



AgVetLink

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SPECIAL ISSUE FOR VETERINARIANS

Agricultural Compounds and Veterinary Medicines (ACVM) Act

The passing of the ACVM Act (Transitional Provisions) Regulations on 1 July 2002 means that the ACVM Act is now fully in force.

The ACVM Act is a much more modern piece of legislation than the Animal Remedies Act and provides a range of product management options – from exempting products from the requirement for registration through to registration and prohibition if needed. However, one of the impacts of the more ‘enabling’ legislation is that the ACVM environment becomes more complicated with a number of grey areas for veterinarians.

Recent compliance incidents and public consultation in such areas as prescription animal remedy (PAR) policy have highlighted the need to clarify this new environment for veterinarians. There seems to be significant misunderstanding of the legislation, the way it is implemented, and what it means for veterinarians.

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We hope this special issue of AgVetLink will help to answer your questions about a veterinarian’s responsibilities, clear up the misconceptions and give you a better understanding of how the ACVM Act affects you.

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Director, ACVM Group*

AgVetLink is provided free of charge. To be added to the mailing list, send your contact details to Gill Wilson (address below). AgVetLink is also available on the ACVM website (www.nzfsa.govt.nz/acvm).

AgVetLink is produced at least six times annually by the New Zealand Food Safety Authority’s Agricultural Compounds and Veterinary Medicines Group. The newsletter is of special relevance to those interested or involved in all aspects of agricultural compounds and veterinary medicines. It contains regular updates on implementation of legislation, notifications, new standards and policies, consultation, international agreements, and other information.

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Disclaimer: This publication is intended only as a guide. It is not a legal interpretation of the legislation discussed.

Product 'legality' under the ACVM Act

The purposes of the ACVM Act that are relevant to veterinarians are:

- 1 managing risks to animal welfare, biosecurity and trade;
- 2 avoiding violative residues in food;
- 3 providing sufficient information to consumers of veterinary medicines.

All veterinary medicines must be assessed to evaluate risks and determine what conditions must be imposed on them to ensure safe, appropriate use. They must be either registered or specifically exempted from registration. A veterinary medicine that is not registered or exempted from registration is illegal.

It is a veterinarian's responsibility to:

- use only products that are legal under the ACVM Act; and
- comply with the relevant conditions of registration.

How can I tell if a product is 'legal'?

Firstly, and most importantly, any registered product in New Zealand is required to have a registration statement and number on the label. At the present time this will indicate that a product is licensed under the Animal Remedies Act or registered under the ACVM Act.

In addition to this, there is a searchable list of all registered products on the ACVM part of the NZFSA website (<http://www.nzfsa.govt.nz/acvm/registers-lists/acvm-register/index.htm>). This list is updated every fortnight and it can be searched by active ingredient, by trade name (or part of the name), by registration number or by registrant.

How can I tell what conditions are placed on a product?

Under the ACVM Act products can be used **only** according to the conditions of registration. These conditions, which will be on the label of a registered product, will state if a veterinarian may use the product in a discretionary manner ('off-label') or if a particular use is prohibited.

Veterinarians frequently use *IVS* for product information, but we have found that *IVS* may not always be correct (see article, page 3) and should not be relied on at this stage.

There is a facility to view the approved label (or the approved label content) of all products that have been updated to ACVM registrations. The label content and the list of conditions provide the most up-to-date information on registered products.

What if a product doesn't have a registration number?

A veterinarian must be aware of the kinds of products that can be exempted from registration. Obviously, these products will not have a number.

When products are exempted from the need for registration, the exemption is for a group of products rather than for specific, recognisable trade names, so it is not as straightforward to check a particular product.

Exemption categories, definitions and conditions are in the Schedules of the Agricultural Compounds and Veterinary Medicines Regulations 2001, which is available on the website (<http://www.nzfsa.govt.nz/acvm/legislation/>). (These Schedules may change over time, so it is advisable to check periodically.)

