STATUTORY INSTRUMENTS

2019 No. 775

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 3

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

Insertion of new regulation 18A (approved country for import)

16. After regulation 18, insert—

"**Approved country for import**

18A.—(1) The licensing authority must—

(a) publish a list of countries from which medicinal products may be imported under a wholesale dealing licence ("approved country for import list"); and

(b) only include in that list a country which is included in the approved country for batch testing list.

(2) In order to determine whether a country should be included in the approved country for import list, the licensing authority may, in particular, take into account—

(a) the country's system for ensuring that each batch of a medicinal product has been manufactured and checked in accordance with the requirements of its legislation and any authorisation in respect of that product;

(b) the country's rules for good distribution practice;

(c) the regularity of inspections to verify compliance with good distribution practice;

(d) the effectiveness of enforcement of good distribution practice;

(e) the regularity and rapidity of information provided by that country relating to non-compliant manufacturers and distributers of medicinal products;

(f) any on-site review of that country's regulatory system undertaken by the licensing authority;

(g) any on-site inspection of a manufacturing site in that country observed by the licensing authority; and

(h) any other relevant documentation available to the licensing authority.

(3) The licensing authority must—

(a) remove a country from the approved country for import list if that country is removed from the approved country for batch testing list;

(b) in any event review the countries it has included in the approved country for import list to determine if it is still satisfied that the country should remain on that list, and if it is not so satisfied, remove that country from the list; and

(c) undertake that review at least every three years beginning with the date on which that country is included in that list.".

Commencement Information

I1 Reg. 16 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 16.