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Consultation on Road Map for the Pharmaceutical Strategy – timely access to affordable medicines

The Danish Government welcomes this opportunity to put forward our response to the Road Map for the Pharmaceutical Strategy launched by the European Commission in June.

The Road Map describes four 'categories' of objectives that each contains a range of sub-topics, which will be pursued through legislative and non-legislative actions. From a Danish perspective, these objectives seem to capture the essence of the broad range of issues that appear to require attention at European level.

The Danish Government supports the Commission's emphasis on the need to build a holistic, patient-centred, forward-looking Pharmaceutical Strategy that covers the whole life-cycle of pharmaceutical products from scientific discovery to authorization and patient access. The Danish Government also supports a strategy that emphasises the sound functioning of the internal market and the sustainability of public finances.

The European pharmaceutical industry contributes significantly to the European trade surplus, and is a major contributor to the EU economy where it creates economic growth and employment.

Shortages of medicines are a potential threat to patient safety in the European Union. Access to and availability of medicines is essential to our health and our confidence in the health system. It is therefore important that the European citizens can trust that they have access to both existing and new medicines of high quality and safety.

The covid19 crisis has amplified many of the objectives set out in the Road Map. The indisputable fact that the pharmaceutical sector is vital for the Union and its citizens in order to safeguard public health and pave the way for research and innovation has become increasingly evident. The crisis has equally underlined the fact that the sector operates in a global setting with many complex dependencies on other actors. Thus, we fully endorse the view that attention shall also be given to the international dimension and the sector's global competitiveness.

The pharmaceutical sector is a knowledge-intensive sector where a strong IP framework and incentives structure contribute to innovation and development of new therapies.

Overall, the Danish Government finds it important that the future EU Pharmaceutical Strategy aims at striking a balance between availability and access to medicines on the one hand, and innovation and the sector's global competitiveness on the other.

The current pandemic has highlighted the need to address the ongoing concerns on shortages of medicines. We believe that the strategy should consider if and how we can make use of strategic stockpiling of critical medicines and medical products in combination with ensuring supply by diversifying supply lines and upholding a level playing field globally with the aim to decrease the dependence of EU countries on the manufacturing capacity of single suppliers from third countries to mitigate these concerns.

The pharmaceutical sector is indeed data driven and we therefore highly welcome the Commission's statement that the artificial intelligence (AI) agenda and opportunities for the sector within data analysis will be part of the future work with the strategy.

We further agree that synergies with other EU policies in areas, such as Europe's beating cancer plan, research, innovation, intellectual property rights and the EU Green Deal must be considered. In this regard, we find it important to ensure that the Pharmaceutical Strategy and the EU4Health programme work in the same direction.

The Road Map takes a very broad approach to all of these topics and the Danish Government would like to stress the importance of the final strategy being action-oriented, setting out clear priorities for further work at European level.

. / . In addition, please find attached a common non-paper from BE, DE, DK, ES, FR and PL outlining some aspects that could be useful to consider in the coming strategy.

In summary, the Danish Government finds that the Road Map sets a good overall direction for the future strategy. We look forward to the political and technical discussions that lie ahead in order to make the EU a strong global player within this highly important sector.

Yours sincerely,

Magnus Heunicke

How to ensure EU's preparedness for pandemics

The corona virus has taken a heavy toll in terms of human lives and let to an unprecedented economic downturn. The present situation has raised questions about Europe's preparedness for pandemics and underlined the need for a common European approach, so that the EU and its member states find themselves better prepared for a second outbreak of the virus and future pandemic crises. The stakes are high and a solution will require a holistic approach that draws on a wide range of instruments in the EU toolbox including industrial policy, research, digitization and EU funding.

This paper will attempt to zoom in on some of the key parameters for ensuring the EU's long-term resilience in case of future public health crises in the EU. These include a sufficient supply of personal protective equipment (PPE), medical devices, critical medicines, and vaccines. Understanding the shortcomings is essential, as was also pointed out in the Spanish non-paper previously circulated regarding the need for stress testing of national health systems.

