Meeting with HPRA Stakeholders

Monday, 27 April 2020

9.00 am to 11.00 am.

The purpose of the meeting was to discuss with stakeholders the outcome of the public consultation on the implementation of HPRA report on the method of supply of antiparasitic veterinary medicinal products that are intended for food-producing animals. The meeting took place by virtual means; an earlier planned physical meeting had to be abandoned due to Covid-19 restrictions.

The HPRA report concluded that, with the exception of products for bees, this group of products did not satisfy the criteria set down in Article 34 of Regulation 2019/6 to allow exemption from prescription control. The primary basis for this conclusion was that resistance to certain anti-parasitic products has been documented and is on the increase and this poses a threat to the long-term availability of effective parasite treatments and, consequently, to animal health and productivity. In order to follow through on the primary recommendation of the report, and indeed to ensure future regulatory compliance, all antiparasitic veterinary medicinal products intended for food-producing animals, with the notable exception of anti-parasitic products for bees, that are currently supplied without veterinary prescription will be subject to prescription control from January 2022. Recognising that this one action, on its own, will not address the issue of antiparasitic resistance, the HPRA report makes a number of supplementary recommendations including that a multi-actor stakeholder approach should be taken to elaborate national guidelines for sustainable parasite control, including the development of consistent scientifically-based advice on targeted selective treatments. It is also recommended that stakeholders, including veterinarians, other health care professionals and licensed merchants be informed of this report and encouraged to engage with the authorities in relation to the elaboration and implementation of any new regulatory framework.

The full HPRA report can be accessed here.

Meeting Agenda

9.00 am	Introduction to the meeting – Ms. Elaine Hynes, Planning & Authorisation Manager, Veterinary Sciences Department, HPRA
9.05 am	Round table introduction of delegates.
9.20 am	HPRA presentation on outcome of report and stakeholder feedback on implementation by Dr. David Murphy, Veterinary Sciences Department, HPRA.
9.50 am	Round table discussion with stakeholders, moderated by Dr. J. Gabriel Beechinor, Director of Veterinary Sciences, HPRA.
11.00 am	Close of meeting.

The HPRA gave a brief presentation for the purpose of:

- Providing some background to the scientific and regulatory considerations that triggered the HPRA review of the method of supply of antiparasitic veterinary medicinal products that are intended for food-producing animals;
- Summarising the outcome of the review, which was undertaken by the independent Expert group on behalf of the HPRA, and its associated recommendations;
- Providing feedback on the recent stakeholder consultation on implementation of the outcome of that review; and,
- Outlining the next steps in the implementation process.

Discussion – the key points made by stakeholders participating in the meeting, together with the HPRA's response

The Irish Farmers Association (IFA) acknowledges that anthelmintic resistance is an animal health concern that needs to be addressed and they recognise the importance of targeted and better use of antiparasitic products on farms. However, while recognising the legal constraints on the HPRA, they expressed concern about what they saw as potential negative consequences of the change of supply category to prescription control. In particular, they would consider it of critical importance that the prescribing and supply of these products does not become the remit of one service provider because this has the potential to increase costs for the farmer and it will not facilitate the recommended multi-stakeholder approach to sustainable parasite control. In addition, due to the difference in prescribing systems for these products operated on the island of Ireland, there is a concern that a two-tier supply system will come into effect on the Island. In this scenario, it may be easier and more cost-effective for all farmers on the island to source these products in Northern Ireland (NI), where suitably qualified persons (SQPs) prescribe these products. It was suggested that a system similar to that which exists in NI must be facilitated in the Republic of Ireland. When drafting the national legislation to complement Regulation 2019/6, the Department of Agriculture, Food and the Marine (DAFM) should ensure the maximum flexibility is provided to allow for the implementation of these changes and to ensure that the current route of supply is not subjected to unfair trading practices and a discriminatory route of supply forced upon farmers.

The Irish Creamery Milk Suppliers Association (ICMSA) recognise the animal health importance of anthelmintic resistance, but are of the view that the action to move all antiparasitic products to prescription control is not an appropriate course of action in that it is expected to increase bureaucracy and cost to farmers and may not have any effect on the resistance situation. It was suggested that the other recommendations in the HPRA report (elaboration of a national strategy to control resistance to antiparasitic medicines, the provision of advice on prudent use of the products concerned, etc.) should be implemented as a first step, before requiring that these products are subject to prescription control. Also, they share the concern that the veterinary profession will have a monopoly on the supply of these needed and extensively used products and that in any future system there should be separation of prescribing and dispensing. Further, they questioned who is responsible for regulating pricing of veterinary medicinal products.

