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ANNEX

**ANNEX**

*to the*

**Communication to the Commission**

**Approval of the content of a draft Commission Notice on the application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland**

## ANNEX

Draft Commission Notice on the application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland



Brussels, XXX  
[...] (2021) XXX draft

### Commission Notice

**Application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland**

**Commission Notice**  
**Application of the Union’s pharmaceutical *acquis* in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland**

**DISCLAIMER**

This guidance notice is intended to facilitate the application of the EU’s pharmaceutical *acquis* in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland after 1 February 2020 by indicating the manner in which the Commission will apply to this specific situation the relevant provisions of Directives 2001/82/EC<sup>1</sup>, 2001/83/EC<sup>2</sup> and 2001/20/EC<sup>3</sup> as well as Regulations (EU) 2019/6<sup>4</sup> and (EU) 536/2014<sup>5</sup> and Commission Delegated Regulation (EU) 2016/161<sup>6</sup>. While this notice seeks to assist authorities and operators, only the Court of Justice of the European Union is competent to authoritatively interpret Union law. On 1 February 2020, the United Kingdom withdrew from the European Union and thereby became a ‘third country’ <sup>(7)</sup>. The Withdrawal Agreement <sup>(8)</sup> provides for a transition period which ended on 31 December 2020. Until that date, Union law in nearly all areas applied to and in the United Kingdom <sup>(9)</sup>. This included the pharmaceutical *acquis* of the Union, in particular Directive 2001/82/EC of the European Parliament and of the Council, Directive 2001/83/EC of the European Parliament and of the Council, Commission Delegated Regulation (EU) 2016/161, Article 13 of Directive 2001/20/EC of the European Parliament and of the Council and Chapter IX of Regulation (EU) 536/2014, which are of relevance for this Notice.

At the end of the transition period, Union law ceased to apply to the United Kingdom, whilst the main provisions of the Protocol on Ireland and Northern Ireland (‘the IE/NI Protocol’), which forms an integral part of the Withdrawal Agreement, became applicable. In accordance with Article 5(4) of and point 20 of Annex 2 to the IE/NI Protocol, the pharmaceutical *acquis* of the Union including the abovementioned legal acts, as well as legal acts of the Union implementing, amending or replacing those legal acts apply to and in the United Kingdom in respect of Northern Ireland.

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<sup>1</sup> Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p.1).

<sup>2</sup> 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 (OJ L 311, 28.11.2001, p. 67).

<sup>3</sup> Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

<sup>4</sup> Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, pp. 43-167).

<sup>5</sup> Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1–76).

<sup>6</sup> 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).

<sup>7</sup> A third country is a country which is not a member of the EU.

<sup>8</sup> 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’).

<sup>9</sup> Subject to certain exceptions provided for in Article 127 of the Withdrawal Agreement, none of which is relevant in the context of this notice.

In practical terms, this means, in particular, that:

- Medicinal products (in the scope of the abovementioned legislation) placed on the market in Northern Ireland must comply with the regulatory requirements laid down in Union law;
- Medicinal products placed on the market in Northern Ireland must have a valid marketing authorisation granted by the Commission (EU wide authorisation) or by the competent authorities of the United Kingdom in respect of Northern Ireland, the holder of which is located in the Union or in Northern Ireland;
- Movements of medicinal products from parts of the United Kingdom other than Northern Ireland to Northern Ireland or to the Union constitutes an import within the meaning of applicable Union law;
- Movements of medicinal products from the Union or Northern Ireland to parts of the United Kingdom other than Northern Ireland or any other third country constitutes an export within the meaning of applicable Union law;
- Marketing authorisations issued by UK authorities are, in principle, not valid within the Union but only in Northern Ireland if adopted in accordance with applicable Union law (cf. Article 7(3) of the IE/NI Protocol);
- Any action in the supply of medicines which must be carried out in the Union (e.g. batch testing) in order to allow for the placing on the market of medicinal products in accordance with Union law must occur in the Union or Northern Ireland, and only such actions that may be carried out in third countries may occur in parts of the United Kingdom other than Northern Ireland.

