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The European Commission's public consultation on the roadmap for the pharmaceutical strategy

Opinion of the German Social Insurance from 6 Juli 2020

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 come together because of their common European policy interests to form the "German Social Insurance - Working Group Europe".

The German Social Insurance represents the interests of its members vis-à-vis the bodies of the European Union (EU) and other European institutions and advises the relevant players in the context of current legislative proposals and initiatives.

As part of Germany's statutory insurance system, health and long-term care insurance, pension insurance and accident insurance offer effective protection against the consequences of major life risks.

I. Preliminary remark

On 2 June 2020, the European Commission launched the consultation phase on the roadmap for the pharmaceutical strategy. With its strategy, the European Commission not only wants to provide answers to future challenges but also to current problems in the supply of pharmaceuticals. The needs of ageing societies with increasing health burdens, new challenges such as the current coronavirus pandemic and also the diversity of innovations in the industry must be balanced with the financial viability of health systems. New therapies should be improvements over existing ones.

The pharmaceutical strategy should follow a holistic approach. Availability of, equal access to medicinal products and their affordability, while falling within the competence of the Member States, presupposes the proper functioning of the internal market. The quality, safety and efficacy of drugs must be ensured in the future and Europe's competitive position in the world must be strengthened.

The pharmaceutical strategy is part of the industrial strategy. According to the European Commission, it is a matter of reorienting strategic sectors, including the pharmaceutical industry. It was necessary to review the dependence on imports along with supply routes. According to the current planning status, the strategy must be published in the last quarter of this year.

1. EU objectives and actions

The overall objective of the initiative is - as the roadmap shows - to ensure the supply of safe, high-quality and affordable medicines in Europe and to underline the European pharmaceutical industry's global leadership in innovation. Pharmaceutical production and supply chains must be strengthened, strategic autonomy in the pharmaceutical sector must be secured and Europe's global competitiveness must be increased.

The basis for this would be evidence-based assessments and the review of the regulatory framework with the aim of developing a system that is future-proof and consistently addresses all areas of the supply chain - from research and development to market authorisation and patient access to drugs. Scientific and technological progress as well as ecological aspects must be considered.

Market failures (e.g. the lack of new reserve antibiotics) alongside questions of the financial and fiscal resilience of health systems must be addressed.

The Pharmaceutical Strategy must consider what legislative and non-legislative measures are necessary and in which areas the EU should invest.

Legislative measures are expected to include legislation on orphan and paediatric medicines and on the fees of the European Medicines Agency (EMA), as well as a review of the EU's basic pharmaceutical legislation and other legislation, where appropriate. They are complemented by non-legislative measures. The EU intends to invest in various programmes such as the EU Framework Programme for Research and Innovation - Horizon Europe, the InvestEU investment programme or the Digital Europe programme, which aims to develop and strengthen strategic digital capacities in Europe.

According to the roadmap, the legislative and non-legislative objectives and measures are as follows:

1.1 Ensure greater access and availability of pharmaceuticals to patients

- Review incentives and obligations for innovation, for market launch/entry and for continuous supply of products.
- Simplifying legislation and administration (e.g. through better use of electronic product information and multilingual packaging) and increasing overall transparency in the industry to support the development of need-driven innovation.
- Ensure the quality, safety and efficacy of products, among others, by improving the supervision of global production and clarifying responsibilities for ensuring the quality of medicines.
- The proper functioning of the internal market, among others, for generic and biosimilar products, must be warranted.

1.2 Ensure affordability of medicines for patients and health systems financial and fiscal sustainability

- Supporting EU cooperation on evaluation, cost-effectiveness and measurement of added therapeutic value, pricing and reimbursement and procurement practices through non-legislative measures, while improving cooperation between Member States through the exchange of information and best practices.
- Strengthening EU cooperation on health technology assessment (HTA), as foreseen in the Commission's legislative proposal.

1.3 Enable innovation including for unmet medical needs in a way that harnesses the benefits of digital and emerging science and technology and reduces the environmental footprint

- Supporting breakthrough innovation through timely approval, market access and innovative procurement.
- Promotion of interdisciplinary cooperation for the need-driven development of new products and services and their acceptance in clinical practice, especially in areas of unmet needs.
- Review procedures for accelerated development and assessment of medicines for major public health needs, taking into account emerging technologies, to respond in a timely manner to public health threats such as the coronavirus pandemic. In view of emerging health threats, mechanisms for cooperation and coordination between regulators will be strengthened.

