IRISH MEDICINES BOARD

Report

of

IMB

Working Group

on the

Classification of Methods of Supply

for

Veterinary Vaccines

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Chapter 1 Introduction and Preamble

1.1 Introduction

The Working Group (WG) on classification of methods of supply of veterinary vaccines was established by the IMB's independent scientific committee on veterinary medicines, the Advisory Committee for Veterinary Medicines (ACVM), on 21st February 2007 with the approval of the IMB Board. The WG was charged with the preparation of a guidance document for the IMB on the most appropriate criteria for the allocation of new and existing veterinary vaccines[1] to the various national supply routes available in accordance with the legislation. 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

Vaccination has played and continues to play a major role in the management of many animal diseases. Veterinary vaccines are but one of the available measures for animal owners for disease prevention; on farms other tools include the farmer's animal purchase policy, husbandry methods and other factors. Vaccines are not a panacea and should be used selectively.

Only vaccines which meet the prescribed European Union standards for quality, safety and efficacy are authorised for sale and use in Ireland. Vaccines must be authorised either *via* the Centralised Procedure by the European Commission or alternatively *via* National, Mutual Recognition or Decentralised Procedures by the IMB. Nationally authorised medicines are allocated to one of seven routes of sale in accordance with national legislation[2] and the perceived risks associated with the supply and use of the medicine. The route of supply assigned to a particular product may be a significant factor in determining product availability. Furthermore, the assignment of a prescription only medicine category to a veterinary vaccine confines the advertising of the product to veterinarians, pharmacists and licensed merchants whilst veterinary vaccines allocated a less restrictive status may be advertised freely to end users.

European Community legislation[3], dating from 2004, placed an increased emphasis on the benefit/risk balance of product use in the authorisation process for veterinary medicines. The WG was also mindful of the need for a balance to be achieved between the benefits for animals and society from greater availability of vaccines versus the potential risks involved. The WG was of the view that the allocation of a suitable category of supply to a veterinary vaccine should follow an assessment of the risks of the product insofar as they affect the safety and efficacy of the product generally and in particular, the health and welfare of the animal[4], the safety of the product for the user as well as the expected means of use of the product (e.g. for active or passive immunity). In the food-producing animal sector, the primary goal of vaccination is to increase herd immunity rather than in individual animals. However, this might not be the case for vaccines intended for use in companion animals or other species of animals.

It has been suggested that undue restrictions on certain vaccines could compromise animal health and welfare and might pose competitive financial challenges for farmers. On the other hand, vaccines are not simple commodity products and can differ significantly from each other. Various features of a vaccine influence the benefit/risk balance as it relates to the supply classification, including the nature of the vaccine itself (fungal, protozoal, bacterial or viral); whether the vaccine agent is live or inactivated; whether the vaccine contains an innovative or mineral oil adjuvant; whether the vaccine is multi-component or single component; whether the vaccine is a multi-dose or single unit dose. Certain vaccines can be

[1] Autogenous vaccines are outside the scope of this document as they are not subject to authorisation by the IMB

[2] Schedule 1, Part I, European Communities (Animal Remedies) Regulations, 2007, SI no 144 of 2007.

[3] 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.

[4] In the context of this document, animal includes birds and fish.

harmful to human health if accidentally injected. Moreover, inappropriate use of certain vaccines might pose a risk to the user of acquiring a zoonotic infection.

As vaccines are temperature-sensitive products, a cold-chain system should be in place from the point of manufacture to the time of administration. For most vaccines the temperature should be maintained between 2^0C and 8^0C. However, more stringent storage conditions are required for certain labile vaccines e.g. Marek's disease vaccine which requires storage in liquid nitrogen.

The complexity of the distribution system for veterinary vaccines in Ireland is a point of concern. In addition to veterinary practitioners and pharmacists, certain retail outlets have been approved by the Department of Agriculture (DA) to supply particular classes of animal remedies. In authorising these outlets as 'licensed merchants' (LM) for the supply of animal remedies the DA has, in the past, approved courses which those retailing medicines were required to attend. While the content of the courses was considered by the WG, it was not clear to it whether all personnel supplying vaccines from each LM store have suitable qualifications and competence, or whether they have a proper understanding and training to provide appropriate point-of-sale advice in relation to veterinary vaccines.

The WG noted that the users of vaccines themselves are not a homogenous group but are comprised of animal owners with varying degrees of expertise and knowledge about the safe and effective use of these medicines. Even amongst livestock farmers, the WG was of the opinion that the level of knowledge and expertise varies, with some farmers moderately well-informed and others with limited knowledge of this complex area.

Chapter 2 Background

2.1 Historical Perspective on the Supply of Veterinary Vaccines in Ireland

Although legislation dealing with veterinary vaccines dates back to the 1930s, it does not address the issue of distribution. Effectively, the products were on unrestricted sale. The animal health industry voluntarily restricted supply to veterinary practitioners, pharmacists and licensed merchants as they deemed appropriate. Prior to 1996, vaccines were authorised by the Department of Health with advice from the DA. The applicable national legislation[5] did not provide for controls governing the method of supply of veterinary vaccines in Ireland. In the period from 1996 to November 2005, the DA was the competent authority responsible for the authorisation of immunological veterinary medicines. Under the regime in place at the time, both new and existing vaccines were evaluated by IMB who provided the DA with assessment reports on the quality, safety and efficacy of individual products. The eventual decision on the most appropriate route of supply was made by the DA. Over time and for various reasons differences arose in the route of supply allocated by the DA to similar classes of vaccines. An IMB policy document on the classification of veterinary vaccines was developed in 2004. It was non-binding on the DA and did not address those vaccines previously authorised by this body.

With the transfer of competence to the IMB in November 2005 in accordance with national legislation[6], discussions between the DA and the EU Commission in relation to the compilation of criteria for exemption of veterinary medicines intended for food-producing animals from the requirement for prescription control were ongoing. These discussions reached a conclusion in October 2006 leading to the publication of a directive on this issue[7]. The criteria established did not make a significant difference to categorisation of vaccines insofar as they did not alter any existing national distribution routes.

A further feature of the 2005 legislation was a change in relation to the rules governing the granting and dispensing of veterinary prescriptions. This change was introduced by the DA in light of experience of the operation of the very prescriptive criteria in the 1996 Regulations. The 2005 amendments provided for (i) more rational and less stringent requirements for issuing a prescription for animals under the care of a veterinary practitioner; (ii) changes to those entitled to dispense a prescription for vaccines and certain other classes of veterinary medicines and (iii) restrictions on the advertising of prescription-controlled medicines. Since 1st January 2007, veterinary vaccines categorised as a '*Prescription only medicine'* may on foot of a veterinary prescription be supplied by (i) a registered veterinary practitioner for animals under his/her care; (ii) a pharmacist and (iii) a responsible person from a premises to which an animal remedies merchant's licence relates in accordance with the veterinary prescription. However, veterinary vaccines designated as '*Prescription only medicine (exempt)'*, may be supplied without a prescription but may be dispensed only by a pharmacist from a pharmacy, or by a registered veterinary practitioner where the animal is under his or her care.

