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Manatū Ahu Matua

Guidance Document

Operating Plans for Restricted Veterinary Medicine Sellers

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Title

Guidance Document: Operating Plans for Restricted Veterinary Medicine Sellers

About this document

This document specifies the information that needs to be in an operating plan to sell restricted veterinary medicines (RVMs). Such a plan must be approved by MPI under section 28 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 so that the seller can meet the condition of registration relating to sale of RVMs.

Document history

This document replaces *ACVM Expectations of Restricted Veterinary Medicine (RVM) Sellers with an Approved Operating Plan*.

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1 Purpose

(1) This document specifies the information that needs to be in an operating plan to sell restricted veterinary medicines (RVMs). Such a plan must be approved by MPI under section 28 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 so that the seller can meet the condition of registration relating to sale of RVMs.

2 Background

(1) A condition of registration imposed on each RVM is that the product must be sold by either:

a) a veterinarian recognised under section 44G to authorise its purchase and use on animals under that veterinarian's care (group 1); or
b) a person specified to sell the product or similar products in, and acting in accordance with, a relevant operating plan approved by MPI under section 28 of the ACVM Act (group 2).

(2) Group 1 includes veterinarians who authorise and sell RVMs to their clients and do not routinely sell RVMs under authorisations issued by third parties (i.e. veterinarians from outside their clinical practice or persons other than veterinarians specified in an approved operating plan governing the use of a particular RVM).

(3) Group 2 includes any other person (veterinarian or non-veterinarian) who sells RVMs to:

a) another approved RVM seller; or
b) veterinarians in Group 1; or
c) a person holding a valid authorisation to purchase and use the RVMs specified (this activity is referred to in this document as operating a veterinary pharmacy).

(4) An RVM seller in Group 2 must submit an operating plan to MPI for approval. For the Director-General to be satisfied that the operating plan should be approved, it needs to provide certain information about activities, processes, and responsibilities.

(5) Veterinary authorisations specify the RVM, the authorising veterinarian's instructions, and the individual or entity who is authorised to purchase and use the RVM. They must not specify the seller.

3 Definitions

(1) In this document, unless the context otherwise requires:

authorisation means a written direction issued by an authorising person to allow a specified person or entity to purchase and use an RVM

authorising person means the person who has the authority to issue an authorisation to purchase and use an RVM because that person is a veterinarian recognised under section 44G or is specified as the authorising person in an approved operating plan for that RVM

breaking-down means to repack or dissemble product by removing proprietary secondary and/or tertiary packaging keeping primary packaging intact

broaching means opening the primary packaging to expose the product and includes inserting a needle into a sealed bottle.

critical control point means a point in quality management procedures that should be monitored to ensure specified outcomes are met

dispensing means preparing a veterinary medicine to transfer possession to the owner or caretaker of the animal(s) to be treated, and includes transferring one or more doses of a veterinary medicine from its approved commercial primary packaging into adequate and appropriately labelled alternative packaging

end user means the person or entity who is the owner or caretaker of the animal(s) to be treated

label means any written, pictorial or other descriptive material (including cartons, vials, leaflets), affixed to or contained in or on the packaging, which gives information about the veterinary medicine that is to be marketed or sold

label content means the information that is intended to be included with the product when it is supplied for sale. It is approved as part of the application for registration and must be complied with when generating the actual label, packaging and information sheets

packaging means, any material employed in the packing of a medicinal product, excluding any outer tertiary packaging used for transport or shipment. Packaging materials are referred to as either primary or secondary according to whether or not they are intended to be in direct contact with the product

primary packaging means packaging that is in direct contact with the finished product e.g. HDPE drum with lid, blister pack, glass or plastic vial/bottle with stopper or plastic/foil sachets

registrant means, in relation to a registered trade name product, the person or entity to whom the registration of that product has been issued

RVM seller means the person or entity with an approved operating plan who sells, and, in particular, who supplies the RVM to another RVM seller or an end user specified in an authorisation. The RVM seller is responsible for complying with the approved operating plan

secondary packaging means packaging that is not in direct contact with the finished product and is additional to the primary packaging. It is often used for the protection of the primary packaging or collation of individual units for sale or transport, e.g. cardboard carton containing blister packs or vials, and includes leaflets

veterinary pharmacy means a business with the intent to sell RVMs to end users holding an authorisation to purchase and use RVMs.

