

Met vriendelijke groet,
(10)(2e)

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(10)(2e) Directie Geneesmiddelen en Medische Technologie | Ministerie van Volksgezondheid, Welzijn en Sport
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CC: (10)(2e) @ec.europa.eu

Onderwerp: Written Consultation - Pharmaceutical Committee - Input by 8/9 - COVID-19 - Draft Memorandum of understanding on early use of vaccines/regulatory flexibility

Dear members of the Pharmaceutical Committee,

During the last meeting of the Pharmaceutical Committee on 2 July, the Commission, in the context of the recently adopted Vaccine Strategy for COVID 19 vaccines and under its Regulatory Pillar, presented a concept paper that aimed to provide a common understanding among Member States on:

- a) procedural facilitations related to national Emergency Use Schemes in order to support early access to the vaccines, for certain parts of the population, in so far as Member States decide to temporarily authorise the distribution of a vaccine prior to its authorisation. It builds on a harmonised scientific assessment performed by EMA and a national implementation phase. The objective is not to encourage early access uses prior to a marketing authorisation, but to have a framework in place in case there and
- b) labelling and packaging flexibilities, in order to facilitate more rapid deployment of authorised vaccines.

Based on the agreed follow-up, the paper was subsequently shared with all national medicines regulators through the Heads of Medicines network for consultation until mid- August. It was subsequently updated and further discussed at the EU Executive Steering Group during its meeting of 26 August 2020, where it was endorsed.

We are still working on a "national addendum" to this MoU, which would complement the EU procedure around the harmonized EMA scientific assessment with details regarding the national implementation. We are in the process of setting up a small working group with representatives from Member States to see what is feasible.

With this email, we would like to consult the Pharmaceutical Committee on the attached document. You are kindly requested to provide comments if any, **by 8 September 2020, eob** to the following email address: (10)(2e)@ec.europa.eu. Subsequently, we will finalise the document and then may make it publicly available, as appropriate.

Yours sincerely,

Unit "Medicines: policy, authorisation and monitoring"



European Commission
DG Health and Food Safety

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