EXPLANATORY MEMORANDUM TO

THE VETERINARY MEDICINES AND ANIMALS AND ANIMAL PRODUCTS (EXAMINATION OF RESIDUES AND MAXIMUM RESIDUES LIMITS) (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 No. 676

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.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residues Limits) (Amendment etc.) (EU Exit) Regulations 2019 amend the Veterinary Medicines Regulations 2013 ("VMR") and the Animal and Animal Products (Examination of Residues and Maximum Residue Limits) (England and Scotland) Regulation 2015 ("Residues Regulations") and amend and revoke relevant retained direct EU legislation to ensure that the regulatory regimes for veterinary medicines and residues surveillance remain operable and enforceable in the UK after the UK leaves the EU.

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. Regulation 470/2009 establishes maximum residues limits for pharmacologically active substances in foodstuffs from animal origin. 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). These Regulations help ensure animal welfare, protect the safety of treated animals, people handling the medicines, consumers of produce from treated animals and the environment.

Why is it being changed?

2.3 To ensure that the veterinary medicines framework continues to operate effectively once we leave the EU, and that we can continue to operate a residues surveillance programme covering the same objectives. The changes made by the instrument are necessary to ensure that retained EU legislation and the domestic legislation enforcing it continue to operate effectively. The instrument introduces a change in relation to the location of holders of marketing authorisations for veterinary medicines which is required as a consequence of leaving the EU.

What will it now do?

The 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 monitoring the residues of veterinary medicines in animals and produce from treated animals. It will also require veterinary medicines authorisation holders to be based in the UK.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments or the Select Committee on Statutory Instruments

3.1 The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residues Limits) (Amendment etc.) (EU Exit) Regulations 2019 were laid before the sifting committees on 26 November 2018.

3.2 Both the Lords' Secondary Legislation Scrutiny Committee and the Commons' European Statutory Instruments Committee provided their responses on the 12 December 2018 and recommended that the Regulations should be upgraded to affirmative. Their recommendation is based on the introduction of a new requirement on holders of marketing authorisations for veterinary medicines to establish themselves in the UK if they wish to continue to market their medicines after exit and concerns that the effect of certain amendments is unclear and could potentially lead to a lowering of safety standards.

3.3 Consequently, the Parliamentary Under Secretary of State for the Department for Environment, Food and Rural Affairs, Lord Gardiner of Kimble, has agreed for this instrument to be made subject to the affirmative procedure.

3.4 No substantive changes have been made to the instrument since it was presented to the Sifting Committees.

3.5 The territorial application of this instrument varies between provisions.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is the United Kingdom, save that amendments made by Parts 2 and 3 have the same extent as the provisions being amended and so the amendments to the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015 extend to Great Britain only.

4.2 The territorial application of this instrument is applicable to the United Kingdom, save that amendments made by Parts 2 and 3 have the same application as the provisions being amended and so the amendments to the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015 apply in relation to England and Scotland only.

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 Animals and Animal Products (Examination of Residues and Maximum Residues Limits) (Amendment etc.) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 The key legislative context for the instrument is set out at paragraph 2 above.

6.2 In addition to this instrument the Department will also introduce another instrument as part of the exit process, which will provide for Maximum Residue Limits (MRLs) to be established on a UK basis following EU exit. MRLs are currently established by the European Commission when classifying substances under Regulation (EC) No 470/2009. These limits are used to establish withdrawal periods; the period that must elapse after the last administration of a medicine before produce from that animal may enter the food chain. MRLs also facilitate trade in animals and produce, as compliance with MRLs and food safety regulations provides assurance of the safety of animal derived produce. In addition the further instrument will make provision as to fees, including the fees payable for MRL applications.

6.3 Section 8(1) of the European Union (Withdrawal) Act 2018 provides that a Minister of the Crown may by regulations make such provision as the Minister considers appropriate to prevent, remedy or mitigate any failure of retained EU law to operate effectively or any other deficiency in retained EU law arising from the withdrawal of the United Kingdom from the EU. The instrument is made in exercise of these powers, and the power in paragraph 21 of Schedule 7 to the same Act which allows for supplementary etc provision to be made, including provision which restates retained EU law in a clearer or more accessible way.

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. The Animal and Animal Product regulations set out provisions for ensuring that animal produce is suitable for human consumption following the administration of veterinary medicines.

7.2 The Government shares the British public's high regards 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 UK has left the EU. No substantive policy changes are being introduced by this instrument. The policy objective is to maintain existing laws.

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 the power in paragraph 21 of Schedule 7 to the Withdrawal Act 2018. 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.

11. Guidance

11.1 The Veterinary Medicines Directorate publishes guidance 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 This instrument will require holders of authorisations for veterinary medicine to establish themselves in the UK. This would increase the burden and likely costs of those holders currently based outside of the UK. We calculate that there are 90 companies that will need to establish a UK base out of a total of 178 companies that hold authorisations for veterinary medicines. The affected companies hold a total of 751 authorisations for veterinary medicines out of a total of 2721 authorisations for veterinary medicines. Our estimated cost per business (including registration with Companies House and using a legal firm's registered office service) is an initial cost of £100 with annual costs of £40. These costs are estimates as detailed information for individual businesses is not publicly available. These figures are provided to give an indication of the scale of the costs. However, imposing this requirement ensures that all UK authorisation holders are within the UK's enforcement jurisdiction and provides for a level playing field with those holders already established in the UK. A UK presence helps to protect animal and public health by facilitating enforcement. The ability to prosecute a holder in appropriate circumstances is an important deterrent to bad practice.

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

12.4 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 The legislation 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.defra.gsi.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 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	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
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 Animals and Animal Products (Examination of residues and maximum Residues Limits) (Amendment etc) (EU Exit) Regulations 2019 does no more than is appropriate".

1.2 This is the case because the instrument largely corrects technical deficiencies that will arise from withdrawal and ensures that the existing regimes continue to ensure appropriate availability and regulation of veterinary medicines. This is in line with government policy. Requiring holders of marketing authorisations for veterinary medicines to be established in the UK, in order to continue to market veterinary medicines will ensure we have the ability to take appropriate enforcement action should they be found to be in breach of the veterinary medicines legislation.

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, for example by having the ability to prosecute those who do not comply with the legislation.

3. Equalities

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

"This 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."

3.3 Little or no impact on equalities is expected.

4. Explanations

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