

Beste collega's,

Op woensdagochtend 9 september 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 9 september

In de bijeenkomst van 9 september werden de volgende punten besproken:

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

- Ad hoc Working Group discusses comments on demand forecast model.
- Comments from Ireland, Spain and the Netherlands discussed.
- EU SG in general satisfied with content of reflection in terms of methodology proposed.
- Next step: pilot will be launched to see whether the data asked for is manageable by member states.
- Particular attention raised to Dutch concerns regarding the the collecting of supply and demand data: tension with antitrust rules is prevalent in other member states as well. DG Santé had understood previously that some flexibility with regard to competition laws is permissible during a crisis situation, but will explore further with DG Competition.
- Netherlands underlines that any further development of centralized collection of demand and supply data into a structure of a more permanent nature may soon reach its limits all is based on voluntary cooperation of the parties involved.

Regulatory capacity in the network - launch of the mapping survey on the currently available and the forecasted (vaccine) expertise within the Network

• EMA will launch survey among NCAs on current and forecasted (vaccine) expertise with regard to COVID-19 – and hopes to receive feedback by 21 September 2020.

International randomized trial of candidate vaccines against COVID-19 - The Solidarity Vaccines trial under preparation by WHO

- EC has been asked by WHO to support solidarity vaccine trials.
- WHO has developed a scientific assessment protocol and asks the EMRN to perform a regulatory and scientific assessment of the protocol.

Bijgevoegd vinden jullie ter info:

- Vergaderagenda met aantekeningen
- Belangrijkste onderliggende vergaderstukken.

De volgende bijeenkomst vindt plaats op 23 september 2020.

Voor meer informatie weten jullie mij te bereiken.

Met vriendelijke groet,

(10)(2e)

(10)(2e)

Senior advisor international governance and regulatory affairs



Medicines Evaluation Board (10)(2e) @cbg-meb.nl

, (10)(2e) www.cbg-meb.nl

Graadt van Roggenweg 500 | 3531 AH Utrecht The Netherlands

in y

GOOD MEDICINES USED BETTER