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COMMISSION DELEGATED REGULATION (EU) …/...

of 17.12.2021

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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

On 1 February 2020, the United Kingdom withdrew from the European Union and became a 'third country'[1]. The Withdrawal Agreement[2] provided for a transition period ending on 31 December 2020. Until that date, EU law in its entirety applied to and in the United Kingdom[3].

The safety features (namely an anti-tampering device and unique identifier) are mandatory for prescription medicinal products placed on the market in the EU, as laid down in Articles 54(o) and 54a(1) of Directive 2001/83/EC and in Commission Delegated Regulation (EU) 2016/161. Furthermore, unique identifiers must be uploaded to a repository system that allows the authenticity of medicines to be verified by manufacturers, wholesalers and persons entitled to supply medicines to the public.

According to the Protocol on Ireland/Northern Ireland, Directive 2001/83/EC is applicable to and in the United Kingdom in respect of Northern Ireland. Therefore, the safety features laid down in Articles 54(o) and 54a(1) of Directive 2001/83/EC apply to medicinal products placed on the market in Northern Ireland.

Without prejudice to the application of this legislation to and in the United Kingdom in respect of Northern Ireland, the placing on the market of medicinal products in any other part of the United Kingdom does not require the placement of safety features on prescription medicines.

This has meant that, from 1 January 2021, prescription medicines destined for parts of the United Kingdom other than Northern Ireland do not have the same requirements regarding safety features as medicines destined for Northern Ireland, Cyprus, Ireland or Malta, even where the supply route goes through Great Britain. Medicines intended for the Northern Irish, Cypriot, Irish and Maltese markets must carry safety features uploaded in the EU repository system. This is not the case for medicines with a final destination in any other part of the United Kingdom than Northern Ireland.

To prevent the reintroduction of exported medicines into the EU single market, Article 22(a) of Commission Delegated Regulation (EU) 2016/161 obliges wholesalers to decommission the unique identifier on all medicines they export outside the EU before they are exported. If exported medicines are subsequently reimported into the EU, the requirements for importation under Directive 2001/83/EC must be met and a new unique identifier affixed and uploaded to the repositories system. These operations can only be performed by the holder of a manufacturing and importation authorisation.

On 1 January 2021, a derogation from the requirement to decommission the unique identifier on medicines exported to the United Kingdom was granted for one year.

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1 A third country is a country that is not a member of the EU.

2 Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, OJ L 29, 31.1.2020, p. 7 ("Withdrawal Agreement").

3 Subject to certain exceptions provided for in Article 127 of the Withdrawal Agreement, none of which is relevant in the context of this Regulation.

This was to prevent supply disruptions in Northern Ireland, Cyprus, Ireland and Malta. In these markets, many medicines were purchased from the United Kingdom by wholesalers not holding a manufacturing and importation authorisation and therefore unable to meet the importation requirements laid down in Directive 2001/83/EC and Delegated Regulation (EU) 2016/161.

According to information received by the European Commission, these markets continue to be disproportionately dependent on the United Kingdom market for medicines. At the same time, waiving the requirement to decommission the unique identifier on medicines when exported to the United Kingdom without appropriate safeguards creates a risk of falsification and reintroduction of these medicines into the markets of EU Member States other than Cyprus, Ireland and Malta.

The presence of a unique identifier on the medicinal products imported into Northern Ireland, Cyprus, Ireland and Malta through Great Britain is an essential requirement for ensuring a high level of public health protection in those countries, and this presence can as yet only be achieved by means of wholesalers located in the EU not decommissioning the unique identifier on medicinal products.

For these reasons, the Commission has decided to continue to waive the obligation to decommission the unique identifier when medicines are distributed to the United Kingdom for a period of three years, to ensure the supply of medicines in small markets dependent on the United Kingdom. This is coupled with further safeguards to ensure that these medicines are not reintroduced into other EU markets by identifying United Kingdom packs as such in the repository system. The Commission will monitor the functioning of this derogation and the supply of medicines to the small markets dependent on the United Kingdom for its duration, and consider, where necessary, appropriate measures.

