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 Industry first wave lessons learned 20200708 FINAL.pdf

 Vet Industry lessons learnt final.pdf

 Lessons learnt DG SANTE 02-07-2020.pdf

 Transparency on EMA activities in relation to medicines for
- 5. Update from the ad hoc working group on forecasting demand data.pdf 2020 07 08-Agenda-17th TC of EU Executive Steering group +AANTEKENINGEN.docx

Beste collega's,

Op woensdagochtend 8 juli 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 8 juli

In de bijeenkomst van 8 juli werden de volgende punten besproken:

Lessons learned from the first phase of the COVID-19 pandemic:

a) Presentation on pharmaceutical industry's lessons learned – attachments 1 and 2

- Industry presents lessons learned from first wave of pandemic with regard to supply and demand of APIs and medicines please find presentation attached.
- Combination of disruption in supply chain and unclarity about API demands resulted in precarious situation.
- · Crucial actions during first wave: recognizing API supply chain as essential, keeping EU borders open, regulatory flexibility, targeted dialogue between EU and (10)(2a) and organization of intercontinental transport.
- · Current surge of first wave outside EU could already result in less API and drug products being available for EU patients.
- · Second wave proposed actions by industry: maintain open borders both in- and outside EU, establish a clear and transparent picture on the forecasted API demand, strengthen regulatory flexibility to ease regulatory burden in emergency situations.
- Future resilient API supply: understand and identify risks in supply chain through holistic approach based on data available at regulatory authorities
- · Future resilience: establish and enforce level playing field in and outside EU in areas like quality and environmental standards, establish incentives for industry to make API supply more resilient and increased regulatory flexibility/simplification.
- · Strong strategy on API and manufacturing diversification and resilience in Europe needed, but based on reliable data and sound analyses.

b) Presentation by EC on lessons learned – attachments 3 and 4

- 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,