Since 2017, the Commission and the European Medicines Agency have actively been disseminating all relevant information in order to draw the attention of all relevant stakeholders to the impact of the United Kingdom's withdrawal and to alert them of the need to adapt in time before the end of the transition period. The necessary changes have notably been explained in BREXIT Notices as last amended and published on 7 May 2020 for clinical trials <sup>(10)</sup> and on 13 March 2020 for medicinal products <sup>(11)</sup>.

Nonetheless, at the end of the transition period, operators in certain markets which have historically relied on the supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland (i.e. Cyprus, Ireland, Malta and Northern Ireland) <sup>(12)</sup> still needed additional time to adapt supply chains and take account of the end of the transition period. Against that background and given that it was considered crucial that the Union's pharmaceutical *acquis* was implemented and enforced in a manner that both prevented shortages of medicines and ensured the high level of public health protection foreseen by Union law, on 25 January 2021 the Commission adopted a Notice explaining how

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<sup>10</sup> [https://ec.europa.eu/info/sites/info/files/brexit\\_files/info\\_site/clinical-trials\\_en.pdf](https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/clinical-trials_en.pdf)

<sup>11</sup> [https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/notice-stakeholders-withdrawal-united-kingdom-eu-rules-medicinal-products-human-use-veterinary\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/notice-stakeholders-withdrawal-united-kingdom-eu-rules-medicinal-products-human-use-veterinary_en.pdf)

<sup>12</sup> These Member States are singled out in this Notice because of their historical dependence on the UK market for their supply of medicinal products and the fact that a large proportion of their imports of medicinal products is coming from UK.

it would apply, until 31 December 2021, the EU's pharmaceutical *acquis* in those markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland <sup>(13)</sup>.

The period covered by that Commission Notice is now coming to an end, but the situation remains challenging in those markets which have historically relied on supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland (i.e. Cyprus, Ireland, Malta and Northern Ireland). Supply chains of medicines have not yet been adapted, in particular those of suppliers of generics, over-the-counter medicinal products for human use and medicinal products for human use which are supplied on the basis of national marketing authorisations granted by the competent authorities in the United Kingdom. In addition, with regard to medicinal products for human use, certain new challenges have been identified during the past year.

In order to address this situation, and with the aim of preventing shortages of medicines and ensuring a high level of public health protection, with regard to medicinal products for human use, the Commission on 17 December 2021 adopted legislative proposals amending relevant provisions of Directive 2001/83/EC, Directive 2001/20/EC <sup>(14)</sup> and Regulation (EU) 536/2014 <sup>(15)</sup>, as well as a delegated regulation amending Commission Delegated Regulation (EU) 2016/161 <sup>(16)</sup>. It is necessary to bridge the gap between 31 December 2021 and the entry into force of these amendments. In this context, it should be noted that the Commission proposals for a directive amending Directive 2001/83/EC and Directive 2001/20/EC and for a Regulation amending Regulation (EU) 536/2014 provide for the application of those amendments from 1 January 2022 and 31 January 2022, respectively (the latter being the date on which Regulation (EU) 536/2014 becomes applicable). Likewise, the delegated regulation amending Commission Delegated Regulation (EU) 2016/161 provides that it shall apply from 1 January 2022.

As regards medicinal products for veterinary use, more time is needed for companies to adjust to the changes brought about by the provisions of the IE/NI Protocol referred to above. There is therefore currently still a risk of shortages of veterinary medicinal products in those markets which have historically depended on medicines supply from or through parts of the United Kingdom other than Northern Ireland. The Commission will continue to gather information on the current situation on the ground with a view to identifying any outstanding

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<sup>13</sup> Commission Notice – Application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period, 2021/C 27/08, OJ C 27, 25.1. 2021, p. 11.