The amendment also clarifies that the geographical scope of the repository system is the European Economic Area and that repositories outside the EU should not be connected to the system. This is to ensure, given the limited means of supervision, that such entities are not able to upload and access sensitive content in the system.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The European Commission presented the proposed amendment to the European Commission Expert Group ‘Delegated act on safety features for medicinal products for human use’ at a meeting on 1 September 2021. It received a generally positive opinion during a written consultation of the Expert Group from 16 to 28 September 2021.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The definition of an ‘active unique identifier’ in Article 3 of Delegated Regulation (EU) 2016/161 is amended to exclude unique identifiers on medicines intended for the United Kingdom market and scanned in a Member State other than Cyprus, Ireland and Malta.

Article 20 is amended to require wholesalers to verify the presence of the safety features on shipments received from manufacturers, marketing authorisation holders and designated wholesalers.

Article 22(a) is amended to exceptionally extend the derogation from the obligation to decommission the unique identifier when medicinal products are exported to the United Kingdom for a further three years.

Article 26 is amended to allow the United Kingdom supervisory authority the possibility to waive the requirement to decommission the unique identifier on medicines supplied to the entities listed in Article 23 for three years.

Article 32(1), point b, is amended to clarify that repositories outside the European Economic Area cannot be connected to the EU repository system.

Article 36 is amended to require that medicines intended for the United Kingdom with respect to the Northern Irish market or multiple markets including Cyprus, Ireland or Malta, and the United Kingdom with respect to Northern Ireland, generate an alert when scanned in another Member State.

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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), point (d), thereof,

Whereas:

(1) 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.

(2) 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 was applicable to and in the United Kingdom during a transition period that ended on 31 December 2020 ('the 'transition period').

(3) 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 continued to apply in Northern Ireland after the end of the transition period.

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

(5) On 13 January 2021, Delegated Regulation (EU) 2016/161 was amended by Commission Delegated Regulation (EU) 2021/457[3] to provide a derogation from the requirement to decommission unique identifiers of products exported to the United Kingdom until 31 December 2021. This derogation was intended to ensure the supply of medicinal products to small markets historically dependent on the United Kingdom,

1 OJ L 311, 28.11.2001, p.67.

2 OJ L 32, 9.2.2016, p. 1.

3 OJ L 91, 17.3.2021, p. 1.

i.e. Northern Ireland, Cyprus, Ireland and Malta. In those small markets historically dependent on the United Kingdom, many medicinal products were and continue to be purchased from the United Kingdom by wholesalers not holding manufacturing and importation authorisations and therefore unable to meet the importation requirements laid down in Directive 2001/83/EC and Delegated Regulation (EU) 2016/161.

(6) In order to ensure that medicinal products continue to be marketed with a unique identifier in Northern Ireland, Cyprus, Ireland and Malta, it is necessary to further extend the temporary derogation from the requirement to decommission unique identifiers of products exported to the United Kingdom. An additional three-year period is needed to allow industry sufficient time to adapt the supply chains of medicines destined for Northern Ireland, Cyprus, Ireland and Malta. The derogation should, however, be limited to medicinal products solely intended for the United Kingdom market or for the United Kingdom market jointly with Cyprus, Ireland or Malta. It should not apply to medicinal products intended for markets other than the United Kingdom or packaged in EU-wide or global labelling. 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.

(7) In order to accommodate the specific characteristics of national supply chains, Article 23 of Delegated Regulation (EU) 2016/161 allows Member States to require wholesalers to verify and decommission unique identifiers on behalf of a list of persons or institutions referred to in that Article. In many cases, this would mean that wholesalers established in parts of the United Kingdom other than Northern Ireland should verify and decommission the unique identifiers of medicines supplied to those persons or institutions in Northern Ireland. Since those wholesalers are not connected to the Union repository system, it is necessary to grant an exceptional derogation from the requirement to decommission the unique identifiers of a medicinal product in order to allow these wholesalers time to move the verification and decommissioning operations to Northern Ireland.

