SCHEDULES

SCHEDULE 2

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 2

Amendment of Part 3 (amendment of Part 3 (manufacture and distribution of medicinal products and active substances))

26. In regulation 36 (amendment of regulation 45 (requirement as to responsible persons))—

(a) for paragraph (2) substitute—

"(2) After paragraph (1) insert—

"(1A) In respect of a licence holder in Great Britain, paragraph (1) is subject to regulation 45AA.".";

(b) for paragraph (3) substitute—

"(3) For paragraph (2)(b) substitute—

"(b) ensuring that the quality of medicinal products handled by the licence holder is being maintained in accordance with the requirements of—

(i) in the case of a licence holder in Great Britain, the UK marketing authorisations, certificates of registration or traditional herbal registrations, and

(ii) in the case of a licence holder in Northern Ireland, the marketing authorisations, Article 126a authorisations, certificates of registration or traditional herbal registrations,

applicable to those products."."