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# "A pharmaceutical strategy for Europe"

## Opinion of the German Social Insurance
## 20th January 2021

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and the national associations for statutory health and long-term care insurance have joined together because of their common European policy interests to form the "German Social Insurance - European working group".

The German Social Insurance represents the interests of its members vis-à-vis the EU bodies and other European institutions and it will advise the relevant actors with regard to the context of current legislative projects and initiatives.

Being part of Germany's statutory security system, the health and long-term care insurance, pension insurance and accident insurance organisations all provide effective protection against the consequences of major life risks.

## I. Preliminary remarks

On 25th November 2020, the European Commission published a communication[1] about its "Pharmaceutical strategy for Europe". Under four headings, it subsumes a comprehensive set of proposals that should ensure the quality and safety of pharmaceutical supplies and will also simultaneously increase the sector's global competitiveness:

- covering unmet medical needs and ensuring access to and the affordability of medicines,
- the competitiveness and innovation potential of the European pharmaceutical industry,
- crisis preparedness, response and resilience, supply chains and strategic autonomy, sustainable medicines,
- international cooperation.

[1] (COM)2020 761 final

The pharmaceutical strategy is intended to be a further building block in stabilising the EU pharmaceutical market with regard to its global context and it will also contribute to ensuring supply reliability. As a result, there will be a comprehensive review of the current regulatory framework for medicinal products over the next two years.

**The German Social Insurance ...**

... welcomes the European Commission's focus on the availability and affordability of medicines. This means that it will deal justly regarding the importance of these products for health care. It must be possible to guarantee the supply of medicines to the general public at all times.

Pharmaceutical expenditure by the statutory health insurance sector in Germany together with co-payments by the insured increased again in 2019 by 5.4 percent to more than 43 billion euros. They account for 17.2 percent of the health insurance sector's expenditure on benefits, making them the second-largest expenditure block. Slightly less than half of sales are generated by patent-protected medicines. They are seven times more expensive than non-patented medicines and represent only 6.4 percent of the volume of prescribed DDD (Defined Daily Doses)[2]. Patent-protected medicines have been the main cause of rising medicinal expenditure by the health insurance sector for many years now. Although orphan drugs have a small share in the health insurance market they show pronounced price dynamics. Their share of the total DDD volume is only 0.04 percent; however, they still cost the health insurance sector 3.41 billion euros (2019). Their sales have increased 6-fold since 2007. They are 27 times more expensive than the already expensive patent-protected medicines.

Unforeseen events such as the COVID-19 pandemic demonstrate the importance of sustainable and effective healthcare systems. Therefore, the opportunities provided by European cooperation should be used in order to protect healthcare systems from being financially overstretched. Pharmaceutical prices are of prime importance in this context.

Therefore, the forthcoming review of the regulatory framework for medicinal products at European level must be carried out from the perspective of patients' interests and the sustainability of healthcare systems: As a matter of principle, the interests of the insured and patients must take precedence over corporate interests.

[2] Quoted from Ulrich Schwabe et al., 2020 Drug prescription report

The smooth functioning of the internal market also plays a central role in ensuring a sustainable, comprehensive and economic supply of medicinal products in Europe. This applies all the more so as the pressure on the resources of the healthcare systems increases due to the ageing of societies, progress in medical technology as well as the high-price strategies implemented by pharmaceutical companies.

# II. Comments

## 1. Covering unmet medical needs and ensuring access to and the affordability of medicines

**The European Commission would like to ...**

... promote access to necessary, innovative and affordable medicines and cover unmet medical needs such as antibiotics or medicines for orphan diseases. Research is to be supported and approval accelerated by facilitating cooperation between the institutions involved. It also intends to review the incentive system, the legislation on the obligations of manufacturers, the interchangeability of generics and biosimilars and the competitive functioning of the markets. Innovative procurement concepts are to be promoted. Non-legislative measures should create transparency regarding the R&D costs of medicines and the exchanging of best practices for pricing, payment and procurement policies should be intensified at relevant authorities level. Measures should be specifically proposed for antibiotics to optimise their use.

