EXPLANATORY MEMORANDUM TO

THE VETERINARY MEDICINES AND RESIDUES (AMENDMENT) (EU EXIT) REGULATIONS 2020

2020 No. [XXXX]

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 amends the Veterinary Medicines Regulations 2013 ("VMR"), the Animal and Animal Products (Examination of Residues and Maximum Residue Limits) (England and Scotland) Regulation 2015 ("Residues Regulations"), and the relevant retained European Union (EU) law as set out in Section 6. This instrument will ensure that the regulatory regimes for veterinary medicines and residues surveillance remain operable and enforceable in the UK after the end of the Transition Period. The amendments to the VMR also reflect the requirements and effect of the protocol on Ireland/Northern Ireland ("the Protocol").

Explanations

What did any relevant EU law do before exit day?

2.2 The VMR implement the requirements of Directive 2001/82/EC and set out the controls on the production, distribution, possession, dispensing and administration of veterinary medicines in the UK. In England and Scotland, the Residues Regulations prohibit the use of certain substances as growth promoters and provide for a surveillance programme for residues of veterinary medicines. Equivalent secondary legislation exists in Wales and Northern Ireland. Regulation 470/2009 establishes maximum residues limits for pharmacologically active substances in foodstuffs from animal origin. Regulation 2019/1871 establishes Reference Points for Action for non-allowed pharmacologically active substances present in food of animal origin. Regulation 2019/2090 sets out actions on suspected or established non-compliance with rules applicable to use of, or residues from, prohibited or unauthorised pharmacologically active substances. Decision 2002/657/EC sets out the methodology for the performance of analytical methods and the interpretation of results in relation to the surveillance of residues of veterinary medicines. These instruments protect the safety of the treated animals, the people handling the medicines, the consumers of produce from treated animals and the environment, as well as helping to ensure animal welfare.

Why is it being changed?

2.3 To ensure that the veterinary medicines framework continues to operate effectively, and so that we can continue to operate a residues surveillance programme covering the same objectives. The changes made by this instrument are necessary to ensure that

retained EU legislation and the domestic legislation enforcing it continue to operate effectively.

What will it now do?

2.4 This instrument will allow veterinary medicines to continue to be regulated and marketed in the UK in order to safeguard animal health and welfare. It will ensure consumer safety through continued monitoring for residues of veterinary medicines in animals and produce from treated animals.

2.5 For the Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019, and the Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 amendments are made to reflect that, as a result of the effect of the Protocol, the changes made by these instruments will only apply to Great Britain when they come into force at the end of the Transition Period.

2.6 This instrument implements the Government's commitment to ensure unfettered market access for Northern Ireland Businesses in relation to veterinary medicines.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Matters relevant to Standing Order Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of this instrument includes Scotland.

4. Extent and Territorial Application

4.1 As regards Part 3 of this instrument the territorial extent and application is Great Britain.

4.2 As regards Part 4 of this instrument the territorial extent is England and Wales and Scotland and the territorial application is England and Scotland.

4.3 As regards the retained direct EU legislation amended by this instrument in Part 5, and the retained law amended by the domestic regulations amended by Part 2 of this instrument, this is incorporated into domestic law under section 3 of the European Union (Withdrawal) Act 2018 save insofar as it applies to Northern Ireland for the purposes of the Protocol. Accordingly, this instrument will be of no practical application in Northern Ireland as the Protocol instead applies the EU law provisions in Northern Ireland.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State for Rural Affairs and Biosecurity, Lord Gardiner of Kimble has made the following statement regarding Human Rights:

"In my view the provisions of the Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument amends the following domestic legislation concerning veterinary medicines and residues:

- The Veterinary Medicines Regulations 2013 ("S.I. 2013/2033");
- The Animal and Animal Products (Examination of Residues and Maximum Residue Limits) (England and Scotland) Regulation 2015 ("S.I. 2015/787");
- The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 ("S.I. 2019/865"); and
- The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 ("S.I. 2019/676").

6.2 This instrument also amends the following retained direct EU legislation concerning veterinary medicines and residues:

- 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);
- Commission Regulation (EU) 2019/1871 on Reference Points for Action for non-allowed pharmacologically active substances present in food of animal origin; and
- 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.

7. Policy background

What is being done and why?

