



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: **quality, safety, innovation**

Summary minutes: Call with Commissioners Kyriakides and Breton and pharmaceutical and medical device industry on 03/04/2020

Summary

*Commissioners Kyriakides and Breton held the fourth 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 outbreak. Commissioner Kyriakides called on the pharmaceutical to increase production to meet the **vastly increased demand for critical hospital medicines**. In general, demand for medicines and medical devices also continues to be high. Industry continues to **report shortages of PPE, ventilators and diagnostic tests**. While industry is generally able to increase output to satisfy demand, their main concerns continue to be **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 EMA for compiling data from MS on the availability of stocks of ICU medicines and medicines on the Indian export ban list. There are increasing concerns about shortages of ICU medicines, paracetamol and COVID-19 therapeutics. Commissioner Kyriakides informed industry that she has sent a letter today with a strong call on all producers (originators, generics, OTC and API) to increase production capacity. She also reported that she had alerted the EU Health Ministers of the current pressing issues, including national stockpiling.

She explained that EMA is collecting information on demand from MS for the APIs and medicines subject to the Indian export ban. From her side, she will speak to her Indian counterparts again. She reported that the Commission has issued guidelines on coordinating COVID-19 healthcare responses between MS, including taking patients in ICU and allowing healthcare professionals to work in another MS. The Commission has also updated the clinical trials guidelines and published guidance to manufacturers producing medicines equipment. The Commission is currently discussing with ECDC on

recommendations for the use of masks. The proposal to delay the implementation of Medical Device Regulation by one year has been adopted by the Commission.

The Emergency Support Investment has also been launched including EUR 300 million for rescEU to purchase medical devices and to allow the Commission to directly support MS to buy PPE. The Commission is currently working on an exit strategy.

Commissioner Breton thanked the participants for their efforts. He said that we are currently experiencing the peak of the epidemic. The Commission is monitoring the situation closely. For medical devices, he reported further progress on the efforts to increase production of ventilators. For example, in FR, there is a cluster of companies working to produce 10,000 ventilators by mid-May. The Commission has reached out to traditional manufacturers, other industries (automotive and aeronautic) in the EU, as well as third country producers. For PPE, there is now better clarity on the ability to supply masks. We need EU self-sufficiency for masks and EU production capacity has increased considerably. There should be an additional 15 million masks produced in the coming weeks. Solidarity between MS is important and we have positive examples of EU solidarity (FR sending masks to IT). Commissioner Breton stressed the importance of the single market and shared industries concern about free flow of goods. He explained that guidelines on critical workers were published this week. The Commission is still working to eliminate export restrictions and has been clear that total export bans are against the EU treaties. He asked on industry to inform of any new measures. On the hydroxychloroquine bans in FR and HU, the Commission is in contact with the MS concerned. This is also true for the component ban from IT. On Monday, he called on ministers to lift any export restrictions that endanger the single market. Commissioner Breton stressed the usefulness of the weekly calls and the need to enhance efforts to meet the increase in demand for medical products in the coming days and weeks.

EMA reported from their industry contacts that many of the issues raised in previous calls are still valid. The EU pharmaceutical industry still reports issues in relation to stockpiling, logistics and EU export bans. EMA reported that they are currently working on the industry requests for regulatory flexibility and will inform industry of the outcomes. EMA is also compiling additional information on ICU medicines and national demands for APIs subject to the Indian export restrictions.

EFPIA thanked Commissioner Kyriakides for her letter calling on increased production which they have shared with their members.

EFPIA continues to be concerned about national stockpiling. Although they have implemented pandemic plans and increased production, they are still under pressure due to stockpiling of experimental treatments. This has implications for on-label use and they have been working with patient organisations. They would like a concrete set of measures from the Commission to discourage and act on MS implementing stockpiling. They would also like to use the I-SPOC, rather than joint procurement, to discuss with MS on where to allocate production and stocks at EU level.

In terms of logistics, EPFIA reported that air freight remains a problem. Prices have increased up to 300% due to a reduction in capacity. Usually, 40-50% of their cargo is sent on passenger flights.

For experimental COVID-19 treatments, the EFPIA companies reported that a number of clinical trials are ongoing but there is limited evidence on effectiveness so far. EFPIA

asked that the Commission ensure that MS apply the clinical trial guidelines in the same way.

Medicines for Europe thanked Commissioner Kyriakides for her letter. Due to the current problems for ICU medicines, they have set up a group to assess supply imbalances and increase production. They are inviting all companies producing ICU medicines to participate. MfE asked for a clear mandate and legal certainty from the Commission to continue their data collection and cooperation, as managed by a contractor. They will share all the information they collect with authorities.

MfE stressed the need to better calibrate their information on EU stock levels to MS demand and would like a structured exchange with MS managed by the Commission and EMA. Many MS are setting up national coordination mechanisms and they would like this replicated at EU level. MfE would also like the Commission to take action against MS acting unilaterally on ICU medicines.