The backdrop for an initiative to ensure the EU's preparedness for future pandemics is Member States' experiences of varying degrees of shortages during the current COVID-19 crisis. A key goal is therefore to identify ways to ensure stronger long-term European resilience to withstand future crisis. A broader, holistic EU strategy could be more efficient than each member state attempting to enhance preparedness on their own, as also emphasized by the BENELUX-countries in their letter to the Commission of 16 April 2020 on joint procurement.

As an initial step, a comprehensive diagnosis is needed in order to get a clear picture of the magnitude, the character and the believed causes of the supply deficiencies and challenges observed during the first stage of the COVID-19 crisis. An EU strategy on availability of critical medicines, medical devices, PPE and vaccines to prepare for potential future health crises should address: (i) efficient monitoring and possibility of data sharing, (ii) coordination of supplies, (iii) research and innovation, (iv) the regulatory framework, (v) global value and supply chains, and (vi) production facilities. Below are some preliminary considerations on these issues.

1. Efficient monitoring and data sharing

In order to boost resilience and preparedness, efficient surveillance, sharing, analysing and comparing data will be key. With respect to privacy and use of personal data, an EU strategy that aims to enhance preparedness for future pandemics should look into how the EU could significantly increase its ability to track pandemic development in order to help identify health emergencies on the rise, and to increase situational awareness across the EU. Key considerations in this respect would be:

- **Central data points should be identified** in order to ensure monitoring and thereby obtain a common baseline and understanding of key measurements in the prelude to a crisis. Key measurements could include the spread of a given pandemic, but also available stock etc. The potential for establishing common European standards or harmonised methodology for health data interoperability and key figures of future epidemics should also be explored.

- **Continuous monitoring, comparing, sharing and analysis** of such data is necessary in order to be able to have a shared and up-to-date understanding of the situation and identify the right actions in order to respond firmly and swiftly.

- A strengthened mandate for **The European Centre for Disease Prevention and Control (ECDC)** to coordinate, with national health authorities, prevention and reaction plans against future epidemics within a future EU health task force.

2. Coordination of supplies

To ensure better distribution and coordination of supplies, the strategy should look into:

- **Efficient division of labour within the EU** in order to optimize European production, drawing on national and regional expertise in existing life science clusters and production facilities. A key feature of the division of labour could be cooperation agreements and legal commitments on a voluntary basis from Member States towards common EU goals and targets. Experiences from shared responsibilities and management in cohesion policy could be considered as inspiration for the working methods. Such an approach would allow for the use of smart specialisation and place based mechanisms.

- **Size of the stocks,** where Member States could seek to agree on dynamic criteria ensuring flexibility in terms of the crisis to be addressed, resulting in:
  i. Lists of critical medicines, critical protective equipment, critical medical devices, and critical vaccines that need to be stocked as a minimum;
  ii. Size of the stocks - e.g. 3 months of supplies for the entire EU.

  Common goals should reflect the responsibilities of each Member State to secure its own resilience, and how quickly the industry can be expected to restructure their production. It is to be expected that it will be more time-consuming and economically burdensome to switch production to advanced pharmaceuticals than to PPE such as masks.

- The EU should establish **common strategic stocks of critical medicines and medical products** (protective equipment, testing kits etc.). In this respect, **The European Civil Protection Mechanism's rescEU-program** should be evaluated with a view to ensure that it is being used adequately to build (relevant) stocks of critical medicines, medical devices, PPE, and vaccines.

- As a supplement to national crisis management, **the capacity of the European Civil Protection Mechanism**, to coordinate distribution across Member States, including whether Member States need to play a greater role in the distribution based on common criteria for access and cooperation between member states.