These changes required the IMB to re-evaluate the criteria for allocating an appropriate supply category to veterinary vaccines.

[5] Therapeutic Substances Act 1932, No 25/1932

[6] Animal Remedies Regulations 2005, SI no 734 of 2005

[7] Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription was published in the Official Journal on 12 December 2006.

2.2 Legal and Regulatory Constraints on the Distribution of Veterinary Vaccines in Ireland

The WG notes that IMB policy in relation to the supply classification of veterinary medicinal products has been based on both legislative constraints and scientific principles in accordance with the requirement of Article 67 of the Veterinary Directive[8] 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:

…those products subject to official restrictions on supply….

…veterinary medicinal products for food-producing animals. However, Member States may grant exemptions from this requirement according to criteria established….

...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.

...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".

The criteria for exemption from the requirement for a prescription established by Commission Directive 2006/130/EC may be summarised as follows:

(a) the administration of the vaccine 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 vaccine does not contain any warnings of potential serious side effects deriving from its correct use;
(d) neither the vaccine in question nor any other vaccine containing the same active substance has previously been the subject of frequent serious adverse reaction reports;
(e) the summary of product characteristics does not refer to contraindications related to other veterinary medicinal products commonly used without prescription;
(f) the vaccine is not subject to special storage conditions;
(g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the products are used incorrectly.

It should be noted that to qualify for exemption, the product in question must meet *all* of the criteria given.

National legislation[9] established seven supply categories for veterinary medicines authorised in Ireland. These are described in Appendix 4. The IMB is obliged to follow specified criteria outlined in the legislation[10] in designating a suitable route of sale.

The WG noted, in particular, the changes to the rules governing the granting and dispensing of veterinary prescriptions as described in section 2.1.

[8] Directive 2001/82/EC as amended by Directive 2004/28/EC.
[9] Schedule 1, Part 1 of the European Communities (Animal Remedies) Regulations 2007, (SI no 144 of 2007).
[10] Schedule 1, Part II of the European Communities (Animal Remedies) Regulations 2007

2.3 Current Situation in Relation to the Distribution of Veterinary Vaccines in Ireland
The main interested parties involved in the dispensing and supply of vaccines 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 licensed merchants. The roles of the interested parties are described below.

Animal Health Industry
Vaccine manufacturers supply their products to users usually *via* a network of wholesalers to veterinary practitioners, pharmacists and licensed merchants. The industry promotes and advertises vaccines through the common media to various end users. The distribution of veterinary medicines is governed by legislation and is under the control of the DA. A feature of the control exercised is a significant emphasis on record keeping and traceability of medicines from manufacturer through to user.

Veterinary Practitioners
This group plays a unique role in the control of veterinary vaccines. Veterinary practitioners spend five years as undergraduates reading veterinary medicine to degree level. They are trained in the control of diseases, in immunology, 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 or herd history and prevailing management conditions. They also have knowledge of biosecurity measures and diagnostics as well as available therapies and other methods for controlling disease. They are also expected to be in a position to evaluate the understanding and competence of the stockman or animal owner to adhere to advice given and to administer medicines. Veterinary practitioners are the profession qualified and authorised[11] to conduct a clinical examination of animals, and have a specific role in ensuring that any veterinary certification following the use or supply of vaccines by registered persons complies with their code of conduct. Only veterinary practitioners are entitled to write a veterinary prescription.

Veterinary practitioners are subject to annual registration with the Irish Veterinary Council and, under recent legislation, 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 vaccine, such prescriptions may be dispensed by the veterinary practitioner, by another colleague within the same group practice, by a pharmacist or by a licensed merchant.

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. The advent of new legislation[12] means that all pharmacists and pharmacies within the State are now subject to annual registration with the Pharmaceutical Society of Ireland (PSI). 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.

[11] Veterinary Practice Act 2005, No 22 of 2005
[12] Pharmacy Act 2007, No 20 of 2007

It has been estimated that, at present, there are approximately 300 pharmacies actively involved in supplying veterinary medicines.

Licensed Merchants

Since 1996, legislation[13] has been in force to allow certain veterinary medicines to be supplied *via* licensed merchants (LM). This trade is operated both by private merchants and by co-operative societies. Only those premises which meet specified standards established by the DA and where a retail assistant accredited as a 'responsible person' is present are deemed to qualify as LM.

Persons engaged by licensed merchants to retail veterinary vaccines 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 DA and as such their licences may be 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.

[13] Animal Remedies Regulations 1996, SI No 179 of 1996.

Chapter 3 Problem Analysis

3.1 Position of Other EU Member States and Additional Considerations

The WG considered the position of veterinary vaccines in other EU Member States. From the information available from 18 Member States, it appears that vaccines are subject to prescription control in all Member States except Ireland. However, in two Member States (UK and Norway) suitably qualified persons other than veterinary practitioners are permitted to prescribe for certain species. Whilst appreciating that the information available was incomplete, the WG notes that the Irish situation appears to differ from what applies in other Member States, insofar as certain vaccines are currently available without prescription in this country.

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.

The WG observed that other professions in Ireland, e.g. veterinary nurses and pharmacists might have an interest in prescribing 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 there have been few adverse reactions to veterinary vaccines since the inception of the IMB's pharmacovigilance monitoring system in 1989. 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 certain vaccines where some adverse reactions associated with the administration were reported, the available information did not call into question the general suitability of the method of supply assigned.

3.2 Methodology Used and Feedback Analysis

A public call for submissions was posted on the IMB website on 30 March 2007. The WG also made a call for submissions by contacting 16 interested parties. A total of 11 written submissions were received (see Appendix 3). Those who made submissions were also invited to an oral hearing before the WG on 7 June 2007 and eight bodies sent representatives. The hearings provided the WG with an opportunity to clarify the written submissions and to explore the reasoning behind the points made.

3.3 Perspective of Interested Parties

Interested parties appreciated the opportunity to have a discussion with the WG.

