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From: 5.1.2e	
Sent: Thur 11/5/2020 3:53:28 PM	
Subject: COVID-19: verslag EU Executive Steering Group - 4 november 2020	
Received: Thur 11/5/2020 3:53:33 PM	
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 Impact of COVID-19 pandemic -Update from EU SPOC Network and i-SPOCsystem.pdf 	

Beste collega's,

Op woensdagochtend 4 november vond een bijeenkomst plaats van de EU Executive Steering Group (SG) on shortages of medicines caused by major events.

Hieronder volgt een terugkoppeling van hetgeen daar is besproken.

Bijeenkomst 4 november

In de bijeenkomst van 4 november werden de volgende punten besproken:

Demand forecast for ICU medicines in the EU/EEA in the context of COVID-19

- · Update on submissions of demand forecasts to EMA in the framework of the pilot for demand forecasting
- Per 3 November 21 MS have submitted forecasts (82% of total EU/EEA population).
- Estimated total needs by substance reported on for 6 month period (through April 2021).
- EU SG warns for overestimation of expected need by member states.
- Outlooks should not be taken as facts rather only as one piece of information.
- Based on feedback received so far demand forecasting group will clarify guidance to MS, as well as integrate lessons learned as on how to make demand forecasting easier in the future.

• Ad hoc WG will update reflection paper on basis of available information. To be agreed upon final reflection paper in next SG meeting. No decision on further steps yet.

Impact of COVID-19 on the availability of human and veterinary medicinal products

• EMA received reports from several member states for anticipated shortages of immunoglobulins due to decrease in blood donations.

- Also shortages reported for pneumovax 23 (pneumococcal vaccine) due to unexpected increase in demand.
- Risk of shortages of seasonal influenza vaccines EMA has conducted survey to understand risk of shortages following signals from NCAs in October.
- Root cause: significant increase in demand related to pandemic. Most member states anticipate risk of supply disruptions mostly in private sector, not in public sector (at level of national vaccination programmes).
- Industry-SPOC system (ICU medicines only): a total of 300 shortage notifications are currently 'active', none of which are considered critical.
- Austria and Belgium report concerns about availability influenza vaccines.

COVID-19 and regulatory flexibility

• Regulatory flexibilities during pandemic so far have made significant difference for companies.

- Industry would like to ensure that flexibilities will be sustained throughout next wave.
- Industry claims that flexibilities are needed beyond closed list of COVID-19 related treatments and vaccines.
- Request from industry on regulatory flexibility will be discussed with EMA and CMDh before a position is taken.

Bijgevoegd vinden jullie ter info:

- Vergaderagenda met aantekeningen
- Belangrijkste onderliggende vergaderstukken

De volgende bijeenkomst vindt plaats op 18 november 2020.

Voor meer informatie weten jullie mij te bereiken.

Met vriendelijke groet,



	5.1.2e	
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