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European Federation of Pharmaceutical Industries and Associations

Policy proposals to minimise medicine supply shortages in Europe
Lessons from COVID-19 crisis

Ensuring the supply of medicines to patients who need them, remains a top priority for EFPIA and its members. Throughout the Covid-19 pandemic, the pharmaceutical industry has acted as a responsible partner working together with relevant EU and national authorities. This Paper summarises the challenges in securing supply of crucial medicines during the COVID-19 crisis and proposes a number of policy recommendations to help ensure that patients across Europe get the medicines they need. The COVID-19 crisis has highlighted five key issues to be addressed in order to minimise any shortages of critical medicines in and within Europe:

1. The importance of a **preparedness plan for critical medicines and the need for regulatory flexibility**: having instigated pandemic preparedness plans since December 2019, EFPIA member companies have been able to increase production through exceptional effort to meet the needs of patients for COVID-19 treatments. The increase in production was facilitated through a timely and continued dialogue with competent EU and national authorities on regulatory processes that ensure rapid availability of therapies needed to manage COVID-19 patients (e.g. Intensive Care Units - ICU medicine) to the broader population in need;

2. The need for **understanding and transparency of Member States demand**: companies are facing an enormous increase in demand for some medicines due to the pandemic, especially medicines used in ICU and Covid-19 treatment candidates. Apart from the increase in production by EFPIA member companies to meet this exceptional growth in demand, all the evidence suggests that there is also an underlying allocation challenge. The real issue is not simply about producing and supplying more drugs – it is about getting the right drug to the right hospital in the right country at the right time, and having a clear picture of what is likely to be needed for any future waves of the outbreak. Practices as parallel export and stock piling are disruptive.

3. The need for **timely (current and forward looking) epidemiological data**: the European Centre for Disease Control (ECDC) should release modelling data about the likely progression of the pandemic in each country, as well as patient need data and hospital capacity data in the Member States. Industry needs real data on patients in need and in addition, a collaboration mechanism for better coordination of allocation of medicines across Member States.

4. The need for **transparency of the supply chain**: authorities should use the information contained in the EMVS (European Medicines Verification System) data repositories set up in the context of the EU Falsified Medicines Directive to monitor, at aggregate level, when and how various medicinal products/INNs are placed on which markets as well as the rate of their 'consumption' at national level. These data exist and could be used as a powerful tool to plan and manage the allocation of medicines to ensure patients get the treatments they need.

5. The need for **Member States solidarity**: the concrete actions taken by the European Commission and the European Medicines Agency have led to clear improvement after the early weeks of the crisis. However, industry continues to observe various forms/degrees of export bans, which risk impacts not only in Europe, but to patients globally. In order to ensure the optimal and continued supply of medicines in Europe, the Commission, EMA and regulatory authorities in the Member States need to maintain open borders via Green Lanes; list pharmaceutical companies on the priority list of distribution and supply of personal protection equipment (PPE) at national level and designate manufacturing and distribution staff as essential workers facilitating crossing borders and going to sites; continue to monitor and take proactive measures to limit hoarding by patients and other actors in the supply chain; and maintain the guidelines on regulatory flexibilities. The EU and Member States should also avoid actions that threaten supply to countries beyond Europe, where the Covid-19 crisis

may be epidemiologically worse; such actions also risk retaliation from trading partners, threatening supply into Europe. Focus should rather be on leveraging the EU's leadership on trade policy, and wider international momentum to advance liberalisation measures such as customs facilitation and waiving tariffs on medicines.

10 proposals from diagnosis to action	
ENSURE OBJECTIVITY (right diagnosis)	**MAKE RECOMMENDATIONS IN LINE WITH EXISTING EU POLICIES**
1. **Ensure a consistent and workable definition of medicine shortages** - A shortage of a medicinal product for human use occurs when supply does not meet patient need at a national level for a period of more than two weeks.	**Revise the scope and definition of shortages included in the July 2019 Guidance on detection and notification of shortages of medicinal products for Marketing Authorization Holders** (MAHs) in the Union endorsed by EMA and Heads of Medicines Agencies[1], which has yet to be implemented through a pilot with MAHs. Standardised reporting requirements for information on clearly defined shortages based on patient need and not on national demand should be agreed, giving priority to critical products with high potential impact. The information should be uploaded onto a common portal to ensure a streamlined and effective alert system as well as an alignment across the data provided from different sources.
2. Ensure a better understanding of the root causes and drivers of shortages.	**Use by competent national and EU authorities of the information contained in the EMVS (European Medicines Verification System) data repositories set up in the context of the EU Falsified Medicines Directive** to monitor, at aggregate level, when and how various medicinal products/INNs are placed on which markets as well as the rate of their 'consumption' at national level.
3. Improve understanding and transparency of patient needs at member state level for appropriate planning forecasting.	**Call for the European Centre for Disease Control (ECDC) to release modelling data about the likely progression of the pandemic in each country as well as patient need and hospital capacity data in the Member States.** This information is crucial for manufacturers to adequately forecast demand and make the necessary planning in terms of manufacturing capacity and detailed distribution arrangements to supply those medicines to the right regions at the right time.
4. Address national stockpiling requirements.	**Oppose Member States introducing unilateral stockpiling requirements that put at risk the overall supply of critical medicines in Europe and work with Marketing Authorisation Holders in order to build safety stocks for critical medicines enabling to buffer unexpected increased EU patient demand.** An increasing number of EU countries but also wholesalers/traders, healthcare professionals and patients are requesting stockpiles. These are not

