

## COVID-19: EU GUIDANCE NEEDED ON *CONTROLLED* SUBSTANCES DUE THE SURGE IN DEMAND DURING EMERGENCY

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European Commission

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Brussels, 25 March 2020

Dear 5.1.2e, Dear Commissioners,

Medicines for Europe members supply 70% of Medicines to European patients, and most of the medicines currently being used to help patients fight the COVID-19 pandemic. Generic manufacturers are committed to keep manufacturing these medicines for patients in Europe and worldwide.

Some of the substances with a surge in demand are *Controlled substances* for which additional regulations apply and have additional import procedures in place that have an impact on supply timelines.

Examples of those products include analgesics used in support treatment for patients in intensive care and agents that support ventilation – such as morphine, fentanyl, remifentanyl, midazolam.

On top of all logistics issues such as delays on the European border controls and fewer flights (that would also transport pharmaceuticals) available today, these *Controlled substances* require special documentation in the form of import permit from the office in the country of import followed by an export permit, in the country of export. The granting of these permits can each take two weeks or longer, depending on the country of export/import. Currently, as a result of understaffed permit offices caused by Covid-19, the processes are prolonged.



The regulation on *Controlled substances* is very important to secure those medicines do not get abused, however in these very difficult times presents an additional major hurdle.

Obstacles are emerging on movements of controlled substances:

- **Between the EU Member states**

We observe delays with obtaining export authorisations that would allow us to transport products from one EU Member state to another. Some of our members are waiting for several weeks to obtain an export permit after obtaining the import permit in these very critical times. The export authorisations are becoming a major hurdle that blocks movement of these critical medicines for one Member state to another.

- **Import to the EU from the third companies and vice-versa.**

At the moment, many export permits need to be obtained in countries outside the EU (such as India) and import licenses in European member states, but due to the uncertainty of the situation and increased demand possibility outside Europe we might also foresee the need to export from Europe very quickly to other parts of the world to those in need.

We propose a certain level of simplification that would allow us to supply hospitals with increased demands of essential products.

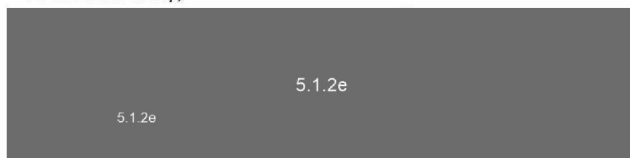
**For the limited time period we propose that a notification process would replace the need for an export permit/authorisation.**

After obtaining an import permit (from the authority of the importing country), only a notification by the importing company to the authority of the exporting country would replace the need for an export permit/authorisation. This would result in a significant and beneficial shortening of the time needed to obtain stock in the country where it is needed. **EU guidance on this issue** would help us immensely, coordination between Member states and also international cooperation is needed. We will continue doing everything in our power to secure supply to those in need. Retroactively, after this defined time period which would allow us a flexible approach, we would make sure to obtain all necessary documentation.

In the surge of demand, when we receive demands for additional quantities daily, we are trying our best to keep these products available to patients and therefore we need to find a way to expedite the import processes of controlled substances and coordinate the international approach to expedite export/import and get medicines to the patients in need around the world.

We need to coordinate on this with great urgency.

Yours sincerely,



Medicines for Europe