- Taking into account the opportunities offered by gene therapies and personalised medicine, for example in cancer and neurodegenerative diseases.
- To reduce the consumption of resources, emissions and pollution of the environment throughout the life cycle of pharmaceuticals and to promote the rational use of medicines.
- Developing expertise and promoting the acquisition of skills.

1.4 Support EU influence and competitiveness on the global level, reduce direct dependence on manufacturing in non-EU countries, seek a level playing field for EU operators

- Increasing the EU's regulatory presence and global influence with the aim of achieving a level playing field for EU companies through harmonised international quality and safety standards for medicines and addressing production-related environmental risks.
- Supporting the production capacity for active pharmaceutical ingredients and pharmaceutical precursors in the EU, which are key elements of a single chemical pharmaceutical strategic value chain.

II. Comments

1. Statement from the German Social Security

The German Social Security comments as follows on the objectives and measures listed in the Roadmap to the Pharmaceutical Strategy:

1.1 Ensure greater access and availability of pharmaceuticals to patients

Drugs are special products which may be lifesaving. It is of huge importance to the German Social Insurance that the supply of pharmaceuticals is guaranteed at all times. Nevertheless, supply bottlenecks or shortages do happen. However, not every supply bottleneck is a shortage[1]. Even if, as a rule, care can be provided

[1] There is (still) no definition at European level of which medicinal products or active substances are relevant to healthcare provision.

through alternative treatments or temporarily guaranteed by stockpiling, supply bottlenecks must be avoided from the perspective of those with statutory health insurance and patients.

The discussion on the question of which medicines and active substances should be considered indispensable for the care of patients should be continued at European level; also in order to gain clarity on which products the measures under political discussion are aimed at. In principle, divergent assessments at Member State level do not prevent this.

Delivery bottlenecks

The proper functioning of the internal market is essential for the sustainable, comprehensive and economic supply of medicinal products in Europe. This applies all the more so as the pressure on the resources of the health care systems increases due to the ageing of societies, medical-technological progress, but also high-price strategies of pharmaceutical companies. Unforeseen events such as the COVID-19 pandemic illustrate the importance of financially sustainable and efficient health systems. The opportunities arising from European cooperation should therefore be exploited. This should be done with a view to guaranteeing the supply and ensuring the availability of medicines, minimising (storage) costs, joint research into care and the use of opportunities arising from digitisation and data generation. Given that the production of pharmaceuticals and active ingredients is distributed and specialised worldwide, it is essential to improve our own resources - and this is first and foremost the common internal market.

The continuous supply of the dispensing points (pharmacies, hospital pharmacies, etc.) requires the establishment of intelligent solutions that render the availability of required therapeutic agents transparent in real time, enable smooth supply, and - unless medically or pharmaceutically contraindicated - enable substitution. Ideas such as an internet based leaflet in all European languages are a step in the right direction. In addition, the rules on repackaging for different pack sizes and pharmaceutical forms should be reviewed and optimised to ensure their practicability and to facilitate cross border exchange. Greater standardisation of packaging may be helpful. However, the simplification of regulatory procedures must not lead to a lowering of standards - pharmaceutical laws primarily serve to protect patients and the general public. This protection is particularly necessary for new technologies.

It seems essential to improve the networking of cooperation between the competent authorities at European and national level. In order to increase transparency

on the availability of goods, it is necessary to harmonise the notification procedure with regard to existing production problems, imminent bottlenecks, their causes and their presumed duration. This requires a uniform, mandatory, electronic reporting system coordinated at European level. To achieve this, Europe-wide, mandatory guidelines must be formulated for reporting to the competent national authorities. Notifications to the competent authorities of current or imminent shortages, their cause and expected duration must be mandatory throughout Europe for pharmaceutical companies, wholesalers and pharmacies. Their non-compliance should be sanctioned. Where necessary, the capacity of national authorities to act should be strengthened.

