

Call with Commissioners Kyriakides and Breton and pharmaceutical and medical device industry 09/04/20

Summary

*Commissioners Kyriakides and Breton held the fifth call with representatives of the pharmaceutical and medical devices industry as well as EMA to discuss possible shortages of medicines and medical devices for the Covid-19 pandemic. In general, demand for medicines and medical devices continues to be high. There are **continued worries about the supply of ICU medicines**, although work has started to map supply and demand. Industry continues to **report shortages of PPE and ventilators and the need to increase availability of diagnostic tests**. Industry continue to express concerns about **disruptions to transport**, the need to maintain **international supply chains**, and need for **coordination and guidance on allocation of stocks** as companies are receiving a multitude of requests at regional, national, EU and global level.*

Report

Commissioner Kyriakides thanked the industry for their written updates. She stressed that the situation is constantly evolving and as some issues are resolved, new difficulties arise. She informed that EU Health Ministers expressed a reinforced show of solidarity at their last call. She and Commissioner Breton have also written to MS asking them to lift any remaining or new export bans. In response to industry concerns, she will also speak bilaterally to BE and HU on their export bans.

There is continued outreach to India. Yesterday, she and Commissioner Hogan sent a letter to the Indian Minister of Commerce asking to facilitate exports and lift restrictions. Commissioner Kyriakides also participates in the calls of G7 health ministers that cover research and medicines supply and allow exchange with Canada, Japan and the US.

Commissioner Kyriakides informed that the ECDC has published their latest risk assessment including information on the next stage after the confinement measures end. The risk assessment covers health system capacity and PPE. The ECDC risk assessment outlines information on masks, and this is also being discussed with the Commission's Expert Advisory Group. The Commission continues to stress that masks must be available for healthcare workers first and then professionals. Although there have been some conflicting guidelines from MS, she explained that the Commission is working to publish information for MS and citizens. She explained that ECDC and JRC are currently working on epidemiological modelling, as are the national CDCs in MS.

She reported that on Wednesday, the Commission published guidelines on the rational use of medicines. MS must now implement these guidelines.

Commissioner Kyriakides explained that the EU is launching an additional joint procurement for PPE. Furthermore, the Emergency Support Instrument is being set up by European Commission to allow rescEU to stockpile PPE and ventilators to more quickly respond to MS needs.

Commissioner Kyriakides asked the associations to provide new information on possible bottlenecks and updates on new treatments and devices. She also asked for an update on their work to increase production for ICU medicines and COVID-19 treatments. She asked the associations to send important points to her Cabinet after the call, so that they can prioritise and move on them.

In terms of long-term solutions to the issues raised by the pandemic, such as dependence on third countries, she explained that the EU pharmaceutical strategy is planned for end of 2020.

Commissioner Breton thanked the associations for their continued work and stressed the need to continue our efforts. He reported that the Commission continues to work for the integrity of the single market and free flow of medicines and medical devices. The Commission has organised the first single market enforcement task force. For this, the implementation of the green lanes and allowing critical workers to reach their place of employment is important and hopefully improving. He asked that associations immediately report remaining or new barriers to the movement of goods. The Commission will act on any information received without delay. Commissioner Breton also asked industry to send precise information about any requisitioning so that he can contact MS bilaterally.

For PPE and ventilators, Commissioner Breton explained that the Commission was in constant contact with industry on the ramping up of production. He reported an increase in production and delivery of these products and that this important work must continue. He explained that some companies have agreed to publically share design specifications of ventilator models and called on other companies to follow suit. This sharing of design specifications has allowed the automotive sector to start producing ventilators. He thanked the medical device associations for attending the joint video conference with the car industry.

He urged members of MedTech Europe and COCIR to reply to the questions they have received on ventilators and components as this was vital to the achievement of a clear market overview, which will facilitate supply and demand estimation within MS and the whole EU.

In terms of the lifting of confinement measures, both MS and industry are thinking about next steps and the need to provide PPE to the public and workers is essential. The lift of these measures will require an increased availability of masks, MS and companies need to build up these as soon as possible.

