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Summary on discussion of ICU project during 8th Teleconference of the EU Executive Steering Group on shortages of medicines caused by major events

22 April 2020 – Teleconference - 10:30-12:00, CET

1. Introduction and background

The project has been initiated by Medicines for Europe (hereafter MfE) at the end of March 2020 and it aims to follow up on the request of Commissioner Stella Kyriakides for pharmaceutical industry to increase production of medicines used on COVID-19 patients in Intensive Care Units (ICU). The model is designed to enable industry to better plan production, taking into account the lead times required for manufacturing of ICU medicines in highest demand by Member States.

MfE and its member company Accord Healthcare have hired a third party, the management consulting firm A.T. Kearney, to implement the project for a period of two months, from April to May 2020. They have invited all interested companies to participate, including non-member companies affiliated to other trade associations. So far, EFPIA have indicated they support the project.

2. Presentation of the model (open session with industry)

MfE, Accord Healthcare and A.T. Kearney have developed a model to estimate the demand in the EEA (at MS level) for ICU medicines due to COVID-19. The demand estimation is calculated for 17 molecules[1] (injectable formulations only) identified by MfE and used for patients on mechanical ventilation. The model projects the medicine demand, broken down by week, for a two months period (April and May 2020) based on anticipated number of patients going into ICU and number of deaths per MS in a given week, using data from the Worldometer Coronavirus reports and extrapolated using a methodology developed by experts on the basis of the in-depth analysis of, in particular, the outbreak in Italy. The key assumptions of this methodology are that:

- Number of deaths decreasing around 28-days post-lockdown
- All deaths preceded by mechanical ventilation
- 75% of COVID-19 patients in ICU requiring mechanical ventilation

[1] Cisatracurium, Propofol, Alfentanil, Noradrenaline, Dexmedetomidine, Atracurium, Fentanyl, Dopamine, Vecoronium, Remifentanil, Metaraminol, Lorazepam, Pancuronium, Morphine, Adrenaline, Midazolam, Sufentanil

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- 75% mortality rate for patients on mechanical ventilators
- 14 days on mechanical ventilation

Based on the model, EU/EEA countries have been ranked and colour coded as red, yellow or green depending on expected new COVID19 related deaths per million inhabitants. AT Kearney explained that the model on purpose overestimates demand and presents a snapshot in time that does not take into account changes in lockdown measures. Medicines for Europe considers however that the methodology can be adapted in future to include data acquired, following relaxing of lockdown measures and during additional waves of infections as the situation evolves. AT Kearney and MfE asked Member States to validate estimates of this model against their national data to improve the forecast output.

Secondly, the model is also expected to estimate supply capacity from all participating companies. Broadly, it is understood that companies would provide A.T. Kearney with Kgs of APIs that they can produce for the concerned substances for the next two months. This pillar of the model is dependent on the rate of participation of companies to the project. As of 22 April, MfE has informed that 90 MAHs have been approached with a request for information on their supply capacity. MfE asked if the Steering Group could make a statement encouraging companies to participate and provide data in a timely manner.

Further details on the model are available in the annexed slides from AT Kearney and presented on 22 April. These slides are strictly confidential.

Following the presentation the Executive Steering Group (ESG) thanked Kearney and asked on what basis it was decided to set the mechanical ventilation period at 14 days, and if it should not be extended as for instance in DK to 3 weeks period. AT Kearney responded the two-week period was decided as estimate of the EEA average, taking into account in some countries, e.g. UK, the average mechanical ventilation period is one week. Some further clarifications on the assumptions were requested. Some MS noted using averages is not sufficient to allocate demand to MSs, it can guide on expected need as an indication, but it is not accurate for predicting demand. AT Kearney suggested that feedback by MSs with their demand estimates would be needed to fine tune the model: aggregated estimates of demand across the EU could be provided initially and then, for those ICU medicines where a potential issue has been identified, estimates could be fine-tuned with input by Member States. Other MSs also highlighted that the model does not consider additional waves of infection following a reopening, which will change the number of future deaths extrapolated via the model. AT Kearney acknowledged this development cannot be predicted, but data on new numbers of deaths can be fed into new iterations of the model. Some ESG members mentioned that their national industry associations had the impression that the project was about experimental medicines and antivirals for COVID-19 rather than for ICU medicines, possibly due to unclear communication with national associations within Medicines for Europe.

3. EU Executive Steering Group discussion (closed session)

Following departure of MfE/ Kearny the ESG discussed the proposal. HMA members in the ESG expressed strong concerns about the simplistic nature of the model presented by the industry, which is using average indicators that do not consider regional hot spots and might therefore lead to inaccurate results. National models exist in some countries which are more accurate about local differences and allow national authorities to move stocks to most affected local communities; such situations cannot be predicted by the model and might further increase its level of inaccuracy over time. Some ESG members also criticised the model for not being dynamic enough to capture a very rapidly changing

situation. The inability to factor in reopening of lockdowns and subsequent additional waves of infections was highlighted again as a strong limitation by a few ESG members.

Furthermore, concerns were raised about the provision of demand data from national authorities to the industry. Besides concerns related to confidentiality and potential conflict of interests in sharing NCA data which has high marketing value for industry, ESG felt this action could be perceived as a transfer of responsibilities from national public authorities to industry.

EMA noted that, taking into account recent experience in obtaining information from the Member States in relation to national demand needs for the 14 APIs that were subject to the Indian Authorities' export ban, forecasting the demand of medicines on an EU level is highly challenging. The EC suggested that, in the absence of better data, the predictions made based on this model could be used together with demand requests of MSs. The EC also suggested that ESG consider the need to collect demand data from MSs for a subset of medicines at a later stage based on the results of the industry project and data on supply capacity via the i-SPOC. EMA clarified it can contribute towards a repository of demand and supply information, including with more resources for data collection through a temporary reallocation of existing resources, if MSs are interested and participate and there is a clear objective and process for the use of the data.

EC also provided information about a new EU joint public procurement for ICU medicines. So far, some MS have indicated interest. It was agreed that EC would provide further information on this initiative to the HMA in due course.

4. Next steps

Since MfE/AT Kearney informed the ESG they will share 1st results, including information on production from industry, at next week's ESG meeting, the ESG agreed for the slide deck provided by Kearny/ MfE to be circulated to all Heads of Agencies (confidentiality of the information to be emphasised) together with a summary of the discussion (i.e. this document, to be agreed by the ESG through written procedure). In addition, all Heads of Agencies will be invited to attend next week's ESG meeting so that the whole Regulatory Network can be informed on the project and the 1st set of results provided by MfE/ Kearny.