AUSTRALIAN POULTRY INDUSTRIES ASSOCIATION

THE USE OF ANTIBIOTICS AND OTHER DRUGS IN THE POULTRY INDUSTRY

A CODE OF PRACTICE FOR USE BY COMPANIES

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Contents

Preface

This is the first edition of the APIA's document "The Use of Antibiotics and Other Drugs in the Poultry Industry". The document has been prepared by the Veterinary and Public Health Committee of the Australian Poultry Industries Association and relies heavily on two related documents "Uses, Poisons Schedules and Withdawal/Withholding Periods for Drugs used in the Poultry Industry" modified from a paper presented by Ian Bell at the University of Sydney Post-Graduate Foundation Poultry Disease Course in May 1986, and the Australian Veterinary Poultry Association (AVPA) document "Code of Practice for the Use of S_4 Restricted Substances in the Poultry Industry".

This document has been developed for use as a Code of Practice for those companies associated the the Australian Poultry Industries Association. The Association recognises that it has a responsibility to ensure that poultry meat and eggs produced by associated companies are not only wholesome and nutritious, but free from any undesirable residues. It also recognises it has a responsibility to control its use of antibiotics so as to minimise the risk of antibiotic resistance developing in bacteria with the unlikely but potential risk of this resistance being transferred to human pathogens.

Adherence to this code will assure that poultry meat and eggs will be free from any undersirable residues.

Antimicrobials

In the early 1960's an epidemic of salmonellosis due to an antibiotic resistant salmonella in calves drew attention to the possible problems due to widespread antibiotic resistance among human pathogens. Largely as a result of this epidemic, the UK Government in July 1968, set up the Swann Committee to examine the problem and report accordingly. Recommendations from the Swann Committee included the following:

- that permission to supply and use drugs without prescription in animal feed should be restricted to antibiotics which:

  (a) are of economic value in livestock production under UK farming conditions,

  (b) have little or no application as therapeutic agents in man or animals and

  (c) will not impair the efficacy of a prescribed therapeutic drug or drugs through the development of resistant strains of organisms and

- that "therapeutic antibiotics" should be available for use in animals only if prescribed by a member of the veterinary profession who has those animals under his care.

The Australian poultry industry considered its use of antibiotics and the Swann Report at the first Combined Conference in Surfers Paradise in 1972 (Craven, J.A. 1972; Royal, A. 1972 and Greville, R.W. 1972). When, in 1977, the NH & MRC Working Party on antibiotics in animal feedstuffs made recommendations in keeping with those put forward by overseas authorities including the Swann Committee (1968), the WHO Working Group (1973) and the Food and Drug Administration in the US, the Australian chicken meat industry had already modified its use of antimicrobials in accordance with the Swann Report and consequently found the NH & MRC requirements easy to embrace.

The industry acknowledges that antibiotic resistance in human pathogens is a significant problem. Although the widespread (mis)use of antibiotics in human medicine is seen as the major source of resistance, any misuse of antibiotics by the poultry industry could be a potential source of resistance. The industry consequently accepts its responsibility to minimise this potential and all APIA companies work within the following broad quidelines -

i Antimicrobials should never be used as a substitute for good management and/or good housing.

ii Growth Promotants

- Only those antimicrobials recommended by the NH & MRC as suitable for use as feed additives for growth promotant purposes be used for such purposes. These are listed in the BAH, DPI Document PB 144C - Livestock Feed Additives - their Recommended Claims, Use Levels and Limitations.

- Only antimicrobials which don't result in the development of resistance in bacteria and which have no significant value in human or animal medicine and which are not absorbed from the gut, should be used for growth promotant purposes.

- Withdrawal times for antimicrobials used for growth promotant purposes should be strictly observed. See Appendix I.

These guidelines still leave a reasonable range and should not inconvenience any producer wishing to use a growth promotant. Antimicrobials most frequently used for growth promotant purposes by the chicken meat industry and which meet all of the above requirements are -

Bacitracin
Flavophospholipol (Flavomycin)
Avoparcin
Nitrovin (Payzone)
Virginiamycin (Stafac)

iii Prophylatic and Therapeutic Use

- use of any "therapeutic" antimicrobial i.e. an antimicrobial which is not a "feed" antimicrobial registered for growth promotant purposes, should be under the direct control of a veterinarian.

