DRAFT STATUTORY INSTRUMENTS

2022 No.

The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022

Amendment of regulation 41

- 6. In regulation 41(1) (requirements as to qualified persons), after paragraph (11) insert—
 - "(12) The licence holder is not obliged to meet the requirements of this regulation in relation to any activities under the licence which relate to EAMS medicinal products, unless the conditions attached to the scientific opinion in respect of that product in accordance with regulation 167C(2)(c) provide otherwise."