

AVPA CODE OF PRACTICE FOR THE USE OF SCHEDULE 4 RESTRICTED  
SUBSTANCES IN THE POULTRY INDUSTRY

**1. INTRODUCTION**

**1.1 Organisation of the Modern Australian Poultry Industry.**

The Australian Poultry Industry is structured in a way which differs significantly from that of other livestock industries. This greatly influences the provision of veterinary services and the supply of S4 drugs within poultry companies. In the chicken meat industry a limited number of companies own most of the levels of production, including the livestock and some licenced wholesale drug outlets, and also employ veterinarians. Some companies also own feed mills which employ veterinarians. In the layer industry, livestock ownership by poultry companies commonly ceases as soon as chickens are sold to egg producers. Veterinary services to egg producers may either be obtained from veterinarians in private employment, Government veterinarians, or from poultry company veterinarians. Smaller independent poultry processors may also obtain veterinary services in this way.

In many of these situations, the role of the veterinarian has evolved into one of flock health management, often necessitating treatment or preventative measures on a flock basis. Practices of Schedule 4 drug supply and useage in the poultry industry have legal and ethical restraints and are outlined below. A Company veterinarian has a responsibility to ensure his actions maintain the commercial viability of the company for which he works, but this should not override his legal or ethical obligations as a veterinarian.

**1.2 Background to specific guidelines.**

1.2.1 There are practices of supply of S4 restricted substances in the poultry industry which have developed in recent years which contravene the Poisons Act.

1.2.2 These practices have commonly involved the failure of a veterinarian to provide "professional intervention" in the supply of (S4) restricted substances.

1.2.3 In an integrated poultry company, the supply of drugs from the wholesale purchasing arm of the company to the end user (the farm manager or broiler grower), has now been interpreted clearly as a retail practice, and therefore illegal without "professional intervention".

1.2.4 Veterinarians, whether in private practice or not, have obligations under the Poisons Act and Veterinary Surgeons Act to provide "professional intervention" in the supply of S4 restricted substances to stock under their control.

1.2.5 Regulation 43A of the Poisons Act came into force on 1 April, 1985. This Regulation requires that those undertaking wholesale dealing in therapeutic substances listed in Schedules 1,2,3 and 4 of the Poisons List, including veterinary wholesalers, must hold a licence under the Therapeutic Goods and Cosmetics Act, or a written authority from the Secretary of the Department of Health.

1.2.7 The written authority from the Department of Health, N.S.W., stipulates that goods may only be supplied to others licenced under the Therapeutic Goods and Cosmetics Act, another holder of an authority under Regulation 43A, or to:

- a) veterinary surgeons;
- b) pharmacists;
- c) Government Departments, Universities or Hospitals;
- d) interstate distributors;
- e) overseas countries; and
- f) other persons who may be entitled to supply with such goods, but these are rare circumstances and should be verified with the Pharmaceutical Services Branch (02- 887 5678).

1.2.8 All holders of written authorities under Regulation 43A are aware of the conditions attached to the authorisation which they hold and have been advised of their responsibilities. There is, therefore, no excuse for illegal supply of S4 restricted substances.

## 2. RESPONSIBILITIES OF THE VETERINARIAN IN TERMS OF SUPPLY OF S4 RESTRICTED SUBSTANCES WITHIN THE POULTRY INDUSTRY.

### 2.1 Veterinary care and supervision of recipient stock.

2.1.1. The veterinarian must not only be involved in the supply of a restricted substance, but also demonstrate due care and supervision of the recipient flock. This care and supervision should be real and not merely nominal.

2.1.2 When given the responsibility for the health of the flock in question by the agent or owner, the veterinarian demonstrates care and supervision by at least either:

- i) having seen the flock for the purpose of diagnosis or prescription immediately prior to supply; or
- ii) having visited the farm or other premises on which the flock is kept, sufficiently often and recently enough, to have acquired from personal knowledge and inspection an accurate picture of the current health state on the farm or premises, to enable him/her to diagnose and/or prescribe for the flock in question.

2.1.3 When dealing with stock not owned by his employer, the veterinary surgeon must practice in his own name. There is no obligation for the veterinarian to own the drugs he is supplying, or is responsible for supplying.

### 2.2 Areas of responsibility.

In situations where a veterinarian is called on to prescribe or supply restricted substances, responsibilities additional to the legal obligations to be taken into account are:

- i) the care and welfare of the poultry flock which is the subject of the proposed drug supply; and
- ii) the professional responsibility of the veterinarian as described by the Code of Ethics of the profession.

### 2.3 The S4 drug supply chain.

Veterinarians should carefully analyse the drug supply chain in which they are involved and delineate wholesale from retail activities. They should also check the bona fides of persons to be supplied.

