

Medicines for Europe update regarding medicines production and supply related to Covid-19

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Our industry supplies 67% of prescription medicines and most of the critical medicines needed to treat infected patients. Our 400 factories/sites across Europe are operating at 100% capacity to maintain medicines supplies – both emergency and chronic – to all Europeans. At this time, there are no shortages of medicines in our sector related to the outbreak to our knowledge and our situation rooms are continuously monitoring stock levels and adapting production according to health needs. Our industry is ready to coordinate as closely as possible with the EU (and in parallel at national level) to keep the flow of medicines to all countries throughout the crisis. We thank our employees and our drivers/logistics for their tremendous efforts to continue working throughout this crisis.

We thank the Commission and the EU for rapidly establishing guidelines for member states to establish green lanes for the transport of medicines and related supplies for their manufacture and we hope this will be done quickly. This will facilitate our manufacturing and the flow of medicines to where they are needed. We are closely monitoring the situation and highlight the challenge regarding restrictions on the movement of truck drivers from Italy (requirement to quarantine) and is likely to be extended to Spanish drivers. As the outbreak spreads, more truck drivers of different nationalities could be subject to quarantine measures – which will mean that eventually we could run out of drives allowed to cross borders. We strongly advise that precautionary safety measures would replace quarantines for truck drivers. Some countries have introduced such measures that could serve as guidelines. We will share information regarding the blockage of transit points with the services regularly. We would like to make the additional request that technicians needed to repair machinery in our factories should receive a dispensation to cross internal EU borders. As our factories are running at full capacity, the maintenance of critical production equipment becomes ever more critical.

We urge the Commission to continue its cooperation with other related industries that can supply much needed health related supplies (Cefic – chemicals, Euratex/plastics Europe – PPE, etc). It is vital that each industry can bring maximum production and efficiency to deliver the different needs based on its industrial specialisation. We would like to reiterate that our members are still facing challenges shipping PPE across internal EU borders to their production sites. Our factories cannot manufacture without this equipment.

There is a growing challenge with air freight into the EU which is important for the supply of materials for our production. We may need a coordination mechanism to get those supplies to different EU countries on a national or a regional basis. This is particularly challenging for smaller manufacturers to manage. We are consulting with our national associations on how this could be managed.

The other challenges we are seeing relate to employees working in factories. They are not systematically recognised as essential health workers and therefore do not benefit from national measures (like access to child day care services) to support, for example, hospital workers. In addition, there are some restrictions on the movement of cross border workers (Slovakia to Hungary) which is affecting our production. We will develop

proposals for guidelines for manufacturers if critical personnel (such as QPs) cannot work due to illness and will undertake the most appropriate efforts to maintain compliance to every extent possible.

Regarding the supply of medicines, we do not know of any declared shortages from our companies related to the crisis and we are producing with existing stocks of materials. Some supplies are arriving sporadically from China with logistics issues presenting the main challenge as well as a backlog of manufacturing due to the extended shut down. We are carefully monitoring supplies from India as the industry and the government are planning to upscale manufacturing for the crisis for local needs. Our company situation rooms are managing this situation and will establish a Single Point of Contact with the EMA to warn of any potential production bottlenecks and to offer their production support inasmuch as possible to any company or country facing a problem.

For the dialogue with the EU Executive Steering Group on shortages of medicines caused by major events (EU shortages group), we must understand that medicines supply in this crisis is not about static stock levels. The keys are to keep medicine production levels at maximum capacity and to move supplies for that production and medicines to wherever they are needed. We must also plan and manage potential demand surges at EU and national level related to Covid-19. For this we need the dialogue with the EU shortages groups and a parallel dialogue between national authorities and our industry associations at national level. to ensure supply meet demand in a sustainable and equitable way. Ensuring maximum European coordination is key. European solidarity is critical and positive to manage this crisis. The Commission and EMA are responsible for equitable access to medicines across Europe. Disproportionate measures by Member States affecting the availability of critical medicines and fragmenting the single market should not be allowed to disrupt our ability to deliver equitably across Europe.

We emphasize the need in each country to establish a regular structured dialogue between the national competent authority and industry stakeholders to assess the expected needs of hospitals to treat patients as the outbreak develops. This is currently being done in Italy on a nearly daily basis and it has been immensely helpful.

