Use of Restricted Veterinary Medicines for Induction in the New Zealand Dairy Industry: Audit Summary

June 2013

1. Introduction

At the request of the ACVM Manager (Programmes & Appraisals), MPI’s Systems Audit Team (SAT) conducted a Sector Analysis* audit of veterinarians’ use of veterinary medicines for the induction of dairy cow parturition in respect to:

1. compliance with ACVM restricted veterinary medicines (RVMs) conditions of registration; and

2. conformance to the New Zealand Veterinary Council’s Statement on the Induction of Dairy Cattle (6 September 2011) and the New Zealand Dairy Industry’s Operational Guidelines on Induction of Calving (1 June 2010).

DRIVERS

Principal drivers of this of this audit were the ACVM Group’s need:

3. to assess whether or not stakeholders are operating in compliance with the conditions of registration and “in accordance” with the Guideline and the Statement; and

4. to ensure that the current use conditions of registration of induction RVMs meet the purposes of the ACVM Act.

* A Sector Analysis is an audit in a defined area of stakeholder activity not previously assessed by the SAT. It is an initial scoping exercise to obtain an overview and to provide valuable feedback to MPI on stakeholder activities. Sector Analysis audits might lead to further systems audits in the sector or to recommendations for MPI policy/standards or legislation changes.
2. Scope

The scope of the audit included:

- an assessment of the registration, importation, distribution, authorisation/prescription and use of veterinary medicines for induction of parturition in the New Zealand dairy industry
- visits, interviews and examination of records and equipment at all points involved in the use of veterinary medicines for induction of parturition in the New Zealand dairy industry
- an allowance for recommendations to be made for improvements in MPI policies, standards, plans and legislation.

The audit included (but was not limited to) consideration of the following legislation, standards, guidelines and statements:

- Animal Welfare Act 1999
- Animal Products Act 1999
- Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997
- Veterinary Council of New Zealand (VCNZ): *Veterinarian’s Code of Professional Conduct*
- Dairy Industry: *Operational Guidelines: Induction of Calving* (1 June 2010)

3. Background

**INDUCTION IN THE NEW ZEALAND DAIRY INDUSTRY**

The term ‘induction’ in this audit report means the routine and non-therapeutic use of registered RVMs between the 12th and 8th weeks prior to anticipated natural full 9 month term gestation for the purposes of inducing parturition in dairy cows.

Induction drugs have been used in the New Zealand dairy industry since the 1970s for the purpose of shortening gestation length to allow late-conceiving cows to be retained within seasonal pasture systems.

To cause induction it is necessary to inject a dairy cow with a long-acting (LA) corticosteroid either alone or in conjunction with subsequent use of either a repeat LA corticosteroid or a short-acting (SA) corticosteroid or prostaglandin. It is not pharmacologically possible to ‘induce’ dairy cows without the use of an initial LA corticosteroid.

It is important to note that LA corticosteroids are used by veterinarians for therapeutic reasons other than routine inductions, such as existing therapeutic indications considered as non-routine in cattle and other species, e.g. arthritis, acute laminitis, shock, stress, primary ketosis.

In addition, many dairy farms in New Zealand do not undertake any inductions. Many farmers and their veterinarians are known to be ethically opposed to the use of routine inductions.

**PRODUCTS USED FOR INDUCTION**

At the time of the audit two trade name product LA corticosteroids were registered under the ACVM Act (section 23) as RVMs subject to ‘conditions of registration’ (see appendix) for the induction of dairy cows:
• Trimedexil (active 5mg dexamethasone trimethyl acetate)  
  Registrant - Ethical Agents
• Dexavet-AP (active 5mg dexamethasone trimethyl acetate)  
  Registrant - Bayer Animal Health New Zealand.

In addition, several SA corticosteroids and prostaglandin RVMs can potentially be used as a follow up to Trime-dexil or Dexavet-AP to induce dairy cows.

Because it is not possible to induce dairy cows without the initial use of either Trime-dexil or Dexavet-AP, this audit focussed on the distribution and use of these two RVMs. The audit did not consider the 5 SA corticosteroids or 14 prostaglandin products currently registered in New Zealand.

DISTRIBUTION AND USE OF RVMS FOR INDUCTION IN NEW ZEALAND

Sales for 2011 and 2012

At the outset of the audit the key registrants and distributors of Trime-dexil and Dexavet-AP were visited and interviewed. The registrants reported that they sold, either to registered veterinarians or to ACVM registered RVM sellers operating under an approved operating plan, the following quantities:

1. Trime-dexil approximate doses at 5ml per dose (note the approved label provides for a dose of either 4ml or 5ml per cow treatment):
   • 133810 doses sold in 2011
   • 69710 doses sold in 2012.
   This shows an approximate 48% drop in sales between 2011 and 2012.

