medicines for europe
better access. better health.

efpia
European Federation of Pharmaceutical Industries and Associations

Mr. Giorgos Rossides
European Commission
Brussels

27 October 2020

Dear Mr. Rossides,

Thank you for the constructive exchange regarding the pharmaceutical strategy. We appreciate the effort to engage in a more in-depth exchange with industry to apply the lessons learned from COVID-19 in future.

On the call, we raised our concern with the current EMA/HMA definition of shortages which runs contrary to the experience of COVID-19 and effectively undermines the possibility to resolve such challenges. The current definition (as outlined in the 1 July 2019 Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs)in the Union (EEA)) 'A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level' establishes a direct link between supply and market demand (understood as economic demand, not patient need). The COVID-19 experience shows clearly that market players overreact (through hoarding or stockpiling, leading to increased demand for medicines) thus exacerbating shortage risks and that industry and authorities need to coordinate to ensure equitable access to patients in need.

For example:

- When India announced export restrictions on paracetamol API and unfounded rumours circulated regarding the safety of alternative molecules (ibuprofen), distributors, pharmacists and patients panicked and started hoarding paracetamol which threatened access in hospitals. This occurred without any evidence of actual shortages of paracetamol production in Europe (although some OTC manufacturers did face challenges, other manufacturers scaled up production massively with available safety stocks of API thus there was no industry-wide production shortage in Europe). Consequently, most Member States had to intervene in the market to monitor distributor stocks so that hospitals would receive the product. Pharmacists also had to limit sales to patients in many countries to prevent hoarding.
- Most Member States introduced temporary, targeted restrictions on parallel trading activities for COVID-19 relevant medicines combined with distributor stock monitoring to, it was claimed, prevent speculative activities in the EU pharmaceutical market.

Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

- Hospitals in the most affected EU countries adopted hoarding policies for ICU medicines to the detriment of other hospitals or regions. In most EU countries, national governments intervened to monitor hospital stocks and ensure equitable distribution to hospitals with the highest patient critical need.
- Some EU Member States adopted national strategies to hoard medicines COVID-19 relevant medicines – including some temporary restrictions on the legitimate activities of pharmaceutical manufacturers. Medicines for Europe, EFPIA and the Commission cooperated extensively to ensure that EU solidarity would be respected and that the EU would help all patients in need.
- To minimise contact, patients were given longer term prescriptions for many chronic disease medicines which created large demand spikes at national level, not reflecting real patient demand over the long term. Industry stocks were easily able to cover this situation without the need for market panic.
- Through the Joint Procurement Agreement, the European Commission and Member States procured ICU medicines towards the end of the first wave of COVID-19, generating additional market demand at national level. This additional demand was not a shortage signal from the market (as the data collected by AT Kearney demonstrated sufficient stock of critical ICU medicines was sufficient for total EU demand). It was an apparent effort by the Member States to plan for a second wave reserve.

These examples clearly show that in the event of a perceived supply/demand imbalance, market players tend to exacerbate the problem and coordination between industry and authorities (at national or at EU level) may be required to restore equity of access to medicine. We believe that the EMA/HMA guidance should reflect this experience by clearly defining a shortage as:

- *A shortage of a medicinal product for human or veterinary use occurs when supply does not meet patient need at a national level, for a period of more than two weeks.*
- Clarifying that in the event of a supply/demand imbalance, authorities should coordinate with industry at national or EU level to ensure equitable distribution based on patient critical need.

Another lesson learned from COVID-19 is that the EU and Member States lack access to reliable data in a supply/demand imbalance situation. In practice, both Member States and the EU (via EMA) had to collect information on stocks and inventories from manufacturers and from distributors during the pandemic. For example, the EMA relied on the Article 57 database to contact companies for the creation of an industry single point of contact (iSPOC). As the Article 57 database only includes the qualified pharmacovigilance person (QPPV), the EMA did not receive nominations from all relevant MAHs for the list of critical products in the scope of its monitoring.

An IT based project management process (see further details below) could easily introduce relevant supply chain contacts (iSPOCs) to enable a rapid industry-authority cooperation in the event of supply/demand imbalance. In addition, once established, the data collected by agencies was mainly done through excel sheets with stock data. The use of excel sheets is not only time consuming for manufacturers, distributors and regulators, it also prevents authorities from conducting real-time analyses of the situation. We must recall that when industry warned the Commission in March of this year that Member States would see a massive surge in demand for ICU medicines and that they would not have sufficient reserves, most Member States had no visibility whatsoever on their inventory levels. Regrettably, we note there has been only limited improvement of the situation since then. This clearly shows the limits of relying on old-fashioned data collection tools that ultimately do not deliver on patient

access to medicine. Medicines for Europe and EFPIA consider that the EU could dramatically improve the access to relevant data in the near future with the implementation of a coherent digital telematics strategy.

For many years now, the EU telematics strategy has been unreasonably delayed. It is now time to invest in the SPOR process and to implement an efficient IT project management process to enable a rapid deployment. We also underline the critical importance of interoperability across all EU member state medicine agencies. Should these agencies need funding, we believe that the EU recovery fund could be used for this purpose. To improve oversight in a critical supply/demand risk situation, the telematics strategy should embrace a rapid connection to the European Medicines Verification System (EMVS) which contains relevant data for authorities to address epidemiological concerns. The use of this data would dramatically improve the visibility of a supply/demand imbalance for the EU and could serve to inform effective policy solutions and choices to ensure equitable access to medicines. (We attach - for information - a peer review manuscript to be published in the Frontiers Regulatory Journal outlining a proposal for using the data stored in the interoperable network of national repositories being set up in the context of the Falsified Medicines Directive (Directive 2011/62/EU) and its Delegated Regulation 2016/161/EU on safety features for providing additional intelligence in monitoring shortages). This effort could also bring tangible long-term benefits to EU policy – notably the future digital health space which will require a connection the relevant product information held by medicines agencies. Clearly, the EU can and should move quickly to create a digital and interoperable digital system to deal with supply/demand imbalances making best use of existing data which exists in the EMVS.

To conclude, Medicines for Europe and EFPIA are fully engaged to cooperate with the European Commission to improve access to medicines in Europe. We therefore welcome this dialogue and look forward to others in the future to improve EU pharmaceutical policy and to support a highly competitive and responsive EU pharmaceutical industry.

Yours sincerely,

[redacted]

[redacted]

Medicines for Europe

[redacted]

[redacted]

EFPIA