The current categories of exempted products that are likely to be used in veterinary practice are:

- topical preparations (not able to be absorbed through the skin), used solely to prevent dermatological abnormalities;
- non-medicated (no pharmacological or therapeutic ingredients) anti-diarrhoea preparations;
- non-medicated oral laxatives and lubricants;
- cauterising preparations;
- urinary tract modifiers (acidifiers and alkalisers) that are oral preparations used solely for modification of

urinary pH;

- respiratory tract modifiers (expectorants and cough suppressants) that have a locally acting, superficial effect on the respiratory tract; and are given orally, applied to the nose or inhaled; and are used solely in companion animals to promote mucolysis, cough suppression (by alleviating only irritation) and relieve compromised airways and upper respiratory tract congestion;
- homeopathic oral and topical preparations that do not claim to prevent, control or cure a specific disease characterised by pain or distress in animals;
- herbal oral and topical preparations that do not claim to prevent, control or cure a specific disease characterised by pain or distress in animals;
- over-the-counter first aid preparations, including general disinfectants, antiseptics and sanitisers;
- preparations scheduled as pharmacy only, prescription or restricted medicines under the Medicines Act 1981, used as veterinary medicines;
- preparations compounded by a veterinarian and used by that veterinarian;
- oral nutritional compounds, defined as non-medicated substances ingested by animals as feed or nutrition preparations to achieve a nutritional benefit that make no therapeutic or pharmacological claim other than improving nutrition.

What if I am unsure about a product?

If you have a product without a registration number, the supplier of the product should be able to provide an ACVM 'class determination' confirming its status. This must be less than two years old to be valid. If you are unsure about a product, contact the ACVM Group (phone 04 463 2550) to find out if it is legal to use – in most cases there is no charge for this service.

Important notice to all prescribing veterinarians – IVS

As part of a compliance investigation, the ACVM Group has found that it seems that the publication *IVS* is not always up to date with changes in product registration conditions.

One situation that we were investigating involved a product that was not for use in food producing animals likely to be exported to the European Union. Use was limited to pigs and poultry, but there was a comment in *IVS* about use on calves that we consider is misleading.

In another ongoing compliance investigation, it was found that products requiring registration in New Zealand have entries in *IVS* without being registered for use in New Zealand. The same investigation has shown a range of pack sizes for some products not covered by the current registration.

This is of serious concern to the NZFSA because we are aware that many prescribing veterinarians rely heavily on this publication for advice. **We would urge all veterinarians to check the accuracy of information shown in *IVS* with the product packaging prior to prescribing.**

Veterinarians are advised to check the packaging of products to ensure that there is either an Animal Remedies licensing statement and number or an ACVM registration statement and number. Restrictions on the use of the product are also part of the approved label.

The ACVM website (<http://www.nzfsa.govt.nz/acvm>) has a searchable list of registered products and, as products are updated to ACVM

Act registrations, it will include copies of the approved labels or label content.

The ACVM Group understands that registrants provide the information to *IVS*. We have written to all registrants to advise of our concerns and to advise that any incorrect information supplied in this way is likely to constitute an offence under section 55 of the ACVM Act. It is an offence to knowingly sell any agricultural compound in contravention of the ACVM Act.

Veterinarians following such advice would also be in contravention of the ACVM Act as would farmers using the product. Where there are violative residues found in product both the prescribing veterinarian and the farmer concerned may have recourse to the registrant concerned.

Changes in PAR product advertising policy

The ACVM Group's policy on advertising (ref: Product Advertising Policy, 164 ACVM 10/02) states that the prescription only status on the product must be included in any advertisement. All other limitations on advertising in the policy are generic and refer to all agricultural compounds.

Several parties have advised the ACVM Group that this is inadequate guidance for a number of reasons. Some types of PAR products should not be advertised to the public at all. For those that may be advertised, the advertisement should always be consistent with the registrations.

Acting on this advice, the ACVM Group has amended the advertising policy. The New Zealand Veterinary Association code of practice *Promotion of Prescription Animal Remedies by Veterinarians and Industry* was taken into consideration when developing the following amendments.

Classes II and III PAR products must not be advertised in any way to the general public.

It is acceptable for registrants or third parties to advertise (either directly or via trade-specific publications such as special branch newsletters, the *New Zealand Veterinary Journal* or *Vetscript*) classes II and/or III PAR products to veterinarians who have the right to prescribe them. It is not acceptable to advertise such products to the general public or even to particular user groups.

Class I PAR products may be advertised under certain circumstances.

The advertisements must be technically correct and factual. Any product claims must be able to be substantiated (and consistent with the claims approved as part of the product's registration). There

must be no distortion through exaggeration, misleading statements or untrue emphasis. There must be no reference to websites that are not under the control of the registrant and that may present the product in a manner or make claims that are inconsistent with its registration.

Registrants may draw attention (including in television advertisements) to their products in a factual and technically correct manner. However, there must not be any inducement offered or any presentation of the product to the end user in a manner that causes undue influence on the prescribing veterinarian.

