AFFORDABLE MEDICINES EUROPE

WORKING IN PARALLEL FOR A BETTER DEAL

SMEI – PUBLIC CONSULTATION 2022

POSITION PAPER

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1. INTRODUCTION

Affordable Medicines Europe welcomes the launch of a public consultation by the European Commission aimed at collecting views of stakeholders and the general public in order to support the implementation of the Single Market Emergency Instrument. We strongly support the implementation of the Single Market Emergency Instrument.

In the update of the Industrial Strategy Communication[1], the European Commission announced an instrument to ensure the free movement of persons, goods, and services, as well as greater transparency and coordination in times of crisis. The main policy objective of the initiative is to provide adequate coordination and communication mechanisms between EU institutions, Member States, and stakeholders, ensure the resilience of the Single Market, and ensure the free circulation of goods, services, and persons in times of crisis.

Affordable Medicines Europe strongly support the efforts of the European Commission in its wish to create the Single Market Emergency Instrument (SMEI). In this position paper, we elaborate on several points where our sector has additional remarks to those in the hearing questionnaire, which should be taken into consideration when analysing our response. Hence, we do not provide comments to the questionnaire as a whole, nor to each point we may consider of key importance, if this is already evident from our replies, or need no further comments.

The Paper is divided into the following sections: Section 1 focuses on the impact of restrictions on free movement on our sector; Section 2 includes some additional comments to the actions taken at EU level in time of crisis to preserve the Single Market; and finally, Section 3 further elaborates on some policy options and ways forward mentioned in the public questionnaire.

[1] *Communication "Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery", COM (2021)350 final, 05 May 2021.*

2. IMPACT OF RESTRICTIONS ON FREE MOVEMENT

Affordable Medicines Europe have some comments to further elaborate the answers given and better describe the impact suffered by our sector due to restrictions on free movement, introduced in the context of the Covid-19 pandemic. The below comments specifically refer to questions 2 and 2.J of the Questionnaire.

Export restrictions

During the first wave of the COVID-19 crisis, a vast number of Member States introduced hastily made emergency export bans on medicines. Specifically, during the first 2-3 months of COVID, this resulted in a negative effect on our turnover of around 10-20%, which corresponds to approximately 600-1.200 million EUR per year. For those 2-3 months, we estimate a total loss of 150-300 million EUR (the months of March, April and May are usually very busy months).

The costs were felt somewhat uneven on the export side (primarily affecting countries imposing bans), whereas on the importing side, the effects were felt by all importing countries (20+ Member States have established parallel import markets). Furthermore, stockpiling requirements on medicines in some countries exacerbated the problems - acting as de facto export restrictions (usual export volumes were not allowed to leave the countries).

Besides the economic loss related to the export restrictions, more serious consequences were shortages of medicines in the import Member States, where parallel imports were a permanent part of the national supply for years before COVID-19. We would like to *stress very clearly*, that we are in this paper referring medicines which were not directly affected by COVID-19 – meaning medicines not used on the treatment protocols related to COVID-19. Hence, there were no health or safety aspects related to the export bans on said products. Rather we consider it “panic” reactions.

We provided during the first weeks and month of the crisis, the European Commission services (DG GROW and DG SANTE) many concrete examples of medicines going into shortages in some Member States, due to the non-COVID-19 related export bans. We collected examples from more than 10 Member States, from Finland to Bulgaria, where parallel importers were responsible for e.g. more than 70% of normal supply, and where export bans in other Member States thus threatened immediate shortages. We estimate around 5-10 shortages per Member States in about 15 Member States materialised within the first month of the COVID-19 pandemic as a consequence of unjustified export bans on non-COVID-19 related products. This is only related to products normally supplied by parallel import. Considering our sector represent only 2.8% of the total supply of medicines in Europe, this number was significant.

We compiled overview of national COVID-19 related export bans from March-July 2020. While the European Commission did tremendous work to limit these restrictions, too many remained in place for too long (see latest COVID-19 export restrictions overview here – not updated since end-July 2020).

Stockpiling

Stockpiling also proved to be a major obstacle during the first months of the COVID-19 pandemic. Several Member States asked stop to stop export ‘voluntarily’ and to stockpile (e.g. Austria). Again, applying to all products. Other Member States put in force regulation forcing wholesalers and/or manufacturers to stockpile. This interrupted the normal supply chain which our sector has been an established part of for more than 40 years. Essentially, the volumes of given products that had for years been exported from one Member State to another, was suddenly kept in stock, effectively creating the same dynamic as export bans.

Worst was those cases, where stocks were close to expiry date, but could not be moved to other Member States in need. We experienced several situation, where products in shortage in one Member State, was up for destruction in another for this reason.

As stockpiling measures were not *as* widely used as export restrictions, the economic consequences of these measures were more moderate. We estimate the costs of irrational stockpiling measures at national level to have been around 30-50 million EUR.

Transport

Besides this, the very first weeks of the COVID-19 pandemic saw disruptions to transport. However, the impact of this was more limited with the fast establishment of green lanes. Costs are considered to be around 1-5 million EUR. Nonetheless, again on medicines availability the consequences were felt more quickly and did lead to some temporary disruptions, which in turn alarmed some patients and provoked some level of fear-related stockpiling.