<sup>14</sup> Commission proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC and Directive 2001/20/EC as regards derogations from certain obligations concerning certain nationally authorised medicinal products for human use made available in the United Kingdom in respect of Northern Ireland as well as in Cyprus, Ireland and Malta (COM (2021)997)

<sup>15</sup> Commission proposal for a Regulation (EU) of the European Parliament and of the Council amending Regulation (EU) No 536/2014 as regards derogations from certain obligations concerning investigational medicinal products made available in United Kingdom in respect to Northern Ireland as well as in Cyprus, Ireland and Malta (COM (2021)998)

<sup>16</sup> 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 (C (2021)9700)

implementation issues and finding the most appropriate way forward for ensuring long-term continuity of veterinary medicines supply to Cyprus, Ireland, Malta and Northern Ireland. It is therefore necessary to allow more time for companies to adjust.

Therefore, the Commission considers it appropriate to explain in this Notice how it will apply, until 31 December 2022 or, as regards human medicines, until the date of entry into force of the amendments referred to above, if that date is before 31 December 2022, the Union's pharmaceutical *acquis* in those markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland (i.e. Cyprus, Ireland, Malta and Northern Ireland). In that regard, the following areas, which have been identified by the Commission as the principal difficulties currently still faced by Cyprus, Ireland, Malta and Northern Ireland in complying with the Union's pharmaceutical *acquis*, will be covered:

1. Lack of operators holding a manufacturing authorisation necessary for imports of medicinal products from third countries;
2. Difficulties to carry out quality control testing ('batch testing');
3. Difficulties to comply with the provisions of Directive 2001/83/EC and Delegated Regulation (EU) 2016/161 with respect to the placement and verification of the unique identifier;
4. Specifically with regard to medicinal products for human use for the Northern Irish market, difficulties for some operators holding a marketing authorisation for medicinal products as well as for qualified persons for the manufacturing and pharmacovigilance of these products which are currently established in parts of the United Kingdom other than Northern Ireland to transfer their sites to the EU/EEA or to Northern Ireland; and
5. Specifically with regard to medicinal products for human use for the Cypriot and Maltese markets, difficulties to ensure access for patients to certain medicinal products due to the reliance of supply chains on parts of the United Kingdom other than Northern Ireland.

Specifically for veterinary medicinal products, it should be noted that Regulation (EU) 2019/6 will start applying from 28 January 2022. Until that date, veterinary medicinal products will be governed by the relevant provisions of Directive 2001/82/EC. This Notice refers to the provisions of both instruments, with the understanding that references to provisions of Directive 2001/82/EC are to be read as applying until 28 January 2022, and reference to provisions of Regulation (EU) 2019/6 are to be read as applying as of 28 January 2022.

## **1. Lack of operators holding a manufacturing authorisation required for importing medicinal products from third countries**

### ***A. Human and veterinary medicinal products***

According to Article 40(3) of Directive 2001/83/EC, Article 44(3) of Directive 2001/82/EC and Article 88(1)(c) of Regulation (EU) 2019/6, anyone placing medicinal products from third countries on the market in accordance with Union law (in the Union or in Northern Ireland) is an importer within the meaning of Union law, and must therefore hold a manufacturing authorisation issued by the Member State where the importer is established or, in the case of

importers established in Northern Ireland, by the United Kingdom acting in respect of Northern Ireland, in accordance with Articles 41 and 42 of Directive 2001/83/EC for human medicines, Articles 45 and 46 of Directive 2001/82/EC and/or Articles 89 and 90 of Regulation (EU) 2019/6 for veterinary medicines. The conditions for such a manufacturing authorisation include, inter alia, the availability of a qualified person in the Union or Northern Ireland, the inspection of the manufacturer/importer and its compliance with Good Manufacturing Practices.

According to Articles 118 of Directive 2001/83/EC and Article 84(e) of Directive 2001/82/EC, competent authorities applying the Union's pharmaceutical *acquis* are obliged to suspend or revoke the marketing authorisation of a medicinal product where the holder of that authorisation does not have a valid manufacturing authorisation or does not comply with one of the conditions necessary to obtain such a manufacturing authorisation. According to Article 134(1)(d) of Regulation (EU) 2019/6, competent authorities are obliged to prohibit the supply of a veterinary medicinal product and require the marketing authorisation holder or suppliers to cease the supply of or recall the veterinary medicinal product from the market if the control tests referred to in Article 127(1) of that Regulation have not been carried out.