2. Dexavet-AP approximate doses at 5ml per dose:
   • 124000 doses sold in 2011
   • 106000 doses sold in 2012.
   This shows an approximate 15% drop in sales between 2011 and 2012.

Interpretation of sales data

It was reported that in 2011 the registrant and manufacturer of Dexavet-AP had a batch failure which resulted in significant shortage of that product. In response to the market demands, the registrant of Trime-dexil immediately imported and sold increased quantities to supply the shortfall. This comparatively high volume of sales of Trime-dexil in 2011 accounts for the reduction in sales of approximately 50% between 2011 and 2012 when production shortages did not limit the availability of Dexavet-AP.

Taking the above into consideration, there is an overall reduction in sales of LA corticosteroids between 2011 (257810 approximate doses) and 2012 (175710 approximate doses). This represents about a 32% reduction in doses sold between 2011 and 2012.

These sales figures give some idea of the trends of usage of the LA corticosteroids on a per dose and animal treatment basis per annum. However, any interpretation of these figures should also consider the following variables:

• Significant quantities of Trime-dexil and/or Dexavet-AP may be unused in a season and held by veterinary clinics for the next year.
The dose used by auditees was the higher label quantity of 5ml per injection. Two interviewees reported that they used 6 mls per injection routinely, and one interviewee reported that, subsequent to one farmer’s insistence, he used a dose of 10ml per injection.

A significant number of interviewees used Trimedexil or Dexavet-AP for a follow up injection on treated cows some 10-14 days after the first injection. One interviewee reported that occasionally he had to use three injections (3x5 =15mls per cow). Most interviewees only used a SA corticosteroid or a prostaglandin if the treated cow had a very well developed udder which was in lactation “close to dropping the calf” when examined 10-14 days after the initial first injection.

Regional differences

Regional trends show some areas and veterinary clinics known to be actively involved in dairy practice appear to purchase minor amounts of either Trimedexil or Dexavet-AP. For example, comparatively minor amounts of these RVMs are purchased by veterinarians in the Northland and Manawatu regions, which have significant numbers of dairy farms.

In contrast, there is evidence of the purchase of significant quantities of induction RVMs in areas where there has been a recent increase in conversion of land from sheep/beef or forestry into dairy farms. These areas include South Waikato/Central Plateau, Mid-Canterbury and Southland. These latter regions were visited as part of this audit. It appears that inductions are used there more frequently as transitional management tools to align the reproduction and lactation of newly assembled dairy herds.

GUIDANCE FOR INDUCTION

Between 2005 and May 2010 the ACVM Group listed under the ACVM Act a legally binding Code of Practice (COP) for the Induction of Dairy Cows. In May 2010 this COP expired and the ACVM Group’s direct involvement in this COP ceased.

With the expiry of the COP the VCNZ has maintained (since June 2010) the Dairy Industry’s Operational Guideline - Induction of Calving (the Guideline) and since 6 September 2011 VCNZ has published a Statement on the Induction of Dairy Cattle (the Statement).

The Guideline and the Statement are not official MPI publications. However, the documents are included as audit standards and guidelines upon which auditees have been assessed. As these documents are not official MPI standards/guidelines auditees have firstly been assessed as either operating “in accordance with” or “not in accordance with”. And secondly, audit non-compliances have not been raised against auditees by the auditor referencing either the Guideline or the Statement.

4. Audit Summary

Two registrants, two wholesale RVM sellers, 10 veterinarians and their practices, and 14 farms were visited as part of this audit. Veterinary practices seen to be purchasing comparatively significant quantities of RVMs used for inductions were selected and visited in both the North and South Islands.

At each veterinary audit location one or two farms were also visited. Farmers were interviewed and equipment/records were examined in the presence of the relevant veterinarian and dairy company personnel. Although farmers were not principally identified as auditees, some audit findings relating to records being kept on farms (see below) have market access implications.
CONDITIONS OF REGISTRATION

The audit showed that the two key LA corticosteroids (Trimedexil and Dexavet-AP) necessary for the induction of dairy cow parturition are being authorised and used by veterinarians in full compliance with their current ACVM conditions of registration.

STATEMENT AND GUIDELINE

While the audit was conducted principally under the powers of the ACVM Act and the Animal Products Act, the Statement and the Guideline are not official MPI procedures under immediate current Ministry jurisdiction. For this reason, where auditees were assessed to be “not operating in accordance” with the Statement or Guideline, recommendations/strong recommendations rather than non-compliances were signalled to auditees.

The audit showed that the veterinarians audited and their practices were deemed to be operating in full accordance with the Statement and Guideline at only three locations.