The submissions received were focussed mainly on the ruminant livestock sector. Most accepted the need for a holistic approach to disease control on farms based on herd health principles. Many submissions included general references regarding the efficacy of vaccines to reduce disease and minimise antibiotic use. Many submissions discussed the effect of the ban on advertising of prescription-controlled medicines on farmers' access to information about new vaccines for controlling disease. Some of the submissions did not take account of the rules governing the dispensing and advertising of veterinary medicines and in addition expressed misunderstandings of vaccinology and the use of certain vaccines.

Many interested parties considered issues such as cost of vaccines, economics of farming, needs of farmers to have access to vaccines as well as access to appropriate information on vaccines and disease control. Some were of the opinion that unduly restrictive supply categorisation would increase prices of vaccines and might adversely affect their usage and increase the prevalence of disease.

It was stated that the farming environment is increasingly changing with a trend towards fewer and larger herds being run by better qualified and more competent and commercially-minded farmers. It was also stated that farmers rely on vaccine promotional literature in the farming press and on farm group discussions for technical information on vaccines and they were reluctant to seek advice from their veterinary practitioners in the first instance. Some felt that such an approach was false economy and that in the global stage in which Irish farmers now

compete, the status of animal health in the national herd/flock must be improved to reach or exceed those of our competitors and that the best way to achieve this goal was a proactive programme of disease control. The fact that vaccines restricted to POM cannot be advertised in the farming press was felt by those representing farmers and the animal health industry to constitute a loss of an important source of information to farmers.

Most were satisfied that, overall, the *status quo* in relation to the routes of supply for vaccines for companion animals, horses, poultry and fish should remain, albeit that there were some inconsistencies in relation to the method of supply of certain similar classes of vaccines. Some were of the opinion that several vaccines, formerly readily available through the licensed merchant trade, had been transferred to a more restrictive category. When it was pointed out that POM vaccines could be marketed *via* LM outlets, those involved expressed surprise and stated that this was not happening on the ground. The fact that the legislation providing for the supply of vaccines subject to prescription control took effect only in January 2007 may mean that the situation will change as licensed merchants become familiar with the operation of the new system.

There was a divergence of views relating to the need for a prior professional diagnosis before selecting an appropriate vaccine. Some were of the view that vaccination was a routine preventative programme and the advice of a veterinary practitioner was not essential where the disease was ubiquitous, or where the risk was known to be very high and where control was straightforward. There was strong support for the theory that an effective vaccination programme on farms can lead to improved animal health and welfare, reduced mortality and a reduction in the use of other medicines. Some felt that by designating vaccines 'LM', access by farmers would be improved, 'bureaucracy' would be minimised and farmers might be encouraged to develop preventative animal health programmes. Others disagreed, suggesting that vaccination should be considered as a preventative medicine measure rather than as a routine procedure and therefore should always be justified. Moreover, many diseases are complex and occur sporadically and the constraints surrounding the use of certain vaccines are not widely understood. Some of the interested parties stated that over-reliance on vaccination without a proper understanding of the disease and without due consideration of other control points could lead to reduced effectiveness and impaired animal health and welfare.

It was generally acknowledged that farmers are facing increased pressures to maintain income and could not afford to misuse veterinary medicines in general and vaccines in particular. It was stated that farmers only use vaccines as part of a herd health plan to deal with specific problems that had been identified on their farms and following consultation with their herd health advisors. It was also stated that whilst veterinary practitioners are legally entitled to write a prescription without seeing the animal, the experience of farmers up to now is that this is not happening and therefore costs had increased. For their part, veterinary practitioners stated that they had no wish to monopolise the distribution of vaccines and that more than one-third of their number wrote prescriptions that they themselves did not dispense. Following recent changes to the legislation relating to veterinary prescriptions, veterinary practitioners are required to visit a farm at least once a year to familiarise themselves with the field situation while a prescription was valid for a period of six months. Any prescription issued for vaccines could be dispensed by a range of outlets including 'LM' outlets.

Some interested parties were of the view that all medicines must be supplied through systems where accountability and responsibility are provided along with an appropriate and operational sanction system. While some argued for the availability of vaccines labelled specifically for different target user groups, the WG noted that experience to date was that for commercial reasons associated with the costs of vaccine production, licensing and distribution, the animal health industry would not be in a position to meet a demand for the manufacture of separate products for what were regarded as niche markets. Indeed, by contrast, it was noted that IMB was working to harmonise labels of many vaccines with the UK's Veterinary Medicines Directorate in order to ensure the continuity of those vaccines in Ireland (harmonised products could be marketed jointly in both countries and would continue to be available in the smaller Irish market).

3.4 Considerations Relating to Routes of Supply of Veterinary Vaccines

Any vaccine available without the professional advice of a veterinary practitioner or pharmacist must be capable of being easily administered and must present neither a risk to the animal being treated nor to the person administering the product. Vaccines intended for use in food-producing animals must meet all the additional criteria established by Directive 2006/130/EC. The WG was of the opinion that it was necessary to consider the variety of circumstances on a species-specific basis before formulating recommendations.

Vaccines for Companion Animals

The WG noted that prior to vaccination, there was a need to ensure animals were healthy and fit for vaccination (e.g. absence of maternal antibodies). An understanding and knowledge of changes to the local prevailing infection patterns and pressures was necessary in order to make an informed judgment on vaccination. Some animal breeds might be more susceptible to adverse effects and this information was not widely known outside the veterinary profession. Moreover, in many circumstances animal owners have a requirement for veterinary certification. Not all pet owners would have the scientific knowledge and or skill required to correctly administer a vaccine to their pet. There was a risk of needle-stick injury, which might have potentially serious consequences for the person involved. For those involved in commercial breeding, it was noted that the keeping of the *status quo* (POM) would enable an owner or breeder to obtain a prescription from his/her veterinary practitioner and to purchase the vaccine(s) from their veterinary practitioner, pharmacist or licensed merchant and to have the option of the veterinary practitioner or owner administering the vaccine(s). The WG was of the opinion that POM(E) was not an appropriate option for the reasons set out above. The WG was of the opinion that POM was the most appropriate category for vaccines intended for companion animals.

Vaccines for Horses

The WG again noted (i) the need to ascertain that the animals were clinically healthy before vaccination; (ii) the need to confirm absence of medication which might interfere with the safe and effective use of the vaccine and (iii) the need for veterinary certification of vaccinated animals. Moreover, it was felt that many horse owners did not possess the scientific knowledge or skill required to administer vaccines. It was noted that vaccination by lay persons might lead to local infections. In addition, for some vaccinations, the possibility of adverse reactions and treatment thereof needed to be considered. The WG was of the opinion that POM(E) was not appropriate for the reasons set out above. The WG was of the opinion that POM was the most appropriate category for vaccines intended for horses.

