Council of the
European Union

Brussels, 19 January 2021
(OR. en)

5371/21

PHARM 9
SAN 20
MI 22
COMPET 31
DELACT 6
UK 14

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	13 January 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2021) 251 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 13.1.2021 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

Delegations will find attached document C(2021) 251 final.

Encl.: C(2021) 251 final

EUROPEAN
COMMISSION

Brussels, 13.1.2021
C(2021) 251 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 13.1.2021

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a 'third country'[1]. The Withdrawal Agreement[2] provides for a transition period ending on 31 December 2020. Until that date, Union law in its entirety applies to and in the United Kingdom[3].

The safety features (namely the anti-tampering device and the unique identifier) are mandatory for the medicinal products placed on the market in the EU/EEA as laid down in the Articles 54(o) and 54a(1) of Directive 2001/83/EC and the Commission Delegated Regulation (EU) 2016/161.

As the Ireland/Northern Ireland protocol makes Directive 2001/83/EC also applicable to and in the United Kingdom in respect of Northern Ireland in its current version, 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 Union 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 than Northern Ireland will not require the use of these safety features, like the unique identifier, foreseen in Union law.

This means that, as from 1 January 2021, packs of medicines destined for Great Britain should be separated from packs destined for Cyprus, Ireland, Malta or Northern Ireland – even where the supply route goes through Great Britain. Like for any medicinal product placed on the market in the Union, the information of the Cypriot, Irish, Maltese and Northern Irish packs needs to be uploaded in the European hub, or the repository systems of the respective territories. This does not apply to the information of the packs with a final destination in any other part of the United Kingdom than Northern Ireland (Great Britain).

As regards packs exported from the Union to any third country like the United Kingdom, Article 22(a) of Commission Delegated Regulation (EU) 2016/161 obliges the wholesalers exporting the medicinal products to verify and decommission any unique identifier that may have already been affixed to the pack prior to the export.

Where medicinal products are supplied, through Great Britain, to Cyprus, Ireland, Malta or Northern Ireland, it would then, in principle, be for the importer holding a manufacturing authorisation to affix a new unique identifier on the medicinal products in question when they are placed on the market (cfr. Article 4 of Commission Delegated Regulation (EU) 2016/161). Nevertheless, there are currently no importer holding a manufacturing authorisation located in Cyprus, Ireland, Malta

---

1 A third country is a country not 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 notice.

and Northern Ireland, with capacity to meet the obligation to affix a new unique identifier as required by Union law as of 1 January 2021 so that compliance would be practically impossible. At the same time, allowing medicinal products without safety features on the Union market must be prevented, in order to ensure a high level of public health protection and to avoid the presence of falsified medicinal products in the Union.

Therefore, the Commission has decided to waive the obligation to decommission the unique identifier when the products are distributed to the United Kingdom for a period of twelve months to ensure the presence of a unique identifier in the small markets dependent of the UK.

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

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The European Commission has received a positive opinion on the proposed amendment of the Delegated act on safety features for medicinal products for human use which the European Commission Expert Group gave at its meeting held on 8 December 2020.

The group supported the proposal to waive the decommissioning of the unique identifiers on the packs intended to go to the small markets in the EU. Nevertheless, the group considered that the supply chain will not be reorganised in 6 months and a derogation of 12 months would be more appropriate.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Article 22(a) of delegated Regulation is amended to waive the obligation to decommission the unique identifier during a period of 12 months when the medicinal products are exported to the United Kingdom.

COMMISSION DELEGATED REGULATION (EU) …/...

of 13.1.2021

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[4], 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[5], 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

[4] OJ L 311, 28.11.2001, p. 67.

[5] 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).

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 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, 13.1.2021

For the Commission
The President
Ursula VON DER LEYEN