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Consultation response on Inception Impact Assessment on the revision of the EU legislation on medicines for children and rare diseases

The Danish Government welcomes this opportunity to put forward our response to the consultation over the inception impact assessment on revision of the EU legislation on medicines for children and rare diseases published by the Commission on 25 November 2020.

The Regulation for medicines for rare diseases and the Regulation for medicines for children were initially adopted to improve treatment options for children and patients affected by rare diseases. Both Regulations introduced a mixture of obligations, incentives and rewards to address the apparent market failure in these areas. The joint evaluation of the two Regulations has shown that although both legislative instruments have stimulated research and development of medicines for children and rare diseases the legal framework also has significant shortcomings.

The inception impact assessment lists a number of different policy options for revision of the two regulations, respectively, and describes how interested parties will be consulted in the process.

The Danish Government welcomes the initiative to address the shortcomings of the existing legal framework.

However, the design of incentives and rewards under the two regulations have a heavy impact on business decisions involving investments, research and development for new medicines, where a solid IPR protection ensures and maintains an innovative life science sector in the EU. Business decisions are also influenced by a number of other factors such as national systems and regulations for pricing and reimbursements of medicine and global competition, why it is important that a comprehensive impact assessment is performed before policy decisions are made and the legislation is drafted.

The inception impact assessment reveals that there are many interconnected and complex issues once you start looking at the current regulation. The Danish Government notes with satisfaction that an impact assessment will be performed and that a study to support the assessment will be commissioned to provide a solid base for the contents of the future legal proposals.

The Danish Government stresses the importance of any future legal proposals striking a proper balance between incentives, rewards, competitiveness and innovation on one side and access and availability of medicines as well as health systems' budgetary sustainability on the other side.

I am looking forward to working together with the Commission and the other Member States in this area.

Yours sincerely,

Magnus Heunicke