PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

Tenth Delegated Legislation Committee

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

Tuesday 12 March 2019

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not later than

Saturday 16 March 2019

The Committee consisted of the following Members:

Chair: Joan Ryan

† Bryant, Chris *(Rhondda)* (Lab)
† Burns, Conor *(Bournemouth West)* (Con)
† Chishti, Rehman *(Gillingham and Rainham)* (Con)
† Debbonaire, Thangam *(Bristol West)* (Lab)
† Hayman, Sue *(Workington)* (Lab)
† Kinnock, Stephen *(Aberavon)* (Lab)
Powell, Lucy *(Manchester Central)* (Lab/Co-op)
† Rutley, David *(Parliamentary Under-Secretary of State for Environment, Food and Rural Affairs)*
† Seely, Mr Bob *(Isle of Wight)* (Con)
† Slaughter, Andy *(Hammersmith)* (Lab)
Smith, Owen *(Pontypridd)* (Lab)
† Soames, Sir Nicholas *(Mid Sussex)* (Con)
† Stewart, Iain *(Milton Keynes South)* (Con)
† Thomson, Ross *(Aberdeen South)* (Con)
† Throup, Maggie *(Erewash)* (Con)
† Twist, Liz *(Blaydon)* (Lab)
† Wood, Mike *(Dudley South)* (Con)

Ben Street, *Committee Clerk*

† attended the Committee

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[Joan Ryan *in the Chair*]

Draft Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019

2.30 pm

The Parliamentary Under-Secretary of State for Environment, Food and Rural Affairs (David Rutley): I beg to move,

That the Committee has considered the draft Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019.

It is an honour to serve when you are in the Chair, Mrs Ryan. Veterinary medicines are tightly regulated, both here in the UK and in Europe. They are essential for the treatment of animals and ensuring animal welfare, but can also present a risk to human health and the environment. If misused, they can affect human health directly, or may enter the natural environment, causing long-lasting damage. The existing Veterinary Medicines Regulations 2013 set out the requirements for the manufacture, authorisation, supply, possession and administration of veterinary medicines in the UK. Separately, the surveillance of residues from veterinary medicines in animal produce is an important safeguard, providing assurance that any meat, eggs or milk consumed is free from harmful residues of medicines used in animals.

The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015 provide for a surveillance programme for residues in England and Scotland. Those regulations adopt the level of permissible residues set by the EU, and prohibit the use of certain substances as growth promoters. As residue surveillance is a devolved matter, there is equivalent secondary legislation covering Wales and Northern Ireland.

The Government share the British public's high regard for animal welfare, and understand the need for safe and effective veterinary medicines. This instrument addresses operability issues in our veterinary medicines legislation to ensure that such legislation continues to operate effectively when we leave the EU. The instrument will make sure that the legal framework continues to provide an effective regime for the regulation of veterinary medicines through which we can safeguard the wellbeing of our animals, and does not diminish the high standards of the established veterinary medicines and residues surveillance regimes. Notwithstanding the concerns raised by both the Secondary Legislation Scrutiny Committee in the House of Lords and the European Statutory Instruments Committee in the House of Commons, I emphasise that the amendments in this instrument are to ensure operability, and are very technical in nature. The high safety standards that are in place will continue, and will not be watered down.

The current UK legislation is designed to work in the context of EU membership, and therefore some existing elements will not work sensibly in a national context. Part 3 of the instrument amends the existing national legislation; for example, the mutual recognition provisions for medicine approvals between member states are no longer relevant. Similarly, as approvals of generic marketing authorisations rely on sharing of information between member states, they cannot continue to operate in the same way. Minor corrections are also made to the text to address references concerning EU membership that are no longer accurate or appropriate.

This instrument introduces one change that is necessary as a consequence of leaving the EU. It relates to the location of holders of marketing authorisations for veterinary medicines. Marketing authorisation holders must be established in the UK. As set out in the explanatory memorandum, that may result in a small increase in costs for those marketing authorisation holders currently based outside the UK, in the order of £100 initially and £40 annually. That cost increase is necessary to make sure that there are appropriate regulatory controls to ensure full compliance with UK law and standards, and that all marketing authorisation holders are treated equally.

Chris Bryant (Rhondda) (Lab): The Minister refers to UK law, but as I understand it there is going to be separate legislation for Wales and Scotland, because this is a devolved matter. I do not quite understand how those two things match.

David Rutley: The arrangements that I am talking about are UK-wide; we are bringing what currently sits in EU law into, and across, the UK. If the hon. Gentleman wants further clarification, I can seek some inspiration, but it is a UK-wide statutory instrument.

