



IRISH MEDICINES BOARD

Report

of the

Working Group

on the

Methods of Supply

of

Companion Animal Antiparasitic Medicines

June 2010

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Chapter 1, Introduction & Preamble

1.1 Introduction

The Working Group (WG) on classification of methods of supply of veterinary antiparasitic products was established by the Board of the Irish Medicines Board (IMB) on 25 June 2009 following an earlier recommendation by the IMB's independent scientific committee on veterinary medicines, the Advisory Committee for Veterinary Medicines (ACVM). The WG was charged with the tasks of reviewing the current methods of supply of veterinary antiparasitic agents intended for use in companion animals and preparing a guidance document for the IMB on the most appropriate criteria to allocate such products to the various national supply routes available, taking into consideration the effect of national legislative changes in 2007 to the distribution of veterinary medicines as well as the relevant risks and benefits associated with use of the products and any practical considerations. The scope of the review excluded medicines which have been authorised by the EU Commission. The terms of reference of the WG are attached in Appendix 1. The members of the WG are presented in Appendix 2.

1.2 Preamble

Veterinary medicines which can treat or control internal and external parasites of dogs and cats offer both animal health and public health benefits. Under Directive 2001/82/EC¹ (hereafter referred to as 'the Directive') applicant companies must provide data on the quality, safety and efficacy of each medicine so that the conditions under which a product will perform effectively and safely can be ascertained and documented. In relation to the safety assessment, the legislation requires that the risks be identified and characterised and that appropriate risk management measures be applied. Amongst the risk management options available to the IMB as competent authority is that of restricting the distribution of the medicine to professional persons such as veterinary practitioners or pharmacists.

The policy of the IMB in allocating a method of supply for veterinary antiparasitic products for dogs and cats pre-dates the change in national legislation relating to the supply of prescription medicines in 2007. One of the consequences of the change was that certain medicines which were subject to veterinary prescriptions could be dispensed by certain non-pharmacy outlets (previously veterinary prescriptions could be dispensed only by pharmacies). Many such products which were originally restricted as prescription-only medicines have maintained this classification since the date of their original authorisation many years ago and despite a long record of safe and effective use in the meantime.

Given the impact of the 2007 legislative changes relating to the supply of certain categories of veterinary medicines and following a review of methods of supply of such antiparasitic medicines for dogs and cats in a number of EU Member States it is timely for the IMB to review the suitability of the allocated national methods of supply of the antiparasitic group of veterinary medicines which

¹ Consolidated Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products as amended by Directive 2004/28/EC

are used for routine or prophylactic use for the control of parasites in companion animals (even if only to confirm the suitability of the existing methods of supply). National legislation² provides that antiparasitic drugs intended for use solely for aquarium fish, caged birds, homing pigeons, terrarium animals, small rodents, ferrets and pet rabbits may, following an application to the IMB, be exempted from the requirement of having an animal remedies authorisation. Therefore, this Report is concerned exclusively with recommendations for supply of antiparasitic medicines to dogs and cats.

As with all medicines there are certain risks related to the use of antiparasitic medicines and the IMB must, as the national competent authority, ensure that the risk mitigation measures are appropriate and sufficient. Risk mitigation measures have to take into account the intended target user group for the product and will include such controls as:

- The quantity or strength of drug available or amounts to be administered,
- The potential user exposure to the drug and the nature of the product container,
- The adequacy and prominence of product warnings and instructions,
- The adequacy of any literature accompanying the product advising on safe and effective use,
- The method of supply of the product to the end user,
- The need for professional involvement in their use (e.g. point-of-sale advice, need for prior diagnosis, administration).

In exercising its role, the IMB must be mindful of the proportionality of any new proposed restrictions, especially in relation to veterinary medicines which have been authorised for several years. However, the rationale for any approach should be clearly set out as the principles will form the basis for future decisions on new products in this sector.

It should be noted that all new veterinary medicines are authorised for an initial period of five years. Those that contain a new active substance are required to be restricted to supply on a prescription-only basis at the time of initial authorisation³ (see also section 3.3 of this report). After the initial five-year period, an authorisation may, on application to the IMB and provided the benefit/risk balance underpinning it remains favourable, be renewed indefinitely thereafter. The principles enunciated in this document are expected to be applied at the time of renewal of the marketing authorisations for antiparasitic veterinary medicines for dogs and cats which are authorised nationally.

² Regulation 3(3)(a)(ii) of the European Communities (Animal Remedies)(No.2) Regulations 2007 [SI No 786 of 2007]

³ Article 67, Directive 2001/82/EC as amended

Chapter 2, Background

2.1 Historical Perspective on the Supply of Companion Animal Antiparasitics in Ireland

Until the mid 1980s there were limited controls on the supply of antiparasitic veterinary medicines in Ireland. Those which existed were based on a schedule of active ingredients e.g. the Poisons Regulations, 1983 and the Animal Remedies (Control of Sale) Regulations, 1985. Following the establishment of national legislation governing the authorisation of veterinary medicines in 1986, companion animal antiparasitic medicines were assigned supply routes varying from prescription control to general sale based either on the legal schedules or an evaluation of the risks involved in using the products concerned. In point of fact, many products were not assigned a method of supply by the Irish Medicines Board or its predecessor, the National Drugs Advisory Board, until the late 1990s by which time new legislation, the Animal Remedies Regulations, 1996 came into being. That legislation set out six supply categories as follows: Veterinary Surgeon use Only (VSO), Prescription Only Medicine (POM), Prescription Only Medicine Exempt (POM[E]), Pharmacy Sale (PS), Licensed Merchant (LM) and Companion Animal Medicine (CAM). The criteria applied by the IMB in allocating a suitable method of supply to veterinary medicinal products at that time are provided in Appendix 3.

The national legislation has been revised several times since the criteria were set.

2.2 Legal and Regulatory Constraints on the Distribution of Companion Animal Antiparasitics In Ireland

European Union legislative constraints and scientific principles on the supply of veterinary medicinal products are established under Article 67 of the Veterinary Directive⁴. This states that:

“Without prejudice to stricter Community or national rules relating to dispensing veterinary medicinal products and serving to protect human and animal health, a veterinary prescription shall be required for dispensing to the public the following veterinary medicinal products:

- (a) those products subject to official restrictions on supply or use,*
- (b) those products in respect of which special precautions must be taken by the veterinarian in order to avoid any unnecessary risk to the target species, the person administering the products to the animal and the environment,*
- (c) those products intended for treatments or pathological processes which require a precise prior diagnosis or the use of which may cause effects which impede or interfere with subsequent diagnostic or therapeutic measures.*

In addition, a prescription shall be required for new veterinary medicinal products containing an active substance that has been authorised for use in veterinary medicinal products for fewer than five years unless, having regard to the information provided by the applicant, or experience acquired in the practical use of the veterinary medicinal product, the competent authorities are satisfied that none of the criteria referred to in (a) to (c) apply”.

⁴ Directive 2001/82/EC as amended

Article 68 of the Veterinary Directive states that Member States shall take all measures necessary to ensure that only persons empowered under their national legislation in force possess or have under their control veterinary medicinal products which have antiparasitic properties.

