



Submission to the IMB Working Group in relation to Classification of Method of Supply of Veterinary Vaccines

Introduction

Pharmacy is entering a new era in Ireland with the introduction of the Pharmacy Bill 2007 which has been signed by the President. For the first time the Pharmaceutical Society of Ireland (PSI) will have an effective robust regulatory framework for pharmacies and pharmacists in the Republic of Ireland. This will ensure that both pharmacists and pharmacies, including pharmacy owners, will be held accountable for the professional services provided by them. All pharmacies within the state will be registered with the PSI on an annual basis, and will be subject to a rigorous and robust inspectorate and enforcement regime. Each pharmacy must comply with regulations and standards specified by legislation and through adherence to codes of conduct to be issued by the Society. Pharmacists and pharmacies can be prosecuted in the courts and depending on the nature of indictment if found in breach can face up to a maximum sanction of 10 years in jail and/or a fine of €320,000.

In addition all pharmacy undergraduates in the State undergo training in veterinary pharmacy as part of their primary degree and practical training period. The advent of new legislation also requires continuing professional development (CPD) which will encompass all aspects of pharmacy practice including veterinary pharmacy. Modern pharmacy practice involves the applicability of evidence based pharmacy practice and involves the pharmacist and pharmacies being held accountable for the professional advice they provide to patients or animal owners and farmers. They will also be subject to fitness to practice provisions which encompass both owner and practitioner. Evidence based pharmacy practice requires pharmacists and pharmacies to work in a proper and collaborative way with colleagues in other healthcare professions and the veterinary profession. Pharmacists are professionally trained and competent to give advice on all aspects of medicines and medicines utilisation and are an easily accessible and available resource for patients and individuals seeking such a service.

As a regulator the PSI considers effective vaccination regimes and systems as being hugely important in contributing to both animal and public health and prevention of disease. The role of the pharmacist encompasses the primary prevention of disease and maintenance of health in the first instance and subsequent co-operative working with other professions, including the veterinary profession, in relation to treating disease states which may arise. The Society's view is that all medicines both human and animal must be supplied through systems where accountability and responsibility are provided for along with an appropriate and operational sanctions system.

In consideration of the appropriate criteria to allocate new and existing veterinary vaccines to the various national supply routes available, the PSI would recommend the following criteria for consideration:

In deciding the route of sale or supply for an animal remedy, the Working Group should have due regard to the need to protect public health, animal health, animal welfare and the environment and accordingly should have due regard to:

1. The need for prior professional assessment and diagnosis;
 - i. 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 others;
 - ii. The need for professional or specialist training in relation to the storage, handling or disposal of the vaccine.

2. In making a decision on these matters it should be noted that vaccines are well placed to fit into the category of (POM) E having regard to:
 - i. The purpose for which the animal remedy is intended;
 - ii. The extent to which the container, label and package leaflet are specific to such purpose;
 - iii. The potency of the active substance;
 - iv. The maximum dose specified in the veterinary product authorisation;
 - v. The pharmaceutical form;
 - vi. The potential for misuse.

3. The category of POM(E) refers to an animal remedy which may be sold or supplied only by:
 - i. A pharmacist from a registered pharmacy;
 - ii. A registered veterinary practitioner for an animal under his or her care.
 - iii. In categorising a medicine as POM(E) the IMB should satisfy itself that only those authorised to supply a product so categorised are in possession of POM(E) medicines.

4. A clinical assessment of the animal(s) is not a pre-requisite when prescribing or dispensing this category of veterinary medicines. Pharmacists have competency to assist and train individuals with regards to dosage, delivery systems and storage as they do with human medicines and competency to provide advice on how to use the product, taking special account of any warnings or contra-indications relevant to the medicine. Pharmacists should not provide medication to persons who are not competent to administer the vaccine or anyone who may cause the product to be administered in any way other than that which is intended.

5. In making a decision to categorise a particular Veterinary medicine as POM(E), the Committee should consider accessibility to the end user of the product. Farmers are based essentially in rural locations and need ready access to these medicines to ensure effective treatment and prevention programmes. The Pharmacy network is easily accessed in all rural communities and by allowing pharmacists to dispense this category of medicines continuity of supply is guaranteed. Furthermore through the increased accessibility and usage of vaccines by those competent to supply and administer them, over time more effective disease prevention and control is guaranteed. In farmed species, emphasis is moving away from therapeutic or prophylactic use of antimicrobials. "Food safety" vaccines are likely to be used to protect animals (and therefore the consumer) against zoonotic pathogens such as *Salmonella* and *Campylobacter*.

6. A product may be suitable for inclusion in the POM(E) category when:
 - i. It is used to reduce, prevent and control the effects of any disease in herds or flocks or in individual animals;
 - ii. It's use carries risks to the user, the animal, consumer safety or the environment but users are made aware of suitable countermeasures through simple, oral or written, advice;
 - iii. A competent user can be given adequate training in its regular use.
7. Only persons who have the competency to review the epidemiology and understand the implications of such matters as herd immunity should have control of vaccine provision.
8. Vaccines therefore fit quite strongly in the category of POM(E) medicines. Those engaged in the supply of POM(E) products must be accountable, registered practitioners who can be held responsible and accountable for their practice and the integrity of the supply chain.

There are significant changes taking place in pharmacy practice across the world of interest to the Working Group including the fact that in forty of the states in the United States of America, pharmacists are directly supplying and administering vaccines against influenza and pneumonia to target populations who do not have a compromised medical status. Many experts in the United States of America have reported a very strong correlation between vaccine uptake and the accessibility and availability of the vaccine coupled with an easy direct route of administration. All pharmacies are equipped with the latest information technology which facilitates easy analysis of uptake in particular the benefits associated with timely administration.

Taking into consideration all of the points listed above it is therefore the view of the Society that the Working Group should seek to continue to place vaccines into the category of POM(E) as pharmacists are well placed to interact with veterinary practitioners, farmers and animal owners in the interest of public health and the health and welfare of animals.