(2) Any words or expressions used but not defined in this document that are defined in the ACVM Act have the meaning given to them in the Act.

4 MPI approved operating plan for RVM sellers

(1) Registrants, wholesalers, retailers, veterinary pharmacies, and any other entity wishing to sell RVMs must have an MPI approved operating plan. This includes companies that provide warehousing and supply of RVMs under contract for third parties and companies that only export RVMs.

(2) Veterinarians who routinely sell RVMs outside the course of their own veterinary service (i.e. operate a veterinary pharmacy filling authorisations from veterinarians outside of their own clinical practice on a regular, non-urgent basis) must also have an MPI approved operating plan.

(3) Recognised veterinarians selling RVMs for use on animals under their care (as part of the veterinary service they provide) do not have to have an approved operating plan, but they must comply with the ACVM Notice: Requirements for Authorising Veterinarians.

(4) If unsure whether you require an approved operating plan, contact MPI for advice (approvals@mpi.govt.nz).

5 Information required in the operating plan

(1) The following information relating to activities, processes, and responsibilities needs to be outlined and provided in an RVM seller's operating plan.

(2) MPI has created a template to assist RVM sellers to organise and document their operating plans. Using the template makes it easier to document a plan and also facilitates MPI's appraisal of the plan, saving time and minimising costs. Sellers who organise and document their operating plan differently should still fill out the template, referencing the parts of their plan in the appropriate boxes. This will speed up the review and appraisal process.

(3) Sellers need to provide a description of their plan and all applicable procedures. They do not have to include associated supplementary operating procedures in full but they may reference those procedures.

5.1 Personnel, inwards goods, premises and storage

5.1.1 Personnel

(1) Only the person responsible for the administration of the operating plan (who is also the point of contact with MPI) needs to be specifically named in the plan.

(2) Personnel with other responsibilities can be referenced in the plan by role. For example, the person who is responsible for quality control checks on inwards goods could be designated in the plan as 'Inwards Goods Manager' rather than by name so that the operating plan does not have to be updated every time there is a change of staff. However, these people should be listed by name in operational records.

(3) Personnel/role specified in the operating plan to carry out specific activities and procedures related to the supply of RVMs should be trained to carry out those activities in compliance with the plan.

(4) Records of personnel training and performance should be kept as evidence that activities are carried out only by trained personnel.

5.1.2 Inwards goods

(1) Inwards goods should be checked to ensure the consignment corresponds to the order and delivery note.

(2) Incoming product should be kept separate from product already in stock until the relevant quality checks have been made.

(3) For each consignment, containers should be checked for integrity of the packaging and seal, and maintenance of storage conditions.

(4) Damaged containers or any problem that might adversely affect product quality or registration conditions (including temperature conditions) should be investigated.

(5) Rejected products should be clearly marked and stored separately. Rejected products should be returned to suppliers or, if appropriate, securely destroyed.

(6) Products returned from the buyer should be destroyed securely unless there is no doubt that the quality and registration conditions (including temperature conditions) have been maintained.

(7) Records of inwards goods and checks conducted should be kept.

5.1.3 Premises and storage

(1) The premises should be maintained to suit the operations carried out.

(2) The facility, layout, design and relevant documentation and procedures should:

a) ensure product is securely controlled; and
b) minimise the risk of errors; and
c) permit effective cleaning; and
d) ensure correct product storage conditions and integrity are maintained.

(3) If supplying to end users in accordance with a valid authorisation requires dispensing and/or breaking-down of RVM products to limit the quantity to the amount specified in the authorisation, the operations, equipment and facility should be appropriate to avoid contamination or mix-up of product, packaging, and labelling materials.

(4) Storage conditions should be adequate and of sufficient capacity and capability to maintain product quality, prevent damage (e.g. from temperature excursions, leaks, pests), and allow orderly storage of products (and packaging/labelling materials) to permit product and batch segregation and stock rotation.

(5) All RVMs must be kept securely out of reach of the public.

(6) Storage areas should be clean, dry, well maintained and free from pests.

(7) Cleaning procedures should be appropriate for the facility and records of cleaning maintained, if appropriate.

(8) If specific storage conditions are required (i.e. temperature, humidity), the temperature conditions and storage should be monitored and records retained.

(9) Expired, damaged, or rejected product should be separated from released stock and disposed of securely.

(10) If a third party is contracted to provide a warehouse or storage service, the control and storage of product at the third party facility should be included in your operating plan at the relevant steps, unless that third party has its own MPI approved operating plan for supplying RVMs.

