of new antibiotics over the same period. Even if the duration of the extension is limited to one year, overcompensation remains highly likely.

One has to ask if vouchers are indeed the best and most cost-efficient instrument to tackle the silent pandemic.

TAGS

FEATURES

PATENTS



Marco Stief

PARTNER Maiwald
