



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

3 November 2020  
EMA/569718/2020

## Agenda – 23<sup>rd</sup> teleconference of the EU Executive Steering group on shortages of medicines caused by major events

4 November 2020, from 10:30 to 12:00 CET

Chair: 5.1.2e EC

Item	Topic for discussion	Topic lead
1.	Adoption of the agenda	5.1.2e
2.	Introduction from the European Commission	
3.	Adoption of the action points from the previous meetings (21 October)	All
4.	TC with Industry Trade Associations - post-meeting discussion <ul style="list-style-type: none"> <li>Regulatory flexibilities during pandemic so far have made significant difference for companies.</li> <li>Industry would like to ensure that flexibilities will be sustained throughout next wave.</li> <li>Industry claims that flexibilities are needed beyond closed list of COVID-19 related treatments and vaccines.</li> <li>Request from industry on regulatory flexibility will be discussed with EMA and CMDh before a position is taken.</li> </ul>	All
5.	Impact of COVID-19 pandemic on the availability of human and veterinary medicinal products - update from the EU SPOC Network and i-SPOC system <ul style="list-style-type: none"> <li>Shortages of influenza vaccines</li> <li>shortages of immunoglobulins</li> </ul> <ul style="list-style-type: none"> <li>EMA received reports from several member states for anticipated shortages of immunoglobulins due to decrease in blood donations.</li> <li>Also shortages reported for pneumovax 23 (pneumococcal vaccine) due to unexpected increase in demand.</li> <li>Risk of shortages of seasonal influenza vaccines – EMA has conducted survey to understand risk of shortages following signals from NCAs in October.</li> <li>Root cause: significant increase in demand related to pandemic. Most</li> </ul>	5.1.2e

	<p>member states anticipate risk of supply disruptions – mostly in private sector, not in public sector (at level of national vaccination programmes).</p> <ul style="list-style-type: none"> <li>• Industry-SPOC system (ICU medicines only): a total of 300 shortage notifications are currently 'active', none of which are considered critical.</li> <li>• Austria and Belgium report concerns about availability influenza vaccines.</li> </ul>	
5.	<p>Demand forecast for ICU medicines in the EU/EEA in the context of COVID-19 pandemic</p> <ul style="list-style-type: none"> <li>• Update on submissions of demand forecasts to EMA in the framework of the pilot for demand forecasting</li> <li>• Per 3 November 21 MS have submitted forecasts (82% of total EU/EEA population).</li> <li>• Estimated total needs by substance reported on for 6 month period (through April 2021).</li> <li>• EU SG warns for overestimation of expected need by member states.</li> <li>• Outlooks should not be taken as facts – rather only as one piece of information.</li> <li>• 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.</li> <li>• 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.</li> </ul>	5.1.2e
6.	Identification of urgent action needed, including communication	All
7.	Closure of the meeting	5.1.2e

**List of participants:****Regular EU Executive Steering Group**

	Name	Affiliation
1.		EC
2.		EC
3.		EC
4.		EC
5.		EC
6.		EC
7.		EC
8.	5.1.2e	EC
9.		EC
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14.		EMA
15.	5.1.2e	EMA
16.		EMA
17.		EMA
18.		EMA
19.		EMA
20.		HMA
21.		HMA
22.		HMA
23.	5.1.2e	HMA
24.		HMA
25.		HMA
26.	5.1.2e	HMA
27.		HMA
28.		CMDh

**HMA (Human)**

	Name	Affiliation
1.		HMA
2.	5.1.2e	HMA
3.		HMA
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17.		HMA
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20.		HMA
21.	5.1.2e	HMA
22.		HMA
23.		HMA
24.	5.1.2e	HMA
25.		HMA