DRAFT STATUTORY INSTRUMENTS

2019 No.

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

Amendment of regulation 20 (authorisation procedure for clinical trials involving medicinal products with special characteristics)

9. In regulation 20(1)(a), for paragraph (i) substitute—

"(i) which do not have a marketing authorization and are developed by means of one of the following biotechnological processes—

(aa) recombinant DNA technology,

(bb) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells,

(cc) hybridoma and monoclonal antibody methods, or".