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Non-objection to a delegated act: Examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products

European Parliament decision to raise no objections to the Commission delegated regulation 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 (C(2021)01603 — 2021/2616(DEA))

(2021/C 506/31)

The European Parliament,

— having regard to the Commission delegated regulation 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 (C(2021)01603),

— having regard to the Commission's letter of 9 March 2021 asking Parliament to declare that it will raise no objections to the delegated regulation,

— having regard to the letter from the Committee on the Environment, Public Health and Food Safety to the Chair of the Conference of Committee Chairs of 16 April 2021,

— having regard to Article 290 of the Treaty on the Functioning of the European Union,

— having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([1]), and in particular Article 23b and Article 121a(6) thereof,

— having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ([2]), and in particular Article 16a(3) and Article 87b(6) thereof,

— having regard to Rule 111(6) of its Rules of Procedure,

— having regard to the recommendation for a decision of the Committee on the Environment, Public Health and Food Safety,

— having regard to the fact that no objections have been raised within the period laid down in the third and fourth indents of Rule 111(6) of its Rules of Procedure, which expired on 27 April 2021,

A. whereas Commission Regulation (EC) No 1234/2008 ([3]) lays down provisions concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products;

B. whereas, based on the scientific assessment of the European Medicines Agency, the Commission has authorised several COVID-19 vaccines;

C. whereas, in order to ensure the continued effectiveness of authorised COVID-19 vaccines, it may be necessary to modify them in ways that involve changing their composition so as to protect against new or multiple variant strains in the context of the pandemic or otherwise;

D. whereas, in its communication of 17 February 2021 entitled 'HERA Incubator: Anticipating together the threat of COVID-19 variants' ([4]), the Commission announced a number of measures that will be put in place to effectively cater for a situation where new variants of the COVID-19 virus may potentially impact the fight against the current pandemic; whereas the announced measures included the amendment of the current regulatory procedure in order to allow for an accelerated approval of COVID-19 vaccines adapted to the new variants;

([1]) OJ L 311, 28.11.2001, p. 67.
([2]) OJ L 136, 30.4.2004, p. 1.
([3]) 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 (OJ L 334, 12.12.2008, p. 7).
([4]) COM(2021)0078.

E. whereas, on 24 March 2021, the Commission transmitted to Parliament the delegated regulation, which opened the three-month scrutiny period for Parliament to object to that delegated regulation;

F. whereas the Commission delegated regulation provides that subject to specific conditions, the Commission may, where certain pharmaceutical, non-clinical or clinical data are missing, exceptionally and temporarily accept a variation to the terms of a marketing authorisation for a human influenza vaccine or a human coronavirus vaccine; whereas, however, where such a variation is accepted, its holder shall submit the missing pharmaceutical, non-clinical and clinical data within a time limit set by the relevant authority;

G. whereas the Commission delegated regulation will allow that a variation request by the marketing authorisation holder can be analysed on the basis of an initial dataset, which will be complemented with additional data by the marketing authorisation holder post-approval, and therefore make the regulatory process simpler and easier, both for regulatory authorities and vaccine developers;

H. whereas the Commission delegated regulation should enter into force by 26 April 2021 to ensure that vaccine developers, which are starting to prepare their COVID-19 vaccines for variants, as well as regulators can make full use of the adapted system;

1. Declares that it has no objections to the delegated regulation;

2. Instructs its President to forward this decision to the Council and the Commission.