To: 5.1.2e .[5.1.2e @cbg-meb.nl]
Cc: 5.1.5 5.1.2e @ema.europa.eu]; 5.1.2e [5.1.2e @ema.europa.eu]; 5.1.2e .[5.1.2e @cbg-meb.nl]; 5.1.2e .[5.1.2e @cbg-meb.nl]; 5.1.2e .[5.1.2e @cbg-meb.nl]; 5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e .[5.1.2e @cbg-meb.nl]; 5.1.2e [5.1.2e @ema.europa.eu]
From: 5.1.2e
Sent: Tue 6/7/2022 11:46:16 AM
Subject: RE: MSSG - list of critical medicines for COVID-19 - comment NL
Received: Tue 6/7/2022 11:46:43 AM

Dear 5.1.2e

Thank you very much for your email and submitting the two additional comments on the list of critical medicines for COVID-19. We acknowledge the receipt of the comments.

We would like to kindly ask you to address the first comment during the discussion of agenda point 5a. I will make a reference during the presentation to the additional comment that you submitted earlier today while presenting the comment received on 17 May. Regarding the second comment, I would like to mention that this topic will be addressed in agenda point 5b, presented by 5.1.2e

Thank you very much and with kind regards,
On behalf of the EMA secretariat,
5.1.2e

Classified as confidential by the European Medicines Agency

From: 5.1.2e . < 5.1.2e @cbg-meb.nl>
Sent: 07 June 2022 11:18
To: 5.1.2e < 5.1.2e @ema.europa.eu>
Cc: 5.1.5 < 5.1.2e @ema.europa.eu>; 5.1.2e < 5.1.2e @ema.europa.eu>; 5.1.2e . < 5.1.2e @cbg-meb.nl>; 5.1.2e . < 5.1.2e @cbg-meb.nl>; 5.1.2e . < 5.1.2e @cbg-meb.nl>; 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e . < 5.1.2e @cbg-meb.nl>
Subject: RE: MSSG - list of critical medicines for COVID-19 - comment NL

Dear 5.1.2e and colleagues,

Thanks again for your confirmation of receipt and further information with regard to the list of critical medicines for COVID-19.

With regard to the list and in run-up to the MSSG meeting this afternoon we would like to raise two further comments with regard to agenda item 5 – the list of critical medicines for COVID-19:

- As medicines are included on the list based on the fact that they are authorized for the treatment of COVID-19 (marketing authorization), we understand why dexamethasone should be included where this is the case. However, we would like to include a clarification in the list that this is only valid for dexamethasone products that are authorised for Covid treatment (i.e. in which the art 5.3 opinion is implemented in the product information). Otherwise, it could be interpreted that an article 5.3 opinion is the same as an authorisation, and more products should then be included (e.g. molnupiravir).

- When it comes to implementation of the list at a later stage we would like to further discuss the consequences for the medicines that are placed on the list. Is vital that proportionality for all parties that have to share, gather and combine data is taken into account. Specific questions would be which data will be asked, at what point will the data be gathered and what will be the frequency? We could imagine that this will differ depending on whether there are or are not any (expected) availability issues.

Looking forward to the meeting this afternoon.

With kind regards,

5.1.2e
5.1.2e
Tel.: +31 5.1.2e

Van: 5.1.2e <5.1.2e @ema.europa.eu>
Verzonden: vrijdag 27 mei 2022 10:20
Aan: 5.1.2e . <5.1.2e @cbg-meb.nl>
CC: 5.1.5 <5.1.2e @ema.europa.eu>; 5.1.2e <5.1.2e @ema.europa.eu>; 5.1.2e . <5.1.2e @cbg-meb.nl>; 5.1.2e . <5.1.2e @cbg-meb.nl>; 5.1.2e . <5.1.2e @cbg-meb.nl>; 5.1.2e) <5.1.2e @minvws.nl>; 5.1.2e) <5.1.2e @minvws.nl>; 5.1.2e . <5.1.2e @cbg-meb.nl>
Onderwerp: RE: MSSG - list of critical medicines for COVID-19 - comment NL

Dear 5.1.2e and colleagues,

Thank you very much for your email and we acknowledge its receipt.

We would like to take the opportunity and briefly comment on the consideration to include dexamethasone in the list of critical medicines for COVID-19 under the Regulation 2022/123.
Dexamethasone was included in the list of critical medicines for COVID-19 since it is authorized in several Member States for the treatment of COVID-19. The proposal was to include all authorized vaccines and therapeutics for COVID-19 in the list of critical medicines, irrespective of their current supply situation.

Regarding the consultation process, the industry consultation on the list of critical medicines for COVID-19 under the Regulation 2022/123 was initiated on 13 May 2022 and will end on 30 May 2022. The comments will be compiled and sent to all members of the MSSG for consideration.

In the period 31 May 2022 until 06 June 2022 members of the MSSG will have the opportunity to provide further comments, also in relation to the comments that we receive from European Industry (Trade) Associations.

The following steps are generally applicable:
1.) The submission of the comment will be made to the EMA secretariat via email to 5.1.2e @ema.europa.eu.
2.) The comments will be submitted to the MSSG for further consideration.
3.) Individual comments will be discussed in the meeting of the MSSG prior to the adoption process.
4.) Once the list is adopted by the MSSG it will be subsequently published in the EMA website.

We will include aforementioned information in the package that will be sent to all MSSG members on 31 May 2022.

We hope this information is helpful and if you have further questions, please let us know.

With kind regards,
On behalf of the EMA secretariat
5.1.2e

5.1.2e
5.1.2e
Regulatory Science & Innovation Task Force

European Medicines Agency
Domenico Scarlattilaan 6 | 1083 HS Amsterdam | The Netherlands
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