Response of the Netherlands to the public consultation of the Roadmap of the European Commission on the Pharmaceutical Strategy

We welcome the publication and the opportunity to respond to the open consultation of the Roadmap of the European Commission on the Pharmaceutical Strategy.

Access to affordable medicines and a **healthy, competitive EU market** are crucial for the health of the European people and for the security and autonomy of the European Union. Medicinal products are not only essential for the health of patients and the wellbeing of citizens, they are also of strategic importance to the EU's industrial landscape. The European pharmaceutical industry plays a valuable role in the research and development of innovative treatments and in the production of key enabling technologies that should match the **green and digital transformations**. Ensuring the **supply of high quality, safe, efficacious and affordable medicines** in the single market is urgent and decisive to the future of the European Union.

On 17 June 2016, the Council adopted Council Conclusions **"strengthening the balance in the Pharmaceutical Systems** in the EU and its Member States". These Conclusions addressed a number of key concerns and challenges in the EU-pharmaceutical system, in particular in the field of accessibility, availability and affordability. The Member States and the Commission were invited to undertake a range of actions to mitigate these challenges and problems. In addition, the outcome of the December 2019 EPSCO Council was a call for a concrete pharmaceutical agenda with actions placed in time. It is important that the Commission will incorporate this recent Council's plea for an agenda into the announced pharmaceutical strategy.

The strategy should be in line with the division of competencies and powers between the EU and Member States and respect the distinct roles of the Commission and the Member States.

NL perspective on the roadmap

We consider that the **problems** outlined in the roadmap that are to be tackled by the pharmaceutical strategy have been correctly identified. They include, among others, **unequal access to medicines due to high prices, occurrence of medicines shortages, misalignment between public health needs** and **new medicines being developed,** as well as **the existence of a regulatory framework that is not sufficiently responsive to technological and scientific advancements**. Furthermore, we **support** the overall **aims** of the strategy to help ensure **the supply of high quality, safe, efficacious and affordable medicines that meet patients' needs,** as well as **to encourage the EU pharmaceutical industry to secure the European autonomy.** In our view, these goals should serve to redress the balance of a sustainable pharmaceutical system where public interests are guaranteed.

We are pleased to recognise elements in the Roadmap which were put forward in the June 2016 Council Conclusions, such as the need to promote cooperation between EU Member States within the fields of health technology assessment and pricing and reimbursement; to strengthen the EU regulatory framework in the field of pharmaceuticals; to address market failures and ensure accessibility, availability and affordability of medicinal products for human use.

The publication of the Commission strategy should be followed up by a Council EU-working plan on pharmaceutical policy (2020-2025) in close cooperation between the Member States and the

European Commission. This would involve defining a joint programme of objectives and concrete activities, engaging the Member States in the planning and development process, defining coordination roles, and establishing clear and transparent governance and procedures. All this while ensuring proactive exchange of information between the Member States and the Commission.

Bearing this in mind, we believe that the European Commission is on the right path towards the development of a pharmaceutical strategy to help secure access to high quality, safe, efficacious and affordable medicines to its citizens. Nevertheless, there are four key procedural principles to be met throughout this process.

In our view, the process around the pharmaceutical strategy should be:

1. **Jointly developed, user-centric and responding to real needs.**

   The pharmaceutical strategy should result from a joint collaboration between the European Commission and all Member States. This is essential to ensure that the content of the pharmaceutical strategy meets **the needs of its target groups**, i.e. the Member States at a macro-level, cascading ultimately into their health systems, their health professionals, their patients and their citizens at grass-root level. It should therefore be **user-centric**. This requires active dialogue with the various stakeholders and joint preparation of the content.

2. **Based on evidence and thorough analysis.**

   The development of the pharmaceutical strategy and its ensuing measures are to be based on **evidence and analysis**. Therefore, studies on which the European Commission will build the pharmaceutical strategy must be shared in a timely manner, in order to stimulate debate and exchange of views between the Member States and the Commission. This would include inter alia granting access to any studies, their terms of reference, results, related reports as well as the Commission's analysis thereof.

3. **Holistic yet concrete.**

   In order to reach the aforementioned objectives, the pharmaceutical strategy requires a holistic approach. While we welcome such an all-inclusive strategy, we encourage the European Commission to provide more clarification on the short term. Given that the specific objectives in the roadmap are stated using relatively general terms, we would appreciate further clarification, discussion and translation of the objectives into **concrete and operational actions.** For this we point to the outcome of the EPSCO Council of December 2019 where Member States urged for a concrete agenda with actions placed in time. For instance, by tackling the necessary legislative reviews on the short term rather than at a later stage.