(11) The process for secure transport between facilities should be included in the plan.

5.2 Verifying the purchaser

5.2.1 Selling/supplying to wholesaler/distributor/retailer or veterinary pharmacy

(1) Before selling/supplying RVMs, it must be confirmed that the purchaser has an MPI approved operating plan to sell RVMs. This can be checked on the MPI website list of RVM sellers with approved plans.

(2) Once the status of the purchaser has been confirmed, it does not have to be confirmed prior to each sale/supply. However, if in doubt, the status should be reconfirmed. A client list of regular clients should be checked at least annually to confirm the continued status.

5.2.2 Selling/supplying to veterinarians

(1) Before selling/supplying RVMs, it must be confirmed that:

a) the authorising veterinarian is a registered practising veterinarian who has no restrictions associated with the authorisation of RVMs; or
b) the veterinary practice has registered veterinarians employed if only a clinic name is on the order.

This can be checked on the Veterinary Council of New Zealand's website online register of practising veterinarians and/or online register of veterinary practices and organisations employing registered veterinarians.

(2) Once the status of the veterinarian has been confirmed, it does not have to be confirmed prior to each sale/supply. However, if in doubt, the status should be reconfirmed. A client list of regular clients should be checked at least annually to confirm the continued status.

5.2.3 Selling/supplying to veterinarians ordering on behalf of veterinary pharmacy or veterinary wholesaler

(1) If the veterinarian is ordering on behalf of a veterinary pharmacy or a veterinary wholesaler, it must be confirmed that the veterinarian/veterinary practice has an MPI approved operating plan to sell RVMs. This can be checked on the MPI website list of RVM sellers with approved plans.

(2) Once the status of the purchaser has been confirmed, it does not have to be confirmed prior to each sale/supply. However, if in doubt, the status should be reconfirmed. A client list of regular clients should be checked at least annually to confirm the continued status.

5.2.4 Selling/supplying to end user with an authorisation

(1) The request/order will generally be in the form of a veterinary authorisation (i.e. issued by a registered veterinarian). Alternatively, the conditions of registration may allow use of the RVM in accordance with an approved operating plan governing that use. That operating plan will detail who can authorise, purchase and use the RVM.

(2) The hard copy of the authorisation (or a secure electronic version) should be provided. If an authorisation is issued electronically, it must be issued directly from the authorising person to you as the seller, unless the transfer is provided for in the management system and agreed to by the authorising person as secure and not reusable. This should be confirmed with the authorising person.

(3) If receipt of the authorisation is by email or phone due to urgency, the hard copy (or secure electronic version) should be requested and received before dispatch. If this is not practical and there is confidence that the authorisation is valid, the order may be dispatched. However, the hard copy should be checked as soon as practical (no longer than 7 days) after the event to confirm that it was valid. Hard copies (or electronic copies of the hard copies) must be retained for your records.

(4) If the validity of the authorisation is in doubt, the authorising veterinarian should be contacted.

(5) The order must be prepared as instructed in the authorisation. Only the authorising veterinarian may make amendments or change an authorisation. Any changes require revoking the original and replacing with a new authorisation.

(6) If the authorisation specifies a quantity less than the smallest registered pack size, the authorisation can be filled only if dispensing and/or breaking-down (as applicable) are approved in the scope of your activity and detailed in your procedures.

(7) The authorisation will specify if it can be used for repeat supply/filling. If in doubt clarify the authorisation with the authorising person and handle the order accordingly. You must have a system in place to manage repeats (for authorisations that specify repeat supply is required). If the authorisation does not specify repeat supply, the complete authorisation must be filled at the time the authorisation is presented or you must contact the authorising veterinarian to discuss alternative options.

(8) If there is a computerised system that provides for the direct input of authorisations from the authorising veterinarian, the computerised system must specify the security and verification of the authorisations as generated by the appropriate authorising party (e.g. secure entry code).

(9) Operating an on-line veterinary pharmacy is not prohibited, but the operating plan must explain how on-line transactions are carried out and show how the level of control is equivalent. If this cannot be shown to be equivalent, an operating plan for an on-line veterinary pharmacy will not be approved.

