Danish non-paper on the revision of the EU pharmaceutical legislation

Europe is faced with a unique chance to position itself in the global race of developing and delivering healthcare solutions in a resilient manner to patients. This requires a resolute and visionary effort that leverages innovation, industrial and public capabilities and accessibility of medicines to patients through a future-proof pharmaceutical regulatory framework.

The upcoming revision of the pharmaceutical legislation is an opportunity to address three key challenges for Europe: 1. How to ensure timely access to affordable medicine for all Europeans, 2. How to support Europe's ability to innovate and play a leading role in developing new medicines, and 3. Enhance security of supply of pharmaceuticals and thereby strengthening European open strategic autonomy in this vital area, while taking environmental impacts into consideration.

We see several interesting elements among the considerations of the Commission such as repurposing medicine, streamlining the approval processes and accommodating new concepts of adaptive clinical trials and real-world evidence. These measures will contribute to the accessibility and to the future-proofing of the legislative framework. Development of medicines that address unmet medical needs including novel antimicrobials is also needed. Further, we welcome the Commission's focus on security of supply which is becoming increasingly important. The same goes for the Commissions focus on the environmental impact of producing pharmaceuticals. This is a very welcome step which could make important contributions towards the tackling of the climate crisis.

While the upcoming proposal is timely and necessary, Denmark has deep concerns that some of the measures under consideration to ensure better access to affordable medicines in all Member States will not solve the current problems and could in fact lead to adverse consequences for Europe and European life science industry's innovation capacity to develop and provide new medicines to Europeans.

Access to affordable medicine for all Europeans

Multiple factors influence patients' access to medicines and ensuring better access is a shared responsibility between industry, national authorities, and the European level. It is important that all Member States, including smaller countries with limited markets, have access to affordable medicines. At European level we should encourage sharing of best practices among Member States, notably on sharing data, ensuring transparency of national processes and efficient administrative procedures.

The idea under consideration to reduce the period of regulatory data protection for companies is a cause for deep concern as it may have adverse impacts. A reduction of the data protection period increases the uncertainty for companies' investments and may lead to fewer new medicines for patients and make EU less attractive for placing research, development and production. Further, we do not believe that making a conditional period of the regulatory data protection to companies launching new medicines in all Member States will improve access to medicines for the patient. For that reason, new incentives should be added to already existing incentives. Denmark therefore proposes an alternative and more balanced tool based on the principle of shared responsibility with the following main elements:

- An obligation for companies to report on plans for marketing of products in the Member States, if the companies have not taken steps to market in all Member States within a reasonable time. Alternatively, an obligation to file for pricing and reimbursement in all Member States.
- This could be supported by efforts to ensure better transparency on national processes for reimbursement and launch status.

- These measures should be followed by a call to all Member States to ensure sufficient capacity in competent authorities to streamline national pricing and reimbursement procedures, including providing early advice to support companies. Also, collaboration on best practices among national authorities as well as a proper implementation of shared health technology assessments.

Strengthen innovation and keep a leading role in developing the medicines of the future

Encouraging further innovation will raise Europe's ability to handle the next pandemic and provide cutting-edge medicines across Europe. Further this will be to the benefit of patients all across Europe. Framework conditions can drive or impede the development and uptake of innovative new products. To keep Europe at the forefront of global innovation, the regulatory framework has to set competitive and predicable conditions to support development and approval. The pharmaceutical sector is also an important source of high-skilled jobs and growth in Europe. Protecting and developing the European economy – of which the pharmaceutical sector constitutes a significant part – should be an important aim of the revision. To maintain and further strengthen Europe's strong culture of innovation the upcoming proposal should take the following into consideration:

- Ensuring predictability in the regulatory protection periods as it is core of the pharmaceutical research and innovation cycle. Conditional regulatory protection periods can create great uncertainty for long-term and risky investments – especially for SME's.
- The upcoming revision should strengthen regulatory efficiency by simplification and streamlining of approval procedures and flexibility to ensure adaptation to the rapid scientific and technological developments. We encourage a closer, earlier and on-going public-private collaboration in the regulatory phase while maintaining high standards and robust assessment of quality, safety and efficacy of medicines.
- Timely and effective implementation of the health technology assessments as a way to decrease the burden on national authorities when assessing new products.
- Earlier scientific advice in general but especially for SMEs which may have more difficulties to overcome barriers related to market launch.

Security of supply and future health threats

Medicinal products are not only essential to restore the health of European patients and ensure the well-being of citizens; they are also of strategic importance in a time, where multiple world crises call for autonomy in Europe. Learnings from the pandemics show that security of supply to European patients is an increasing issue due to vulnerable global supply chains. Actions should balance administrative burdens for the industry and transparency. The following points could be taken into consideration to further strengthen security of supply:

- Transparency with regard to the expected need and actual use of medicines in the national health care systems and as well as transparency with regard to supply capacity of companies.
- Steps towards diversification of production sites and supply chains where needed.
- The use of electronic patient information leaflets.

In this regard, we find it to be a timely opportunity to prioritise attention to the environmental impacts of the production and distribution of medicines.