The S4 drug supply chain between manufacturer and end user comprises:

2.3.1 The wholesaler - may purchase medications directly from a manufacturer and subsequently supply to a veterinarian, a pharmacist, another licenced or authorised wholesaler, or an authorised receiver, as listed in 1.2.7. All wholesalers in N.S.W. supplying S4 drugs must be either licenced or authorised to do so. A wholesaler may not supply direct to an end user and cannot be authorised to do so by any person. Poultry companies can maintain a wholesale drug operation independent of veterinary involvement but must meet their obligations under the Poisons Act to hold, record and supply to authorised persons or companies only.

2.3.2 The feed mill - can supply feedstuffs containing restricted substances at S4 levels under specified conditions, i.e., on the written authority of a veterinarian.

2.3.3 The pharmacist - may dispense S4 drugs to an end user or a veterinarian, but only on veterinary prescription.

2.3.4 The veterinarian - accepts responsibility for the supply and use of S4 restricted substances in the animals under his care. Any veterinarian involved in the supply chain of restricted substances should continually update his understanding of those individuals or corporate entities who are registered as authorised veterinary wholesalers. Within N.S.W., an updated list of those wholesale dealers authorised under Regulation 43A of the Poisons Act (1966) is maintained by the Department of Health.

2.3.5 The Veterinary Assistant is a responsible person nominated by a veterinarian. The assistant may receive a drug prescribed by the veterinarian and can administer that drug to a flock under the directions of the veterinarian. In many instances, the assistant may also be a serviceman or farm manager. He need not be a veterinarian.

2.3.6 The End User is the person who actually administers the drug, usually the farm manager or broiler grower.

### 2.4 Supply of non-registered S4 drugs (generics)

A veterinarian can only legally supply unregistered products for the treatment of flocks under his direct control. Direct control is outlined in Section 2.1. In such cases the veterinarian must be confident the drug is safe and efficacious. With unregistered drugs, the veterinarian may be liable for any untoward reactions resulting from the use of the drug. With unregistered S4 drugs, the same conditions of documentation (see Part 7) apply.

## 3. PROFESSIONAL INTERVENTION

3.1 Veterinarians should fulfil the definition of "professional intervention" in the supply chain of S4 restricted substances. "Professional intervention" can be defined as intervention between the drug wholesaler and the end user of the substance, in such a way as to ensure that the drug is necessary, appropriate and will be used correctly.

3.2 Veterinarians must not act as "rubber stamps" for transactions between wholesalers and end users but should instead be fully involved in the disease treatment and/or control programme requiring the use of restricted drugs.

#### 4. GENERAL OBLIGATIONS OF POULTRY VETERINARIANS.

4.1 Poultry veterinarians must fulfil the obligations imposed upon them by the Poisons Act, Veterinary Surgeons Act, the Stock Foods and Medicines Act and any other Acts or Regulations of their States that direct procedures to be followed in the supply of (S4) restricted substances.

4.2 Any current practices which are contrary to these Acts or Regulations should be either curtailed or modified to meet all requirements.

4.3 Contrived arrangements between veterinarians and wholesalers that attempt to circumvent these regulations are to be avoided, since they jeopardise both the wholesaler's authority and the veterinarian's registration.

4.4 Supply in the physical absence of a veterinarian can only be done by his assistant when the veterinarian is involved and is confident, after consultation, that the correct drug and dose will be used. In such instances, the veterinarian's responsibility is undiminished. Records must be correct maintained and the supply must be accompanied by an invoice bearing the veterinarian's name.

4.5 Routine preventative programmes may be conducted by veterinarians. In such instances the veterinarian must fulfil his obligations as outlined under "Professional Intervention".

#### 5. Veterinarians Employed by Poultry Companies.

5.1 Poultry veterinarians employed by poultry companies must still meet their obligations under the various State Acts and Regulations pertaining to the use of S4 restricted substances and their own professional activity.

5.2 A veterinarian has an obligation to point out to his/her employer any activities in contravention of the Regulations affecting the supply of S4 restricted substances, and should make every endeavour to have them eliminated.

5.3 There should be no direct supply and no appearance of direct supply by the wholesale arm of the company to outside customers, franchises (unless they also hold a wholesale licence), or the company's own poultry. The veterinarian must intercede in the supply chain of S4 drugs and demonstrate "professional intervention". This should include the use either of his own stationery or his stamp on invoices, his own label on drugs and his obvious recorded direction to supply.

5.4 If the company veterinarian is responsible for the management of the wholesale arm of the company, he is liable for any illegal activities committed by that wholesale arm.

5.5 The obligations and responsibilities of a veterinarian, fully employed by a poultry company, where that company is directly involved in ownership of poultry, and where that company also is an authorised wholesaler of S4 restricted substances, are the same as those of any other veterinarian.

## **6. SUPPLY OF S4 RESTRICTED SUBSTANCES WITHIN A POULTRY COMPANY**

6.1 The N.S.W. Department of Health makes no distinction between the supply to outside customers of the Company or to farms on which the Company's own poultry is grown. All are recognised as end users and can only be supplied by a veterinarian (company or private practitioner). They cannot be supplied directly by the wholesale arm of the Company.