Vaccines for Poultry and Fish

The WG was of the opinion that vaccines for poultry and aquatic species are generally used as part of a preventative 'herd' health programme under the direction of a veterinary practitioner. Notwithstanding the high knowledge and skill levels of the owners and managers of such farms, the WG was of the opinion that the continuing engagement of veterinary practitioners to monitor disease in these farms and to provide laboratory diagnoses meant that a prescription-based control system was appropriate. The WG noted that some vaccines for poultry were subject to special storage conditions. Accordingly, the WG was of the opinion that POM was the appropriate supply category for vaccines intended for poultry and fish.

Vaccines for Pigs

The WG noted that pig farming was an intensive enterprise where farmers, in the main, received specialist training and were very knowledgeable of disease control and biosecurity measures. Certain diseases, such as erysipelas, enteritis and porcine respiratory disease are known by farmers to be present or to be highly likely to occur on most farms. The use of vaccines for these disease conditions was routine. Farmers did not require special skill to administer the vaccines involved. The WG agreed that certain vaccines met the criteria of Directive 2006/130/EC. The WG accepted, therefore, that for those vaccines 'LM' access was appropriate and a more restrictive regimen was unnecessary. However, in the case of vaccines which contained an oil adjuvant, the WG felt that these did not meet the criteria of Directive 2006/130/EC due to the risks of self-injection and the consequences thereof. Additionally, the WG noted that adverse reactions had been reported for one mycoplasma

vaccine and decided that the vaccine in question also did not meet the exemption criteria. For some diseases, the supply of vaccines licensed for use in pigs are restricted under S.I No 528 of 2002 as amended (Disease of Animals Act 1966) and therefore could only be available as prescription medicines.

In conclusion, the WG was of the opinion that LM supply of vaccines to farmers was appropriate in some instances without prescription; others should be supplied under the POM(E) category and the remainder should be supplied on the basis of a prescription.

Vaccines for Cattle and Sheep

The WG noted the changing demographics of farmers keeping cattle and sheep, acknowledging the trends towards fewer but larger commercial herds and flocks. The WG also noted that many farmers in Ireland today operate in a part-time capacity and that labour is much less available on farms than formerly. The WG was of the opinion that the knowledge and skill levels of those involved in cattle and sheep farming was not uniformly high and felt that it was difficult to find one single solution which would satisfy the diversity of situations encountered in Ireland today. That said, the WG was of the opinion that certain diseases, such as clostridial diseases, leptospirosis, enteric diseases, ringworm, footrot and pasteurella pneumonia in sheep were known by farmers to be present or to be highly likely to occur on many farms. The preventive use of vaccines for these diseases was routine. Farmers did not require special skill to administer the vaccines involved. Many of the available vaccines met the criteria for exemption described by Directive 2006/130/EC. The WG agreed that for some vaccines therefore, ‘LM’ access was appropriate and that a more restrictive regimen was unnecessary.

For vaccines which contained an oil adjuvant, the WG was mindful of the risks to human health of accidental self-injection and the serious consequences thereof. The WG felt that these products did not meet the criteria of Directive 2006/130/EC and could not therefore be exempted from the requirement for a veterinary prescription. The WG considered that for those vaccines for diseases where there was a zoonotic potential such as toxoplasmosis and orf in sheep, the risk to human health was such that the vaccines would also require designation in the POM category.

In respect of vaccines for bovine viral diarrhoea and for respiratory diseases where the aetiology of the disease was complex, the WG considered that these vaccines could be placed in the POM(E) category.

In conclusion, the WG was of the opinion that LM supply of vaccines to farmers was appropriate in some instances without prescription; others should be supplied under POM(E) category and the remainder to be supplied on the basis of a prescription.

3.5 Observations of the Working Group on Submissions Received

The WG felt that generalisations made by various interested parties in respect of the use, potential benefits and categorisations of veterinary vaccines were not appropriate, given the differences between vaccines themselves, their mode of action and the epidemiology of disease. The WG agreed with interested parties that vaccines should not be used indiscriminately and that a balance was needed to provide for informed use and availability.

The WG was of the opinion that over-reliance by farmers on advertising as a source of reliable information on vaccination policies was open to bias. It was recognised that farmers have more objective means of acquiring appropriate information.

The WG recommended that for all vaccines designated LM and permitted for sale without prescription, the following advice be added to the product labelling or package leaflet: (i) the disease condition for which the vaccine induces protection; (ii) the requirement that consideration be given to herd history and (iii) the desirability of seeking veterinary advice before use.

Chapter 4 Conclusions, Impact Analysis and Proposed Classification Criteria

4.1 Conclusions

The WG examined the currently allocated supply categorisation for veterinary vaccines for cattle, sheep, pig, fish, poultry, horses and companion animals with a view to ascertaining whether they were appropriate. The WG noted that considering the wide availability of veterinary vaccines through a variety of merchant outlets and pharmacists in the past and the risk profile associated with veterinary vaccines in general, it was possible to classify some vaccines in non-prescription control categories in compliance with existing EU legislation. The WG did not consider it necessary to restrict any vaccine to veterinary practitioner use only category. However, the WG considered it necessary, in a minority of cases, to restrict certain vaccines to one of the more restrictive categories available in the legislation on the basis of the risk profile of the products or on the basis of EU legislation. The WG agreed, with some exceptions, to classify similar vaccines to the same category. While the WG considered that overall the criteria currently used by the IMB were generally appropriate, certain amendments, which are set out later in this chapter, have been proposed.

4.2 Impact Analysis

The WG considered that the impact of the recent changes in national legislation to the rules governing the issue of a prescription and the supply of vaccines by licensed merchants has been limited, as POM vaccines are not widely available from LM outlets as envisaged by the legislation. The WG acknowledges that the changes in the legislation might take some time to have a tangible effect.

The WG considered the likely impact of any change to the method of supply of existing veterinary vaccines for animal health and welfare and practical accessibility. It also considered the effect on interested parties involved in prescribing and supplying the vaccines. The WG is of the opinion that no change in the existing regimen is necessary in respect of vaccines for companion animals and horses.

In respect of vaccines for poultry and fish, the change in the route of supply from POM(E) to POM recommended by the WG is expected to have minimal effect on the supply of vaccines as it appears that most of these vaccines are currently supplied by veterinary practitioners. However, the fact that POM vaccines can be dispensed by veterinary practitioners, pharmacists and LM outlets is expected to improve access to such products in the future.

With regard to vaccines for pigs, the WG recommends that many of the current vaccines could be supplied as LM products. This recommendation is expected to have many positive effects for farmers and for animal welfare. The route of supply of several vaccines for pigs currently restricted to POM and LM categories should remain unchanged.