Regarding human medicinal products, in order to bridge the gap with the entry into force of the directive amending Directive 2001/83 referred to in the introduction of this Notice and regarding medicinal products for veterinary use, in order to provide more time for operators to adjust to the changes brought about by the IE/NI Protocol, the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland could apply the following practice. This practice could be applied between 1 January 2022 and 31 December 2022, or, for human medicines, between 1 January 2022 and the date of entry into force of these amendments, if that date is before 31 December 2022:

- The competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland would allow medicinal products to be imported from other parts of the United Kingdom than Northern Ireland by wholesalers which are not in possession of a manufacturing authorisation as required by Article 40 of Directive 2001/83/EC, Article 44 of Directive 2001/82/EC and Article 88 of Regulation (EU) 2019/6; and they would not suspend or revoke the marketing authorisations of those medicinal products as required by Article 118 of Directive 2001/83/EC, Article 84(e) of Directive 2001/82/EC and Article 134(1)(d) of Regulation (EU) 2019/6, provided that the following conditions are fulfilled:
- The medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland and placed on the market in accordance with Union law (i.e. imported into the Union or Northern Ireland) have undergone batch testing (<sup>17</sup>) either in the Union, as provided for in Article 51(3) of Directive 2001/83/EC for human medicinal products

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<sup>17</sup> According to Article 51(1)(b) of Directive 2001/83/EC, Article 55(1)(b) of Directive 2001/82/EC and Article 97(7) of the Regulation (EU) 2019/6, medicinal products imported into the EU have to undergo batch testing in the EU/EEA. These provisions prescribe that in the case of medicinal products coming from third countries, irrespective of whether the product has been manufactured in the Union, each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation.

and in Article 44(3) of Directive 2001/82/EC and Article 88(1)(c) of Regulation (EU) 2019/6 for veterinary medicinal products, or in parts of the United Kingdom other than Northern Ireland in compliance with Article 20(b) of Directive 2001/83/EC for human medicinal products and with Article 24(b) of Directive 2001/82/EC or the conditions set out in Section 2 of this Notice for veterinary medicinal products (see Section 2 of this Notice);

- The medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland and placed on the market in accordance with Union law (i.e. imported into the Union or Northern Ireland) have been subject to batch release by a Qualified Person (QP) in the Union or Northern Ireland or, for products authorised by the competent authorities of Cyprus, Ireland, Malta or the United Kingdom in respect of Northern Ireland, by a QP or a person having an equivalent qualification to a QP in parts of the United Kingdom other than Northern Ireland applying equivalent quality standards to those laid down in Union law, thus ensuring an equivalent level of protection of human and animal health;
- The operator importing medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland into Cyprus, Ireland, Malta or Northern Ireland holds a distribution authorisation issued in accordance with Article 77(1) of Directive 2001/83/EC for human medicinal products and Article 65(1) of Directive 2001/82/EC or Article 99(1) of Regulation (EU) 2019/6 for veterinary medicinal products;
- The marketing authorisation of the medicinal product concerned has been issued, based on and in accordance with Union law, by the competent authority of a Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom in respect of Northern Ireland in compliance with Union law;
- The medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland are made available to retailers or the end consumer in the same market historically dependent on medicines supply from parts of the United Kingdom other than Northern Ireland where they are imported, and they are not made available in other Member States;
- With regard to medicinal products for human use, they bear the safety features referred to in point (o) of Article 54 of Directive 2001/83/EC.

For veterinary medicinal products, the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland would in this case also report to the Commission, on a monthly basis, as regards the progress made by wholesale distributors importing medicinal products in fulfilling the conditions necessary to obtain a manufacturing authorisation laid down in Article 45 of Directive 2001/82/EC and Article 89 of Regulation (EU) 2019/6.