At national level, small changes such as extended prescription times (1-month to 3-months) can create panic in the retail distribution chain. This can be managed through rapid checks with our members and finding alternative solutions such as electronic prescribing where extended prescriptions would be disruptive to supply. As the crisis developments, more daily contacts will be required to manage supplies.

At EU level, we must plan for the specific needs of the outbreak to provide that supply and to maintain the supply of other essential and chronic medicines that are not required specifically for the outbreak but still necessary for healthcare (i.e. the management of chronic diseases). By helping chronic patients maintain their health, we can avoid that they would require an escalation of their care such as going to hospital. Medicines for Europe is reviewing available lists of critical medicines required for the crisis and would like to assess with you the volume requirements to ensure maximum efficiency in production and transport. For this, we will need some insights from the EU Supply Group on what will be done at national level and as much transparency as possible for our members to respond as efficiently as possible. This includes the possible production of medicines to be used experimentally for infected patients as well as the medicines required to treat patients in ICU. We reiterate that the dedication of production and supply for these purposes should also take account of the needs of patients that may currently be using these medicines for their chronic or other care. If necessary, this may include carefully managed switching from current treatment to equally effective alternative treatments.

We must also anticipate possible regulatory flexibilities to ensure maximum production levels as well as possible requests to shift production to address new needs. Our team would like to align with the EU on these measures now so that our members can plan for this possibility in a centrally coordinated manner. This would be the most efficient approach.

At international level, we believe that the global cooperation is essential to maximise production levels for all countries. We welcome the efforts to coordinate with the G7 countries. We also believe that there must be coordination with the major pharmaceutical volume producing regions which includes China (for chemicals), India (for medicines and API), Europe at large (EU-UK-Switzerland for medicines and API) and the US (for medicines) as well as any other major manufacturing country (i.e. Canada, Ukraine, Turkey, etc) that recognises the benefits of cooperation and supply chain efficiency to maximise production. The WHO could lead this dialogue involving volume manufacturers and industry/health ministries (EU should lead here for Europe).

We thank you again for your urgent action on these issues.

In this annex, you will see some specific problems our companies are encountering:

1. Border closure is affecting the flow of trucks with API, finished product and all related material such as vials, packaging and devices. There are long lines and heavy administrative processes. A European communication of the green lanes and how to pass them fast could be helpful. Really “green” lanes for all pharmaceuticals (we are placing a sign on the truck). Another concern is that some European states keep their borders open for the goods but have personal restriction to the drivers. For example, this was the case at the border between Croatia & Austria.
2. Backlog to export & release finished products imported to countries not belonging to the Schengen zone. It would be helpful if the countries can give priority to pharmaceutical products and released them faster.
 - a. Germany to Latin America, Middle East & CIS
 - b. Austria to Balkan countries
3. Educational Establishments close even for children with their parents working in the pharmaceutical industry. This is slowing down the production of essential medicines. The pharmaceutical industry is a system relevant industry especially during a health crisis. There for employees in the pharmaceutical industry should be treated the same way as healthcare professionals, when it comes to emergency childcare. Parents in the pharmaceutical industry should receive childcare option, that they can continue to work for the patient’s safety. We have encountered the issue so far in the following countries:
 - a. Bulgaria
 - b. Germany
 - c. Austria
 - d. Belgium & Netherlands
 - e. Denmark
 - f. France
 - g. Italy
 - h. Portugal
 - i. Spain
4. Stock piling requirement from MOH, from hospitals and customers. This action is tightening supply as there are additional needs in all countries but would lead to only increasing unnecessary safety stock. there is no possibility to create safety stocks now If one country will receive a preferential treatment this could lead to a massive imbalance of the supply chain and endanger access to much needed medicines. The following countries have asked for safety stocks:
 - a. Czech Republic
 - b. Slovakia
 - c. Poland
 - d. Denmark
 - e. Germany
 - f. Italy
 - g. Portugal

5. Final customers (hospitals, wholesalers, distributors, pharmacies...) starting to hoard medicines. However, these shortages are already covered with a normal level of safety stock. We need to ensure that supply flow is smooth and regular to be able to react to real additional demands of countries with higher number of sick patients than to stockpile. A communication to calm down the network could be very appreciated.
6. Airborne delivery of products is endangered by the cancellation of most passenger flights to the EU. A significant cargo amount of air freight for medicines is delivered via spare loading capacities of passenger planes.