The Irish Co-operative Organisation Society (ICOS) also recognise the animal health importance of resistance to antiparasitic products and the need to protect efficacy into the future by implementing best practice for use of such products. However, supply of products through Licensed Merchant (LM)

outlets does not in itself pose a risk. They are of the view that a consequence of the planned move to prescription control will be less competition: farmers will now be forced to attend their local veterinary surgeon's office to secure a prescription and will be unlikely to then go to a LM, when the VMPs in question will be available at the point of issue of the prescription. This will drive up costs to the user. SQP's employed by co-ops are ideally positioned to advise and influence farmers decisions on the correct type and dosage of anti-parasitic treatments required by their livestock. Their view is that these VMPs should be available under similar criteria outlined under Schedule 8 of S.I No 786 of 2007 (for intramammary antibiotic tubes for the control of mastitis). On this point, they argue that current arrangements for the prescribing and dispensing of intramammary antimicrobials has, together with complementary actions/activities, facilitated a reduction in somatic cell count in the national herd in recent years and that this example exemplifies that a lot can be achieved with this model of a multi-stakeholder approach. Further, they argue that there should be regulatory alignment on the Island. They also suggested that there is a need for new solutions to facilitate data collection which in turn would allow for data driven decisions and, to address this point, the ability to prescribe electronically requires serious consideration in any future regulatory framework.
They also asked if any consideration had been given to allowing for wider availability of preventative medicines, such as vaccines.

The view of the Irish Pharmacy Union (IPU) is that it does not agree with the decision of the HPRA to move antiparasitic products to prescription control in that there is no evidence at this time that it will solve the resistance issue. Further, they are of the view that a significant regulatory decision such as this should only be taken after a comprehensive impact assessment has been conducted. However, it was acknowledged that this was not the remit of the Expert group. Also, they suggest to separate the prescribing and dispensing of veterinary medicinal products and they expressed a concern that the products in question could be supplied from Northern Ireland if a different regulatory model is adopted in the Republic of Ireland. On the issue of e-prescribing, it was noted that this was a topic that the Department of Health have been wrestling with for some time and, as yet, have not come up with a satisfactory solution. From its perspective, if this is a solution to be pursued, a single system that applies to all the professions (vets, doctors, dentists, ….) should be developed.

The Veterinary Ireland view is that they support the decision to move all anti-parasitic products for food-animals to prescription control and that this will be an important element to addressing the resistance situation in that it will ensure greater control over product use and facilitate more veterinary input into decision making on the farm (in terms of diagnostics, product choice, treatment approaches, etc). It also recognises the importance of training in this area, but the nature of that training and how it is rolled out needs to be agreed with the veterinary profession. In response to the suggestion that vets would have a monopoly on supply and that this would increase costs, it was stated that the facts do not show this to be correct in that the profit margins on many POM products supplied primarily or only by vets are very low. Further, it was stated that any move to separate prescribing from dispensing as a general principle would undermine the viability of practices which could have a significant impact on the provision of veterinary services to rural areas. On the issue of e-prescribing, the Veterinary Ireland view is that this sounds ideal if the appropriate tools are in place to allow for it. However, at this time veterinary practices do not have the necessary tools and these would have to be provided.

The Animal and Plant Health Association (APHA) recognise that resistance to anti-parasitic products is an animal health concern that needs to be addressed and that measures must be taken now to ensure

that the products available remain effective into the future. In addition, it acknowledges the need to move to prescription control to ensure compliance with Regulation 2019/6. However, it is of the view that this action will, on its own, do little to address the resistance situation and that there is a need for a more holistic approach to sustainable parasite control. In terms of the practicalities of implementing the change, the APHA view is that reduced access to these products could result in animal health and welfare issues and therefore, during the transition period, the supply chain must remain frictionless and able to meet demand. A communication strategy should be put in place to ensure that farmers are aware of the new regulations ahead of the changes.

The National Association of Veterinary Wholesalers has a concern that the change in supply category will reduce access to needed medicines and that the cost of these medicines may increase. It was suggested that if change is needed, the POM(E) supply route may be preferable to POM.

