EU guidance documents referred to in the Human Medicines Regulations 2012

Links to EU guidance (the version in force immediately before exit day) which is specifically referred to in the Human Medicines Regulations 2012.

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Leaving the EU with a deal remains the Government's top priority. This has not changed. However a responsible government must plan for every eventuality, including a no deal Brexit.

In the event of the UK leaving the EU with no deal the Government has put in place legislation to allow the continued sale of and access to medicines. This has been done by amending the Human Medicines Regulations 2012 to the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019.

The 2012 Regulations set out a comprehensive regime for the authorisation of medicinal products for human use; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance. They also provide for enforcement powers for the authorisation and supervision of medicinal products for human use.

The amendments to the 2012 Regulations address the fact that the UK will no longer be part of the harmonised EU medicines network following exit day in a no deal scenario.

They replicate the current arrangements so far as possible but also make appropriate changes to reflect the fact that the Medicines and

Healthcare products Regulatory Agency is acting as a stand alone regulator outside the EU network.

Part of maintaining the current position involves continued reliance on EU guidance documents. Where existing EU law refers to various pieces of EU guidance, those references are inserted into the 2012 Regulations. The relevant version of the EU guidance is the version as it stood immediately before exit day, which can be accessed below.

EU guidance

Good Manufacturing Practice

Good Manufacturing Practice including for active substances and IMPS, and formalised risk assessment regarding excipients, and good distribution practice (Regulation C17(3)).

Guidelines to Good Manufacturing Practice requirements for Active Substances (PDF, 599KB, 49 pages)
Guidelines to Good Manufacturing Practice requirements for and Investigational Medicinal Products (PDF, 66.8KB, 19 pages)
Guideline on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use (PDF, 314KB, 4 pages)
Good Distribution Practice for medicinal products for human use (PDF, 810KB, 14 pages)

Guidance on applications for Marketing Authorisations

See the list of EU guidance in Regulation 50(5C) (part of Notice to Applicants on Common Technical Document, scientific guidelines and active substance guidelines).

(a) Medicinal products for human medicines (PDF, 1.01MB, 303 pages)

(b) The scientific guidelines relating to the quality, safety and efficacy of medicinal products as adopted by the Committee for Medicinal Products for Human Use and published by the EMA.
(c) Guidelines published by the EMA for the purposes of paragraph 3.2.1.2 of Part I of Annex I to the 2001 Directive on Manufacturing process of the active substance(s).

Guidelines specifying the criteria to be met by generic medicinal products for the purpose of omitting bioavailability studies from an application (Regulation 51(7)).

Guidelines on the investigation of bioequivalence (PDF, 232KB, 27 pages)

Guidelines concerning the type and quantity of supplementary data to be provided by a bio-similar applicant for an MA (Regulation 53(2C)).

Guideline on similar biological medicinal products (PDF, 121KB, 7 pages)

Variation Guidelines (Regulation 65C(6))

Commission regulation concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (PDF, 99.8KB, 18 pages)
Guidelines on the details of the various categories of variations (PDF, 1.79MB, 84 pages)

Guidance on packaging and leaflets (Regulation 257D(2))

Guidance on packaging and leaflets (PDF, 118KB, 27 pages)
Annex to the European Commission guideline on Excipients in the labelling and package leaflet of medicinal products for human use (PDF, 222KB, 25 pages)

Guidance on inspections (Regulation 331A(3))

Compilation of Community Procedures on Inspections and Exchange of Information (PDF, 1.49MB, 253 pages)