

Report on the availability of veterinary medicines in Ireland

January 2005

**This report has been prepared by the
Farm Animal Welfare Advisory Council
Working Group on Veterinary Medicines**

Introduction to this report

This Report was prepared for the Farm Animal Welfare Advisory Council by the Working Group on Veterinary Medicines. The report was requested as it was felt that there was a significant problem in the availability of an adequate range of veterinary medicines for use in animals in Ireland. The Working Group on Veterinary Medicines met under the chairmanship of Mr. Dermot Sparrow MRCVS. The participants of the Working Group are given in Appendix 1.

Objectives of this report

1. To define the perceived animal welfare problem caused by the lack of veterinary medicines in Ireland which impacts mainly on the freedom from pain, injury and disease.
2. To list in a logical form the factors which restrict the availability and use of animal medicines for the benefit of the individual animal, group of animals of the species of animal.
3. To review in detail by species the medicines availability where veterinary surgeons in Ireland have already defined problems.
4. To make recommendations to the Farm Animal Welfare Advisory Council to propose remedial action.

1. INTRODUCTION

EU legislation governing the licensing and marketing of veterinary medicines is primarily designed to protect public health with animal health and welfare being a secondary consideration.

Under this legislation, veterinary medicines may not be marketed unless they have been licensed (have received a marketing authorisation) following a scientifically based assessment of the quality, safety and efficacy of the product. It is also the case that before a veterinary medicine can be licensed for a food-producing animal, a maximum residue limit (MRL¹) must have been set for the active substance(s) contained in it.

This regime has resulted in strict limitations on the flexibility allowed to Veterinary Surgeons in using or prescribing veterinary medicines for animals under their care. However, the unique role of Veterinary Surgeons is recognised in the so-called 'Cascade' provision of both the EU Directive and national legislation. This provision, which is intended as being exceptional, allows Vets where it is necessary in order to avoid unacceptable suffering and where no suitable product exists for the treatment of an animal, to prescribe medicines 'off-label' within very strict limitations. These limitations include the restriction that the medicine must be administered by the Vet or given under his/her direct personal responsibility; that an MRL must be established for the active substance(s) in the medicine; that the use of the product is confined to a single animal or to a small number of animals on a particular holding and that the Vet specifies an appropriate withdrawal period for the slaughter of treated animals or for the production of milk, eggs or honey.

The EU regulatory regime is predicated on the basis that the primary responsibility for product development and bringing forward products for licensing rests with the veterinary pharmaceutical industry. This reflects the fact that the industry carries the general legal liability for any harm caused by the product under normal conditions of use. Clearly, the legitimate objective of the pharmaceutical industry is to operate profitably.

This situation has resulted in there being a dearth of veterinary medicines available in Europe for the prevention and treatment of diseases for those conditions which are encountered rarely and for those species where the number of animals, birds or fish is comparatively small and insufficient to justify the costs for the development of suitable remedies.

Consequently, markets for minor use medicines, or medicines intended for small markets, such as Ireland, present particular challenges in this environment. One of the

¹ Under EU legislation (Council Regulation 2377/90), active substances used in veterinary medicines used for food-producing animals must have been validated and a safety threshold from a human health perspective (Maximum Residue Limit) set on the basis of extensive data furnished by the sponsoring company. The scientific committee tasked with the setting of MRLs is the Committee for Veterinary Medicinal Products which is within the European Medicines Agency. Irish representation on this Committee is provided by the Irish Medicines Board. A scientific report is published on each substance evaluated and the substance is assigned a legal category – "Annex I, II, or III" in the case of substances which may be used and "Annex IV" in the case of substances which are considered unsafe for consumers and may not be used.

effects of this situation is that Vets are faced with increasing reliance on the Cascade provision, which means that the product is being used under their personal responsibility.

It is a fact that even with the flexibility of the Cascade provision, some therapeutic gaps remain. A case in point is treatment for blackhead in turkeys, where there is currently a potentially significant disease problem as there is no suitable treatment available in the EU. However, it needs to be pointed out that the reason for withdrawal of the single existing product was on public health grounds, (i.e. the active substance, Dimetridazole, was found to be unsafe for human health and categorised “Annex IV” within the MRL legislation and therefore banned from veterinary medicines).

