

## II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES  
AND AGENCIES

EUROPEAN COMMISSION

COMMUNICATION FROM THE COMMISSION

**Addendum to the Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures**

(2021/C 215 I/01)

In view of Commission Delegated Regulation (EU) 2021/756 of 24 March 2021 amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products <sup>(1)</sup>, the following sections are added to the Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of the Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures (2013/C 223/01).

2. PROCEDURAL GUIDANCE ON THE HANDLING OF VARIATIONS

2.5a *Human coronavirus vaccines*

This guidance relates to the application of Article 21 and Annexes I and II of the Variations Regulation. It enables the active substance of authorised human coronavirus vaccines to be updated.

Such changes include replacing or adding a serotype, strain, antigen or coding sequence or a combination of serotypes, strains, antigens or coding sequences provided the technological platform of the vaccine remains similar. Such changes are classified as a type II variation and apply to all human coronavirus vaccines.

During a pandemic situation duly recognised by the World Health Organization or the Union, an accelerated timetable, agreed with the competent authorities, will be followed. The competent authorities can request additional data during the assessment in order to reach a decision.

Marketing authorisation holders are advised to discuss submission of such variation in advance with the Agency or, as applicable, the reference Member State or the national competent authority, to consider the appropriateness of the change to the active substance, taking into account the epidemiological situation, the urgency and the vaccination campaigns.

<sup>(1)</sup> OJ L 162, 10.5.2021, p. 1.

Any other variation to human coronavirus vaccines follows the variation procedures foreseen in other sections of this Guideline. The application must be presented in accordance with the appropriate headings and numbering of the EU-CTD format and should include the following:

- A cover letter;
- Module 1, including the completed EU application form (published in the Notice to applicants) together with the overview of changes made in all modules to accommodate the replacement or addition of a serotype, strain, antigen or coding sequence or the combination thereof and the revised product information presented in the appropriate format;
- an update or addendum to quality summaries, non-clinical overviews and clinical overviews as relevant;
- supporting data relating to the proposed variation. For Module 3, the marketing authorisation holder should discuss its structure in advance with the competent authority.

The co-existence of different versions (e.g. different serotypes, strains, antigens or coding sequences or combination of serotypes, strains, antigens or coding sequences) of the vaccine under the same marketing authorisation is possible. In order to distinguish the instructions for use for the various versions of the vaccine, there should be a separate product information per version of serotype, strain, antigen or coding sequence or combination. It is also understood that it can result in different international non-proprietary names.

Furthermore, in order to provide for appropriate differentiation which may help healthcare professionals and/or patients to prescribe/select the appropriate version of the vaccine and to facilitate traceability, marketing authorisation holders should propose qualifiers/abbreviations as part of the invented name and differentiation in the packaging of the different versions of the vaccine as well.

Qualifiers or abbreviations may exceptionally be subject to translation, as needed. Naming of the different versions should be discussed in advance with the competent authority. For centrally authorised vaccines it should be subject to acceptability by the Agency.

For applications for the update of human coronavirus vaccines under the centralised procedure, the relevant fee for the variation as provided for in Council Regulation (EC) No 297/95 must be paid in accordance with the Agency's financial procedures.

For applications for the update of human coronavirus vaccines under the mutual recognition procedure, the reference Member State should also receive the list of dispatch dates. This list must indicate the procedure number, the dates on which the applications have been sent to each of the Member States concerned, and confirmation that the relevant fees have been paid as required by the competent authorities concerned.

#### 4. ANNEX

##### B. QUALITY CHANGES

##### B.I Active Substance

##### B.I.a) Manufacture

B.I.a.6 Changes to the active substance of a vaccine against human coronavirus	Conditions to be fulfilled	Documentation to be supplied	Procedure type
a) Replacement or addition of a serotype, strain, antigen or coding sequence or combination of serotypes, strains, antigens or coding sequences for a human coronavirus vaccine			II