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Addressing the impact of a withdrawal of the United Kingdom from the Union without an agreement: the Union's coordinated approach

Medicinal products and medical devices:
Coordinated approach in case of a withdrawal of the United Kingdom from the Union without a deal

1. INTRODUCTION

On 29 March 2017, the United Kingdom notified its intention to withdraw from the Union. The Commission continues to consider that an orderly withdrawal of the United Kingdom from the Union on the basis of the Withdrawal Agreement, which has been agreed by the United Kingdom Government and which the European Council (Article 50) endorsed on 25 November 2018, is the best outcome. The Commission continues to focus its efforts on that goal. However, two days before the deadline of 12 April 2019, as extended by the European Council[1], the likelihood of a disorderly withdrawal of the United Kingdom from the Union has significantly increased.

2. PREPAREDNESS IN THE MEDICAL SECTOR

The medical sector has been a priority of the European Commission's preparedness work from the start. Full compliance of medicinal products (human and veterinary) and medical devices with EU legislation is key to patient safety and critical to ensure continued availability in case of a withdrawal of the United Kingdom without a withdrawal agreement.

The Commission has called on stakeholders to prepare for the eventuality of a no deal as early as May 2017 when issuing its first notice on medicinal products[2]. Several notices and questions and answers documents on medicinal products and medical devices have been issued and regularly updated since[3]. The notices invite relevant stakeholders to get prepared for the eventuality of a no-deal withdrawal of the United Kingdom from the EU and identify all the required actions.

Economic operators are responsible for taking the necessary measures to ensure their continued compliance with EU legislation, including as regards EU-localisation requirements for certain functions (e.g. market authorisations holders for medicinal products or authorised representatives for medical devices) and activities (e.g. batch release sites), as well as the replacement of UK competent authorities and UK notified bodies by EU27 authorities and EU27 notified bodies in the approval process for placing products on the EU market.

The Commission, the European Medicines Agency (EMA) and the EU27 Member States have transferred the role of the rapporteur Member State from the United Kingdom to an EU27 Member State, and facilitated the transfer of the role of the Reference Member State, where necessary. Furthermore, the Commission has issued guidance[4] to EU27 Member States to address situations in which the timely transfer of batch testing sites from the United Kingdom to the EU27 is not possible. In particular, an existing exemption in the

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1 European Council Decision 2019/476 taken in agreement with the United Kingdom of 22 March 2019 extending the period under Article 50(3)TEU, OJ L 80I, 22.3.2019, p. 1.

2 https://ec.europa.eu/info/sites/info/files/medicinal_products_for_human_use-veterinary_medicinal_products_en.pdf

3 https://ec.europa.eu/info/sites/info/files/file_import/medicinal_products_for_human_and_veterinary_use-qa_en_0.pdf
https://ec.europa.eu/info/sites/info/files/file_import/industrial_products_en_1.pdf
https://ec.europa.eu/info/sites/info/files/qa_brexit_industrial_products_en.pdf

4 https://ec.europa.eu/health/sites/health/files/files/documents/brexit_batchtesting_medicinalproducts_en.pdf

Directives on human[5] and veterinary[6] medicinal products can be used by competent authorities, in duly justified cases, to allow marketing authorisation holders to rely on quality control testing performed in the United Kingdom for a limited period of time.

For medical devices, the Commission and Member States have been closely monitoring the steady progress of the transfers of certificates from UK notified bodies to EU27 notified bodies (i.e. qualified entities designated by Member States competent authorities to perform conformity assessment tasks under Union product legislation). Neither the Commission nor Member States are part of the process. Where the transfer of critical medical devices may not be completed by the withdrawal date, the Commission has issued guidance to the EU27 Member States on existing national derogations in the Directives on Medical Devices[7] and In-vitro Diagnostics Medical Devices[8]. These derogations may allow Member States, in duly justified cases, to authorise UK certificate holders to continue placing their products on the market in the territory of the Member State concerned for a limited period of time.

The preparation actions and the possible use of the aforementioned exemptions and derogations are expected to significantly mitigate the risk of shortages of medicinal products and of critical medical devices in case of a no-deal. For this reason, no EU-level contingency action has been identified as necessary for medicinal products or medical devices.

3. REMAINING ISSUES IN THE MEDICAL SECTOR

Based on available information, the majority of medical products concerned by the UK withdrawal should be compliant with EU legislation on the withdrawal date. It is however possible that, despite best efforts, some medicinal products and medical devices may not be compliant in time and thus there could be a risk of shortages if the economic operators do not act swiftly to remedy the situation. The Commission and Member States will continue to monitor closely the progress of ongoing preparedness actions and provide support to affected stakeholders.

4. COORDINATED ACTION TO MANAGE SHORTAGES

To ensure a coordinated approach to potential shortages of medicinal products across the EU Regulatory Medicines Network[9], EMA together with national medicines regulators and the Commission will rely on its experience of responding to unexpected situations, such as safety incidents or shortages. This includes coordination of key decision makers from

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5 Article 20 (b) of 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.

6 Article 24(b) of 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.

7 See Article 9(9) of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17) and Article 11(13) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

8 See Article 9(12) of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

9 The Network consists of the European Commission (EC), the National Competent Authorities (NCAs) of the Member States (MSs) and the European Medicines Agency (EMA).

national regulators, the EMA and the Commission to monitor the situation, address problems and inform patients and doctors appropriately. This structure is built on existing strategies to deal with such incidents and shortages under the Network's Incident management plan[10] and the Heads of Medicines Agency (HMA)/EMA Task Force on Availability of Authorised Medicines for Human and Veterinary Use (TF AAM)[11], but may take account of the specificities of the UK withdrawal.[12]

In the area of medical devices, the Commission is working closely with the EU27 Member States in the context of the Medical Device Coordination Group (MDCG) and the Competent Authority for Medical Devices (CAMD) network to monitor the progress of certificate transfers and identify critical medical devices that may be at risk of shortages. In particular, the Commission will coordinate a transparent and coherent use of the national derogations by Member States across the EU to avoid any fragmentation of the Single Market.

5. ADDITIONAL INFORMATION

Public authorities and stakeholders can find further information on the impact of the United Kingdom's disorderly withdrawal on medicinal products and medical devices on the following website of the Commission and EMA:

https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en

https://www.ema.europa.eu/en/about-us/united-kingdoms-withdrawal-european-union-brexit

[10] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/incident-management-plan

[11] www.hma.eu/522.html

[12] In addition, as regards medical radioisotopes, the European Observatory on the supply of medical radioisotopes is keeping the impact of the United Kingdom's withdrawal under review.