Current national legislation⁵ sets out seven supply categories for veterinary medicines authorised in Ireland. These are presented in Appendix 4 and the legislative criteria underpinning them are presented in Appendix 5. The IMB is obliged to follow specified criteria outlined in the legislation in designating a suitable route of sale. There are no criteria established by legislation relating to medicines which might be designated Licensed Merchant (LM) or Companion Animal Medicine (CAM).

At the time of initial drafting of this Report (April 2010) all antiparasitic products authorised for cats and dogs had been assigned to either POM or CAM routes (53 POMs and 47 CAMs).

2.3 Current Situation in Relation to the Distribution of Antiparasitic Agents for Companion Animals in Ireland

The main interested parties involved in the dispensing and supply of antiparasitic products for companion animals in this country are the animal health industry itself, veterinary practitioners (either directly or under prescription for animals under their care), pharmacists (from pharmacies, either by the pharmacist or under the personal supervision of the pharmacist) and those licensed by the Department of Agriculture, Fisheries and Food (DAFF) either to supply animal remedies generally or to supply companion animal medicines specifically. While Licensed Merchants are entitled to supply companion animal medicines such products are typically not supplied through LM outlets.

The roles of the interested parties are described below.

Animal Health Industry

Veterinary manufacturers supply their products to users usually *via* a network of wholesalers to veterinary practitioners, pharmacists, Licensed Merchants and licensed CAM outlets. The animal health industry is not entitled to advertise prescription-only medicines to the public. However, it is entitled to promote and advertise antiparasiticides which are not subject to prescription-control through relevant media to various end users. The distribution of veterinary medicines is governed by legislation and is under the control of the DAFF. A feature of the control exercised is a significant emphasis on record keeping and traceability of medicines from manufacturer through to user. Veterinary Practitioners, Pharmacists and Licensed Merchants are required to keep records of all animal remedies supplied (including those labelled CAM). However, companion animal medicine outlets which are registered with the Department of Agriculture, Fisheries and Food are not required to keep such records.

⁵ Schedule 1, Part 1 of the European Communities (Animal Remedies) (no. 2) Regulations 2007, (SI No. 786 of 2007)

Veterinary Practitioners

This group plays a unique role in the control of veterinary medicines. Veterinary practitioners are trained in the control of diseases, in epidemiology and veterinary medicine. They are expected to have first-hand knowledge of animal diseases including any change in the local prevalence and expression of the disease. They are also expected to be familiar with the animal history and husbandry conditions. They also have knowledge of biosecurity measures and diagnostics as well as available vaccines and therapies and other methods for controlling disease. They are also expected to be in a position to evaluate the understanding and competence of the animal owner to adhere to advice given and to administer medicines. Veterinary practitioners are the profession qualified and authorised⁶ to conduct a clinical examination of animals. Only veterinary practitioners are entitled to write a veterinary prescription. In accordance with Regulation 28(6) of SI No. 786 of 2007, a veterinary practitioner does not have to write a prescription for companion animals under his care, where an offer to do so has been made but declined. Pending the lifting of a derogation in 2011, Veterinary Practitioners are required to certify the passports of dogs and cats entering the European Union and transiting from the European mainland to Ireland to ensure that such animals have received appropriate treatment for the control of ticks and the tapeworm *Echinococcus multilocularis*.

Veterinary practitioners are subject to annual registration with the Irish Veterinary Council and they must register their practice premises to ensure compliance with minimum standards. Those who fail to abide by the ethical and statutory rules in force or who fail to meet or maintain fitness to practice standards are liable to disciplinary procedures, including removal from the Register with consequential effects for their livelihood. If they fail to conform to the national legislation they may also face prosecution by the courts.

In accordance with the applicable legislation, where a prescription is written for a POM designated veterinary medicine, such prescriptions may be dispensed by the veterinary practitioner, by another veterinary practitioner within the same group practice, by a pharmacist or by a licensed merchant. As regards the supply of veterinary medicines which are designated POM, veterinary practitioners may supply such products only in respect of animals entrusted to their care and may not supply them to members of the general public whose animals have not been so entrusted. Veterinary practitioners are not entitled to supply medicines labelled LM to the general public unless the animals concerned have been entrusted to their care or unless an appropriate licence has been obtained from the DAFF. Veterinary practitioners are however entitled to supply antiparasitic products labelled CAM to the general public.

Pharmacists

Pharmacy undergraduates spend four years reading pharmacy to degree level. On graduation, pharmacists spend a further year under the supervision of a tutor pharmacist further developing their dispensing and advisory skills. All pharmacy graduates in Ireland undergo training in veterinary pharmacy. They are therefore trained and competent to give advice on all medicines and are an easily accessible resource for the public seeking such advice. All pharmacists and pharmacies within

⁶ Veterinary Practice Act 2005, No. 22 of 2005

the State are now subject to annual registration with the Pharmaceutical Society of Ireland (PSI)⁷. Pharmacists must undertake continued professional development and are also subject to fitness to practice provisions. Each pharmacy must comply with regulations and standards specified by legislation through adherence to codes of conduct issued by the PSI. Those who fail to abide by the ethical and statutory rules in force or who fail to meet or maintain fitness to practice standards are liable to disciplinary procedures, including removal from the Register with consequential effects for their livelihood. Pharmacists and pharmacies may also be prosecuted in the courts for failing to comply with the legislative requirements.

A pharmacist may supply veterinary medicines classified as POM products to the public on foot of a veterinary prescription. A pharmacist may supply veterinary medicines labelled as POM(E) to members of the general public provided that the veterinary medicine in question is dispensed in person by the pharmacist. Veterinary medicines labelled as LM or CAM may be also supplied to the public (with or without prescription) from a pharmacy shop. Veterinary medicines labelled as 'Pharmacy Sale' (PS) may also be supplied from a pharmacy shop, although such products need not be dispensed by the pharmacist in person.

It is estimated that, at present, the majority of the 1700 registered pharmacies in the State are involved in supplying veterinary medicines for use in companion animals.

Licensed Merchants

The national legislation provides that endo- and ecto- parasitic veterinary medicines can be supplied *via* licensed merchants in two situations:

1. Those which are regulated as CAM or LM products may be supplied to the general public without prescription.
2. Those which are regulated as POMs, provided a veterinary prescription has been issued for the product specified. While licensed merchants typically supply medicines intended for food-producing animal species, the legislation does not discriminate between antiparasitic medicines for livestock and those intended for dogs and cats. Therefore, such outlets may also dispense antiparasitic medicines labelled POM and intended for dogs and cats (on foot of a valid prescription).

Licensed merchants are not entitled to supply medicines labelled as POM(E).

The licensed merchant trade is operated both by private merchants and by co-operative societies. Only those premises which meet specified standards established by the DAFF and where a retail assistant trained and accredited as a 'responsible person' is present are deemed to qualify as LM.

Persons engaged by licensed merchants to retail antiparasitic medicines are not ordinarily members of a regulated professional body and are not therefore subject to fitness to practice sanctions in the event of lack of conformity with legislative requirements. However, LMs are regulated by the DAFF and as such are subject to inspection by authorised officers of DAFF whereby their licences may be

⁷ Pharmacy Act 2007, No. 20 of 2007

suspended, varied or revoked by the Minister if necessary. They may also be subject to prosecution in the courts if they fail to uphold their legal requirements.