**The German Social Insurance ...**

... welcomes the European Commission’s intention to promote R&D and to create incentives for novel antimicrobial medicines. Optimisation of existing regulatory instruments in terms of their use to combat resistance and promote prudent use of antibiotics is also welcomed.

Reform of the legislation on orphan medicinal products must ensure that only medicinal products offering a proven additional therapeutic benefit are promoted. Considerations to link the duration of the SPCs (Supplementary Protection Certificates) to additional conditions, such as the obligation to deliver to all member states are also supported, but they will not eliminate the problem that many dis-

eases still cannot be treated on the one hand and some orphan drugs have become blockbusters due to their exorbitantly high prices and extended indications on the other.

The possibilities for using large amounts of data are increasing as well as the potential for therapeutic advances and healthcare research. The EU should use its opportunities here to promote pan-EU cooperation and generate new knowledge.

The German Social Insurance also stands by the strengthening of HTA (Health Technology Assessment) cooperation. However, member states must retain individual room for manoeuvre. The member states must continue to decide on prices and reimbursements due to the differences in system conditions.

The fact that competition in the generic and biosimilar sectors is to be explicitly promoted in the reform of the legislation on medicinal products is to be welcomed.

The European Commission is reluctant to make proposals on the affordability of medicines. However, the fact that the R&D costs of pharmaceuticals are to be made transparent is a right step. This can positively support price and reimbursement negotiations at the national level. In addition, the European Commission is focusing both on the development of best practice exchanges between competent authorities and on the European semester and the issuing of country-specific recommendations to ensure access and efficiency in supplying medicines.

## 2. Competitiveness and innovation in the European pharmaceutical industry

**The European Commission would like to ...**

... strengthen the competitiveness of the European pharmaceutical industry by streamlining authorisation procedures, further developing authorisation conditions and adjusting European Medicines Agency (EMA) fees. The system of supplementary protection certificates is to be revised as part of the action plan covering intellectual property and a European health data governance, to which the industry will also have access, should also be established. By 2025, a pool of ten million genomes is to be built up and made available for research and innovation. Electronic product information (ePI) is intended to make medicinal products even easier to trade within the European internal market and therefore be available across the board.

**The German Social Insurance ...**

... agrees with the European Commission that reliable and competitive industrial partners are needed to ensure the supply of medicines to the general public.

However, a revision of pharmaceutical legislation must not lead to a lowering of protection and safety standards. An extension of the special regulations for accelerated approval procedures would unjustifiably shift the risks for patients from controlled clinical trials to the less controllable everyday practice. Market exclusivity rights must not be extended any further when optimising the SPC system.

In the opinion of the German Social Insurance, the potential offered by digitisation should be harnessed for the innovative development of medicines. It is good that the EU wants to support such joint projects. The establishment of open platforms that can also be used for monitoring the safety and efficacy of vaccines following their approval, is also welcomed. The latter should also include the possible side effects of vaccinations. In principle, clear rules are needed to also determine the data for the future European health data governance, to which the industry should have access, and under what conditions.

The establishment of common access to a cross-border pool of ten million genomes for research, innovation and clinical use is welcomed. However, a sense of proportion is required when promoting developed products that focus more on individual patients. Despite more precise diagnosis of disease agents, progress in stratifying medicine does not always lead to therapeutically relevant improvements. Costs and benefits must be weighed up properly here.

The intention to strengthen the exchanging of goods in the internal market via electronic product information and therefore reducing barriers, is explicitly welcomed. Given that the production of pharmaceuticals and active ingredients is distributed and specialised worldwide, it is essential to improve our own resources by removing existing barriers - and this is first and foremost the common internal market. However, the simplification of the exchange of goods must not lead to a lowering of standards of protection for patients.