As these programs and mechanisms are meant to be utilised in a time of crisis, further consideration should be given to more long-term solutions, which would allow time for capacity building. Joint Procurement Actions could hold considerable potential and be deployed more broadly, notably with a view to encourage EU capability build-up.

3. Research and innovation

Strong investments in fundamental research and alignment of research and innovation efforts and better linking of these to European manufacturing of products and medicines are essential in order to be better prepared for the next pandemic, in terms of both vaccine development, diagnostics, treatment, sharing research data and the understanding of public behaviour. It is vital to increase European capacities on research and development for vaccines and treatments, as well as to coordinate at the international level

(ACT-A initiative) in order to ensure capacity to develop and produce vaccines. Drawing on expertise from all Member States, the following initiatives could be considered:

- **Joint vaccine development**. Developing a vaccine is a huge and expensive task, and a unified European strategy holds great European added value; in this regard, it is necessary to ensure coordinated dialogue with the pharmaceutical industry as regards critical components and procedures. This includes a coherent, transparent, and coordinated approach towards the selection of vaccine candidates, support mechanisms, possibly including financial support via EU funds. Fast track procedures, mapping the most promising candidates with manufacturing capacity in close dialogue with industry for instance on how to limit the liability in engaging in such production can play a role. It should be considered, whether funds should be allocated at EU level specifically for the establishment of a clinical preparedness platform, as this would accommodate the urgent need of enabling EU to speed up the time from the outbreak of a future pandemic to the successful deployment of a vaccine. Decreasing liability of producing vaccines through guaranteed public purchase could make such efforts more attractive to engage in and EU-level contracts in order to scale up the production of developed vaccines could be explored.

- **Diagnostics.** A coordinated European approach and more precise diagnostic tools, test reliability, and better knowledge of the impact of different test strategies is needed. Establishing networks of laboratories that can be activated when the need occurs, i.e. in case of a pandemic, could be explored.

- **Treatment.** The development of innovative medicines is essential for progress in preventing and treating new diseases. This calls for long-term, continuous R&I investments e.g. in the fields of virology end epidemiology, and the implementation of large-scale clinical trials in order to obtain robust results in a timely manner. It should be examined whether EU should aim to scale up innovation capacity by strengthening the framework conditions for conducting medical research and medical trials and how EU-funds could to a greater extent finance large-scale clinical trials and getting medical products ready for the market.

- **Sharing research data.** Swift dissemination of research results throughout the EU will increase chances of breakthroughs. To realise the objectives of the European Open Science Cloud (EOSC), initial deployment of a new European COVID-19 Research Data Platform Pilot should be a priority.

- **The value of social sciences and humanity (SSH).** A key aspect in a pandemic is the regulation of public behaviour. Research in the effects of public communication, (mis)information campaigns, the role of social media, and other IT communication, including tailor-made apps for tracking and information sharing, will be highly relevant.

4. Regulatory framework

In order to support cooperation between public and private partners there might also be a need to look further to the regulatory framework, building on the EU's own strengths and principles:

- Ensure resilience through a **strategically strengthened Single Market** as this is one of our greatest assets and a key element in building resilience. The free flow of trade across borders, common rules and standards can accelerate the development of optimal solutions to future crisis.

- **Examine the option of more permanent antitrust guidelines relevant in times of crisis** concerning limited and temporary cooperation among businesses in response to urgent situations related to pandemics. In the current situation, the 'Temporary Framework Communication' has been

valuable to companies willing to temporarily cooperate and coordinate activities in order to increase production.

- **Examine the effectiveness of the public procurement procedures and Joint Procurement Agreement (JPA).** The 'guidance for public buyers' has helped to ensure rapid and efficient purchases of necessary equipment, but evaluations of national and European level procurement processes should be conducted to examine how the practical modalities, speed of the implementation etc. could be improved .

