II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/1686

of 7 July 2021

amending Delegated Regulation (EU) 2016/161 as regards the evaluation of notifications by national competent authorities to the Commission and the inclusion of cicatrizants with ATC code D03AX and pharmaceutical form fly larvae in the list of medicinal products that shall not bear the safety features

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to 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 54a(2), points (b) and (c), thereof,

Whereas:

(1) Article 54a(1) of Directive 2001/83/EC provides that medical products subject to prescription are to bear the safety features referred to in Article 54, point (o), of that Directive, unless they have been listed in accordance with the procedure pursuant to Article 54a(2), point (b), of that Directive. That list is to be established considering the risk of and the risk arising from falsification relating to medicinal products or categories of medicinal products applying the criteria set out in Article 54a(2), point (b), of Directive 2001/83/EC.

(2) Article 47 of Commission Delegated Regulation (EU) 2016/161 ([2]) provides that where, following a notification as referred to in Article 46 of that Regulation, the Commission or a Member State considers, on the basis of casualties or hospitalisations of citizens of the Union due to exposure to falsified medicinal products, rapid action is required to protect public health, the Commission is to assess the notification without delay and at the latest within 45 days. In order to better fulfil the objective of that Article, the reference to citizens of the Union should be replaced by a reference to people in the Union as all adverse events in the Union should be considered and monitored regardless of citizenship.

(3) Article 46(2) of Delegated Regulation (EU) 2016/161 establishes that national competent authorities may inform the Commission of medicinal products which they deem not to be at risk of falsification.

(4) Annex I to Delegated Regulation (EU) 2016/161, sets out a list of medicinal products or product categories subject to prescription that shall not bear the safety features. The product category 'cicatrizants with ATC code D03AX' with pharmaceutical form 'fly larvae' is not included in that list.

([1]) OJ L 311, 28.11.2001, p. 67.

([2]) Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

(5) On 22 August 2019, the Commission received a notification from the competent German authority stating that it deemed the prescription medicinal product BioBag (ATC code D03AX and pharmaceutical form 'fly larvae') not to be at risk of falsification in accordance with the criteria set out in Article 54a(2), point (b), of Directive 2001/83/EC, and that the medicinal product should therefore be exempted from the requirement to bear safety features.

(6) The Commission assessed the risks of and arising from falsification of the medicinal product concerned taking into account the criteria listed in Article 54a(2), point (b), of Directive 2001/83/EC. In particular, the specific characteristics and short shelf life of the pharmaceutical form fly larvae means that risk of falsification is negligible and, therefore, those criteria can be considered to be met.

(7) The Commission consulted the expert group 'Delegated act on safety features for medicinal products for human use', which noted the extremely short shelf life and the fact that the product contains living organisms ([3]).

(8) It is, therefore, appropriate to include the product category 'cicatrizants with ATC code D03AX' with pharmaceutical form 'fly larvae' in the list of medicinal products or product categories subject to prescription that shall not bear the safety features, set out in Annex I to Delegated Regulation (EU) 2016/161.

(9) Delegated Regulation (EU) 2016/161 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2016/161 is amended as follows:

(1) Article 47 is replaced by the following:

'*Article 47*

Evaluation of the notifications

Where, following a notification as referred to in Article 46, the Commission or a Member State considers, on the basis of casualties or hospitalisations of persons in the Union due to exposure to falsified medicinal products, that rapid action is required to protect public health, the Commission shall assess the notification without delay and at the latest within 45 days.';

(2) Annex I is amended as set out 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*.

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

Done at Brussels, 7 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

([3]) Minutes of the 29th Expert Group on the delegated act on safety features for medicinal products for human use: https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=20450&fromExpertGroups=true

ANNEX

In Annex I to Delegated Regulation (EU) 2016/161, the following entry is added:

Name of active substance or product category	Pharmaceutical form	Strength	Remarks
'Cicatrizants with ATC code D03AX	Fly larvae'		