BPI Bundesverband der Pharmazeutischen Industrie e.V.

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BPI e.V. additional response to the survey on the Pharmaceutical Strategy

The BPI e.V., representing more than 270 members, comprises the whole spectrum of the pharmaceutical industry, ranging from multinational corporations to SMEs, Mid-Caps as well as Start-ups. These companies ensure timely and safe drug supply for all patients across the EU and globally.

We welcome the European Commission's initiative to create a Pharmaceutical Strategy that envisions ensuring patient's access to medicines across Europe while at the same time creating an environment which fosters the competitiveness of the European pharmaceutical industry in the global context.

As we acknowledge the difficulty to elaborate these aspects in the form of a multiple choice system, we would like to further elaborate on certain aspects of the four categories of the survey that we deem important to achieve the goals set out in the Roadmap.

I. International dependency and manufacturing

The pharmaceutical industry – as most other sectors – operates in a highly globalised environment with complex supply chains. These supply chains need to be stable and functioning even under challenging circumstances. Trade barriers such as export bans as seen during the Covid-19-Pandemic need to be avoided under all circumstances.

Rather than calling for "re-shoring"/ "re-patriation" of production to Europe we should work on an effective global network and solid supply chains including a strengthened European production. In order to achieve this global network with manufacturing capacities across the globe and not only in certain regions of the world, the focus should also lie on strengthening and redeveloping existing EU production capabilities as well as creating an attractive environment for new technologies in the EU.

The dependency on other global regions stems from the fact that it has become harder over the years to produce medicines – and here especially off-patent medicinal products – in Europe in an economically sustainable way. A price race to the bottom, which is not compatible with a healthy functioning competition, has led many manufacturers to look for other viable options to keep a product on the market e.g. the relocation of production sites to other regions outside the EU.

In order to preserve and redevelop existing production in Europe and to create an attractive environment for new technologies, production in the EU needs to be transformed from cost factor to competitive advantage. In this respect, appropriate and competitive requirements instead of overregulation will be key.

II. Access to affordable medicines

The reasons for shortages in Europe are manifold the EU should refrain from ad-hoc measures which will only work as a band-aid but rather rethink and change existing mechanisms which led to the current situation in the first place.

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One aspect to look at, are existing procurement procedures. In many Member States, these are not fit for the current challenges, rather being part of the underlying problem by forcing production out of the EU through extreme price pressure. The BPI therefore strongly suggests at least the establishment of sector specific guidelines to clarify the situation for Member States, recognising not only the price as sole criterion a decision is based on, but also considering other criteria such as a European production site as a condition for tenders.

Also awarding contracts to more than one tenderer should be the norm to ensure a functioning competition on the market and to avoid shortages. Ensuring a critical diversity of producers would enable compensation of missing production capacities in case of production problems of one producer. For critical substances it should be possible to have a prohibition of tenders.

Another way to mitigate shortages is to establish more regulatory flexibility. During the Corona crisis EMA, HMA and CMDh enabled some regulatory flexibility for products for treatment of COVID-19 patients in order to avoid shortages. This flexibility should be kept and transferred into future regulations. Flexible measures should be applied to all products at risk of shortages to prevent stock-out and supply disruptions as well as for innovative products in areas of unmet medical need in general.

With regard to the debate evolving around access to medicines, we acknowledge that there is an existing imbalance throughout the EU. This situation has to be ameliorated and the access to medicines has to be secured for all citizens throughout the EU. However, it is to be noted that turning a centralised market authorisation into an obligation to market a product is not a solution. There are several other factors which influence the business decisions of pharmaceutical companies as for example the existence of claw-back systems or other cost-containment measures. Companies do depend on the financial outcome of their products, especially with regard to the reinvestment in R&D projects.

Additionally, one key element to consider when evaluating the affordability of a medicine, is to look at the savings it can bring for healthcare systems. By bringing the right medicines to the right patient, at the right time, health systems can avoid additional costs that can heavily impact on national health budgets (eg palliative care; transplants). Rewarding and encouraging innovation should not be seen as a cost, but as an investment in more efficient and targeted solutions able to generate savings for the healthcare systems.

