EUROPEAN COMMISSION

Brussels, 3.2.2023
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Dear Chair,

The Commission would like to thank the Sénat for its Opinion on the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Pharmaceutical Strategy for Europe {COM(2020) 761 final}.

The Pharmaceutical Strategy aims to create a future proof regulatory framework and support industry in promoting research and technologies that reach patients in order to fulfil their therapeutic needs. The Pharmaceutical Strategy is a central pillar of a strong European Health Union.

The main actions announced in the Strategy will be addressed in the revisions of the general pharmaceutical legislation and of the legislation on medicines for children and for rare diseases. The main objectives pursued are:

- *Ensuring access to affordable medicines for patients, and addressing unmet medical needs (for example in the areas of antimicrobial resistance, cancer, rare diseases);*
- *Supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines;*
- *Enhancing crisis preparedness and response mechanisms, and addressing security of supply;*
- *Ensuring a strong EU voice in the world, by promoting a high level of quality, effectiveness and safety standards.*

The Commission concurs with the Sénat on the importance of EU-funded research activities on medicines, such as those under the Horizon Europe programme. It takes note of the examples that the Sénat raises requiring research support and reiterates its determination in providing research support through EU-funded research activities and through initiatives under the European Health Union.

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cc.

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The Commission supports the view of the Sénat that more targeted support is needed towards medicines that address unmet medical needs (including for antimicrobial resistance and rare diseases) and it is working towards proposing a common understanding of criteria which, if adopted, will allow for support to real innovation in such areas.

The Commission notes the Sénat's call to build on proven concepts for accelerated medicine development and authorisation through concepts, such as the European Medicines Agency Priority Medicines (PRIME) scheme and rolling reviews. The Commission supports their codification in legislation but notes that such tools can only be used selectively for priority areas and not as a default in all cases, given their heavy impact on resources of the EU medicines regulatory network.

The Commission shares the objective of strengthening the environmental sustainability of medicines. This objective is served through the entire corpus of the EU legislation, notably the rules on wastewater treatment and relevant international conventions. The Commission's upcoming proposal on the pharmaceutical legislation will aim to complement those rules through strengthened environmental risk assessment of medicines and measures covering the whole lifecycle of medicines. The Commission fully agrees with the conclusion of the Sénat that any rules supporting the environmental sustainability of medicines should not be to the detriment of access to medicines for patients.

The Commission also fully supports the Sénat's call to enhance supply and availability of medicinal products to patients. This is done through measures that improve monitoring, reporting and management of shortages starting from an EU wide definition of shortage, critical shortage and critical medicinal product. The Commission also agrees that, to improve the prevention, mitigation and resolution of actual or potential critical shortages, the procedures and the respective roles and obligations of concerned entities should be clarified. The Commission notes the support of the Sénat for providing language flexibilities in the information provided to patients for critical medicines and considers that the possibilities presented by electronic products information can be an enabler in this regard.

The Commission takes due note of the call of the Sénat to achieve more for the EU's health sovereignty and strategic autonomy. However, the solutions rely on strong trade relations, diversification of supplies and investment in projects of common European interest. The Commission also continues to deliver on the pharmaceutical strategy's goal to ensure EU leadership and influence on global standards and principles within international and multinational organisations.

The Commission shares the Sénat's objective to achieve more affordable medicines and notes the call to support Member State coordination in this respect, notably on joint public procurement, with full respect of the division of competences between the EU and the national level. As part of the Pharmaceutical Strategy, the Commission is developing cooperation in a group of competent authorities, based on mutual learning and best-practice exchange on information on pricing, payment and procurement policies, to

improve the affordability and cost-effectiveness of medicines and health system's sustainability.

At the same time, the Commission has set ambitious, yet achievable, targets in terms of real access to medicines in all Member States. It will make proposals to achieve this through regulatory support and through the system of regulatory incentives, which will enable a positive change of behaviour from all players.

The Commission looks forward to discussing the upcoming proposal with the co-legislators in the inter-institutional negotiation phase of the legislative process and values the prompt engagement of the Sénat. The Commission takes note of the views expressed and will consider them in view of the forthcoming proposal. In addition, it welcomes the fact that many points raised in the Opinion reflect a common understanding of the challenges and match the Commission's views on the way forward.

