Ms. Stella KYRIAKIDES
Commissioner for Health and Food Safety
European Commission

Health Ministers from countries taking part in the joint call for tender

c/c
Ms. Ilze JUHANSONE
Secretary General
European Commission

Mr. Peter WAGNER
Principal Adviser to the Secretary General
Clearing house for medical equipment (COVID-19)
European Commission

Brussels, 25 June 2020

Call for tenders SANTE/2020/C3/29 for the supply of medicinal products used for intensive care patients subject to the novel coronavirus (COVID-19) disease – policy and technical concerns

Dear Commissioner,
Dear Ministers,

Medicines for Europe members supply most prescription medicines for European patients and are likewise the suppliers of a large share of medicines currently used for intensive care patients subject to the novel coronavirus (COVID-19) disease. From the outset of the pandemic, Medicines for Europe has played an important role in addressing the demand surge for intensive care unit (ICU) medicines: supporting coordinated and transparent collaboration via the i-SPOC system; proposing solutions to address the needs of patients and healthcare systems; setting up a group of companies which identified the relevant products, predicted volume needs, compared existing supply capacity and found ways to increase the supply thereby ensuring equitable access to patients; ultimately operating under Commission competition law guidance for this purpose.

As previously communicated, the joint procurement legislation was not designed for competitive multi-source products and especially for products with national licences and presentations. In addition, we fail to see the benefits of such a complex process which undermines the sustainability that has been recognised by all stakeholders as one of the main factors influencing security of supply and medicines availability.

We strongly oppose the manner in which this joint call for tender for the supply of ICU medicines was coordinated by the Commission and participating countries. We regret that the Commission and Member States have chosen to enact this procedure without prior industry consultation and proper definition of the purpose and rules of the procedure which contravenes the spirit of the EU's own procurement directive and undermines the trust that industry may have had in an open dialogue with the EU institutions. We see no apparent justification for this opaque approach, given the high level of price competition in the multisource market and the high degree of technical complexity of this initiative.

In the context of the COVID-19 pandemic, we alerted that the joint procurement mechanism would not correct the need for governments to plan for the pandemic with safety reserves. In fact, we presented the European Commission and Member States with credible alternatives for the purchasing of ICU medicines for the risk of a second wave, based on the experience of supplying the European market during the first pandemic peak in Europe. One of the most relevant aspects presented as a success factor to address the possible next wave of COVID-19 is a fair and coordinated commitment approach, where industry assumes the responsibility for doing everything possible to ensure medicines availability and Health Authorities overtly commit to obtaining extraordinary pandemic volumes.

Regarding the tender, there are multiple concerns with the set up. Among many others, we list the following:

- The absence of volume commitments does not provide security and visibility for companies to allocate manufacturing capacities for the risk of a second wave.
- The opening of a new tender offers no clarity as to what companies should expect of existing supply contracts previously agreed in the countries participating in the tender and, in particular, who holds the supply obligation in relation to a contract which may be unilaterally modified by this joint tender.
- The notice period until tender submission is extremely short, with diverging deadlines in the email and invitation letter. Some members have reported technical problems accessing the tender documentation, shortening the period even further.
- Tender specifications do not provide sufficient information regarding the type of Market Authorisation necessary to bid for the different lots. Specifically, as regards the "EC" allocation in the tender, there is no clarity as to important matters, such as licencing or the country of destination for narcotic export/import licences.
- There are several controlled substances for which cross border circulation is time consuming, difficult and cannot be adapted according to market needs. This will pose significant, if not irremediable, issues at the time of tender execution.
- Launching a new tender and fixing new contracts will create additional strain in manufacturing capacities as bidding companies will need to stockpile to fulfil orders which may never be made.
- In a constrained environment where EU and non-EU markets intend to build emergency stocks, this comes as an additional demand that will put further pressure on a supply chain that is already very solicited, leading to supply risks in all markets, posing a Public Health issue,
- It is uncertain whether the tender volumes are aligned with relevant national actors and considering both the non-COVID demand and COVID-driven additional demand, risking the assurance of therapeutic continuity to address exceptional pandemic demands. This could result in additional supply tensions, rather than securing access to medicines where needed.
- There is no visibility regarding the liabilities for failure to supply or the liabilities of suppliers of existing national contracts that may be superseded by this contract.
- Technical specifications of the tender do not specify the delivery point for products, even though this directly affects the cost for the manufacturer.
- The awarding criteria include time-bound factors such as shelf-life/expiry dates or speed of delivery times. However, there are no fixed dates in the tender for delivery making it difficult to understand how these points can be reliably estimated and awarded under the tender.

- There are technical specifications in the contract which seem to have no relevance for pharmaceuticals (ISO standards) while the critical specifications such as licences are not indicated clearly.
- All technical aspects (e.g. Pharmacovigilance and Liability topics) have to be clarified if products are used in member states where the supplier has no local presence.

Regrettably, these issues confirm our position that joint procurement should not be used for multi-source products. Furthermore, the technical challenges with the tender SANTE/2020/C3/29 could create disruption for existing supply agreements, confusion of expected demand and constraints in terms of production and supply, and lead to inefficient allocation of medicines to patients.

We strongly believe that more credible alternatives to this joint procurement call should be considered for the reasons highlighted above. Again on this specific tender, which in our view should not proceed, at a minimum, we recommend that the submission deadline for this tender is extended and that the technical requirements are extensively discussed with the concerned companies to avoid supply misallocation at this time of dire need for Europe and European patients. Beyond this tender, we strongly recommend continuing our dialogue to jointly discuss how supply resilience can be improved.

Yours faithfully,

Adrian van den Hoven
Director General