UK’s exit from the EU

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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.
Thank you

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