Veterinary medicines intended for use for food-producing species therefore face two legislative hurdles; viz. the MRL legislation and the legislation defining the quality, safety and efficacy requirements of medicines. In relation to the latter, technical developments have resulted in progressively demanding requirements for the manufacture, development and authorisation of veterinary medicines. A case in point is the rules governing manufacturing plants, where good manufacturing practice requirements now require more stringent production standards. It should also be remembered that the definition of what constitutes a veterinary medicine is quite wide and includes any product presented for the prevention or treatment of a disease in animals. This could, for example, include a foot bath containing copper sulphate, traditionally used for the prevention of foot rot in sheep.

Ironically, while Ireland is one of the biggest food exporters in the northern hemisphere, the national cattle and pig herds, sheep and poultry flocks, fish and bee numbers are comparatively small when compared to our EU and US neighbours. This means that the market for veterinary medicines in Ireland is very small by international standards and only a fraction (less than 10%) of the equivalent market for human medicines in Ireland.

The net effect of this is that while companies may market veterinary products on mainland Europe, they choose for legitimate commercial reasons not to bring them to the Irish market.

It should be acknowledged that at EU level, measures have been taken to address aspects of the problem. Under the recently adopted medicines legislation (Directive 2004/28) there are some specific measures designed to alleviate the situation:

- Improvements in procedures for licensing medicines, in particular under the mutual recognition system for licensing medicines which are already licensed in one Member State – this should help small markets like Ireland’s;
- Removal of the regulatory burden to renew marketing authorisation every five years;
- A more flexible approach to the operation of the Cascade provision, in particular to allow for import, under licence, of veterinary medicines authorised in other Member States;
- Specific measures for horses, including the elaboration of a list of medicines which, though not authorised, are deemed essential for horses, as well as the option of categorising individual horses as a non-food producing species.

The European Medicines Agency is also working with stakeholders to establish if the regulatory burden for products intended for minor species can be reduced.

While these measures are to be welcomed, they will not of themselves provide a total solution and certainly not in the short term, to the problems faced by Ireland with regard to the lack of availability of some veterinary medicines.

2. RELEVANT LEGISLATION GOVERNING THE REGULATION AND USE OF VETERINARY MEDICINES IN IRELAND

(A full list of relevant legislation is given at Appendix 2)

At European level, there are two main bodies of legislation governing the authorisation of veterinary medicines. These are Directive 2001/82/EC (defines the procedures and standards of quality, safety and efficacy applicable to the evaluation of veterinary medicines) and, in the case of medicines that are intended for use in food-producing animals, Regulation 2377/90 (establishes procedures and standards for the establishment of Maximum Residue Limits [MRLs] in tissues and produce of animals. It should be noted that Directive 2001/82/EC has recently been amended by Directive 2004/28/EC. Other EU directives (Council Directive 96/22/EC) on the control of hormonal substances, beta-agonists, and on miscellaneous other matters also impinge on the control of veterinary medicines in the EU Community.

The primary aim of Regulation 2377/90 is the protection of consumer health by ensuring that only those substances in veterinary medicines which have received a positive EU wide evaluation for the safety of residues can be authorised for use in food-producing species. The authorisation procedure for veterinary medicines was originally established by EU Directive in 1981. The procedures and standards for the authorisation of veterinary medicines are akin to those for the licensing of human medicines. A process has now begun at EU level to review legislation governing maximum residue levels with the circulation by the European Commission of its "Reflection Paper". While the time scale for this review is not evident at this stage, it is likely that it will be a number of years before any changes in the regime arising from it will come into effect.

At a national level, the MRL Regulation is directly applicable to the control of residues in tissues and produce of treated animals and is enforced by the National Residue Plan. This plan is the subject of annual review by the EU Commission and a regular audit by the Commission's Food and Veterinary Office.

The principal legislation implementing the relevant EU directives on the authorisation and control of veterinary medicines is the Animal Remedies Act 1993. Various Regulations made under the Act include the following:

- The Animal Remedies Regulations 1996, S.I. No. 179 of 1996 (as amended)
- Control of Animal Remedies and their Residues Regulations 1998, S.I. No. 507 of 1998 (as amended)
- The European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations 1994, S.I. No. 176 of 1994
- The Disease of Animals Act 1966 (Control of Animal and Poultry Vaccines) Order 2002, S.I. No. 528 of 2002 (as amended.)

3. BACKGROUND TO THE PROBLEM OF MEDICINES AVAILABILITY IN ANIMALS

(A list of relevant publications from the European Agency for the Evaluation of Medicinal Products (EMA), is given at Appendix 3).

