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Feedback on the impact assessment from the initial phase of evaluating and revising the general pharmaceutical legislation

Healthcare systems in the EU are faced with the challenge of ensuring affordable, high-quality pharmaceutical care in the face of high prices. Therefore, German Social Insurance welcomes the fact that the EU intends to revise the European pharmaceutical legislation.

Product development and approval for unmet needs: The criteria and definitions used to identify UMN (Unmet Medical Needs) as triggers of regulatory tools and incentives should all be consistent and population-based. Member State organisations should be involved in the proposed revision of the orphan medicinal product and paediatric medicine regulations. Support for products that address UMN must be aimed at generating robust clinical data about the actual added benefits of the medicinal products. This would require a strong European Medicines Agency (EMA) mandate to enforce appropriate study programmes.

Incentives: The existing incentives are based far too much on the economic success of the medicinal product concerned. This leads to high prices and the avoidance of less commercially attractive areas. Alternative incentives for medicines that only address the highest medical needs and provide a relevant benefit would appear to be appropriate. It is appropriate to oblige developers to make the results available throughout Europe since these incentives are used to promote innovation in a uniform way throughout Europe. Inequalities in accessing new medicines cannot be justified.

Reducing the administrative burden: The EU already offers the pharmaceutical industry uniform and, therefore, low-bureaucracy access to the entire internal market through its centralised authorisation procedure. Reducing unnecessary administrative requirements and, where appropriate, harmonising and merging requirements at European level might also be useful, provided that this does not entail any loss of information.

Competition in generics and biosimilars: The regulatory authority should provide statements about interchangeability when approving biosimilars. These should be limited to an indication that there is sufficient consistency for an exchange, e.g. through statements about biosimilarity that are generally abstract. This could also be extended to cover hybrid registrations and include other registration channels that have proven to be problematic. The regulatory authority should also be given the ability to compel marketing authorisation changes designed to keep dossiers up to date with current medical and regulatory requirements.

Introducing flexible elements: Greater emphasis should be placed on comparative evidence during the approval process. Studies attached to the marketing authorisation application for new medicines should be comparable with the current standard of care. This will improve the ability of Member States to set benefit-based prices, thus maintaining the sustainability of healthcare systems against a background of continuously increasing burdens from patent-protected medicines, especially those with new technologies.

Bottlenecks: It must be possible to enforce the supply, delivery and reporting obligations of pharmaceutical manufacturers throughout Europe in a binding manner and through the use of sanctions. Effective sanction regulations will also be needed in the event of obligation breaches that are attributable to a production-related bottleneck. Voluntary measures taken by industry to create transparency in supply chains are just not enough. In order to avoid supply bottlenecks, the competent authorities need to be better networked and cooperate better at EU level. They should

be able to implement specific steps to avert or preventively eliminate any actual or feared bottlenecks. Strengthening the EMA in crisis situations is a correct step in this respect.