EUDRAC

QUALITY FOR SUCCESS

BREXIT Update

Supply Chain Manufacturing

No Deal Scenario

17 September 2020

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Key Changes Since 2019 Guidance

- Transition period ends 31 Dec 2020
- Guidance now refers to Great Britain (GB) i.e. Northern Ireland (NI) excluded which will follow EMA route, i.e.
  - NI will continue to align with all relevant EU rules relating to the placing on the market of manufactured goods
  - Not currently reflected in EMA documentation

Information Sources

- EMA - https://www.ema.europa.eu/en/about-us/brexit-united-kingdoms-withdrawal-european-union
- CMDh - https://www.hma.eu/535.html
- MHRA - https://www.gov.uk/government/collections/mhra-post-transition-period-information
- HPRA - https://www.hpra.ie/homepage/about-us/stakeholders/brexit/brexit---latest-information
- MMA - http://www.medicinesauthority.gov.mt/brexit

Agenda

- Active Substances
  - MAA requirements
  - Import/Export
- Import/Export of Medicines
  - Wholesale Dealer Authorisations (WDA)
    - Responsible person for Importation (RPi)
  - QC testing & QP Certification/Batch Release
- Import/Export of Investigational Medicinal Products

MAA requirements

- **Active substances - CEPs**
  - MHRA will continue to accept Certificates of Suitability (CEPs) issued by EDQM
    - Issuing body is independent from the EU (EDQM is part of Directorate of the Council of Europe)
    - UK will remain a member of the Council of Europe and signatory to the Convention on the elaboration of a European Pharmacoepia (Ph. Eur.)

MAA requirements

- **Active substances - ASMF**
  - MHRA will continue to accept Active Substance Master Files (ASMFs)
    - No longer part of EU worksharing procedures so ASMF will be assessed independently by MHRA
    - MHRA will take into account ASMF assessment by EU MS prior to Jan 2021
    - Submission requirements and timelines remain as per CHMP guideline (CHMP/QWP/227/02 Rev 4)

Import of medicines

- **Active substances**
  - GB will continue to accept importation from same countries as currently:
    - EEA, USA, Japan, Brazil, Australia, Israel, Republic of Korea and Switzerland
    - For all other countries, the competent authority will need to issue written confirmation of GMP oversight
  - EU will consider GB as a "third-country"
    - "Written confirmations" will be generated for GB Active Substance manufacturers
      - Will be required for shipment of each batch of Active Substance to EEA
      - Will be published on MHRA website

Import of medicines

- **Medicinal Products**
  - Wholesale Dealer Authorisations (WDA) remain in force from Jan 2021
    - Within 6 months, must notify MHRA of intention to continue current importation activities
    - Within 2 years must appoint a Responsible Person for import (RPi) and all new WDA applications from Jan 2021 must include an RPi
  - RPi is responsible for confirming QP certification has taken place
    - Applies to medicinal products imported from countries on the approved *country for import* list - currently EEA only

Import of medicines

- **Medicinal Products**

  - RPi oversight is required for importation of
    - UK or GB licensed medicine for use in GB or supply to another third country
    - NI or approved country for import licensed medicine for supply to fulfil special clinical needs
    - NI or approved country licensed medicine imported as an introduced medicine (formerly import for export) for supply to another third country
    - NI or approved country licensed medicine for use as a parallel import

Import of medicines

- **Medicinal Products**

  - Exemptions to requirement for RPi apply
    - If the medicine imported is not licenced in the UK or the listed country and is

    either
    - Intended for use as a special medicinal product

    or
    - To be exported by the importer as an introduced medicine

Import of medicines

- **Medicinal Products**

  - UK will continue to recognise batch testing and QP certification from same countries as currently
    - QP Certification: EEA
    - Batch Testing: EEA, Australia, Canada, Israel, Japan, New Zealand, Switzerland, USA

Import of medicines

- **Medicinal Products**
  - EMA required MAHs to specify importer and batch control site in the EEA by 01 January 2020
  - GB considered a third country - supply chains including GB shipment/storage/distribution sites have additional requirements

Import of medicines

- **Medicinal Products “in transit” via GB**

- Treated as being imported from a “third country”

  so

- Must be received by company with a Manufacturers Authorisation and QP-certified before sale

  so

- Need to find an alternative supply chain avoiding GB distribution/storage

  or

- Use current EU QP certification and supply transport records to support re-certification of product following shipment

Import of medicines

- **Investigational Medicinal Products**
  - GB will require Manufacturing and Import Authorisation MIA(IMP)
    - IMPs can be QP certified in a listed country (EEA)
    - These IMPs will not require re-certification in the UK before release to a trial, but QP oversight at the MIA(IMP) holder is required
      - 1 year transition period to implement oversight system following EXIT day
    - IMPs coming to GB from NI are exempt from this requirement
  - EMA will require EU QP to certify the batches of IMP

Joint labelling

- **HPRA, MMA and MHRA**
  - Draft guidance indicates they are still willing to accept joint packs
  - Not clear if EMA will accept eg trilingual pack with GB MA details for eg Orphan Medicines
    - Seems unlikely given EU stance on other areas but not yet clear from guidance