PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

Third Delegated Legislation Committee

DRAFT VETERINARY MEDICINES (AMENDMENT ETC.) REGULATIONS 2024

Tuesday 23 April 2024

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Saturday 27 April 2024

The Committee consisted of the following Members:

Chair: Dame Maria Miller

† Blake, Olivia *(Sheffield, Hallam)* (Lab)
Bonnar, Steven *(Coatbridge, Chryston and Bellshill)* (SNP)
† Bradshaw, Mr Ben *(Exeter)* (Lab)
De Cordova, Marsha *(Battersea)* (Lab)
† Fletcher, Colleen *(Coventry North East)* (Lab)
† Fuller, Richard *(North East Bedfordshire)* (Con)
† Garnier, Mark *(Wyre Forest)* (Con)
† Hamilton, Mrs Paulette *(Birmingham, Erdington)* (Lab)
† Hayes, Sir John *(South Holland and The Deepings)* (Con)
† Hunt, Jane *(Loughborough)* (Con)
† Knight, Sir Greg *(East Yorkshire)* (Con)
† Loder, Chris *(West Dorset)* (Con)
Menzies, Mark *(Fylde)* (Ind)
† Morrissey, Joy *(Lord Commissioner of His Majesty's Treasury)*
† Spencer, Sir Mark *(Minister for Food, Farming and Fisheries)*
† Tolhurst, Kelly *(Rochester and Strood)* (Con)
† Zeichner, Daniel *(Cambridge)* (Lab)

Abi Samuels, Francis Morse, *Committee Clerks*

† attended the Committee

Third Delegated Legislation Committee

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[Dame Maria Miller *in the Chair*]

Draft Veterinary Medicines (Amendment etc.) Regulations 2024

4.30 pm

The Minister for Food, Farming and Fisheries (Sir Mark Spencer): I beg to move,

That this Committee has considered the draft Veterinary Medicines (Amendment etc.) Regulations 2024.

It is a pleasure to serve under your chairmanship, Dame Maria. The draft regulations, which were laid before the House on 4 March, will amend the Veterinary Medicines Regulations 2013 in respect of Great Britain to ensure that our legislative regime for veterinary medicines is fit for purpose to protect animal health, the environment and public health, including the people handling the medicines or the treated animal and those consuming produce from treated animals.

It is estimated that more than half of our households have companion animals. Many of those households will rely at some point on veterinary medicines to keep their pets healthy and well. Farmers also rely on veterinary medicines, including vaccines, to prevent disease and protect the health and welfare of, for example, more than 9 million cattle and 21 million sheep. That, in turn, helps to protect our food chain.

Veterinary medicines are necessarily highly regulated goods. The 2013 regulations set out controls on their marketing and manufacture, as well as their supply, prescription and use. Those regulations, which have not had a major update since 2013, now require amendment to reflect advances and developments in the industry. The draft instrument will make the biggest change to them in a decade. We received strong support from our stakeholders across the supply chain in response to our public consultation in 2023 on the proposed changes to the 2013 regulations.

Given the length and the technical nature of the draft regulations, I will focus on the key changes in them. They will ensure that safe and effective veterinary medicines of high quality continue to be available to treat our animals. They will also encourage the appropriate and responsible use of veterinary medicines, which is especially important for medicines to which bacteria and parasites can develop resistance, making them harder to treat.

The draft regulations will modernise the regulatory requirements for veterinary medicines and ensure that they are fit for purpose by reflecting technological advancements and developments, for example by allowing electronic package leaflets or QR codes on packaging and by adopting a flexible approach to novel therapies. The latter will make it possible to deal with their novel nature, in respect of the data required for the technical dossier supporting an application to market such a medicine.

With these amendments, we can ensure that the most innovative veterinary medicines can be brought to our market without unnecessary regulatory barriers and without compromising our assurance of their quality, safety or effectiveness. We will maintain the UK as an attractive market for companies by removing the renewal requirements for marketing authorisations, increasing certain data protection periods and harmonising across the UK the requirements for post-authorisation monitoring of adverse events related to the medicines, such as side effects.

Sir Greg Knight (East Yorkshire) (Con): In respect of the supply of veterinary medicines, paragraph 7.8(d) of the explanatory memorandum notes the requirement for

"online retailers to register with the regulator."

Will a registration fee be payable?

Sir Mark Spencer: My right hon. Friend asks an interesting question. There is no fee to register, but it is important that those who are selling these medicines into the UK market take the trouble to register so that we can guarantee the safety of our pets, our farm animals and our consumers.

