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Medicines for future generations – greater supply reliability through strategic independence?

Food for Thought paper by the German Social Insurance from 28 October 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 funds have joined forces to form the "German Social Insurance – Working Group Europe" in the interests of their common European policy interests.

The German Social Security 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 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. Background

The COVID-19 crisis has given political impetus to the desire for greater safety, increased stockpiling of key pharmaceuticals and protective equipment, but also greater independence for key pharmaceuticals and active substances from third country production.

Germany has also made the secure supply of medicines a priority topic of its Council Presidency in the second half of 2020. The focus is on quality, more transparency in production and secure supply chains. Europe is to cooperate more closely on key pharmaceuticals, become more independent of producers from countries such as China or India and secure its supply of essential medicines.

Some calls in the political arena go so far as to shift production to European Member States. There is little talk at this stage about the additional costs this will entail. Yet the prices being called for medicines - especially new medicines - are already extremely high in some cases.

A pharmaceutical strategy, which the Commission intends to present in draft form towards the end of 2020 will provide a set of measures to achieve, among others, the above-mentioned objectives. In addition, questions of access to medicines, their availability and affordability are also in focus. On the one hand, national health systems must not be overburdened. On the other, the aim is also to promote the competitiveness and innovative capacity of the European pharmaceutical industry.

The European Union has legislative powers in the field of pharmaceuticals. This gives it a special responsibility. It will have to correct undesirable trends that have become apparent in recent years. As part of the pharmaceutical strategy, the entire pharmaceutical legislation is to be reviewed. The regulations on orphan drugs and paediatric medicines have shown a particularly strong need for action.

II. Strategic independence - what does that mean?

Coronavirus has triggered a desire for more protection among the public and politicians. People want to be better prepared for future crises. In important areas such as health protection or essential medicines, it should be possible to guarantee a comprehensive supply at all times. Europe's focus is on third countries. However, EU Member States also initially reacted to the crisis by going it alone and banning exports.

But for which goods does the EU want to become more independent of world markets? Among other things, we are talking about important, supply-relevant, indispensable, critical or strategic pharmaceuticals. The WHO has a list of essential medicines with several hundred different substances. Many vaccines are listed among them. It is intended as a recommendation for the governments of individual countries to develop their own supply standards adapted to national guidelines and regional conditions. In Germany, too, a national list (without vaccines) of supply-critical drugs is published by the Federal Institute for Drugs and Medical Devices (BfArM) and regularly reviewed by an advisory board to assess the supply situation of drugs. With a view to measures to be determined politically, the discourse will

also have to be conducted at the European level as to which drugs and active substances are to be regarded as critical to supply and to which more far-reaching political measures are to apply.

In a globalised world, competition does not stop at national borders or at the external European border. The production of pharmaceuticals and active ingredients is based on strategic decisions of the industry, is partly organised on a global scale and, for individual active ingredients, is concentrated in a few countries and a few production sites. However, fair competition needs to be equal across the board. This is not always the case today with very different production conditions at times. The European Commission sees problems in the social and ecological conditions of production and a lack of monitoring facilities, but also the dangers of monopoly formation and increasing dependencies. Relocating the production of medicines and active substances for supply-critical drugs to Europe is only one of several possible answers to these problems.

The fact that some medicines are produced outside Europe is not responsible for all the bottlenecks that occur. Supply bottlenecks have many causes. They also existed before coronavirus and they pose a serious supply problem for important therapies. But is it absolutely necessary to produce more pharmaceuticals in Europe in order to secure supply? What additional aspects need to be taken into account? A rational discourse on causes and appropriate solutions must be conducted. The additional costs associated with the relocation of production and production sites must also be taken into account.

The single market is the heart of the European Union. And it has potential. Digitisation in particular opens up opportunities in the Internal Market, for example to make the market for pharmaceuticals more transparent and to better manage bottlenecks. So one question must be: What structures do we need to set up in Europe to tap the potential offered by the single market?

III. Main points of discussion

1. Health crises are also opportunities

Global or regional health crises are recurring. Using the example of the supply of personal protective equipment, medical devices and downstream in the pharmaceutical market, Coronavirus in particular has shown where the systemic weaknesses of global production chains, European distribution channels or national supply paths lie. The European Commission is looking for improvements and takes up issues such as joint procurement, strategic stockpiling or own production in the European pharmaceutical strategy and the EU4Health programme.

- Should joint procurement and stockpiling of essential supplies become a future EU task?
- How much of a service of general interest should the EU provide in terms of public health protection? What should remain the responsibility of the Länder?
- How much health expertise does the EU need to respond more effectively to future health crises?
- What is the role of the vision of an "EU Health Union" in the context of the negotiations on the Multiannual Financial Framework and the EU4Health programme envisaged therein?

2. Single market

Europe's strength is its single market. Its potential is far from exhausted. And it is supposed to become more digital. A well-functioning single market can help to avoid supply shortages.

a. European solidarity, which has been strengthened by the crisis, can be used to make full use of the resources and information available in the single market. Cross-border information on stock levels, but also on bottlenecks, is a valuable tool for reacting quickly to market changes. The concerned national authorities need this information, as do hospitals, doctors, pharmacies and health insurance companies that manage on-site care.

- What instruments does the EU provide to promote this? The possibilities of digitisation must also be taken into account in order to make information available electronically as quickly as possible.

- And what legal steps need to be considered in order to oblige all parties involved to provide the required information in an appropriate form?

b. In addition, there are still obstacles in the single market. The cross-border exchange of pharmaceuticals is not always easy due to quite meaningful regulations on patient protection. It fails due to the non-availability of comprehensible package inserts in some cases and due to package sizes in others. Nevertheless, there are ideas on how to remove such obstacles, while fully respecting patient protection.

- What practical ideas are likely to strengthen the functioning of the single market in the pharmaceutical sector?
- What specific proposals can be expected within the framework of the pharmaceutical strategy?

3. Prices

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 extremely high prices. This threatens to overburden even financially well-equipped health care systems such as those in Germany. In economically less powerful countries, such therapies often arrive late or lead to financial overstrain of the systems.

In view of the high prices, ensuring an affordable and high-quality supply of medicines is a Europe-wide challenge.

- So, how can the price of medicines be captured?
- What assistance will the EU offer within the framework of the Pharmaceutical Strategy to keep medicines affordable?
- How does the pharmaceutical industry itself see its responsibility in this regard?

b. Accessibility, availability and affordability of medicines go hand in hand. Even though pricing and reimbursement decisions are the responsibility of the Member States, the EU has a special responsibility here due to its legislative powers.

- How should it be ensured that people in economically weaker Member States also receive the medicines that are important for their treatment?

4. International competition

Because of the existing international interdependencies, efforts to develop and implement or harmonise international quality, environmental and safety standards are an instrument to avoid encouraging problematic production conditions. Competitive disadvantages can be reduced for European pharmaceutical manufacturers. The Pharmaceutical Strategy is embedded in the industrial strategy of the EU.

- Are specific EU initiatives needed to ensure that more international standards are applied and enforced in the global production of pharmaceuticals in the future?