## **B. *Investigational medicinal products***



According to Article 13 of Directive 2001/20/EC and Article 61 of Regulation (EU) 536/2014, the placing on the market of investigational medicinal products from third countries in accordance with Union law also requires the importer to hold a manufacturing and import authorisation. This also applies to the supply of investigational medicinal products from or through parts of the United Kingdom other than Northern Ireland to Cyprus, Ireland, Malta and Northern Ireland. Article 13(2) of Directive 2001/20/EC, Article 61 of Regulation (EU) No 536/2014 require the holder of the manufacturing and import authorisation to have, permanently and continuously, at his disposal the services of at least one qualified person in the scope of application of Union law, i.e. in the Union or in Northern Ireland.

In order to bridge the gap with the entry into force of the directive amending Directive 2001/20 and the regulation amending Regulation 536/2014, referred to in the introduction of this Notice, the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland could apply the following practice between 1 January 2022 and 31 December 2022, or, between 1 January 2022 and the date of entry into force of these amendments, if that date is before 31 December 2022: The competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland would allow investigational medicinal products to be imported from parts of the United Kingdom other than Northern Ireland by clinical trial sites or sponsors which are not in possession of a manufacturing and import authorisation as required by Article 13 of Directive 2001/20/EC and Article 61 of Regulation (EU) No 536/2014, provided that the following conditions are fulfilled:

- The medicinal products imported into Cyprus, Ireland, Malta and Northern Ireland from or through parts of the United Kingdom other than Northern Ireland and approved for use in accordance with Union law have undergone certification of batch release either in the Union or in parts of the United Kingdom other than Northern Ireland in compliance with the requirements set out in Article 13(3) of Directive 2001/20/EC or Article 63 of Regulation (EU) No 536/2014;
- The medicinal products imported into Cyprus, Ireland, Malta or Northern Ireland from or through parts of the United Kingdom other than Northern Ireland are made available to clinical trial participants as the end consumer in the same market historically dependent on medicines supply from other parts of the United Kingdom than Northern Ireland where they are imported, and they are not made available in other Member States.

## **2.a) Batch testing of human and veterinary medicinal products**

According to Article 51(1)(b) of Directive 2001/83/EC, Article 55(1)(b) of Directive 2001/82/EC and Article 97(7) of Regulation (EU) 2019/6, medicinal products imported into the EU have to undergo quality control testing ('batch testing') in the Union/EEA. The requirement of a batch testing site established in the Union is a fundamental pillar of the Union system of ensuring quality of medicinal products being placed on the Union market. However, with regard to batch testing, there may be objective reasons beyond the control of the marketing authorisation holders that may have prevented the timely transfer of such testing activities to be carried out in the Union or Northern Ireland.

In these cases, Article 20(b) of Directive 2001/83/EC and 24(b) of Directive 2001/82/EC allow importers placing medicinal products supplied from or through other parts of the United Kingdom than Northern Ireland on the market in Cyprus, Ireland, Malta or Northern Ireland or wholesale distributors placing such medicinal products on those markets as described under Section 1 above, to have, in justifiable cases, certain controls carried out in other parts of the United Kingdom than Northern Ireland. Taking into account the exceptional circumstances described in this Notice, with regard to medicinal products authorised by the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland, the Commission considers that a ‘justifiable case’ within the meaning of Article 20(b) Directive 2001/83/EC and 24(b) of Directive 2001/82/EC occurs when the following conditions are fulfilled:

- Each batch of the medicinal product concerned is released by a qualified person (QP) on a site in the Union or Northern Ireland or, in case the manufacturing authorisation holder declares that he does not have a qualified person established in the Union or Northern Ireland at his disposal, or in cases falling under Section 1 above, by a QP or a person having an equivalent qualification to a QP on a site in parts of the United Kingdom other than Northern Ireland applying equivalent quality standards to those laid down in Union law, thereby ensuring an equivalent level of protection of human or animal health;
- The establishment designated by the third party conducting the batch testing is regularly supervised by a competent authority of the Union/EEA or a Member State or the competent authority of the United Kingdom in accordance with Union law;
- For veterinary medicinal products under Directive 2001/82/EC, the marketing authorization holder takes tangible and credible steps towards transferring the batch testing sites to the Union or Northern Ireland by the 31 December 2022.