Companion Animal Medicine Sellers

The DAFF has registered some 450 CAM sellers. Currently, there is no requirement for any inspections of premises or vetting of applicants. Unlike the position of other retailers and veterinary practitioners supplying companion animal medicines, a CAM seller is not required to keep records of purchases and sales. Persons engaged as CAM sellers of retail veterinary antiparasitic products are not ordinarily members of a regulated professional body and are not therefore subject to fitness to practice sanctions in the event of lack of conformity with legislative requirements. However, CAMs are registered by the DAFF and as such their registrations may be suspended or revoked by the Minister if necessary. They may also be subject to prosecution in the courts if they fail to uphold their legal requirements.

Chapter 3, Problem Analysis

3.1 Scope

In order to understand the impact of the route of supply category on the benefits and risks associated with use of antiparasitic medicines the WG considered the situation insofar as it might affect animal welfare, as well as the risk implications related to the use of the products, including zoonotic risks and related matters. In the knowledge that any change to the route of supply will have a consequential impact on the wider availability of the products concerned, while restricting products might act as a barrier to remove potentially useful veterinary medicines from the casual reach of the public, the risks are further considered hereunder.

3.1.1 Zoonotic considerations

Several parasites of dogs and cats may be transmitted to humans and therefore pose a potential zoonotic risk. These include *Toxocara* spp. in particular, although infestations with parasites not native to Ireland e.g. *Echinococcus* spp. might also occur exceptionally. Regular treatment of animals with appropriate medicines is necessary to minimise infestation pressure, while control of the parasitic eggs and larvae in the environment is needed to reduce the zoonotic risks. Such risks are greatest in young children and in immunocompromised individuals.

No direct risk to humans from ticks attached to dogs or cats has been reported. Lice are host specific and are not considered to present a zoonotic risk. However, fleas are capable of transferring easily between animals and humans.

3.1.2 Resistance

Although anthelmintic resistance is a developing issue in respect of livestock and bloodstock, there have been few documented reports of anthelmintic resistance in dogs and cats⁸. Concern has been expressed however⁹ that the use of regular anthelmintic treatments for dogs, regardless of their ages and without any association with a particular parasite or strategy might hasten the appearance of drug resistance. The European Scientific Counsel on Companion Animal Parasites (ESCCAP)¹⁰ recommends that treatment strategies for anthelmintics avoid excessive or unnecessary worming and be risk-based rather than blanket-based.

There have not been any proven cases of resistance or treatment failure concerning the treatment of ticks or insect dwellers in companion animals. However, ESCCAP¹¹ recommends that unnecessary treatments be avoided and rotations between drug classes at intervals of one to two years be considered.

⁸ Koop, S. 2008. Pyrantel Resistance in the Canine Hookworm, *Ancylostoma caninum*. *PhD Thesis*, School of Veterinary Science, University of Queensland. (<http://espace.library.uq.edu.au/view/UQ:159784>)

⁹ Thompson R.C.A. and Roberts, M.G. 2001. Does pet helminth prophylaxis increase the rate of selection for drug resistance? *Trends in Parasitology*, 17 (12), 576-578.

¹⁰ European Scientific Counsel Companion Animal Parasites, Guideline 1, December 2006, (http://www.esccap.org/index.php/fuseaction/download/lrn_file/001-esccap-guidelines-ukfinal.pdf)

¹¹ European Scientific Counsel Companion Animal Parasites, Guideline 3, March 2009, (http://www.esccap.org/index.php/fuseaction/download/lrn_file/esccap-ecto-guidelines-27march09.pdf)

3.1.3 Benefit risk assessment

An evaluation of the benefit:risk balance of the product is an integral part of the assessment procedure¹² which takes place before a marketing authorisation is granted. This analysis is a complex process based on the intended use and the indications of the product with respect to its overall safety. The risk assessment considers any risk relating to the quality, safety and efficacy of the product as regards animal or human health and any risk of undesirable effects on the environment as well as the adequacy of risk management or risk mitigation measures.

An assessment of the user exposure is made as part of the benefit : risk assessment. This involves consideration of the relevant exposure scenarios as well as the frequency of such exposures which are likely to arise in using the product. When there is a predicted risk for the user, any proposed measures for risk reduction are evaluated for their effectiveness and practicality. In the case of medicines for companion animals, the risks to persons and children living in close proximity to animals is considered.

In respect of veterinary medicinal products which have been authorised for more than five years, the benefit: risk assessment might not be well-described (as this has only been a relatively recent requirement of the authorisation process). However, the existence of a marketing authorisation with its attendant conditions is testimony to the existence of a favourable benefit: risk balance and to the method of supply established.

3.1.4 Internet selling

The IMB considers that there is a risk that any medicine supplied from orders made over non-licensed internet sites might be counterfeit and advises caution in this regard. In the case of animal remedies, national legislation¹³ allows such trade provided the supplier has been granted an internet retail licence by DAFF. It is a requirement of the licence that the DAFF approved licence number is displayed on the website. Only veterinary medicines designated with a route of sale - *Licensed Merchant (LM)* - or - *Companion Animal Medicine (CAM)* - may be sold under an internet sales licence.

3.1.5. Advertising

Article 85(3)(a) of Directive 2001/82/EC prohibits the advertising to the general public of veterinary medicinal products which are available only on prescription. Animal remedies of non-prescription status can be directly advertised to the general public.

3.2 Position of Other EU Member States

The WG noted that the operation of prescription controls is not harmonised within the European Community. It appears that procedures for prescribing and dispensing veterinary medicines vary widely between Member States. From a national perspective, this matter is of greatest significance

¹² Recommendation on the Evaluation of the Benefit-Risk Balance of Veterinary Medicinal Products, 20 April 2009, Committee for Medicinal Products for Veterinary Use, European Medicines Agency, (<http://www.ema.europa.eu/pdfs/vet/euleg/24849907enfin.pdf>)

¹³ Regulation 36 (3)(a) of SI No. 786 of 2007

in respect of those veterinary medicines which have a joint UK/Irish label and where the existence of specific national codes representing the approved route of supply in each territory is different and potentially confusing. Given the fact that each authority has independence in deciding the appropriate method of supply and that national legislation governing the controls imposed differ between UK and Ireland, this situation must be tolerated. In fact, the situation in the UK is dynamic with the routes of supply of products for companion animals under review currently.

The routes of supply of anthelmintic and ectoparasitic medicines for dogs and cats within the European Economic Area vary between countries. In some Member States (e.g. Greece, Norway) all such products are supplied on prescription. For the majority of Member States (e.g. the UK, Denmark, Germany, Spain, the Netherlands, Italy, the Czech Republic, Slovakia, Slovenia and Finland) the situation is mixed, with some products being supplied on prescription and others (typically collars) not. For a few Member States (e.g. Portugal, Sweden, Hungary, Romania, such products are available from licensed shops or pharmacies. In respect of several Member States (e.g. the UK, France, Portugal, Slovakia and Finland) there are ongoing developments which are expected to result in changes to the regulatory regime over the coming years.

3.3 Additional Considerations

Though outside the scope of this review, it is noted that all veterinary medicines for companion animals which have been authorised under the EU's centralised procedure have, up to now, been designated a prescription route of supply. The European Medicines Agency (EMA) has acknowledged¹⁴ that Marketing Authorisation Holders should have the opportunity to change to a less restrictive classification five years post-authorisation where there is adequate assurance that such a change would not lead to safety problems and provided that the requirements of Directive 2001/82/EC are met and has proposed criteria for this (Appendix 6). The document is expected to be finalised during the summer 2010.