When we were part of the EU, officials in my Department contributed to the development of new EU laws on veterinary medicines, with the main aim being to reduce the regulatory burden. It has always been the expectation that the requirements will also apply in the UK. We are making changes to the regulations in respect of Great Britain, which will, for example, make it easier for businesses to apply for licences for medicines on a UK-wide basis, reducing the regulatory burden for pharmaceutical companies. These companies, which are often global companies, are set up largely to serve the European market as a whole. Changes will also enable common labelling and packaging to be used across the UK. Altogether, this will encourage companies to continue marketing much-needed veterinary medicines here in the United Kingdom.

We are maximising our ability to take appropriate action in the case that a safety concern arises about a product or an active substance—the ingredient that gives a medicine its therapeutic activity. We are doing so by introducing simple registration schemes for manufacturers, importers and distributors of active substances, for online retailers of veterinary medicines, and for manufacturers of exempted medicines for small pet animals. That will improve our regulatory oversight in those areas, without creating an unnecessary burden.

This draft regulations will require pharmaceutical companies and wholesale dealers to report information on supply shortages, which will help us to secure the supply chain and maximise our ability to take action when there is a shortage and maintain the availability of treatment options for our animals.

We are progressing the Government's plan to tackle antimicrobial resistance through a further reduction in the unnecessary use of antibiotics in animals. The draft regulations make it clear that antibiotics must not be used routinely or to compensate for poor farming practice, while still allowing for preventive use of antibiotics in critical cases in which animal welfare is at risk.

Olivia Blake (Sheffield, Hallam) (Lab): I admire the ambition in the Minister's statement, but does he share my view that antifungal resistance is not taken seriously enough in this country and that more could be done on prevention, especially in relation to agents that help to get rid of fungal infections, which are dangerous to animal and human health? It is just as serious an issue as antibiotic resistance.

Sir Mark Spencer: The hon. Lady is right to highlight that point. We pay a lot of attention to antimicrobial resistance, but she is right to say that we do not always take antifungal resistance as seriously. We need to be aware that nature has the ability to mutate and change, and we need to meet the challenges head on. That is why the regulatory regime is so important: to prevent the overuse of some of these treatments, which could lead to resistance forming.

Making changes to farm infrastructure and practices takes time. The changes that we are making will allow for that, while putting trust in our farmers, who have voluntarily reduced their antibiotic use by 59% since 2014.

Finally, the draft regulations will update the fees for the regulatory services provided under the 2013 regulations, in line with the cost recovery principles in the "Managing Public Money" guidelines. They will allow us to continue the effective regulation of the veterinary medicines sector, protecting animal health, human health and the environment. I commend them to the Committee.

4.38 pm

Daniel Zeichner (Cambridge) (Lab): It is a pleasure to see you in the Chair, Dame Maria. I thank the Minister for his customarily thorough introduction to this substantial and weighty 209-paragraph instrument on an important subject.

The Opposition support the primary objectives and the key components of this legislation, and we will not be opposing it. Many stakeholders have pointed out that it is long overdue and much needed, as the 2013 regulations are no longer fit for purpose. I thank the National Office of Animal Health, the National Farmers Union and the British Veterinary Association in particular for the information and observations that they have provided. We have also had the benefit of a very well-informed discussion of the draft regulations in the other place.

Fundamentally, we agree with measures that will render the Veterinary Medicines Regulations more effective and modern and enable the development and marketing of veterinary medicines. We hope that these measures will facilitate greater confidence and investment in the UK's animal health industry, which is a high-value, high-growth and high-skill sector that contributes significantly to the UK.

It is hard not to note the force of the comments from the Veterinary Medicines Directorate, as reported by the Secondary Legislation Scrutiny Committee, which makes it very clear just how important it is that our rules be closely aligned with those of our European neighbours:

> "The changes introduced by this SI mirror the requirements in EU law…This further reduces the current levels of UK-EU divergence in relation to labelling".

I heard similar points made strongly at a recent presentation at the NOAH conference here in Westminster, over the road.

We agree that we must redouble our efforts to tackle antimicrobial resistance. It is important to recognise that UK livestock sectors have made considerable progress in reducing their reliance on antibiotics. The Veterinary Medicines Directorate's UK veterinary antibiotic resistance and sales surveillance report, which was released in November 2022, shows that UK antibiotic sales for food-producing animals have reduced by 55% since 2014, representing the lowest sales to date. The efforts made also include an 83% reduction in the use of the highest-priority antibiotics for human medicine.

