STATUTORY INSTRUMENTS

2020 No. 1461

The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020

PART 3

Amendments to secondary legislation in Great Britain

The Veterinary Medicines Regulations 2013

4.—(1) The Veterinary Medicines Regulations 2013(**1**) are amended as follows.

(2) In regulation 4, after paragraph (4)(**2**) insert—

"(5) Schedule 1B (Northern Ireland qualifying good marketing authorisations) has effect.".

(3) For regulation 9(1) substitute—

"(1) No person may import, or move into Great Britain from Northern Ireland, a veterinary medicinal product authorised for use in Great Britain except in accordance with this regulation.".

(4) In regulation 25—

(a) in paragraph (6)(b)(iii), for "the United Kingdom" substitute "Great Britain";

(b) after paragraph (8) insert—

"(9) For the purposes of this regulation, references to the import or importation of an unauthorised veterinary medical product include the movement of such a product into Great Britain from Northern Ireland.".

(5) In regulation 26(4), for "the United Kingdom" substitute "Great Britain".

(6) Omit regulation 45.

(7) In Schedule 1—

(a) in the heading, at the end insert "in Great Britain";

(b) in paragraph 48(1)(i), after "authorisation holder" insert ", the local representative designated under paragraph 18 of this Schedule";

(c) in paragraph 58(1), for "the United Kingdom" substitute "Great Britain".

(8) After Schedule 1A insert—

(**1**) S.I. 2013/2033, to which there are amendments not relevant to these Regulations. It is prospectively amended by S.I. 2019/676, 865.

(**2**) Paragraph (4) of regulation 4 is prospectively inserted by S.I. 2019/865.

"SCHEDULE 1B Regulation 4(5)

Qualifying Northern Ireland good (QNIG) certificates

1. In this Schedule—

"QNIG certificate" means a certificate issued under paragraph 3;

"QNIG certificate holder", in relation to a QNIG certificate, means the person to whom that certificate was issued under paragraph 3;

"qualifying Northern Ireland goods" has the meaning given to it from time to time in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

"Northern Ireland VMRs" means the Veterinary Medicines Regulations 2013 as they have effect in Northern Ireland.

2. This Schedule applies to a veterinary medicinal product which is—

(a) a qualifying Northern Ireland good in respect of which there is a marketing authorisation valid in Northern Ireland under the Northern Ireland VMRs,

(b) not a product in respect of which there is a marketing authorisation which is valid in Great Britain (including any marketing authorisation which has effect under paragraph 3 of Schedule 1A),

(c) not a product in respect of which a QNIG certificate issued under this Schedule already applies, and

(d) not a product to which Article 41(1) of the EU withdrawal agreement applies.

3. If the condition in paragraph 4 is met in respect of the veterinary medicinal product, the Secretary of State must issue a QNIG certificate in respect of that product to the person who holds a marketing authorisation in respect of the product which is valid in Northern Ireland under the Northern Ireland VMRs.

4. The condition is that the person who holds a marketing authorisation in respect of the product which is valid in Northern Ireland under the Northern Ireland VMRs, who must be a person established in Northern Ireland, has provided the Secretary of State with the following information—

(a) the Northern Ireland address of that person;

(b) all necessary administrative information, and all scientific documentation necessary for demonstrating the safety, quality and efficacy of the veterinary medicinal product, equivalent to that which would need to be provided under Schedule 1 if an application for a marketing authorisation was to be made in respect of that product under paragraph 1 of that Schedule (allowing for any relevant derogations provided for in Part 2 of that Schedule);

(c) the name and address of a person who resides in the United Kingdom or in a member State who is to provide in respect of the veterinary medicinal product, permanently and continuously, the services of a qualified person (pharmacovigilance) for the purposes of Part 8 of Schedule 1.

5. A QNIG certificate has effect as if it were a marketing authorisation granted by the Secretary of State under these Regulations subject to the modification that the qualified person (pharmacovigilance) for the purposes of Part 8 of Schedule 1 is the person identified under paragraph 4(c).

6. The QNIG certificate holder must provide to the Secretary of State from time to time such further information as is appropriate to ensure that the information provided under paragraph 4 remains accurate and complete.

7. Without prejudice to any other power to suspend a marketing authorisation under Schedule 1, if the Secretary of State considers that a QNIG certificate holder is in breach of these Regulations

as modified by paragraph 5, or that the information provided in respect of the matters specified in paragraph 4 is no longer accurate or complete, the Secretary of State may by notice suspend the QNIG certificate.

8. The Secretary of State must publish any notice given under paragraph 7 in such manner as the Secretary of State considers appropriate from time to time.

9. Paragraphs 39 and 40 of Schedule 1 apply to the suspension of a QNIG certificate under paragraph 7 as they would to the suspension of such a certificate under paragraph 38 of that Schedule as read with paragraph 5.".

(9) In Schedule 5, in paragraph 28(b), for "the United Kingdom" substitute "Great Britain".

(10) In Schedule 7 omit paragraph 45.