The WG observed that other professional persons in Ireland, e.g. veterinary nurses and pharmacists might have an interest in prescribing veterinary medicines. However, the current legislative situation does not provide for veterinary nurses or pharmacists to write prescriptions and the WG decided that this was outside of its remit.

The WG noted that since the inception of the IMB's pharmacovigilance monitoring system in 1989 there have been few adverse reactions reported to the IMB concerning companion animal antiparasitic agents. On the basis of the causality assessments conducted by the IMB in relation to the reports received since 2000, the WG was of the opinion that apart from spot-on formulations of permethrin where some adverse reactions associated with the administration of the product in cats (contrary to the product marketing authorisations concerned) were reported, the available information did not call into question the general suitability of the method of supply assigned. In respect of the spot-on formulations of permethrin, it was noted that even where the products were contraindicated for cats, there were several instances reported where a member of the general

¹⁴ Draft Guideline on the Change of Classification of Veterinary Medicinal Products Authorised by the Community, European Medicines Agency, 17 September 2009. (<http://www.ema.europa.eu/pdfs/vet/regaffair/43050909en.pdf>)

public used preparations authorised only for dogs as a treatment for cats, often with serious, or fatal outcomes. The WG was of the opinion that it was prudent to restrict such products in the circumstances in order to safeguard the welfare of cats.

3.4 Methodology Used and Feedback Analysis

A public call for submissions was posted on the IMB website on 24 September 2009. The WG also made a call for submissions by contacting 24 potentially interested parties. A total of six written submissions were received (see Appendix 7). Where issues were identified, further clarification was requested and provided.

The survey of routes of supply which apply in other EU Member States was undertaken on 2 March 2010.

On the 31 March 2010 concerned companies and interested stakeholders were contacted for their observations on the proposed criteria and the proposed route of supply. Two external contributions were received prior to the deadline of 26 April 2010.

3.5 Perspective of Interested Parties

Interested parties, in general, put forward opinions which supported their own interests.

Some felt that the current routes were overly restrictive and anti-competitive, noting that similar products licensed for human use in Ireland were available from pharmacies as over-the-counter remedies. It was proposed that the supply of antiparasitic products be not more restrictive than is the situation currently and that it was preferable to maintain access to such products rather than risk that animals would be untreated.

Others felt that given the diversity of the weight range, physiological and clinical status of animals and the lack of familiarity of certain owners with particular product presentations, there was a likelihood that owners would administer products incorrectly, thereby placing the animal, themselves and others at increased risk. There was also a view that anthelmintic resistance might increase if greater access (and wider advertising) was given to such products and that there was an important educational role in animal and public health which could be compromised by more liberal access.

Concern was also expressed regarding the impact of any change on medicines availability in Ireland, were it to result in a loss of harmonised labels between Ireland and the UK. In fact, this concern appears misplaced as the routes of supply of veterinary medicines differs between the UK and Ireland and this has not acted as a barrier to the achievement of a common UK/Irish label where the two national routes of supply are given.

Finally, it was noted that permethrin-containing spot-on formulations which were authorised for use in dogs in various Member States had been reported to cause significant adverse reactions when used inappropriately in cats. It was recommended that consideration be given to such events in contemplating any change to the supply category of these products in Ireland.

3.6 Observations of the Working Group on the submissions received

The WG noted that although anthelmintic resistance was a potential risk, in practice there was little evidence to date that this was a problem in companion animals. The WG noted the polarity of opinions and the rationale for them. The WG noted that it would be up to the IMB to implement any recommendations for change in the method of supply, and that any criteria should be objective and scientifically based. The WG appreciated the need to avoid any increased risk to animal welfare, such as that which might occur if spot-on products containing permethrin were derestricted, given the experience of adverse reactions to such products in cats even though the products concerned were labelled for use in dogs.

Regarding the contributions received following the second consultation on the draft criteria and the effect that the proposed criteria would have on particular products, the WG considered that the risks for owners of companion animals of self-selection of antiparasitic medicines for dogs and cats was different to that pertaining to the use of such types of medicines by livestock farmers. Typically, pet owners have limited experience and varying knowledge of the risks in handling and using veterinary medicines while farmers are expected to be familiar with handling veterinary medicines and agrichemicals.

The WG confirmed its view that permethrin-containing anti-parasitic products which were supplied as spot-on formulations for dogs should be regulated as POMs, given the potential for serious adverse reactions if used off-label in cats. The WG noted that, to its knowledge, a safe concentration limit had not been documented for other formulations of permethrin in cats. The WG decided that in the absence of any reports of suspected adverse reactions regarding non spot-on formulations of permethrin currently on the market the restriction of the legal category of supply is not necessary. The WG recommended that the IMB continue to monitor the position regarding the safety of permethrin in cats and stressed that the approach taken in this instance should be understood in the context of existing products only.

The WG accepted that where a specific indication which required a diagnosis by a veterinary practitioner was listed as an indication for use (e.g. flea allergic dermatitis), the product in question should be restricted to supply as a POM. However, where this would be the only criterion which led to a restriction as a POM product, should the indication be removed, the product concerned or a generic copy without the indication could be de-regulated to that of a POM(E) product.

As a consequence of application of the proposed criteria, the WG changed the proposed classification in respect of a number of products on the basis of comments received. The WG noted that any change to the method of supply of a particular product to conform to its proposed recommendation would be the subject of an application to vary the existing marketing authorisation and would not be automatically applied.

Chapter 4, Conclusions, Proposed Classification Criteria and Impact Analysis

4.1 Conclusions

The WG noted that although there were potentially seven supply categories available to the IMB for antiparasitic products for companion animals, in practice only two (POM and CAM) had been used. The WG noted that a balance should be achieved between the availability of suitable medicines for routine use in otherwise healthy animals on the one hand and the need to ensure professional input and advice to safeguard animal and public health and welfare on the other. The WG also noted that the situation was not harmonised in the EU and that the matter was under review in the EMA and some Member States. The WG noted that the risk of resistance was largely theoretical. In reviewing the various risks posed by veterinary medicines which have been on the market in Ireland for several years the WG was mindful of the conditions which must be met before applying the precautionary principle¹⁵, particularly in cases where no adverse reactions have been reported to the IMB.

The WG noted certain peculiarities in respect of national legislation on animal remedies, whereby antiparasitic products designated as prescription-only could be supplied on prescription by veterinary practitioners, pharmacists and licensed merchants but not advertised to the public while products designated POM(E) could be supplied only by veterinary practitioners and pharmacists but could be advertised to the public. The WG also noted that unlike other retailers of veterinary medicines, retailers registered to supply CAM-designated products did not have to keep records of batch numbers of stock purchases and sales.

Taking into consideration:

- the criteria set out in 4.2 below,
- the hazard characteristics of the active substances containing in the individual products,
- the associated potential risks for animals, users, those in contact with animals and risks to the environment,
- the history of use of the products in Ireland,
- the history of use of the active substances in the European Union,
- the effect of any change on the advertisement of the products to the public

the WG made a number of recommendations for changes to the existing supply categories as set out in Appendix 8.

