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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 20/03/2020

Summary

Commissioners Kyriakides and Breton held the 2nd 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. Up to date, ***no critical shortages of medicines or medical devices have been observed*** *but* ***demand continues to be high****. While industry is generally able to increase output to satisfy demand, their main concerns were* ***disruptions to transport****, 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 welcomed the participants. She summarised some of the Commission actions undertaken so far: accelerated joint procurement of protective equipment, ventilators and laboratory supplies, work with EMA to monitor shortages of medicines, guidelines on border actions, containment and testing strategies which aim to align the approaches of Member States.

Commissioner Breton emphasized three areas the Commission is working on now: ensuring free flow of medicines and devices (green lanes, border management), providing protective equipment to all who need it (domestic production, joint procurement, aid from China) and increasing the production of ventilators. He called on the industry for creative approaches, e.g. involvement of companies from other sectors in production of the needed equipment.

MedTech Europe welcomed the Commission recommendation on conformity assessment and market surveillance. They asked whether ventilators were covered by it. On free movement of products, they pointed to remaining problem with supply to EFTA countries and Turkey, and the need for a solution for rapid transport from China to the EU. MTE welcomed the joint procurement actions but questioned the lack of

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transparency over selection of companies. They underlined that industry finds it difficult to prioritise the numerous requests at regional, national and EU level and requested guidance to ensure appropriate distribution of the stock. On ventilators, industry is doubling output and in some cases working with automotive companies to 3D-print parts. Sufficient numbers could be produced to satisfy demand forecast by the ECDC. The industry is more concerned about efficient distribution. On diagnostics, industry is also ramping up capacity. Shortages of needed reagents are possible. Industry is in favour of using the tests only for patients with symptoms rather than for screening to avoid device shortages. Finally, MTE noted that implementation of Regulation 2017/745 (EU) on medical devices (MDR, applicable from 26/05/20) can become a problem as activities on this have mostly come to a halt.

COCIR underlined that care must continue for all patients, not only COVID-19. Difficulties with business continuity include not only shortages of devices (besides ventilators, also patient monitors, X-ray, ultrasound, CT, consumables) but also absence of essential employees such as service engineers and drivers. COCIR reported concerns with Member State protectionist measures and need for guidance on allocation of supplies. Imminent application of the MDR was also highlighted as problematic.

Medicines for Europe welcomed actions already taken and called for rapid decision-making, faster and less bureaucratic regulatory measures as well as an EU-level discussion group. No shortages were reported but there are surges of demand in the most affected countries. They highlighted the balance between stockpiling and supplying stock where it is needed. It was also important for MfE to ensure that patients reliant on medicines have access to them. This is in particular case of antiviral HIV medicines used off label to treat COVID19 patients, as the demand for those may raise. On transport, according to MfE it is essential to keep supplies flowing. They asked for a list of green lanes to be communicated to industry. It is also important that this covers empty returning trucks. Problems on some internal and external borders persist (RO, SK, HR, DE, AT, Serbia) and MfE requested the help of COM to deal with national authorities. There is a major problem with air freight especially for frequently shipped small volumes. MfE reported difficulties with export licensing in India and stressed the need for diplomatic channels also with US and China. MfE have developed guidance on how to keep plants running in case of infection but are concerned about the impact of Member State containment measures on continued and upscaled production (lack of protective equipment, availability of workers). At the request of Commissioner Breton, the association will sent detailed update in writing.

EFPIA identified the risk of shortages of certain medicines used to treat COVID19 in Italy and Spain, due to increased hospital demand. Any export bans may lead to shortages. EFPIA considers that there is a need of coordinated approach to control the demand and EMA advice on therapeutic options. The risk for ensuring supply is excessive stockpiling by patients and a guideline by the Commission on the measures preventing stockpiling would be welcome. EFPIA also considers that HIV patients needs to have ensured access to their medication, in particular taking into account that the data on the efficacy of HIV treatments for COVID-19 patients are not conclusive. The association reported problems with logistics, as well as concerns regarding the safety of the staff working at the manufacturing plants - those companies should be entitled to keep their stock of protective equipment. EFPIA noted as well that the current situation impacts clinical trials.

Vaccines Europe did not report any new shortages however the manufacturers noticed increased demand for certain vaccines. They also report as well transport issues. The green lines initiative is welcomed, but this does not always work in practice. The association reported aslo cancelations of air cargo shipments. The containment measures are also potentially impacting the manufacturing capacity: some employees have difficulties reaching the sites. The production of vaccines cannot be increased quickly due to long lead times of production. The current situation will impact clinical trials on vaccines as the epidemiological situation is not usual.

AESGP noted increased demand for non-prescription medicines and welcomed the initiatives of some Member States to reduce stockpiling (FR and DK limits to one month's supply). The association is concerned about limits on export from India which may lead to shortages of paracetamol. On transport, green lines were seen as very helpful and it was important for AESGP to ensure that biocides (hand sanitisers, disinfectants) can also benefit from them. The association also requested that the medicines agencies, including EMA, implement contingency plans as some regulatory steps have been delayed.

EMA reported on the new steering group on availability of medicines to which all industry associations were invited. Calls are weekly with an open and regulators' only sessions. For the call between Commissioners and industry, EMA suggested that associations could submit a status report in writing prior to the call.

DG ECHO announced that the Commission Decision enabling rescEU to be used for COVID-19 was published in the Official Journal on 19/03/2020. It was clarified that the difference from joint procurement is the possibility for central stockpiling of supplies.