EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

UK's withdrawal from the EU - preparedness activities update

Pharmacovigilance industry stakeholders platform

Presented by Marie-Helene Pinheiro on 30 October 2020
Industry Stakeholders Liason, Public and Stakeholders engagement department

UK's withdrawal from the EU

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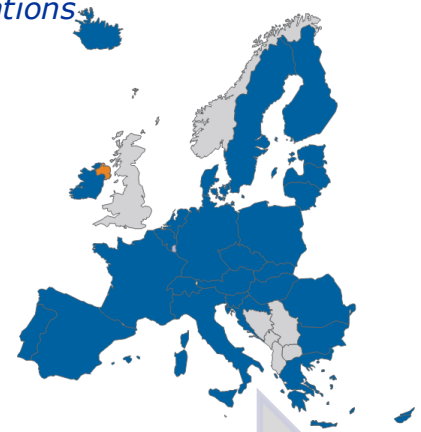
All statement given today is without prejudice to on-going negotiations



1973 (UK join EU)

31.01.2020

31.12.2020

EU Membership

- EU Law applies
- Participation in EU Decision making
- Full access to data

Transition Period

- EU Law applies
- No participation in EU decision making (no UK Committee or WP members)
- Access to most databases

Protocol on Ireland/ Northern Ireland (NI)

- Parts of EU Law apply in the NI
- No participation in EU decision making
- Exceptionally, access to some EU databases

EU LEGISLATION

WITHDRAWAL AGREEMENT (WA)

PROTOCOL on IRELAND/NORTHERN IRELAND incl. WA

EMA 25 years

UK's withdrawal from the EU-preparedness activities update

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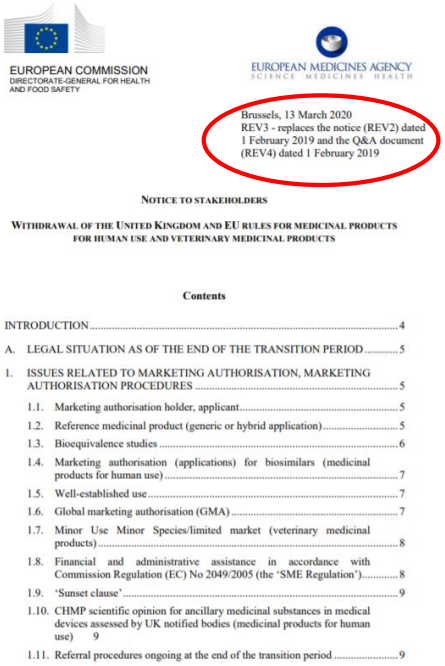
- **EC, EMA and HMA** published **Notices, guidance to MAHs** of centrally and Nationally authorised medicines products for human and veterinary use and held many industry interested parties meetings since **May 2017**

Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use

The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that unless a ratified withdrawal agreement[1] establishes another date, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET).[2] The United Kingdom will then become a 'third country'.[3]



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Brussels, 13 March 2020
REV3 - replaces the notice (REV2) dated 1 February 2019 and the Q&A document (REV4) dated 1 February 2019

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES FOR MEDICINAL PRODUCTS FOR HUMAN USE AND VETERINARY MEDICINAL PRODUCTS

Contents

- Companies have been reminded to **plan in advance in order to avoid any impact on the continuous supply of medicines** for human and veterinary use within the Union (EEA).

  Latest update March 2020 includes sections B. and C. on provisions of th Withdrawal Agreement and applicable rules in Northern Ireland after the end of the transition period (March 2020)

UK's withdrawal from the EU-preparedness preparedness activities at EMA

- EMA continues to track and monitor all Brexit-affected CAPs
- EMA prepares for required changes to the EMA IT databases and systems at the end of the transition period
- EMA is introducing the required adjustments to EMA's internal processes in view of the implementation of the IE/NI Protocol and the end of the transition period
- Additional 'practical' guidance for companies considered
- Further communication activities are planned

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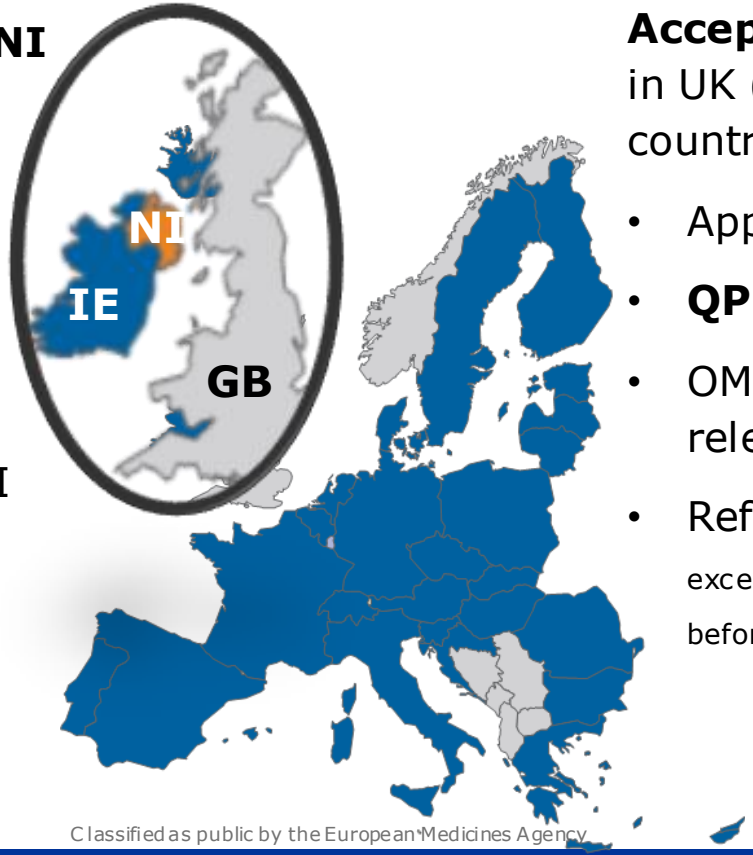
Centrally Authorised Products