Both national and international issues have contrived over the last 15 years or so to lead to the current medicines availability problem as it is experienced in Ireland. Whole areas of treatment in terms of organ systems and specific diseases have lost essential medicines which were approved and seen to be effective in the past, but are now seen as potentially dangerous or are unsupported by the pharmaceutical industry or have no MRL established (Ref. EMA/CVMP/073/99). The two step regulatory evaluation of veterinary medicines, which has been in place since 1992, has resulted in the progressive loss of many useful products and limited new product introductions (Ref. EU Reflection paper on Residues in Foodstuffs of Animal Origin, EMA/CVMP/069/02 and EMA/CVMP/477/03 FINAL). These issues are considered separately below:

(I) International issues:

- a. Since the early 1990s, the Animal Health Industry, unlike its human pharmaceutical sister, has been consolidating in order to maintain sufficient returns for their shareholders. This consolidation has brought about a reduction in the number of products available in the marketplace. The combined costs of increasing regulatory requirements for new products and, especially, the costs of generating residue data to support existing products with indications for use in food-producing species, have been cited by the industry sources as contributing to the decision to cease support for certain products. This, in turn, has led to a medicines availability problem in the EU for certain species and therapeutic classes with veterinary surgeons having to consider resorting to the use of human medicines or unlicensed veterinary medicinal products under the provisions of the Cascade in order to treat animals.
- b. Very few new drugs have been launched for use in food-producing animals in the EU in recent years.
- c. Initiatives by the Scientific Committee of the European Medicines Agency (EMA), the Committee for Medicinal Products for Veterinary Use (CVMP), over recent years to reduce the number of the scientific studies needed to support the safety and efficacy of veterinary medicines for minor use in a major species (such as cattle or pigs), or for use in a minor species (such as goats or horses) [the so-called MUMS use] have met with little success to date.
- d. Animal Health Companies are, in the main, not interested in generating new scientific studies to support products for MUMS. They state that they have sufficient challenge in maintaining existing products on the market and developing new products for major species and do not have the resources for this task.

- e. Problem of small national markets, geographic spread of animal species, regional disease expression, unique national labelling requirements such as differences in the withdrawal periods, differences in warnings and indications between Member States, have necessitated the manufacture of small batch sizes of the same product or, the carrying out of multiple packaging runs for the same product. At the same time, the economics of production of veterinary medicines, as with human medicines, mean that, in order to afford the manufacturing controls on veterinary medicinal products, the minimum batch sizes have to be ever larger or the products are deemed not commercially viable.
- f. In order to facilitate the free movement of medicines, the EU Commission and Member States already accept the parallel importation of medicines under certain conditions, including the provision of national language labels. However, it appears that the repackaging or, particularly, overstickering of medicines with a comparable label to one already approved nationally, is not compatible with Good Manufacturing Practice and is not routinely permitted under EU manufacturing requirements.
- g. Companies operating in the Animal Health Industry, like any commercial organisation, are profit motivated. Investments in licensing medicines must be offset by profit and balanced against use of product currently (even if such usage is not supported by a national licence in the Member State concerned).
- h. The definition of what constitutes a veterinary medicine is the subject of disharmony between Member States. This means that a product may be regulated as a medicine in one country and not regarded as a medicine in another.

(II) National issues:

- a. Despite the existence of a very low fee structure in Ireland for certain veterinary medicinal products with a limited market share, there have been very few applications for MUMS in this country, even though such products are licensed elsewhere in the EU (and therefore are supported by an EU dossier).
- b. No local anaesthetic agents for use in the surgery of livestock are authorised in Ireland and in many other Member States.
- c. For veterinary surgeons operating a cross-border practice between the Republic of Ireland and Northern Ireland, a product can be authorised in one area and prohibited in another. Furthermore, an authorised product may have different withdrawal periods in different Member States, which causes difficulties for the prescribing veterinary surgeon and logistical problems for the feed miller or supplier. It also leads to a lack of confidence among farmers (who may have holdings on each side of the border) and to consumers in the regulatory system.
- d. The regulatory costs on companies to pay a supplemental fee to an existing regulatory authority for an assessment report prepared by that authority for use as a basis for Mutual Recognition in Ireland or

another Member State can prevent the commercialisation of a product in this country.

