Feedback on consultation on the implementation of the HPRA report on the method of supply of antiparasitic veterinary medicines that are intended for use in food-producing species - public
April 2020

Background
Since 2004, when the current legislation that established the ground rules for allocation of a method of supply for veterinary medicinal products in the EU was set, there have been a number of important developments:

- Anthelmintic resistance has been widely reported in parasites of a number of livestock species in Ireland. The reports highlight an increasing problem nationally.
- Globally, resistance to all currently used antiparasitic veterinary medicinal products has been demonstrated. Resistance is developing year-on-year and is now a significant animal health issue.
- Under existing EU legislation, veterinary medicinal products that contain new drugs that have not been authorised previously cannot benefit from the exemption from prescription supply for a 5-year period. This restriction has resulted in products that contain novel drugs being restricted to supply only under prescription, while existing products containing established drugs that are indicated for the same parasites being supplied without prescription.
- All antiparasitic veterinary medicinal products for food-producing animals that have been authorised centrally by the EU Commission following the opinion of the European Medicines Agency, with the exception of medicines for bees, have been designated a prescription supply category.
- In recent years a number of European Union focus meetings and publications on this topic have recommended that antiparasitic veterinary medicinal products be restricted to veterinary prescription, in order to safeguard the efficacy of the products concerned for the future and to halt the spread of resistance.
- Regulation 2019/6 introduced new provisions for the authorisation of veterinary medicinal products that are targeted at limiting the development of antiparasitic resistance.

For these reasons, the HPRA set up an expert group to review the available scientific evidence and produce a report on the matter. The expert group concluded that:

- There is widespread resistance to anthelmintics and flukicides in livestock in Ireland,
- Anthelmintic resistance in parasites of other food-producing species has been demonstrated in European countries which have similar farming and animal husbandry conditions to those in Ireland,
- Resistance in ectoparasites to several veterinary drug classes has been identified in European countries that have similar farming and animal husbandry conditions to those in Ireland,
- Resistance to anti-coccidial veterinary medicinal products has been shown in European countries that have similar farming and animal husbandry conditions to those in Ireland,
- Risks have been identified about environmental safety of anthelmintic and ectoparasitic veterinary medicinal products, as well as for user safety, particularly if the products are administered incorrectly. However, evidence concerning environmental risks of anti-coccidial drugs is sparse,
- In view of the widespread use of the products concerned over many years and the excellent record of compliance with the food residue standards, the availability of antiparasitic veterinary medicinal products through licensed merchant outlets does not present a particular risk to public health as regards residues,
- The labelling of veterinary medicinal products is generally very comprehensive and includes information on warnings, contraindications, withdrawal periods and potential adverse reactions. The products concerned have been used for many years by farmers and end-users in

compliance with the instructions. Noting that adverse reactions to veterinary medicinal products have been reported annually to the national competent authority, the incidence of adverse reactions appears low and does not signal a particular problem associated with particular pharmaceutical forms, or a lack of skill or information in their use. Therefore, the availability of antiparasitic veterinary medicinal products through licensed merchant outlets does not present a particular risk in that respect,

- Knowledge of parasitology and best practice in the use of antiparasitic veterinary medicines has changed over recent years and is not evenly distributed amongst stakeholders. This fact does not preclude that antiparasitic products should be used correctly and only when necessary.

The group advised that the antiparasitic products that are supplied without a veterinary prescription do not comply with all of the criteria contained in Article 34 of Regulation 2019/6. Their report was considered and adopted by both the HPRA's expert Advisory Committee for Veterinary Medicines and the Authority of the HPRA itself during 2019. Following the adoption of the report, the HPRA held an online public consultation regarding its implementation. The consultation, which was aimed at determining the next steps and timelines needed for ensuring market compliance with the findings of the report, took place from 13 December 2019 to 28 February 2020.

Results of the consultation

Twelve responses were received, including two from industry, four from farming organisations / individual farmers, one from a cooperative organisation, two from pharmacy representatives / individual pharmacist, and three from wholesalers / individual licensed merchants.

Furthermore, on 27 April 2020, the HPRA held a (virtual) meeting with 11 interested parties, including the Department of Agriculture, Food and the Marine, farming organisations, veterinary and pharmacy organisations, animal health and research organisations, the pharmaceutical industry and wholesalers organisation.

