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Deutsche Sozialversicherung
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DSV's position in brief

Reform of the EU pharmaceutical legislation

In April 2023, the European Commission presented legislative proposals for the reform of the European pharmaceutical legislation. The proposals aim to secure and improve access, affordability and availability of medicinal products in the European Union (EU). In addition, there is a greater focus on modernising authorisation procedures and creating a binding environmental risk assessment. In addition, parallel to the reform of the pharmaceutical legislation, intellectual property rights are to be revised in order to create more transparency for supplementary protection certificates and to make their award uniform throughout the Union.

The German Social Insurance (DSV) welcomes the objectives of the European Commission pursued with the reform proposals. In order to ensure financially sustainable and resilient healthcare systems, the availability of medicinal products with a proven high benefit as well as high-quality care for the insured persons, the DSV believes that improvements to the regulatory proposals are necessary. The solidarity community must not be burdened by expenses that do not bring any actual benefit to patients.

Affordability – shorten regulatory and patent protection

For 61 per cent of new medicinal products, the longest effective protection against competition is provided by patent law or a supplementary protection certificate and not by pharmaceutical legislation.[1] The longer the corresponding protection periods for medicines, the later competition from cheaper generics and biosimilars will set in. This leads to higher pharmaceutical prices, which place a greater financial burden on health insurance systems in the Member States. From the DSV's point of view, the European Commission's proposals to shorten regulatory protection periods and patent protection must therefore be coordinated.

➔ In order to promote price-cutting competition, regulatory protection in pharmaceutical legislation should be limited to a maximum of eleven years and the period of validity of an SPC should be shortened to a maximum of four, instead of five years.

[1] Copenhagen Economics: Study on the economic impact of Supplementary Protection Certificates, pharmaceutical incentives and rewards in Europe, 29 May 2018. Please visit https://health.ec.europa.eu/latest-updates/study-economic-impact-supplementary-protection-certificates-pharmaceutical-incentives-and-rewards-2018-05-29_en

- To strengthen transparency, a database for all regulatory and patent deadlines should be established at the European Union Intellectual Property Office (EUIPO).

- The procedure for granting SPCs at European level, centralised by the European Commission, should always take precedence over national awards and the granting of an SPC should be limited to the primary patent in order to prevent a "patent thicket".

- The proposed exemption from intellectual property protection ("Bolar exemption"), which allows successor products, generics and biosimilars of patent-protected medicines to prepare for marketing authorisation, HTA assessment or pricing and reimbursement while the patent is still valid, is welcome.

- The regulations on re-purposing, the identification of new therapeutic uses for established medicinal products by organisations without financial interests, are sensible as they allow the results of independent studies on established medicines to be used without leading to unreasonable price increases.

Access – Targeting incentives for orphan drugs and closing therapeutic gaps, ensuring quality of authorisation procedures

Improving access to medicinal products is a priority of the amendment to the legislation on medicinal products and helps ensuring medical care for patients. The focus here is on medicinal products for rare diseases ("orphan drugs") and those needed to close therapeutic gaps ("Unmet Medical Needs - UMN"). From the point of view of the DSV, the steering mechanisms proposed by the European Commission, which are aimed at incentivising orphan drugs, must therefore be adapted.

- The prevalence threshold for defining a rare disease must be tightened and false incentives through ever new indications for the same preparation must be prevented by introducing an "overall prevalence".

- The profitability criterion for orphan drugs should be reintroduced. In addition, the orphan privilege should expire if sales of more than €100 million are achieved in the Union within twelve consecutive months.

- Market exclusivity for orphan drugs must be shortened to seven years instead of nine in order to provide stronger incentives for the development of orphans that close a therapeutic gap.

➔ Evidence generation for conditional marketing authorisations must be strengthened. Faster market access does not represent a healthcare advantage if risks are shifted to patients by medicinal products that have not been adequately tested in clinical trials.

Availability – Avoiding delivery and supply bottlenecks through improved monitoring

Shortages of medicinal products are a Europe-wide and global phenomenon. In order to improve availability and security of supply, the DSV believes that the marketing authorisation holders must be held more accountable in the future and that EU-wide monitoring must be expanded. It must not be interfered with the competence of the Member States with regard to the pricing and reimbursement of medicinal products.

➔ The existing system for monitoring medicinal products must be used to establish a monitoring system that provides an overview of the current supply-demand situation of medicinal products at all times. This could be done through the further use of safety features for medicinal products and an AI-enabled automatic evaluation of the collected data.

➔ Requiring marketing authorisation holders to report impending supply bottlenecks and to draw up plans to systematically avoid such bottlenecks is an appropriate way to avoid supply shortages.

➔ Strengthening the role of the European Medicines Agency and closer cooperation between national and European authorities makes sense in order to identify shortages in medicinal products at an early stage.

Antimicrobial resistance – Preventing the development of resistance, accelerating pharmaceutical research

Multi-resistant germs are responsible for about 33,000 deaths a year in Europe. Effective antimicrobial medicinal products are rare and cannot generate sufficient market sales as "reserve antibiotics". Where entrepreneurial initiative turns out to be futile, the DSV therefore believes that joint strategies are needed to safeguard research, development and prescription of these important medicinal products.

➔ It makes sense to prevent antimicrobial resistance from developing in the first place by establishing stewardship plans and improving the education of health workers.

- There should be a general prescription requirement for antimicrobials. Exceptions are only appropriate for harmless indications and low-risk agents in everyday care.

- Trying to stimulate research and development of antimicrobials through transferable exclusivity vouchers ("vouchers") does not make sense. This tool is very expensive. In addition, neither access nor the market introduction of effective agents with new modes of action can be guaranteed. In the view of the DSV, what is needed instead are targeted measures to promote research; if necessary, also joint procurement of active ingredients.

Ecological sustainability – Sanctioning pollution, avoiding pharmaceutical waste

Ecological sustainability is of high importance in the production, distribution and use of medicinal products. In view of climate change and the numerous ecological challenges facing society, the DSV expressly supports the binding and comprehensive regulations proposed by the European Commission with regard to environmental sustainability.

- The Environmental Risk Assessment (ERA) of medicinal products must become a mandatory part of the marketing authorisation. Therefore, the benefit-risk assessment should not only focus on the quality, safety and efficacy of the medicinal product, but also include adverse effects on the environment.

- In order to limit pharmaceutical waste and waste of resources, the specification of therapy-appropriate packaging sizes should apply not only to antimicrobial medicines, but to all medicinal products.

- The planned electronic package leaflet also makes sense for reducing paper waste. However, at the patients' request, a free printout should still be possible. According to the DSV, the pharmaceutical company shall bear the costs for this.

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 of statutory health and longterm care insurance funds as well as 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 and other European institutions and advises the relevant players in the context of current legislative projects and initiatives. The health and long-term care insurance with 74 million insured persons, the pension insurance with 57 million insured persons and the accident insurance with over 70 million insured persons in 5.2 million member companies, including the agricultural social insurance with its insured persons and 1.4 million member companies, offer citizens in Germany effective protection against the consequences of major life risks as part of a statutory insurance system.