Acceptable in EU/EEA and NI but not GB and other 3rd countries:

- Manufacturers responsible for importation, batch control testing and batch release
- Local representatives for NI
- Parallel distributors and \ re-packagers



Acceptable in EU/EEA but not in UK (incl. NI) and other 3rd countries:

- Applicant/ MAH
- **QPPV and PSMF**
- OMCL for official batch release
- Reference products (certain exceptions for products authorised in UK before 1.1.2021, see guidance)

Centrally Authorised Products: Status update

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- **Most MAHs have made the necessary changes** and are now ready to be regulatory compliant after 31 December 2020
- **All MAH transfers have been submitted** for authorised CAPs and therefore there are no CAPs with a MAH in the UK
- A number of CAPs for which changes to the QPPV, PSMF or manufacturing sites (where batch release, batch control testing and/or importation currently are only authorised for UK sites) **are still pending**, but these **changes are only required to be implemented by the end of the transition period**

Contents

EMA has sent a communication to the MAHs of these CAPs in September to remind them of the need to update the Art 57 database before 31 December 2020 (feedback awaited, reminder sent in October)

- MAHs only need to update the QPPV and/or PSMF in the Art 57 database- (no variation required)

Impact on the UK and its involvement

- UK already **does not participate** in EU decision making – no change
- After 31.12.2020 UK will **not be able to trigger a referral**
- UK's access to EMA **IT systems and databases** more limited
- UK **nationally authorised products** with respect to Northern Ireland (but not with respect to the rest of UK) have to comply with EU Law, which means they continue to be included in referral, PSUSA and PASS procedures, as applicable, with related fee liability

Impact on EMA IT systems and databases (1/2)

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EMA Impact assessment and preparedness on-going:

- Correct representation of UK(NI) new status in all EMA systems and system outputs (e.g. templates etc.) and necessary adjustments to technical validation rules to reflect the new status pertaining to entities located in UK(NI);

Industry Impact and preparedness :

- Change on **ICSR reporting in Eudravigilance for Applicants/MAHs** i.e.
  - →For Post-marketing cases: ICSR arising in UK(NI), EU/EEA reporting rules will apply and for those arising in UK(GB), 3rd country reporting rules will apply.
  - →For Clinical Trials (CT) cases: ICSRs arising in UK (NI/GB), 3rd country reporting rules will apply as CT not part of IE/NI Protocol

- Access to register users will remain in place for organisations that have PhV reporting obligations

Impact on EMA IT systems and databases (2/2)

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Industry Impact and preparedness (Cont'd):

- **Update to Article 57 QPPV database** to be made by QPPVs (or person delegated within the Company) to change UK to UK(NI), where applicable
  - **QPPVs to** update the **country location** with the **new ISO code (XI) between 15/12/2020 until 31/01/2021** for data related to **QPPVs location, MAHs location and MA validity in UK/NI**

- Process for **NAPs for PhV fee calculations to include UK(NI) NAPs**:

  - Current UK QPPVs should be located in EU/EEA (including UK(NI)) for EU/EEA+UK(NI) marketing authorisation in order to **receive the advice note**;
  - MAHs should be **located** in EU/EEA (**including UK/NI**) with a **UK/NI valid MA**: they will be **liable to pay the PHV fee**

UK's withdrawal from the EU - Communication

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Guidance for companies

Brexit-related guidance for companies

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The United Kingdom (UK) formally left the European Union (EU) on 31 January 2020 and became a third country. A transition period began on 1 February 2020, during which EU pharmaceutical law remains applicable to the UK. This is due to end on 31 December 2020.

Since 2017, the European Medicines Agency (EMA) and the European Commission have been providing guidance to help pharmaceutical companies responsible for both human and veterinary medicines prepare for the consequences of Brexit.

To Be Updated Soon

UK Withdrawal updates web link: https://www.ema.europa.eu/en/about-us/brexit-uk-withdrawal-eu/brexit-related-guidance-companies

EMA 25 years

Any questions?

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