5.3 Preparing an order, packaging and labelling

5.3.1 Supplying to wholesalers/distributors/retailers/veterinary pharmacies and veterinarians

(1) If selling/supplying RVMs to veterinarians or parties with their own MPI approved operating plan to sell RVMs the pack size, packaging and labelling of an RVM must comply with the registered pack size, and packaging and labelling for the product and must not be altered. Dispensing or breaking-down is not appropriate.

(2) There must be a contractual agreement with any third party used to store and/or deliver RVMs. That party must be subject to the seller's operating plan or have an MPI approved operating plan themselves because they perform the activity for more than one seller.

5.3.2 Supplying to end user with a valid authorisation

(1) If supplying an RVM in accordance with a valid authorisation and it is not being given directly to the end user (i.e. transported via a third party storage facility or veterinary practice for collection by the end user), the seller is responsible for ensuring the product information (e.g. label) and authorisation instructions are met; and must comply with the requirements listed in clause 5.2.4, 5.3 and 5.4.

(2) There must be a contractual agreement with any third party used to store, label and/or deliver RVMs to the end user. That party must be subject to the seller's operating plan or have an MPI approved operating plan themselves if they perform the activity for more than one seller.

(3) All orders of RVMs supplied under, and in accordance with, an authorisation must be supplied to the person or entity specified in the authorisation with the following information:

a) name and contact details identifying the seller/supplier;
b) name and contact details of the authorising person;
c) name of the RVM and quantity specified in the authorisation; and
d) any instructions specified in the authorisation.

(4) RVM seller labelling must not mask essential proprietary product information on the label (e.g. precautions, contraindications, safety, and handling information).

(5) If an authorisation specifies the pack sizes approved as part of a product's registration, the primary packaging and labelling must not be altered.

(6) If an authorisation specifies a quantity less than the smallest registered pack size, dispensing or breaking-down may be necessary. Dispensing or breaking-down is allowed only if that activity is specified in the approved operating plan.

(7) If dispensing or breaking-down, the following requirements apply:

a) Liquid and injectable RVMs must not be supplied in quantities less than the amount in the smallest registered pack size if this would require broaching the primary packaging. Breaking-down of registered pack sizes where the secondary packaging contains multiples of primary packaged product, and therefore does not include broaching of the primary packaging, is permitted (e.g. packs containing multiple single-dose vials).
b) Solid dose RVMs (tablets/boluses and capsules) may be counted out and repackaged in suitable containers and packaging to supply only the quantity specified by the authorisation.
c) Packaged single doses (e.g. blister packed tablets or capsules, intra-mammary syringes) may be removed from the proprietary outer/secondary packaging to supply the quantity specified by the authorising veterinarian (breaking-down).
d) Any alternative packaging used for the product must be suitable for the type of RVM being supplied. It must prevent damage, contamination, and deterioration of the RVM.
e) Any alternative package must be large enough to contain (or to have attached to it) the information specified in clause 5.3.2(3) plus the registered proprietary label information, and hazard and safety information if a leaflet is not available.

f) If there is no leaflet available, information on the outer packaging must be transferred to the end user by other means. The RVM seller is responsible for ensuring this information is transferred accurately.
g) Any alternative package must specify product shelf life if the intended use will not be immediate.
h) There must be procedures governing either the disposal of the remaining product or temporary storage, labelling, security, and protection from contamination or deterioration until the remaining product is used to fill another order or is destroyed.

5.4 Dispatch and transport

(1) Final release of an order must be authorised by the person(s) or role specified in the operating plan to release order.

(2) A person should be responsible for checking that the order is as specified and that person should sign the release for every order.

(3) Release records should be monitored and intermittently cross-checked with dispatched orders to confirm compliance.

(4) Product should be transported securely, under the necessary conditions to maintain product quality according to labelling (i.e. cold chain products).

(5) If RVMs are dispatched via an intermediary transporter, outlet, or other entity, the RVM seller retains responsibility for the product until it is delivered to the seller specified in the purchase order or the person/entity specified in the authorisation.

(6) Any third party involved in dispatch must be subject to your operating plan or have an approved operating plan themselves.

(7) The order must be prepared as if it was to be handed directly to the person/entity specified in the authorisation, with all the information specified in clause 5.3.2(3) and the third party directed not to alter the package and labelling.

(8) Any third party must be made aware of any special storage and handling requirements and responsibilities outlined in a contractual agreement. Each party's responsibilities should be clearly identified in the operating plan.