## 3. Crisis preparedness, crisis response and resilience, supply chains and strategic autonomy, sustainable medicines

**The European Commission would like to ...**

... see Europe more crisis-proof, strengthen its strategic autonomy and make medicines more sustainable. This means that manufacturers are to be subjected to stricter supply and transparency obligations, which the EU wants to coordinate in the event of shortages. A structured dialogue should analyse the vulnerabilities in

the supply chains for critical medicines, raw materials and intermediates and propose countermeasures. The framework for good manufacturing practice will be reviewed and the requirements for environmental impact assessment revised. Environmentally friendly disposal of pharmaceuticals should also be considered as well as a reduction in package sizes. The EU's crisis response mechanisms are to be strengthened through the establishment of a new agency for crisis preparedness and response (HERA: Health Emergency Response Authority).

**The German Social Insurance ...**

... considers it appropriate to make the supply and reporting obligations of pharmaceutical manufacturers more binding, so that they can meet their commitments in terms of both product quality and supply - in all EU countries - and avoid shortages. The German Social Insurance welcomes promotion of the cooperation amongst the member states when it comes to inspections, which will allow a more comprehensive review of the manufacturing processes used for medicinal products and their distribution. Manufacturers must fulfil their responsibility to ensure an adequate and continuous supply of medicinal products. In return, manufacturers will be assured of the immediate eligibility for reimbursement of medicinal products once they have been placed on the market. The obligation of the pharmaceutical companies to make the products available is already regulated under pharmaceutical law. However, there is a lack of specific sanction options. Effective sanction regulations are necessary in the event of obligation breaches that are attributable to a production-related shortage.

The reporting system must also be harmonised throughout Europe as part of the reform of the pharmaceutical legislation. Measures by industry to achieve transparency in supply chains, based solely on voluntary action, which the European Commission intends to study, do not appear to be adequate.

It is essential to improve cooperation between the relevant authorities at European level in order to avoid supply shortages. The envisaged "structured dialogue" appears to be adequate for ensuring analysis of the exact causes of weaknesses in the supply chains and shortages, which has also been requested by the German Social Insurance. In the long term, an electronic reporting system is to be established on the basis of harmonised, binding reporting obligations throughout Europe. The procedure foreseen in the proposal on an enhanced role for the EMA in crisis preparedness and management in relation to medicinal products and medical devices might provide a starting point for this.

The European Commission rightly points out that measures intended to increase Europe's strategic autonomy must also comply with EU competition regulations

and the WTO (World Trade Organisation) rules. In this respect, it is useful to work on an initiative with WTO members to facilitate trade in health products, to enable an effective response in the event of a health emergency and to contribute to the resilience of supply chains within the EU and beyond.

The German Social Insurance agrees that the ecological aspects of pharmaceutical production, consumption and disposal must be taken into consideration. The review of the framework for good manufacturing practice, the provisions for environmental impact assessments and the intensification of checks are welcomed. The adaptation of package sizes to therapeutic needs appears to be expedient for ecological reasons, e.g. to avoid pharmaceutical waste; nevertheless, it must not become a pawn in marketing considerations, which will ultimately lead to higher prices per daily dose.

## 4. International cooperation

**The European Commission would like to ...**

... strengthen global supply chains and minimise disruptions in the production and distribution of medicines through greater international cooperation. Enhanced cooperation between EMA and national regulators should promote regulatory convergence. International standards should be enforced and a level playing field created.

**The German Social Insurance ...**

... shares the European Commission’s view that it is important to work internationally towards the reliability of global supply chains and a level playing field. In some countries, the production of active pharmaceutical ingredients and medicines is carried out under partial problematic working conditions and with serious ecological side effects, but on favourable financial terms. Social and fair working conditions as well as ecologically sustainable production processes are to be established along the entire supply chain.

There is also a risk of production monopolies with corresponding uncertainties for the supply chain. Production sites and supply chains should be diversified to reduce monopolies and strengthen Europe's independence in supplying medicines.

Closely linked free trade agreements and a functioning multilateral trading system are the best way of ensuring that multiple production sources are available for essential medicines and that regulatory standards are aligned globally. In this re-

spect, the German Social Insurance welcomes the fact that the European Commission intends to promote WTO-based measures to strengthen the resilience of global supply chains for essential goods within the framework of an initiative.