

- Main problems: export bans/restrictions in/outside EU, transport, import license on narcotics, regulatory issues, conduct of clinical trials, vaccines supply – please see attached presentation.
- EC outlines coordinated actions and guidance issued on managing shortages among which outreach to (10)(2a) joint procurement efforts and identifying crucial ICU medicines.
- Need to formalise and reinforce the EU Executive SG, mechanisms and reporting tools (such as (i)-SPOC), improve data-

gathering.

- Need to reinforce joint procurement, traceability of API supply chain, strengthen coordination of clinical trials (harmonised assessments and protocols).
- SG mentions medical device availability as crucial element to be added to lessons learned.
- EMA proposes to publish standard set of new information on COVID-19 products under regulatory review as a result of increased demand for transparency as a result of pandemic – please see attached presentation.

Demand forecast for ICU medicines in the EU/EEA in the context of COVID-19 - Update from the ad hoc Working Group on forecasting demand data – attachment 5

- Modelling beyond 30 days based on epidemiology unreliable.
- Building longer term scenarios will be pursued by ECDC based on other bases – e.g. information from first wave.
- But certain circumstances beyond first wave already changed (testing capacity, response measures etc.).
- Scenario based on total ICU capacity will likely lead to an overestimation.
- Current IT aspects of data collection have potential to be transformed into more uniform, aggregated data.
- List of ICU medicines requiring EU wide forecast of the demand established by ad hoc group, based on certain selection criteria and input from 20 NCAs – resulting in list of roughly 24 active substances.
- EU SG proposes to automatically include approved new emerging COVID-19 medicines
- List will be reviewed by EU SPOC Network and matched against results of survey to intensive care clinicians.
- Reflection paper will be presented at August meeting.

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

- Report on progress of working group on forecasting demand data. So far one meeting took place.
- Revised national lists of medicines to be collected from MSs, including information on their experience from the first wave as well as prioritisation of the most critical medicines.
- ECDC flagged that it is very difficult to provide long term estimates for a second wave – ECDC therefore not supporting going beyond 30 days for modelling.
- EU SG calls on ECDC to be as cooperative as possible.

Other topics

Remdesivir – supply by Gilead in EU

- EC in daily contact with Gilead to secure access to remdesivir.
- EC preparing reservations of doses, to be allocated to member states based on hospital admissions.
- EC hopes to launch joint procurement in September to cover supply for rest of the year.

EU Strategy for COVID-19 vaccines

- EC targeting to use existing legal provision to facilitate early access use of COVID-19 vaccines, including using labelling and packaging flexibilities (e.g. reduction language requirements).

Bijgevoegd vinden jullie ter info:

- Vergaderagenda met aantekeningen
- Belangrijkste onderliggende vergaderstukken.

Een volgende bijeenkomst is voorzien omstreeks half augustus.

Voor meer informatie weten jullie mij te bereiken.

Met vriendelijke groet,

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