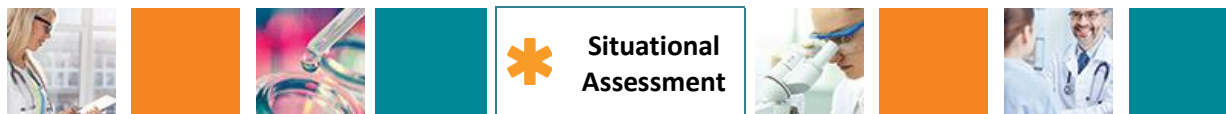


Date 30/09/2020

Final



## Overall assessment

From mid-July (time of the last call) to 30 September, we can report that no EFPIA member has voiced concerns regarding any negative developments threatening to jeopardize their preparedness plans to continue the supply of medicines across the European Union. While EFPIA member companies continuously monitor the worldwide spread of COVID-19 and its potential impact on demand for medicines overall as a result, they are in control of their manufacturing and supply chain planning operations. Today's external environment is relatively better compared to that in March/April 2020 (no widespread lockdowns, no widespread restrictions to movement of people and medicines, better understanding of the disease, improved treatment guidelines optimizing use of medicines etc.) while the worldwide epidemiological context is different (high incidence rates on other continents that may negatively impact overall supply in Europe).

**However, looking forward the industry is concerned that some on-going national legislative developments introducing unilateral stockpiling requirements will prove disruptive and weaken the overall resilience of the supply chain model. In addition, we wish to raise the following points as we believe they would further strengthen and reinforce manufacturers' actions:**

### 1. Information sharing between manufacturers and Member States

As we have discussed a number of times during our calls earlier this year, also thanks to the regulatory flexibilities put in place, manufacturers continue to manufacture and supply medicines for the EU market and have increased manufacturing capacity in response to Commissioner Kyriakides' letter of April 2020. However, the increased manufacturing capacity still needs to find its way to the patients who require it the most and this continues to be the biggest bottleneck to date. Industry absolutely needs to have better and clearer data regarding the demand side from Member States, in the worldwide epidemiological context.

We need better information regarding Member States capacity (hospital beds capacity & availabilities, ventilation/intubation capacity; existing stockpiles accumulated during the first wave etc.). We understand that Member States may be struggling technically to share information on inventories and demand (scenario) planning for COVID-19 related matters.

As industry, we recognise that there are technical limitations to the information that may be readily available to Member States, since they may not have yet operationalized the connection to the data contained in the interoperable Falsified Medicines Directive network (EFPIA/Medicines for Europe have been recommending to use the data contained therein as part of the "lessons learned", and invite the European Commission to support this recommendation towards Member States). However, sharing available non-confidential information on demand scenarios and inventories based on best available industry and Member States data, could fill the data/information gap and provide a better service to patients across Europe.



Along the same lines, we would like to reiterate our plea for reliable **timely** ECDC forecasts on the evolution of the outbreak including how this translates in terms of COVID-19 medication needs at country level.

**During the call on 30 September, we were extremely encouraged to hear both from Commissioner Kyriakides and from EMA that there is an initiative to collect data and forecast demand at Member State level. We would very much like to join this dialogue and make the connection with the EFPIA-Medicines for Europe ICU supply data collection exercise in order to validate assumptions and bring together the two sides of the equation. We stand ready to help in any way we can!**

## **2. National stockpiling requirements & threats to impose measures with similar effect as export restrictions**

We believe it is necessary to resume the discussions initiated at the European level to ensure that lasting solutions are put in place at the European level and not only at the national level. We urge the European Commission and Member States to draw the lessons from the past 6-months, and develop a collective preparedness plan based on the solidarity principle, rather than on each individual national interest. Isolated national measures taken hastily during the peak of the crisis have proven extremely disruptive for companies' supply chain. Uncoordinated national policies such as export restrictions and stockpiling requirements do not allow for an optimal supply allocation to European patients, tend to exacerbate supply tensions and shortages, and will weaken the resilience of the European supply chain structure. **Unfortunately, we are observing with great concern that a number of stockpiling requirements are being shepherded through the legislative process in countries such as the Netherlands or Portugal.**

We recognise the principle of subsidiarity with regard to such national decisions as raised a number of times in the past. We believe however that the best outcome in addressing supply tensions challenges will be achieved through European coordination. It is crucial to build on the results achieved by the European Commission in overcoming obstacles caused by national measures in the first half of 2020 and align behind a European solidarity principle, that can hopefully continue to be front of mind in the coming months and guide Member States' actions coordinated at EU level.

For initiatives directly falling in the EU remit, i.e. affecting the free movement of medicines such as export restrictions, the European Commission's action has proven instrumental in avoiding a paralysis during the peak of the crisis in Spring this year. **Going forward and as we are preparing for a potential second wave of COVID-19, we suggest that the European Commission sets up a standard protocol known from Member States to report and deal with such restrictions.** This might prevent some measures being taken, and streamline the reporting/management of such initiatives.

**In this respect, we have also recently been made aware that the Belgian emergency measures implemented in April have been extended. They require a notification to be sent if a drug needed in the treatment of COVID-19 is to be exported. The FAMHP (BE regulator) can then file an opposition to the possible export. The decision announced on Monday will extend the measure until October 28.**



We were grateful to hear from Commissioner Breton on today's call that the EU is in close dialogue with major trade partners worldwide. While EFPIA members have not received any concerning signals that there are consideration of imposing trade barriers again at global level, they are concerned that the main upward trends in COVID-19 infections continue to be in territories outside the EU (e.g. US, India, Brazil, Russia etc.). We will proactively share any intelligence that we receive from EFPIA members in case the situation changes.

