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Pharmaceutical strategy for Europe: Combined evaluation roadmap/inception impact assessment

Denmark would like to use this opportunity to thank the European Commission (EC) for all the efforts made in terms of the highly important work on the pharmaceutical strategy for Europe. We agree on the need for an ambitious, long-term project in order to make the system patient-centered, future-proof and crisis-resistant while ensuring safe medicines of high quality. Of equal importance is the focus on the sector's global competitiveness and thus maintaining the EU as an attractive hub for research, development and investment. Last, but not least the possibilities offered by the increasing use of data for regulatory purposes should be further explored in order for the legislative framework to be better equipped to respond to the scientific and technological developments (including in a timely fashion for the benefit of patients in particular and society in general).

From a Danish perspective, all of the objectives listed in the roadmap are key in order to ensure the above. At the same time, Denmark acknowledges that there are many different possible policy options to choose from in order to reach these objectives. Denmark also shares the challenges pointed out by the EC that the strategy needs to tackle. However, we believe that overall, the work with the pharmaceutical strategy is on track.

The pharmaceutical strategy for Europe is multifaceted as it covers many aspects. A substantial number of details, dependencies and interfaces between the various objectives will inevitably be revealed over time as the work progresses. We would, however, like to highlight some reflections for the purpose of the on-going work. We consider that the areas outlined are vital in order to ensure a strengthened pharmaceutical agenda within the EU.

Security of supply and APIs
APIs are a necessity in order to produce pharmaceuticals. Due to lower production costs, a substantial number of API's (for generics and biosimilars in particular) are produced outside the EU and some API's are manufactured only at a very limited number of sites world-wide. Obviously, this makes the EU vulnerable, in particular when demand increases as we have seen it happen during the pandemic.

It is vital that these challenges are not only addressed through the pharmaceutical strategy, as the handling of the matter needs a multi-sectoral approach. Various means may be considered in order to strengthen the supply chain. Potential initiatives could include:

- Strengthened role for the EU, including in crisis situations;

- Strengthened resilience in the production stage, i.e. more diversity and increased incentives to produce off-patent pharmaceuticals, including antibiotics;
- Registration requirements, i.e. registration of API as well as indication of production capacity for the API registered.
- Increased transparency in terms of production – and distribution pathways would equally contribute positively as would the competence for member states to act accordingly if the production of essential API is deemed too fragile. Increased transparency would also make it easier to track and trace the entire supply chain. The registration of APIs to improve transparency is going to have to be supported by a robust database and changes in law to oblige manufacturers to update information regularly.

Real world data and big data
The use of real-world data and big data provide for a substantial potential of strengthening the entire life cycle of a pharmaceutical. National competent authorities need to match the (data driven) development in this field. From a regulatory perspective, it is critical to map the challenges that this (also) provides, including evidence requirements.

That said, technological possibilities lead to a shift in paradigms where data may provide for the following:

- Compensate for lack of evidence, i.e. in relation to orphan drugs where small patient populations make gold-standard clinical trials more difficult;
- Strengthened pre-marketing phase as products may be authorized at an earlier point in time and strengthened scientific advice;
- Strengthened post-marketing phase;
- Strengthening of the compiled set of decisions, including those to be made by authorities as real-world data may lead to a more multifaceted dataset for decision makers;
- Strengthened basis for HTA-decisions to ensure timely access;
- Strengthened possibilities to identify fraudulent data, e.g. in relation to clinical trials

A strengthened digital agenda
From a Danish perspective, a strengthened digital agenda is vital in order for the EU to remain an attractive region for research, development and production of pharmaceuticals.

Increased digitalization will also facilitate overview and integration of data for the benefit of data analysis. Overview of data will indeed strengthen decision making by both competent authorities and industry as well as the public more generally and will contribute positively in terms of e.g. the accessibility agenda.

Another aspect stemming from digitalization is the potential of reducing (administrative) burdens and increasing the involvement of patients in order to better capture patients' views, preferences etc. in relation to their treatment.

A strengthened digital agenda can not be achieved solely through the pharmaceutical strategy. It requires attention in other strategies such as the strategies on digitalization and on industry.

At the same time, health data contain sensitive information so it is important to ensure that data is used in a lawful and secure manner with respect for EU's and Member States' data protection regulation and principles.

Increased integration between innovation and technology in the development of pharmaceuticals and focus on innovation throughout the life cycle of a pharmaceutical

The technological development indeed also contributes significantly to the development of new medicines, e.g. within advanced therapy (ATMP).

Precision medicine, nano technology, 3D print, in-situ manufacturing etc. in many aspects have positive implications on the patient. Therefore, it obviously also prompts attention from national competent authorities as regards awareness on public health and patient safety through regulatory means.

In view of the above, Denmark considers it appropriate to evaluate if the existing regulatory processes are up to date as well as future-proof, including in terms of authorization of medicines.

In view of the fast development in science and technology, we also find it advisable to promote a more adaptive legislative framework. This work also needs to be continuously coordinated with associated legislative fields, e.g. medical devices, where the rapid technological development increasingly blurs the lines between medicinal products and medical devices.

A balanced approach as regards incentives in order to ensure innovation within the EU and continuous development of generics and biosimilar products

Denmark considers it vital to ensure the region's attractiveness in terms of financial investments, research and development within the life science sector. Therefore, a well thought out and balanced approach to incentives as well as an up-to-date and future proof regulatory framework is key, taking into account the financial sustainability of national health systems and the relationship with intellectual property rights. The pursuit of affordable medicines must not counter vital incentives to innovate, as this will undermine the long-term positive effects of having a strong innovative pharmaceutical industry, whose importance to the EU has been amplified in the current COVID-19 crisis.

In this regard, it is vital that the objective of establishing a tailored system of incentives does not cause a destabilisation of the existing structures, bearing in mind that predictability is key for investments in R&D. In addition, incentives should be considered in a broader perspective, taking into account that other key factors such as digitalization, a sound competitive environment, education, access to highly qualified skills also form part of this agenda.

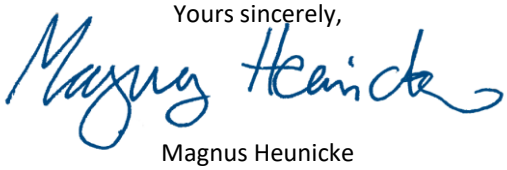
Dissemination of "best practice" globally and focus on the environment

Production and distribution of medicines, science and technology all have global dimensions, which accentuates the need for dialogue and knowledge sharing between competent authorities at global level.

Therefore, it is key that the EU maintains and further increases our collaboration globally. The current Covid-19 crisis has also amplified the need for international engagement, including harmonization and knowledge and information sharing on (quality) standards, collaboration and cohesion of regulatory frameworks.

Along the same lines, Denmark would like to stress the need for a green approach across the entire pharmaceutical value chain, and that such an approach must equally be promoted by the EU at international level.

Yours sincerely,



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