4.2 Proposed Classification Criteria

The allocation of a 'Veterinary Practitioner Only (VPO)' status is considered appropriate for a nationally authorised animal remedy when the benefit/risk assessment is very finely balanced or when there is a need for particular skill or training in the administration of the animal remedy in order to avoid unnecessary risk to the target animal or the person administering the product to the animal. Experience to date suggests that this category has never been necessary for antiparasitic products for dogs and cats.

¹⁵ Hygeia Chemicals Ltd v Irish Medicines Board, Supreme Court of Ireland, 27 January 2010 (<http://www.bailii.org/ie/cases/IESC/2010/S4.html>)

The allocation of a prescription-only-medicine (POM) status is considered appropriate for a nationally authorised animal remedy when any of the conditions below are met:

- (a) the product contains a new active substance.
- (b) the administration of the product requires particular knowledge or skill in using the product which is unlikely to be learnt following demonstration by a veterinary practitioner;
- (c) a precise diagnosis prior to treatment is required for the product with certain indications;
- (d) the product presents a direct risk, if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;
- (e) another veterinary medicinal product containing the same active substance has previously been the subject of frequent serious adverse event reporting;
- (f) there are known contraindications relating to the use of other commonly used veterinary medicinal products;
- (g) the product may impede or interfere with a subsequent diagnosis or therapeutic measures.

The rationale for this approach is that it is in accordance with national legal requirements and scientific principles of risk management.

The allocation of a prescription-only-medicine (exempt)[POM(E)] status is considered appropriate when the conditions below are met:

- (a) the administration of a particular product requires particular skill in using the product which can be explained to animal owners by a pharmacist;
- (b) the product presents a risk, if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;
- (c) there is a risk to animal health as regards the development of resistance to anthelmintic substances where the veterinary medicinal products containing those substances are used incorrectly;
- (d) the summary of product characteristics of the veterinary medicinal product contains warnings of potential serious side effects deriving from its correct use;
- (e) the veterinary medicinal product is subject to special storage conditions.

The rationale for this approach is that it is in accordance with national legal requirements and scientific principles of risk management.

The allocation of a companion animal medicine (CAM) status is considered appropriate when the conditions below are met:

- (a) no particular skill is needed to use or administer the veterinary medicinal product;
- (b) there is no risk to the animal or animals treated, to the person administering the product or to the environment;
- (c) the summary of product characteristics of the veterinary medicinal product does not contain warnings of potential serious side effects deriving from its use;

- (d) the product itself or other veterinary medicinal product containing the same active substance have not previously been the subject of frequent serious adverse reaction reporting;
- (e) the veterinary medicinal product is not subject to special storage conditions.

The rationale for this approach is that it is in accordance with national legal requirements and scientific principles of risk management.

The WG was of the opinion that it would be potentially confusing for stakeholders and animal owners, as well as being unnecessary, to propose criteria for the allocation of antiparasitic products uniquely for the category of pharmacy sale. This category is similar to prescription-only-medicine (exempt) in its requirements, and such fine tuning was seen as an over-complication and not adding any additional benefits or safeguards.

4.3 Impact Assessment

The WG noted in respect of the list of products concerned for dogs that the existing supply category was deemed satisfactory for 65 of 75 medicines¹⁶. For 10 medicines for dogs, a change from POM to CAM was recommended.

In respect of the medicines for cats, the WG recommended that the method of supply for 24 out of 27 medicines remain as is currently. For a single one medicine, the WG recommended that the supply route be changed from POM to POM(E) and for two products the WG recommended a change from POM to CAM.

The WG felt that on balance, the changes would, if implemented, result in improved access to a greater number of antiparasitic medicines for dogs and cats than is the case currently, while safeguarding animal and public health. The WG felt that the omission of use of the Licensed Merchant category as an appropriate supply category which could be used was not likely to have any impact as few Prescription-Only-Medicine companion animal antiparasitic medicines are dispensed by this route currently and Licensed Merchant outlets can still dispense anti-parasitic medicines with a Companion Animal Medicine route of supply.

The WG made the following observations regarding its recommendations:

- There was no safety reason why a fenbendazole-containing product for cats and dogs should be restricted to POM; similar products had been assigned a CAM route and were in use for many years without any appreciable risk to public or animal health;
- There was no safety reason why other long-established active substances (e.g. nitroscanate, levamisole, niclosamide) should be restricted to POM as their safety profile was satisfactory;

¹⁶ The number of veterinary medicines is subject to change over time as new products are authorised by the IMB. The numbers cited here relate to the position as taken on 28 May 2010.

- Given international evidence relating to the safety of spot-on products containing permethrin which when used off-label in cats, the continued supply of such products for dogs as POM products was appropriate;
- Appreciating that in the UK veterinary medicines which were indicated for animals where an existing Flea Allergic Dermatitis (FAD) had already been confirmed could be prescribed under UK legislation by registered persons other than veterinary practitioners, the WG was of the view that the legislative position relating to prescribing and dispensing veterinary medicines in Ireland was somewhat different to the UK.

The WG noted that flea control in a household with a flea allergic pet must be especially rigorous so that fleas do not have the opportunity to bite the pet and that a combination of medicines to treat the animal appropriately and/or to break the life cycle of the flea might be necessary. The WG was also of the view that FAD could manifest as a range of dermatologically different clinical presentations and that treatment and control of FAD were complex matters. The WG believed that given the risks to animal welfare of not treating FAD appropriately as might be expected if the products were available without prescription, the health and welfare needs of animals (whether already diagnosed with FAD or otherwise) was better served by restricting all products with an FAD indication to POM.

A consequence of the WG's reflection on this matter is that a product of identical composition presented with an indication for FAD would be regulated as a POM product while one without the FAD claim would not.

Appendix 1

Terms of Reference of Working Group on Classification of Methods of Supply of Veterinary Anthelmintic and Antiparasitic Medicines

Objective: To review the current methods of supply of veterinary anthelmintics and antiparasitic agents intended for use in companion animals and to prepare a guidance document for the IMB on the most appropriate criteria to allocate such products to the various national supply routes, taking into consideration the effect of the 2007 legislative changes to the distribution of veterinary medicines as well as the relevant risks and benefits associated with use of the products and any practical constraints.

The Report is intended to advise the Irish Medicines Board in relation to the suitability or appropriateness of its current policy in this matter.

Guidelines for the Working Group:

1. To examine the current supply categorisation for veterinary anthelmintic and antiparasitic pharmaceuticals for companion animals with a view to ascertaining whether they are appropriate.
2. To review the impact of changes in SI no. 786 of 2007 to the rules governing the issue of prescriptions and the supply of such medicines by licensed merchants in formulating any proposals for amendment.
3. To take account of the relevant legislation for allocating veterinary medicines to an appropriate supply category.
4. To consider if modification to the IMB's criteria for allocation of a suitable supply category for veterinary medicines for companion animals is required and if so, to suggest amendments.
5. To evaluate the likely effect of any change to the method of supply of existing products for animal health and welfare, practical accessibility, user safety and on stakeholders involved in prescribing, supplying and using the medicine.
6. To assess whether, in view of market conditions or circumstances, there are other criteria which should be considered.
7. To compile a report for the Advisory Committee for Veterinary Medicines by July 2010.