In line with the Government's better regulation principles, a formal impact assessment has not been carried out because the costs involved are small. The impact on businesses has been assessed as well below the threshold requiring an impact assessment. It is vital that marketing authorisation holders can be held accountable for their products, and this regulation provides for that.

Part 4 of the instrument sets out the necessary amendments to retained EU regulations that become UK law as provided by the European Union (Withdrawal) Act 2018. It is linked to another instrument: the Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019, which transfers the power to set maximum residue limits to the UK from the European Commission, and is yet to be debated in this House.

European regulation 470/2009 sets out how maximum residue limits for substances used as veterinary medicines are set. MRLs are the maximum safe limit of a particular substance in produce from animals. 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. Without these amendments, the UK would be unable to regulate the marketing and use of veterinary medicines effectively. That would have negative impacts on businesses and our ability to protect human and animal health and the environment.

Although a formal public consultation has not been carried out, and has not been required under existing guidelines, the Government have proactively engaged with the animal health industry to discuss how we ensure that the regulatory regime continues to function effectively after exit day. Lord Gardiner of Kimble has met the veterinary pharmaceutical industry association, the National Office of Animal Health, on a number of occasions as part of our extensive engagement. Officials from the Veterinary Medicines Directorate continue to hold regular meetings with key industry representatives. The industry has welcomed our proactive and continued engagement with it. We have worked closely with the devolved Administrations on this instrument, and where it relates to devolved matters they have given their consent.

Liz Twist (Blaydon) (Lab): I would like to ask about the different standards in different UK devolved areas and when it comes to trading with other countries. Is there not a risk that we will have different standards as time goes on? We therefore need co-operation to ensure that we can continue to trade effectively.

David Rutley: Well, we will be leaving the EU, so we need our own mechanisms in place to validate veterinary medicines. That is primarily what we are talking about here. We are bringing back to the UK powers by which medicines are authorised. We will carry on doing that. As it happens, most authorisations already take place in the UK. Unlike for some medicines used for humans, veterinary medicine authorisations often take place in the national states themselves. It will be important to maintain high standards. The hon. Lady and I have exchanged views on that matter in other situations, and I know that she will continue to hold me and the Government to account on these matters. The steps that we are taking in this legislation will bring across powers that are currently in the EU so that we can do what currently takes place. The only thing that is different is the market authorisations. We are requiring those entities to have a market presence in the UK, but at a very low cost. That is the approach we felt was most appropriate to get the balance right.

The Government are committed to ensuring continued levels of protection for human and animal health, as well as making it straightforward for businesses to put medicines and relevant food products on the market, ensuring that UK businesses and individuals continue to have access to a range of veterinary medicines. This instrument will help to maintain the established veterinary medicines and residues surveillance regimes, and will ensure that an effective regulatory framework for veterinary medicines is in place. This instrument does no more than is appropriate to remedy deficiencies in law arising from leaving the EU. For the reasons I have set out, I commend this statutory instrument to the Committee.

2.39 pm

Sue Hayman (Workington) (Lab): It is a pleasure to serve under your chairmanship, Ms Ryan.

This legislation is very important for the protection of human health and the environment, and for maintaining important safeguards to ensure food safety and the health and welfare of farmed livestock, pets and animals used in sport and recreation. Misuse and overuse of veterinary medicines can lead to long-lasting damage to health and the environment. We know, for example, that the overuse of antibiotics in animals is contributing to the public health crisis that we see in antimicrobial resistance. The leakage of powerful growth and other hormones into our water supply is also of concern.

It is very important that there is no loss of collaboration and exchange of knowledge and expertise as we leave the EU. What guarantees can the Minister give that we will continue to have access to the best and latest scientific advice in this field? The Opposition take all of these matters extremely seriously and intend to do everything we can to maintain and enhance our country's record of high standards and scientific excellence as we prepare to leave the EU.

I do not plan to detain the Committee long or to press the measure to a vote. The SI has already been subject to considerable scrutiny, having been recommended for upgrade by the scrutiny Committees and debated in the House of Lords. The Minister in the House of Lords was clear that the SI would not lead to any reduction in safety standards, which was a key concern raised by the scrutiny Committees. He also confirmed that nothing in the SI would enable the USA, for example, to start exporting hormone-injected beef to the UK. Will the Minister also provide a straightforward assurance for the record that there is nothing here that would allow the import of meat or dairy products treated with excessive antibiotics?

I welcome the clear, definitive statement in the explanatory memorandum that says:

"This instrument retains the current standards for veterinary medicines."

