BPI Bundesverband der Pharmazeutischen Industrie e.V.

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In addition to our general considerations on the Roadmap/Inception Impact assessment, please find more detailed comments on certain policy options below. The letters in parentheses refer to the proposed policy options laid out in the Roadmap by the European Commission

Unmet medical need

a) We agree with the objective to reach a common understanding of what exactly constitutes an "unmet medical need". However, we do not recommend opting for a rigid definition, as we believe that a flexible set of criteria is needed depending on the therapeutic area. Furthermore, it is of utmost importance to involve physicians, pharmacists, patient representatives and industry in the discussions and development of a common understanding.

Simplify legislation and create regulatory attractiveness

b) We support the Commission's objective to create a reliable EU regulatory system, which needs to be attractive in a competitive global environment with fast approval times and reduced costs. For medicinal products for unmet medical needs, the concept of rolling review and coordination between the EMA and the Member States should be established in the legal framework besides the PRIME scheme and adaptive pathways to allow for faster access to these medicinal products. To support innovations based on known active substances, BPI proposes to scientifically develop the system of bioavailability studies for developing new dosage forms and new routes of administration to replace Phase III clinical studies.

BPI calls for establishing a simplified and streamlined variation system by enhancing companies' responsibility in handling changes to the marketing authorisation under GMP-conditions. This approach should be supported by the possibility to notify changes via databases (e.g. CEP-Variations and administrative changes) and by flexible elements, like the ECMP, to allow fast changes to prevent shortages.

BPI supports the implementation of electronic product information as it enhances patient safety and security of supply. However, there should be regulatory incentives for companies. The electronic product information should be used to decrease the workload on maintenance of the product information. To allow SMEs and Midcaps to adapt to electronic product information the Commission should follow a phased approach.

A strong system of incentives

c) Essentially, the market-economy based approach as a driver of progress and innovation in the health care industry in the EU must remain. Therefore, functioning incentive systems for the 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 emphasised 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 evaluating incentives for the development of medicinal products, it should be borne in mind that, overall, pharmaceutical research is associated with high financial risks.

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With five years of data protection, valuable innovation on known substances will be promoted adequately/sufficiently. In addition, a framework, which supports the marketing and use of the medicinal product with the approved new label claim - instead of off-label use -, should be considered to make repurposing attractive in the EU.

Incentives must not be linked to an obligation to launch, as this depends on the structure and requirements of each Member State. For SMEs and Midcaps it is particularly difficult to navigate through the various systems in a certain period of time due to their operational and financial restrictions. Linking incentives to more transparency of R&D costs will prove unfeasible: Developing medicinal products is a complex process with a high failure rate, and methodologies are unlikely to capture the true R&D costs and investments. Consequently, linking the incentive system to the above mentioned obligations would substantially weaken the EU's ability to attract and promote innovation.

It should be noted that the EU can only take legislative action within the limits of its competences laid down in the Treaties. Its legislative competences in the important area of financing innovation are very limited. In further discussions, policy-makers at EU level should resist the temptation to use the means of pharmaceutical law, patent law or intellectual property rights to try to solve problems whose causes should in fact be tackled elsewhere and by the Member States individually.

Creation of specific incentives to promote the development of new classes of antimicrobials

d) Regarding the fight against antimicrobial resistance (AMR) in the EU and respectively the development of new antibiotics, possible new approaches have to be explored and implemented. We agree that the current situation is not satisfactory. The European Commission correctly recognises that new incentives for the development of antimicrobials are needed. Therefore, the BPI proposes to think about new models for the creation of incentives, which would have to work across Europe to effectively guarantee a 'return of investment'. These could take the form of so-called 'pull mechanisms' (e.g. purchase guarantees) to guarantee manufacturers an appropriate return on investments made in this area.

Existing treatment options e.g. with herbal medicinal products are an important contribution in reducing AMR. They either help to reduce the use of antibiotics, to reduce their side effects or, in the interests of prevention, to even possibly avoid their use in a particular case entirely. The BPI suggests - if the requirements are met - that such medicinal products must be included in the official action and strategy plans for the global reduction of antibiotic resistance.

Authorisation and life-cycle management of different generic medicines

h) BPI supports the single assessment of active substance master files. Finished product monographs for different generic medicines to facilitate their authorisation and lifecycle management should complete these. This would provide a facilitation for authorities as well as for companies. It would be good to include the environmental risk assessment (ERA) in these considerations as well. Pharmaceutical companies using the same APIs run a series of basic tests multiple times, which is not efficient.

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Security of supply

i) Instead of further transparency, reporting or even storage obligations, whose bureaucratic effort is not in proportion to their benefit, the BPI calls for smarter supply and distribution strategies in order to ensure that medicinal products are available where needed. Furthermore, an effective global network and solid supply chains including a strengthened European production are crucial. 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.

Environmental sustainability

k) Future strategic approaches of the EU concerning the topic of medicinal products and the environment must not be an obstacle to future research, authorisation and the maintenance of authorisation. All measures should therefore be taken with a reasonable sense of proportion and should also be feasible for SMEs and Midcaps. The inclusion of environmental aspects in decisions about regulatory processes for the authorisation, supervision and distribution of medicinal products makes this considerably more difficult and leads to increased costs and personnel expenses without great benefit for the environment or an improvement in patients treatment.

As every substance is different, a tailored approach with measures to reduce the environmental impact (e.g. education about the correct use and disposal of medicines and the improvement of wastewater treatment plants) would prove more useful than general legislative rules.

BPI appreciates a system that avoids unnecessary repetition of environmental studies. A system for sharing comprehensive active-substance-based Environmental Risk Assessments (ERA) at EU level would be useful. The inclusion of the ecotoxicological data to the generic principle like clinical and toxicological data would strengthen the procedure as well. Exemptions from the environmental risk requirements for innovative products for high unmet medical needs should be considered.