(8) The purpose of Delegated Regulation (EU) 2016/161 is to set out the specifications of the unique identifier, the safety features and the repositories system with a view to establishing a reliable authentication system for medicinal products in the Union. This mutual trust is undermined if repositories outside the Union can upload and access sensitive content in the system, in particular in light of the limited means to supervise such repositories.

(9) In order to ensure that medicinal products re-imported into the Union are not placed on the market elsewhere than Northern Ireland, Cyprus, Ireland and Malta, it is necessary to ensure that the repositories system provide an alert when the medicinal product is verified elsewhere in the Union. Wholesalers in Northern Ireland, Cyprus, Ireland and Malta should also perform checks of shipments of medicinal products intended for the United Kingdom market received from manufacturers, marketing authorisation holders and wholesalers designated by the marketing authorisation holder to ensure the products they receive comply with the rules on safety features.

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

(11) Having regard to the imminent end of the current derogation, this Regulation should enter into force as a matter of urgency. As the current derogation ends on 31 December 2021, this Regulation should apply from 1 January 2022,

HAS ADOPTED THIS REGULATION:

Article 1

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

(1) in Article 3(2), point (d) is replaced by the following:

‘(d) ‘active unique identifier’ means a unique identifier which has not been decommissioned or which is no longer decommissioned, and which has not been identified as a “non-Union pack” as referred to in Article 36, point (p);’

(2) Article 20 is replaced by the following:

‘*Article 20*

Verification of the authenticity of the unique identifier by wholesalers

A wholesaler shall verify the authenticity of the unique identifier of at least the following medicinal products in his physical possession:

(a) medicinal products returned to him by persons authorised or entitled to supply medicinal products to the public or by another wholesaler;

(b) medicinal products he receives from a wholesaler who is neither the manufacturer nor the wholesaler holding the marketing authorisation nor a wholesaler who is designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf.

A wholesaler established in Northern Ireland, Cyprus, Ireland or Malta shall perform adequate verifications to ensure that shipments of medicinal products manufactured and labelled for the United Kingdom market comply with the requirement to bear safety features under Article 54a(1) of Directive 2001/83/EC when received from the manufacturer, the marketing authorisation holder or a wholesaler who is designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf.’

(3) in Article 22, the final paragraph is replaced by the following:

‘By way of derogation from point (a), until 31 December 2024, the obligation to decommission the unique identifier of medicinal products which the wholesaler intends to distribute outside of the Union shall not apply to medicinal products manufactured and labelled for the United Kingdom market or for the United Kingdom market and the markets of Cyprus, Ireland or Malta, which he intends to distribute in the United Kingdom. ’

(4) in Article 26, the following paragraph 4 is added:

‘4. Until 31 December 2024, the authorities of the United Kingdom in respect of Northern Ireland may waive the obligation to verify the safety features and decommission the unique identifier of a medicinal product supplied to the persons or institutions listed in Article 23 for products for the market of the United Kingdom in respect of Northern Ireland supplied from wholesalers located in other parts of the United Kingdom.’

(5) in Article 32(1), point (b), a final sentence is added:

‘Repositories which serve territories outside of the Union shall not be connected to the hub.’

(6) in Article 36, the following point (p) is added:

‘(p) the triggering of an alert identified as a “non-Union pack” in the repositories system and in the terminal where the verification of the authenticity of a unique identifier in accordance with Article 11 takes place when both of the following conditions are met:

(i) the verification finds that the medicinal product bearing the unique identifier is manufactured and labelled for the United Kingdom market or for the United Kingdom market and the markets of Cyprus, Ireland or Malta;

(ii) the verification does not take place in Northern Ireland, Cyprus, Ireland or Malta.’

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 2022.

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

Done at Brussels, 17.12.2021

For the Commission
The President
Ursula VON DER LEYEN