Appendix 2

Membership of the Working Group

The membership of the Working Group comprised persons with relevant experience in risk assessment, regulation, use and disposal of medicines. The members of the Working Group are as follows:

Chair:

Dr. Iona Pratt, MSc, PhD, Toxicologist, Food Safety Authority of Ireland

Members:

Dr. J.G. Beechinor, MVB, MVM, PhD, MRCVS, C.Dip.AF, Director of Veterinary Medicines, IMB

Dr. Ruaidhrí Breathnach, MVB, MSc, PhD, MRCVS, Member of the ACVM and specialist in veterinary internal medicine and dermatology.

Mr. Diarmuid Dooge, MVB, MRCVS, Parasitologist and Veterinary Officer, Cork City Council

Ms. Caroline Garvan, MVB, MRCVS, Cert Food Safety, Veterinary Inspector, Department of Agriculture, Fisheries and Food

Professor Peter Weedle, B.Pharm, LLM, PhD, MRPharmS, MPSI, Community Pharmacist and Adjunct Professor of Clinical Pharmacy, University College Cork

Appendix 3

Original criteria for allocating veterinary medicines to the specific categories

Category	Criteria to be applied
VSO:	<p>Products which require special skill in their administration.</p> <p>Products which have a very high risk/benefit ratio.</p>
POM:	<p>Products which require specific advice on the method employed in their administration.</p> <p>Products which present particular risk to the target species, person administering the product, the consumer of the treated animal or the environment.</p> <p>Products which may cause effects which impede or interfere with subsequent diagnostic tests.</p>
POM(E)	<p>As for POM with the following requirements of the Animal Remedies Regulations, 1996, Article 13 (6) - regarding:</p> <ul style="list-style-type: none"> • the purposes for which the animal remedy is intended, and • the extent to which the container, label and package insert are specific to such purpose, and • the strength of the active ingredient contained therein, and • the maximum dose specified in the product authorisation, and • the pharmaceutical form, and • the potential for misuse.
PS	<p>Products which require no specific skill for their administration</p> <p>Products which require professional point of sale advice (according to the Animal Remedies Regulations, 1996, Article 13 (7) regarding:</p> <ul style="list-style-type: none"> • potential risk to the person administering the product, or • possible contra-indications with other commonly used animal remedies, or • the method of administration or use or the handling or preparation prior to use, or • storage conditions, in particular unusual conditions, both prior to and during use or • unusual conditions for safe disposal of used, or unused, material including containers.
LM CAM	<p>& Products which require no special skill for their administration or preparation for administration.</p> <p>Products which require no special storage conditions.</p> <p>Products which do not require professional point of sale advice.</p> <p>Products which do not present a particular risk to the person administering the product.</p> <p>Products which do not present a particular risk to the target animals, the consumer of treated animals or to the environment.</p>

Appendix 4

Routes of supply of Veterinary Medicines established by Schedule 1, Part 1 of SI No. 786 of 2007

'Veterinary Practitioner Only (VPO-1)' – refers to an animal remedy which may be supplied only by a registered veterinary practitioner under specific circumstances.

'Veterinary Practitioner Only (VPO)' – refers to an animal remedy which may be supplied only by a registered veterinary practitioner under specific circumstances (different to VPO-1).

'Prescription Only (POM)' – refers to an animal remedy which may be sold or supplied only by –

- (i) a pharmacist from a pharmacy in accordance with the prescription of a registered veterinary practitioner,
- (ii) a registered veterinary practitioner and the animal is under his or her care and he or she has issued a veterinary prescription in respect of the animal remedy, or
- (iii) a responsible person from a premises to which an animal remedies merchant's licence relates in accordance with a veterinary prescription, in the case of an endo or ecto parasiticide animal remedy (if designated Prescription Only).

'Prescription Only Exempt [POM(E)]' – refers to an animal remedy which may be sold or supplied only by –

- (i) a pharmacist from a pharmacy,
- (ii) a registered veterinary practitioner and the animal is under his or her care.

'Pharmacy Only (PS)' – refers to an animal remedy which may be sold or supplied only –

- (i) from a pharmacy under the personal supervision of a pharmacist, or
- (ii) by a registered veterinary practitioner and the animal is under his or her care.

'Licensed Merchant (LM)' – refers to an animal remedy which may be sold or supplied only –

- (i) from a pharmacy,
- (ii) by a registered veterinary practitioner and the animal is under his or her care, or
- (iii) from a premises to which an animal remedies merchant's licence relates.

'Companion Animal Medicine (CAM)' – refers to a companion animal medicine which may be sold or supplied only –

- (i) from a pharmacy,
- (ii) by a registered veterinary practitioner,
- (iii) from a premises to which an animal remedies merchant's licence relates, or
- (iv) from a premises to which a companion animal medicine seller's registration relates.

Appendix 5

Criteria established by SI No 786 of 2007 in Designating the Route of Supply

1. In deciding the route of sale or supply for an animal remedy, the Board has due regard to the need to protect public health, animal health, animal welfare and the environment and accordingly has due regard to –

- (a) the need for prior professional diagnosis,
- (b) the need for particular skill or training in the administration of the animal remedy in order to avoid unnecessary risk to the target animal or the person administering the product to the animal, and
- (c) the need for professional or specialist training in relation to the storage, handling or disposal of the animal remedy.

2. If, in the opinion of the Board, an animal remedy requires to be administered by or under the direct supervision of a registered veterinary practitioner, because

- (a) the method of administration is novel, or
- (b) the professional skill of a registered veterinary practitioner is necessary in order to avoid unnecessary risk to the animal to be treated or to the person administering the animal remedy, or
- (c) to comply with the Law of the State, or restrictions arising from Community Law or the relevant United Nations Conventions on narcotic or psychotropic substances,

the animal remedy is restricted to administration by, or, as the case may be, under the direct supervision of a registered veterinary practitioner (VPO).

3. Without prejudice to stricter provisions pursuant to the law of the State, an animal remedy to which the following conditions apply is restricted to supply in accordance with the prescription of a registered veterinary practitioner (POM) –

- (a) an animal remedy subject to official restriction on sale, supply or use, such as –
 - (i) the restrictions resulting from the implementation of the relevant United Nations conventions on narcotic and psychotropic substances,
 - (ii) the restrictions on the use of animal remedies from Community Law,
- (b) an animal remedy in respect of which special precautions shall be taken by a registered veterinary practitioner when prescribing the animal remedy in order to avoid any unnecessary risk to –
 - (i) the target species,
 - (ii) the person administering the animal remedy to the animal,
 - (iii) the environment;
- (d) an animal remedy intended for treatments or pathological processes which require a precise prior diagnosis or the administration of which may cause effects which impede or interfere with subsequent diagnostic or therapeutic measures,
- (d) officinal formulae intended for animals,

Appendix 5 cont. /

- (e) an animal remedy containing an active substance which has been authorised for use in animal remedies for less than five years unless, having regard to the information and particulars supplied by the applicant, or experience acquired in the practical use of the product, the Board is satisfied that none of the other criteria referred to in this paragraph apply.

4. In the case of an animal remedy to which some or all of the provisions of paragraph 3 apply, other than subparagraph (b) or (d), the Board having regard to –

- (a) the purposes for which the animal remedy is intended,
- (b) the extent to which the container, label and package leaflet are specific to such purpose,
- (c) the strength of the active substance,
- (d) the maximum dose specified in the veterinary product authorisation,
- (e) the pharmaceutical form, and
- (f) the potential for misuse,

may designate the animal remedy as prescription only exempt (POM(E)).