But we need to push harder and go further. That is why we support one of the key objectives of this legislation, which is to put an end to the routine or predictable prophylactic use of antibiotics and restrict treatments to exceptional use only. I can understand why the Veterinary Medicines Directorate stopped short of a blanket ban, but will the Minister clarify what is defined as "exceptional use"? Will he provide more explanation as to how the scope of the exemptions will be contained so that the apparent spirit of that provision is respected? Some stakeholders would certainly appreciate reassurance on that important point.

We agree with the rationale underpinning the requirement for the holder of a marketing authorisation who identifies a shortage of any veterinary medicinal product to notify the Secretary of State. We need to improve our intelligence and foresight of shortages in order to protect animal health and welfare more effectively. I am told that there were shortages of Heptavac this year. Farmers have had historical issues with Enzovax, and pain relief products continue to be in short supply, creating significant issues for timeliness of treatment. It would make a difference to farmers if they could rely on a certain supply of the medications that have significant impact on their livestock.

I appreciate the British Veterinary Association's point that the reporting system must be implemented in a way that avoids panic buying and stockpiling. It will also depend for its efficacy on timely and reliable intelligence gathering and data reporting. Will the Minister provide more details of the progress on the development of that system? Can he say how he will ensure that it is underpinned by timely and robust information and that it mitigates unintended consequences such as the potential for stockpiling?

One of the main strengths of this legislation is that it should help to ensure that the UK has access to a more reliable and comprehensive supply of medications by reducing divergence from the EU. If we want the UK market for veterinary medicines to continue to offer a broad range of products to vets and animal owners, and to be an attractive place to bring new licensed medicines and innovations, UK regulations should not act as a barrier to trade.

I note the divergence on the issue of data collection: the EU has a mandatory system for the recording of antibiotic use, whereas this legislation maintains a voluntary approach in the UK. I further note that it is intended that the voluntary approach be continued, but that the VMD should have the power to introduce a mandatory approach if it is deemed necessary, as is provided for in the legislation.

[Daniel Zeichner]

The main area of remaining divergence, which is still a significant concern, relates to Northern Ireland. Many people are worried that farmers in Northern Ireland might not be able to access a wide range of important medicines after the December 2025 deadline, when the grace period for the supply of veterinary medicines from Great Britain to Northern Ireland ends. We are talking about approximately 30% to 50% of products ceasing to be available—a significant proportion, which could compromise animal health and welfare and could have an impact on the competitiveness of Northern Ireland's agriculture. Will the Minister please explain whether and how his Government plan to find a permanent solution to ensure that veterinary medicines remain accessible to farmers in Northern Ireland? Will he update us on any negotiations with the EU to achieve that aim? The Opposition support the draft regulations but, as ever, there are questions to be answered.

4.44 pm

Sir Mark Spencer: I am grateful to the shadow Minister for his support and co-operation. He mentioned divergence, but it is important to recognise that we do not want divergence for divergence's sake. We want to align with the EU to make things as simple as possible for our food producers, but to maintain our ability to do things differently if we so choose.

Antibiotic use is an important part of the strategy, which I know interests a lot of hon. Members across the House. We have considered it very closely, and it is something that we are very much looking to do.

The shadow Minister asked why we do not fully ban the preventive use of antibiotics in healthy animals. We have included provision for vets to prescribe antibiotics to prevent disease in animals in exceptional circumstances, because a blanket ban might result in a risk to animal welfare and a risk of increased spread of disease.

Our position for many years has been that we do not support antibiotic use to compensate for poor animal husbandry or hygiene. That is now laid out in legislation. The way we would describe that exceptional circumstance, I suppose, is that the use of veterinary antibiotics to prevent disease would have to be prescribed by a veterinary professional. That would be permitted only where there would be a risk of infection or severe consequences if antibiotics were not applied.

The shadow Minister asked about supply in Northern Ireland. We are very conscious of that issue. The changes being made are in line with international standards and, to a large extent, with European regulations. This will encourage applications for new and innovative medicines for the whole UK, including Northern Ireland; such applications could include those for new vaccines to reduce the reliance on antibiotics. They would apply in Northern Ireland, as well as the rest of the UK.

The shadow Minister talked about shortages, which we recognise could be a challenge. The review of shortages will be on a case-by-case basis. We will work with veterinary officers, as well as suppliers and wholesalers, to ensure that there is reliable and available information as soon as an issue is known and identified. In instances of temporary supply issues, the VMD will permit the import of alternatives only until the supply issue is resolved or another suitable product is authorised.

I hope that I have answered the shadow Minister's questions. I am grateful for the Committee's support this afternoon.

Question put and agreed to.

4.47 pm

Committee rose.