Prescription animal remedy (PAR classes I, II or III) products must not be displayed for general sale.

The revised product advertising policy can be viewed on the ACVM Group website.

The PAR system – what is happening?

Background

Unlike the Animal Remedies Act, the ACVM Act does not provide for a prescription animal remedy (PAR) system. Under the ACVM Act, the system of PAR classes is set up through conditions imposed when a product is registered. The PAR class reflects the level of risk associated with a product (see page 2).

Use of PARs has been reviewed and adjusted to ensure that management of risk and expectations of New Zealand's trading partners are met. For example, during the past few years, concerns about the risks of antibiotic resistance have resulted in a significant amount of work to deal with the problem. The ACVM Group has drawn heavily on this work to modify conditions of use for antibiotic products.

Consultation

Consultation with interested and affected parties is ongoing. The current proposed changes to PAR policy have been the subject of consultation with interested parties for nearly a year.

At present, the main consultation regards operational policy. Responses to date cover a wide range of views.

Submissions received on the latest draft of the policy are available on the website (<http://www.nzfsa.govt.nz/acvm/archive/draft/policies/index.htm>). The ACVM Group is working through the submissions to address concerns raised, and the Compliance Investigation Group (CIG) is carrying out 'slice of life' audits:

- to see whether those concerns are valid;
- to determine if the present level of PAR control is appropriate.

Concerns raised over long-term impacts of policy implementation are being considered carefully. The submissions have also shown us that further clarification and explanation of the policy are required.

What is happening?

The operational policy developments being considered at the moment are implementation issues. They don't imply changes to the ACVM Act or its Regulations.

The ACVM Group is not proposing major changes. We do not wish to impede legitimate veterinary activities such as clinical practice, integrated

intensive livestock management, research or specialised services. However, we require adequate management of PARs in all of these activities. Preliminary results of the 'slice of life' audits indicate a lack of knowledge of the ACVM Act and responsibilities associated with it. It is obvious that more education and communication are needed.

Prescribing and dispensing

We believe that current practices of prescribing and dispensing make good sense, and one development of the review of the PAR system has been the New Zealand Veterinary Association/Veterinary Council of New Zealand prescribing code of practice.

This code of practice has been approved and is in place, but we have been advised by specialist veterinarians that it does not adequately cover veterinary activities beyond general clinical practice.

Therefore, a prescribing standard with appropriate PAR management across a wider range of veterinary activity is being developed by the ACVM Group.

There will be no change in the definition of a veterinary consultation because it appears to cover the range of veterinary activities.

Trading

We are recommending a more robust system that takes into account the risks around 'trading', which includes distribution, dispensing, and/or sale of PARs.

A standard for trading in veterinary medicines is out for public consultation. The standard will require traders to be approved and registered. (This includes dispensing veterinarians.) There will be a low compliance cost associated with this registration for current traders. Implementation of the trading standard will be phased.

Who is responsible for the ACVM Act?

The ACVM Act and all other NZFSA administered legislation, including the Food Act, the Meat Act, the Animal Products Act, the Dairy Industry Act and the Winemakers Act, are now the responsibility of the Minister for Food Safety, Hon Annette King.

In some parts of the ACVM Act, such as section 21 (Decision on Application) and section 28 (Codes of Practice), there is reference to the powers of the Director-General (of MAF) to make decisions or approve. In each of these instances the powers and functions of the Director-General have been delegated to the ACVM Group Director and, in some cases, to members of the ACVM Group.

There will be a requirement for a new trader to be confirmed as a 'fit and proper' person, and there is likely to be a requirement for a code of practice – both areas of concern in the public submissions on the draft PAR policy.

Compliance

Where non-compliance by existing traders is identified, positive compliance checks will be introduced. There will be compliance audits for new entrants.

The system may also be subject to policy directives from the Minister (as per section 38 of the ACVM Act).

We will be working with the CIG and Border Services. We also hope to work closely with the Veterinary Council of New Zealand (see page 6). It is likely to take two years to formalise compliance programmes for traders based on 'slice of life' audits.

Non-compliance will be addressed in a number of ways from education to prosecution. The Act provides several mechanisms, e.g. 'hold' notices and prohibition on manufacture, sale or use of a product, when non-compliances are confirmed.

Related areas for vets

Discretionary use

The code of practice for discretionary or 'off-label' use of products is already in place and is unlikely to change significantly. Some education may be needed ('slice of life' audits will identify areas) to avoid offences under the Act.