For veterinary medicinal products under Regulation (EU) 2019/6, importers placing veterinary medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland on the market in Cyprus, Ireland, Malta or Northern Ireland or, in cases falling under Section 1 above, wholesale distributors placing such veterinary medicinal products on those markets, certain controls may be carried out in parts of the United Kingdom other than Northern Ireland until 31 December 2022, if the following conditions are fulfilled:

- a) Each batch of the medicinal product concerned is released by a qualified person (QP) on a site in the Union or Northern Ireland or, in cases falling under Section 1 above, by a QP or a person having an equivalent qualification on a site in the parts of the United Kingdom other than Northern Ireland applying equivalent quality standards to those laid down in Union law, thereby ensuring an equivalent level of protection of human or animal health;
- b) The establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including through on-the-spot checks.
- c) The marketing authorization holder takes tangible and credible steps towards transferring the quality control testing site to the Union or Northern Ireland by 31 December 2022.

In order to make use of the derogation foreseen in Article 20(b) of Directive 2001/83/EC for human medicinal products and Article 24(b) of Directive 2001/82/EC for veterinary medicinal products, or of the derogation for veterinary medicinal products under Regulation (EU) 2019/6, marketing authorisation holders should notify the competent authority that granted the marketing authorisation of the product concerned (Cyprus, Ireland, Malta or Northern Ireland), specifying that – and for what reason – the above criteria of a ‘justifiable case’ within the meaning of Article 20(b) of Directive 2001/83/EC or of Article 24(b) of Directive 2001/82/EC, or the criteria for the derogation for veterinary medicinal products under Regulation 2019/6, are fulfilled.

Any such notification should be submitted without undue delay and should be received as soon as possible, and in no case later than by 31 January 2022<sup>18</sup>.

## **2b) Batch testing for medicines for human use already carried out in the Union**

For batches of medicinal products for human use which are exported from a Member State to parts of the United Kingdom other than Northern Ireland and subsequently imported into Northern Ireland or into Cyprus, Ireland or Malta, the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland may, until 31 December 2022, or, until the date of entry into force of the directive amending Directive 2001/83 referred to in the introduction of this Notice, if that date is before 31 December 2022 exceptionally not require additional controls upon importation as referred to in the first and second subparagraph of Article 51(1) of Directive 2001/83/EC, if those batches have already undergone these controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and if they are accompanied by the control reports referred to in the third subparagraph of Article 51(1) of Directive 2001/83/EC.

## **3. Requirements relating to the placement of the unique identifier for medicinal products for human use**

The safety features (i.e. an anti-tampering device and unique identifier) are mandatory for medicinal products subject to prescription 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, 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.

According to the IE/NI Protocol, 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. However, these safety features do not apply to medicinal products placed on the market in other parts of the United Kingdom.

As a consequence, from 1 January 2021, prescription medicinal products destined for parts of the United Kingdom other than Northern Ireland are not subject to the same requirements regarding safety features as products destined for Cyprus, Ireland, Malta or Northern Ireland,

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<sup>18</sup> For human and veterinary medicinal products to be placed on the market in Northern Ireland, the competent authorities are the Medicines and Healthcare products Regulatory Agency (MHRA) and the Veterinary Medicines Directorate (VMD) respectively.

even where the supply route for the latter goes through parts of the United Kingdom other than Northern Ireland.

As from 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 <sup>(19)</sup>. Subject to scrutiny by the European Parliament and the Council, by means of an amendment to Delegated Regulation 2016/161, a derogation from the obligation to decommission the unique identifier when medicines are distributed to the United Kingdom will continue to apply for a period of three years, coupled with additional safeguards, to ensure the continued supply of medicines Cyprus, Ireland, Malta and Northern Ireland.

#### **4. The location of the marketing authorisation holder and the qualified persons for manufacturing and pharmacovigilance with regard to medicinal products for human use**

In accordance with Article 8(2) of Directive 2001/83/EC, read in conjunction with the IE/NI Protocol, a marketing authorisation may only be granted to an applicant established in the Union or in Northern Ireland.

