Draft Regulations laid before Parliament under paragraph 8F(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2020 No. 0000

EXITING THE EUROPEAN UNION

FOOD, ENGLAND

FOOD, SCOTLAND

MEDICINES

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

Made - - - - ***

Coming into force in accordance with regulation 1(2)

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 8 and 8C(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**).

A draft of this instrument has been laid before Parliament and approved by resolution of each House of Parliament in accordance with paragraph 8F of Schedule 7 to that Act.

PART 1

Introductory

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020.

(2) These Regulations come into force—

(a) as regards this regulation and Part 2, immediately before IP completion day;

(b) otherwise, on IP completion day.

(3) Part 3 extends to Great Britain.

(**a**) 2018 c. 16. Section 8 was amended by section 27 of the European Union (Withdrawal Agreement) Act 2020 (c. 1) and paragraph 21 of Schedule 7 was amended by paragraph 53(2) of Schedule 5 to that Act. Section 8C was inserted by section 21 of that Act and paragraph 8F of Schedule 7 was inserted by paragraph 51 of Schedule 5 to that Act.

PART 2

Amendments to exit-related secondary legislation

The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019

2.—(1) The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019(**a**) are amended as follows.

(2) In regulation 1—

(a) in the heading, for "and commencement" substitute ", commencement and extent";

(b) at the end insert—

"(3) Regulation 17 and Schedule 8 extend to Great Britain.".

(3) In regulation 18(5)(a), in the substituted paragraph 1, for the words from "appropriate authority" to "State)" substitute "Secretary of State".

(4) In Schedule 8, in Part 2, in the first column of the new table, for "the UK authorised product", in both places it occurs, substitute "a product which is authorised for sale in the United Kingdom";

(5) In Schedule 9—

(a) in Part 1, in the substituted Article 8—

(i) in paragraph 1, for "appropriate authority" substitute "Secretary of State";

(ii) in paragraph 3, for "appropriate authority" substitute "Secretary of State";

(iii) in paragraph 4, for "appropriate authority" substitute "Secretary of State";

(iv) in paragraph 6, for "appropriate authority" substitute "Secretary of State";

(v) in paragraph 7—

(aa) for "appropriate authority" substitute "Secretary of State";

(bb) for "it" substitute "the Secretary of State";

(vi) omit paragraph 8;

(b) in Part 2, in the substituted Article 9(1), for "appropriate authority" substitute "Secretary of State";

(c) in Part 3, in the new Article 10(1C), for the words from "has the" to the end, substitute "means the Scottish Ministers or the Welsh Ministers";

(d) in Part 4, in the new Article 14A—

(i) in paragraph 1, for "appropriate authority" substitute "Secretary of State";

(ii) in paragraph 5, for "appropriate authority", in both places it occurs, substitute "Secretary of State".

The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019

3.—(1) The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019(**b**) are amended as follows.

(2) In regulation 1—

(a) in the heading, for "and commencement" substitute ", commencement and extent";

(b) at the end insert—

(**a**) S.I. 2019/865.
(**b**) S.I. 2019/676.

"(3) Regulation 3 extends to Great Britain.".

(3) In regulation 3—

(a) for paragraph (3) substitute—

"(3) For regulation 4(1) substitute—

"(1) No person may place a veterinary medicinal product on the market unless the Secretary of State has—

(a) as regards a product to which Schedule 1B applies, issued a QNIG certificate in respect of that product;

(b) otherwise, granted a marketing authorisation in respect of that product.".";

(b) in paragraph (9), in the inserted sub-paragraph (2A)—

(i) in paragraph (a), for "the United Kingdom" substitute "Great Britain";

(ii) in paragraph (b), for "national pharmacopoeia of the United Kingdom" substitute "British Pharmacopoeia";

(iii) in paragraph (d), for "exit day" substitute "IP completion day";

(c) omit paragraph (13)(c);

(d) omit paragraph (14);

(e) in paragraph (36)—

(i) for sub-paragraph (b) substitute—

"(b) in that sub-paragraph—

(i) in paragraph (a), for "the United Kingdom" substitute "Great Britain";

(ii) omit paragraphs (b) and (c);";

(ii) in sub-paragraph (c), in the inserted sub-paragraph (2), after "does not apply" insert "where the exporting country has demonstrated equivalent standards to the United Kingdom or".