Commissioner Breton stressed the importance of feedback from industry especially as we are entering a new stage of the pandemic in the US and Africa.

EFPIA thanked for the Commission for the guidance on rational use. EFPIA highlighted three important issues for them: stockpiling, export restrictions and the ISPOC.

On stockpiling, they stressed that MS need to stop stockpiling since it makes it very difficult for them to supply the entities that need the medicines the most. They would also like demand data to help them plan their supply better. Their companies have made demand projections but these need MS data to improve accuracy (either epidemiological data or data on hospitalisations and ICU rates weekly by MS). Without this data, it is very hard to decide which orders should be honoured.

In terms of export restrictions, MS still prohibit or severely restrict export of medicines. For example in BE, it is not possible to release medicines for another MS unless there is a stock reserved for the Belgian market. In HU, it is not possible to export propofol or hydroxychloroquine even if it was manufactured for another MS.

EFPIA stressed the need to make the ISPOC operational as quickly as possible, as they need to know MS needs to avoid shortages.

In terms of new treatments, their companies continue their work and would like regulatory flexibility in case clinical trial results are positive. They also request a two-way dialogue on protocols and guidelines for proven treatments. They would like to continue supplying these new treatments through their usual channels and not by joint procurement.

EFPIA reported that they see bottlenecks at the Turkish, EL and BG borders due to quarantine restrictions for drivers entering Turkey. In terms of the Indian restrictions, issues with paracetamol and

hydroxychloroquine remain. They would also like the Commission to provide letters to the Indian authorities to allow their workers to continue working despite the Indian lockdown.

Medicines for Europe thanked the Commission for the positive decision towards their project to discuss demand and production capacity for ICU medicines managed by the consultant AT Kearney. They explained that the cooperation is open to all companies regardless of affiliation. The project has a model to estimate demand based on number of patients and average use of medicines. Once they have collected more information on production capacity, they would like to share this with both the Commission and MS to have a discussion on actual needs as opposed to stockpiling.

MfE thanked Commissioner Breton for his efforts on export restrictions. They stressed the need for support from Commission services since some of the restrictions are 'opaque' meaning it is hard to negotiate permissions with authorities.

On India, MfE reported there is a need for help from the Commission to negotiate with the Indian authorities to release shipments of paracetamol and hydroxychloroquine.

MfE thanked the Commission for the guidelines on rational use. They will share them with their national associations to reach out to MS.

AESGP welcomed the Commission's guidelines on rational use. They also thanked us for our outreach to India and requested that it continue. AESGP reported that they have not had any shipments of paracetamol from India since the beginning of March. There is also decreased production capacity in India due to the lockdown measures.

AESGP thanked the Commission for its quick reaction on pharmaceutical grade ethanol. They stressed their continued worries about the availability of FFP2 masks and gloves. They would like clear guidelines to ensure that they don't need to compete with the general public for PPE.

Vaccines Europe reported that situation remains the same for vaccines producers. Access to PPE remains a concern for them. Vaccines Europe requested access to epidemiological modelling data to allow them to prepare clinical trials for COVID-19 vaccines.

CEFIC (EFCG) reported that API producers play a central role in the pharmaceutical supply chain. They explained that EU API producers are dependent on starting materials from Asia. The closure of the Chinese and Indian borders coupled with increased demand has led to an increase in prices. They stressed that without raw materials, API production cannot continue having a detrimental effect on finished product manufacturing. CEFIC explained that it is hard to ramp up API production and it can take six months or more to switch to production of a new API. This can be fast-tracked with some regulatory flexibility. CEFIC requested Commission support on global supply and would like critical APIs produced in the EU. Longer term, they would like an EU industrial policy to bring critical API production back to Europe.

EUCOPE thanked the Commission for the guidance on rational use and the letter calling to increase production. EUCOPE explained that their members have not experienced shortages of orphan medicines. There are, however, issues for patients to receive their treatments since ICUs are crowded. EUCOPE explained that some of their mid-size producers in Europe could help to produce some critical medicines in the mid-term.

