BPI Bundesverband der Pharmazeutischen Industrie e.V.

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BPI e.V. response to the consultation on the EU-Pharmaceutical Strategy Roadmap

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 strategy that aims to support the industry's competitiveness at the same time as ensuring high quality medicinal products for the European citizen.

The European Commission's roadmap and its Industrial Strategy both highlight the economic importance of the pharmaceutical sector for the EU. This sector comprises a huge variety of companies, from global corporations to SMEs and Mid-Caps. This must be taken into account by the Commission and should lead to a strategy feasible for all. The aim of the Pharmaceutical Strategy should be to create a balanced approach which creates an environment that allows the industry to grow and compete globally and sets a solid framework for it to function properly.

Regarding prevalent shortages of certain medicinal products, especially off-patent medicinal products, we believe such a framework needs to acknowledge existing legal obstacles which need to be reviewed and adjusted accordingly. The focus of the strategy should not solely lie in the "re-shoring" of production. Instead, we need to focus on creating an environment that offers the means to strengthen already existing production sites along the whole chain of production throughout Europe as well as making it an attractive region for new production sites and new technologies. However, this also requires attractive regulatory conditions within the EU. A review or the mapping of existing procurement strategies in all member states as well as a possible extension of the state-aid exemptions in relation to the Covid-19-pandemic could offer solutions to the problem of shortages.

The strategy should aim to foster and support all areas of research. Both innovative medicinal products 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 the EU (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). Regarding the innovation aspect, it is crucial to maintain and improve existing incentives in areas of a high medical need and market failure, e.g. medicinal products for rare, super rare diseases and for children as well as to fight antibiotic resistances.

We welcome the European Commission's approach to establish a harmonised HTA-process of pharmaceuticals, especially with regards to common standards and joint scientific consultations aiming to avoid duplication of work for national HTA bodies and industry which leads to a more sustainable system.

During the ongoing pandemic EMA, HMA and CMDh enabled a 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.

As pharmaceutical research is closely connected with public and private research institutions, a common European data platform would ensure the necessary interoperability to exchange research data between these institutions and industry across Europe.

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BPI agrees that the environmental situation has to be improved. However, this cannot be seen as the sole responsibility of particular industrial sectors. The importance of protecting the environment is clearly noticed but it has to be avoided that medicinal products do not reach a patient because their environmental profile may be questioned.