It also says:

"No substantive policy changes are being introduced by this instrument. The policy objective is to maintain existing laws."

Although there is no complete impact assessment, the explanatory memorandum at least provides much more information about the impacts and costs than many of the other DEFRA SIs we have seen. Why has it not been possible for the Department to provide, right across all of DEFRA's EU exit legislation, consistently worded clear assurance and impact information to Parliament?

Veterinary medicines are already costly items. Will the Minister set out the Department's estimate of the cumulative impact on the veterinary medicines sector of all the legislative changes that are being made to prepare for our EU exit? How much of the increased cost to pharmaceutical companies does he expect to be passed on to vets, farmers and, ultimately, the consumers of meat, eggs and dairy products?

The statutory instrument would require 90 companies, which hold marketing authorisations, to establish a UK base. Does the Minister share concerns that that could mean that some companies will exit the UK market, potentially leading to gaps in supply or increased cost? The National Office of Animal Health, to which the Minister referred earlier, has said that the Veterinary Medicines Directorate's proposed extension of the parallel import scheme, to enable products to be sourced in any country, is inconsistent with the approach for human medicines. The Medicines and Healthcare Products Regulatory Agency further states that the human

"parallel import regime will remain limited to EU and EEA countries"

in the event of a no-deal Brexit.

[Sue Hayman]

NOAH also asks the Veterinary Medicines Directorate to consider adopting the same approach as the MHRA if there is a no-deal Brexit and, in the longer term, abolish the scheme, as it undermines the marketplace for companies holding UK marketing authorisations. What assessment has the Department made of the risks to UK business? Will the Minister consider NOAH's request in this instance?

Last week we heard a lot about the arrangements for the priority transport of human medicines across the channel in the event of no deal. Will the Minister set out the practical arrangements to ensure that there is no interruption in the supply of vital veterinary medicine if there is no deal? Will there be capacity in the contracts to ensure that medicines for animals as well as humans can receive priority shipping?

Research published by NOAH in October found that nearly two thirds—62%—of UK pet owners are concerned that the supply of pet medicines could be interrupted in a no-deal Brexit. There were problems in December with the supply of the veterinary anaesthetic isoflurane, with some vets postponing pet operations. What advice can the Minister give to animal owners who are concerned that veterinary procedures or operations may be delayed or cancelled due to a lack of supplies in a no-deal Brexit?

I hope that the Minister will respond seriously to the matters I have raised. I confirm that Opposition Members will not vote against the draft instrument.

2.45 pm

David Rutley: I thank the hon. Member for Workington for her contribution, which as usual was thoughtful and thorough. I will respond to some of the points she made. It is obviously vital that we continue to access science. The good news is that the Veterinary Medicines Directorate is regarded as an EU leader in veterinary medicines assessment and has considerable expertise already. We will make sure that it continues to meet that high standard—regardless of what we decide in Parliament today, or over the next few days—so that we have access to the very best.

It is also important to recognise antimicrobial resistance, which the hon. Lady rightly highlighted. As she knows, because we have talked about this in other debates, there will have been an overall reduction in antibiotics sales of 25% between 2016 and 2020, owing to the implementation of livestock-specific targets, which is good. New objectives will be defined by 2021, to sustain longer-term progress. Good progress is being made there.

The hon. Lady asked some challenging questions about the effect of all the legislative changes. I have to say that I do not have the answers to all of them.

Sue Hayman: Is the Minister prepared to write to me, to reassure me on certain issues I have raised? I am happy to receive that information in writing if he does not have it now.

David Rutley: I will do my very best to give the best possible estimates in answer to those questions. I was going to say that a lot of different factors need to be brought into play here. It is not just about the legislation but about market risk and people's appetite for the changes that are going on and for the things that we will vote on in just a few hours' time.

However, I assure the hon. Lady that I have been working closely with the Department for Transport and other Government Departments to ensure the continued supply of vet meds, which will be vital not only for pet owners but for agriculture as well. In the prioritisation that has taken place, medicines for human consumption stand out as key, but right next to that is veterinary medicines. They have a strong place in our priorities, and the Government have been working to ensure their continued supply, which I hope reassures the hon. Lady and many others. Again, we will have to wait and see what the House decides today, which will have quite an influence on what goes on.

I hope I have dealt with most of the issues that the hon. Lady raised. With her permission, I will come back to her on the wider concerns and with an estimate of the wider costs. I hope that Committee members now more fully understand the need for the draft regulations and the need to maintain the operability and consistency of our legislation after leaving the EU. For the reasons I have set out, I once again commend the draft instrument to the Committee.

Question put and agreed to.

2.48 pm

Committee rose.