

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c. 16) and amend the Medicines for Human Use (Clinical Trials) Regulations 2004 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.

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.