Department for Environment Food & Rural Affairs

The Rt Hon Lord Benyon
Parliamentary Under Secretary of State

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Lord Jay of Ewelme
Chair of the Protocol on Ireland/Northern Ireland
Sub-Committee
House of Lords
London
SW1A 0PW

17 June 2021

Dear Lord Jay,

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

Thank you for your letter of 20 May 2021. Under the Northern Ireland Protocol, the proposed Regulation will, like EU Regulation 2019/6 (on veterinary medicinal products), apply in Northern Ireland. Northern Ireland's import regime therefore will need to be adapted to implement official controls on imported animals and products of animal origin from third countries to confirm compliance with Article 118(1) of EU Regulation 2019/6. The Veterinary Medicines Regulations 2013, as they have an effect in Great Britain, do not contain provision similar to Article 118(1) and there is no requirement for similar official controls in Great Britain.

As explained in the Explanatory Memorandum, Article 118(1) sets out prohibitions for operators in third countries on the use of antimicrobial medicines in animals for the purpose of promoting growth or increasing yield, and on the use in animals of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, where this relates to animals and products of animal origin exported from those countries to the EU (and those moved from Great Britain to Northern Ireland). EU Regulation 2019/6 has previously been subject to Parliamentary scrutiny. During the scrutiny process, implications of the import requirements as set out in Article 118(1) were discussed.

My officials from the Veterinary Medicines Directorate (VMD) have indeed consulted on the Explanatory Memorandum with officials from the Scottish and Welsh Governments and the Northern Ireland Executive. No concerns were raised on the proposed Regulation by the Devolved Administrations, but officials from the Northern Ireland Department of Agriculture, Environment and Rural Affairs (DAERA) have requested to be kept informed of future supplementing legislation relating to Article 118(1) of EU Regulation 2019/6, which the VMD has agreed to. Officials from the Welsh Government did enquire about the implication of Article 118(1) of EU Regulation 2019/6 for operators in Great Britain exporting to the EU and

the farms supplying them. They are aware that those operators, and by extension the farms supplying them, need to adhere to the prohibitions set out in Article 118(1), should they wish to continue exporting animals or products of animal origin to the EU.

As the Government has acknowledged, the Protocol does give rise to some additional controls and processes on the movement of agrifood goods from Great Britain to Northern Ireland. We have been clear that these need to be implemented in such a way as to minimise disruption to the everyday lives of people in Northern Ireland. We are working closely with colleagues in DAERA, and in the EU, in order to achieve this.

DAERA and/or the Northern Ireland Department of Health (DoH(NI)) continue to be responsible for the devolved activities in Northern Ireland relating to veterinary medicines and import of animals and products of animal origin. VMD officials have engaged extensively, and continue to meet regularly, with DAERA officials to provide advice and expertise on the implementation of the Veterinary Medicines Regulations 2013 as well as EU Regulation 2019/6 in Northern Ireland. The VMD continues to advise DAERA/DoH(NI) on requirements to deliver the devolved activities relating to veterinary medicines and the resources/expertise they will need to have in place.

You asked about the current policy position of the UK Government and Devolved Administrations on the use of antimicrobials in imports of animals and products of animal origin. I take 'the use of antimicrobials' in your letter to mean 'the use of antimicrobial medicines in animals for the purpose of promoting growth or increasing yield, and on the use in animals of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans'. All products of animal origin imported into the UK, including those under free trade agreements, must continue to comply with our existing import requirements. Existing EU legislation and standards on food safety and animal health and welfare were enshrined in UK law on 31 December 2020 under the European Union (Withdrawal) Act 2018 and associated legislation. This means that our import conditions reflect those of the EU as of 31 December 2020. Our import requirements include clear controls on limits of veterinary medicine residues, including antimicrobials, in meat and other products of animal origin. Changes to our regulations will be considered through Parliamentary and public scrutiny in the same way as any legislative initiative and will always be in the best interest of UK citizens and businesses.

A key priority for the UK Government and Devolved Administrations is to protect human and animal health by minimising the development and spread of antimicrobial resistance. The UK Government and Devolved Administrations are committed to working alongside global partners to encourage responsible antibiotic use. We promote global 'One Health' action on antimicrobial resistance through our commitments under the UK National Action Plan for Antimicrobial Resistance (AMR) (2019-24). The inclusion of similar prohibitions on certain uses of antimicrobials in animals and products of animal origin imported from other countries, to those set out in Article 118(1) of EU Regulation 2019/6, in legislation in Great Britain is under consideration. The development of such policy involves officials from several policy areas across the UK Government and Devolved Administrations who work closely together to ensure appropriate legislation and policy is in place.