A discussion is currently taking place in the European Parliament on whether the European Commission and the Member States should be invited to set up one or more European non-profit and general interest pharmaceutical bodies capable of producing certain priority medicinal products of public health and strategic importance. The German Social Security System will accompany such considerations with an open mind.

Antimicrobial resistance

It should be noted that for some products and product groups shortages arise due to the fact that changed market conditions make the provision of such pharmaceutical products economically unattractive within the traditional business model of the pharmaceutical industry. One such example are reserve antibiotics. No new class of antibiotics has been approved since the 1980s. Antibiotics that are important for the supply and against which no resistance has as of yet developed fail to occupy the market shares that would be appropriate to their role as important reserve therapeutics. Here, new concepts must be developed on how to create conditions that make the necessary development of reserve antibiotics attractive by means of financial incentives or support for research. In the context of the orphan medicine procedure, it has been observed that new products with little therapeutic benefit have been brought to the market, without bringing about any real innovation. The orphan legislation is therefore not suitable as a blueprint to address the market failure in the development of new antibiotics as it also ultimately makes volume expansion attractive over longer exclusive marketing periods.

1.2 Ensure affordability of medicines for patients and health systems financial and fiscal sustainability

Medicines must remain affordable. In recent years, a development has become apparent in which inexpensive drugs (often generics) cover a good part of the supply, but new drugs and therapies are offered in part at astronomically high prices. Examples include the gene therapy drug Zolgensma, which has just received conditional approval from the European Medicines Agency (EMA) (costs for the health insurance in the amount of approximately two million euros for a single patient, without the effectiveness having already been proven with long-term data), but also the CAR-T cell therapy for certain forms of lymphoma or leukaemia (costs for the health insurance in the amount of 300,000 euros). This threatens to overburden even well-equipped health care systems such as those in Germany. In economically less powerful countries, such therapies often arrive late compared to Germany or lead to financial overstrain of the health care systems.

In view of the high prices of medicines, ensuring an affordable and high-quality supply of medicines for patients is a Europe-wide challenge. The uniform European rules on the marketing authorisation of medicinal products and common incentive systems for certain groups of medicinal products require the EU to share responsibility for a safe, effective, high-quality and innovative supply of medicinal products.

The German Social Insurance is calling for comprehensive transparency regarding the costs of research, development and production of pharmaceuticals. In future, pricing decisions by national systems must take greater account of development costs and the degree of further therapeutic development and be less determined by the profit interests of pharmaceutical shareholders. This applies to all medicines.

New reimbursement models are being discussed for extremely high-priced medicines, for example Advanced Therapy Medicinal Products (ATMPs). In Germany too, success-based remuneration models which shift the cost risk between the manufacturer and the health insurance company are under discussion. Whether such models are useful can only be assessed on a case-by-case basis. A prerequisite for their applicability is that there is a consensus that in certain cases a benefit, measured against therapeutic endpoints, can be achieved.

The German Social Insurance supports the European Commission in its efforts to monitor the innovations in the pharmaceutical market at the European level and to jointly carry out benefit assessments. The cooperation between national HTA authorities has proven to be successful. However, pricing and reimbursement issues remain a matter for individual Member States to decide because of the very different system conditions. A strengthening of cooperation in health technology assessment (HTA) is explicitly desired. German Social Security welcomes the objective of the Commission proposal[2] to consolidate and gradually expand cooperation in the assessment of health technologies within the European Union dated 31 January 2018. It must also be possible to explicitly evaluate medical devices in order to do justice to their significance for the care of patients.

Future cooperation should be characterised by a leading role for Member State HTA organisations and a high degree of consensus orientation and transparency. An essential step towards more intensive EU cooperation must reach a consensus on the design of the evaluation process. The underlying methodology must be based on international standards of evidence-based medicine and must not fall short of what has already been achieved in the Member States.

1.3 Enable innovation including for unmet medical needs in a way that harnesses the benefits of digital and emerging science and technology and reduces the environmental footprint

The desire to make innovations available in a timely manner and to optimise the procedural processes can be well understood by the German Social Insurance. However, it is also necessary to consider the risks associated with premature, too rapid or insufficiently considered decisions. Once on the market, drugs can only be removed under extreme conditions such as danger to life or impairment to the health of the users. Pharmaceuticals with their effects and side effects are special products that require strict testing. The protection and safety interests of patients must be considered as a priority. Economic interests must be put aside.

