

Call with Commissioners Kyriakides and Breton and pharmaceutical and medical device industry 23/04/20

Summary

Commissioners Kyriakides and Breton held the seventh call with representatives of the pharmaceutical and medical devices industries, as well as EMA and ECDC 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 **export restrictions**, 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.

Follow up actions

- The Commission, and Commissioner Breton in particular, will follow up on export bans/restrictions in the Member States.
- The Commission will continue its outreach to India at political and technical level.
- Commissioner Breton will send precise information on requirements to individual associations.
- EMA will provide further clarification to companies on the differences between the I-SPOC and industry ICU medicine cooperation project.
- The Commission will share the ECDC projections as soon as they are available.
- The Commission will consider the request by EFPIA, Vaccines Europe and MfE for a further dialogue on new COVID-19 treatments and vaccines (e.g. on regulatory issues/flexibility).
- The Commission will follow up on PPE supply to the pharmaceutical and device industries.
- DG SANTE to consider how to address the expected increasing demand for masks.
- DG SANTE to raise with DG EMPL whether there is a need for guidance to MS on quarantine measures related to critical staff (such as MD engineers and service technicians). Alternatively, a letter could be sent to Member States.
- Commission to investigate whether informational webinars or other solutions on access to structural funds could be provided to hospitals beneficiaries.

Report

Commissioner Kyriakides thanked everyone for their presence. She stressed that the weekly calls are a very important part of our joint efforts in relation to COVID-19. On ICU medicines, Commissioner Kyriakides said that we have taken important measures but the situation remains critical. There is a need to monitor their supply closely. She also stressed the need for industry increase production.

Commissioner Kyriakides reported that she raised industry concerns with EU foreign ministers yesterday, especially in relation to export restrictions. She has also been informed of transport bottlenecks for radiopharmaceuticals. In particular, there is a problem sending these medicines to CY and concerns that oncology patients are not receiving their treatments. She will raise this directly with CY and would appreciate further information from industry.

Commissioner Kyriakides reported that an update to the Q&A on regulatory flexibility covering GMP aspects was published on Monday. A new update on the clinical trials guidelines will soon be finalised.

Commissioner Kyriakides reported that we continue our diplomatic outreach to India. Some progress has been made on finished paracetamol but the restriction for paracetamol APIs remain. For hydroxychloroquine, case by case exemptions for shipments to certain MS are allowed.

Commissioner Kyriakides explained that her services have been informed that EU API producers have capacity to produce in Europe. She asked industry to consider sourcing APIs in the EU.

Commissioner Kyriakides informed that following repeated requests from industry, the setting up of a collaborative platform for discussions of MD related issue has been initiated under the auspices of the Clearing House and that a first meeting of the group was organised for Wednesday next week. On diagnostics, Commissioner Kyrakides informed that concerns on the reliability of device remain and that the ECDC has recommended the undertaking of additional validation testing prior to usage of devices as part of a national strategy.

She explained that ECDC would present their work on projections to allow industry to anticipate demand. She stressed that we are still expecting to have pressure on health systems and demand for medicines and devices.

Commissioner Kyriakides explained that the global pledging initiative on 4 May, supported by the G20, would include funds to manufacture vaccines and new treatments.

Commissioner Kyriakides explained that we are entering a new phase of the pandemic and there is a need to be able to deal with possible increases in cases when containment measures are lifted by MS. This makes the weekly calls are even more important now.

Commissioner Breton stressed that the crisis is not over and will last for a long time. He explained that we continue to see a lot of tensions in the supply of medicines and need to be vigilant in the coming weeks and months. In particular, we need to be prepared for the next phase, when there will even higher demand for medicines. Commissioner Breton explained that the next phase will require a careful follow-up of cases. Tracing apps will be voluntary and will respect personal data.

In terms of export restrictions, Commissioner Breton acknowledged that there are still problems with a few countries and asked industry to flag any issues directly.

EMA gave a short summary of their latest status update. EMA explained that the situation in India has improved with the lifting of some restrictions but there are problems with manufacturing capacity due to the Indian lockdown. EMA reported that export bans-restrictions are still problematic and causing difficulties for industry to supply. EMA explained that discussions on further regulatory flexibility are ongoing with the Commission, EMA, HMA and industry. EMA reported that the pandemic is having an impact on clinical trials and further guidelines will be published soon. EMA reported that the industry cooperation project on supply and demand for ICU medicines will be presented to all MS next week.