In response to the more technical comments in the Opinion, the Commission would like to refer to the attached annex.

The Commission hopes that the clarifications provided in this reply and its annex address the issues raised by the Sénat and looks forward to continuing the political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President

Stella Kyriakides
Member of the Commission

Annex

The Commission has carefully considered the issues raised by the Sénat in its Opinion and, as regards the points to which the Sénat has drawn the Commission's particular attention, the Commission is pleased to offer the following technical observations grouped by topic.

Articles 29 to 56 – Research

The Horizon Europe programme supports research and innovation, contributing to the Pharmaceutical Strategy. Under Horizon Europe, the Commission establishes partnerships with Member States and with the industry. The Innovative Health Initiative is one of the several public-private partnerships between the EU and the European life science industries. Its core goals are to translate health research and innovation into tangible benefits for patients and society, and ensure that Europe remains at the cutting edge of interdisciplinary, sustainable, patient-centric health research. The Innovative Health Initiative is currently the largest public-private partnership of this kind.

The Innovative Health Initiative will support cross-sectoral projects involving the biopharmaceutical, biotechnology and medical technology sectors, including companies active in the digital domain. By adopting an integrated, cross-sector approach, the Innovative Health Initiative will be well placed to have an impact on health research and healthcare, both of which are increasingly interdisciplinary in nature.

Like its predecessors, the Innovative Health Initiative will therefore focus on unmet public health needs. This means that the partnership will cover the different stages in the healthcare pathway at which it intends to intervene, including prevention, detection, diagnostics, treatment, and disease management.

Articles 50,52,54 and 55 – Unmet medical needs and innovation on established medicines (repurposing)

The Commission supports the view of the Sénat that more targeted support towards medicines that address unmet medical needs (including for antimicrobial resistance and rare diseases as well as paediatric diseases, considered as a priority for the Commission) is needed and it is working with Member States to propose criteria in legislation which will allow for support to real innovation in such areas.

The Commission also supports the repurposing of off-patent medicines and envisages regulatory measures to enhance the use of repurposing.

Moreover, the Commission joins the Sénat in its opinion that measures for the prudent use of antimicrobials, an essential element for addressing the antimicrobial resistance threat, need to be proportionate to the objective of protection of health and the protection of environment. This issue is at the centre of political attention, both for the Commission and the Member States. The Commission is exploring legislative and non-legislative measures in this context.

Articles 143-154 – Intellectual property

The intellectual property (IP) issues raised are important in the context of the implementation of both the Pharmaceutical Strategy and the IP Action Plan[1]. Legislative proposals are envisaged to be presented in 2023 regarding the unitary supplementary protection certificate and of a centralised procedure for granting national supplementary protection certificates. Work is also ongoing regarding improvements to be introduced as regards compulsory licensing for EU cross-border crisis management purposes.

Articles 149 and 150 - Orphan and paediatric medicines – IP aspects

The Commission considers that the current extension of the supplementary protection certificate which can be granted following the completion of the paediatric studies has been appropriate to support timely paediatric developments and encourage the conduct of clinical research for children. The Commission would like to recall that the extension of the supplementary protection certificate coexists with other incentives provided by the pharmaceutical legislation, like regulatory protection and market exclusivity in the case of medicines for rare diseases.

Articles 153-161 – Access and market launch

The Commission agrees with the recommendation of the Sénat regarding the extension of the possibility of off-patent medicine producers to conduct clinical trials on medicines covered by IP protection. The Commission is looking into the broadening of the so called 'Bolar' provision in this respect.

The Commission shares the objective of ensuring wide access to medicines across the EU. In this respect, the Commission's planned modulation of incentives would encourage timely market launch of innovative products in all Member States and facilitate off patent medicines to enter a market. In addition, the Commission is also examining the possibility to clarify and support non-private bodies (for example academia and non-profit organisations) to become marketing authorisation holders.

The Commission recognises that withdrawals of medicines on the basis of reasons other than safety and efficacy of the product can be further regulated to enhance in particular the security of supply of medicines. The Commission is examining measures in relation to earlier notification of withdrawals as well as the obligation to offer medicine authorisations under withdrawal to another marketing authorisation holder before the withdrawal takes place.

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[1] COM(2020) 760 final. COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Making the most of the EU's innovative potential An intellectual property action plan to support the EU's recovery and resilience.