5. If the Board considers that sale or supply of an animal remedy should be accompanied by professional point-of-sale advice regarding –

- (a) potential risks to the person administering the animal remedy,
- (b) possible contra-indications with other commonly used animal remedies,
- (c) the method of administration or use or the handling or preparation prior to use,
- (d) storage conditions, in particular unusual conditions, both prior to and during use, or
- (e) unusual conditions for safe disposal of used or unused material including containers

the animal remedy is designated pharmacy only sale (PS).

Appendix 6

Draft EMA criteria for exemption of veterinary medicinal products authorised under the centralised system from the requirements for a veterinary prescription

The change to non-prescription status is considered appropriate for a centrally authorised veterinary medicinal product when all the conditions below are met and the product has been authorised and on the market for 5 years or longer for a particular target species:

- (a) the administration of veterinary medicinal products is restricted to formulations requiring no particular knowledge or skill in using the products;
- (b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;
- (c) the summary of product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;
- (d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent serious adverse reaction reporting;
- (e) the summary of product characteristics does not refer to contraindications related to other veterinary medicinal products commonly used without prescription;
- (f) the veterinary medicinal product is not subject to special storage conditions;
- (g) there is no risk to human or animal health as regards the development of resistance to anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly. A precise diagnosis prior to treatment might not be required for veterinary medicinal product with certain indications such as commonly treated parasitic diseases.

In addition, the product does not impede or interfere with the subsequent diagnosis or therapeutic measures.

Appendix 7

Interested parties which responded to the call for submissions

Acorn Sales & Distribution
Bayer Animal Health
Beaphar UK Ltd.
Irish Pharmacy Union & Pharmachem
Veterinary Council of Ireland
Veterinary Ireland

Appendix 8. Listing of Antiparasitic Medicines for Dogs and Cats with their existing and proposed routes of supply¹⁷

Canine listing (page 1/4)

VPA no.	Target Species	Product Name	Method of Sale & Supply	
			Current	Recommended
10021/041/001	Dogs	Advantage 40 Spot-on solution for Dogs	POM	POM ¹⁸
10021/041/002	Dogs	Advantage 100 Spot-on solution for dogs	POM	POM
10021/041/003	Dogs	Advantage 250 Spot-on solution for dogs	POM	POM
10021/042/001	Dogs	Advantage 400 Spot-on Solution for Dogs	POM	POM
10021/047/001	Dogs	Advantix Spot-on solution for dogs up to 4 kg	POM	POM ¹⁹
10021/047/002	Dogs	Advantix Spot-on solution for dogs over 4 kg up to 10 kg	POM	POM
10021/047/003	Dogs	Advantix Spot on solution for dogs over 10 kg up to 25 kg	POM	POM
10021/047/004	Dogs	Advantix Spot on solution for dogs over 25 kg	POM	POM
10996/101/001	Dogs	Aludex 50 g/L concentrate for cutaneous solution	POM	POM ²⁰
10875/002/001	Dogs	Beaphar Flea collar for dogs	CAM	CAM
10021/055/001	Dogs	Big Dog Wormer Tablets	CAM	CAM
10881/001/001	Dogs	Bob Martin All in One Wormer Tablets for small dogs & puppies	CAM	CAM
10881/002/001	Dogs	Bob Martin All in One Wormer Tablets for dogs	CAM	CAM
10881/006/002	Dogs	Bob Martin Easy to Use Wormer Granules for small dogs	CAM	CAM
10881/006/003	Dogs	Bob Martin Easy to Use Wormer Granules for large dogs	CAM	CAM
10881/008/001	Dogs	Bob Martin Flea Shampoo	CAM	CAM
10881/010/001	Dogs	Bob Martin Flea Spray	CAM	CAM
10987/077/001	Dogs	Cazitel Plus Tablets for dogs and puppies	CAM	CAM

¹⁷ Unless otherwise explained by footnotes, the proposed changes are based on the criteria set out under 4.2 of this document

¹⁸ The Advantage range of products are indicated for flea allergic dermatitis, therefore use requires veterinary diagnosis before treatment

¹⁹ The Advantix range of products are indicated for flea allergic dermatitis, therefore use requires veterinary diagnosis before treatment

²⁰ Based on safety profile of the product

10988/061/001	Dogs	Cyclio 2% Spot-on for small dogs	POM	CAM ²¹
10988/061/002	Dogs	Cyclio 30mg Spot-on for medium size dogs	POM	CAM
10988/061/003	Dogs	Cyclio 60mg Spot-on for large dogs	POM	CAM
10988/053/001	Dogs	Defendog cutaneous solution	CAM	CAM ²²
10021/060/001	Dogs	Dog Wormer Tablets	CAM	CAM
10966/032/001	Dogs	Dolpac Tablets Small dogs	POM	POM ²³
10966/032/002	Dogs	Dolpac Tablets for Medium dogs	POM	POM
10966/032/003	Dogs	Dolpac Tablets for Large dogs	POM	POM
10021/013/001	Dogs & Cats	Droncit Tablets 50 mg	CAM	CAM
10021/053/001	Dogs	Drontal Oral Suspension for puppies	CAM	CAM
10021/014/001	Dogs	Drontal Plus Tablets	CAM	CAM
10021/014/002	Dogs	Drontal Plus XL Tablets	CAM	CAM
10988/054/001	Dogs	Duowin Cutaneous Spray solution	POM	CAM ²⁴
10988/072/001	Dogs & Cats	Effipro 2.5 mg/ml cutaneous spray solution	POM	POM ²⁵
10988/076/001	Dogs	Effipro 67 mg Spot-on solution for small dogs	POM	POM
10988/076/002	Dogs	Effipro 134 mg Spot-on solution for medium dogs	POM	POM
10988/076/003	Dogs	Effipro 268 mg Spot-on solution for large dogs	POM	POM
10988/076/004	Dogs	Effipro 402 mg Spot-on solution for very large dogs	POM	POM
10878/001/001	Dogs	Eirpet Flea & Tick Collar for dogs	CAM	CAM
10987/078/001	Dogs	Exitel Plus Tablets for dogs & puppies	CAM	CAM
10857/063/001	Dogs	Frontline Combo Spot-on Dog S	POM	POM ²⁶

²¹ The Cyclio range of products have a satisfactory safety profile with no indication for use requiring veterinary diagnosis prior to treatment

²² Defendog contains permethrin and is administered by means of a pump (and not a spot-on formulation). The product has a satisfactory safety profile.

²³ For information: the Dolpac range was first authorised by the IMB in January 2008. As a new combination of active substances the method of supply cannot be relaxed below POM before January 2013, after which time it could be eligible for CAM if it has a satisfactory safety profile.

²⁴ Duowin has a satisfactory safety profile, does not have a claim for flea allergic dermatitis, and meets the relevant criteria for CAM.