- Wherever possible, antimicrobials for therapeutic and prophylactic purposes should be administered via the drinking water rather than added to the feed.

- Withdrawal times should be strictly observed. Where no withdrawal times are given, it is the responsibility of the prescribing veterinarian to ensure that there are no antimicrobial residues in chicken or poultry products for human consumption. See Appendix I.

- Where the antimicrobial is classified as Schedule 4, the "Code of Practice for the Use of Schedule 4 Restricted Substances in the Poultry Industry" developed by the AVPA should be strictly adhered to. See Appendix II.

Hormones

There seems to be a fairly widespread misconception by the public that hormones, specifically oestrogens, are used in poultry production.

Although oestrogens were once administered to young male chickens as a hormonal alternative to castration to produce capons, the practice is now universally banned. The administration of oestrogens to chickens was banned in Australia in the early 1960's and capons have not been marketed for over two decades.

No hormones are fed or otherwise administered to poultry in Australia.

Further Information and Reading

Chemotherapy and Drugs

Proceedings No. 39: The Therapeutic Jungle 1978. The University of Sydney Post-Graduate Committee in Veterinary Science.

Proceedings No. 71: Clinical Pharmacology and Therapeutics 1984. The University of Sydney Post-Graduate Committee in Veterinary Science.

Veterinary Prescribers Index. PVP Publications.

Index of Veterinary Specialists. IMS Publishing.

Read the drug label.

Contact the manufacturer for literature and advice.

Ian Bell: Rational Therapeutics. Presented at the University of Sydney Post-Graduate Foundation Poultry Disease Course, May 1986.

Legality and Ethics

The following publications may be obtained from The Secretary, Technical Committee on Veterinary Drugs, Bureau of Animal Health, Department of Primary Industry, Canberra, ACT, 2600; or from the Australian Government Publishing Service:

Withholding Periods, Maximum Residue Limits and Poisons Schedules for Agricultural and Veterinary Chemicals. Document PB431. Pesticides Section, Department of Primary Industry.

Livestock Feed Additives: their recommended claims, use levels and limitations. Document PB144C. Australian Bureau of Animal Health, Department of Primary Industry.

Antibiotics in Stockfeeds: report of the NH&MRC Working Party on Antibiotics in Stockfeeds, June 1986.

Regulatory Control of Veterinary Drugs.
Document PB 237A.
Pesticides Section, Department of Primary Industry.

Legislation

The following Acts and Regulations may be obtained from the Government Book shop or printer in the relevant State of Territory:

Federal:

Therapeutic Goods Act 1966 and Regulations
Customs (Prohibited Imports) Regulations
Quarantine Act 1908

New South Wales

Veterinary Surgeons Act 1923/1957 and Regulations
Poisons Act 1966 and Regulations
Stock Foods and Medicines Act 1940 and Regulations
Stock (Chemical Residues) Act 1975 and Regulations
Stock Diseases Act and Regulations
Pesticides Act 1978 and Regulations
Pure Food Act 1908 and Regulations
Public Health Act 1902 and Regulations
Poultry Processing Act 1969 and Regulations

Victoria

Veterinary Surgeons Act 1958 and Regulations
Poisons Act 1962 and Regulations
Stock Medicines Act 1958 and Regulations
Stock Foods Act 1958 and Regulations
Stock Diseases Act and Regulations
Agricultural Chemicals Act 1958 and Regulations
Health Act 1958 and Regulations

Queensland

Veterinary Surgeons Act and Regulations
Agricultural Standards Act 1952-1981 and Regulations
Agricultural Standards Act Amendment Act 1981 and Regulations
Stock Acts 1915-1981 and Regulations
Health Act 1937-1979 and Regulations