7.1 Veterinary medicines, although essential for the treatment of animals and ensuring animal welfare, also present a range of potential risks to human health and the environment. If misused, they can affect human health directly or may enter the natural environment through production, use, or disposal, causing long lasting damage. The existing EU and UK veterinary medicines legislation sets out the requirements for placing veterinary medicines on the market to ensure their safe use and the protection of public health and the environment.

7.2 Her Majesty's Government shares the British public's high regard for animal welfare and the need for safe and effective veterinary medicines. This instrument retains the current standards for veterinary medicines set out in EU legislation, and EU derived domestic regulations, to ensure the availability of medicines and the safety of produce from treated animals to continue after the end of the Transition Period. No substantive policy changes are being introduced by this instrument. The policy objective is to maintain existing laws.

7.3 In order to facilitate unfettered market access for veterinary medicines, this instrument introduces light touch regulatory controls on medicines that are approved in Northern

Ireland and not Great Britain and that move from Northern Ireland onto the Great Britain market. These controls are necessary to ensure that the UK regulator , the Veterinary Medicines Directorate, has the necessary assurances of safety quality and efficacy for medicines on the UK market for the purposes of ensuring public health, animal health and welfare and consumer safety.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the power in section 8 of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. The instrument is also made under section 8C and paragraph 21 of Schedule 7 to the 2018 Act. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 This instrument is not consolidating any other provisions.

10. Consultation outcome

10.1 The Scottish, Welsh and Northern Irish Devolved Administrations have been consulted about the proposed amendments and are content.

10.2 A public consultation was not carried out for this instrument. However, there has been significant informal engagement with the animal health industry which supports these proposals.

11. Guidance

11.1 The Veterinary Medicines Directorate publishes guidance on gov.uk on the regulation of the manufacture, distribution and use of veterinary medicines. The required changes to guidance have been made.

12. Impact

12.1 The impact on business, charities or voluntary bodies is minimal.

12.2 The impact on the public sector is minimal. There will be no change to monitoring and enforcement requirements.

12.3 An Impact Assessment has not been prepared for this instrument as there are limited impacts on business. There will be a very limited administrative impact on the public sector and no change to monitoring and enforcement requirements.

13. Regulating small business

13.1 This instrument applies to activities that are undertaken by small businesses.

13.2 To minimise the impact of the requirements on firms employing up to 50 people, the approach taken by the Veterinary Medicines Directorate is to carry out a continual process of informal consultation with stakeholders on proposed legislative developments.

14. Monitoring & review

14.1 The Veterinary Medicines Directorate will monitor and review the impact of the instrument as part of its standard policy-making procedures.

14.2 As this instrument is made under the EU Withdrawal Act 2018, no review clause is required.

15. Contact

15.1 Lea Reynolds at the Department for Environment Food and Rural Affairs Telephone: 01932 338321 or email: l.reynolds@vmd.gov.uk can be contacted with any queries regarding the instrument.

15.2 Paul Green, Director of Operations, at the Department for Environment Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.

15.3 Lord Gardiner of Kimble at the Department for Environment Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals, or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.

Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 The Parliamentary Under Secretary of State for Rural Affairs and Biosecurity, Lord Gardiner of Kimble has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 does no more than is appropriate".

1.2 This is the case because this instrument largely corrects technical deficiencies that will arise at the end of the Transition Period and ensures that the existing regimes continue to ensure appropriate availability and regulation of veterinary medicines. This is in line with government policy.

2. Good reasons

2.1 The Parliamentary Under Secretary of State for Rural Affairs and Biosecurity, Lord Gardiner of Kimble has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 These are: that there is real public concern about the welfare of animals and the need for safe and effective veterinary medicines. The government should at least maintain the protections that currently exist. The public would also expect us to be able to take enforcement action against those who market veterinary medicines and that are in breach of the Veterinary Medicines Regulations.

3. Equalities

3.1 The Parliamentary Under Secretary of State for Rural Affairs and Biosecurity, Lord Gardiner of Kimble has made the following statement:

"The instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006, or the Equality Act 2010 or subordinate legislation made under those Acts."

3.2 The Parliamentary Under Secretary of State for Rural Affairs and Biosecurity, Lord Gardiner of Kimble has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the instrument, I, Lord Gardiner of Kimble have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this Explanatory Memorandum.