Industry Stakeholder meeting on Brexit and operation of the centralised procedure for human and veterinary medicinal products

Update from the European Commission

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UK's withdrawal from the EU

- The Treaties will cease to apply to the United Kingdom from the date of entry into force of a withdrawal agreement or failing that, two years after that notification, i.e. from 30 March 2019, unless the European Council, in agreement with the United Kingdom, unanimously decides to extend that period. The UK will then be a third country.
- However, irrespective of the scenario envisaged, the UK's choice will cause significant disruption
- The Commission consistently called on businesses to prepare for all possible scenarios

Bottom-line: You need to prepare for 30 March 2019

Commission's work on Brexit

Negotiations

- **Withdrawal Agreement & Political Declaration**

Preparedness

- **Communication of 19 July 2018 "Preparing for the withdrawal of the United Kingdom from the European Union on 30 March 2019**

Contingency

- **Communication of 13 November 2018 "Preparing for the withdrawal of the United Kingdom from the European Union on 30 March 2019: a Contingency Action Plan**
- **Communication of 19 December 2018 : "Preparing for the withdrawal of the United Kingdom from the European Union on 30 March 2019: Implementing the Commission's Contingency Action Plan"**

Withdrawal agreement

- Since 2017, the UK and the EU have been negotiating a withdrawal agreement
- Purpose: "Winding down" of EU membership
- The text, the EU and the UK have agreed, at negotiators' level, has been published end of 2018
- It has been endorsed by the European Council (EU27) in November 2018
- The withdrawal agreement includes a transition period (in turn it means that in the absence of a withdrawal agreement there will be no transition period)
- The withdrawal agreement needs to be ratified by both sides.

"Transition period"

- Full acquis applies to the UK
- Dynamic reference, i.e. including acquis that starts applying in the transition period
- No UK participation in EU institutions or EU bodies
- No UK role as "leading authority"
- Full role of Court of Justice, Commission, Court of Auditors, etc.
- Duration: until 31/12/2020 (if withdrawal agreement is ratified)

Bottom-line: Do not rely on the transition period

No withdrawal agreement

- In the absence of a withdrawal agreement, there will be no transition period and EU law ceases to apply to and in the UK as of 30 March 2019
- To avoid disruption all businesses have to prepare, make necessary decision and complete all administrative actions before 30 March
- Commission has stepped-up its preparation for a no-deal scenario and is in continuous contact with Member States

Compliance with EU law requirements and adaptations of Marketing authorisations (CAPs and NAPs):

- Industry: to implement Brexit-related changes required by legislation and submit corresponding amendments of marketing authorisations to regulators;
- Regulators (EU and national): to process increased number of regulatory submissions (transfers, variations) efficiently and in a timely manner.
- For example:
  - Marketing authorisation holders need to be established in EU27;
  - Testing and batch release sites need to be located in EU27;
  - Qualified persons need to be established in EU27;
  - Brexit-related changes need to be made to clinical trials;
  - Labelling needs to be adapted, etc.

Background and reference information

Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use concerning UK's withdrawal from the EU:

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

Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure:

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

EMA Website related to UK's withdrawal from the EU ('Brexit'):

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/general/general_content_001707.jsp&mid=WC0b01ac0580a809a7

Notice to marketing authorisation holders of nationally authorised medicinal products for human use concerning UK's withdrawal from the EU

http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/BREXIT/CMDh_360_2017_Rev1_06_2018_clean.pdf

Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the nationally authorised medicinal products for human use:

http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/BREXIT/CMDh_361_2017_Rev2_06_2018_clean.pdf

Thank you !