II

*(Non-legislative acts)*

# REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2021/457

## of 13 January 2021

## amending Delegated Regulation (EU) 2016/161 as regards a derogation from the obligation of wholesalers to decommission the unique identifier of products exported to the United Kingdom

**(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)(d) thereof,

Whereas:

(1) Article 54a(1) of Directive 2001/83/EC provides that medical products subject to prescription shall bear safety features.

(2) Pursuant to Article 22(a) of Commission Delegated Regulation (EU) 2016/161 ([2]), a wholesaler is to decommission the unique identifier of medicinal products which he intends to distribute outside of the Union.

(3) On 1 February 2020, the United Kingdom withdrew from the European Union and from the European Atomic Energy Community. Pursuant to Articles 126 and 127 of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (the 'Withdrawal Agreement'), Union law is applicable to and in the United Kingdom during a transition period that is to end on 31 December 2020 ('transition period').

(4) In accordance with Article 185 of the Withdrawal Agreement and Article 5(4) of the Protocol on Ireland/Northern Ireland, Union legislation on medicinal products apply in Northern Ireland after the end of the transition period.

(5) The withdrawal of the United Kingdom from the Union would, in the absence of a derogation from the applicable rules, thus have the effect that the unique identifiers must be decommissioned for medicinal products intended to be distributed in the United Kingdom.

(6) A number of medicinal products are supplied to Cyprus, Ireland, Malta or Northern Ireland through Great Britain. After the end of the transition period, in accordance with Article 54a(1) of Directive 2001/83/EC, it would be for importers holding a manufacturing authorisation in those areas to affix a new unique identifier on the medicinal products when they are placed on the market. However, there are currently no importers holding a manufacturing

([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).

authorisation in Cyprus, Ireland, Malta and Northern Ireland and therefore no importers in those areas that could meet that obligation from 1 January 2021. In order to ensure supplies in compliance with the obligation to affix a new unique identifier, the supply chains need to be redesigned.

(7) In order to ensure that medicinal products are marketed with a unique identifier in the small markets currently dependent on the United Kingdom for their supplies of medicinal products, it is therefore necessary to grant a temporary derogation from the obligation of wholesalers to decommission the unique identifier of the products which they intend to distribute in the United Kingdom as those products may be re-exported to the Union. This derogation should not affect the application of Union law to and in the United Kingdom in respect of Northern Ireland in accordance with Article 5(4) of the Protocol on Ireland/Northern Ireland to the Withdrawal Agreement in conjunction with Annex 2 to that Protocol.

(8) Delegated Regulation (EU) 2016/161 should therefore be amended accordingly.

(9) Having regard to the imminent end of the transition period, this Regulation should enter into force as a matter of urgency. As the transition period of the withdrawal agreement ends on 31 December 2020, this Regulation should apply from 1 January 2021,

HAS ADOPTED THIS REGULATION:

*Article 1*

In Article 22 of Delegated Regulation (EU) 2016/161, the following paragraph is added:

'By way of derogation from point (a), from 1 January 2021 to 31 December 2021 the obligation to decommission the unique identifier of medicinal products which the wholesaler intends to distribute outside of the Union shall not apply to products which he intends to distribute in the United Kingdom (*).

(*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Article, references to the United Kingdom do not include Northern Ireland.'

*Article 2*

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

It shall apply from 1 January 2021.

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

Done at Brussels, 13 January 2021.

*For the Commission*
*The President*
Ursula VON DER LEYEN