DRAFT STATUTORY INSTRUMENTS

2019 No.

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 regulations 45AA and 45AB (responsible persons: import)

37. After regulation 45, insert—

"**Requirement as to responsible persons where licence holder imports from an approved country for import**

45AA.—(1) Subject to paragraph (2), this regulation applies where the licence holder imports a medicinal product from an approved country for import under a wholesale dealer's licence.

(2) The requirements of this regulation do not apply where an unlicensed medicinal product falling under paragraph (1) is imported—

(a) from an approved country for import for the sole purpose of distribution by way of wholesale dealing as a special medicinal product; or

(b) for the sole purpose of wholesale distribution of that product to a person in a country other than an approved country for import.

(3) The licence holder must ensure that there is available at all times at least one person (referred to in this regulation as the "responsible person (import)") whose name is included in the register established under regulation 45AB.

(4) A responsible person (import) must—

(a) carry out the functions under regulation 45(2), unless a responsible person under regulation 45 is performing those functions in respect of the licence; and

(b) ensure that there is appropriate evidence to confirm that each production batch of a medicine imported from an approved country for import under the licence has been certified as provided for in Article 51 of the 2001 Directive, or such equivalent certification procedure as applies in the approved country for import.

(5) The licensing authority must publish guidance on the documentation that it considers to be appropriate evidence for the purposes of paragraph (4)(b).

(6) Guidance published under paragraph (5) may be taken into account by the licensing authority in determining whether it considers there has been a failure to comply with this regulation.

(7) The licence holder must apply to vary the licence if a change is proposed to the responsible person (import).

(8) The licence holder must not permit any person to act as a responsible person (import) other than the person named in the licence.

(9) Paragraph (10) applies if—

(a) the person acting as responsible person (import) in respect of the licence is no longer included in the register under 45AB;

(b) the licensing authority thinks, after giving the licence holder and a person acting as a responsible person (import) the opportunity to make representations (orally or in writing), that the responsible person (import) is failing to carry out the functions referred to in paragraph (4) adequately or at all.

(10) Where this paragraph applies the licensing authority—

(a) must notify the licence holder in writing that the person is not permitted to act as a responsible person (import) in respect of that licence; and

(b) may, subject to regulation 45AB(3)(b), remove that person's name from the register under regulation 45AB.

(11) In this regulation, "unlicensed medicinal product" means a medicinal product in respect of which—

(a) there is no marketing authorisation, within the meaning of the 2001 Directive, in any EEA State in respect of that product, where the product is imported from an approved country for import that is an EEA State; or

(b) there is no licence or authorisation in respect of that product as regards its sale or supply in the approved country for import, where the product is imported from an approved country for import that is not an EEA State.

Register for responsible persons (import)

45AB.—(1) The licensing authority must maintain a register of persons ("the responsible person (import) register") who may carry out the role of responsible person (import) under regulation 45AA.

(2) The licensing authority may only include a person's name in the responsible person (import) register if that person—

(a) holds—

(i) a diploma, certificate or other evidence of formal qualifications awarded on completion of a university or other higher education course of study in pharmacy, chemistry, medicine, biology or a related life science, or

(ii) such other qualification as the licensing authority is satisfied is equivalent;

(b) is a member of—

(i) the Royal Society of Biology,

(ii) the Royal Pharmaceutical Society,

(iii) the Pharmaceutical Society of Northern Ireland,

(iv) the Royal Society of Chemistry, or

(v) such other body as may be specified by the licensing authority for the purpose of this paragraph; and

(c) has a minimum of 2 years' experience in performing the functions of a responsible person under regulation 45, or in performing such other functions that appear to the licensing authority to be equivalent.

(3) The licensing authority—

(a) may remove a person's name from the responsible person (import) register if it no longer considers that the person satisfies the requirements of paragraph (2); but

(b) it may not exercise that power unless it has given that person the opportunity to make representations to it (orally or in writing).".