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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 27/03/2020

Summary

Commissioners Kyriakides and Breton held the third 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. There are ***now worries that there will soon be shortages of critical hospital medicines.*** *Industry continues to* ***report shortages of PPE, ventilators and diagnostic tests.*** *In general, demand continues to be high. 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 the participants for their written contributions and asked for the latest updates and urgent issues. She reported that at the last ministerial meeting on 26 March 2020, she asked MS to lift export bans and implement green lanes. She also asked MS to impose limits on the amount of medicines that can be purchased.

Commissioner Kyriakides informed that she had a call with the Indian Minister of Commerce where she asked for the Indian export bans to be lifted. India asked for information on the concrete needs of the EU Member States and DG SANTE/EMA will request this today to allow further contacts with India on Tuesday. She stressed that it would be **useful to have more specific information on the most critical products, in particular paracetamol, from industry by Tuesday.**

In relation to hydroxycholoroquine, **she asked industry to be prepared for an increase in demand and to send clinical trial data to EMA**.

She informed that yesterday the Commission adopted guidelines on facilitating air transport for medicines, including a recommendation on fair pricing.

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For medical devices, she informed that the decision on listing of harmonised standards had been adopted and the Commission is tabling a proposal to postpone the implementation of the Medical Device Regulation.

Commisioner Kyriakides asked the associations to **send written notes of the issues they have raised to allow appropriate follow-up**. She also requested MfE to send **further information on the INSERM and WHO clinical trials**. The Commission would like both trials to go ahead as long as they don't hamper each other. Both can generate data relevant for regulatory decisions.

Commissioner Breton reported from a meeting with ventilators producers and other industries (automotive and aeronautical). There is a lot of goodwill from EU producers to increase production or convert production lines to ventilators. Ventilator producers will also share knowledge to facilitate production.

He stressed that free flow of goods in the EU is critical to ensure delivery of medicines and starting materials. The Commission has issue guidelines on green lanes and requirements for drivers to cross borders. The Commission is also monitoring the EU borders via satellite images. He asked that **companies report any issues at borders**.

In terms of export bans, he reported that DE has lifted their export ban and BG will do so next week. He expects that the remaining two countries (CZ, PL) will lift their bans as well.

For PPE and other equipment, Commissioner Breton reported that contacts with industry are very positive and the Commission has a good overview of production capacity in the EU. There are also many new production lines being added to make masks.

Commissioner Breton stressed that the information provided in the calls is extremely helpful and should also be sent in writing.

EMA reported from the call with the EU steering group on availability of medicines and industry. The main issues highlighted by the pharmaceutical industry were problems with hoarding and stockpiling, a lack of PPE, logistical problems, intra-EU export restrictions and the need for regulatory flexibility. Additionally, there was a request for financial support by SMEs due to the need to close facilities or postpone clinical trials. The steering group has agreed to facilitate reporting of medicines shortages through and industry SPOC. They are also exploring increased regulatory procedure flexibility. EMA is working to compile and EU list of priority medicines in relation to COVID-19 and will ask industry to scale up production or find alternatives based on this list. Guidelines on clinical trials have also been adopted. EMA warned that there may be export restrictions introduced by other third countries besides India.

DG ECHO reported that on 23 March the Commission adopted the second decision on rescEU to be used for COVID-19 stockpiling. This is complementary to work on joint procurement.

EFPIA raised concerns that national stockpiling by some MS will make it difficult to ensure supply for all MS. They also reiterated their need for ECDC projections to more accurately predict demand. they stressed the need to prioritise PPE for pharmaceutical companies and asked the EU to help. EFPIA is also concerned about MS potentially requisitioning manufacturing. In terms of logistics, they reported that shipments are becoming more and more difficult. Although green lanes are working for finished

medicines, there are still problems moving components around the EU. There are also problems supplying products from IT since it is difficult to find drivers that can cross the border. They are worried this will extend to DE, ES and FR. Their cross border workers, for example in Alsace, are also struggling to commute to work and should be classed as essential. EFPIA is also concerned about future difficulties in importing active substances from the US due to US restrictions, import testing requirements and the fact that API are on the retaliation list prepared in the context of the Boeing-Airbus case.