At seven out of the ten locations audited veterinarians and their practices were operating in accordance with substantial parts of the Statement and the Guideline. However, there is a failure on the part of some veterinarians at these seven locations to operate in full accord with the requirement to induce no more than 4% of some individual dairy herds without prior approval and exemption being sought from key stakeholders. Audit recommendations to veterinarians to operate in accord were made in these cases.

In two cases seen during the audit, up to 19 and 22% respectively of herds of cows were induced without any prior approval or exemption being sought by veterinarians. Strong audit recommendations (see below) were made to the veterinarians involved in these two cases to consider the need to operate in accord with the current and any other future requirements regarding percentages of dairy cows being induced per farm or herd.

In the auditor’s opinion such failures to operate in accord with the Statement or Guideline have the potential to both undermine MPI market access assurances and also to compromise the ability of MPI to ensure that the purposes of the ACVM Act are being met in the arenas of animal welfare and residues control.

REPORTING INDUCTION ACTIVITY

Not all of the veterinary practices visited reported their induction activities to the Dairy NZ Liaison scientist using the standard traceable and officially provided triplicate reporting forms DCANZ, DairyNZ NZVA Record of Routine Induction of Dairy Cows – Operational Plan (the Triplicate form).

Seven practices out of the ten practices visited used the Triplicate form.

Of the other three practices, two used their own tailored form and one used a spreadsheet to anonymise the farm identity. These three practices’ submissions to DairyNZ were devoid of official Triplicate numbering traceability. Only three of the seven practices using the Triplicate form were assessed by the auditor as always providing fully completed Triplicate forms to DairyNZ.

Some key audit observations from this comparison were made:

- Because it is not mandatory for veterinarians to record and submit data on the numbered Triplicate form, accurate audit assessment of inductions by veterinarians is compromised.
- At one clinic, examination of a numbered Triplicate form showed 201 cows in a herd of 3018 had been induced (6.6% of the Herd) but DairyNZ did not have a record of this.
- At another clinic there were incomplete records supplied to DairyNZ on the Triplicate forms, leading to the inability to calculate the percentages of cows being induced or the number of farms on which inductions had occurred.
In the auditor’s opinion the above observations compromise the overall ability to be confident that the inductions performance and reporting process is fully accurate and traceable. An audit recommendation (see below) is made to veterinarians to improve their induction record keeping submissions to DairyNZ.

RECORDKEEPING ON FARMS

Many farmers visited did not adequately record the identity, induction treatments, dates of gestation and the appropriate withholding period compliance record to show that milk/colostrum was supplied for human consumption in a compliant manner. However, the auditor observed excellent records and full compliance to these matters on two farms. An audit recommendation (see below) was made to dairy RMP personnel, veterinarians and farmers regarding the maintenance and assessment of records of inductions on farms.

AUDITOR’S CONCLUSIONS

To provide a balanced view of induction, the auditor noted that:

- Some veterinarians, practices and farmers visited during this audit were conducting inductions in a manner of full compliance and accord with current requirements.
- Between the 2011 and 2012 spring induction seasons there was approximately a 32% reduction in the volume sale of LA corticosteroids (without which dairy cow inductions cannot occur) sold by registrants to veterinarians in New Zealand.
- Many veterinarians and farmers in New Zealand either do not undertake any inductions or have management procedures in place so less than 4% of cows/herd in herds under their care are induced.

However, the auditor concluded that:

- The failure of some veterinarians to operate in full accord with the Statement and the Guideline potentially poses market access risks and may compromise the purposes of the ACVM Act.
- MPI should now consider the needs for either altered conditions of registration or ACVM - approved Induction Operating Plans and ongoing systems audits of inductions. A recommendation (see below) is made to MPI regarding these matters.

5. Recommendations

Recommendations are non-binding and do not affect subsequent audits. Their implementation may provide efficiencies for both the auditee and MPI.

A recommendation to change existing specifications does not excuse the absolute requirement to conform to the existing specifications. Changes to specifications that may result from these recommendations will be promulgated officially.

STRONG RECOMMENDATION TO TWO VETERINARY PRINCIPALS

It is a strong recommendation of this audit that where herds are to be induced at a rate greater than 4% (or any other future % defined by the Veterinary Council of New Zealand statements or any other legislation) veterinarians at both of these practices must ensure that any stated exemption and approval process or any other relevant requirements under any other legislation are consistently followed.

This recommendation is made on the basis of the listed cases where the percentage of herd induced is above 4% and up to approximately 22% but there is no current audit evidence of
exemption being sought by responsible veterinarians and corresponding approval being given by
the relevant dairy risk management programme (RMP) operator or DairyNZ in 2012.

TO VETERINARIANS: ENSURING THAT DATA RECORDS AND SUBMISSIONS ON INDUCTIONS ARE COMPLETE

It is a recommendation of this audit that veterinarians involved in the induction of dairy cows
ensure that all necessary information relating to the induction of dairy cows is complete and
provided to DairyNZ and other key stakeholders. This necessary information includes current and
ongoing Statement and Guideline requirements, and it may include any possible future legal
recording and reporting requirements.

