EUROPEAN
COMMISSION

Brussels, 19.12.2022
C(2022) 9653 final

Commission Notice

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

1. Legal framework and other relevant considerations

On 1 February 2020, the United Kingdom withdrew from the European Union and thereby became a 'third country'[1]. The Withdrawal Agreement[2] provides for a transition period which ended on 31 December 2020.

At the end of the transition period, Union law ceased to apply to the United Kingdom, whilst 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 Directive 2001/82/EC[3] and Regulation (EU) 2019/6[4], 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.

In practical terms, as far as veterinary medicinal products are concerned, this means, in particular, that:

- Veterinary 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;
- Veterinary 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 veterinary 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;

---

1 A third country is a country which 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 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)

4 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, p. 43)

- Movements of veterinary 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 veterinary 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 information in order to draw the attention of 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 the BREXIT Notices for medicinal products as last amended and published on 13 March 2020[5].

Nonetheless, at the end of the transition period, operators in certain markets which have historically relied on the supply of veterinary medicinal products from or through parts of the United Kingdom other than Northern Ireland (i.e. Cyprus, Ireland, Malta and Northern Ireland)[6] 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 veterinary medicines *acquis* was implemented and enforced in a manner that both prevented shortages of veterinary 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 it would apply, until 31 December 2021, the EU's veterinary medicines *acquis* in those markets historically dependent on veterinary medicines supply from or through parts of the United Kingdom other than Northern Ireland[7].

At the end of 2021, it was clear that the situation remained challenging in those markets which have historically relied on supply of veterinary medicinal products from or through parts of the United Kingdom other than Northern Ireland (i.e. Cyprus, Ireland, Malta and Northern Ireland). Therefore, on 29 December 2021, the Commission adopted "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"[8] that applies until 31 December 2022 with respect to veterinary medicinal products.

---

5 https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/notice-stakeholders-withdrawal-united-kingdom-eu-rules-medicinal-products-human-use-veterinary_en.pdf

6 These markets are singled out in this Notice because of their historical dependence on the UK market for their supply of veterinary medicinal products and the fact that a large proportion of their imports of medicinal products is coming from UK.

7 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.

8 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 2021/C 524/02, OJ C 524, 29.12.2021, p. 2.

The period covered by this Notice with regard to veterinary medicinal products is now coming to an end and supply chains for veterinary medicinal products have not yet been adapted. In current circumstances, there is therefore 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.

2. Extension of the practices referred to in the "Commission Notice –application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply fromor through parts of the United Kingdom other than Northern Ireland"

In order to ensure continuity of supplies of veterinary medicinal products to Cyprus, Ireland, Malta and Northern Ireland, it is necessary to extend for a last time, as regards these products, the practices set out in the 2021 "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" (2021 C524/02). This extension is granted until 31 December 2025.

3. Action Plan

The extension of the practices referred to in Section 2 can only be justified if measures are put in place to ensure that supplies of veterinary medicinal products to Cyprus, Ireland, Malta and Northern Ireland conform to the Union *acquis* on veterinary medicinal products and the provisions of the IE/NI Protocol in full no later than 31 December 2025. Such measures concern operators that are currently involved in the supply of veterinary medicinal products to Cyprus, Ireland, Malta and Northern Ireland as well as the national competent authorities of these territories, which should explore alternatives with a view to take the necessary steps to ensure the availability of the concerned veterinary medicinal products fully compliant with the applicable Union acquis on veterinary medicinal products and the provisions of the IE/NI Protocol in full.

To this end, the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland shall comply with the following obligations:

a) Identify the veterinary medicinal products the supply of which would be at risk in their respective territories if the practices referred to in the "Commission Notice –application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply fromor through parts of the United Kingdom other than Northern Ireland" were not applied.

   The list of the veterinary medicinal products concerned shall be submitted to the Commission in the format provided for in Section 4 at the latest by 28 February 2023.

b) Provide information about the measures that will be taken by the concerned operators and/or the competent authorities, including the timelines for the implementation thereof, to ensure that supplies of the veterinary medicinal products identified under (a) conform to

the Union *acquis* on veterinary medicinal products and the provisions of the IE/NI Protocol.
This information shall be submitted to the Commission in the format provided for in Section 4 at the latest by 30 September 2023.

c) Submit progress reports to the Commission as regards the implementation of the measures identified under (b) by 31 January 2024 and thereafter every three months.

The Commission will, on a regular basis, monitor progress together with the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland and engage with the relevant stakeholders.

4. Reporting format

Product name	Active Substance	Marketing authorisation holder	Measures planned