MedTech Europe (MTE) raised ongoing concerns on the question of access, availability and supply to combat covid-19. One issue highlighted was regarding the foreseen relieve of lockdown measures in Austria, the Czech Republic and Slovakia. MTE stressed that if the relieve of confinement measures are

to take place, then the reliance on PPE and testing would be paramount so that to avert a second wave of COVID-19.

MTE recalled that the issue of export restrictions was still observed in Poland and that requisition orders in France and other member states are increasingly problematic. They informed that requisitions in Italy for both unfinished devices and devices in transit were still taking place. MTE highlighted that the existing EU level export restrictions on PPE was not working as intended as Member States seem to have insufficient capacity to deal with export authorisation requests. MTE urged that the current EU level export restriction should not be extended beyond its current expiry date of 25 April 2020. MTE touched on the impact of the current US Defence Production Act (DPA) on the ventilators sector and highlighted two sources of concerns regarding companies in the EU part of the DPA and about possible reactions from third countries, for example China. They stressed that such reactions will have a severe impact on the global supply chain. MTE repeated concerns on the airfreight costs from China to Europe and noted that costs which were 2.5 EUR/Kg in January were now ramped up to 11-13 EUR/KG. They informed that they were eagerly awaiting to see the relief to be brought about by the foreseen emergency support mechanism.

For tests, MTE again stressed the need for a fast track regulatory pathway. They repeated that access in the EU will need to be facilitated and welcomed the ongoing exchanges with DG SANTE on the topic. On PPE, they highlighted that the ramping up of glove production was an issue faced worldwide and that different jurisdictions have taken actions on this issue. They informed that the ECDC intended to publish guidelines on the lifetime extension of gloves.

Specifically on ventilators, MTE informed that manufacturers were working on strengthening the supply chain but that the recent US DPA raises concerns. They highlighted that issues beyond ventilators have been observed such as the availability of accessories such as masks and tubings intended to be used with ventilators. Additionally, concerns on the availability of infusions pumps and monitoring equipment was raised. They informed that shortages of ECMO (Extra Corporeal Membrane Oxygenation) systems i.e. 'Artificial Lungs' have been noted and although these devices are used in lower quantities, their importance for patients in critical care is paramount. MTE closed by calling for increased cooperation between the Commission, Industry and Member States.

COCIR thanked the Commissioners for the great work done thus far and stressed that this solidarity was of paramount importance. They informed about recent dedicated discussions on digital health with Commissioner Breton and stressed the importance of identifying challenges and opportunities. They referenced the ongoing work in France on the use of teleconsultations and the importance of encouraging the use of such digital platforms for reducing contamination rates. COCIR informed that dedicated calls with DG TRADE on export restrictions were welcomed and stressed the importance of maintaining the global supply chain. They raised concerns regarding increased problems witnessed in India, China and Malaysia for 'three tier suppliers' and informed that overnight, problems related to the exports of ventilator parts from China have arisen (products are being held up by Chinese customs). COCIR called for the Commission to issue letters to both the Indian and Malaysian authorities on the need to facilitate the export of device parts and components. They also highlighted the consequences of the imposed lockdowns in India and Malaysia on the production and supply of these products. COCIR raised that forecasting foresees potential issues coming for availability of monitors, CTs, ultrasounds and X-ray machines.

On hospitalisation data, COCIR stressed the importance of receiving such important information so that to organise appropriate allocation strategies. COCIR supported the suggestion made by MedTech Europe on the setting up of a collaborative platform between the Commission, Member States and Industry in order to investigate issues related to allocation and stockpiling.

Commissioner Kyriakides thanked MedTech Europe and COCIR for their input and informed that she would follow up with Commissioner Hogan on the issues raised on export restrictions on ventilator parts from China and the other issues regarding India and Malaysia.

Commissioner Breton asked MedTech Europe to provide further details concerning MS export restrictions and requisition orders and indicated that he would act immediately on these.