There are limitations on discretionary use. These limits are shown in the conditions attached to a product registration. A veterinarian must be aware that:

- animal owners need to be advised that the use is 'off-label';
- standards/ codes of practice need to be followed;
- changes on conditions of use may not be shown in IVS;

- it is the responsibility of the veterinarian to manage the risks associated with discretionary use;
- a veterinarian must not use any product in a way that has been specifically prohibited (in accordance with label).

Conditions on products

Recent compliance incidents have highlighted the fact that there is some confusion surrounding 'conditions' (see page 2 for ways to check on product conditions). The ACVM Group is working on ways to make it easier to understand who is responsible for meeting these conditions.

Human medicines and compounded medicines

Information from 'slice of life' audits will be used to develop a standard for the use of human medicines. It may include reporting requirements.

A compounding standard is still to be developed. It will use information from the audits and Border Services. At this point, we know some non-compliances exist, and the standard must provide clarity of responsibilities.

It is likely to be 6-12 months before these are completed. Further clarification of when it is acceptable to use a human medicine and/or to compound a remedy is needed.

In the meantime, veterinarians must recognise that when they compound a preparation, or contract someone else to compound a preparation for them, they are in effect the 'manufacturer' and must comply with standards for Good Manufacturing Practice.

Operating instructions

Codes of practice have led to the development of 'operating instructions' as a tool for veterinarians to delegate functions. It has been accepted that in certain specialised areas, PARs can be used by people other than veterinarians

(e.g. police, grooms) if they are trained properly.

The final version of the operating instructions standard is almost in place.

Categories of PARs

We have developed a set of criteria for deciding if a product needs to be a PAR. This *may* result in some PAR products, e.g. some vaccines, moving out of the PAR category. Some over-the-counter products may move to PAR status as recently happened with injectable penicillins. It is likely to mean that there are no class III PAR products.

Prohibited substances

A list of prohibited substances is being prepared. It is likely to be done by Regulation and will take 6-12 months to finalise. It will be in the form of a list of ingredients that is available:

- on the website, and
- at the border for inspectors to check incoming product.

Communication

The ACVM Group will make the results of our audits and other investigations available on the website and through *AgVetLink*. These results will influence policy development, and it is important that you keep up with policy changes that affect you.

The ACVM Act interfaces with a range of other legislation:

- Animal Products Act
- Animal Welfare Act
- Biosecurity Act
- Dairy Industry Act
- Food Act
- Hazardous Substances and New Organisms Act
- Meat Act
- Medicines Act.

Slice of life audits and ‘proactive compliance’

In the past the level of compliance activity in the Animal Remedies Act area was not high, but this is changing markedly with the ACVM Act.

The ACVM Group has been working with the NZFSA Compliance and Investigation Group (CIG)* on a number of ‘slice of life’ audits.

Audits

Over the last few months CIG has undertaken an extensive audit looking at the supply chain for antibiotic products as a follow up to the changes made in the conditions on product registration. This audit concentrated on an ‘ingredient’ product that went through the animal feed chain into the intensive farming industries, and one ‘finished dose’ product. All facets of the process from importing and manufacturing, wholesaling, prescribing, dispensing and using were covered. Initial indications from the audit are that there is a real need for raising awareness of responsibilities under the ACVM Act.

A similar audit looking at the use of human medicines by veterinarians to

measure compliance with Appendix 1 of the *Code of Professional Conduct* is planned. (Appendix 1 is *The New Zealand Veterinary Association Code of Practice for the Discretionary Use of Human and Veterinary Medicines by Registered Veterinarians*, which has been approved under section 28 of the ACVM Act.)

A number of future audits are planned. These will cover the border and the importation of products, and compounding of veterinary medicines by veterinarians. When the standards for trading, prescribing and promoting PAR products are finalised, a series of audits will be undertaken (see below).

Purpose

These audits are not being taken primarily for the purpose of identifying and prosecuting non-compliances. They are intended as an overarching indicator or the effectiveness of regulation under the ACVM Act. We expect that we will find some areas where there is too much regulatory control and others where there needs to be more, or where we need to look for different mechanisms to be effective. In the main, they will

target the areas where we need to work harder on education.

Positive compliance

However, we will follow up on any serious non-compliances that are found. As a minimum response, we will re-visit people or premises where we identify non-compliances and audit them against the appropriate standards. We intend to have a positive compliance programme that will check for ongoing compliance over a period of time.