III. Innovation in early development and authorization

A value-based recognition of innovative medicines is essential to fund further research and development. The Pharmaceutical Strategy needs to create an appropriate framework for this purpose, aiming to foster and support all areas of research. Both innovative medicines as well as medicinal products which have been developed by means of incremental research should be included in funding programmes, as both are equally important to the well-being of patients all over Europe (as the medicinal products being tested in the SOLIDARITY study to fight the Covid-19 pandemic shows, they are all already known substances being repurposed). The repurposing of medicines was essential in securing treatment options in a crisis. A fit for purpose regulatory and market framework is therefore needed to encourage future developments. This should also be reflected in strong IP-protection as for example five years of extra data protection for repurposed generics.

Essentially, the market-economy based approach as a driver of progress and innovation in the EU health care industry must remain. Therefore, functioning incentive systems for the

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development of medicines are paramount. This applies to more frequently occurring diseases as well as to rare diseases. Particularly concerning the latter it must be emphasized that despite all the successes of recent years, most of the approximately 8,000 known rare diseases cannot be treated causally, which is why incentives for the development of medicines for these patients continue to be of great importance.

When assessing incentives for development of medicines, it should be borne in mind that, overall, pharmaceutical research is associated with high financial risks. With regard to advanced therapy medicinal products, it can be seen that after several years of sluggish development highly innovative new medicines are now being authorised and large-scale clinical trials are under way. In the future, a more stringent and tailored networking of the "blood and tissue" legal system with the legal system for the approval of ATMPs is important to allow for patient access and an innovation-friendly framework.

Strong protection of intellectual property rights is key to the research and development activities that take place in a network of European research regions. In these innovation clusters, private and public research work hand in hand. Reliable long-term framework conditions are essential for this inter-regional cooperation. In the long run, this will also contribute to help making Europe more attractive in that respect and to refrain other regions, such as the US, to reap the outcome of ideas that have been created in Europe. We wish for the Pharmaceutical Strategy to be closely aligned with the IP-Action Plan which is supposed to be published this autumn.

IV. Environmental sustainability of medicines and health challenges

The environmental situation in Europe has to be improved which has lately been manifested in the European Green Deal. However, environmental affairs are not suitable to be the sole responsibility of particular industrial sectors. Moreover, environmental protection is a common social task concerning all EU Member States, industrial and agricultural companies as well as consumers and should be solved by a common strategic approach, allowing everyone to take on responsibilities and taking measures to reduce the environmental burden. As medicinal products are used for treating and preventing diseases in human beings and animals, the appropriate and efficient medical therapy has to be given top priority.

It should be considered if a focused wastewater management might be more efficient for the environment than a detailed combination of environmental aspects in any pharmaceutical regulation. This is due to the fact that 80-90 % of medicinal degradation products in water are naturally excreted by human beings. Industry waste accounts for less than 2 %. About 10 % of medicinal products might interfere with the environment due to disposal of unused medicines. Regarding the disposal of unused medicines, measures have already been taken. It is estimated that > 90 % of medicinal products do not have any harm to the environment. Therefore, although the importance of protecting the environment is clearly acknowledged it has to be avoided that medicinal products do not reach a patient because their environmental profile may be questioned.

The BPI supports and promotes a holistic approach to fight the problem of antimicrobial resistance (AMR). Further to fostering strategies that promote rational use of antibiotics in human beings and animals and the research of new antibiotic-based therapies, the BPI also encourages the research performed on known antibiotic substances. AMR is a natural process. It is possible to decrease its pace but it cannot be completely circumvented even under optimal

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circumstances such as the prudent use of antibiotics. It is therefore necessary to create and ensure a good environment for continuous research and development of new antibiotics. Due to the worldwide dimension of AMR this task cannot be tackled on a national level. The approach has to be global.

It is therefore vital to create not only financial mechanisms to support this research but also to implement pull mechanisms (e.g. market entry rewards). Ideally, these measures would be globally approached, but they should at least be tackled on a cross-border level to ensure efficient and well-equipped research.

V. Summarising remarks

In summary, we believe that a thorough evaluation of the aspects mentioned above is essential to create a balanced system that is fit for the future. There should not be any “ad-hoc” measures but rather strategies which create a solid framework for a sustainable health care environment in the EU.

The Covid-19-pandemic has shown that a constructive dialogue is the key to successfully ensure the supply of medicines for citizens across Europe. This form of exchange should be well maintained throughout the future.

Additionally, we consider it vital for the success of the envisioned Pharmaceutical Strategy to be coherent with all other policies such as for example the IP Action Plan, the European Data Strategy, Europe’s Beating Cancer Plan, the SME Strategy and of course the overarching Industrial Strategy of the European Union.