EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND WINDSOR FRAMEWORK

C(2023)1272 FINAL

COMMISSION DELEGATED REGULATION (EU) …/... OF 27.2.2023 SUPPLEMENTING REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS THE APPLICATION OF THE PROHIBITION OF USE OF CERTAIN ANTIMICROBIAL MEDICINAL PRODUCTS IN ANIMALS OR PRODUCTS OF ANIMAL ORIGIN EXPORTED FROM THIRD COUNTRIES INTO THE UNION

Submitted by Department for Environment Food and Rural Affairs

19 May 2023

SUBJECT MATTER

1. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC sets out rules for the marketing, manufacturing, importing, exporting, supply, distribution, pharmacovigilance, control and use of veterinary medicines in the EU.

2. A key objective of the Regulation is to mitigate the risk of development of antimicrobial resistance, including by strengthening the prudent use of antimicrobial medicinal products. Among others, the Regulation prohibits the use of antimicrobial medicinal products for growth promotion and yield increase, and it forbids the use in animals of medicinal products containing antimicrobials that are reserved for treatment of infections in humans.

3. Article 118(1) of the Regulation (EU) 2019/6 requires third country operators exporting animals or products of animal origin (POAO) to the European Union to respect the prohibition on the use of antimicrobial medicinal products for the purpose of promoting growth or to increase yield, and on the use of antimicrobials that have been reserved for the treatment of certain infections in humans.

4. The purpose of this Delegated Regulation is to supplement Regulation (EU) 2019/6 by establishing the detailed rules and conditions necessary for the application of Article 118. A further Implementing Regulation is also planned and the conditions for entry into the EU in Article 4 of this Delegated Regulation will not take effect until two years after the date of application of this subsequent Implementing Regulation.

5. The Notice[1] the EU issued in December 2022 extending the grace period on veterinary medicine supplies to Northern Ireland until December 2025 partially includes Regulation (EU) 2019/6. However, as per the 'standstill' arrangement with the EU, all existing operational arrangements of the Northern Ireland Protocol will continue whilst discussions with the EU are ongoing. During this time, veterinary medicines authorised or approved in the UK, or which are moved via Great Britain, can continue to be placed on the market in Northern Ireland.

SCRUTINY HISTORY

6. The Parliament Scrutiny history relevant to this Explanatory Memorandum is contained in Annex A.

MINISTERIAL RESPONSIBILITY

7. Responsibility lies with the Secretary of State for Environment, Food and Rural Affairs.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

8. Veterinary medicines are a reserved matter in Great Britain but aspects, including enforcement, are devolved to Northern Ireland under the UK's devolution settlements. Policy on antimicrobial resistance is a devolved matter. Import controls on animals and animal products for the purposes of protecting human and animal health are devolved matters.

9. Devolved Administrations have been consulted in the preparation of this Explanatory Memorandum. No substantive concerns were raised.

10. Veterinary medicines are subject to the common framework Animal Health and Welfare.

LEGAL AND PROCEDURAL ISSUES

11.

i. **Legal Base**

Regulation (EU) 2019/6, in particular Article 118(2).

ii. **Voting Procedure**

Not applicable – Commission Delegated Regulation.

[1] http://www.gov.uk/government/news/european-commission-announces-three-year-extension-to-the-grace-period-for-veterinary-medicines

iii. **Timetable for adoption and implementation**

The Delegated Regulation was adopted by the European Commission on 27 February 2023. It will enter into force on the 20th day following publication in the Official Journal. Its provisions with conditions for entry into the Union of consignments of animals or products shall apply from two years following the date of application of the subsequent implementing regulation referred to in paragraph 4.

POLICY IMPLICATIONS

12. For Northern Ireland; as part of the Windsor Framework, the cliff edge on veterinary medicines has been removed, protecting supply in Northern Ireland through to 2025. During this time, veterinary medicines authorised or approved in the UK, or which are moved via Great Britain, can continue to be placed on the market in NI.

13. This safeguards those supplies while providing time to establish a long-term solution which maintains the uninterrupted flow of veterinary medicines into NI from GB. In so doing the Government is clear that the only practical solution will be one that guarantees the existing and long-established flows of trade between GB and NI.

14. From Autumn 2023, the Windsor Framework will allow UK public health standards to apply for goods moved via the agrifood Retail Movement Scheme placed on the NI market. Therefore, POAO moving via this route can continue to meet UK requirements on the use of antimicrobial medicinal products.

15. As the prohibition on the use of antimicrobial medicinal products for the purpose of promoting growth or to increase yield is already in effect UK-wide, there are no practical implications of this Regulation in relation to food producing animals or products of animal origin to be moved from GB to EU or NI. Furthermore, none of the antimicrobial substances that have been reserved for the treatment of certain infections in humans in Regulation (EU) 2022/1255 are currently licensed as a veterinary medicine for any animal species or has a maximum residue limit (MRL) set for any food producing animal species in Great Britain (GB) or Northern Ireland (NI).

16. Pharmacologically active substances without an MRL cannot be used in food producing animals in GB or NI and therefore there are no implications in relation to food producing animals or products of animal origin to be moved from GB to EU or NI.

CONSULTATION

17. The European Commission has consulted on this Delegated Regulation, and the UK Parliament has previously scrutinised EU Regulation 2019/6, including Article 118 – see Parliamentary scrutiny history in Annex A.