6.2 When supply is made from that wholesale arm to a company veterinarian, obligations to record transactions must be taken over by the veterinarian at that point.

6.3 S4 restricted substances supplied to the company veterinarian must be held physically separated from the wholesale drug supplies of the authorised wholesale arm of the company. The veterinarian's supplies should represent sufficient to meet company requirements for a limited period (e.g., one week). This can be at the same location but should be in a lockable cupboard or room accessible only to the veterinarian and his assistant. The veterinarian is required by law to keep a record of the drugs in his possession. In the case of a routine preventative programme under the control of the veterinarian, the date of supply, the drug used, the farmer's name and volume of supply must be regularly recorded and authorised.

6.4 The use of depots to hold drug stocks on farms remote from the veterinarian is permitted in N.S.W. only if the veterinarian can demonstrate he maintains absolute control over these depots. This he must do by limiting access, appointing an assistant to be responsible, maintaining an inventory of stocks in and out, auditing that inventory regularly, and ensuring that no supply occurs without his prior authority. A similar situation must apply to a serviceman's car. In addition, S4 drugs held in a serviceman's car should be stored out of public view in a suitable container and be limited in volume. The S4 drugs must be only carried on veterinary authority and the veterinarian remains accountable for the quantity of each S4 drug in the serviceman's possession. The drugs held by the serviceman can only be obtained from a veterinarian's stock and must be correctly labelled as outlined in 5.3, 7.1, 7.2 and 7.3.

6.5 The N.S.W. Department of Health is not prepared to extend wholesale authorisation to depots.

6.6 The interstate supply of restricted drugs direct to end users by the wholesale arm of a poultry company may be illegal in some states and requires proper "professional intervention".

## **7. DOCUMENTATION OF "PROFESSIONAL INTERVENTION"**

7.1 The veterinarian is required by law to keep a record of the drugs in his possession. In the case of a routine preventative programme, the date of supply, the drug used, the farmer's name and volume of supply must be regularly recorded and authorised.

7.2 When supply is undertaken by the veterinarian each container of the restricted drug must bear labelling as required by law including the name and address of the veterinarian and the name of the animal owner (this would include the name of the broiler farmer or farm manager of the Company).

7.3 Instructions as to drug use should be given to the end user by the veterinarian with clear details of method of administration, dose rate, etc.. These instructions can be part of specific disease control literature distributed by the Company and delivered with the S4 restricted substance by the serviceman. This does not prevent the serviceman from doing dose calculations or physically administering the S4 restricted substance.

## 8. OBLIGATIONS OF GOVERNMENT VETERINARIANS.

8.1 All veterinarians, including Government veterinarians, can only receive restricted drugs from either a pharmacist following the issuing of a prescription or from an authorised wholesale dealer; the latter are not permitted to fill prescriptions under any pretext.

## 9. FEED MILLS.

9.1 Feed Mills do not usually conform to the definition of a wholesaler, but may be recognised as authorised wholesalers under Regulation 43A. However, the conditions attached to the authorisation (and provided for in the Regulation) require that the mill supply feed in which therapeutic substances may be incorporated at S6 level (for unrestricted sale), in circumstances as outlined in Section 9.2, or at S4 level. In the latter case, the medicated feed may only be supplied on and in accordance with the full written instructions of a veterinary surgeon.

9.2 Feed Mills may not, under any circumstances, supply S4 restricted substances other than incorporated in feed. Where a person who mixes his own feed requires medication for his flock, then it must be acquired from a pharmacist (on a veterinary prescription) or from a feed mill as a feed concentrate (in accordance with full written instructions from a veterinary surgeon). The concentrate may contain a therapeutic substance at such a level that it can be further mixed to produce medicated feed containing that drug at a specified therapeutic level.

9.3 The veterinarian (including those in the employ of a feed mill) must show "professional intervention" and be involved in the supply of S4 restricted substances to the end user. Such supply by a veterinarian requires the recording of receipt and supply as would apply to routine S4 drug usage.

9.4 The attached draft from the N.S.W. Department of Health, ie., the "Supply of Veterinary Medicines by Wholesalers" sets out the conditions under which Feed Mills can supply S4 drugs in feed stuffs.

9.5 The authorisation of a feed mill by the Department of Health under Reg. 43A does not permit the Feed Mill to supply S4 restricted stock medicines for retail with or without veterinary authority.

9.6 It has always been illegal for a wholesaler, feed mill or anyone, other than a veterinary surgeon and a pharmacist filling a prescription, to supply restricted substances, for animal use, to the owner or person caring for the animals. Regulation 43A provides for the cancellation of authorisation in certain circumstances (e.g., offence against the Poisons Act) and the cancellation will deny the affected person (Company, etc.) any access to therapeutic substances in Schedules 1,2,3 or 4 of the Poisons List.

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