ECDC explained that the epidemiological situation remains the same in the EU. ECDC reported that they now observe excess mortality in the age group 30+64 and not only for over 65s. ECDC is currently working on an update of their rapid risk assessment. The update will focus on implementation of the road map for lifting confinement measures including additional criteria and information on nursing homes. This is because they are seeing more outbreaks and deaths in nursing homes.

In terms of their forecast model and projections, these will cover 30 rather than 90 days due to problems of reliability. In fact, the most reliable predictions only stretch 10 days into the future. ECDC explained that their model simulates transmission rates to allow predictions of the number of new cases, morbidity and mortality. As new political decisions are taken, ECDC will add them to the model but it is difficult to estimate the impact of lifting confinement measures on transmission. This will only be known after a

couple of weeks. ECDC cautioned that even with confinement measures in place, there are still some MS that see an increase in cases. ECDC stressed that they are aware of the need for companies to have some basis for planning. However, they are reluctant to give unreliable estimates since these may lead to under or over planning.

MedTech Europe (MTE): reported continuous problems with regard to export restrictions from China, especially for products such as thermometer guns and diagnostic tests which are made in China but intended only for export to the EU. On a more positive note, the issues related to exports of ventilator spare parts have been resolved and the shipments which were blocked last week have now been released.

MTE informed that they were looking forward to seeing how the new rules on exports from EU would play out in practice as there is an ongoing need for the export masks to manufacturing sites outside the EU in order to continue production. They welcomed the MDR postponement which now included the possibility of issuing EU-wide derogation and informed that this will be particularly useful for new ventilators. They reported that requests will start coming in shortly, as the prerequisite national derogations are already underway. They expressed their continued frustration with the fact that EU-wide derogations are not applicable for innovative IVDs and cautioned that this may lead to inequality in access across the EU, as only some Member States will take national derogations. MTE raised that the lifting of containment measures will go hand in hand with a demand spike for diagnostic tests and masks and urged for the development of clear criteria on the use of PPEs, masks and tests was necessary.

On cross-border, MTE informed that issues on the movement of critical workers were still existing and that medical device service technicians were being placed in quarantine when travelling back and forth from their jobs. They informed that most recently, cases seem to be coming from FI, but worries that these measures are also taken in other MS was expressed. They raised growing concerns on the availability of gloves due to the limited supply (as these products are mostly manufactured in South East Asia). Actions related to extending the life of gloves and prioritisation to healthcare professionals was necessary. MTE welcomed the setting up of the new MD exchange platform and relayed that the group will be of use for the estimation of demands for ventilators, diagnostic tests and other technologies.

MTE, in response to the Commission questions, informed that the most time consuming step in putting together technical documentation for IVDs was the need to gather data, which usually takes 3-6 months. On validation of assays, they informed that in a traditional scenario, the manufacturer validates the assay performance, then the receiving lab has to conduct a primary validation prior to use (labs have an obligation to validate the tests before use). MTE informed that this is proving to be difficult during COVID-19 as there is limited access to the necessary control materials or standards.

COCIR: COCIR thanked the Commission for establishing the platform for dialogue between the Clearing House and the MD industry. They welcomed the Council adoption of the MDR postponement and repeated the message transmitted by MTE regarding EU-wide derogations. They also concurred with MTE regarding the movement of critical workers engineers and informed that many MS have unclear quarantine rules. They specifically raised issues coming from the Scandinavian MS, but also informed that problems were also faced in LT, EE and HU. They requested that the Commission issue guidance on this topic. Alternatively, they stated that a letter might suffice.

COCIR raised the need for industry to have access to the Clearing House platform on collective demand, in order to meet demand and supply, industry needs access. They raised issues related to public hospitals and liquidity and reported that issues were observed in hospitals and healthcare systems. The ongoing concerns on financial liquidity is resulting in cancellations of treatment. They informed that the medical community required assistance from the Commission in explain how to use the existing funding

instruments as the beneficiaries have no clue how to access to this funding. COCIR also raised the importance of having patient data available for research and innovation.

On airfreight costs, COCIR informed that several contacts have been made but it was still unclear how access to the 3 Billion-support fund was possible.