Costs

While the ‘slice of life’ activity is random and cost recovered from the compliance portions of product registration and annual fees, any positive compliance activity will be cost recovered directly from the parties being audited. The fees for this are regulated and are charged out at \$121.50 per hour (inclusive of GST) plus the cost of disbursements, such as travel.

PARs

Once we have finalised the standards covering PAR trading and dispensing, it is likely that we will undertake 4 to 6 ‘slice of life’ audits over the next 18 to 24 months in order to work out what level of ongoing verification programme is needed. We expect that the initial audits will show a higher level of non-compliance than will be the case later in the process, especially given the positive compliance activities planned.

The New Zealand Veterinary Association has indicated that it will be developing codes of practice in the area of dispensing. We expect these will assist greatly, and they are a welcomed addition to the already approved code of practice covering prescribing.

* CIG Group Director Geoff Allen has a team of auditors and investigators working with him to ensure compliance with NZFSA administered legislation and to investigate allegations of non-compliance.

Veterinary Council of New Zealand

The NZFSA and the ACVM Group have had initial discussions with the Veterinary Council of New Zealand (VCNZ) to discuss ways of working together on compliance related issues.

Veterinarians are a key group of risk managers for the ACVM Group and for NZFSA in a wider context. The mechanisms for ensuring compliance with the *Code of Professional Conduct* are critical to NZFSA processes and, as two regulatory bodies, it makes sense to align our activities in order to be as effective as possible.

The strategies that we hope to develop include a range of activities from education and raising awareness to discipline and prosecution in the most serious cases. It is probable that the parties will develop a Memorandum of Understanding to outline any agreement made, and that we will have a number of operational agreements covering day to day activities. At this stage we have agreed to meet on a regular basis to progress the issues in front of us.

Codes of practice becoming ACVM standards

Some parties have expressed confusion in regard to the nature and content of codes of practice approved under section 28 of the ACVM Act. Other parties have suggested that some of the codes of practice that have been developed by the ACVM Group and approved under section 28 do not have the commonly accepted characteristics of codes of practice.

For example, the *Code of Practice for Own Use of Compounds* is a statement of the regulatory expectations in regard to such use, but it does not provide any operational detail that would guide practice. This code is better described as a standard similar in content to schedule 4 of the ACVM Regulations that specifies the requirements for oral nutritional compounds. The New

Zealand Feed Manufacturers Association was able to use schedule 4 to develop a more traditional type code of practice that provides practical guidance to meet the requirements specifications in the schedule.

It is highly unlikely that the ACVM Group would have a need or be in a position to develop a true code of practice specifying operational requirements in any detail. The ACVM Group sees the soundness of the distinction between standards and codes of practice. Consequently, the Group will develop ACVM standards to state explicitly the regulatory expectations in regard to particular activities. The standards will be used when reviewing codes of practice submitted for approval under section 28 of the ACVM Act.

Standards will be put forward for public consultation as they are developed. There will be standards for other activities developed, but the following will be priority topics:

- use of prescription animal remedies by non-veterinarians;
- trading in prescription animal remedies; and
- distribution, sale and use of vertebrate toxic agents.

For the time being the *Code of Practice for Own Use of Compounds* will remain an approved code of practice to provide a basis for the first exemption in schedule 1 of the ACVM Regulations. However, it will be duplicated as an ACVM standard to be used to review any relevant code of practice proposed by third parties.

What is AVMAC?

The Agricultural Compounds and Veterinary Medicines Advisory Council was set up to give balanced and comprehensive advice to the Director of the ACVM Group. It is **not** a decision-making body but it does form a very important part of the consultation process, given the range of organisations that are represented and the perspectives that they bring to the table.

AVMAC meetings are held every quarter. ACVM standards, guidelines and operational policies (including changes) are all endorsed at AVMAC meetings as part of the development process. ACVM Group staff are not members of AVMAC but they often attend meetings in order to hear the full discussion by AVMAC of relevant papers and issues because this assists in refining operational policies prior to fuller consultation where this is taking place.

Initially the ACVM Group concentrated on aligning AVMAC membership to the primary purposes of the ACVM Act, namely managing risks to trade in primary produce, animal welfare, and agricultural security. More recently we have added a representative of a consumer organisation to bring a new perspective to the discussions at AVMAC meetings.

Adoption of VICH* guidelines

The following are final guidelines that were endorsed by AVMAC members at a recent meeting.