German Social Insurance supports all efforts aimed at developing drugs that target a real need and represent a therapeutic advancement. Both the German and the European market are full of so-called "sham innovations" which offer little or no therapeutic added value but are usually significantly more expensive than products that are already on the market. In this context, the legal framework for

[2] https://ec.europa.eu/transparency/regdoc/rep/1/2018/DE/COM-2018-51-F1-DE-MAIN-PART-1.PDF

the approval practice of the European Medicines Agency must be critically examined.

An example is the legislation on rare diseases ("orphans"), which aims to promote drugs that are not economically viable under current conditions. Practice shows, however, that this is extremely susceptible to strategy and has turned some "orphans" into real "blockbusters". On the other hand, it is worrying that new medicines are being authorised for ever smaller groups of patients at extremely high prices, even though the benefits have not been clearly demonstrated. Incentive systems for the development of medicinal products for truly rare diseases must provide real added value for patients. Experience with accelerated approval procedures shows that commissioned data on safety and benefits are often submitted by manufacturers only incompletely or late. Accelerated approval procedures must not result in a reduction in safety for patients. Not least because it is essential that accelerated approval of drugs should focus on real gaps in supply. These special rules must take account of measures to prevent prices that could jeopardise the sustainable financing of health systems.

Nevertheless, it is essential to maintain a scientific climate in the EU that enables new developments and allows innovation to be detected. Research and development at European level also plays an important role in providing patients with innovative medicines. In order to maximise the benefits for patients and ensure their access to innovative and affordable medicines, public investment in research and development should be directed to areas of urgent medical need. Member States' funding bodies must be involved in setting the priorities of the European Research Agenda. In addition, public investment in the research and development of drugs must be reflected in pricing.

The possibilities of using large amounts of data made possible by ongoing digitisation offer great potential for the further development of therapies and health services research. It would be sensible to cooperate more extensively across borders and generate new knowledge, particularly where rare diseases are concerned. The EU should stand for proactive promotion of these processes, whilst obviously considering data protection laws and the self-determination of the individual. European countries should be internationally sought after as locations for science and research and maintain a high reputation. The conditions for this must be outlined. International specialisation offers particular opportunities in the research and treatment of rare diseases. In principle, the following must apply: Innovations and research must be oriented towards patient benefit.

1.4 Support EU influence and competitiveness on the global level, reduce direct dependence on manufactoring in non-EU countries, seek a level playing field for EU operators

In a globalised world, competition does not stop at national borders or at the external European border. The production of pharmaceuticals, active ingredients and active therapeutic substances is organised on a global scale and, in the case of individual active ingredients, is sometimes concentrated in a few countries. The United States of America, for example, obtains 40 percent of its generic drugs from India. This is where most of the world's generic drugs are produced. 70 percent of the active ingredients for this come from China. In response to the coronavirus pandemic, India stopped exporting 26 active ingredients and medicines, including antibiotics in March 2020[3].

The European Commission - and they are not alone - sees problems on the one hand in the framework conditions of production - primarily in the working conditions - and the sometimes serious ecological side effects. On the other, the formation of monopolies should be prevented. There is no contradiction between the two.

However, the call to relocate the production of drugs and active ingredients to Europe does not provide an effective response to these problems. The fact that production takes place outside Europe is not causal for availability problems or for securing supply. Production in Europe alone will not improve availability. In connection with the COVID 19 crisis, there have also been export restrictions within the EU. There are also limits to the influence on the strategic decisions of internationally operating pharmaceutical companies.

According to the European Parliament's Committee on International Trade (INTA), the EU is the world leader in the export of pharmaceutical products. In its proposals[4] for a report[5] in preparation for a resolution on bottlenecks in the supply of medicines, the Committee emphasises that functioning global supply chains are essential, particularly for medicines, and that an open, rule-based trading system is the basis for ensuring their availability worldwide. Closely linked free trade agreements and a functioning multilateral trading system are the best way to ensure that multiple sources of production of essential medicines are available and that regulatory standards are aligned globally.