The key points of the submissions received have been summarised below together with the HPRA's response to each question (Q) or comment.

Industry / marketing authorisation holders

Q: Can it be clarified that the new classification will not apply to anticoccidials that are licensed as feed additives?

HPRA response: Yes. Products that are regulated as feed additives by the Department of Agriculture, Food and the Marine (DAFM) are outside the scope of the report.

Q: Can it be clarified whether the new classification will apply to flukicides?

HPRA response: Yes. It is correct that flukicides are not anthelmintics, however the report covers all antiparasitic veterinary medicinal products intended for use in food-producing animals. This includes flukicides.

Q: Are horses considered as food producing animals in Ireland and will they be included within the scope of this report?

HPRA response: Yes. Antiparasitic products for horses are included within the scope of this report.

Q: Despite the interest from stakeholders, currently there is insufficient laboratory diagnostic capacity in Ireland to comply with the proposed regulations.

HPRA response: Comment noted. The period between now and 2022 should be used wisely to adapt national infrastructure and practices to the new requirements.

Q: If training in sustainable parasite control is a requirement under the new legislation, who will be responsible to ensure the necessary training is available to prescribers and who will monitor that prescribers have received the required training?

HPRA response: DAFM, rather than the HPRA, is the competent authority for developing or changing the legislative framework for prescribing and dispensing veterinary medicines. The Veterinary Council of Ireland is the competent authority for ensuring the continued professional development and training of veterinarians who will prescribe the products concerned.

Q: Whilst the recommended change from LM to POM may be required under Regulation 2019/6, this change in isolation may do little to address the growing evidence of anthelmintic resistance in cattle and sheep. APHA proposed specific logistical questions for compliance with new requirements.

HPRA response: The HPRA accepts that evidence-based prescribing and appropriate tailored treatment protocols are essential to halt the further development of antiparasitic resistance in Ireland. The HPRA has prepared detailed guidance for marketing authorisation holders to ensure that the changeover to new packaging in the period to January 2022 can be managed as efficiently as possible while ensuring compliance with the requirements.

Q: The current regulations allow prescription veterinary medicinal products to be supplied on receipt of a prescription by a pharmacist, and in the case of some immunologicals and antiparasitic POMs, by a licensed merchant. Will new prescription requirements be put in place to implement the changes foreseen?

HPRA response: DAFM, rather than the HPRA, is the competent authority for developing or changing the legislative framework for prescribing and dispensing veterinary medicines. The HPRA understands that the dispensing of antiparasitic products by veterinary practitioners, pharmacists and licensed merchants (under veterinary prescription) will continue into the future.

Q: For products intended for bees, can we expect that the 'Licensed merchant' category remains valid?

HPRA response: Yes. The HPRA expects that the LM category will remain valid in the future and that antiparasitic products for bees will continue to be allocated to this supply route.

Q: Currently there is provision for LM-labelled products to be supplied by mail-order following online purchase from certain licensed outlets, whilst POMs are not permitted to be supplied in this way. Is there scope for this to be reviewed as part of the change in legislation?

HPRA response: The HPRA understands that currently it is not allowed to supply prescription medicines by mail order. The HPRA does not have information on whether this will change in the future. DAFM, rather than the HPRA, is the competent authority for developing or changing the legislative framework for prescribing and dispensing veterinary medicines.

Q: Reduced access to these products could result in animal health and welfare issues. During the transition period and thereafter, 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.

HPRA response: The HPRA believes that evidence-based prescribing will enhance animal health and welfare. The HPRA is engaged with stakeholders to raise awareness of the pending changes and will continue these efforts over the coming period.

Q: The development of new guidance and best-practice initiatives to improve the prescribing and use of antiparasitic veterinary medicines is key to achieving the ultimate aims of this change in legislation. Certain aspect of this approach will be determined by the structure of the new provisions for prescription/supply. This should include the following elements:

- Cross-industry initiatives involving multiple stakeholders.
- Educational resources and CVE provision for veterinary surgeons.
- Educational resources and KT programmes for farmers.
- Certification of end-user competence/training.
- Embedding parasite control into herd health planning/annual review.
- Diagnostics/monitoring of treatment efficacy.
- Investment in research and development.