In respect of vaccines for cattle, while many existing LM vaccines continue unchanged several other vaccines previously restricted to POM or POM(E) categories, including vaccines for leptospirosis and enteric disease, are to be categorised as LM. The categorisation of vaccines for bovine viral diarrhoea and for respiratory diseases as POM(E) in cattle is expected to harmonise the distribution route of similar vaccines and to ensure fair competition in the market by different animal health companies. A number of vaccines for cattle currently labelled POM will continue in that category.

With regard to vaccines for sheep, many existing LM vaccines continue unchanged. It is recommended that vaccines which contain a mineral oil adjuvant or which have a zoonotic potential be placed in the POM category.

The net effect of the changes to cattle and sheep vaccines is expected to improve farmer access while not compromising animal health and welfare. Where products are restricted to POM(E) supply, farmers can access these products either from veterinary practitioners or from pharmacies where professional advice on their safe and effective use is available. Vaccines assigned to the POM category will be available on prescription from veterinary practitioners, pharmacists and licensed merchants.

If the WG recommendations are accepted by the IMB, it is expected that the marketing authorisation holders will apply to the IMB to change the method of supply in accordance with the revised policy. This will impose a financial cost on the affected companies due to registration, labelling and stock control costs. The WG expects that affected companies will engage with the IMB to ensure that the change process can be optimised to minimise costs to the industry. The WG also expects that the animal health industry will benefit through having a 'level playing pitch' for similar classes of vaccines.

4.3 Proposed Classification Criteria

The WG recommends the revision of the criteria as outlined below.

It is recommended that, notwithstanding paragraph 3.4, vaccines should be assigned to a supply category on a case-by-case basis following a scientific evaluation of the benefit/risk profile of the product. During this process, consideration must be given to Directive 2006/130/EC which lists criteria for exempting certain veterinary medicinal products for food producing animals from the requirement of a veterinary prescription and to the criteria listed in European Communities (Animal Remedies Regulations) S.I. No 144 of 2007.

The benefits/risks associated with the use of a vaccine will differ depending on a variety of factors, some of which include:

1 The need for professional advice to ensure the safe use of the vaccine with regard to the user, the target animal and environment.
2 The need for professional advice or diagnosis of a specific infectious disease by a veterinary practitioner for the effective use of a vaccine.
3 The need for the certification of vaccination and/or a particular skill/training in the administration of the vaccine to the target animal in order to avoid unnecessary risks to the animal or the person administering the product and the requirement for certification of vaccination.
4 Whether serious adverse reactions have been reported with other products containing similar active substances.
5 Whether there is a need for specialist training in relation to the storage and transportation of the vaccine.
6 Whether use of the vaccine interferes with National or Community disease policies.
7 Whether the vaccine contains active substances which differ significantly from existing products.

Further discussions of these points are detailed below.

1. The need for professional advice to ensure the safe use of the vaccine with regard to the user, the target animal and environment

Certain live vaccines contain agents which are zoonotic and are of special concern for immunologically incompetent persons and pregnant women. Other vaccines may contain an agent which may spread to non-target species and cause disease or have special disposal requirements. Some vaccines contain adjuvants which can pose safety concerns for the end-user e.g. mineral oil. Such vaccines should be dispensed on the basis of a prescription.

2. The need for professional advice or diagnosis of a specific infectious disease by a veterinary practitioner for the effective use of the vaccine

Professional advice or diagnosis of an infectious disease by a veterinary practitioner is required to ensure the effective use of certain vaccines. Veterinary advice may also be required when the method of delivery, the vaccination schedule or efficacy profile of the product differs significantly from most other vaccines. Such vaccines should be dispensed on the basis of a prescription.

3. The need for the certification of vaccination and/or a particular skill/training in the administration of a vaccine to the target animal in order to avoid unnecessary risks to the animal or the person administering the product

Different categories of vaccines have their own special requirements for administration and product users will have different levels of expertise in the administration of vaccines e.g. (i) veterinary practitioners have high levels of expertise in the administration of all vaccines; (ii) it

is expected that many farmers and other personnel who are routinely involved in vaccination practices, having regard to product labelling, will have the necessary skills to administer vaccines safely and correctly by most recommended routes and (iii) owners of companion animals and horses are more likely to require advice from a veterinary practitioner and appropriate certification of vaccination.

The route of supply allocated to a particular vaccine should take into account the likely skill level of the end-user and the proposed route of administration.

4. Whether serious adverse reactions have been reported with other products containing similar active substances

The route of supply should be determined taking into account available information which suggests that serious adverse events can occur following product administration.

5. Whether there is a need for specialist training in relation to the storage and transportation of the vaccine

Vaccines are usually stored in the dark at 2^{o}C - 8°C. It is of vital importance that these storage conditions are adhered to as these will influence the efficacy of the vaccine. However, more stringent storage conditions are required for certain labile vaccines e.g. live Marek's disease vaccines, which require storage and transport in liquid nitrogen. The required storage conditions of the vaccine should be taken into consideration when allocating a supply category for the product.

6. Whether use of the vaccine interferes with National or Community disease policies

In some instances the use of vaccines indicated against a notifiable disease can influence the country's disease status or interfere with national disease eradication programmes. Therefore, when allocating a vaccine to a particular supply route, it is important to consider issues such as whether the disease for which the vaccine is recommended is exotic and/or notifiable or if use of the vaccine will interfere with current or future disease eradication programmes.

7. Whether the vaccine contains active substances which differ significantly from existing products

A number of vaccines for use within a particular species contain similar antigenic components which have been used extensively for many years. Consequently, the safety and efficacy profile of these products are well characterised. However, if a vaccine contains an active substance which differs significantly from existing products or is on the market for less than five years, this information might not be available. This constitutes a risk factor which should be taken into consideration when allocating a supply category for the product.

Policy Guide on Classification of Veterinary Vaccines

Prior to the allocation of a vaccine to a supply category a benefit/risk analysis, based on the criteria outlined in this document, is required.

VPO:

Vaccines which fulfil any of the criteria listed below should be allocated to the VPO category:

- Have a very high safety risk.
- Have a novel method of administration that requires special administration skills.
- Have known, or are suspected of having, serious side effects when administered with other commonly-used vaccines.

POM:

Vaccines which fulfil any of the criteria listed below, and where none of the points relating to the VPO category apply, should be allocated to this POM category:

- Require the professional advice of a veterinary practitioner on the special skills for correct administration.
- Require advice and/or diagnosis of a specific disease by a veterinary practitioner for effective use of a product.