(III) Problems of medicines availability for Minor Species in Ireland

The range of medicines for minority species such as fish, deer, ostrich, goats, rabbits, bees, turkeys and game birds, and alpaca is severely limited and there is no commercial potential for the development of medicines for a new species of food animal (Ref. EMEA/CVMP/477/03 FINAL). The definition of minor and major species has been the subject of much debate in scientific committees in the EU. The outcome of the current situation is that cattle, sheep, pigs, poultry and salmon have been categorised as major species with other species categorised as minor. This means that, in order to safeguard consumer health and regardless of the importance of the species to the economy of a Member State, veterinary medicines intended for a major species must meet elaborate standards for the establishment of MRLs and the monitoring of residues in produce of these species. Egg-laying birds and cow's milk are also defined as a major species. However, even though the requirements for the setting of MRLs for the so-called 'minor species' are somewhat less onerous, so too are the commercial markets for such medicines in the Community. There is also a problem with horses and donkeys in that the range of treatment for equines is limited by their classification as food animals within the EU. However, recent developments in the establishment of a horse passport system may make provision for an extended withdrawal period or permanent exclusion of identified animals from the food chain.

Moreover, the EU authorisation system is specific - a product may be licensed for Salmon but not for Trout and vice versa as these are regarded as different species.

4. CONSEQUENCES OF CURRENT AVAILABILITY CRISIS

Animal Health and Welfare

The lack of suitably authorised veterinary medicinal products is a problem both of animal welfare and of public health. In some countries, including Ireland, the lack of authorised products carries legal consequences for veterinary surgeons who may consider using unlicensed medicines in order to treat disease present in animals in this country. This has led to a legitimate concern among veterinary surgeons faced with situations where there is no authorised veterinary medicine available. Farmers too may face problems in releasing the produce of such animals into the food chain.

Problems of animal welfare include the unnecessary suffering of animals either through lack of pain relief or lack of suitable disease treatment. Indeed, the Equine Thoroughbred Racing Industry in Ireland has already stated that operators might be forced to move to a more animal friendly regulatory environment to allow for the treatment of their animals, outside the EU.

However, it is a fact that arising from pressure from both Ireland and other Member States, a number of specific measures have been incorporated into EU legislation aimed at alleviating the difficulties in the horse sector.

Public Health

Problems of public health could potentially arise either through the inability to control zoonotic disease in animals or in their produce or through the use of unlicensed medicines (off-label use of medicines licensed for use in humans or in another animal species or use of illegal medicines) with consequential risks of exposure of consumers to potentially harmful drug residues. There is also a risk that public confidence in the whole regulatory and monitoring systems may be undermined through the lack of authorised medicines.

Professional Judgement

Any occupation or profession that is highly regulated in relation to the usage of medicines, where illegal use could lead to the loss of livelihoods, will be very compliant. The new Veterinary Practice Bill and EU cross-compliance requirements for farmers will reinforce this compliance. Every animal circumstance and therapeutic need is unlikely to be covered. The exercise of professional judgement and experience may carry risks in the interpretation of the Cascade, or mean that only supportive therapy is provided. The animal medicines regulatory requirements may compete with animal welfare needs. The effect of this situation is to place significant personal responsibility on individual veterinary practitioners and the result of a wrong judgement call will have serious implications for him/her. In effect it would appear that the veterinary practitioner rather than the pharmaceutical companies carries the greatest therapeutic responsibility.

5. SPECIFIC AREAS WHERE PROBLEMS HAVE BEEN IDENTIFIED

(a) Anaesthetics

There is a general problem in the area of anaesthetics, painkillers and sedatives e.g. most anaesthetics and sedatives are restricted to use by or under the supervision of a Veterinary Surgeon (Veterinary Surgeon Only) and may only be clinically used by a vet and no one else. Many modern anaesthetics are not licensed. The result of this is that epidural anaesthesia, diagnostic nerve blocks and handling of dangerous large animals would be made unsafe for the animal and the operators. The conflict between animal welfare and human safety and the food safety agenda is not balanced.

The unavailability of local anaesthetic for routine dehorning and castration means that every case must be carried out by a veterinary surgeon or, under his/her direct supervision, with its increased cost. The alternative is that animal welfare may suffer if these interferences

are carried out without anaesthetic; Electro-immobilisation is likely to be a particular problem without anaesthesia.

Specific areas of concern

Local Anaesthetics

1. Lignocaine is licensed for use in horses only. Lignocaine is not suitable for most cases in horses.
2. When Lignocaine is used in other species under the provisions of the Cascade, difficulties in terms of legalities with the Cascade may arise and a minimum withdrawal period of 28 days is mandatory in respect of other food-producing species.