### 3. Expected exacerbated impact of Brexit

EFPIA members are as ready as they can be for the end of the Transition Period without an EU-UK trade deal, and have taken the necessary steps to comply with the new regulatory requirements and supply chain arrangements that need to be put in place as a result. We still need EU support to avoid delays in access to medicines for patients in the EU and UK. **We have been calling for an EU-UK MRA on GMP inspections and import testing. Without such an MRA, the EU will effectively be imposing a 4-6 week time delay for medicines to reach European patients (the UK will waive import testing for 2 years, so this would not apply to UK patients).** In the midst of a pandemic, everything must be done to avoid the risk of any delays.

Despite the overall Brexit preparations, the implementation of the Northern Ireland Protocol is a much more recent development (January 2020), for which the details of implementation are still not clear today. This level of uncertainty only three months before the actual deadline puts manufacturers in a position that they cannot guarantee that there will not be an impact on supplies of medicines to Northern Ireland. EFPIA member companies are committed to work through their portfolios, product by product, to assess impact and redesign supply chains, but clarity is needed first. As a necessity, we continue to request the EU Brexit Task Force and the UK government to agree on:

1. The detailed implementation of the NIP as soon as possible.
2. A phase-in period of one year for the NIP provisions, including the Falsified Medicines Directive, starting at the moment clarity in the NIP's detailed implementation is provided.
3. An MRA on GMP inspections and import testing to avoid exports from Great Britain to Northern Ireland (i.e. Liverpool to Belfast) being subject to testing.

We would be happy to supply more detailed information if needed.



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## EFPIA responses to Commission questions

1. *What is the level of preparedness for the resurgence of COVID-19 cases? Please confirm adequate supply for the ICU medicines until the end of the year in the EU? Do you expect any supply shortages of medicines and medical devices?*

EFPIA member companies prepared themselves largely through 2 different main actions:

- 1) downstream actions: establishment of procedures and protocols to more accurately and properly meet and supply the required demand at country level, avoiding “stockpiling”; interaction with National Regulatory Agencies, in order to respond to their requests for products and or information, however this tends to be only one way (authorities requesting info from manufacturing)
- 2) building of buffer stock and redundancies at each step of the manufacturing and distribution chain (under direct control of the manufacturer) and creation of a level of inventory equal to maximum expected service levels in order to manage a potential 2<sup>nd</sup> wave. With the information that they have today, EFPIA members do not expect any disruption, other than in very specific cases, linked for example to capacity of API production (issues are not linked to COVID-19).

2. *Do you still encounter any export restrictions within the EU?*

We only know of the concrete continuation of the Belgian export notification requirements which have recently been prolonged until the end of October (as mentioned above). Beyond this concrete example, the only concern we have is with psychotropic drugs, which need export/import licenses. The issue here is that the agencies (due to multiple priorities), may have problems to issue the licenses in the agreed timing (this happened in some Countries during the first wave). Export bans must at all costs be avoided.

3. *What kind of EU level or Member States actions do you expect?*

Member states must refrain from building safety stocks like the ones being discussed in Portugal and Netherlands. Another important point is to reapply the good relationship with the Regulatory Agencies on:

- 1) information exchange (proper and quick); building on the current I-SPOC system, which essentially relies a one-way automated communication channel between the EMA and manufacturers, a more elaborated, 2-way communication channel could be put in place in advance to deal with and mitigate difficult cases on a bilateral basis; and
- 2) fast reaction in case we need to bring medicines from another part of the world, to avoid disruptions.

Specifically, on point 2, there is a need to continue implementing the regulatory flexibilities that were agreed upon in Spring, notably on the supply chain/packaging & labelling side so that pharmaceutical companies can continue to ship easily finished products from 1 country with high stock to another country with low stock, even if the packaging is not the same (e.g. 1 country sells 30 tablets in 1 box, whereas the other country sells 20 tablets). This is a much better approach than mandatory stockpiling.



## Vaccines Europe responses to Commission questions

1. *What is the level of preparedness for the resurgence of COVID-19 cases? Please confirm adequate supply for the ICU medicines until the end of the year in the EU? Do you expect any supply shortages of medicines and medical devices?*

This question does not apply to Vaccines Europe (VE).

2. *Do you still encounter any export restrictions within the EU?*

VE members have not raised any concerns related to export restrictions.

3. *What kind of EU level or Member States actions do you expect?*

The COVID-19 pandemic has significantly interrupted national immunization programs (NIPs) across the world, including in Europe. It led during the first peak to a dramatic decrease of vaccines delivery which left a large number of unvaccinated infants, children, adolescents and adults. It would be important if there is a second peak that member States maintain access to routine vaccination.

Regarding COVID-19 vaccines to draw to your attention some issues related to the vaccines' deployment:

- Due to the use of multidose presentations and the characteristics of some of the vaccines being developed, we need to have a better understanding on how the COVID-19 vaccines will be distributed in the Member States as this will have an impact not only in the manufacturing of the COVID-19 vaccines but also on the distribution chain. This includes labelling, cold storage capacity, vaccination points, among others. We have started a dialogue with GGRP with the aim of working together and we will come back to you once we advance on our work.
- As vaccines will be delivered in multi-dose presentations with no syringes and needles, Member States need to secure access to these two devices. Today all vaccine manufacturers are trying to secure access to glass vials in order to deliver the number of doses they are targeting. For the time being there is no full evidence that there will be enough glass vials to cover the needs. We continue to monitor the situation which evolves while we are speaking.

One member company has reported some tension regarding the supply of raw materials and we are monitoring closely the situation.

*Provide a brief update on Brexit preparedness plans:*

We do not anticipate shortages of vaccines after UK Brexit. However, we are aligned with EFPIA on the need for MRA on OMCL testing and GMP inspections.