Article 48 of Directive 2001/83/EC, read in conjunction with Article 49 of that Directive and the IE/NI Protocol, requires the qualified person for manufacturing to reside in and operate from the Union or Northern Ireland.

In accordance with Article 104(3) of Directive 2001/83/EC, read in conjunction with the IE/NI Protocol, the qualified person responsible for pharmacovigilance must be established in and operate from the Union or Northern Ireland. In addition, in accordance with Article 7 of the Commission Implementing Regulation (EU) No 520/2012 <sup>(20)</sup> the pharmacovigilance system master file must be located either at the site in the Union where the main pharmacovigilance activities of the marketing authorisation holder are performed or at the site in the Union where the qualified person responsible for pharmacovigilance operates.

In order to bridge the gap until the entry into force of the amendments to Directive 2001/83/EC referred to in the introduction of this Notice, the competent authorities of the United Kingdom in respect of Northern Ireland could apply the following practice between 1 January 2022 and 31 December 2022, or, between 1 January 2022 and the date of entry into force of the amendments to Directive 2001/83/EC, if that date is before 31 December 2022:

1. The holders of marketing authorisations issued by the authorities of the United Kingdom in respect of Northern Ireland may be located in parts of the United Kingdom other than Northern Ireland;
2. For the mutual recognition and decentralised procedures as referred to in Articles 28 to 39 of Directive 2001/83/EC, the holders of marketing authorisations issued by the national authorities of the United Kingdom in respect of Northern Ireland, or by the

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<sup>19</sup> 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 (OJ L 91, 17.3.2021, p. 1).

<sup>20</sup> Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council, OJ L 159, 20.6.2012, p. 5.

competent authorities of Cyprus, Ireland and Malta may be located in parts of the United Kingdom other than Northern Ireland;

3. Where the marketing authorisation is granted by the competent authority of the United Kingdom in respect of Northern Ireland, the qualified person responsible for pharmacovigilance, as well as the pharmacovigilance system master file, may exceptionally be allowed to be located and operate in parts of the United Kingdom other than Northern Ireland. This shall not apply to situations where the marketing authorisation holder already has at its disposal a qualified person established in the Union;
4. Where the marketing authorisation is granted by the competent authority of the United Kingdom in respect of Northern Ireland, the qualified person for manufacturing may reside in and operate from parts of the United Kingdom other than Northern Ireland. This shall not apply to situations where the manufacturing authorisation holder already has at his disposal a qualified person who is established in the Union.

## **5. Marketing authorisations granted by the Cypriot and Maltese competent authorities under Article 126a of Directive 2001/83/EC**

Until the end of the transition period, the competent authorities of Cyprus and Malta could for justified public health reasons, grant marketing authorisations based on marketing authorisations issued by the United Kingdom, in accordance with Article 126a of Directive 2001/83/EC and under the conditions specified therein.

In order to bridge the gap with the entry into force of the proposed amendments to Directive 2001/83/EC referred to in the introduction of this Notice, the competent authorities of Cyprus and Malta could apply the following practice between 1 January 2022 and 31 December 2022, or between 1 January 2022 and the date of entry into force of the amendments referred to above, if that date is before 31 December 2022:

The competent authorities of Cyprus and Malta could for justified public health reasons validly maintain in force, extend and grant marketing authorisations pursuant to Article 126a of Directive 2001/83/EC which are based on marketing authorisations granted by the competent authority of the United Kingdom.

Where the competent authorities of Cyprus or Malta maintain in force, extend or grant such marketing authorisations, they shall ensure compliance of such marketing authorisations with Union law and in particular with the requirements of Directive 2001/83/EC.

Before granting such a marketing authorisation, the competent authorities of Cyprus or Malta:

- a) should notify the marketing authorisation holder in parts of the United Kingdom other than Northern Ireland of the granting or the extension of a marketing authorisation in respect of the medicinal product concerned being envisaged;
- b) may request the competent authority in the United Kingdom to submit the relevant information regarding the marketing authorisation of the medicinal product concerned.