Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

UK’s exit from the EU

David Churchward, Expert GMDP Inspector, MHRA

Agenda

- Background
- Marketing Authorisations and Certificates
- UK supply chain
- Inspection
- International network

Background

- UK will exit the EU on 29 March 2019
  - Full participation in the EU regulatory network until exit
  - Close future regulatory partnership desired
- Focus remains on negotiating a withdrawal agreement
  - Implementation period (no change) until end 2020
- Responsibility to prepare for all scenarios, including ‘no deal’
  - Legislation prepared
    - Changes only to address new risks
  - Detailed Technical Guidance
  - Information exchange: new submissions and publishing portal for UK.

Product authorisations and certificates

- Clinical Trials
  - Continued participation in multinational trials
- Marketing Authorisations
  - UK legal presence for MAH
  - Grandfathering CAPs
  - New assessment procedures (targeted, accelerated, rolling)
  - Packaging
- Certificates of Pharmaceutical Product
- Recognition of existing Devices approvals
  - Registration in UK after exit day.

UK Supply chain

- Maintaining patient access
- Recognition of existing partners QC, QP and inspection arrangements
- ‘Listed countries’
- Importation into the UK
  - Authorised products
    - Wholesaler importation from listed countries
    - ‘Responsible Person (import)’
  - Investigational Medicinal Products
    - Direct to UK CT site
    - Supply chain oversight by UK QP
- Written Confirmation for API exports from UK to EEA.

Inspections

- Risk based programme
- UK and third country
- Continued integration into PIC/S and ICMRA work sharing initiatives
- GMP certificates for UK & EU MA submissions.

International network

- Close future alignment with EU regulatory system
- Continued participation in the PIC/S network
- Mutual recognition agreements and bilateral working
- Continued participation in international harmonisation initiatives
  - ICH, ICMRA, IPRP
- Council of Europe conventions unaffected
  - Pharmacopoeia, EDQM.

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Thank you

David.Churchward@mhra.gov.uk

Medicines & Healthcare products Regulatory Agency