TO VETERINARIANS, FARMERS AND DAIRY COMPANY RMP PERSONNEL

It is a recommendation that veterinarians, farmers and dairy company RMP personnel take steps
to ensure that the induction RVMs given to individual cows on farms are completed in accordance
with the Statement, the Guideline and farm dairy RMP requirements.

Specifically:

- Veterinarians must ensure that permanent records are provided to dairy farmers, clearly
  identifying the ear tag numbers of individually treated cows, the trade names of induction
  RVMs and the quantities and dates of individual treatments including their withholding period
  (WHP).

- Farmers must ensure that all necessary information provided by veterinarians and the date of
  parturition and that the date that milk/colostrum is supplied for human consumption (return
to vat/silo dates) meet the relevant WHP.

- Dairy company RMP personnel including contract farm dairy assessors must ensure that the
  2013 farm diaries or record templates for on farm recording are updated to permit clear and
  consistent records to be kept by farmers of Induction RVM quantities for each cow and dates
  of individual treatments including their WHP, parturition dates and the date that cow’s
  milk/colostrum is supplied for human consumption (return to vat/silo dates) in order to meet
  the relevant WHP.

TO THE MANAGER ACVM PROGRAMMES & APPRAISALS AND THE MANAGER SYSTEMS ASSURANCE

Consideration to ensure that the purposes of the ACVM Act are met in the authorisation and use of
RVMs for the purpose of induction in dairy cows

It is a recommendation of this audit that the ACVM Group and the Market Assurance Directorate
now consider how to ensure that the purposes of the ACVM Act and market access requirements
are being met where induction RVMs are being authorised and used in the New Zealand dairy
industry. The possible actions may include either:

- altering the conditions of registration of TNP LA corticosteroids under section 23 of the ACVM
  Act, and/or

- considering that where RVMs are authorised and used for the purposes of induction of dairy
  cattle an approved operating plan might be instituted under section 28 of the ACVM Act, and

- considering the need for ongoing systems audits relating to inductions of dairy herds.
Appendix: Conditions of Registration

Both Trimexil and Dexavet-AP are registered pursuant to the conditions of registration 60, 61, 62, 63, 64, 65, 66, 67, 69, 70, 71, 72 and 73.

For the purposes of this audit, conditions 69, 70, 71, 72, and 73 are particularly relevant as they are in general terms ‘use conditions’ incumbent upon veterinarians and farmers.

Condition 69

"The product must be sold only by either:

(a) a registered veterinarian holding a current practising certificate issued under the Veterinarians Act 2005 in the course of his or her own veterinary practice, or

(b) a person specified to sell the product or similar products in and acting in accordance with a relevant operating plan approved under section 28”.

All sales data from registrants reviewed during this audit and all interviews with auditees indicated that Condition 69 is being complied with.

Condition 70

"For the purposes of this condition, 'veterinary authorisation' means that a registered veterinarian with a current practising certificate issued under the Veterinarians Act 2005 has issued a valid authorisation for its purchase and use.

Any advertisement of this product must contain a statement that the product is available for purchase and use only under and in compliance with a veterinary authorisation."

All interviews with auditees indicated that Condition 70 is being complied with.

Condition 71

“"The product must be sold only to:

(a) a person specified in an approved operating plan, or

(b) any person in possession of a valid authorisation either:

(i) issued by a registered veterinarian holding a current practising certificate issued under the Veterinarians Act 2005, or

(ii) issued under and in accordance with an approved operating plan.”

Interviews with veterinarians and examination of sales data from ACVM approved RVM sellers shows that condition 71 is being complied with.

Condition 72

“"The product must be used only under the authority of and in compliance with a valid authorisation issued either:

(a) by a registered veterinarian holding a current practising certificate issued under the Veterinarians Act 2005, or

(b) under and in accordance with an approved operating plan.”

Valid authorisations were viewed at all locations where Trimexil and Dexavet-AP were seen to have been used.
Condition 73

“All veterinarians who are recognised under section 62 for the purpose of issuing a valid authorisation for the purchase and/or use of the product must comply with any performance and technical standards issued by the Director-General, and for the time being in place, under section 62(5) of the Act, for authorising this type of product.”

The ACVM Performance and Technical Standard No1 (December 2009): Veterinarians Recognised (under s62 ACVM Act) to Issue a Valid Authorisation for Purchase and Use of Restricted Veterinary Medicines Requiring Veterinary Authorisation applies to Condition 73.

All veterinarians interviewed complied with Condition 73 and Standard No1.

In summary, all of the conditions of registration for Trimedexil and Dexavet-AP were fully complied with by all auditees at all locations visited.