²⁵ The Effipro range of products are indicated for flea allergic dermatitis, therefore require veterinary diagnosis before treatment

²⁶ The Frontline range of products are indicated for flea allergic dermatitis, therefore require veterinary diagnosis before treatment

10857/063/002	Dogs	Frontline Combo Spot-on Dog M	POM	POM
10857/063/003	Dogs	Frontline Combo Spot-on Dog L	POM	POM
10857/063/004	Dogs	Frontline Combo Spot-on Dog XL	POM	POM
10857/005/001	Dogs	Frontline Spot-on Dog	POM	POM
10857/010/001A	Dogs	Frontline Spray 0.25%	POM	POM
10987/055/001	Dogs	Gullivers Flea & Tick Collar for dogs	CAM	CAM
10987/040/001	Dogs	Gullivers Flea Shampoo	CAM	CAM
10987/083/001	Dogs	Milaxyn Plus Tablets for dogs	CAM	CAM
10835/047/001	Dogs	Milbemax Tablets for small dogs & puppies	POM	POM
10835/047/002	Dogs	Milbemax Tablets for dogs	POM	POM
10999/075/001	Dogs	Norworm Granules 220 mg/g	CAM	CAM
10996/188/001	Dogs & Cats	Panacur PetPaste 187.5 mg/g oral paste for dogs and cats	POM	CAM
10484/021/001	Dogs	Parazole 10% w/v oral suspension	CAM	CAM
10966/211/001	Dogs	Plerion 5 chewable tablets for dogs	CAM	CAM
10966/211/002	Dogs	Plerion 10 chewable tablets for dogs	CAM	CAM
10987/076/001	Dogs	Prazitel Plus Tablets for dogs and puppies	CAM	CAM
10987/063/001	Dogs & Cats	Quanifen Cat & Dog	CAM	CAM
10987/062/001	Dogs & Cats	Quenazole Cat & Dog	CAM	CAM
10966/173/001	Dogs	Scalibor Protectorband 4% w/w 48cm collar	POM	CAM ²⁷
10966/173/002	Dogs	Scalibor Protectorband 4% w/w 65cm collar	POM	CAM
10881/016/001	Dogs & Cats	Sergeants Pet Patrol aerosol	CAM	CAM ²⁸
10875/014/001	Dogs & Cats	Sherley's Flea Spray for cats & dogs	CAM	CAM
10875/004/001	Dogs	Sherley's Insecticidal Dog shampoo 0.2% w/w	CAM	CAM
10987/082/001	Dogs	Strantel Plus Tablets for dogs	CAM	CAM
10983/012/001	Dogs	Stromiten Dogs	POM	CAM ²⁹
10021/046/001	Dogs	Top drop 400 Spot-on solution for Extra Large dogs	POM	POM ³⁰

²⁷ Although Scalibor contains deltamethrin, this is not a spot-on formulation and product has a satisfactory safety profile

²⁸ Sergeants Pet Patrol contains tetramethrin and phenothrin, it is not a spot-on formulation; product has a satisfactory safety profile

²⁹ Product has a satisfactory safety profile and no veterinary diagnosis is needed before treatment

³⁰ The Top Drop range of products are indicated for flea allergic dermatitis, therefore require veterinary diagnosis before treatment

10021/046/002	Dogs	Top drop 100 Spot-on solution for Medium dogs	POM	POM
10021/046/003	Dogs	Top drop 250 Spot-on solution for Large dogs	POM	POM
10021/046/004	Dogs	Top drop 40 Spot-on solution for Small dogs	POM	POM
10879/007/001	Dogs	Troscan 100mg film coated tablets for dogs	POM	CAM ³¹
10879/003/001	Dogs	Troscan 500mg film coated tablets for dogs	POM	CAM
10879/032/001	Dogs	Trostal 100mg film coated tablets	CAM	CAM
10879/032/002	Dogs	Trostal 500mg film coated tablets	CAM	CAM
10987/060/001	Dogs	Zantel	CAM	CAM
10987/052/001	Dogs & Cats	Zantel Cat and Dog Tablets	CAM	CAM
10879/002/001	Dogs & Cats	Zerofen 22% Granules	CAM	CAM

³¹ The Troscan range of products have a satisfactory safety profile and no veterinary diagnosis is needed before treatment

Feline Listing (page 1/2)

VPA no.	Target Species	Product Name	Method of Sale & Supply	
			Current	Recommended
10021/040/001	Cats	Advantage 40 Spot-on solution for cats	POM	POM ³²
10021/040/002	Cats	Advantage 80 Spot- on solution for cats	POM	POM
10021/054/001	Cats	Bayer Cat Wormer Film-coated tablets	CAM	CAM
10875/001/001	Cats	Beaphar Flea Collar for cats	CAM	CAM
10021/056/001	Cats	Big Cat Wormer Film-coated Tablets	CAM-	CAM
10881/006/001	Cats	Bob Martin Easy to use Wormer Granules for cats	CAM	CAM
10988/060/001	Cats	Cyclio 60mg Spot- on for Cats	POM	CAM ³³
10021/013/001	Cats & Dogs	Droncit Tablets 50 mg	CAM	CAM
10021/030/001	Cats	Drontal Cat Tablets	CAM	CAM
10021/030/002	Cats	Drontal Cat XL Film-coated tablets	CAM	CAM
10988/072/001	Cats & Dogs	Effipro 2.5 mg/ml cutaneous spray	POM	POM ³⁴
10988/075/001	Cats	Effipro 50 mg Spot-on solution for Cats	POM	POM(e) ³⁵
10857/062/001	Cats	Frontline Combo Spot-on Cat	POM	POM ³⁶
10857/004/001	Cats	Frontline Spot-on Cat	POM	POM
10857/010/001A	Cats	Frontline Spray 0.25% w/v	POM	POM
10987/014/001	Cats	Gullivers Flea Collar for Cats	CAM	CAM
10835/011/001	Cats	Milbemax Film-coated tablets for small cats and kittens	POM	POM
10996/118/001	Cats & Dogs	Panacur PetPaste 187.5 mg/g oral paste for dogs and cats	POM	CAM ³⁷
10484/021/001	Cats	Parazole 10% w/v Oral Suspension	CAM	CAM
10987/063/001	Cats & Dogs	Quanifen Cat and Dog	CAM	CAM

³² The Advantage range of products are indicated for flea allergic dermatitis, therefore use requires veterinary diagnosis before treatment

³³ Cyclio has a satisfactory safety profile with no indication for use requiring veterinary diagnosis prior to treatment

³⁴ Indicated for flea allergic dermatitis, therefore requires veterinary diagnosis before treatment

³⁵ Effipro Spot-on for Cats does not have an indication for use requiring veterinary diagnosis prior to treatment

³⁶ The Frontline range of products are indicated for flea allergic dermatitis, therefore require veterinary diagnosis before treatment

³⁷ Panacur PetPaste has a satisfactory safety profile with no indication for use requiring veterinary diagnosis prior to treatment

10987/062/001	Cats & Dogs	Quenazole Cat and Dog	CAM	CAM
10881/016/001	Cats & Dogs	Sergeants Pet Patrol Aerosol	CAM	CAM
10875/014/001	Cats & Dogs	Sherley's Flea Spray for Cats and Dogs	CAM	CAM
10021/045/001	Cats	Top drop 40 Spot-on solution for small cats	POM	POM ³⁸
10021/045/002	Cats	Top drop 80 Spot-on solution for large cats	POM	POM
10987/052/001	Cats & Dogs	Zantel Cat and Dog Tablets	CAM	CAM
10879/002/001	Cats & Dogs	Zerofen 22% Granules	CAM	CAM

³⁸ The Top Drop range of products are indicated for flea allergic dermatitis, therefore require veterinary diagnosis before treatment