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Health systems, medical products and innovation
**Medicines: policy, authorisation and monitoring**

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**Expert group Human Pharmaceutical Committee**
**19 February 2021**

# Minutes

The meeting had been convened in order to discuss with experts from Member States a draft Delegated Regulation amending Commission Regulation (EC) No 1234/2008 concerning the examination of variations for human medicinal products.

The meeting was organised via video conference and was attended by representatives from the Commission, 24 EU Member States, Norway, Iceland and the European Medicines Agency (EMA).

## 1. Adoption of the draft agenda of the meeting

The draft agenda was adopted.

## 2. Discussion on the draft delegated act amending Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use

The Commission and the European Medicines Agency presented the main changes proposed to Commission Regulation (EC) No 1234/2008 through a draft delegated Regulation. The proposed changes address the need to specify the applicable provisions for adaptations of the active substance of authorised COVID-19 vaccines in order to ensure their effectiveness against mutations or variants of the virus that may evolve over time. In this regard, it seems appropriate to use procedures that have been established for human influenza vaccines in the context of a pandemic. This will ensure the streamlined handling of any variation and enable the competent authorities to respond to specific needs arising from the COVID-19 pandemic and the associated public health crisis.

There are two main changes concerned:

- Classifying changes to the active substance of a coronavirus vaccine as a type II variation–
- Increase flexibility during pandemic – extending the scope of Article 21 to "human coronavirus vaccine" and providing the possibility that the variation will be authorised on a limited data package that is complemented afterwards.

The proposal and the suggested modifications were supported by the experts from Member States. However, it was suggested to add a reference to changes in the "coding sequence" in the wording that relates to classifying the changes to the active substance to better capture all possible scenarios of possible changes. Some vaccines are based on nucleic acid technology to produce an immune response. Modifications of those vaccines may include changes to the coding sequence. In addition, it was suggested to refer to benefit-risk balance instead of risk-benefit balance in the drafting.

The Commission will take those comments into account in the finalisation of the drafting of the measure and make the necessary adaptations.

The Commission noted that with these comments being taken into account experts support the draft delegated Regulation.

**3. Next steps**

The Commission informed the group that based on the positive feedback, it will now proceed with the internal process for the adoption of the delegated Regulation. No further expert meeting is foreseen. In view of the urgency and the need to adapt the regulatory framework in time for future variation submission for COVID vaccines, the Commission intends to accelerate the adoption procedure for the measure.

**4. A.O.B.**

None