

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made in exercise of the powers conferred by section 8(1) and 8C of the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b), (c), (d), (f) and (g) and (6)) arising from the withdrawal of the United Kingdom from the European Union and to make provision in connection with the Protocol on Ireland/Northern Ireland in the withdrawal agreement. They are also made under paragraphs 1(1) and 7(2) of Schedule 4 to the European Union (Withdrawal) Act 2018, insofar as they make provision in relation to fees, and paragraph 21 of Schedule 7 in relation to consequential and transitional arrangements.

These Regulations make amendments to legislation in the field of the regulation of medicinal products for human use. The majority of the instrument (regulation 4 and Schedule 2) amends the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775) which itself amends the Human Medicines Regulations 2012 (S.I. 2012/1916) and the Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I. 2016/190). Regulation 3 and Schedule 1 amend the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744) which itself amends the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031). Regulation 2 amends the Good Laboratory Practice Regulations 1999 (S.I. 1999/3106), and regulation 5 and Schedule 3 amend the Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385) to remove superseded provisions.

An impact assessment of the effect that this instrument will have on the costs of business, the voluntary sector and the public sector is available from the Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU and is published alongside this instrument at [www.legislation.gov.uk](http://www.legislation.gov.uk).