(4) In regulation 6—

(a) omit paragraph (3);

(b) in paragraph (4)(b), in the substituted first paragraph, for "the United Kingdom" substitute "Great Britain";

(c) in paragraph (5)—

(i) in sub-paragraph (b), in the substituted paragraph 1, for "appropriate authority" substitute "Secretary of State";

(ii) omit sub-paragraph (d);

(d) in paragraph (6), in the substituted text, for "appropriate authority" substitute "Secretary of State";

(e) in paragraph (8), in the substituted Article 11, for "appropriate authority", in both places it occurs, substitute "Secretary of State";

(f) in paragraph (9), for "appropriate authority" substitute "Secretary of State";

(g) in paragraph (14)(a), for "appropriate authority" substitute "Secretary of State";

(h) in paragraph (17), in the substituted Article 21, for "appropriate authority" substitute "Secretary of State".

PART 3

Amendments to secondary legislation in Great Britain

The Veterinary Medicines Regulations 2013

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

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

"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,

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

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

(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.

PART 4

Amendments to secondary legislation in England and Scotland

The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015

5.—(1) The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015(**a**) are amended as follows.

(2) In regulation 2(1), for the definition of "maximum residue limit" substitute—

> ""maximum residue limit" means the maximum concentration of residue, or residues, resulting from the use of a veterinary medicinal product (expressed in µg/kg or µg/L on a fresh weight basis) that the Secretary of State has established in relation to a substance classified under Article 14 of Regulation 470/2009 as being necessary or appropriate for the protection of human health;".

(3) Omit regulation 18.

PART 5

Amendments to retained direct EU legislation

Commission Decision 2002/657/EC

6.—(1) Commission Decision 2002/657/EC implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (notified under document number C(2002) 3044) is amended as follows.

(2) In Article 1—

(a) in the first paragraph, for "Article 15(1), second sentence, of Directive 96/23/EC" substitute "relevant retained EU law";

(b) in the second paragraph, omit "Community".

(3) In Article 2, at the end insert—

"In this Decision—

"appropriate authority" means—

(a) as regards England, the Secretary of State;

(b) as regards Scotland, the Scottish Ministers;

(c) as regards Wales, the Welsh Ministers;

"relevant retained EU law" means—

(a) as regards England and Scotland, the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015;

(b) as regards Wales, the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Wales) Regulations 2019(**b**).".

(4) In Article 3, in the words before point (a)—

(a) for "Member States" substitute "appropriate authority";

(b) for "Directive 96/23/EC" substitute "relevant retained EU law".

(5) In Article 4, in the words before point (a), for "Member States" substitute "The appropriate authority".

(**a**) S.I. 2015/787, prospectively amended by S.I. 2019/676.
(**b**) S.I. 2019/569 (W.125).

(6) In Article 5—

(a) for "Member States" substitute "appropriate authority";

(b) for "Directive 96/23/EC" substitute "relevant retained EU law".

(7) Omit Articles 7 and 10.

Commission Regulation (EU) 2019/1871

7.—(1) Commission Regulation (EU) 2019/1871 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin is amended as follows.

(2) Omit Article 1(c).

(3) In Article 2, in the third paragraph—

(a) for "Commission" substitute "Secretary of State";

(b) omit the words from "European Reference" to "and".

(4) In Article 4—

(a) in paragraph 1, for "EFSA" substitute "the Food Standards Agency";

(b) in paragraph 2—

(i) for "Commission" substitute "Secretary of State";

(ii) for "EFSA" substitute "the Food Standards Agency";

(c) in paragraph 3 for "European and National Reference Laboratories" substitute "approved laboratories";

(d) after paragraph 3 insert—

"4. In paragraph 3, "approved laboratory" has the meaning given in—

(a) as regards England and Scotland, regulation 2 of the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015;

(b) as regards Wales, regulation 2 of the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Wales) Regulations 2019.".

(5) In Article 5—

(a) in the first paragraph, for "the Union" substitute "Great Britain";

(b) in the second paragraph—

(i) for "Union legislation" substitute "relevant retained EU law";

(ii) at the end insert "for reasons relating only to its non-compliance with the relevant provisions of relevant retained EU law";

(c) after the second paragraph insert—

"In this Article, "relevant retained EU law" means—

(a) as regards England and Scotland, the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015;

(b) as regards Wales, the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Wales) Regulations 2019.".