Medicines for Europe reported that they are facing the threat of an EU wide stock out for critical hospital medicines used with ventilators (such as anaesthetics, muscle relaxants, antibiotics). MfE is collecting information on the stocks of these critical medicines this weekend and will report stock outs in MS to EMA. They requested immediate actions from the Commission and EMA, including guidance to MS on stockpiling. Medicine for Europe **was requested to send information on the critical medicines to the Commission and EMA by Sunday for follow-up action on Monday.**

Like EFPIA, the requested the ECDC forecasts for the next 8 weeks in each country to monitor demand. In terms of the new experimental medicines used to treat COVID-19, they reported a lot of demand and hoarding by MS, India and the US. MfE asked for regulatory flexibility to import these products from third countries and stressed the need to design allocation criteria based on needs of MS. They cautioned that we also need to protect patients using these medicines for their current intended indications. MfE asked for high-level diplomatic contacts with India to facilitate export licenses and help getting cargo out of India. The EU may also be able to provide aid to India.

AESGP noted improvements at the borders but stressed that there are delays on the EU side of the EU-Turkey border. There are some difficulties with packaging and moving supplies to the EU. In terms of the Indian export ban, their main problem is paracetamol and not the other APIs. For paracetamol, panic buying by citizens and the Indian export ban are causing shortages. AESGP is also worried that the US will impose restrictions and their members are performing risk assessments. These will be shared with EMA. AESGP thanked the Commission for the proposal on MDR postponement and indicated that they will submit further considerations to DG SANTE.

Vaccines Europe thanked the Commission for the measures they have taken the last week. They reported an increased demand for respiratory vaccines (pneumococcus and influenza). They would also like flexibility to introduce variations since they are not always able to source raw materials and reagents from their usual providers. They reported that the Indian export ban does not affect vaccine production. Vaccines Europe expressed concerns that many countries are delaying their regular vaccination programmes. This is a risk to public health and they would like ECDC to issue guidance on maintaining national immunisation programmes. They are collecting information from MS that they will send the beginning of next week.

MedTech Europe (MTE) noted that they see continued shortages of PPE, ventilators and diagnostic tests. The biggest concern are the remaining MS restrictions, notably in IT, which produces ventilator accessories such as tubes, filters, suction systems, as well as PL, CZ. The ventilator producers are expected to double their capacity in the next weeks. An emerging 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. MTE will share a list of these companies. On diagnostics, the association noted that CE-marking even by self-declaration usually takes

4-6 months and MTE members are still engaged in this process. On the contrary imported CE-marked tests do not perform well. MTE welcomed any comparative test evaluations. For all medical devices, MTE underlined the difficulties with allocation of stock and inconsistency of national guidelines in this respect, as well as persisting questions on allocation in the context of joint procurement. MTE welcomed the postponement of the MDR. It also praised the example of DE on implementation of Recommendation 2020/403, allowing direct import of masks that comply with Japanese, American, Chinese etc. standards. MTE welcomed the guidelines on air freight and enquired whether the EU will be deploying air forces like some other jurisdictions are already doing. MTE expressed concern about the growing number of export restrictions globally, in particular in Malaysia and Thailand which constitute 80% of production of examination gloves, and the US, the source of many components and materials for ventilators. MTE underlined the need to provide PPE to factory workers.

COCIR stressed 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. There are examples of service engineers being denied access to countries and forced to undergo quarantine. Secondly, COCIR underlined the importance of maintaining global supply chains (mentioning in particular India) and impact on prices. Thirdly, COCIR welcomed the JP and rescEU actions, as well as the EUR37 bn of cohesion funds, but highlighted the need to ensure a fair allocation of critical supplies. The association enquired whether further procurement is planned e.g. on haemostasis machines or imaging devices. They requested information on the outcomes and lessons learnt from joint procurement of masks and ventilators. COCIR appreciated the proposal for postponement of the MDR but highlighted other regulatory bottlenecks such as the impact of GDPR on exchanging data on algorithms. COCIR also requested coordination and Commission guidance on the use of non-CE marked devices and off-label use of essential medical devices. COCIR highlighted border issues with RO where additional documentation was imposed for export, and with IT where PPE was requisitioned by customs. The association supported action against hoarding and suggested requesting ECDC for guidance on possible measures by MS.