- GL28 Safety studies for veterinary drug residues in human food: Carcinogenicity studies. (October 2003)
- GL 31 Studies to evaluate the safety of residues of veterinary drugs in human food: Repeat dose (90 days). (October 2003)
- GL32 Studies to evaluate the safety of residues of veterinary drugs in human food: Developmental toxicity testing. (October 2003)
- GL33 Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to testing. (October 2003)

The NZFSA proposes to apply these Step 4 guidelines (as appropriate) in its standards and guidelines for the registration of veterinary medicines under the ACVM Act and Regulations, and in any related legislation. Details of the VICH process and the finalised guidelines can be found on the website (<http://www.nzfsa.govt.nz/policy-law/vich/guidelines>).

* VICH is a group of regulators and industry from USA, EU, Japan (members), Australia/New Zealand and Canada (observers) working to harmonise registration requirements for veterinary medicines.

Codex Committee on Residues of Veterinary Drugs in Foods

Bill Jolly (Veterinary Counsellor, Brussels) and John Reeve (Programme Manager, Toxicology and Residues, ACVM Group) were the New Zealand delegates at the 14th meeting of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), held in Washington DC from 3-7 March 2003.

Residues monitoring

At the 13th CCRVDF meeting, New Zealand had been accepted as the lead country in the development of a revised Codex guideline covering residue monitoring and control. The paper, developed with valuable contributions from other assisting countries, was

presented at the 14th meeting, and was accepted as the basis for proceeding with the development of the revised guideline.

The paper contains new paradigms for the Codex system, and seeks to introduce the concept of proper risk management rather than the currently accepted practice of taking precipitate action on any shipment that contains residues above the Codex limits.

This is particularly important for substances for which no Codex maximum residue limit (MRL) has been set, where the current situation assumes that any detectable residue is unacceptable whether there is any risk to human health or not.

The acceptance of the paper by the 14th Committee means that any opposition can change the guideline only if scientific evidence supports such a move.

Antimicrobial resistance

There was plenty of discussion on the draft code of practice to minimise and contain antimicrobial resistance that was presented to the Committee by the US. Many of the disagreements in the positions of the delegations arose because of the lack of a glossary, and the different perspectives of the delegations as to exactly what was being referred to when the term 'antimicrobial' was used. Most of the time the delegates were commenting only on antibiotics, and not anticoccidia and antifungal treatments, for example.

It was clear that a glossary had to be developed before useful comment could be made, and so the paper is to be recirculated as currently drafted, with a comment deadline of 30 June 2003. The drafting group will then prepare a revised version of the proposed draft code by the end of 2003 for circulation to all Codex countries, so that it and the subsequent comments can be considered at the 15th session of the Committee

(tentatively scheduled for September 2004).

Substances advanced

Substances with residue limits advanced to step 8 Codex MRLs were clenbuterol (when used for approved therapeutic purposes only) and deltamethrin. (Ivermectin in milk was also recommended for adoption as a full Codex MRL.) A limit for dihydrostreptomycin and streptomycin in sheep milk was advanced to step 5/8, and a limit for cefuroxime in cattle milk was advanced to step 5.

Recent events...

- The final report from the United Kingdom Competition Commission on Veterinary Medicines was released on 11 April 2003. The full report and the summary are available on their website (<http://www.competition-commission.org.uk/inquiries/archive.htm>).
- The draft review report from the Australian Pesticide and Veterinary Medicines Authority (APVMA) on Virginiamycin was released in March 2003. See their website (<http://www.apvma.gov.au/>) for details.
- A full summary of submissions received during consultation on the draft Policy for the Regulatory Control of Prescription Animal Remedies is available on the ACVM website (<http://www.nzfsa.govt.nz/acvm/archive/draft/policies/index.htm>).

Fibrosarcomas at injection sites of cats

The European Medicines Evaluation Agency (EMA) Committee for Veterinary Medicinal Products has issued an advisory notice on the development of fibrosarcomas in cats following subcutaneous injection.

This states it is not possible to make firm conclusions on the risk associated with any product or type of product that causes inflammation after subcutaneous injection in cats.

However, it advises that there may be an increased risk of fibrosarcoma at that site and that, if more specific information becomes available, this has the potential to impact on regulatory information requirements and risk assessments.

A copy of this report may be viewed on the EMA website (www.emea.eu.int/pdfs/vet/press/pos/020503en.pdf).