To: (10)(2e) [(10)(2e) @cbg-meb.nl]; (10)(2e) [(10)(2e) @cbg-meb.nl]; (10)(2e) . (10)(2e) [(10)(2e) @cbg-meb.nl]; (10)(2e) .[(10)(2e) @cbg-meb.nl]; (10)(2e) .[(10)(2e) @cbg-meb.nl]; (10)(2e))[(10)(2e) @igj.nl]; (10)(2e) . (10)(2e) [(10)(2e) @minvws.nl]; (10)(2e))[(10)(2e) @minvws.nl]; (10)(2e))[(10)(2e) @minvws.nl]; (10)(2e) . (10)(2e) [(10)(2e) @minvws.nl]; (10)(2e) .[(10)(2e) @cbg-meb.nl]; (10)(2e) (10)(2e) (10)(2e) (10)(2e))[(10)(2e) @ccmo.nl]; (10)(2e) .[(10)(2e) @ccmo.nl]; (10)(2e) .[(10)(2e) @cbg-meb.nl]; (10)(2e) .[(10)(2e) @cbg-meb.nl]; (10)(2e) . (10)(2e) [(10)(2e) @cbg-meb.nl]; (10)(2e) .[(10)(2e) @cbg-meb.nl]; (10)(2e) @minvws.nl[(10)(2e) (10)(2e) @minvws.nl]; (10)(2e))[(10)(2e) @minvws.nl]; (10)(2e) .[(10)(2e) @cbg-meb.nl]; (10)(2e) @rivm.nl' ((10)(2e) @rivm.nl)[(10)(2e) @rivm.nl]; (10)(2e) @rivm.nl'((10)(2e) @rivm.nl)[(10)(2e) @rivm.nl]; (10)(2e))[(10)(2e) @minvws.nl]
Cc: (10)(2e) [(10)(2e) @cbg-meb.nl]; (10)(2e) .[(10)(2e) @cbg-meb.nl]; (10)(2e), (10)(2e), (10)(2e), (10)(2e) [(10)(2e) @cbg-meb.nl]
From: (10)(2e)
Sent: Thur 10/8/2020 10:02:58 AM
Subject: COVID-19: verslag EU Executive Steering Group - 7 oktober 2020
Received: Thur 10/8/2020 10:03:04 AM
2020-10-07-Agenda-21th TC of EU Executive Steering +AANTEKENINGEN.docx
Survey on resumption of GMPGDP inspections-EU Executive StreeringGroup.pdf
Verification of GMP Compliance for COVID-19 vaccines.pdf
4_VE presentation to EU ESG_7 October 2020_FINAL VERSION.pdf
5_20200917- Trends in demand_v01FINAL.pdf

Beste collega's,

Op woensdagochtend 7 oktober 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 7 oktober

In de bijeenkomst van 7 oktober werden de volgende punten besproken:

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

- Pilot to establish demand forecast launched on 28 September. Will run for three weeks and end on 16 October 2020.
- Pilot restricted to 5 medicines (ceftriaxone, fentanyl, propofol, rocuronium bromide and heparin).
- Forecast to cover 6 month period (November 2020 to April 2021). Minimum data to be provided: total demand forecast, COVID-19 patient needs, non-COVID0-19 patient needs.

Challenges to access to COVID-19 vaccines

- Immensely important to maintain regulatory process based on science and steer clear from direct political influencing.
- EC worries that any potential emergency approval by individual member states will undermine surveillance and safety.
- EMA warns for risk of possible quick authorization vaccine in UK and pressure that may arise from this on EU.
- With expected arrival of COVID-19 medicinal products and vaccines, network capacity in the coming years with regard to post-approval safety (surveillance/pharmacovigilance) will have to be strengthened. Both EMA and national agencies will need to expand staff and expertise in these areas.
- EU data network should be established to foster technological solutions to pool EU data-analyses with regard to COVID-19 vaccine surveillance.
- EMA will send out survey on surveillance capacity in member states.
- Several member states inform about shortages of regular flu-vaccines due to high demand. Mitigating communication to ease pressure is warranted.
- EC urges member states repeatedly not to stockpile at national level as it puts availability of medicines and vaccines under pressure.

Impact of COVID-19 on inspections

- Based on EMA survey results EU SG discusses impact of COVID-19 on inspections.

- Majority inspectorates indicate to have resumed on-site inspections on national territory.
- Some inspectorates appear to be close to normal routine inspection planning, others indicate that they limit themselves to COVID-19 priorities.
- Third country inspections are uniformly on hold – inspectorates are using distant assessments.
- Distant assessments to verify GMP compliance, international collaboration with trusted authorities and pro-active engagement with developers are crucial to mitigate COVID-19 restrictions for verification of GMP compliance.
- Compliance with GMP is not waived. Early engagement between EMA, NCAs and developers is key.
- Large scale COVID-19 vaccine and medicine production in combination with upheld third country inspections presents potential oversight risk.

Bijgevoegd vinden jullie ter info:

- Vergaderagenda met aantekeningen
- Belangrijkste onderliggende vergaderstukken – waaronder ook twee presentaties van zijde industrie over respectievelijk vraag naar COVID-19 producten

De volgende bijeenkomst vindt plaats op 21 oktober 2020.

Voor meer informatie weten jullie mij te bereiken.

Met vriendelijke groet,

(10)(2e)

(10)(2e)

(10)(2e)

CBG MEB MEDICINES EVALUATION BOARD

(10)(2e)

(10)(2e) @cbg-meb.nl

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

Graadt van Roggenweg 500 | 3531 AH Utrecht

The Netherlands

GOOD MEDICINES USED BETTER