South Australia

Veterinary Surgeons Act 1935-1968 and Regulations
Stock Medicines Act 1939-1978 and Regulations
Stock Foods Act 1941-1956 and Regulations
Stock Diseases Act 1934-1976 and Regulations
Food and Drugs Act 1908-1981 and Poisons Regulations

Western Australia

Veterinary Surgeons Act 1960-1977 and Regulations
Poisons Act 1964-1970 and Regulations
Veterinary Preparations and Animal Feeding Stuffs Act 1976-1981 and Regulations
Stock Diseases (Regulations) Act 1968-1978 and Regulations
Health Act 1911-1978 and Regulations

Tasmania

Veterinay Surgeons Act 1918 and Regulations
Poisons Act 1971 and Regulations
Stock Medicines and Fertilisers Act 1950 and Regulations
Stock Act 1932 and Regulations
Pesticides Act 1968 and Regulations
Public Health Act 1962 and Regulations

Northern Territory

Veterinary Surgeons Act and Regulations
Poisons Act and Regulations
Stock Diseases Act and Regulations
Food and Drugs Act and Regulations
Dangerous Drugs Act and Regulations
Prohibited Drugs Act and Regulations

Australian Capital Territory

Veterinary Surgeons Ordinance
Stock Diseases Ordinance
Poisons and Dangerous Drugs Ordinance
Poisons and Narcotic Drugs Ordinance

APPENDIX I

Uses, Poisons Schedules and Withdrawal/Withholding Periods for Drugs used in Poultry Production

Generic Name	Proprietary name	Manufacturer	Use	Route	Poisons Schedule	Withdrawing/Withholding period (days)		Max Residue Limit	
					(NSW)	Meat	Eggs	Meat	Eggs
Amoxycillin **			Ab	Oral	4	5	1	0.06	0.018
Ampicillin **			Ab	Oral	4	5	1	0.06	0.018
				Inj.	4	15	15	0.10	0.018
Amprolium plus ethopabate	Amprolmix-Plus	Merck	Ac	Oral	Exempt	0	0	0.50	4
Ascorbic acid (vitamin C)				Oral	Exempt	0	0		
Avoparcin	Avotan	Cyanamid	Gp	Oral	Exempt	0	0	0.50	0.5
Bacitracin			Ab.Gp	Oral	6	0	0	0.50	
Chloramphenicol *			Ab	Oral	4	*	*	*	*
Chlortetracycline	Aureomycin	Cyanamid	Ab.Am	Oral	4	7	?	0.05	0.05
Dimentridazole	Emtryl	May & Baker	Hs	Oral	6	5	-	0.05	
	Dimetryl - 20	Chemical Res.	Hs	Oral	6	5		0.05	
Dinitro-o-toluamide	(DOT)		Ac	Oral	Exempt	0		3	-
Di-n-butyl tin dilaurate			Ah	Oral	6	7	7		-
Erythromycin			Ab	Oral	4	0(1?)	0(1?)	0.30	0.3
Fermentation residues			Gp	Oral	Exempt	0	0		
Flavophospholipol	Flavomycin	Hoechst	Gp	Oral	6	0	0	0.02	0.02
Furaltadone	Furasol	Smith Kline	Ab	Oral	Exempt	0	0	0.10	0.10
Furazolidone	Neftin	Smith Kline	Ab	Oral	Exempt	0	0	0.10	0.10
Gentamicin			Ab	Inj.	4	*	*	*	*
Gentian Violet	GV11		Af	Oral	Exempt	0	0		
Halofuginone	Stenorol	Hoechst	Ac	Oral	7	0	-	0.05	-
Halquinol	Roxolin	Squibb	Gp	Oral	Exempt	0	0	0.1	0.10
Hygromycin	Hygromix	Elanco	Ah	Oral	6	2	2		
Lasalocid	Avatec	Roche	Ac	Oral	Exempt	0	-	0.5	-
Levamisole	Nilverm	ICI	Ah	Oral	5	7	0	0.10	1
	Ripercol	Ethnor	Ah	Oral	5	7	0	0.10	1
Lincomycin plus spectinomycin	Lincospectin	Upjohn	Ab.Am	Oral	4	10	10		
			Ab	Inj.	4	10	10		
Maduramicin	Cygro	Cyanamid	Ac	Oral	Registration pending				
Monensin	Elancoban	Elanco	Ac	Oral	4	0	-	0.50	-
Narasin	Monteban	Elanco	Ac	Oral	4	0	-		
Neomycin			Ab	Oral	4	0	0		
Nifursol	Salfuride	Chemical Res.	Hs	Oral	Exempt	0	-	0.1	-
3-nitro-hydroxy-phenylarsonic acid	3-nitro	Chemical Res.	Gp	Oral	6	5	5	1.15	-
4-nitro-phenyl-arsonic acid (nitarsone)	Histostat	Chemical Res.	Hs	Oral	6	5	-	1.15	-
Nitrovin	Payzone	Cyanamid	Gp	Oral	Exempt	0	0		
Novobiocin			Ab	Oral	4	4	4		
Oleandomycin	OM5	Pfizer	Ab.Gp	Oral	6	0	-	0.1	-
Oxytetracycline	Terramycin	Pfizer	Ab.Am	Oral	4	7	?	0.25	-
	Terramycin LA	Pfizer	Ab	Inj.	4	21	-	0.25	-