Staff

Finally, some of our members were negatively affected by restrictions to the free movement of persons and services in relation to workers operating in border areas, cross-border service providers. This was especially so for re-packaging sites located in border-regions, where for some short periods, staff could not get to work. Re-packaging is a labour-intensive manual endeavour where teleworking is 100% impossible. We estimate, however, the costs to have been moderate, as the disruptions were very short, and *because* the above-mentioned factors had already meant a decrease in needed re-packaging. Nonetheless, had the abovementioned factors not been the case, the movement of people would have been a decisive factor, which could have cost anywhere between 15-25 million EUR despite the very limited time periods and the primary effect on re-packaging sites in border areas.

The COVID-19 crisis clearly highlighted just how detrimental such restrictions can be to the ordinary and long-standing medicine supply chains. The free movement of medicines is a key aspect in ensuring patient access to all Europeans and, therefore, Affordable Medicines Europe welcomes any effort to guarantee as much as possible the free circulation of goods, services, and persons in times of crisis.

3. EU ACTIONS TO PRESERVE SINGLE MARKET

Affordable Medicines Europe have some comments to further elaborate the answers given in relation to the EU response to address weaknesses and barriers in the Single Market in the context of emergency situations. The below comments specifically refer to questions 5, 5.G and 7.H of the Questionnaire.

Our association welcomes the actions taken at the EU level to mitigate or solving the negative effects of past and ongoing crises on the Single Market and, specifically, those aimed at ensuring free movement of goods as well as an adequate distribution of goods and services of potential relevance to a crisis across the Single Market.

The Commission (DG GROW) reacted swiftly to transport related trade problems with the creation of green lanes. Also, strong Commission action on export restrictions and stockpiling was taken. However, for export restrictions and stockpiling, this was mostly successful in relation to a "voluntary" changed behaviour from some Member States. Several other Member States continued to operate damaging export restrictions or stockpiling, even after Commission action. Hence, we consider more solid tools could be beneficial for a new crisis.

Besides the introduction of the abovementioned green lanes system, our sector also benefitted to a great extent from exemptions from restrictions to free movement for cross-border commuters and to free movement for transport and service providers. In relation to this and in order to facilitate the movement of specific groups of persons and service providers, we believe that dedicated binding measures are necessary when it comes to business travels related to the fulfilment of legal and regulatory requirements.

In light of the above, Affordable Medicines Europe acknowledges the added value of the new Single Market Emergency Instrument that by complementing other policy tools would anticipate and prevent disruptions, where possible, and would also prepare for and respond to future crises.

4. POSSIBLE POLICY OPTIONS AND WAYS FORWARD

Affordable Medicines Europe have some comments to further elaborate the answers given concerning some proposed measures outlined in the public questionnaire and aimed to prevent and prepare for disruptions and adequately manage a crisis. The below comments specifically refer to questions 28, 30, 31, 31.J, 34, 34.G, and 35 of the Questionnaire.

Definition of crisis – In the context of the establishment of a new Single Market Emergency Instrument, a crisis could be defined as:

"any event that leads to justified restrictions to the four freedoms, not considered justifiable under normal circumstances."

It would be in such situations, that the Instrument should come into play. Our logic in the above suggestion is, that we have already well-established tools to work with the factors concerning e.g. Articles 34-36 TFEU. In emergency situations, however, there may be instances where e.g. case law from ECJ or other administrative application may need to be reconsidered. During COVID-19 our sector as an example accepted, that medicines used directly in the treatment of COVID-19 may be under special regulation, even if these products were not proven to be in shortage already (i.e. burden of proof shifted). Movement of people is another example, where some Member States had even restricted free movement of people within their own territory, it is clear that a special mechanism is needed to deal momentarily with cross-border movements.

Goods of strategic importance – As a sector, we consider medicines is of strategic importance. However, that is not the same as to say that e.g. Articles 34-36 TFEU should not apply to them. In fact, we believe that in a crisis, strategic goods should enjoy extraordinary protection under Articles 34-35 TFEU with increased scrutiny of exemptions under Article 36 TFEU. This is due to the fact, that it is exactly in times of crisis that the EU Single Market must prove, that solidarity and unity is able to ensure that strategic autonomy must not become a straining factor on the Single Market before, during or after a crisis. *We must be able to trust*, that as long as products are at least produced in Europe, one Member State will not be at a severe disadvantage to another in times of crisis.

Strategic storage or stockpiling system – While we consider that a strategic storage or stockpiling system, coordinated at EU level, could be an efficient solution to crises, when it comes to how this should be organised, we think that industry would be better at stock managing buffer stocks, to avoid e.g., expiry related waste. Also, e.g., medicines are not as well suited for stockpiling in general as maybe PPE.

Ensuring timely availability of critical products relevant to a crisis - We do not see any scenarios where national government involvement in allocating production means can lead to efficient outcomes. During COVID, the market proved it was fairly quick in doing this, and this should be acknowledged. They key is ensuring that demand (and willingness to pay) is expressed clearly by the authorities. On the contrary, we consider it to be highly efficient to streamline EU product rules and prioritize products controls for a limited time to enable swift development of products of potential relevance to a crisis on the market. Likewise, ramping up production capacity by repurposing or extending existing production lines on a voluntary basis could also prove to be a valuable tool to ensure the availability of critical products.

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 patented 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.

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