

**European Commission**

Rue de la Loi 200
1049 Brussels
Belgium

Att.: Commission President von der Leyen, Commissioner Kyriakides and Commissioner Breton

Brussels, March 13th, 2020

Letter regarding the unnecessary disruption of the medicines supply chain

Dear Commission President von der Leyen, Commissioner Kyriakides, and Commissioner Breton,

First and foremost, I would like to express my full support to the European Commission in this difficult situation.

I write with a most urgent appeal for European solidarity in this time of crises. Over the last week, we have seen Member States starting to limit the intra-community movement of medicines unnecessarily. Whereas the restrictions within medical devices have been thoroughly discussed and solutions found by the help of the Commission, the situation is taking a very negative and damaging direction within the supply of medicines.

In general, as President for Affordable Medicines Europe, the membership I represent has univocally send the same message as both Medicines for Europe and EFPIA's members – at the moment we do not see shortages in the European market of medicines. We see limited risks that this situation would change, considering that the appropriate measures are already being taken to continue production and distribution, and that China has re-started most production.

We can assure all Member States, that our sector has not seen an increased activity as a consequence of COVID-19, why those exports and imports that are taking place is *business-as-usual*. This is important to stress, as this means that while the products are *not in shortage or risk of shortage* (the already existing export restrictions in place in most Member States already secures this) in the Member State where the exports are to take place, they may be long-standing and integral part of the supply in other Member States.

Last week, Poland expanded its ban list from 400-500 medicines to more than 1300 medicines. Most of which have no relation to COVID-19, and for which there are *no shortages or risk of shortages* in Poland. As late as yesterday, Romania banned all exports of medicines in its reimbursement list not produced in Romania. Trucks have immediately been stopped at the border. Most of the medicines used in connection with COVID-19 are OTC's (e.g. paracetamol), why the ban does not extend to these products. In other words, the ban seems fully politically motivated with no health assessment or concerns at the forefront. Furthermore, the ban is automatic for six months.

We also understand from our wholesale suppliers, that several Member States have asked them to stop export 'voluntarily' and to stockpile (e.g. Austria). Again, applying to all products. This exacerbates the situation unnecessarily and has taken effect immediately.

Whereas some medicines are used for the treatments associated with the COVID-19 outbreak¹, which has caused a surge in demand and international developments have taken place (India's restriction of certain API's used for production of e.g. paracetamol) and therefore measures are taken to safeguard the national supply of these products, we are now witnessing export bans of medicines from some Member States which are in no way related to medicines used for the treatment of COVID-19 or is indeed in shortage or risk of shortage in the given Member State. This interrupts the normal supply chain which our sector has been an established part of for more than 40 years.

As an example, 26%, 13%, and 8.5% of pharmacy sales of medicines in Denmark, Germany, and Sweden respectively is parallel imports. For some individual medicines parallel imports may account for 70% or more of the supply in countries like Belgium, Austria, Germany, Denmark, Sweden, Finland, Norway, the Netherlands, and Ireland. In yet other Member States, such as the Baltics, parallel imports are from time to time the only source of supply as a consequence of the non-launch or market withdrawals of manufacturers. This means that we may start seeing shortages of e.g. oncology products or insulin in some Member States, potentially leading to further public concerns and medicines hoarding, while surplus stock will be laying unused in other Member States. We simply cannot allow this to happen within our European Union.

We have seen some Member States, such as Spain, adapting sensible measures following the WHO protocols. We can only commend this as an approach for other EU Member States to take. We suggest the Commission urgently establish guidelines to Member States following such examples.

Considering the seriousness of the matter – the continued uninterrupted functioning of the medicines supply chain – we urge the European Commission to do everything in its power to initiate dialogue with for example Romania, to come to a solutions where all Romanian patients get the medicines they need, while citizens in other European countries are not deprived of their everyday medicines unrelated to the current COVID-19 outbreak.

During the last week we have kept your services (DG SANTE and DG GROW) informed of the situation, and we would like to thank you for their timely responses. However, again considering the new developments and the speed at which these measures are spreading, I feel obliged to inform you, the highest levels of the European Commission, considering the effects this will have on the normal supply chain of medicines in the EU.

Kind regards,

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Jörg Geller
President,
Affordable Medicines Europe

Affordable Medicines Europe represents Europe's licensed parallel distribution industry, an integral part of the European pharmaceutical market that adds value to society by introducing price competition for pa-tented medicines and a supplementary layer of product safety. We represent 125 companies in 23 EU/EEA Member States. These members account for approximately 85% of the total parallel import market volume in the EU/EEA. Membership in Affordable Medicines Europe is exclusive to companies holding a wholesale (GDP) license (export and import). All importing members furthermore are GMP licensed.

¹ Here we refer to the International Pharmaceutical Federation's (FIP) Health Advisory publication "Coronavirus SARS-CoV-2 Outbreak: Information and interim guidelines for pharmacists and the pharmacy workforce", Annex I.