

Employment, Social Policy, Health and Consumer Affairs Council - 12 May 2020

An efficient Pharmaceutical strategy should take stock of coronavirus disease (COVID-19) lessons learned to deliver equitable access to medicines by ensuring supply resilience, healthcare systems sustainability and regulatory system modernisation

Introduction

The current COVID-19 pandemic has magnified some long-standing issues in the functioning of pharmaceutical policy, as well as the impact this can have on patient access. The industry has mobilised all efforts to ensure medicines continued to be developed, transported and supplied, in collaboration with the European Institutions.

It is important to take stock of the lessons learned from the COVID-19 outbreak and integrate these into future EU pharmaceutical strategies and policies. Before going into the details of the COVID-19 lessons learned specifically for medicines shortages, it is important to highlight three core considerations that a thoughtful pharmaceutical strategy cannot leave behind.

1. During the pandemic, the critical role of the **off-patent medicines (generic, biosimilar and valued added medicines) industry in health care was clear in ensuring the supply of medicines to patients. This, should be explicitly recognised in the future pharmaceutical strategy.** Without this sector, the number of patients treated would be significantly lower with higher costs, and the negative impact of a pandemic such as COVID-19 would be significantly higher.
2. **This crisis demonstrated that the European Institutions and Member States should coordinate policies to ensure equitable access to medicines.** Initiatives that supported this include the Medicines for Europe Hospital ICU medicines project, the distribution of hydroxychloriquine donations, direct financial support from the European Commission for medical equipment (Emergency Support Instrument) all show that the Commission and industry working together can improve equitable access.
3. **Coordination between European Institutions and the industry to address future healthcare challenges.** There was a major challenge in addressing demand surges which were clearly the root cause of many acute shortages for hospital ICU medicines across Europe. From the early stages of the crisis, Medicines for Europe engaged in a concrete problem-solving dialogue with the Commission and EMA to find solutions for all member states. Once this dialogue was in place, industry and the EU and Governments were able to rapidly align around common objectives such as dramatically increasing the supply of medicines for ICU patients to manage a massive surge in demand due to COVID-19. **This focused dialogue between Commission, EMA, national regulators and Member States should continue to address future public health challenges in pharmaceutical policy, a similar dialogue should be replicated also at national level.**

Medicine shortages: COVID-19 lessons learned that should be included in the pharmaceutical strategy

Among other important policy proposals, an efficient pharmaceutical strategy should aim also to **prevent shortages of medicines**. This issue has been affecting patients in all Member States for some time and now was exacerbated by the COVID-19 pandemic due to the unprecedented surge in demand for medicines.

Shortages of medicines have **multiple root causes**, namely economic causes, increasing regulatory burden, unforeseen surges in demand, supply chain interdependencies and manufacturing and quality challenges. Medicines for Europe stressed-out in our [Position paper on medicine shortages](#) and the related [infographic](#) as long as in the industry consensus paper [“Addressing the root causes of medicines shortages”](#).

There is an abundant evidence – including a recent study by the [US FDA](#) – showing the economic root causes of industry consolidation which in turn, increases the risk of manufacturing shortages or supply bottlenecks. The year of application of cost-containment in most EU countries on generic medicines is having a very similar effect. In addition, the EU has dramatically increased the regulatory requirements on medicine manufacturers over the last three years – FMD, Brexit, new medical device regulation (now postponed), pharmacovigilance requirements among many others. These measures disproportionately impact lower priced (often generic) medicines as cost increases to implement them tend to be uniform in all medicines. As most EU countries apply price regulation to medicines (even in the so called “free pricing markets” there are in practice cost-containment measures in the law that are applied in practice to the industry), it is difficult to compensate these regulatory costs with normal market dynamics. These conditions are not sustainable for manufacturers who struggle to maintain older, but still necessary, medicines available. Frequently, these older medicines are complex in their manufacturing processes such is the case of antibiotics and oncology medicines and, despite their relative low price, they hold great value in achieving desired health outcomes (e.g. Europe’s Beating Cancer Plan). It is therefore essential to incentivize companies to supply the market over time, reducing the risk of medicine shortages by promoting a stronger supply of essential medicines to patients.

Three key reflections emerged, as learning experience from the current COVID-19 pandemic, and the future pharmaceutical strategy should embrace them:

1. Building on resilience of the existing manufacturing capacity
2. Enhancing sustainability of healthcare systems
3. Modernising regulatory systems through:
 - ↳ Regulatory flexibility
 - ↳ A new telematics digital strategy

1. Building on resilience of the existing manufacturing capacity

The European Union should build on the existing manufacturing capacity in both finished dosage form (FdF) and active pharmaceutical ingredient (API) and incentivise its expansion. Supply chain resilience was challenged during COVID-19 by restrictions on exports in India and China but also constraints inside the Single Market. Pharmaceutical manufacturing chains are globalized and interdependent, if one piece is unexpectedly restricted, the entire production suffers.

Europe used to be the “pharmacy to the world” supplying around 80% of chemical substances and around 60% of medicines. Today, Europe continues to be a major manufacturing centre, despite inflated data circulated in Europe. According to the US FDA Generic Drug User Fee Amendments (GDUFA) database, the EU and Switzerland still accounts for around 31% of active pharmaceutical ingredients facilities (ahead of India at 30% and China at 17%; US at 12%; 10% rest of the world). Thanks to the SPC manufacturing waiver, Europe is poised to overtake the US as the manufacturing leader for biological medicines ([CPHI reference link](#)).

