European Commission

A 'NO-DEAL' BREXIT: MEDICINES AND MEDICAL DEVICES

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A coordinated approach in the area of medicines and medical devices in case of a 'no-deal' scenario.

The medical sector: A priority of the European Commission's preparedness work from the start.

The EU is prepared for a 'no-deal' scenario. EU legislation will allow us to mitigate the impact of such a scenario.

What have we done?

The Commission has called on stakeholders to prepare for a possible 'no-deal' scenario as early as May 2017. Since then, several preparedness notices and guidance documents have been issued on medicines and medical devices. These areas were also carefully assessed in the **Commission Communications of July 2018 and November 2018**.

Economic operators are primarily responsible for taking the necessary measures to ensure their continued compliance with EU legislation. This is also the best way to ensure the continued safety and reliability of medicinal and medical device products in the EU and to avoid supply shortages in the case of 'no-deal'. In addition, the following measures have so far been taken:

Medicines:

- The Commission, the **European Medicines Agency (EMA)** and national authorities have been able to **facilitate the transfer of marketing authorisations for medicines from one UK rapporteur competent authority to another.**
- Notices, Questions and Answers, and Guidance documents on preparedness have been published by the Commission as early as May 2017. They have been regularly updated.
- **The European Medicines Agency has been relocated from London to Amsterdam**.
- The Commission has issued **guidance** to EU27 Member States **on the timely transfer of batch testing sites from the UK to the EU27**.
- **A network has been put in place** bringing together the Commission, national regulators and the European Medicines Agency **to monitor the situation, address any problems of supply and inform patients and doctors** accordingly.

Medical Devices:

- The Commission and Member States have been **closely monitoring the progress of the transfers of certificates from UK notified bodies to EU27 notified bodies** (i.e. private entities designated by Member State competent authorities).
- In justified cases where derogations are granted, **UK certificate holders will be allowed to continue placing their products on the EU27 market** for a limited period of time. The Commission has issued guidance to EU27 Member States.

Managing potential shortages

The risk of shortages of medicines and of critical medical devices in case of a 'no-deal' scenario has been significantly mitigated. No contingency action has been identified as necessary.

Medicine

- National regulators, the European Medicines Agency and the Commission will monitor the situation, address problems and inform patients and doctors appropriately. This structure is built on existing strategies to deal with incidents and shortages.

Medical devices

- The Commission is working closely with EU27 Member States in the context of the Medical Device Coordination Group and the Competent Authority for Medical Devices Network to monitor the progress of certificate transfers and to identify critical medical devices that may be at risk of shortages.
- The Commission will coordinate and ensure transparency with regard to derogations for medical devices certified by a UK notified body. This will ensure a coherent approach and avoid any fragmentation of the internal market.