DRAFT STATUTORY INSTRUMENTS

2021 No.

The Human Medicines (Amendment etc.) (EU Exit) (No. 2) Regulations 2021

PART 2

Amendment of the Human Medicines Regulations 2012

Amendment of regulation 60B (submitting of samples and other information: EU marketing authorisations)

11.—(1) Regulation 60B(**1**) is amended as follows.

(2) In paragraph (1), in the definition of "the batch testing exemption", in paragraph (b)(ii), after "United Kingdom" insert "or the European Union"

(3) In paragraph (2)(a), in each place where it occurs, for "immunological product" substitute "immunological medicinal product".

(**1**) Regulation 60B was inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).