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))

22. In regulation 32 (amendment of Schedule 7 (qualified persons))—

(a) after paragraph (3)(a)(i) insert—

"(ia) for "The qualified person" substitute " In Great Britain, the qualified person ";";

(b) in paragraph (3)(a)(ii), before sub-paragraph (aa), insert—

"(zaa) for "the United Kingdom" substitute " Great Britain ";";

(c) in paragraph (3)(a)(iii)(aa) after "medicinal products imported from" insert " a country other than Northern Ireland or ";

(d) after paragraph (3)(a) insert—

"(aa) after paragraph 12 insert—

"**12A.**—(1) In Northern Ireland, the qualified person is responsible for securing—

(a) that each batch of medicinal products manufactured in Northern Ireland has been manufactured and checked in accordance with these Regulations and the requirements of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to those products; and

(b) in the case of medicinal products imported from a country other than an EEA State, irrespective of whether the products have been manufactured in Northern Ireland or an EEA State, that each batch has undergone—

(i) a full qualitative analysis,

(ii) a quantitative analysis of all the active substances, and

(iii) all other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to those products; and

(c) in the case of medicinal products, other than radiopharmaceuticals, that are required to bear safety features pursuant to Article 54a of the 2001 Directive and not intended to be exported to a country other than an

EEA State, that the features specified in paragraph 18A of Schedule 24 have been affixed on the packaging.”.”;

(e) for paragraph (3)(b) substitute—

“(b) in paragraph 13—

(i) in sub-paragraph (1) after “This paragraph applies” insert “ in Northern Ireland ”;

(ii) in sub-paragraph (1)(a) for “paragraph 12 in another member State is imported to the United Kingdom” substitute “ paragraph 12A in a member State is imported to Northern Ireland ”;

(iii) in sub-paragraph (2) for “12” substitute “ 12A ”;”;

(f) in paragraph (3)(c)—

(i) for paragraph (i) substitute—

“(i) in sub-paragraph (1)(a) after “are imported” insert “into Great Britain from a country other than an approved country for import or into Northern Ireland;”;

(ii) for paragraph (ii) substitute—

“(ii) for sub-paragraph (1)(b) substitute—

“(b) appropriate arrangements have been made, in the case of import into Great Britain by the licensing authority with the country from which those products are imported and, in the case of a product for import into Northern Ireland by the European Union with that country, to ensure that—

(i) the manufacturer of the medicinal products applies standards of good manufacturing practice at least equivalent to those laid down—

(aa) in the case of a product for sale or supply in Great Britain, in the Good Manufacturing Practice Directive, as supplemented by the guidelines and principles which apply under, or by virtue of, regulation C17, and

(bb) in the case of a product for sale or supply in Northern Ireland, by the European Union;

(ii) the controls referred to in paragraph 12(b) or 12A(b) (as appropriate) have been carried out in that country.”.”;

(iii) after paragraph (ii) insert—

“(iia) in paragraph (2) after “paragraph 12” insert “ or 12A ”.”.

Commencement Information

I1 Sch. 2 para. 22 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, Paragraph 22.