[3] https://www.deutsche-apotheker-zeitung.de/news/artikel/2020/03/04/indien-stoppt-arzneimittel-export
[4] https://www.europarl.europa.eu/doceo/document/INTA-PA-650551_DE.pdf
[5] https://www.europarl.europa.eu/doceo/document/ENVI-PR-650394_DE.pdf

Given the existing international interdependencies, efforts to develop and enforce international quality and safety standards should be fully supported. This particularly applies to the environmental aspects of production and resource consumption as well as to the (occupational health and safety) rights of workers in industrial production. In principle, compliance with and updating of the CEPs (Certificate of suitability of Monographs often called European Pharmacopoeia), which contain a detailed description of the manufacturing process and the potentially occurring impurities of the active pharmaceutical ingredient, must also be checked more stringently.

In order to increase the security of supply, it should be considered whether the production of drugs and active ingredients should be linked to the condition that the respective product is demonstrably manufactured at least two different production sites, regardless of whether these are in Asia, America or Europe. Intelligent, digitally supported delivery systems also enable fast reactions to bottlenecks and offer short-term solutions. Buffers can be built into the existing supply chain or existing buffers in wholesale or pharmacies can be enlarged. Decentralised, Europe-wide digitally networked storage capacities can ensure that changing requirements or bottlenecks can be reacted to quickly at manageable costs.

Summary statement

- The discussion as to which medicinal products and active substances are considered to be relevant for supply should be conducted at European level.
- European pharmaceutical policy must be geared to developing only those medicines and active ingredients that are necessary and provide real added therapeutic value. Joint HTA evaluations provide valuable support in this respect.
- Access to and affordability of medicines must be ensured. To this end, a strengthening of cooperation among member states would be explored not only in the evaluation but also in the pricing of new drugs.

- Europe's strength is its internal market. This must enable the import and export of drugs and active ingredients, taking into account necessary requirements for product and patient safety. Therefore, the legal framework must be reviewed and further developed.
- Supply bottlenecks can be addressed by a common electronic reporting system if the reporting obligations are made binding and harmonised throughout Europe. The production of drugs and active ingredients should be diversified to reduce the risk of production-related bottlenecks. Digitally networked systems in the field of logistics and warehousing can facilitate procurement and limit the stocking of pharmaceuticals to a necessary level. Possibilities of independent production must be investigated.
- Europe must become stronger with regards to being a research location. In order to take advantage of digitisation and large amounts of data, research into new (drug) therapeutic approaches should be intensified at European level. The research content should be oriented towards patient benefit.

With regard to the expected revision of the existing European legislation, the German Social Security Insurance takes the following positions:

- A revision of pharmaceutical legislation must not lead to a lowering of standards. It is already rightly pointed out today that there are too many medicinal products available on the market whose additional medical benefit has not been proven and that it is often impossible to foresee if and when this proof will be possible. An extension of the special regulations for accelerated approval procedures unjustifiably shifts risks from clinical trials to patients. This shift is only justified by the assumption that new scientific methods, which are brought into the discussion with the keywords Real World Data or Big Data, allow a better recording of the actual benefits and harms of use. Pharmaceutical legislation serves to protect patients and the general population and must not be subordinated to economic interests.
- In relation to orphan drugs, the existing standards are not to be lowered in the case of initial approval in the so-called accelerated procedure. A key recital for the legislation on the promotion of orphan medicinal products was that the development did not seem sufficiently profitable for companies without specific measures. However, as a result of the legislation, especially in the therapeutic area of oncology, orphan drugs are now being developed in parallel and marketed at prices that give them blockbuster or niche status and generate substantial profits. The economic criterion in the

legislation must be strengthened in order to ensure that funding is specifically targeted at those medicinal products which the legislator originally intended to address and which are still neglected today, namely medicinal products for very rare, mostly hereditary diseases.

- In a possible revision of the legislation on the promotion of paediatric medicinal products, a system combining, as before, the obligation to conduct studies with incentives should be applied. Only this combination can work successfully. At the same time, it should be examined how incentives can be designed in such a way that they are no longer dependent on economic success. From the point of view of the German Social Security, this connection hinders the development of drugs for diseases primarily occurring in children as well as the increased research of drugs with no longer existing patent protection. The scheme should be designed to prevent avoid excesses such as the extremely high prices observed for orphan drugs, for example.