Second wave pandemic preparedness: procurement principles

Brussels, 31 July 2020

Mr Jens Spahn,
Minister of Health, Germany

Ms Stella Kyriakides,
Commissioner for Health, European Commission

cc.

Mr Guido Rasi,
Executive Director, EMA

Ms Andrea Ammon,
Director, ECDC

Dear EU Presidency Minister of Health, Dear Commissioner,

Medicines for Europe and EFPIA are coordinating a project on ICU medicines for Covid-19. In that context, we have engaged strongly with the EU to ensure supplies during the first wave of the infection and subsequently assessed the risks of a second wave anticipated after the summer break.

We appreciate that many member states are now engaged actively in planning for the risk of a second wave. We respect that countries may choose different policy options to plan for a second wave risk adapted to local needs and requirements. There are however some common challenges that we believe should be addressed to ensure the most secure supply for Europe. Most member states are using a combination of measures to plan for a second wave including stockpiling requirements and procurement. We would like to ensure that those measures incentivise the industry to supply through sustainability and predictability for manufacturers. We have therefore drafted some key principles that we would kindly request you convey to Health Council and the relevant EU committees involved for best practice sharing.

Firstly, we are concerned by a lack of coordination among government agencies in different member states. While we acknowledge that pandemic management is a new and complex field, on numerous occasions industry has been confronted with different approaches within the same country. For example, regarding the EU joint procurement, our industry has struggled to obtain clear information from government agencies on the intention of the government to use this procurement process as opposed to other national contracts currently in place or to be launched in the near future. In some cases, relevant government agencies were not even aware of the joint tender to which the country had signed up to. We also note discrepancies in the guidance provided by regulatory agencies responsible for medicine supply and crisis management departments responsible for the overall pandemic response.

Second, we would like to request more transparency on the available Covid-19 ICU medicine stocks that governments have either in state warehouses or in wholesaler warehouses for a second wave risk. We are aware that there are, for example, large volumes of compounded medicines with very short stability periods (likely too short to serve a second wave). It would be important to know if countries have sufficient (quality) medicines to get them through a potential second wave. This information would be useful for the industry to plan stock and

production levels and to ensure that products can flow to the countries of need and avoid over-supplying already well stocked countries.

Third, as recommended in the latest Commission Communication, member states should share standardized and epidemiological data at subnational level including hospitalization data and intensive care occupancy to allow accurate modelling of the disease's spread. This data should be collected by the ECDC and/or universities with modelling capacity and shared in a timely fashion with the medicines industry.

Fourth, we are concerned about the propensity to increase national stockpiling requirements through threats of higher fines for manufacturers sometimes combined with higher stock level requirements. In general, stockpiling is counterproductive for industry supply chain models which are based on ensuring the rapid flow of goods to enable manufacturing and to supply patient need. These requirements create considerable uncertainties for manufacturers regarding product ownership and quality oversight that should be clarified. Moreover, hoarding and restrictions to the free movement of goods including medicines were a cause of shortages and potential harm to patients across Europe during the first Covid-19 wave. Going forward, it is critical that we maintain principles of openness and solidarity across Europe. Introducing new stockpiling requirements and higher fines also alters the sustainability balance for companies supplying the market. Europe has already experienced a considerable withdrawal of marketing authorisations for well-established but still essential medicines over the last 10 years due to higher regulatory costs combined with cost-containment measures. Disproportionate stockpiling requirements will further increase market consolidation exposing Europe to over-reliance on a limited number of suppliers.

Finally, as for procurement, we are concerned that some initiatives lack firm undertaking from member state buyers. This can have the effect of locking in stock that may never be used for patients or may disincentivise companies from participating in the market. In addition, the recently launched joint procurement of ICU medicines is, in some cases, adding further uncertainty as some member states have deliberately chosen to launch two tenders simultaneously – the joint procurement and a national procurement procedure. This creates confusion for companies as member states have refused to clarify which procurement initiative and which supplier(s) will be selected. This leads to a lack of transparency on real demand. In some cases, this appears to be a deliberate policy to increase cost pressure on the industry. We question whether this is optimal given the strong demand for Covid-19 medicines globally. Our industry would advise that procurement should reward manufacturers that invest in resilience with clear purchaser commitments. Positive criteria could include sufficient API and finished product stocks, multiple sources of API sourcing and inventory policies or manufacturing sites (if produced by the medicine manufacturer), ability to deliver on reasonable lead times and high historic service and quality levels (ranking by service delivery levels, GMP records, etc).

We look forward to cooperating closely with the Commission and Member States to plan for the risk of a second wave.

Sent electronically, original signed by:

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