4. **Coherent with ongoing and forthcoming EU policies.**

   The European Commission is currently developing and/or discussing several initiatives that have great implications for the future of the European pharmaceutical strategy. We propose linking the various components of a new Industrial Strategy for Europe, the upcoming Pharmaceutical Strategy, the research and development policy (namely the pharmaceutical R&D within Horizon Europe), as well as of the EU recovery plan and its EU4Health programme, to duly align overarching objectives and strategic measures.

In terms of content, we note below several issues that we consider fundamental to the pharmaceutical strategy.

Strengthening the autonomy of European supply

The crisis highlighted **existing vulnerabilities** in medicines' availability as well as **one-sided dependencies** in raw materials and product supply from a few third countries. We encourage a European response to medicines shortages, which can encompass a diversification of sourcing and suppliers, larger stocks and a greater stimulus for relocation of production locations. These measures would aim to increase the resilience of the pharmaceutical chain and enable an efficient response to peaks in demand, whereby the EU could be leading in innovative, sustainable, efficient and cleaner production. We welcome the coordinating role of the EU Executive Steering group on shortages of medicines caused by major events that was chaired by the European Medicine Agency (EMA).

Our aim is to achieve a healthy investment climate and ecosystem within the EU, where we can foster innovation and decreased undesirable dependency and vulnerabilities in medicine supply and where public and private interests are well-balanced.

Pricing and reimbursement

We applaud efforts to **support co-operation between Member States on issues that allow for better pricing and reimbursement policies, such as the assessment of clinical benefits of products through joint Health Technology Assessment (HTA), the facilitation of information exchange and procurement practices**. The Netherlands has advocated increased cooperation on pharmaceutical policy for several years. The Netherlands has combined forces with other countries through the Beneluxa Initiative, focusing on joint assessments and price negotiations of pharmaceutical products. One noteworthy Beneluxa collaborative result is the founding of the Horizon Scanning Initiative, of which currently nine EU and non-EU countries are members.

As to legislative actions, we agree with the goal to strengthen EU cooperation on health technology assessment (HTA) and look forward to the adoption of the legislative proposal.

Legislation on marketing authorisations and exclusivities impact the field of pricing and reimbursement. It is thus essential to look at these areas in an integrated manner.

Adapting the regulatory system to current needs

We welcome the goal to strengthen and review the European legal framework on pharmaceuticals, provided the quality, safety and efficacy of new medicinal products are duly guaranteed.

We welcome the proposal to review incentives and obligations for innovation, market launch/entry and continuous supply of products, and the fact that the Commission is also open to discuss legislative actions so that the regulatory system can be adapted to meet current needs. We appreciate the proposal to review procedures for accelerated development and assessment of medicines for major public health needs. We further support the evaluation of the Orphan and Pediatrics Regulations and look forward to having access to the results of the latest study and to the ensuing discussion. On one hand, we also foresee the need to make EU legislation more responsive to innovative developments, such as Advanced Therapy Medicinal Products (ATMPs), as we are certain that more scientific and technology advancements will follow in the future. Given the challenges on the market of these types of products, these areas require attention in the short term.

On the other hand, we would support changes to the legislation to help maintain medicinal products on the market and to prevent shortages. These include the simplification of the procedure for

variations, as well as the use of electronic leaflets enabling manufacturers to produce packages that can be used in all Member States, thereby introducing greater flexibility, but still safeguarding patient access to high quality, safe and efficacious medicines with the correct product information.

The application of a Supplementary Protection Certificate (SPC) should return to the original intention of the Regulation, where only new active substances which have not yet been on the market should qualify for an SPC.

Transparency

We noticed that **transparency** is only briefly mentioned within the context of regulatory and administrative simplification, but it requires more attention overall. We would like to refer to the WHO resolution on improving the transparency of markets for medicines, vaccines, and other health products that was also adopted by many EU member states, as well as to the Beneluxa statement regarding transparency as a key contributor to achieving sustainability of access to medicines. We welcome a debate on transparency. In our view, transparency is a broad instrument that needs to be clearly defined and that can be applied, amongst others, to the R&D system, clinical research results, public investments and, ultimately, price setting. We therefore ask the Commission for further clarification as to what the European Commission sees as a likely application of transparency within the pharmaceutical strategy.

Environmental aspects

The aim to tackle environmental aspects throughout the whole lifecycle of pharmaceuticals is laudable, also in light of the increase in antimicrobial resistance. However, when establishing any measures, it is important not to jeopardise access to medicines. Environmental risks can therefore not be part of the final benefit/risk assessment of a medicine for human use. Pharmaceutical residues are introduced in the environment during production, use and disposal. Therefore, a routine **dialogue and collaboration** between the healthcare, environmental, agriculture and water sector is key to create mutual understanding and efficient problem-solving. We encourage the improvement of both environmental risk assessment and environmental expertise within the EU. Finally, the EU pharmaceutical strategy should have a clear link with the EU strategic approach to pharmaceuticals in the environment and legislation on water and chemicals.