Recommendations to be included in the pharmaceutical strategy:

- ↳ Consider EU-wide actions to strengthen existing manufacturing base and support its expansion as well as creation of new manufacturing capacity of the medicines value chain through incentives to manufacturers, while accounting for similar incentives being created abroad as third countries also look for strengthening their manufacturing footprint (e.g. define “investment in manufacturing security of supply” as a tax credit under state aid law.).
- ↳ Writing of EC procurement guidelines supporting sustainable procurement practices that reward supply resilience and multiple suppliers to prevent overdependence.
- ↳ Set up mechanisms to stimulate investments in production of medicines in Europe. The reliance on third countries for intermediates/APIs/finished products is subject to disruptions in the supply chain in cases of serious emergency.
- ↳ Measures to stimulate investments in R&D need to be targeted and focused, with clear objectives to be achieved and factor in competition and equitable access policies.
- ↳ Transparency directive reform to sustain investments in manufacturing resilience, aiming at ensuring long-term sustainability, competition and stimulating investment in manufacturing.
- ↳ Avoid national measures that could disrupt the Single market and damaging neighbouring countries, as is happening in some Member States with the purchase of API.

2. Enhancing sustainability of healthcare systems

Several Countries suspended generic medicines reference policies or amended clawbacks during the crisis, hence recognising the direct link between supply and these measures. All stakeholders and Governments recognise the relation between economic factors, supply of medicines and patient access. Thus, it is important that policies affecting market competitiveness are carefully weighted and shift from being focused on achieving the lowest price possible towards considering the need to strengthen supply resilience.

Recommendation to be included in the pharmaceutical strategy:

- ↳ Support long-term competition by creating pro-competitive market conditions
- ↳ Avoid mandated price-cuts not driven by price competition
- ↳ Exclude external reference pricing as pricing policy for off-patent medicines
- ↳ Eliminating clawback or payback mechanisms applied to generic medicines (or reducing their impact by adapting national legislation to the off-patent sector specificities)

3. Modernising regulatory systems

3.1 Regulatory flexibility

The COVID-19 pandemic posed unprecedented challenges in ensuring continuity of supplies of medicines. Therefore, in the situation of crisis and where there is a major shortage risk, it was necessary to propose appropriate regulatory measures to minimise risks of shortages by, for example, permitting MAHs to swiftly source starting materials, reagents, intermediates or active substances from alternative suppliers, addition to new manufacturing sites, among other measures. At the same time, it is necessary to facilitate the movement of medicinal products within the EU so that they can be made available in the Member States where are needed the most (such as accept product information in other language or in electronic format).

The European Commission [Guidelines on the optimal and rational supply of medicines](#) to avoid shortages during the COVID-19 outbreak are clear example on how the simplification of the regulatory process could enable the industry to fast react to critical situations without compromising patient safety. This practical experience should be collected and assessed in view of possible future simplification of the processes by both authorities and

industry to enable both to react faster on patients' needs not only in a crisis but also in case of any risk of major supply challenges.

Recommendation to be included in the pharmaceutical strategy:

- ↳ *Amending the variation regulation to enable the industry to reflect the evolution of science, technological progress, regulatory operational excellence (i.e. Notification process instead of traditional variation process for some operations).*
- ↳ *Optimise the use of Centralised and Decentralised procedures for generic medicines.*
- ↳ *Increase flexibility to accept different pack sizes or multi-country packs to address market needs.*
- ↳ *Lower fees/costs for older molecules that still serve a healthcare need, as has been demonstrated by some hospital molecules during this pandemic.*
- ↳ *More electronic reporting/ digital tools to be used in regulatory activities.*
- ↳ *Single global development for complex follow on medicines, leveraged by acceptance of reference product from jurisdictions outside the EU.*

3.2 A new telematics digital strategy

During the crisis, digital submissions via Common European Submission Platform (CESP) were facilitated in Europe, including countries where CESP submission was not accepted before the crisis. This new tendency to optimise the process and acceptance of digital submission should not be applied only during the crisis period but need to be continued once the crisis will be over to enable industry and regulators to fast react during critical situations.

The challenges that Europe is facing in the current scenario due to the COVID19, could have been mitigated if there were in place a common repository for all medicines in Europe with good quality data, improved data sharing and exchange of information between industry and competent authorities. This would have been possible via full implementation of SPOR (Substance, Product, Organisation and Referential) data management services. These data supported by a Target Operating Model (TOM) can ensure data quality and consistency and optimise the exchange of application data between regulators and applicants, paving the way for meaningful data-sharing across departmental, organisational and geographical borders.

There is also urgent need to establish harmonised and accurate ways of reporting shortages. The I-SPOC system shows that data can be collected in a harmonised way from companies. This could be applied in future. Reporting should include a component to gather information from member states on demand and criticality.

Recommendations to be included in the pharmaceutical strategy:

- ↳ *Prioritise the implementation of a common repository for all medicinal products via SPOR data management supported by a Target Operating Model (TOM) to ensure data-quality and faster decision-making in the EU Regulatory Network.*
- ↳ *Build appropriate telematics infrastructure to achieve an EU centralised mechanism to monitor the entire value chain through interconnection of SPOR and EMVO-NMVs.*
- ↳ *Medicines shortages due to increased demand (as during the current pandemic) or limited manufacturing supply could be handled by authorities via two-way communication between manufacturers and competent authority across EU.*