[1] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf. The definition included in the EMA/HMA Guidance refers to national demand rather than patients needs and therefore implies that it is the supply chain (e.g. wholesalers) that defines the existence of manufacturers' shortages irrespective of patient needs. The EMA/HMA definition goes beyond the responsibilities of a marketing authorisation holder and the scope as identified in Article 81 of Directive 2001/83/EU.

	commensurate with respect to expected demand following from company epidemiological estimates (especially for non COVID-19 treatments, e.g. cardio-metabolic). Effective enforcement is needed for existing regulatory requirements on all actors in the supply chain at national level, coupled with measures to enhance transparency within the supply chain and further dialogue/ best practice sharing between stakeholders. These tools are already easily available to Member States.
5. Facilitate the production and supply of treatments impacted by the pandemic through regulatory flexibility to meet patients needs.	**Ensure emergency measures are applicable to ongoing manufacturing and distribution operations for all medicines to avoid shortages (not just for medicinal products intended for use in COVID-19 patients)**. To avoid exacerbating co-morbidities in vulnerable patient groups or creating additional concerns about supply in the general population, suitable regulatory measures should be introduced for all medicines at risk of shortage in all Member States. An increase in production and supply facilitated through timely and continued dialogue with competent EU and national authorities, on optimal regulatory processes, is needed to ensure rapid COVID-19 therapies availability to a broad population whilst maintaining medicines supply to all patients.
6. Reach a careful balance between free movement of goods and the need to efficiently supply medicines based on patient needs as well as re-balance stocks across borders.	**Request Members States to abolish the distortive effects of national schemes incentivizing parallel imports from lower income to higher income Member States and incentivize the application of the non-extraterritoriality principle. Similarly, national requirements to maintain a significant national stock or limiting supply for other EEA markets should be abolished or at least reduced respecting the proportionality principle.** These practices hinder the much-needed visibility in times of crisis, as the quantities of parallel traded medicines are not known to the manufacturer nor to the authorities, therefore shared liability concept and rules should be implemented.
7. Ensure that procurement policies do not nullify the intended effects of supply side policies.	**Issue specific guidance for medicinal products for the proper application and implementation of the EU Public Procurement Directive by Member States.** Procurement bodies to use the MEAT (Most Economically Advantageous Tender) criteria to ensure continuous supply and avoidance of 'winner takes it all' approach to award contracts for procurement of medicines. The repetitive, yearly focus on lowest possible price, led to consolidation and search for economic efficiencies overseas (industry relocation in third countries). A variety of medicines should be available for physicians and patients instead of a single medicine. Public procurement should foster this diversity of suppliers by ensuring the final award of contract is not limiting doctors/patients to one choice of treatment.
8. Ensure the availability of critical medicines at EU level in line with Member States' patient needs.	**Establish proper pandemic preparedness plans - under strong medical supervision - for critical medicines at EU level based on solidarity between Member States, and**

	ensuring that non-pandemic related medicines continue to reach the patients in need. Such plans must use the learnings from the current crisis such as: ensuring free movement of essential goods and workers, need for proper data at Member States level on resources available as well as needed, use of EU level mechanisms (such as rescUE) to coordinate material (PPE, lab equipment, ventilators etc) purchase and distribution, etc.
9. Ensure continuous dialogue between competent EU and national competent authorities, and manufacturers with a view to addressing any imbalances between demand and supply.	**Set up a collective dialogue with respect to which medicinal products need to be produced, and in which quantity.** There is a strong common need for a coordinated, structured and reliable way to discuss and plan any future waves/pandemics, elaborating on the existing I-SPOC system that would be forward looking. Companies are becoming increasingly hesitant to continue operating and producing in the dark without evidence-based information on Member States' demand, concerned that supply might well exceed the demand for some medications considered to be under shortages by Member States.
10. Provide an environment where the research-based pharmaceutical industry can develop solutions to today's unmet needs, and ensure that Europe continues to be an attractive location for R&D investment and industrial development to respond to tomorrow's patients' needs. Based on a survey in January 2020 to which 17 global EFPIA member companies responded, 76,6% of APIs for on-patent products are sourced from the EU-28, 11.9% from US and 9% from Asia (including Japan and South Korea). For off-patent products APIs, companies source 61,5% from the EU-28, 7.2% from the US and 26,8% from Asia (including Japan and South Korea). In addition, economic data (here) shows that the EU27 already accounts for 60% of all global exports of finished pharmaceuticals (ex- and intra-EU trade).	**Provide global leadership on trade policy** by continuing to promote an open multilateral trading system, to take an active stance against forced localisation of pharmaceutical manufacturing and promote the creation of added value in Europe and beyond. Including pro-trade and pro-innovation policies in the EU's industrial strategy remains essential in linking trade to strengthening Europe's global competitive position. **Champion trade policies that strengthen globally integrated supply chains, promote innovation in Europe and global regulatory convergence.** This would include driving customs facilitation measures, pushing to update the WTO Zero-for-Zero Pharmaceutical Tariff Agreement and widen its membership, including strong IP provisions in EU FTAs and promoting regulatory convergence (via promoting membership of PIC/S and via mutual recognition agreements on GMP standards). **Set up a dialogue on the optimal regulatory processes to ensure rapid COVID-19 therapies availability to a broader population in need** eg.: ○ Possibilities and scope of rapid aligned scientific assessment across regulatory agencies, collaboration in the pre-assessment phase prior to availability of critical clinical data and aligned post-approval data generation and support manufacturing upscaling; ○ Lessons learned from regulators and industry from, as an example, the H1N1 and Ebola vaccine developments; ○ Role of ICMRA (and EMA as its Chair) in driving the international collaboration to assess new treatments for COVID-19.

Most recommendations included in this paper do not apply to vaccines due to the vaccines sector specificity (e.g. long production lead times, different distribution channels, etc.).