- Contain a live zoonotic agent.
- Present a defined risk to the target and/or non-target species, to the person administering the product, to the consumer of the treated animal or to the environment.
- Where the strain of the infectious agent contained within the vaccine is not representative of the strains of the infectious agents present in Ireland.
- May cause effects which impede or interfere with disease control policies.
- Where, in the case of certain intensive farming systems, there is a need for the monitoring of laboratory results by a veterinary practitioner to ensure an ongoing effective vaccination programme.
- Contain a new active substance.

POM(E):
Vaccines which fulfil any of the criteria listed below, and where none of the points relating to either the VPO or POM categories apply, should be allocated to this POM(E) category:

- Require professional point-of-sale advice regarding effective use of the vaccine.
- Require professional point-of-sale advice regarding safety risks associated with the vaccine.
- Require professional point-of-sale advice regarding disposal of unused vaccine or vaccine containers.

PS:
Vaccines which fulfil any of the criteria listed below, and where none of the points relating to the VPO, POM or POM(E) categories apply, should be allocated to this PS category:

- Require professional point-of-sale advice.

LM:
Vaccines which fulfil any of the criteria listed below, and where none of the points relating to the VPO, POM, POM(E) or PS categories apply, should be allocated to this LM category:

- Where the storage requirements, point-of-sale information and advice are easily understood.

Vaccines falling into this category should have a package leaflet specifying (a) what the vaccine induces protection against, (b) the necessity for consideration of herd history and (c) the desirability of seeking advice from a veterinary practitioner when first purchased by the end-user.

Appendix 1

Terms of Reference of Working Group on Classification of Methods of Supply of Veterinary Vaccines

Objective: To review the current methods of supply available and to prepare a guidance document for the IMB on the most appropriate criteria for allocating supply categories to new vaccines or altering the existing national supply routes for veterinary vaccines.

The Report offers advice to the Advisory Committee for Veterinary Medicines (ACVM) of 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 vaccines for livestock, aquaculture, poultry, bloodstock and companion animals with a view to ascertaining whether they are appropriate.
2. To take account of the relevant legislation for allocating medicines to an appropriate supply category.
3. To consider if modification to the IMB's criteria for allocation of a suitable supply category for veterinary vaccines is required and if so, to suggest amendments.
4. To review the impact of changes to the rules governing the issue of prescriptions and the supply of vaccines by licensed merchants in formulating any proposals for amendment.
5. To evaluate the likely effect of any change to the method of supply of existing veterinary vaccines for animal health and welfare, practical accessibility and on stakeholders involved in prescribing and supplying 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 before 27 July 2007.

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:

Mr. P.J. O'Connor, (Chairman) MVB, DVSM, MRCVS, Veterinarian

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

Mr. Matt Browne, B.Sc(Pharm), FPSI, Retired Pharmacist

Mr. Denis Healy, MVB, MRCVS, Veterinary Inspector, Department of Agriculture, Fisheries and Food

Dr. Una Moore, BA Mod, H.Dip.Ed, PhD, Senior Immunological Assessor, IMB

Prof. Joe Quinn, MVB, PhD, MRCVS, Retired Professor of Veterinary Microbiology & Parasitology

Prof. Peter Weedle, B.Pharm, LLM, PhD, MRPharmS, MPSI, Community Pharmacist

Appendix 3

Interested Parties who made Submissions to the Working Group

ACORN Independent Merchants Group
Animal and Plant Health Association #
Irish Co-operative Organisation Society #
Irish Creamery Milk Suppliers Association #
Irish Farmers Association #
Irish Greyhound Board #
Irish Pharmaceutical Union #
Pharmaceutical Society of Ireland #
Teagasc
Veterinary Council of Ireland
Veterinary Ireland #

# denotes parties who also made an oral submission

Appendix 4

Routes of Supply as set out by the European Communities (Animal Remedies) Regulations 2007

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

'**Veterinary Practitioner Only (VPO)'** – refers to an animal remedy which may be administered only by a registered veterinary practitioner, or under the direct supervision of a registered veterinary practitioner where the registered veterinary practitioner is present at the time of administration and is in a position to render assistance if required.

'**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 immunological 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 the European Communities (Animal Remedies) Regulations 2007 to be taken into account by the IMB in Designating the Route of Sale

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) with effect from 1 January 2007, an animal remedy authorised for administration to a food–producing animal, except for an animal remedy exempted in accordance with criteria established under Article 67(a)(aa), second indent, of the Directive,
(c) 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,

(e) officinal formulae intended for animals,

Appendix 5 cont. /

(f) 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

Listing of Veterinary Vaccines with their Existing and Recommended Routes of Supply

List of all nationally authorised vaccines

VPA no.	Target Species	Product Name	Method of Sale & Supply	
			Current	Recommended
10974/013/001	Bovine	BOVIDEC	POM(E)	POM(E)
10996/152/001	Bovine	BOVILIS BOVIPAST RSP	POM(E)	POM(E)
10847/001/001A	Bovine	BOVILIS BVD	POM(E)	POM(E)
10996/081/001	Bovine	BOVILIS HUSKVAC - ORAL LUNGWORM VACCINE	POM(E)	POM(E)
10996/078/001	Bovine	BOVILIS IBR	POM	POM
10996/200/001	Bovine	BOVILIS IBR MARKER INAC	POM	POM(E)
10996/172/001	Bovine	BOVILIS IBR MARKER LIVE	POM	POM(E)
10996/082/001	Bovine	BOVILIS IBR+PI3 LIVE	POM	POM
10996/184/001	Bovine	BOVILIS RINGVAC	POM	POM(E)
10996/165/001	Bovine	BOVIVAC S	POM(E)	POM(E)
10846/005/001	Bovine	HIPRABOVIS PNEUMOS	POM	POM
10846/003/001	Bovine	HIPRABOVIS-4	POM	POM
10019/066/001	Bovine	IMURESP RP	POM	POM
10007/034/001	Bovine	INSOL TRICHOPHYTON	LM	LM
10996/183/001	Bovine	LACTOVAC	POM	LM
10277/062/001	Bovine	LEPTAVOID-H	POM(E)	LM
10857/034/001	Bovine	MILOXAN	POM(E)	LM
10857/029/001	Bovine	PASTOBOV	POM(E)	POM(E)
10019/104/001	Bovine	PREGSURE BVD	POM	POM
10019/103/001	Bovine	RISPOVAL 3 - BRSV - P13 - BVD	POM	POM(E)
10019/080/001	Bovine	RISPOVAL IBR-MARKER INACTIVATED	POM	POM(E)
10019/081/001	Bovine	RISPOVAL IBR-MARKER LIVE	POM	POM(E)
10019/069/001	Bovine	RISPOVAL PASTEURELLA	POM(E)	POM

