EU response to the Covid 19 Pandemic, den Haag, German Embassy 29.9.2020

Presentation [redacted] European Commission

5.1.2e

Main points

- Legal context (EU Treaty, International health regulations)
- Eu cross border health threats system (Surveillance, alert system, rapid risk assessment, risk management coordination)
- Joint procurement, Emergency support instrument
- Borders, testing, vaccine procurement, international aspects
- Lessons learnt

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European Medicines Agency

Main Points

- EMA in the Netherlands
- COVID-19 treatments (therapeutics and vaccines): EMA's role in development support, evaluation and safety monitoring
- Supply of medicines: EMA's role in preventing and managing shortages of critical medicines
- EMA's role in providing public health advice on medicines

EMA in the Netherlands

- Brexit impact on EMA has been very substantial in terms of the consequences for its operations and the relocation from UK-London to the Netherlands-Amsterdam (de facto 2 physical moves)
- Continuity of operations throughout the whole period has always been the objective → not one single day of interruption of its core activities was encountered
- This has been achieved despite a staff loss of some 25%
- However, EMA had to introduce a BCP to safeguard its core activities (authorising human and veterinary medicines, supervising and monitoring these medicines)
- Once EMA could revert its BCP, it was confronted with the COVID-19 pandemic

EMA's role in the therapeutic response

- EMA is involved in development support, evaluation and safety monitoring of COVID-19 treatments (both therapeutics and vaccines) through early scientific advice up to post-authorisation safety and effectiveness monitoring
- Benefiting from the experiences of the 2009 H1N1 Pandemic Influenza, EMA has in place rapid procedures for evaluating data as and when they become available without compromising the quality, robustness and independence of its scientific review process
- EMA already
  - Recommended to the EC a conditional marketing authorisation for remdesivir
  - Recommended the use of dexamethasone for the treatment of COVID-19 patients admitted to hospital
- EMA is currently in discussion with pharmaceutical companies for some 154 therapeutics and some 38 vaccines

EMA's role in supply chain aspects

- EMA is going beyond its legal remit in this field, but has been asked by MSs and the EC to increase its involvement, primarily by coordinating at an EU level
- Examples of EMA's involvement:
  - Obtaining during the 1st wave information from MSs on their needs in ICUs for a set of medicines (including paracetamol) subject to a ban by the Indian government → the information obtained by EMA was subsequently successfully used by the Commissioner to convince the Indian government to lift the ban
  - Recently obtaining feedback from the MSs about their demand needs for a 2nd wave of the pandemic in order to identify if shortages ICUs are expected and if escalation at EU level is needed → no escalation currently needed
  - Co-leading an *ad hoc* working group with the MSs and the EC to develop a methodology and tools for facilitating demand forecasts at national level → a pilot is launched to check the feasibility of the principles agreed by the *ad hoc* working group

EMA's role in providing public health advice on medicines

- Closely working together with the experts of the MSs, EMA is also providing -on top of the information given for the medicines subject to the centralised licensing process- public health advice on other medicines
- An example is the advice given by EMA on the use of hydroxychloroquine/ chloroquine for the treatment of COVID-19 patients