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Vouchers in the revision of the pharmaceutical legislation – costly and inefficient

Opinion from German Social Insurance
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I. Statement

1 _ The German Social Insurance rejects the incentive system with vouchers planned by the European Commission

The European Commission plans to present its proposals for the revision of the pharmaceutical legislation this spring. The legislative proposal aims to improve access, availability and affordability of medicines as well as to strengthen the competitiveness of the European pharmaceutical industry. The revision is part of the implementation of the pharmaceutical strategy. In particular, the focus is on promoting innovation in unmet medical needs, reducing the environmental impact of medicines and ensuring better access to innovative and proven medicines for patients.

The European Commission is also focusing on the development of new antibiotics needed to treat infections caused by multi-resistant bacterial pathogens. As reserve antibiotics, they should at best only be used after strict indication. Due to foreseeable lower sales figures, there is therefore no sufficient entrepreneurial incentive for pharmaceutical companies to develop new products. In order to provide incentives for the development of new antibiotics, the European Commission plans to introduce transferable exclusivity vouchers (also known as vouchers or TEE - Transferable Exclusivity Extension). The developer or licence holder of the new antibiotic can apply it once to a medicinal product of his choice that has a central marketing authorisation. The voucher then extends its data protection period by one year under certain conditions. The voucher can also be sold to another pharmaceutical company.

According to the current considerations of the European Commission, it should be possible to issue the vouchers if the manufacturer develops a new antibiotic that fulfils the criteria of a so-called "priority antimicrobial", i.e. represents a new class of antimicrobial agents, has a different mode of action than the other already approved medicinal products or generally uses an active ingredient not yet approved in the EU. The preclinical and clinical data must also indicate a significant clinical benefit with regard to antimicrobial resistance. The manufacturer should also be able to supply the new antimicrobial agent in sufficient quantities and disclose any public research funding received for it. Finally, the voucher should only be usable within the first four years of the data protection period of the medicinal product to which it is to be applied. The European Commission is currently planning with this regulation that no more than 10 such vouchers can be issued in a period of 15 years from the date of application of the new regulation.

Regardless of the intended supposedly restrictive framework of application, the German Social Insurance rejects the new voucher system. Should, as the European Commission intends, a system be created that keeps medicines affordable for health systems and at the same time rewards innovation, a voucher system is counterproductive.

1.1 _ High costs

Vouchers are disproportionately expensive as manufacturers could apply them to any medicinal product of their choice that fulfils the conditions mentioned and records maximum sales according to the current plans of the European Commission. Extended terms of patent inhibit the development of competing products and delay their market access.

This includes profitable blockbusters with annual sales of over one billion euros. However, it is precisely here that generic competition is particularly important for the affordability of medicines and the financial sustainability of healthcare systems. The European Commission estimates the value of a voucher at an average of around 360 million euros. Patients and contributors have to bear a higher financial burden: In addition to the expenses for incentivisation, delayed generic competition also inevitably leads to higher pharmaceutical expenditures.

1.2 _ No guarantee of access to antibiotics

Merely the grant of a marketing authorisation does not guarantee the availability of an antibiotic on the market. Part of the launch strategies of pharmaceutical companies is also, especially in less financially strong markets, a strongly delayed market entry with submission of the documents relevant for benefit assessment and price negotiation in the national healthcare systems. The present draft therefore does not guarantee that patients will actually have access to the newly developed antibiotic when they use the voucher. It must be ensured that urgently needed new antibiotics are available in all Member States and that all patients can benefit from them.

1.3 _ Distortion of competition

Competition is not only negatively affected by vouchers, in that the extension of market exclusivity periods delays generic entry for top-selling medicines. Transferable vouchers are also systematically favoured by large pharmaceutical companies that have correspondingly high-turnover medicinal products in their portfolio for which the purchase of a voucher is worthwhile. They benefit from additional profits due to the extended exclusivity and can strengthen their market

power, although no additional incentives would have been needed. Thus, only a part of the financial incentives associated with the voucher reaches the actual developers and producers of antimicrobials, which are often smaller companies.

1.4 _ Alternative incentive mechanisms

It is questionable whether the European Commission's voucher strategy offers any feasible incentive at all to obtain the availability of the desired new antimicrobial agents, which are particularly effective against multi-resistant pathogens. In view of the high costs for health systems, the focus should be on approaches that ensure use of a new (reserve) antibiotic with restraint and in small quantities, and that access is guaranteed across the single market.

There are alternative proposals for incentive schemes that could better address the problem of lack of investment in the development of new antibiotics. One example of this is market launch premiums, which are paid independently of prescribed quantities, thus decoupling the income or payment from sales. There is also the possibility of direct development funding in the form of milestone bonuses or the establishment of research funding funds through so-called play-or-pay mechanisms. Also under discussion are a Europe-wide annual revenue guarantee, the purchase of patents or production licences, or compensation for research and development expenses.

1.5 _ Increased preventive measures against antibiotic resistance

As a creeping pandemic, antimicrobial resistance is a global problem. In addition to the development of new antibiotics, focus must be on the need for preventive measures, which in particular ensure that antibiotics and especially reserve antibiotics are used with restraint and according to indication. A study published in November 2022 on behalf of the European Commission shows that relevant quantities of antibiotics continue to be taken in Europe without a doctor's prescription or without indication. Obligations to limit prescription durations and package sizes are also not handled in the sense of an objectively appropriate use of antibiotics to prevent resistance. To combat antibiotic resistance, the European Commission already has plans to introduce mandatory stewardship programmes for the proper use and prevention of resistance. The first measures to reduce the use of reserve antibiotics in livestock farming were also adopted. Consistent hygiene measures to pre-vent nosocomial infections and an expansion of surveillance of resistance and antibiotic use are also indispensable. These measures must be consistently implemented and further developed - also by strengthening international cooperation.

About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations for statutory health and longterm care insurance funds at the federal level and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance - Working Group Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e. V.) with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union (EU) as well as other European institutions and advises the relevant stakeholders in the context of current legislative projects and initiatives. As part of the statutory insurance system in Germany, health and longterm care insurance, pension insurance and accident insurance offer effective protection against the consequences of major risks to life.