Orla Keane (Teagasc) declared herself to be a member of the Expert group that conducted the review on behalf of the HPRA and that, while an employee of Teagasc, the views expressed at the meeting were to be considered her personal views. She advised that there is a need for change on the ground to address the issue of resistance – there is a need to understand the risk factors and then consider what can be done to mitigate those risks. In terms of the practicalities of prescription control for these products, she would not envisage a system requiring a written prescription every time a wormer is needed on a farm, rather the approach should be on a herd health basis.

The Veterinary Council of Ireland (VCI) indicated that it was listening to the views of the various stakeholders with interest, that it recognised the potential challenges for end users in terms of access to these vital medicines that may arise with the change in supply route and that it looks forward to working with other stakeholders to implement the change. In line with a broader VCI strategy, it is committed to a greater degree of oversight of the veterinary profession generally and that this would encompass applying best practice when it comes to prescribing.

The Animal Health Ireland (AHI) position is that they are willing to play a role in facilitating compliance with whatever future system is put in place relating to the supply of anti-parasitic products. AHI is happy to provide advice on best practice, to provide input into any required training and to communicate, as appropriate, on resistance generally or the change in supply route and associated consequences.

The DAFM indicated that it was listening carefully to the views expressed by all stakeholders and advised that, over the coming months, it will meet with each of the stakeholders individually to further discuss the change and receive input on the design of the future regulatory system which must, ultimately, be in the best interests of animal health, ensure that users can continue to farm profitably while at the same time operating within the legislative/regulatory framework. It also advised that an online public consultation will be launched in the coming weeks relating to national legislation required to complement Regulation 2019/6. All participants at the meeting were invited to consider and make a contribution to that consultation.

HPRA response to selected comments:

The HPRA believes that the scientific evidence is that there has been a significant increase in antiparasitic resistance, even if many stakeholders are unaware of it as being a clinical problem on farms. If left unchecked, anthelmintic and fluke resistance has the potential to negatively impact animal health and productivity. However, if scientific parasite management principles are applied, reversion of resistance parasites towards susceptibility may be achieved. In addition, the review conducted by independent Experts concluded that antiparasitic veterinary medicinal products for food-producing animals do not comply with the future legal criteria to allow them to be supplied without a veterinary prescription. Therefore, the HPRA believes that the decision taken by the Authority is necessary to ensure compliance with the legal requirements. In accordance with existing national law, prescriptions may be issued by veterinary practitioners only; however, antiparasitic veterinary medicinal products that are prescribed may be supplied by vets, pharmacists and licensed merchants. Responsibility for the legislative framework to underpin the operation of the future system for the supply of veterinary medicinal products, including the operation of prescriptions, rests with the DAFM and there will be further opportunities for stakeholders to engage directly with DAFM on the elaboration of that future system. The proposal to restrict these products to POM (E) supply is not an option as the legislation requires that they be subject to prescription control.

The HPRA accepts that the requirement for a veterinary prescription will pose an additional challenge for many farmers. However, the HPRA points out that there may be savings through avoiding unnecessary or inappropriate treatments, and changing treatment practices to target certain animals / categories of animals. Moreover, there is an opportunity to develop bespoke treatment protocols for each farm, with potential animal health and productivity enhancement.

The HPRA is engaged with stakeholders to raise awareness of the pending changes and will continue these efforts over the coming period. The HPRA is in the course of preparing detailed guidance for marketing authorisation holders to ensure that the changeover to new packaging can be managed as efficiently as possible while ensuring compliance with the requirements.

The development of best practice protocols to improve the prescribing and use of the products to address resistance is encouraged. The HPRA has, in the past, contributed to the elaboration of such protocols nationally and is happy to contribute or participate in this task again in the future.
The HPRA undertakes to communicate the outcome of the public consultation on the implementation of HPRA report to all stakeholders.

Attendees:

Organisation	Representative
IFA	Tomas Burke
ICMSA	Aine O'Connell
ICOS	Eamonn Farrell
Teagasc	Orla Keane
APHA	John Keogh
National Association of Veterinary wholesalers	Donal O'Sullivan
Veterinary Council of Ireland	Niamh Muldoon
Veterinary Ireland	Conor Geraghty
Irish Pharmacy Union	Pamela Logan
Animal Health Ireland	Natascha Meunier
Department of Agriculture, Food and the Marine	Rob Doyle
Department of Agriculture, Food and the Marine	Colm Forde
HPRA	J. Gabriel Beechinor
HPRA	David Murphy
HPRA	Elaine Hynes

ENDS