Generic Name	Proprietary name	Manufacturer	Use	Route	Poisons Schedule	Withdrawing/With-holding period (days)		Max Residue Limit	
					(NSW)	Meat	Eggs	Meat	Eggs
Pencillin			Ab	Oral	4	5	5	0.06	0.018
				Inj	4		5		-
Piperazine			Ah	Oral	Exempt	0	0		
Reserpine			Tr	Oral	4	7	7		
Salinomycin	Coxistac	Pfizer	Ac	Oral	?	0	-	0.10	0.02
Spiramycin	Rovamycin	May & Baker	Am	Oral	6	14	-	0.10	-
Streptomycin			Ab	Oral	4	0	0	0.30	0.20
				Inj.	4	30	30	0.30	0.20
Sulphaquinoxaline (SQ)			Ab.Ac	Oral	6	10(7?)	-		
SQ + diavericine	Poultro	DHA Rural	Ac	Oral	6	7	-		
	Toltro	Avian VS	Ac	Oral	6	7	-		
Sulphonamides			Ab	Oral	6	10	10		
Sulpha chloro-pyridazone	Sulphazine	May & Baker	Ab	Oral	6	4	4		
Tiamulin	Dynamutalin	Squibb	Am	Oral	4	3(5?)	3	0.10	-
Trimethoprim plus sulphadiazine	Tribrissen	Wellcome	Ab	Oral	4	10	10		
Tribrissen plus sulphadoxine	Trivetrin	Glaxo	Ab	Inj.	4	10	10		
Tylosin	Tylan	Elanco	Am	Oral	4 (chickens)	2	3	0.20	-
					(turkeys) 5		3	0.20	-
				Inj.	4 (chickens)	3	-	0.20	-
					(turkeys) 5		-	0.20	-
Virginiamycin	Stafac	Smith Kline	Gp	Oral	6	0	-	0.10	-

Key

Ab = antibacterial
Ac = anticoccidial
Af = antifungal
Ah = anthelminthic
Am = antimycoplasmal
Gp = growth promotant
Hs = histomonostat
Tr = tranquiliser

Withdrawal/Withholding Period: the recommended period of time that the drug must be withdrawn before processing or, after medication has finished, that birds must be withheld from processing or that eggs must be withheld from marketing, in order to avoid illegal residues, (i.e. exceeding maximum residue limits), in human food.

Egg withholding periods may commence 12 hours after medication starts (as eggs already in the shell gland are unlikely to become contaminated), but must continue throughout the period of medication and for the period of time indicated after medication has concluded.

- = not recommended for use in layers. Eggs containing any residues must not be marketed.
* = not permitted for use in food-producing animals. No residue is allowable.
** = not registered for use in poultry. The prescribing of these drugs should be limited. The veterinarian would be held responsible should residues be detected in meat or eggs.

APPENDIX II

FINAL DRAFT 14th May, 1986

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 independant 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 correctly 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.

END