HPRA response: The HPRA agrees that the solution to antiparasitic resistance will involve a multi-stakeholder approach. 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 more than happy to contribute or participate in this task again in the future. The HPRA notes that aspects of the proposed approach will depend on the legal framework for prescribing veterinary medicinal products. DAFM, rather than the HPRA, is the competent authority for developing or changing the legislative framework for prescribing and dispensing veterinary medicines.

Farming organisations / farmers

Q: Prescriptions for routine non-antibiotic dosing products such as wormers and fluke products should not be required given that such products are not relevant to human resistance and AMR.

HPRA response: The issue does not specifically relate to antimicrobial resistance. The issue is that antiparasitic resistance is on the increase in Ireland and around the world. Unless addressed now this issue will negatively impact on animal health and productivity and could threaten the viability of certain livestock farms in this country. Moreover, because of the known resistance, antiparasitic products for food-producing animals do not comply with the criteria in Regulation 2019/6 to allow them to be supplied without a veterinary prescription.

Q: Antiparasitic products are vital tools in reducing dependence on and the need to use antibiotics on farms. It is of critical importance that the prescribing and supplying of these products does not become the remit of one service provider. In addition, due to the difference in prescribing systems for these products operated on the island of Ireland, a two-tier supply system will come into effect. It would be easier and more cost-effective for all farmers on the island to source these products in Northern Ireland, where SQPs prescribe these products. SQP prescribing of these products must be facilitated in the Republic of Ireland.

HPRA response: The issue does not directly relate to antimicrobial resistance or link to antibiotic use in animals. Although it is often unrecognised, anthelmintic resistance is a significant issue on many farms in Ireland and needs to be addressed using scientific principles for sustainable animal management including parasite control. Moreover, the HPRA report indicates that the antiparasitic products concerned do not comply with the criteria in Regulation 2019/6 to allow them to be supplied without a veterinary prescription.

Responsibility for the design and implementation of the legislative framework to underpin the operation of the future system for the supply of veterinary medicinal products, including the operation of prescriptions and the avoidance of anti-competition practices, rests with the DAFM.

The HPRA appreciates the difficult economic challenges faced by farmers and animal owners. The HPRA is obliged to be compliant with EU legislation and understands the benefits of EU Membership in facilitating trade with Member States. Sourcing veterinary antiparasitic products from Northern Ireland to circumvent the goal of evidence-based prescribing would not be helpful in halting the development of resistance. Moreover, there are also implications in terms of the possession and use of unauthorised animal remedies, including compliance with Bord Bia quality schemes and DAFM farm controls.

Q: Medications for bees should be exempted from any requirement for prescriptions.

HPRA response: The report clearly states that medicines for bees are a special case and antiparasitic products comply with the criteria for exemption from veterinary prescription control.

Q: Farmers will not go to a vet for a prescription for anthelmintics. Farmers are very well educated and know exactly what anthelmintics are required as a result of co-op testing.

HPRA response: 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. The goal is for evidence-based prescribing and effective animal management to ensure sustainable parasite control. There is an opportunity to develop bespoke treatment protocols for each farm, with potential animal health and productivity enhancement.

Evidence of resistance to antiparasitic veterinary medicinal products is increasing in Ireland and around the world. However, it is often not recognisable clinically until it is too late. Unless effective action is taken now, the viability of livestock farming in certain farms in Ireland may be threatened, as chemotherapy will no longer work. The HPRA cannot comment on co-op testing as we are not aware of what specific tests are being conducted, which animal samples are taken for testing, what validation has been carried out on the testing methods and how the results are used to inform the choice of chemotherapy.

Q: The current route of supply and prescribing methods via Suitably Qualified Persons (SQP's) has not resulted in Ireland having a significant increase in resistance being detected. Therefore, in the first instance, there should not be a change in the route of supply or the prescribing method. 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. The HPRA and DAFM should ensure the maximum flexibility is provided to allow for the implementation of these far-reaching 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. Farmers will now be forced to attend their local veterinary surgeon's office to secure a prescription. They will be unlikely to then go to a LM when the VMPs in question will be available to them at the point of issue of the prescription. An unintended consequence of this recommendation will be a potential market distortion, which will result in less market competition. All prescriptions for food producing animals to be made available on the Animal Identification and Movements Database (AIM) or another equivalent national database. ICOS wants to clearly state that these VMPs should be available under the similar criteria outlined under Schedule 8 of S.I No 786 of 2007.