10019/067/001	Bovine	RISPOVAL RS	POM	POM(E)
10019/105/001	Bovine	RISPOVAL RS+PI3 INTRANASAL	POM	POM(E)
10277/070/001	Bovine	ROTAVEC CORONA	POM(E)	POM
10019/070/001	Bovine	SPIROVAC	POM(E)	LM
10983/036/001A	Bovine	TECVAX PASTEURELLA 1/6	POM	POM(E)
10974/014/001	Bovine	TORVAC	POM(E)	POM(E)
10861/033/001	Bovine	TRIANGLE BVD	POM(E)	POM(E)
10277/065/001	Bovine	TRIBOVAX T	LM	LM
10857/035/001	Bovine	TRIVACTON 6	POM(E)	LM
10996/079/001	Ovine	ENZOVAX	POM	POM
10277/064/001	Ovine	FOOTVAX	LM	POM
10996/146/001	Ovine	HEPTAVAC P PLUS	LM	LM
10996/147/001	Ovine	OVIPAST PLUS	LM	LM
10996/149/001	Ovine	OVIVAC P PLUS	LM	LM
10277/067/001	Ovine	SCABIVAX CONTAGIOUS PUSTULAR DERMATITIS (ORF) VACC	POM	POM
10996/080/001	Ovine	TOXOVAX	POM	POM
10277/063/001	Bovine & Ovine	BLACKLEG VACCINE	LM	LM
10996/142/001	Bovine & Ovine	BLACKLEG VACCINE	POM(E)	LM
10277/088/001	Bovine & Ovine	COVEXIN 10	LM	LM
10277/060/001	Bovine & Ovine	COVEXIN 8	LM	LM
10857/033/001	Bovine & Ovine	IMOCOLIBOV	POM	LM
10861/086/001	Companion Animals	BRONCHI-SHIELD	POM	POM
10861/090/001	Companion Animals	DURAMUNE PI + L	POM	POM
10861/091/001	Companion Animals	DURAMUNE PI + LC	POM	POM
10861/088/001	Companion Animals	DURAMUNE PUPPY DP+C	POM	POM
10857/036/001	Companion Animals	EURICAN DHPPI	POM	POM
10857/055/001	Companion Animals	EURICAN L	POM	POM
10857/056/001	Companion Animals	EURICAN P	POM	POM
10019/071/001	Companion Animals	FELOCELL CVR	POM	POM

10861/074/001	Companion Animals	FEL-O-VAX IV	POM	POM
10277/084/001	Companion Animals	INTRAC	POM	POM
10996/174/001	Companion Animals	NOBIVAC DHP LYOPHILISATE FOR RECONSTITUTION FOR INJECTION	POM	POM
10996/166/001	Companion Animals	NOBIVAC DHPPI	POM	POM
10996/182/001	Companion Animals	NOBIVAC DUCAT	POM	POM
10996/195/001	Companion Animals	NOBIVAC FORCAT	POM	POM
10996/129/001	Companion Animals	NOBIVAC KC	POM	POM
10996/169/001	Companion Animals	NOBIVAC LEPTO 2	POM	POM
10996/167/001	Companion Animals	NOBIVAC PARVO C	POM	POM
10996/176/001	Companion Animals	NOBIVAC PI	POM	POM
10996/170/001	Companion Animals	NOBIVAC RABIES	POM	POM
10996/171/001	Companion Animals	NOBIVAC TRICAT	POM	POM
10996/204/001	Companion Animals	NOBIVAC TRICAT TRIO	POM	POM
10277/090/001	Companion Animals	PROCYON DOG DA2PPI/CVL	POM	POM
10857/054/001	Companion Animals	RABISIN	POM	POM
10019/075/001	Companion Animals	VANGUARD 7	POM	POM
10019/072/001	Companion Animals	VANGUARD CPV	POM	POM
10019/073/001	Companion Animals	VANGUARD CPV-L	POM	POM
10019/074/001	Companion Animals	VANGUARD LEPTO-CI	POM	POM
10861/087/001	Equine	ARTERVAC	POM	POM
10861/068/001	Equine	DUVAXYN IE	POM	POM
10861/069/001	Equine	DUVAXYN IE-T PLUS	POM	POM
10861/067/001	Equine	DUVAXYN T	POM	POM
10996/158/001	Equine	EQUILIS RESEQUIN	POM	POM
10996/158/002	Equine	EQUILIS RESQUIN	POM	POM
10277/081/001	Equine	EQUIP F	POM	POM
10277/079/001	Equine	EQUIP T	POM	POM
10277/080/001	Equine	EQUIP FT	POM	POM
10996/153/001	Equine	PREVAC PRO	POM	POM
10996/153/002	Equine	PREVAC PRO	POM	POM

10996/154/001	Equine	PREVAC T PRO	POM	POM
10996/154/002	Equine	PREVAC T PRO	POM	POM
10804/001/001	Piscine	ALPHA JECT 3000	POM(E)	POM
10277/089/001	Piscine	AQUAVAC ERM	POM	POM
10277/094/001	Piscine	AQUAVAC ERM ORAL	POM	POM
10277/091/001	Piscine	AQUAVAC FNMPLUS	POM	POM
10277/097/001	Piscine	AQUAVAC FUROVAC	POM	POM
10277/096/001	Piscine	AQUAVAC VIBRIO IMMERSION & INJECTION	POM	POM
10277/095/001	Piscine	AQUAVAC VIBRIO ORAL	POM	POM
10974/019/001	Piscine	FUROGEN 2 INJECTION VACCINE	POM(E)	POM
10996/175/001	Piscine	NORVAX COMPACT 4	POM(E)	POM
10996/140/001	Porcine	COLISORB	POM(E)	LM
10007/041/001	Porcine	ENTERISOL ILEITIS	POM	POM
10996/159/001	Porcine	ERYSORB PLUS	POM(E)	LM
10857/044/001	Porcine	GESKYPUR	POM	POM
10277/071/001	Porcine	GLETVAX 6	POM(E)	LM
10857/030/001A	Porcine	HYORESP	POM(E)	LM
10007/038/001	Porcine	INGELVAC M HYO	POM	LM
10007/037/001	Porcine	INGELVAC PRRS KV	POM	POM
10277/087/001	Porcine	M+PAC	POM	POM
10846/004/001	Porcine	MYPRAVAC SUIS SUSPENSION FOR INJECTION	POM(E)	LM
10857/046/001	Porcine	PARVORUVAX	POM(E)	LM
10857/045/001	Porcine	PARVOVAX	LM	POM
10996/100/001	Porcine	PORCILIS APP	POM(E)	POM(E)
10996/085/001	Porcine	PORCILIS AUJESZKY	POM	POM
10996/077/001	Porcine	PORCILIS BEGONIA DF	POM	POM
10996/084/001	Porcine	PORCILIS BEGONIA IDAL	POM	POM
10996/096/001	Porcine	PORCILIS ERY	POM(E)	LM
10996/097/001	Porcine	PORCILIS ERY+PARVO	POM(E)	LM
10996/179/001	Porcine	PORCILIS GLÄSSER	POM	POM