AESGP explained that their main concern remains supply of paracetamol APIs. AESGP explained that India is the biggest paracetamol API producer in the world. AESGP explained that it is difficult for their members to change suppliers and there is a limit in stock for other suppliers. AESGP is in touch with their Indian counterparts to collect data on current stocks of paracetamol in India. They hope this will reassure the Indian authorities and they will lift the remaining restriction. AESGP thanked the Commission for their work with India and reported that they have provided technical details to SANTE and TRADE. AESGP explained that they are still worried about the availability of PPE (masks and gloves). They also thanked the Commission for the newly established platform for dialogue on medical devices.

Medicines for Europe reported that their members have put in place contingency planning and increased production of ICU medicines, COVID19 treatments and medicines for chronic diseases. The pandemic has not impacted the production capacity of their members. MfE reported that the industry ICU medicine cooperation project has been launched to predict demand. The results are being shared with the Commission, EMA and MS. MfE will contact the API industry on the project tomorrow. In general for APIs, MfE reported problems with MS intervening in the API market by buying APIs or stopping exports. MfE explained that raw material costs have gone up for COVID-19 related medicines.

For new COVID-19 treatments, their member companies have made donations to clinical trials and hospitals. MfE would like to work closely with authorities on regulatory issues and scaling up production once new effective treatments are identified.

MfE reported that transport issues have improved but there are problems with CY and MT since they are islands and problems with airfreight remain. There are also problems at the EU external borders with the Balkan countries and Turkey. On PPE, MfE asked that the pharmaceutical and device industries be covered by exemptions on exports.

MfE explained concerns about the coming months until there is a vaccine or cure available. They would like support from MS to anticipate demand in case of new waves of cases. MfE also thinks that there will be requests to strengthen security of supply in Europe. This may be difficult if MS are in debt and introducing new austerity measures.

MfE would like a continued exchange between MS, the Commission and industry for the post-COVID-19 pharmaceutical strategy.

EFPIA stated that they look forward to receiving the ECDC predictions. They explained that there are three current issues for their members. In terms of export restrictions, BE, FR, HU and PT are still problematic. In particular, the HU restrictions are very severe. They are also worried that the BE restrictions could seriously affect global supply and lead to retaliation. Airfreight remains an issue and EFPIA confirmed that there are problems supply CY. EFPIA is looking at a number of options including a new cargo route via BE, moving patients to EL or chartering flights. EFPIA is in touch with patient organisations on the ground. EFPIA reported that they see a significant increase in demand for COVID19 related treatments. They still don't know if this increase is due to current patient needs or stockpiling by MS. EFPIA stressed that their members are doing everything they can and some companies have increased production by more than 200%. EFPIA requested that the HMA/EMA guidance defining a shortage should be linked to patient needs rather than national demand. EFPIA explained that they are

not affected by API shortages, since 70% of APIs for innovative medicines come from Europe and 11% from the US.

For COVID-19 vaccines and treatments, EFPIA concurred with MfE that there is a need to identify regulatory bottlenecks and look at manufacturing capacity. There is a need to ensure there is enough manufacturing capacity in the EU to meet demands in all MS. EFPIA would like MS, EMA and industry coordination to allow the collection of information on manufacturing capacity across the EU and how to ensure equitable supply to MS.

EFPIA stressed that the new pharmaceutical strategy should foster R&D infrastructure in the EU to allow continued development of vaccines in Europe. EFPIA also asked for a public/private partnership to respond to emerging biomedical threats.

Vaccines Europe reported that they continue to have problems with access to PPE in BE, FR, DE and IT. Their members' main priority is to develop or support manufacturing of new COVID-19 vaccines. VE stressed that this will have impact on the development of other new vaccines. VE would also like an early discussion with authorities on regulatory bottlenecks, manufacturing and distribution before clinical trials start this summer.

EUCOPE stressed the importance of need continuing clinical trials during the crisis. There is also a need to look scale up production in Europe and identify available production lines to produce a new vaccine. EUCOPE will raise this issue with their board of this week. EUCOPE enquired whether a list of COVID-19 labs that conducted preclinical tests existed.

CEFIC (EFCG) reported that their major issue is currently availability and price of solvents (increased by 400%). This covers in particular, four key solvents, including ethanol and isopropanol. CEFIC reported that there are sufficient quantities of APIs for paracetamol and HCQ in Europe. Further information has been sent to SANTE. CEFIC reported that they are providing data to GROW and SANTE to allow them to prepare a long term approach on APIs. This includes giving numbers for reinforcing the supply chain in Europe and reducing dependency.