EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND NORTHERN IRELAND PROTOCOL

6864/22
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PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN TRANSITIONAL RULES FOR THE PACKAGING AND LABELLING OF VETERINARY MEDICINAL PRODUCTS AUTHORISED IN ACCORDANCE WITH DIRECTIVE 2001/82/EC AND REGULATION (EC) NO 726/2004

Submitted by the Department for Environment, Food and Rural Affairs

13 April 2022

SUBJECT MATTER

1. The proposed Regulation on veterinary medicinal products makes provision for further transitional rules in relation to the new European Union Regulation on veterinary medicines (2019/6). The proposal will enable veterinary medicines that comply with the packaging and labelling rules under the previous veterinary medicines legislation to remain on the market until 29 January 2027, even if they are not in compliance with the new EU regulation. The application of this proposal is back dated to 28 January 2022.

2. The new European Union Regulation on veterinary medicines (Regulation (EU) 2019/6)[1] came into effect on 28 January 2022 in the EU. Article 152 of the Regulation provides for transitional rules for medicines that were authorised and placed on the market under the previous legislation for veterinary medicines, (Directive 2001/82/EC and EU Regulation 726/2004). This provision provides that medicines that have been *placed on the market* prior to 28 January 2022 may remain on the market until 29 January 2027 (even if they are not in compliance with Regulation 2019/6).

3. Placed on the market is defined in Regulation 2019/6 as: *the first making available of a veterinary medicine on the whole of the union or in one of more member state*. This is the point at which the manufacturer completes its quality control checks and releases the product into the supply chain.

[1] Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC

4. The proposed Regulation ensures that veterinary medicines may continue to remain available on the market while pharmaceutical companies update the packaging and labelling of their product portfolios in line with the requirements of the Regulation 2019/6. It addresses the concerns raised by Member States' authorities and the pharmaceutical industry that Article 152 only provides for products that have been released into supply chains prior to 28 January 2022 to remain on the market until 29 January 2027.

5. If the changes in the proposed regulation are not adopted, Regulation 2019/6 would require all labelling and packaging updates to have been approved by Member State authorities and implemented by 28 January 2022. This was not achievable and would have had significant medicines availability implications (and therefore animal health and welfare implications) as new batches of products could not be legally placed on the market until those changes had been made.

SCRUTINY HISTORY

6. The Parliamentary 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 generally devolved to Northern Ireland under the UK's devolution settlements, with the exception of the subject matter of certain technical standards and requirements that were in effect prior to leaving the EU.

9. Devolved administrations have been consulted in the preparation of this Explanatory Memorandum. No concerns were raised on these new requirements.

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

LEGAL AND PROCEDURAL ISSUES

11.

i. **Legal Base**

Articles 114 and 168(4), point (b) of the Treaty on the Functioning of the European Union

ii. **Voting Procedure**

Ordinary legislative procedure (ex-co decision procedure)

iii. **Timetable for adoption and implementation**

We do not know when this instrument is to be made, but it is described by the European Commission as urgent and is to have retrospective application. Regulation (EU) 2019/6 of the European Parliament and of the Council applied from 28 January 2022. This proposal sets out transitional rules that would also apply from this date.

POLICY IMPLICATIONS

12. The Government is clear that the Northern Ireland Protocol, in its current form, is not delivering on its core objectives and is seeking a new, consensual approach to implementing the Protocol, that ensures it operates in an enduring way, as outlined in the Government command paper – 'The Northern Ireland Protocol: the way forward' published on 21 July 2021. The Command Paper proposes that medicines, including veterinary medicines, are removed from the scope of the Protocol, so that the rules here can be determined by the UK alone.

13. The relevant EU acquis on veterinary medicines is included in Annex 2 of the Northern Ireland Protocol. As per Article 13(3) of the Protocol, the EU acquis in Annex 2 is automatically updated now that Regulation (EU) 2019/6 has come into force. However, while discussions on veterinary medicines continue between the UK and the EU, the Government does not propose to take steps to implement or supplement Regulation (EU) 2019/6 in Northern Ireland. This includes the transitional rules in Article 152, therefore, there are no current implications from the proposal as medicines may continue to be marketed in Northern Ireland in line with the packaging and labelling requirements under the previous legislation.

14. UKG are continuing to press the Commission on veterinary medicines issues and are urgently seeking a long-term solution that safeguards the availability of veterinary medicines in Northern Ireland. While the EU proposal for an extension to the existing grace period covering veterinary medicines is welcome, further progress is urgently needed to resolve the supply issues for veterinary medicines.

15. Neither Regulation (EU) 2019/6 nor the Commission proposal will be applicable in Great Britain. The UK Government was significantly involved in the negotiations on the EU Regulation on veterinary medicines and many of the changes are desirable from a UK policy perspective. The VMD is currently in the process of reviewing and updating the Veterinary Medicines Regulations 2013 (VMR) as they have effect in GB. Any proposed changes to the VMR will be subject to public consultation.

CONSULTATION

16. As the proposal sets out transitional rules that are necessary for the entry into application of Regulation (EU) 2019/6 consultation is not considered by the European Commission to be necessary.

FINANCIAL IMPLICATIONS

17. There will be no economic or financial burdens as a result of this proposal.

THE RT HON LORD BENYON
PARLIAMENTARY UNDER SECRETARY OF STATE (MINISTER FOR RURAL AFFAIRS AND BIOSECURITY)
DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

ANNEX A

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO A:

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN TRANSITIONAL RULES FOR THE PACKAGING AND LABELLING OF VETERINARY MEDICINAL PRODUCTS AUTHORISED IN ACCORDANCE WITH DIRECTIVE 2001/82/EC AND REGULATION (EC) NO 726/2004

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

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

DEFRA EM DATED 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