AESGP welcomed the progress so far, especially in setting up the I-SPOC. Their members' main challenge is increasing production, especially considering the continued export restrictions from India. AESGP asked again to have the ECDC projections to help estimate future demand. AESGP does not support joint procurement for OTC medicines since it would impact their supply through regular channels (community pharmacies). They reported that the RO export ban has created problems on the RO-Moldova border. In terms of PPE, their companies have another week of stock and are concerned about increasing demand for masks in the US. They would like MS to adopt harmonised standards on the use of masks for the public versus masks for manufacturing and health care workers.

Vaccines Europe reported that their manufacturers see an increase in demand for respiratory vaccines in 12 countries due to WHO guidance to vaccinate against influenza and pneumococcus during the pandemic. Vaccines Europe stressed the need for regulatory flexibility, in particular on packaging, to allow them to reallocate stocks within and from outside the EU. They said that it takes a long time to increase production of vaccines. Vaccines Europe asked for Commission support to ensure that MS consider service and raw material providers for pharmaceutical companies as essential businesses. They also reported good progress on the development of COVID-19 vaccines but asked for help to ensure quick GMO authorisations in the MS to start clinical trials as soon as possible.

MedTech Europe (MTE) thanked the Commission for all efforts and measures taken during the last week. They alerted that a growing number of availability concerns for many types of devices such as tests, personal protective equipment and ventilators have been noted as a result of the massive spike of demand in the United States which is depleting the supply across the world. Additionally, MedTech Europe raised concerns on export restrictions being undertaken at global level, which is rendering meeting demand extremely difficult. They warned that if the US chooses to impose similar restrictions, then the EU's capacity for production would be crippled. Additionally, continued issues with regards to movement of devices in the EU for protective equipment, ventilators and ventilator parts/accessories were raised. As an example, they remarked that FR companies were still not capable of exporting surgical facemasks. They also raised concerns, notably in IT, which produces ventilator accessories such as tubes, filters, suction systems, as well as in PL, CZ.

MedTech Europe reminded that the changing recommendations on use of PPE and IVD assays at national level severely impacted demands and those impacted companies required notice in advance or time to adjust. EU recommendations on the different uses of PPE and tests would be welcome. They highlighted that increasing concerns regarding medical glove supplies have also been noted and underlined that unlike surgical facemasks, the production process was rather complicated. They informed that companies are working closely with the WHO on disinfection protocols for gloves with the aim of increasing glove lifespan.

Market access problems for IVDs were also raised. They informed that many manufacturers have been able to access other markets such as the US, AU, CN and JP but that the access route in the EU was proving to be the most difficult. MedTech Europe alerted that unlike those other countries, the EU doesn't not have a simple pathway which provides access to the entire EU. They complained that Member States were hesitant of issuing national derogations and that much of the already available stock was not being made available to the EU. They stressed for the need of a new mechanism to enter the market without the CE marking process.

MedTech Europe welcomed the news on the new requirements for cross-border workers but highlighted that in many member states, medical device workers were not considered as 'critical industry' (referencing the Czech Republic). Regarding logistics, new measures under the emergency support instruments funds will be useful in mitigating the rapidly accelerating price and availability of airfreight transportation. MedTech Europe enquired if it would be possible to have a list of contacts of those responsible for access to these funds. They stressed that this would support shipment for individual member states but not necessarily for 'bundled shipments' intended for distribution in multiple member states.

A recurrent issue is possible shortages of components and MTE highlighted the need to designate manufacturers of components as essential suppliers. Many of these are SMEs and need financial assistance.

COCIR thanked the Commission for all the hard work and activities undertaken during the last week. They underlined the need to keep the internal market open including movement of essential staff, and requested that clear guidance be given to MS on this in particular regarding common understanding on what are critical goods and suppliers. They enquired whether any initiatives regarding temporary waivers of tariffs on medical equipment would be undertaken to alleviate difficulties faced for import of needed materials. COCIR highlighted that a similar approach such as the one currently underway for medicinal products should be undertaken for medical devices. They stressed that in order to ensure the effective functioning of the global supply chain where many parts and components come from different parts of the world, governments and regions need to refrain from protectionist actions. COCIR informed that they are experiencing similar issues raised by the medicinal products associations regarding airfreight limitations and increase in pricing up to 300%. COCIR enquired whether prioritisation of flow of goods for medical devices is possible and if the letter sent by Commissioner Kyriakides and Breton to Member States could be shared with industry. They re-iterated that devices other than ventilator devices need to also be prioritised such as those used for patient monitoring (portable x-rays and CT equipment). They also informed that besides COVID-19 patients, other patients, such as those with critical health complications still need access to healthcare.

COCIR welcomed the announcement made by Commission President VDL on the emergency support mechanism budget, of which a considerable amount is being allocated to the healthcare system. They underlined that it was not yet clear how this budget would work in practice and if financing of transportation of medical equipment would be included. They stressed the need to ensure a fair allocation of critical supplies.

They highlighted that a Commission led fast track procedure/mechanism was needed for medical devices so that to avoid unnecessary administrative burden. The need for a more structured dialogue between the Commission, Member States and EU associations was requested. They called for a similar mechanism as the one put in place for medicinal products.

DG SANTE reported that they are working with **DG COMP** to see how to facilitate a structured cooperation on ICU medicines. This would allow companies to share information on stocks and manage production. Industry will receive updates as soon as they are available.