General Anaesthetics

1. There is a problem of lack of products for all species.
2. Most are combination or “Poly-pharmacy” and are not licensed for use in this manner by the Irish Medicine Board (IMB).

(b) Analgesics

Many chronic pain relieving products have been lost from most food animal species e.g. *phenylbutazone* (but these are available for non-food producing animals).

Lameness is the condition that causes great suffering in cattle and sheep practice and essential preventative foot baths, while permissible, products such as formaldehyde, zinc sulphate and copper sulphate are increasingly difficult to obtain.

Specific areas of concern

1. Non availability of pain relief is a welfare problem. Availability of analgesics which act by means of the Central Nervous System is very poor (Most opiates are controlled drugs).
2. Non-steroid anti-inflammatory drugs (N.S.A.I.D.s), though more widely available and licensed for a number of species are not suitable for very many cases.

(c) Products for lactating animals

Many medicines are expressly secreted at high levels in the milk of lactating animals and there can be a conflict between treatment and food safety during lactation. This is a disincentive to the development of medicines for lactating animals.

Specific areas of concern

1. Mastitis antibiotic treatment residues have been largely solved by the polluter pays principle.

2. Few anthelmintics are authorised and available for use in animals producing milk for human consumption. This is a major problem in all species but especially for milk producing sheep and goats

(d) **Products for Laying Birds**

A similar situation applies to the accumulation of potential harmful residues in eggs. There are no licensed anthelmintics or external parasite treatments for laying hens.

Specific areas of concern

1. No antibiotics permitted except Erythromycin (not licensed in Ireland)
2. No anthelmintics authorised (real problem with free range hens)
3. No ectoparasiticides authorised (real problem with red mite)
4. No antiprotazoals authorised (real problem with black head in turkeys)
5. The impact of these shortages can be altered by changes in the breed and husbandry systems used.

(e) **Anti Fungals**

All effective anti-fungals have been lost for cattle and fish e.g. *Malachite green* is gone as is *Griseofulvin* for ringworm in cattle. When one considers that ringworm is very common, up to 30% in cattle and is a zoonotic disease, it is very concerning that we have no effective treatments. However, Griseofulvin continues to be used in human medicine. While effective vaccination of animals is possible and should be encouraged, it does not seem to be popular.

(f) **Anti Protozoals**

Coccidiostats are being lost in all species and particularly in poultry medicine and this is producing increased reliance on the existing limited supply.

Metronidazole, a human medicine, is essential in horses for the treatment of colic and deep seated chronic wounds involving anaerobic bacteria. Colic surgery is virtually impossible without Metronidazole. It is commonly used to treat vaginal thrush in humans so its danger to the human population must be limited.

(g) **Antibiotics**

Some excellent antibiotics have been lost in the past 10 years and this list is getting longer particularly in minor species e.g.

Specific areas of concern

1. Only one antibiotic is currently available for use in fish as all other licensed products are not being marketed, they have lost Oxolinic Acid, Amoxicillin, Potentiated Sulphonamides and Sarafloxacin.
2. No effective routine preventative medication available. Often farmers do not have Penicillin or Penicillin Streptomycin available for treatment of lambing ewes and post difficult calving preventative treatment. The legislation governing the supply of veterinary medicines in Ireland is currently under review and is likely to change when new regulations come into effect.
3. In-feed medication creates difficulties in terms of cross contamination at the mills and on-farm. Suitable alternative soluble products for pigs are in short supply. Wastage and accuracy of dose are further problems.

(h) **Chemo Therapy and Radio Therapy**

This is potentially important in horses and small animals and does not necessarily conflict with the food chain. Most experience and products come from human medicine and the usage is likely to be off label using the Cascade. Availability and legal problems may restrict development of these important treatments.

(i) **Other problem areas**

Cardio-vascular, chronic respiratory disease and eye treatments in horses, red water in cattle and louping ill vaccine in sheep are specific problem areas. Although adrenaline, atropine and calcium edetate are permitted in the EU, no licensed medicines are available in Ireland. These medicines are essential for the control of shock or the treatment of poisoning in animals.

