

February 22, 2021

Commissioner Thierry Breton  
Commissioner Stella Kyriakides  
Rue de la Loi 200  
1049 Brussels  
Belgium

Cc: Sylvain Giraud, Head of Unit - DG Health and Food Safety  
Giuseppe Casella, Head of Unit - DG Internal Market, Industry, Entrepreneurship and SMEs

**RE: Prevention of medicine shortages through the constitution of safety stocks**

Dear Commissioners Breton and Kyriakides,

Medicines shortages have been a serious and growing concern for patients and healthcare professionals across the European Union for many years, long before the COVID-19 pandemic brought this major issue under the spotlights. In 2019, there were 1,499 shortages of medicines notified in France<sup>1</sup> (compared to 868 in 2018), 1,492 in the Netherlands (compared to 769 in 2018) and 2,208 in the Czech Republic (compared to 1,630 in 2018)<sup>2</sup>. Most of the medicines in shortage are essential in the care of chronic patients, including cancer patients.

In its recent “Report on the shortage of medicines”<sup>3</sup>, the European parliament “*stresses that for patients, the consequences of drug shortages include: progression of the disease and/or worsening of symptoms due to a delay in treatment, avoidable transmission of infectious diseases, increased risk of exposure to falsified medicines, and significant psychological distress for patients and their families*”, echoing the conclusions of several national and European surveys reported in “EPHA position on medicines shortages in Europe”<sup>4</sup>. In the Pharmaceutical Strategy for Europe, the Commission itself acknowledges that “*Shortages compromise patient health and severely burden healthcare systems and healthcare professionals*”<sup>5</sup>.

We welcome the initiatives proposed by the Commission to secure the supply of medicines across the EU and avoid shortages, especially the inclusion of stronger obligations for supply and transparency in the pharmaceutical legislation. We are aware, though, that any revision of the EU

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<sup>1</sup> Only supply disruptions of medicines of major therapeutic interest are notified in France.

<sup>2</sup> Based on the data published on the websites of the national medicine agencies of those three countries.

<sup>3</sup> Report on the shortage of medicines – how to address an emerging problem (2020/2071(INI))

<sup>4</sup> EPHA position on medicines shortages in Europe, published on 27 April 2020 <https://epha.org/position-medicine-shortages/>.

<sup>5</sup> Communication from the Commission: Pharmaceutical Strategy for Europe, COM(2020) 761 final.

legislation is a long process, and those new obligations may not become effective before years. On the other side, patients cannot wait any longer and need immediate actions that concretely improve the availability of their treatments.

The constitution of safety stocks of medicines is an important instrument that carried out in a coordinated manner can support the prevention of shortages because *“pharmaceutical firms operate according to the just-in-time method, which can leave manufacturers vulnerable to supply shocks where there are unanticipated production and supply chain interruptions and fluctuations in market demand”*, as mentioned in the report of the European Parliament. Since 2008, Finland has successfully imposed mandatory stock levels to producers, the duration of which depends on medicine categories. Other EU countries, such as France and the Netherlands, are currently in the process of adopting similar rules. The objective is that pharmaceutical companies adapt their production to comply with their new stock obligations, without diverting supplies from one Member State to another.

National initiatives aimed at fighting medicine shortages should be encouraged and coordinated by the European Commission, with the objective to develop good practices that can be extended to other Member States and eventually transformed into EU provisions. The mandatory constitution of safety stocks of medicines by market authorisation holders is one of those measures. It should go hand in hand with a closer cooperation and coordination among Member States, and with the transparency of available stocks proposed in the Pharmaceutical Strategy to guarantee a fair distribution of medicines across the EU.

We therefore ask you to both support current national initiatives on safety stocks of medicines, and to consider including mandatory stock levels among the supply obligations of the revised EU pharmaceutical legislation.

With kind regards,

**Signatory organisations (in alphabetical order):**

EAHP – European Association of Hospital Pharmacists

EATG – European AIDS Treatment Group

ECL Access to Medicines Task Force

EPHA – European Public Health Alliance

France Assos Santé

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