Animals or products of animal origin entering Northern Ireland will have to meet EU requirements, whether they are UK origin or from other non-EU countries. In terms of the practical impact of Article 118(1) of EU Regulation 2019/6, animals or products of animal origin not reared or produced in accordance with the prohibitions set out in Article 118(1) cannot be imported from non-EU countries into the EU or into Northern Ireland.

The use of antibiotics as growth promoters remains banned in the UK under retained EU law (EU Regulation 1831/2003). Article 107(2) of EU Regulation 2019/6 supplements the ban in EU Regulation 1831/2003 by prohibiting the use of antibiotic veterinary medicines for the purpose of promoting growth or increasing yield. The Government intends to make provision corresponding or similar to Article 107(2) of EU Regulation 2019/6 in the Veterinary Medicines Regulations 2013 for Great Britain. Any changes to the Veterinary Medicines Regulations 2013 as they will have an effect in Great Britain will be subject to formal public consultation to allow stakeholders to give their views on the proposed changes.

As such, with regard to movement or export of animals or products of animal origin to Northern Ireland/the EU by operators based in Great Britain, or from Northern Ireland to Great Britain, the prohibition on the use of antimicrobials for growth promotion/increase of yield is not foreseen to create a barrier.

Article 118(1) also prohibits the use in animals of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. The European Medicines Agency have published guidance on the decision-making process which will be followed when designating these reserved antimicrobials. This will be based on assessment of their importance for human health, importance for animal health and the risk of transfer of resistance. The Delegated Regulation setting out the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans has recently been adopted by the European Commission. The reserved list has not yet been published, and whilst we do not anticipate that it will limit the availability of existing antibiotics used in veterinary medicine, it is not possible to establish the full implications prior to seeing the release of named antimicrobials/groups of antimicrobials.

With regard to the content of the list of reserved antimicrobials, the UK has had limited input. However, the UK Government played a significant role in the negotiations on EU Regulation 2019/6 and agrees with the principle of reserving certain Critically Important Antimicrobials for treatment of infections in humans. It should be noted that there are currently at least three lists setting out relative importance of antimicrobials/groups of antimicrobials, which all differ. These are lists created by the World Health Organization, the World Organisation for Animal Health (OIE) and the European Medicines Agency (through their Antimicrobial Advice Ad Hoc Expert Group (AMEG)).

You also asked about the interaction between the direct application in Northern Ireland of EU Regulations in the field of veterinary medicines, with Northern Ireland's participation in the Animal Health and Welfare Common Framework. I can assure you that the Framework, which is being developed collaboratively between the UK Government and the three Devolved Administrations, will be a UK-wide Framework and will provide the necessary governance structures to manage any divergence which may occur within the UK, irrespective of the source. The Northern Ireland Protocol has implications for a number of the Common Frameworks currently under development, and my officials are therefore continuing to work closely with their counterparts in the Cabinet Office and the Devolved Administrations to finalise the detailed arrangements.

While the Framework is being developed, the established ways of working between the UK Government and Devolved Administrations at official level continue when it comes to veterinary medicines. The VMD continues to regulate veterinary medicines in Great Britain and to co-ordinate with DAERA. The VMD holds regular Regulatory Committee meetings to keep under review the Veterinary Medicines Regulations 2013 and to provide governance and oversight for projects and plans for amending or supplementing that legislation, using the primary powers in the Medicines and Medical Devices Act 2021. Policy representatives

for the Devolved Administrations, which includes representatives for DAERA, are members of this Committee, ensuring that the Devolved Administrations are updated on and involved in discussions around the Veterinary Medicines Regulations 2013 and any changes proposed to them.

Tertiary legislation has yet to be drafted and adopted by the European Commission under Article 118(2) of EU Regulation 2019/6. When made, it will provide detailed rules on the application of Article 118(1). Those rules will allow DAERA to consider any potential implications arising from Article 118(1) and engage with Northern Ireland stakeholders as appropriate.

I am copying this letter to Sir William Cash, Chair of the European Scrutiny Committee, the Clerks of the Commons and Lords EU Committees, Les Saunders, Cabinet Office; and Steve Wigham, Defra Scrutiny Co-ordinator.

Yours sincerely,

THE RT HON LORD BENYON