HPRA response: 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 resistance and fluke resistance have the potential to render certain farms in the country as unsuitable for livestock in the future, as chemotherapies fail. However, if scientific parasite management principles are applied before it becomes too late, reversion of resistance parasites towards susceptibility may be achieved. The HPRA believes that now that the evidence for resistance is manifest in Ireland it must act to ensure compliance with the legal requirements. To act otherwise would not be in the national interest. It would also run the risk of a negative finding from EU auditors and could have negative trade implications. Regulation 2019/6 does not allow for licensed merchants to be given new powers to write veterinary prescriptions, even if the Regulation recognised that in those countries where such authority existed before the new Regulation was adopted in 2019 (i.e. the

UK) the practice could continue. The HPRA does not have a role in how the animal identification and movements database operates or how the products concerned might be supplied under a new national legal supply system.

Pharmacy organisations / pharmacists

Q: More than 300 pharmacies are actively involved in supplying veterinary medicinal products in Ireland. LM ensures good access, but if change is needed POM(E) would be better. If Ireland reclassifies antiparasitics to POM and if the UK does not, this may pose a big hurdle for companies who would have to make separate packs for the UK and Irish markets.

HPRA response: The issue is that antiparasitic resistance is progressing in Ireland and unless effectively addressed now it could have a significantly negative impact on animal health and welfare, as well as sustainability of livestock farmers in the future. Furthermore, veterinary medicinal products for food-producing animals do not comply with the criteria to allow them to be supplied without a veterinary prescription. LM is therefore not appropriate. However, in accordance with existing national law, antiparasitic veterinary medicinal products that are prescribed may be supplied by vets, pharmacists and licensed merchants. If the products were restricted to POM (E) supply, this would mean that the products could no longer be supplied by licensed merchants (under prescription) and this would negatively impact users. Prescribing by non-vets is not allowed under Regulation 2019/6, so POM(E) is not an option.

While the UK left the European Union on 3 January 2020, Ireland remains a member and therefore must be compliant with EU legislation, as opposed to being influenced by non-EU countries. It is possible that over time there could be regulatory divergence between the EU and the UK on many issues and that separate packs for the UK and Irish markets may be inevitable. However, the HPRA enjoys a close working relationship with the UK and both the UK authority and the HPRA are committed to maintaining harmonisation for as long as possible.

Q: To upregulate antiparasitic VMPs to strict POM status will not resolve resistance to anthelmintics. Rather the products should be supplied in the POM(E) category. Also suggest to separate the prescribing and dispensing of veterinary medicinal products. Issue of products concerned being supplied from Northern Ireland or over the internet.

HPRA response: The change in method of supply to prescription-only is expected to be part of a wider national initiative to halt the development of antiparasitic resistance. While it would be a matter for the Department of Agriculture, Food and the Marine, together with other stakeholders, to develop appropriate use guidelines and control systems, the period between now and January 2022 allows a period of time to address the issue. The HPRA hopes that by bringing this matter to public attention now, a multi-stakeholder approach can be brought to bear on the matter. Should this opportunity be wasted, antiparasitic resistance will continue to develop and negatively impact on the sustainability and viability of Irish livestock and food-production.

If the products were restricted to POM (E) supply, this would mean that the products could no longer be supplied by licensed merchants (under prescription) and this would negatively impact users. DAFM, rather than the HPRA, is the competent authority for developing or changing the

legislative framework for prescribing and dispensing veterinary medicines. Furthermore, prescribing by non-vets is not allowed under Regulation 2019/6, so POM(E) is not an option.

The separation of prescription and dispensing of antiparasitic veterinary medicinal products would be expected to pose additional costs for farmers, and might not be workable in remote parts of the country. However this matter is outside the role of the HPRA, and is a matter for the Department of Agriculture, Food and the Marine to consider.