Specific areas of concern

1. Inhaler type products in horses
2. Eye treatments essential in horses
3. Red water in cattle
4. Obscure or exotic vaccines
5. Louping ill in sheep, duck vaccines & Botulinus vaccine

6. PROPOSED SOLUTIONS

It is appreciated that food safety is paramount and this has driven the current regulatory climate for veterinary medicines. However, as essential medicines continue to be withdrawn, and notwithstanding the 'Cascade' provisions, the issues of professional judgment by veterinary surgeons and animal health and welfare are necessarily subject to the parameters defined by regulatory system driven by European legislation.

We are concerned that, despite the measures in place, animals could suffer and food safety prejudiced by the development of a black market particularly, where due to the commercial considerations there is deficit of veterinary medicines compared to neighboring EU states.

We can see that the Irish horse industry needs a full and legal veterinary armoury. This is essential to maintain its competitiveness and base in Ireland. It is to be hoped that the new measures contained in revised EU medicines legislation will facilitate this objective.

We are concerned that by not taking a strong and pro-active stance for change of the attitude of pharmaceutical companies and the regulatory environment we will jeopardize:

1. Animal health and thereby food safety
2. Animal welfare

It is recognised that many of the solutions to the medicines availability problem are complex and not within the gift of a single government agency. The proposed solutions may involve remedies at EU level as well as more local solutions. Some solutions may only be achieved in the longer term while for others the pending changes in the national legislation to implement Directive 2004/28/EC afford more immediate actions. Active engagement by the pharmaceutical industry is required for measures to have any significant success in preventing animal welfare problems.

There is an information deficit both at farm level and at the level of veterinary surgeons on the availability and permitted use of medicines. In particular, the operation of the Cascade and the legal responsibility on the farmer and the Vet in complying with regulations. An education campaign involving farmers, Department of Agriculture and Veterinary Surgeons should be undertaken. This must be addressed as a matter of urgency.

These proposed solutions are considered below:

a) EU Solutions:

- a. The Animal Health Industry has repeatedly called for a more benevolent regulatory environment in the EU and a roll-back of some of the current requirements. The EMEA has already committed to examine this possibility for products for minor use and for minor species.

- b. Various producer or farmer groups (such as turkey growers, horse producers etc.) should be encouraged to fund the development cost of medicines which are currently unavailable in the whole Community to meet their needs.
- c. The 'free movement of goods' promise needs to be more effectively underwritten by the legislation. A product authorised in one Member State should be mutually recognised in another through a more co-operative approach to the Mutual Recognition procedure. Any differences in the conditions of authorisation which may be manifest in cross-border veterinary practices should be the subject of forced harmonisation by the EU Commission.
- d. The EU Commission should ensure that the costs for the provision of the authorisation services in Member States should not themselves become a barrier to trade in veterinary medicines between States.
- e. The EU Commission should consider to grant aid the cost of development of veterinary medicines for MUMS and improve the legal protection for companies willing to undertake this task.
- f. The EU Commission should remove the requirement for national language labels where they are not needed currently and for centralised products.
- g. The EU Commission should amend the interpretation of the laws governing Good Manufacturing Practice to allow for appropriately regulated overstickering of products in another language.
- h. The EU Commission should amend laws governing Mutual Recognition of authorisations to force harmonisation for all veterinary medicines on the market in the EU. Where three or more Member States have an agreement on such particulars, these conditions should become normative for the rest of the EU. Alternatively, a series of EU monographs could be established which would define the characteristics for a particular medicine which would be acceptable throughout the Community.
- i. The EU Commission should consider the therapeutic gaps identified in this report and bring forward incentives for industry or universities to develop products to meet these requirements.

b) **National Solutions:**

- a. The IMB, as the competent authority for veterinary medicines in Ireland should further explore whether it could accept products authorised in another EU Member State without changes to labelling.
- b. The Veterinary, Pharmacy and Farming Professions should work to encourage companies with approved dossiers to make application for authorisation of their medicines in Ireland