10996/196/001	Porcine	PORCILIS M HYO SUSPENSION FOR INJECTION	POM	LM
10996/098/001	Porcine	PORCILIS PARVO	POM(E)	LM
10996/099/001	Porcine	PORCILIS PORCOL 5	POM(E)	POM
10996/128/002	Porcine	PORCILIS PRRS-IDAL	POM	POM
10996/128/001	Porcine	PORCILIS PRRS-IM	POM	POM
10996/141/001	Porcine	PORCOVAC PLUS	POM(E)	LM
10857/048/001	Porcine	PROGRESSIS	POM	POM
10019/068/001	Porcine	STELLAMUNE MYCOPLASMA	POM(E)	POM
10019/077/001	Porcine	STELLAMUNE ONCE	POM(E)	POM
10861/048/001	Porcine	SUVAXYN AUJESZKY	POM	POM
10861/051/001	Porcine	SUVAXYN E. COLI P4	POM(E)	LM
10861/085/001	Porcine	SUVAXYN ERY	LM	POM
10861/047/001	Porcine	SUVAXYN I-AUJESZKY O/W	POM	POM
10861/046/001	Porcine	SUVAXYN M HYO	POM(E)	LM
10861/050/001	Porcine	SUVAXYN PARVO	POM(E)	LM
10861/081/001	Porcine	SUVAXYN PARVO/E	POM(E)	POM
10857/052/001	Poultry	AVINEW	POM(E)	POM
10857/050/001	Poultry	CRYOMAREX RISPENS	POM	POM
10857/065/001	Poultry	GALLIMUNE 302 ND+IB+EDS	POM	POM
10857/066/001	Poultry	GALLIMUNE 303 ND+IB+ART	POM	POM
10857/067/001	Poultry	GALLIMUNE 407 ND+IB+EDS+ART	POM	POM
10857/051/001	Poultry	GALLIVAC IB88	POM(E)	POM
10857/049/001	Poultry	GALLIVAC IBD	POM	POM
10857/059/001	Poultry	GALLIVAC SE	POM	POM
10857/035/001	Poultry	NEMOVAC	POM(E)	POM
10996/130/001	Poultry	NOBILIS AE 1143	POM	POM
10996/131/001	Poultry	NOBILIS CAV P4	POM(E)	POM
10996/083/001A	Poultry	NOBILIS E COLI INAC	POM	POM
10996/134/001	Poultry	NOBILIS GUMBORO 228E	POM	POM
10996/133/001	Poultry	NOBILIS GUMBORO D78 LIVE	POM(E)	POM
10996/135/001	Poultry	NOBILIS IB H120	POM	POM

10996/136/001	Poultry	NOBILIS IB MA 5	POM	POM
10996/094/001	Poultry	NOBILIS IB+ND+EDS	POM	POM
10996/192/001	Poultry	NOBILIS IBMULI+ND+EDS	POM	POM
10996/137/001	Poultry	NOBILIS MAREK THV LYO	POM(E)	POM
10996/187/001	Poultry	NOBILIS ND C2	POM	POM
10996/091/001	Poultry	NOBILIS ND CLONE 30 LIVE	POM	POM
10996/090/001	Poultry	NOBILIS ND HITCHNER LIVE	POM	POM
10996/190/001	Poultry	NOBILIS RHINO CV	POM	POM
10996/086/001	Poultry	NOBILIS RISMAVAC + CA126	POM	POM
10996/087/001	Poultry	NOBILIS RT+IBMULTI+G+ND	POM	POM
10996/181/001	Poultry	NOBILIS RT+IBMULTI+ND+EDS	POM	POM
10996/180/001	Poultry	NOBILIS TRT	POM	POM
10996/088/001	Poultry	NOBILIS TRT LIVE	POM(E)	POM
10277/069/001	Poultry	PARACOX 5	POM(E)	POM
10861/059/001	Poultry	POULVAC AE	POM(E)	POM
10861/060/001	Poultry	POULVAC BURSINE 2	POM	POM
10861/055/001	Poultry	POULVAC IB H120	POM(E)	POM
10861/058/001	Poultry	POULVAC IB MM	POM	POM
10861/083/001	Poultry	POULVAC IBBM + ARK	POM	POM
10861/093/001	Poultry	POULVAC ISE	POM	POM
10861/056/001	Poultry	POULVAC MAREK CVI	POM(E)	POM
10861/039/001	Poultry	POULVAC MAREK CVI + HVT (SUSPENSION)	POM(E)	POM
10861/061/001	Poultry	POULVAC MAREK HVT	POM(E)	POM
10861/062/001	Poultry	POULVAC MD VAC CA	POM	POM
10861/063/001	Poultry	POULVAC MG	POM	POM
10861/057/001	Poultry	POULVAC PAST M	POM(E)	POM
10861/064/001	Poultry	POULVAC TRT	POM	POM
10857/047/001	Poultry	TUR-3	POM	POM
10861/054/001	Pigeons	COLOMBOVAC PMV	POM(E)	POM(E)
10996/191/001	Pigeons	NOBILIS PARAMYXO P201	POM	POM

10007/039/001	Equine & Companion Animals	INSOL DERMATOPHYTON	POM	POM
10996/150/001	Equine, Ovine & Companion Animals	TETANUS ANTITOXIN BEHRING	POM	POM
10996/145/001	Ovine & Porcine	HEPTAVAC	LM	LM
10996/151/001	Ovine, Bovine, Equine, Porcine & Companion Animals	TETANUS TOXOID CONCENTRATED	POM	POM

Total no. of products: 177

Glossary of Abbreviations

ACVM	Advisory Committee for Veterinary Medicines
DA	Department of Agriculture*
EU	European Union
IMB	Irish Medicines Board
LM	Licensed Merchant
POM	Prescription only medicine
POM(E)	Prescription only medicine (exempt)
PSI	Pharmaceutical Society of Ireland
WG	Working Group
UK	United Kingdom

*The current official title of the Department of Agriculture, Fisheries and Food was formerly termed the Department of Agriculture and Food. For ease of reference, the Department of Agriculture has been used throughout the report.