Brexit Bullets

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29 March 2019?? – 11pm

Overall

On Exit	Deal (Transition Period)	No-Deal
• EU Regulations - transposed into UK law by EU (Withdrawal) Act. • UK legislation implementing EU Directives - remain in force	• Withdrawal Agreement applies, plus supporting legislation • UK Courts - to *have regard* to European courts' decisions	• If not covered by a wider international treaty - would have to be agreed between EU and UK • UK can unilaterally implement laws in the UK

Patents

Mainly no change - EPC

Supplementary Protection Certificates/Paediatric Extensions

- Patents (Amendment) (EU Exit) Regulations 2018 - *the earliest of any EEA authorisation, the granting of which predates the granting of the UK authorisation*

Unitary Patent

Other IP Issues

- TMs/designs - Automatic entry of existing rights onto UK register – seniority retained
- Database rights - equivalent enforceable rights maintained in UK
- Copyright – unaffected
- Exhaustion - in EU and UK during Transition Period

Regulatory – Medicines – No Deal

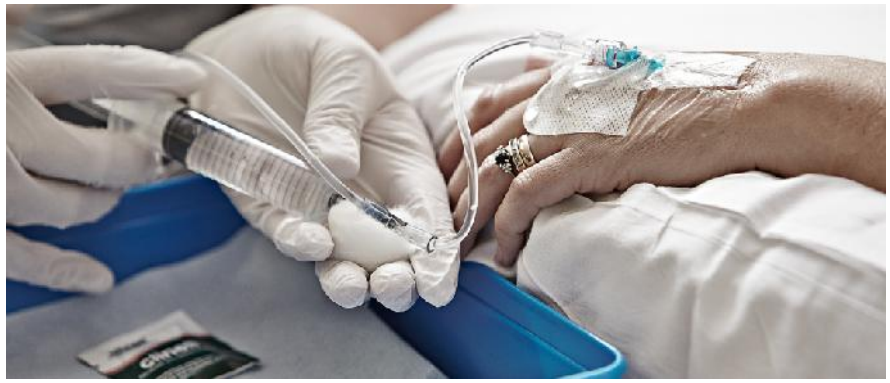
- **Marketing Authorisation (MA)** - Centrally Authorised Product becomes UK MA
- **Undecided EU procedures** will not be valid in UK but MHRA *will take EU decisions into account where possible*
- **Data/market exclusivity** – no changes proposed - start of exclusivity is date of authorisation in EU or UK, whichever is earlier
- **Generic applications** based only on UK authorised reference products
- **Legal presence**
  - MA holder (MAH)/ Qualified Persons (QP) batch release/pharmacovigilance (PV)/ Orphan drug sponsor/ Clinical trial sponsor
  - MAH in UK by end of 2020/QPPV immediately (EU QPPV allowed until end of 2020)

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

Regulatory – Clinical Trials – No Deal

- Existing regulatory/ethics approvals automatically recognised
- Sponsor/legal representative in UK or other approved country
- IMP QP certification in approved country accepted
- 2004 Regulations continue to apply (slightly modified)
- Commitment to align with new EU Clinical Trials Regulation

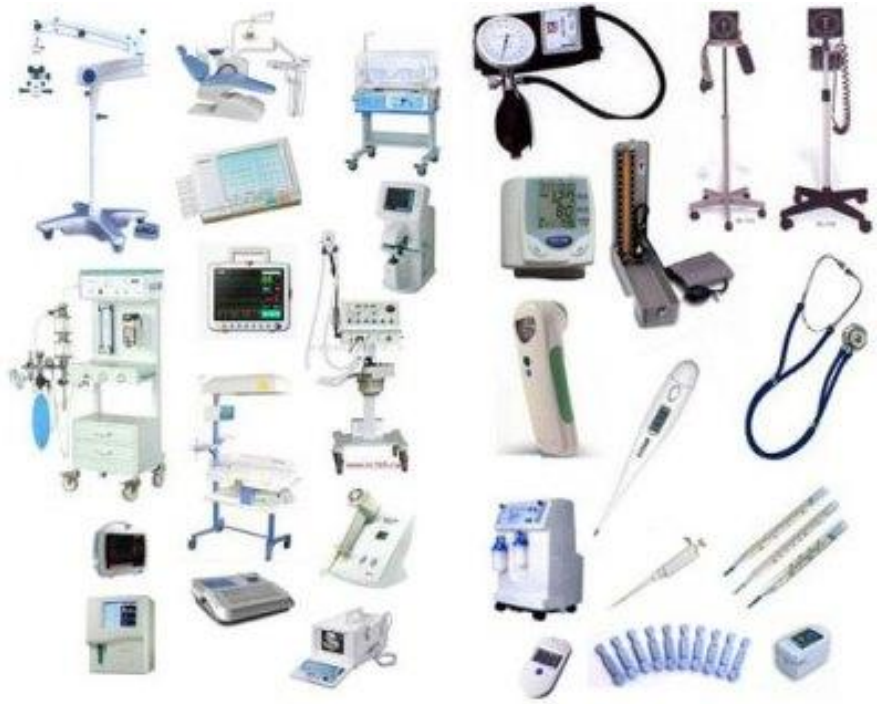
The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019



Regulatory – Medical Devices – No Deal

- UK will mirror key elements of Medical Devices Regulation/ In Vitro Diagnostic Regulation
- CE-marked devices accepted in UK (time limited)
- UK-based Notified Bodies no longer able to assess conformity for CE mark

The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019



Useful Links

https://www.ema.europa.eu/en/about-us/uks-withdrawal-eu/brexit-related-guidance-companies

https://www.gov.uk/government/collections/mhra-guidance-and-publications-on-a-possible-no-deal-scenario

https://www.gov.uk/government/news/contingency-legislation-covering-regulation-of-medicines-and-medical-devices-in-a-no-deal-scenario

https://www.gov.uk/guidance/technical-information-on-what-the-implementation-period-means-for-the-life-science-sector

https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal

Thank you

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