- c. The Department of Agriculture and Food should review the operation of the *AR16 ‘licensing’ system, to establish if it can be made more responsive to the needs of Irish agriculture in line with European legislation.
- d. The IMB should continue to ensure fees for applicant companies seeking a licence for their medicines in Ireland are kept to a minimum.
- e. The Department of Agriculture and Food, in implementing the new EU provisions governing the Cascade, should ensure that the importation of veterinary medicines which are licensed elsewhere in the Community is speedily implemented with the minimum bureaucracy needed for the control of this system.
- f. While it is accepted that residue positives arising from ongoing residue monitoring under the National Plan must be investigated, we support the farming industry’s commitment to a responsible residue prevention system while looking after the welfare of animals. We further encourage the development of quality assurance schemes in this regard. It is important that a residue issue should be effectively communicated so as not to automatically become a food scare.
 - i. Eliminate the 4 plate screening test and replace it with a calibrated 6 plate test to reflect more accurately the MRL threshold at screening i.e. don’t screen down to very low levels. We encourage the progress that is already taking place and it is believed that the six plate test will be the test of choice in the very near future.
 - ii. The development of confirmatory methods for accurate residue testing is desirable and it is necessary to invest in analytical systems and a verifiable residue testing system.
 - iii. Investigation and exploration should not assume guilt and wrong-doing but is preventative and investigative in the majority of cases.
 - iv. It is not desirable that there would be different withdrawal periods on the same product in neighbouring jurisdictions as this undermines the credibility of the MRL regimes. Such products need to be identified and harmonisation initiatives undertaken.
- g. By 2007 it is estimated that all medicines intended for use in food producing animals will be subject to prescription control by veterinary surgeons, but it is suggested that the control system be modified to allow access that is commensurate with the level of risk and where animal welfare considerations are adequately considered.
- h. The pharmaceutical industry has a responsibility to present these essential medicines for authorization in Ireland. Their commitment must be real if any other measures are to succeed. In particular the

*** AR 16 Licence**

An AR 16 licence, otherwise known as a Special Treatment Authorisation is a licence issued under Regulation 16 of The Animal Remedies Regulations of 1996. The licence is issued in exceptional circumstances where the animal health situation requires and where there is no animal remedy authorised in the State. The licence authorises the manufacture, importation, possession, sale or supply and the administration of an animal remedy which is authorised in another Member State in accordance with the provisions of the Council Directive. The Department of Agriculture and Food has issued several such licences some of which are listed in this table, resulting in these medicines being available for the particular conditions to be treated.

pharmaceutical industry must exploit the new mutual recognition arrangements to the fullest extent to bring more products to the Irish market.

Appendix 1

Members of the Working Group on Veterinary Medicines

- Chairman: Mr. Dermot Sparrow, MRCVS, Chairman of the Working Group on Veterinary Medicines, Veterinary Ireland, Farm Animal Welfare Advisory Council
- Members: Dr. Tom Barragry, MRCVS, PhD – University College Dublin, National University of Ireland
Mr. Pat Brangan, MRCVS – Department of Agriculture & Food
Ms. Colette Connor - Department of Agriculture & Rural Development, Northern Ireland
Mr. Tom Doyle – Irish Co-operative Organisation Society Ltd
Mr. Philip Kirwan – Department of Agriculture & Food
Mr. Lorcan McCabe – Irish Creamery Milk Suppliers’ Association
Mr. Sean O’Laoide, MRCVS - Veterinary Ireland, Farm Animal Welfare Advisory Council
Mr. John Stack – Irish Farmers Association, Farm Animal Welfare Advisory Council
- Secretary: Ms. Paulette O’Riordan
- Guest advisor: Dr. J. G. Beechinor, MRCVS, PhD – Irish Medicines Board

Appendix 2

Legislation

1. National

- The Animal Remedies Act 1993, S.I. No. 23 of 1993
- The Animal Remedies Regulations 1996, S.I. No. 179 of 1996 (as amended)
- Control of Animal Remedies and their Residues Regulations 1998, S.I. No. 507 of 1998 (as amended)
- The European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations 1994, S.I. No. 176 of 1994
- The Disease of Animals Act 1966 (Control of Animal and Poultry Vaccines) Order 2002, S.I. No. 528 of 2002 (as amended)

2. European

- 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
- Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82 on the Community code relating to veterinary medicinal products
- Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of B-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
- Council Directive 96/23 of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
- Council Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation of medicinal products for human use and veterinary use and establishing a European Medicines Agency
- Council Regulation (EEC) No. 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin
- Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community.

All legislation is available on the Website of the attorney General <http://www.attorneygeneral.ie>

Appendix 3

Publications by the EMEA European Agency for the Evaluation of Medicinal Products

- EMEA/CVMP/069/02 – Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin.
- EMEA/CVMP/073/99 – Availability of Medicines
- EMEA/CVMP/477/03 FINAL – Position Paper regarding Availability of Products for Minor Uses and Minor Species (MUMS)

EU Reflections paper attached