(6) In Article 6—

(a) in the first paragraph—

(i) for "competent authority" substitute "enforcement authority";

(ii) after "2017/625 and" insert "the retained EU law which transposed";

(b) in the second paragraph—

(i) for "competent authority" substitute "enforcement authority";

(ii) after "2017/625 and" insert "the retained EU law which transposed";

(c) in the third paragraph—

(i) for "competent authority", in both places it occurs, substitute "enforcement authority";

(ii) for the words from "shall inform" to the end substitute "must (in a case where the enforcement authority is not also the appropriate authority) immediately inform the appropriate authority and the enforcement authorities of the other constituent nations of Great Britain and the equivalent authority in Northern Ireland";

(d) in the fourth paragraph, for "Commission" substitute "Secretary of State";

(e) omit the fifth paragraph;

(f) after the fifth paragraph insert—

"In this Article—

"appropriate authority" means—

(a) as regards England, the Secretary of State;

(b) as regards Scotland, the Scottish Ministers;

(c) as regards Wales, the Welsh Ministers;

"enforcement authority" has the meaning given in—

(a) as regards England and Scotland, regulation 2 of the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015;

(b) as regards Wales, regulation 2 of the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Wales) Regulations 2019.".

(7) Omit Article 7.

(8) In Article 8—

(a) omit the first paragraph;

(b) in the second paragraph—

(i) omit the words from the beginning to "paragraph";

(ii) for "Union" substitute "United Kingdom".

(9) After Article 9 omit the words from "This Regulation" to "States.".

Commission Delegated Regulation (EU) 2019/2090

8.—(1) Commission Delegated Regulation (EU) 2019/2090 supplementing Regulation (EU) 2017/625 of the European Parliament and Council regarding cases of suspected or established non-compliance with Union rules applicable to the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or with Union rules applicable to the use or residues of prohibited or unauthorised pharmacologically active substances is amended as follows.

(2) In Article 1 omit "Union".

(3) In Article 2—

(a) in point (b), for the words from "which are" to "Regulation (EU) No 37/2010" substitute "the administration of which have been prohibited under Article 14(2)(d) of Regulation (EC) No 470/2009";

(b) in point (c)—

(i) in the second indent—

(aa) omit "Union";

(bb) omit "or, where appropriate, in national legislation";

(ii) in the second subparagraph—

(aa) in the first place it occurs, omit "Union";

(bb) omit "Union or national";

(c) in point (d) omit "Union";

(d) in point (e) omit "Union".

(4) In Article 3—

(a) in paragraph 3—

(i) in the first subparagraph, for "Directive 2001/82/EC" substitute "the Veterinary Medicines Regulations 2013";

(ii) in the second subparagraph omit "Union";

(b) in paragraph 4, in the third indent—

(i) for "Article 11 of Directive 2001/82/EC", in the first place it occurs, substitute "with paragraph 2 of Schedule 4 to the Veterinary Medicines Regulations 2013";

(ii) for "Article 11 of Directive 2001/82/EC", in the second place it occurs, substitute "that paragraph";

(c) in paragraph 5, for "Directive 2001/82/EC" substitute "the Veterinary Medicines Regulations 2013".

(5) In Article 4(3) omit "Union".

(6) In Article 6(3), in the second indent omit "Union".

(7) In Article 9—

(a) for "Member State", in each place it occurs, substitute "country";

(b) omit the last sentence.

(8) After Article 11 omit the words from "This Regulation" to "Member States".

Name
Parliamentary Under Secretary of State
Date Department for Environment, Food and Rural Affairs

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b) and (g)) arising from the withdrawal of the United Kingdom from the European Union and to reflect the Protocol on Ireland/Northern Ireland in the withdrawal agreement.

Part 2 amends exit-related legislation, Parts 3 and 4 amend domestic legislation and Part 5 amends retained EU legislation in the area of veterinary medicines and residues. The amendments in Part 3 include provisions facilitating the access to the market within Great Britain of qualifying Northern Ireland goods.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.

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