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To: [redacted])[[redacted]@minvws.nl]; [redacted])[[redacted]@minvws.nl]; [redacted]. [redacted])[[redacted]@minvws.nl]; [redacted])[[redacted]@minvws.nl]; [redacted])[[redacted]@minvws.nl]
From: [redacted])
Sent: Wed 4/22/2020 8:16:36 PM
Subject: RE: COVID-19 verslag EU Executive Steering Group - 22 april 2020
Received: Wed 4/22/2020 8:16:37 PM

Hoi [redacted], de vraag gaat over het geven van info over de vraag aan firma's. Dat is geen onderdeel van de Nederlandse monitor. CBG ontvangt die info. [redacted]

Verzonden met BlackBerry Work
(www.blackberry.com)

Van: [redacted]) < [redacted]@minvws.nl>
Datum: woensdag 22 apr. 2020 5:55 PM
Aan: [redacted]) < [redacted]@minvws.nl>, [redacted]) < [redacted]@minvws.nl>, [redacted]) < [redacted]@minvws.nl>, [redacted]) < [redacted]@minvws.nl>, [redacted]) < [redacted]@minvws.nl>
Onderwerp: FW: COVID-19 verslag EU Executive Steering Group - 22 april 2020

Allen,

Wat we nationaal doen (monitor) gaat ook Europees opgezet worden (er zijn iig plannen voor). We moeten kijken wat we antwoorden op de volgende vraag:
MS are requested to consider whether they want to cooperate by giving national information on demand to industry through EMA

Met vriendelijke groet,
[redacted]

Van: [redacted]. < [redacted]@cbg-meb.nl>
Verzonden: woensdag 22 april 2020 12:29
Aan: [redacted] < [redacted]@cbg-meb.nl>; [redacted] < [redacted]@cbg-meb.nl>; [redacted]. [redacted]. < [redacted]@cbg-meb.nl>; [redacted]. < [redacted]@cbg-meb.nl>; [redacted]. < [redacted]@cbg-meb.nl>; [redacted]. < [redacted]@cbg-meb.nl>; [redacted]) < [redacted]@igj.nl>; [redacted]) < [redacted]@minvws.nl>; [redacted] < [redacted]@minvws.nl>; [redacted]) < [redacted]@minvws.nl>; [redacted]) < [redacted]@minvws.nl>; [redacted]. < [redacted]@cbg-meb.nl>; [redacted]. ([redacted]) < [redacted]@minvws.nl>; [redacted]. < [redacted]@cbg-meb.nl>; [redacted] < [redacted]@ccmo.nl>; [redacted]. < [redacted]@ccmo.nl>; [redacted]. < [redacted]@cbg-meb.nl>
CC: [redacted]. < [redacted]@cbg-meb.nl>; [redacted]. < [redacted]@cbg-meb.nl>; [redacted] < [redacted]@cbg-meb.nl>
Onderwerp: COVID-19 verslag EU Executive Steering Group - 22 april 2020

Beste collega's,

Op woensdagochtend 22 april 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 22 april

In de bijeenkomst van 22 april werden de volgende punten besproken:

- *Industry project on ICU medicines*

  - Industry has taken the initiative to develop a model calculating demand side for ICU medicines in all EEA countries and connecting it to mapped available supply.

- Membership is broad and involves both Medicines for Europe and EFPIA.
- Model favours overestimation of cases and does not address impact of flexing of containment measures.
- Model results in prediction of expected new COVID-19 deaths per million inhabitants – industry uses this model to estimate future demand.
- EU Steering Group notices shortcomings in model. For instance based on reported deaths rather than actual ICU-cases, expected time on ICU 2 rather than 3 weeks, possible 2nd or multiple waves of infections not taken into account. Model is only snapshot in time and will be adjusted as time progresses.
- Industry encourages both countries as well as individual companies to supply as much accurate data as possible. Information on supply and demand available in national coordination centres is crucial to feed into the model.
- ICU medicines reallocation is very complicated affair – even within national borders. Member states in EU SG collectively are of view that current model is too simplistic. Applying it on EU level based on current simplistic model would lead to misguided and inaccurate decision making.
- However, EC and EMA point at fact that there currently is no alternative overview of demand and supply for ICU-medicines at EU level.
- EMA is willing to act as coordinator to collect information on MS-level to feed into model.
- MS call on EC to think about constructing central repository for demand and supply of medicines to prevent these situations from occurring in the future.
- **MS are requested to consider whether they want to cooperate by giving national information on demand to industry through EMA.**
- Digital presentation on model as given by industry will follow as soon as possible.

- *TC with industry associations – post-meeting – post-meeting discussion*

- Paracetamol API export permits still not granted by Indian authorities – 4-5 months worth of supply in Indian storehouses.
- Manufacturing capacity in India dropping due to workers absentees – comparable to what happened in China. EC will continue to monitor situation in India.
- Export restrictions in France, Belgium, Hungary and Portugal remain. However, member states show more flexibility to move individual substances.
- Demand for non-Covid-19 treatment medicines has dropped by 50%. Concern for treatment of non-COVID-19 patients.
- France and UK currently show extremely high demand-levels for COVID-19 medicines.
- I-SPOC system: notable information through I-SPOC system will be channelled through EU SG for possible regulatory remedial measures. Since launch on 17 April 5 notifications received by companies.

- *Potential impact of COVID-19 infection on availability of human and veterinary medicinal products*

  - Not discussed at meeting – information will be provided afterwards in writing.

- *Q&A on regulatory flexibility: need for further regulatory flexibility taken into account industry's feedback*

- Industry calls on regulator to apply regulatory flexibility as displayed in Q&A in spirit of the document and extend scope of some Q&As beyond crucial medicines.
- Working group (EC, EMA, CMDx) dealing with Q&As will look into industry feedback at next meeting. CMDx will also organize interested parties meeting if and when needed.

Bijgevoegd vinden jullie ter info:

- Vergaderagenda met aantekeningen
- Belangrijkste onderliggende vergaderstukken volgen zsm.

Een volgende bijeenkomst is voorzien voor woensdag 29 april a.s. – hierin zal met gehele HMA-netwerk uitgebreider stil worden gestaan bij monitoring systeem zoals vandaag door industrie gepresenteerd.

Voor meer informatie weten jullie mij te bereiken.

Met vriendelijke groet,

[redacted]

[redacted]

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