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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Strengthening the pharmaceutical ecosystem in support of competitiveness and equitable access to medicines *- Exchange of views*

Delegations will find in Annex a background note from the Presidency to steer the exchange of views on "Strengthening the pharmaceutical ecosystem in support of competitiveness and equitable access to medicines" at the EPSCO Council (Health) on 13 June 2023.

ANNEX

Strengthening the pharmaceutical ecosystem in support of competitiveness and equitable access to medicines

On 25 November 2020, the Commission proposed a new pharmaceutical strategy for Europe[1], a patient-centred strategy that aims to ensure the quality and safety of medicines, while boosting the sector's global competitiveness. Since then, the Council has addressed different aspects of the pharmaceutical ecosystem as information items, for instance market entry (EPSCO Council of June 2022) and most recently shortages of medicines (EPSCO Council of March 2023). On 26 April 2023, the Commission published a communication[2], together with proposals to reform the pharmaceutical legislation and a proposal for a Council Recommendation on anti-microbial resistance (AMR). Building on discussions on access to medicinal products at the informal meeting of health ministers in Stockholm on 4-5 May 2023, the Presidency considers it useful for the Council to reflect on the pharmaceutical ecosystem in support of equitable access to medicines and competitiveness .

The competitiviness of the EU's pharmaceutical sector

According to the Commission communication of 26 April 2023, the EU is one of the largest pharmaceutical markets in the world and has a strong and competitive pharmaceutical industry. The sector directly employs 840 000 people and three times that number indirectly. Europe (the EU, UK and CH) is a major research and development (R&D) investor in pharmaceuticals, with EUR 39,7 billion in 2020. The EU is also a global leader in manufacturing high-tech medicines, as evidenced by its leading role in supplying the world with COVID-19 vaccines. In 2021 the EU has exported pharmaceuticals worth EUR 235 billion, which is EUR 136 billion more than it imported. The EU spends around 1.5% of its GDP on medicines – EUR 230 billion in 2021 – of which more than 80% goes to innovative products, making the EU pharmaceutical market the second most attractive market for industry, especially for innovators.

1 13158/20
2 8415/23

These figures show the EU's considerable success in a sector based on a complex, costly and high-risk research process, and where there is intense international competition to attract pharmaceutical R&D, including through the applicable legal frameworks.

On the other hand, evaluation of the current legislation concluded that the regulatory system does not sufficiently cater for innovation and in some instances creates an unnecessary administrative burden. In addition, the industry itself is noticing a relative decline in Europe's attractiveness as a centre for biopharmaceutical investment, with the gap between the US and Europe increasing from EUR 2 billion in 2002 to EUR 20 billion in 2020, while China is also emerging as an increasingly competitive region for companies to locate their activities[3].

Unequal access to pharmaceutical innovation in the EU

Today medicines authorised in the EU are not reaching patients quickly enough and are not equally accessible for patients in all Member States. Patient access to medicines varies across the EU in terms of the number of products entering the market or time of entry. As a comparison, while in one Member State, 133 out of 152 (i.e. 88%) new medicines authorised between 2016 and 2019 at EU level were accessible to patients, fewer than 50 of these were available in small Member States or Member States with comparatively low prices or with low GDP. The time to patient access is also longer for most of these latter countries, e.g. approximately two years or more after marketing authorisation compared to four months at the other end of the spectrum. As a result, patients may not have access to any appropriate treatment for their disease[4].

In order to reach patients, medicines require a marketing authorisation – which for most innovative medicines in the EU is granted through a centralised procedure – and must then be launched on individual Member State markets by the company that holds the authorisation. The decision to launch a medicine in a given Member State is taken by the company based on factors such as market size, promotion and distribution networks, as well as national pricing and reimbursement policies. This leads to smaller Member States often facing limited or delayed product entries on their markets.

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3 Factors affecting the location of biopharmaceutical investments and implications for European policy priorities. CRA, 2022.

4 8759/23 ADD 4

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Both the development of new medicines and the availability of medicines depend on a strong pharmaceutical industry, for the benefit of both the EU economy and its patients. The need for a strong and competitive pharmaceutical industry, driven by high investment in R&D, and equitable access to the fruits of that investment, has indeed been at the heart of recent discussions on the future of the EU's pharmaceutical policy. The Presidency therefore considers it important to table this topic for discussion by the Ministers at the EPSCO Council (Health) meeting of 13 June 2023.

Ministers are encouraged to address the following questions during the debate:

– What measures on EU level do we need in your view to ensure equitable access to medicines to all patients in EU?

– What do you consider as important elements in order to ensure a highly competitive and innovative pharmaceutical industry in EU for the benefit of EU citizens?