5. Global value and supply chains

As commodities from international trading partners are essential, the following should be considered:

- **Ensure open, fair and flexible global value chains.** A key part of ensuring affordable supply of commodities and critical products involves diversifying supply lines and upholding a level playing field globally. This includes identifying new trading partners with the aim to decrease the dependency of EU countries on single suppliers. The EU should also strengthen EU and national investment screening towards non-EU investments in the EU in strategic sectors (including health, pharmaceuticals, biotech etc.), while at the same time encouraging investments (re)located in the EU.

- While making value chains more robust it is important to consider the **need for sourcing certain critical input**. This requires openness in terms of ensuring continued access, but also points to the possible further potential in circular models, which could improve access to relevant materials. Also in this area resilience of supply chains is important and it could be also necessary for companies to diversify their sourcing regarding critical medicines in order to have more than one active substance supplier.

- Amidst growing global trade tensions, **preventing protectionism will be key** when considering temporary measures. There is a real risk of the current situation leading to withdrawal from global markets, which should be tempered through a focus on flexible and robust value chains within and outside the EU as well as drawing on expertise from global markets. Consideration should be given to important trading partners and in particular developing countries, who depend on imports from the EU and are vulnerable because of weak capacity and health systems.

- **Ensure flow of trade by transport.** During the COVID-19 pandemic open European supply lines has been essential in ensuring the regular flow of trade by sea, land and air and the operation of supply chains. Therefore, it should be considered how the EU in the future could facilitate regular flow of trade for the undisrupted availability of critical commodities to e.g. the life science industry.

- Any trade measures should be **compliant with WTO-rules, IPR regulation** and **support the multilateral trading system**, minimizing the risk of retaliation or dispersion of measures in other sectors than health.

6. Production facilities

In order to ensure supplies, looking into increasing the production facilities in the EU, could be relevant. Here, the following could be considered:

- A **public commitment to buy a certain number of specific products** could ensure the incentive to increase production facilities in the EU and alleviate insecurity of companies in terms of whom

to sell the products in times of low supply. Consideration could be given to guidelines, the current state aid rules, the principle of equitable global access, distribution keys and how to best ensure smooth operations, transparency and trust – through EU-level decisions or bottom-up cooperation.

- The European Commission should **allow incentives to develop and invest in production capacity** for select and critical active ingredients, raw materials and medicines in the EU including support for innovation and more efficient production technologies as well as reduction of regulatory burden.

- **Encouraging adaptability as an economically efficient way of strengthening resilience.** During the current crisis, many European businesses have shown excellent adaptability and been able to produce i.e. hand sanitizer and face shields to cope with the increasing demand and to shift production depending on different suppliers. The particular Danish experience shows that digitization and public-private partnerships can help build resilience. Based on this, the Commission could study similar experiences across the EU to explore to what extent **adaptability - based on modern and digitalized production** - could be an economically efficient way to ensure self-sufficiency and resilience without initiating large-scale production with risks of overproduction etc. Such adaptability could furthermore be underpinned by **collaboration agreements between Member States and larger companies** where these agree to produce a number of specific products in times of crisis against expected sales to governments and national health care systems and thus not jeopardizing businesses normal production with limited or no benefit. The role of Small and Medium-sized companies should also be taking into account in these consideration (e.g. by open calls to participate in collaborations agreements). Finally, a broader focus on digitalization and automation could be explored to strengthen the structural capacity of our industry to quickly adjust production processes.

- **Exploring the potential of fostering industrial ecosystems and structuring them within European projects,** for critical medicines, medical devices, PPE and vaccines, maintaining an innovative and competitive life-science sector in the EU through solid IPR protection, favourable framework conditions for conducting medical research and clinical trials, and sharing of data and coordination of R&D. We should consider the creation of **Important Projects of Common European Interest** for the production of active substances, vaccines, medical equipment and for e-health, health data and biotechnologies, where appropriate to address specific market failures. A special focus could be on removing regulatory barriers in order to allow for innovation and greater control of supply lines of critical products and also the role of Small and Medium-sized companies.