



EUROPEAN COMMISSION

*Brussels, 18.6.2021
C(2021) 4605 final*

Dear President,

The Commission would like to thank the Camera Deputaților 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 on the Pharmaceutical Strategy for Europe {COM(2020) 761 final}.

The Commission is pleased that the Camera Deputaților recognises the importance of the strategy as a key pillar for a stronger European Health Union and has taken due note of the views expressed in its Opinion.

In proposing this strategy, the Commission aims at ensuring that the EU citizens have access to innovative and affordable medicines across the EU. The strategy also aims to support the European pharmaceutical sector to be an innovator and strong global player in the development, production and provision of high quality, safe and effective pharmaceuticals as well as to create a resilient supply chain and address shortages. The strategy also takes into account the lessons learned from the current COVID-19 pandemic and will integrate them towards the creation of a crisis-resilient EU pharmaceuticals system.

An innovation-friendly framework, which allows for simplification is key. The Commission aims to work with Member States in harnessing the possibilities brought by digitalisation and innovation to the benefit of the patient as a means to increase access through new tools and possibilities. This is especially true for certain specific patient population groups, such as older people and patients in less developed areas. We also intend to support infrastructure investment through our projects related to a European Health Data Space. Moreover, we aim to reduce administrative burden and adapt

*Mr. Ludovic ORBAN
President of the Camera Deputaților
Palace of the Parliament
Str. Izvor nr. 2-4, sector 5
RO – 050563 BUCHAREST*

regulatory processes to take into account technological developments. In addition, there will be strong incentives where we need them, for example for rare and paediatric cancers, neurodegenerative diseases, vaccines or antimicrobials.

Supporting small and medium sized pharmaceutical businesses is one of the objective of the strategy. This is combined with actions aiming to contribute to skills investment within the European medicines regulatory network and in the EU pharmaceutical sector workforce. The health ecosystem is eligible for participation in the Erasmus+ action “Blueprint Alliances” launched on 20 April 2021. In addition, under the Pact for Skills initiative there is a health ecosystem skills partnership.

While pricing and reimbursement policies are a national competence, as part of the strategy, the Commission has stepped-up its cooperation with Member States on the exchange of information and best practices on principles and methods for pricing, payment and procurement policies. It also plans to reinforce competition in the pharmaceuticals market notably through enabling easier access to the market of generics and biosimilar medicines. Such policies will foster better access to all patients, and will especially benefit disadvantaged patients.

The strategy aims to give a holistic response to the challenge of a sustainable system that allows equal access to medicines and the opportunities, for example coming from scientific breakthroughs and digital transformation, by making the necessary links to related policies such as digital, environment, intellectual property and others. We have launched studies to further understand the reasons for delayed market launches of medicinal products or the root causes for shortages, in order to inform appropriate policy answers. While the immediate work of the Commission will focus on the priorities expressed in the Communication, it remains available to discuss policy needs that may arise in the process.

The Commission hopes that these clarifications address the issues raised by the Camera Deputaților and looks forward to continuing the political dialogue in the future.

Yours faithfully,

*Maroš Šefčovič
Vice-President*

*Stella Kyriakides
Member of the Commission*