Medicines & Healthcare products Regulatory Agency

EU exit transition guidance

CPRD NIBSC MHRA

Guidance

- Published 1 September 2020
- 31 items of guidance relating to regulation of medicines and medical devices in GB from 1 January 2021
- NI to follow the EU medicines regulatory system
  - Further guidance on Northern Ireland and Unfettered Access regulation to follow
- Engagement with industry trade associations scheduled for detailed review exercise
- Additional webinars planned for industry Q&A when all guidance published.

Clinical Trials

- MHRA CTU will assess/authorise CTA applications for UK (NI and GB)
- The sponsor or legal representative of a clinical trial can be in the UK or a country on an approved country list which would initially include EU/EEA countries.
- Preparation of a CTA application post transition will be via IRAS (as is currently possible).
- Submission of a CTA application post transition will be via the new MHRA portal for standard applications and via IRAS for CWoW applications.
- You should continue to use existing and established international registers so the public is aware of the trial.
- You should publish your summary results within these timeframes in the public register (or registers) where you have registered your clinical trial.

Marketing Authorisations – (1)

- Applications pending in CAP, MR/DC procedures or referrals - completed as nationals taking account of stage of assessment already completed. Positive CHMP opinion recognised.
- Conversion of CAPs to GB MAs - MHRA will be in touch with each MAH (as before)
  - 21 days after end of Transition to opt out of conversion to GB MAs
  - Baseline submission of current data needed within 12m or at next variation
  - Establish UK MAH within 24 months
  - IP protection dates retained
- Four pieces of guidance to follow:
  - Routes to Market in UK/GB
  - Handling Variations
  - Orphan Medicinal Products – UK designation
  - Handling pending MR/DC Applications

Marketing Authorisations – (2)

- Current EU Guidance “copied over” including variations classification rules, classification of ATMPs
- Exceptions:
  - Reference Medicinal Product – needs to be UK RMP (pending applications based on ERP remain valid)
  - Comparator Products (CP) for BE/TE testing - for applications to GB (only) acceptable CP widened to include non-GB (or EU products) providing the CP is shown to be representative of GB product
- EDQM CEPs are unaffected
- UK will be able to issue MAs granted under exceptional circumstances and Conditional MAs

Pharmacovigilance

- Guidance covers pharmacovigilance data/procedures including UK and non-UK Individual Case Safety Reports (ICSRs), Periodic Safety Update Reports (PSURs), Risk Management Plans (RMPs) and Post-Authorisation Safety Studies (PASS) to be submitted to the MHRA
- Guidance on QPPV and PSMF to be issued shortly
- Good Vigilance Practice (GVP) modules will remain in force (exceptions and modifications will be published in due course
- Continue to accept EU versions of RMPs and PSURs (UK specific annexes)
- Some replacement systems –ICSRs and PSURs
- Major safety reviews to replace safety referrals

Manufacture and supply

- No changes to manufacturing authorisation requirements (QPs etc)
- Active Substances Written Confirmation scheme for supply to EEA and NI
- Medicines QP certified in listed countries will not require re-certification in GB
- Wholesalers may source authorised products for GB market from ‘listed countries’ if QP certified. Responsible Person (Import) required.
  - 6 month period for notification; 2 year period to name RPI
  - Registration scheme for RPI candidates
- Investigational Medicinal Products may be supplied direct to CT sites in GB, if QP certified in a listed country
  - UK MIA(IMP) oversight of supply chain; 12 month period to implement

Medical Devices

- CE marking – 2.5 years
- Registrations of all devices – grace period
- UK Responsible Persons
- Authorised representatives

- UKCA marking
- UK Approved Bodies – can issue new UKCA certificates and existing certificates ‘roll over’

- MDR / IVDR will not apply