Regarding the supply of antiparasitic veterinary medicinal products from Northern Ireland or over the internet, this is a matter outside the remit of the HPRA. There is a risk that products supplied over the internet by agents or companies that are not regulated within the State are short dated, and storage conditions necessary to maintain the product quality and efficacy might not have been respected. In such cases users risk wasting their money and putting the health of their animals at risk. There are also implications in terms of the possession and use of unauthorised animal remedies, including compliance with Bord Bia quality schemes and Department rules for cross-compliance subsidies.

Wholesalers / licensed merchants

Q: Both about the timeline for introduction of the new classification for antiparasitic VMPs and also the precise definition of Veterinary Prescription and who may write them are a cause for concern. There are considerable costs involved in changing packaging.

HPRA response: The timeframe for the change to prescription control is more than 18 months. This timeline is the maximum possible to ensure compliance with the requirements of Regulation 2019/6, which has an application date of 28 January 2022. By flagging this matter now, the HPRA expects that all stakeholders will make the necessary changes to ensure compliance. The HPRA is conscious that antiparasitic resistance continues to develop across the country and that timely actions are needed to halt this development.

Concerning the controls and definition of veterinary prescriptions, DAFM, rather than the HPRA, is the competent authority for developing or changing the legislative framework for prescribing and dispensing veterinary medicines.

Concerning the costs involved in changing packaging, the HPRA recognises that this is the case. However, by flagging the matter to the industry now and by implementing a change programme for the companies concerned, the HPRA expects that the changes can be introduced at an appropriate time (e.g. when other changes are being made) to facilitate a smooth transition.

Q: There are concerns over natural run down of products when new labelling comes into force.

HPRA response: The HPRA will work with marketing authorisation holders and the DAFM to implement the change process as smoothly as possible.

Q: The HPRA should have consulted directly with Licensed Merchants as their livelihood is being threatened if the products are removed from them.

HPRA response: Licensed Merchants are expected to continue to have an important role in the supply of antiparasitic veterinary medicinal products for food-producing animals. They will still be able to supply the products concerned; however the products will be subject to veterinary prescription. The HPRA did reach out to Licensed Merchants during the consultation:

- *Through the DAFM (the competent authority for regulating LM products), an email that was prepared by the HPRA was sent in mid December 2019 to all Licensed Merchants advising of the HPRA consultation and its importance. Hyperlinks to both the HPRA report and the consultation on the implementation were provided.*
- *The consultation was highlighted on the HPRA website. It was open to the public, including interested parties and Licensed Merchants to reply to the consultation.*
- *The HPRA highlighted the development in various media articles, including in a magazine that is directed specifically towards Licensed Merchants. Furthermore, the development was widely reported in farming journals and press.*
- *The HPRA targeted a number of organisations known to operate or associated with Licensed Merchants during the consultation.*

Q: Over 2,000 qualified persons sell LM products in Ireland. They have supplied customers with LM products for over 40 years. Their skills should not be cast aside. These highly skilled personnel should be deployed and upskilled to be able to write prescriptions like their counterparts in the UK, as otherwise there will be redundancies. Animal health will suffer as people will not go to the expense of paying large vet fees to get a wormer and people will be buying products without proper advice. Irish customers will go online (where they will get no advice whatsoever) and buy direct from NI and the UK.

HPRA response: Licensed Merchants will continue to have a role in dispensing antiparasitic veterinary medicinal products, on foot of a veterinary prescription, even when they are designated as prescription medicines (as is the case currently in relation to intramammary antibiotics). Regulation 2019/6 will not be applied in the EU until January 2022 so there is time for Licensed Merchants to assess the implications of the change for their businesses and to decide the actions that are needed.

Antiparasitic resistance will continue to develop and spread unless action is taken to address it. The HPRA hopes that stakeholders will respond to the opportunity to work together to develop appropriate infrastructure, protocols and guidelines in the available time. Buying products online from organisations or agents that are not regulated within the State carries risks; products might be short dated or not properly stored. Moreover, possession of unauthorised animal remedies is an offence and may jeopardise compliance with Bord Bia quality systems and DAFM regulations.

The HPRA encourages all stakeholders to work together to address the challenge of antiparasitic resistance in the time available.

ENDS