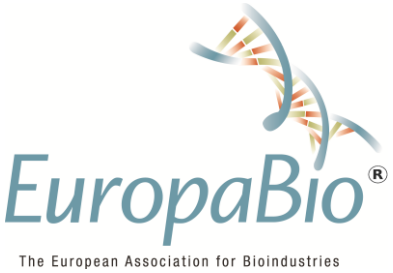
Industry stakeholders webinar on the UK withdrawal from the European Union

- Joint industry presentation

November 30th

Joint presentation: pharmaceutical and biotechnology industry associations



Industry preparedness

Following the European Commission preparedness communications, as indicated in previous meetings, pharmaceutical companies have done everything in their control to prepare for the UK exit from the EU.

We need to avoid as a priority any disruption to the supply of medicines and medical devices to patients, consumers and citizens

Uninterrupted supply of medicinal products and medical devices: need for a comprehensive trade agreement between the EU and the UK

- **Joint EU-UK interpretation of the phased implementation process of the Northern Ireland Protocol** (NIP) provisions regarding pharmaceutical products.
  - The industry welcomes the decision of the EU and UK authorities and requests further details on the phased approach to allow companies to prepare and put operational procedures in place.

Uninterrupted supply of medicinal products and medical devices: need for a comprehensive trade agreement between the EU and the UK

Need for long-term solution for patients, industry and regulators alike. The industry's **immediate priorities** in the negotiating discussions are:

- A medicines-specific **EU-UK Mutual Recognition Agreement** on GMP, inspections, conformity assessment to cover medical devices, batch and import testing by manufacturers and OMCLs in order to:
  - *Ensure continuity of supply of medicines, including in Northern Ireland*: MRA would help to ensure continued ease of supply of medicines to patients in the EU and the UK by removing the need for an additional, repetitive test in the usual supply chain for NI medicinal products without any reason for this additional formality and moreover a negative healthcare impact (ca 4-6 weeks of delays)
  - *Minimise negative economic consequences of BREXIT:* not having an MRA would not only lead to negative economic consequences within key EU Member States, it would also reduce the competitiveness of both the EU and the UK vis-à-vis the US Japan and China
  - *Continue the EU's best practices* by strengthening existing regulatory cooperation and simplification of procedures via e.g., ICMRA, PIC/S, ICH

Q&A on the implementation of the protocol on Ireland / Northern Ireland –

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 November 2020
EMA/520875/2020

Questions and answers to Stakeholders on the implementation of the Protocol on Ireland/Northern Ireland

Additional practical guidance on the applicable rules in Northern Ireland after the transition period with respect to EMA activities and medicinal products for human and veterinary use within the framework of the centralised procedure

Clarification on a 12-months phase-in:

"*Conversely, medicinal products shipped from Great Britain to Northern Ireland after 31 December 2020 will be considered imports and will be subject to the above requirements concerning importation, quality control testing and batch release*"

Q&A