FINANCIAL IMPLICATIONS

18. The proposed legislative measure has no budgetary implications for the UK Government.

THE RT HON LORD BENYON
MINISTER FOR BIOSECURITY, MARINE AND RURAL AFFAIRS
DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

ANNEX A

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO A:

COMMISSION DELEGATED REGULATION (EU) …/... OF 27.2.2023 SUPPLEMENTING REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS THE APPLICATION OF THE PROHIBITION OF USE OF CERTAIN ANTIMICROBIAL MEDICINAL PRODUCTS IN ANIMALS OR PRODUCTS OF ANIMAL ORIGIN EXPORTED FROM THIRD COUNTRIES INTO THE UNION

EM 9216/21, C (2021) 3552 FINAL: COMMISSION DELEGATED REGULATION (EU) …/... OF 26.5.2021 SUPPLEMENTING REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL BY ESTABLISHING THE CRITERIA FOR THE DESIGNATION OF ANTIMICROBIALS TO BE RESERVED FOR THE TREATMENT OF CERTAIN INFECTIONS IN HUMANS

DEFRA SUBMITTED AN EM DATED 9 DECEMBER 2021

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	**LORDS**
SCRUTINY COMPLETED (OUTCOME AGENDA NO 26 26/1/22)	DRAWN TO THE ATTENTION OF THE PROTOCOL ON IRELAND/NORTHERN IRELAND SUB-COMMITTEE (AT CHAIR'S SIFT NO 12; 16/12/21)

EM 6916/21, PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING REGULATION (EU) 2017/625 AS REGARDS OFFICIAL CONTROLS ON ANIMALS AND PRODUCTS OF ANIMAL ORIGIN EXPORTED FROM THIRD COUNTRIES TO THE UNION TO ENSURE COMPLIANCE WITH THE PROHIBITION OF CERTAIN USES OF ANTIMICROBIALS

DATE DEFRA EM SIGNED: 30/03/2021

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
SCRUTINY COMPLETED (OUTCOME AGENDA NO 1 12/5/21)	SIFTED FOR EXAMINATION TO THE PROTOCOL ON IRELAND/NORTHERN IRELAND SUB-COMMITTEE (AT CHAIR'S SIFT 1 22/4/2021)

EM 8280/20: COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A FARM TO FORK STRATEGY FOR A FAIR, HEALTHY AND ENVIRONMENTALLY-FRIENDLY FOOD SYSTEM

8280/20 ADD 1: ANNEX TO THE COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A FARM TO FORK STRATEGY FOR A FAIR, HEALTHY AND ENVIRONMENTALLY-FRIENDLY FOOD SYSTEM

DATE DEFRA EM SIGNED: 26/06/2020 SEM 15/7/2020

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
SCRUTINY COMPLETE (ESC OUTCOME AGENDA 24) 21/10/2020	DRAWN TO THE ATTENTION OF (EU ENVIRONMENT SUB COMMITTEE) AT CHAIR'S SIFT 23 23/7/2020

EUROPEAN COURT OF AUDITORS: SPECIAL REPORT NO 21/2019. ADDRESSING ANTIMICROBIAL RESISTANCE: PROGRESS IN THE ANIMAL SECTOR, BUT THIS HEALTH THREAT REMAINS A CHALLENGE FOR THE EU

DATE DEFRA EM SIGNED: 20/12/2019

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
CLEARED AS NOT IMPORTANT (ESC OUTCOME AGENDA 30/4/2020)	CLEARED (ENERGY AND ENVIRONMENT) AT CHAIRMAN'S SIFT 1760 - 16/1/2020

EM 11128/17: COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT A EUROPEAN ONE HEALTH ACTION PLAN AGAINST ANTIMICROBIAL RESISTANCE (AMR)

ADD1: COMMISSION STAFF WORKING DOCUMENT SYNOPSIS REPORT ACCOMPANYING THE DOCUMENT

DATE DHSC EM SIGNED: 02/08/2017

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
REPORTED AS POLITICALLY IMPORTANT IN REPORT 3 & 13, 17/19 AND NOT CLEARED	CLEARED AT SIFT 1664 ON 06/09/2017

EM 13240/14: PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING REGULATION (EC) NO 726/2004 LAYING DOWN COMMUNITY PROCEDURES FOR THE AUTHORISATION AND SUPERVISION OF MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE AND ESTABLISHING A EUROPEAN MEDICINES AGENCY

EM 13289/14: PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON VETERINARY MEDICINAL PRODUCTS

13289/14 ADD 1: ANNEXES TO THE PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON VETERINARY MEDICINAL PRODUCTS

13289/14 ADD 2: COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT ACCOMPANYING THE DOCUMENT PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON VETERINARY MEDICINAL PRODUCTS

13289/14 ADD 3: COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT ACCOMPANYING THE DOCUMENT PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON VETERINARY MEDICINAL PRODUCTS

DATE DEFRA EM SIGNED: 26/09/2014

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
13240-14 CLEARED AS POLITICALLY IMPORTANT, (AGENDA FOR REPORT NO 21; 21/3/2018 13289-14 POLITICALLY IMPORTANT CLEARED, FURTHER INFORMATION REQUIRED (AGENDA FOR REPORT NO 32; 20/6/2018)	CLEARED BY HOUSE OF LORDS LETTER DATED 11/10/2017

EM 9464/13, COM (2013) 265 FINAL: DRAFT INSTRUMENT CONCERNING A PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES PERFORMED TO ENSURE THE APPLICATION OF FOOD AND FEED LAW, RULES ON ANIMAL HEALTH AND WELFARE, PLANT HEALTH, PLANT REPRODUCTIVE MATERIAL AND PLANT PROTECTION PRODUCTS

DATE FSA EM SIGNED: 03/06/2013

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
REPORT NO: 09 DATED: 10/07/2013: RECOMMEND: LPINC REPORT NO: 39 DATED: 24/03/2015: RECOMMEND: LPINC REPORT NO: 07: DATED: 28/10/2015: RECOMMEND: LPIC	SIFT NO: 1508: DATED: 11/06/2013 FINAL CLEARED ON 14/11/2016