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BPI e.V. response to the combined evaluation Roadmap/ Inception Impact Assessment

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

Concerning the evaluation and revision of the general pharmaceutical legislation, we welcome the Commission's objective to simplify legislation and create regulatory attractiveness with the aim to reduce, where possible, regulatory approval times and regulatory costs while keeping the high standards of robust assessment of quality, safety and efficacy. BPI believes that some measures, which have been applied during the ongoing Covid-19-pandemic, should be integrated into a future framework. This would also have a positive impact on the security of supply. We strongly encourage improving the security of supply of medicinal products within the EU. However, a future framework should not impose more obligations on manufacturers and responsibilities should be equally distributed between all stakeholders along the supply chain. Further to this, we welcome the objective to strengthen the current system of incentives to foster innovation and international competitiveness of the sector. This approach should be in coherence with the recently published EU IP Action Plan, which rightly takes into account the role of a strong, coherent and predictable IP framework in fostering competitiveness and innovation. In addition, a strengthened incentive system also needs to include repurposed medicinal products as they deliver a great value for patients throughout the EU. A targeted approach in reducing environmental residues will prove to be more sustainable than general legislative regulations.

When considering the policy options proposed in the Inception Impact Assessment, the European Commission should carefully examine the economic and regulatory burden they would impose on the pharmaceutical industry. It is of utmost importance to keep the broad spectrum of the sector in mind, especially with regards to SMEs and Mid-Caps.

BPI fully supports the approach of the Commission to focus the revision of the pharmaceutical legislation on those provisions related to the objectives of the Pharmastrategy (i.e. "targeted approach"). The current structure of the basic pharmaceutical legislation, i.e. the coexistence of Directive 2001/83/EC and Regulation (EC) No 726/2004, should be kept. Amendments of provisions to be changed/improved should be done within the current structure. The current dual marketing authorisation system built on the Directive for decentralised/national procedures and the Regulation for the centralised procedure ensure a complete framework covering the whole lifecycle of medicinal products. This system that is in place since 2004 generally functions well. It secures the suitable allocation of tasks to the respective competent authorities and eliminates competition hurdles, especially for SMEs. The uncertainties, practical difficulties and increased efforts and costs, which would be associated with a transition from a Directive to a Regulation, should be avoided. A stable regulatory environment is not only needed for centrally authorised, innovative medicinal products, but also for established medicinal products approved by national competent authorities. These products are often non-prescription medicinal products for self-medication. They are an integral part of health care enabling citizens to take responsibility for their personal health and often support the routine patient care in Member States' health systems.

Please see attached document for further elaboration on some of the proposed policy options.