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Brussels, 8.3.2021
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COMMISSION DELEGATED REGULATION (EU) …/...

of 8.3.2021

amending Annex II to Regulation (EU) No 2019/6 of the European Parliament and of the Council

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2019/6 of the European Parliament and of the Council lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products.

In line with Article 8(1) of Regulation (EU) 2019/6, its Annex I and II to contain administrative and technical details that need to accompany an application for a marketing authorisation of veterinary medicinal product.

In the course of negotiations of the text of the Regulation (EU) 2019/6, it was conveyed by the co-legislators that there is a need to adjust the requirements for the quality, safety and efficacy of veterinary medicinal products presented when applying for a marketing authorisations (covered in Annex to Directive 2001/82/EC and transferred as Annex II to the Regulation (EU) 2019/6).

Therefore, the requirements in Annex II to Regulation (EU) 2019/6 need to be updated, because the existing Annex II took over the dossier requirements set out in Annex I to Directive 2001/82/EC, without updating them at the time of adoption of Regulation (EU) 2019/6.

The requirements in Annex II to Regulation (EU) 2019/6 need to be revised, updated and adapted to scientific and technical progress, in particular in relation to the novel therapy veterinary medicinal products and biological veterinary medicinal products.

According to Article 146(2) of Regulation (EU) 2019/6, the Commission should amend its Annex II in order to achieve a sufficient level of detail that ensures legal certainty and harmonisation as well as any necessary updating. In accordance with Article 153(3), that delegated act shall be adopted at the latest by 12 months before the date of application of the VMP Regulation, i.e. by 28 January 2021.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with Article 147(5) of Regulation (EU) 2019/6, the Commission has carried out substantial consultation with Member States' experts on veterinary medicines.

Consultations with Member States' experts in the area of veterinary medicines supported the proposed content of Annex II to Regulation (EU) 2019/6.

In addition, the Commission has carried out targeted stakeholder consultations as well as consulted European Medicines Agency.

This draft Delegated Regulation was also made available to the European Parliament and the Council.

There were no comments received from the Council.

There were no comments received from the European Parliament.

In addition, stakeholders' comments on the draft Delegated Regulation were collected in the context of the Better Regulation feedback mechanism during the period between 10 November 2020 and 8 December 2020. Comments from 3 business associations, 3 company/business organisations and one citizen were received via the online platform 'Have

your Say'[1]. Comments from 2 public authorities and from EDQM were received via email, sent to the relevant Commission service.

A vast proportion of the comments included requests which were not relevant to the scope of the present draft delegated act, but rather related to the scope and provisions of Regulation (EU) 2019/6. Such comments were therefore not taken into account in the context of the present delegated act.

Some comments were of pertinence to the scope of the present draft delegated act and were examined carefully by the Commission. The Commission adapted the wording accordingly to take into account comments that aimed at clarifying the text.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act amends Annex II to Regulation (EU) 2019/6, and adapts it to scientific and technical progress.

Annex II provides details on the technical data to be provided by the applicants for marketing authorisations of veterinary medicinal products. In particular, it details the technical documentation necessary for demonstrating the quality, safety and efficacy for the following types of products:

– technical requirements for a full dossier for a marketing authorisation in accordance with Article 8 of Regulation (EU) 2019/6:

- data set requirements for quality, safety and efficacy for veterinary medicinal products other than biologicals, including any particular requirements for antimicrobial veterinary medicinal products;
- data set requirements for quality, safety and efficacy for biological veterinary medicinal products, including any particular requirements for; (i) immunological veterinary medicinal products, (ii) biological veterinary medicinal products which contain or consist of engineered allogeneic tissues or cells, and (iii) novel therapy veterinary medicinal products;

– specific requirements for:

- generic veterinary medicinal products,
- hybrid veterinary medicinal products,
- combination veterinary medicinal products,
- application based on informed consent,
- application based on bibliographic data,
- applications for limited markets,
- applications in exceptional circumstances;
- homeopathic veterinary medicinal products.

The structure of Annex II takes account of the order of the presentation of the data as prescribed in the current electronic application form for marketing authorisations (eAF).

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11574-Veterinary-medicines-applying-for-marketing-authorisation

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC[2], and in particular Article 146(2) thereof,

Whereas:

(1) It is appropriate to substantially update the requirements set out in Annex II to Regulation (EU) 2019/6, which took over the dossier requirements set out in Annex I to Directive 2001/82/EC of the European Parliament and of the Council[3], as that Regulation did not update those dossier requirements at the time of repealing that Directive. The dossier requirements set out in Annex I to Directive 2001/82/EC had last been updated in 2009. Therefore, Annex II should be amended to take account of scientific progress and developments since 2009, including international guidance from the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), World Health Organisation (WHO) and the organisation of Economic cooperation and development (OECD) standards.

(2) It is also appropriate to set out requirements for biological veterinary medicinal products and novel therapy veterinary medicinal products introduced as new categories of veterinary medicinal products by Regulation (EU) 2019/6. For those products, specific technical requirements to be presented when applying for a marketing authorisation should be defined.

(3) Recognising that antimicrobial resistance to medicinal products is a growing health problem in the Union and worldwide, Regulation (EU) 2019/6 introduced specific legal provisions aimed at limiting the risk of development of antimicrobial resistance to medicinal products. It is therefore appropriate to introduce specific technical requirements for antimicrobial veterinary medicinal products.

(4) This Regulation should apply from 28 January 2022 in accordance with Article 153(3) of Regulation (EU) 2019/6.

(5) Regulation (EU) 2019/6 should therefore be amended accordingly,

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2 OJ L 4, 7.1.2019, p. 43.

3 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EU) No 2019/6 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 28 January 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8.3.2021

For the Commission
The President
Ursula VON DER LEYEN