5.5 Using a veterinarian to deliver RVMs to the end user

(1) If a veterinarian (including the authorising veterinarian) is requested to deliver the RVMs to the end user/s and is expected to be responsible for carrying out any of the matters specified in clauses 5.2.4, 5.3 and 5.4 there must be a contractual agreement, in writing, that specifies the veterinarian agrees to and accepts the responsibility for those specific matters and details how they will carry out those matters. This must also be clearly stated in the approved operating plan.

6 Compliance monitoring

(1) Regular stocktakes of RVMs should be conducted to reconcile quantities ordered, in stock, sold and/or discarded. Discrepancies in reconciliation should be noted and the cause investigated.

(2) A record of non-compliances with procedures and remedial action taken should be kept.

(3) The performance of the operating plan, associated procedures, and records should be monitored and reviewed regularly at a frequency that provides confidence that the operating plan reflects the actual operations conducted. In addition, a full review should be carried out every 3 years in anticipation of

the renewal of the MPI approval of the plan. Any required amendments should be made and notified to MPI as part of the renewal.

7 Documented operating plan, associated procedures, and record keeping

(1) There should be appropriately documented procedures and adequate records kept for all of the critical control points that are necessary in order to comply with Parts 5 and 6. This should include the relevant documentation and records listed below.

(2) The operating plan should identify and provide verification of procedures and/or records. The following information should be included in the application for approval of your operating plan to sell RVMs.

(3) The operating plan should include the following information for every site involved in the process:

a) Provide a brief summary of the seller, including company name, address, contact details and the nominated responsible person.
b) Detail the scope of the sales activity (such as sales to a wholesaler, retailer, or directly to the end user in accordance with an authorisation, or an overseas registrant selling via a New Zealand agent).
c) Provide details of the next step in the distribution chain including wholesalers, veterinary pharmacies, and veterinarians. This may be provided in the form of a list of individual trade name products or as categories of products with similar characteristics. Veterinarians or veterinary pharmacies can state 'all registered products in New Zealand as applicable'. If your range of RVMs includes controlled drugs, you will also have to comply with the requirements imposed under the Medicines Act 1981 and Misuse of Drugs Act 1975. None of the ACVM requirements overrule requirements imposed under these Acts.
d) Keep records and verification of all of the activities relating to the requirements for receipt, storage and dispatch of RVMs (including dispensing or breaking-down, if applicable). This includes the documents associated with the categories listed above and also includes the following, as applicable:

    i) training records of staff in relation to handling and supply of RVMs;
    ii) records verifying internal review of operating plan and stock levels;
    iii) receipt and storage conditions for RVMs;
    iv) records of transport (and conditions) of products;
    v) records of sales (including sale information with dates, batch numbers and other details that make it possible to reconcile stocks on the premises and to contact clients in the event of a product recall);
    vi) records of authorisations received;
    vii) records of dispensing, filling, and labelling in accordance with authorisations, including provision of instructions for use, as required by the authorising person, along with other required information;
    viii) records of breaking-down, dispensing, repacking and relabelling product in cases where that is permitted;
    ix) records of disposal/destruction (if applicable).

e) State the information to be recorded at each critical control point in your procedures.
f) Describe the records that will be kept and the procedures for recording the required information.

7.1.1 Sale to wholesalers/distributors/retailers/veterinary pharmacies and veterinarians

(1) The following information should be retained:

a) name of purchaser;
b) purchase order reference;
c) date order received;

d) details of the RVM ordered and supplied (trade name, quantity and batch number);
e) date of dispatch and transaction reference;
f) details of storage conditions while at the premises;
g) details of transport (and conditions);
h) the next step in the supply chain (direct to seller, dispatch to specified intermediary); and
i) name of staff member who released the order.

7.1.2 Sale to end user with an authorisation

(1) The following information should be retained:

a) name of authorising person;
b) authorisation reference;
c) date issued;
d) name and address of the person or entity authorised to purchase the RVM;
e) date order received;
f) details of the RVM being supplied (trade name, quantity and batch number);
g) details of storage conditions while at the premises;
h) instructions for use of the RVM from the authorising person;
i) details of packaging and labelling (if breaking-down or dispensing is necessary and required as directed in the authorisation - refer clause 5.3.2);
j) details for managing and documenting authorisations requiring repeat supply where the complete authorisation may not be filled in one consignment
k) date of dispatch and transaction reference;
l) details of transport (and conditions);
m) the next step in the supply chain (direct to end user or representative or dispatch to specified intermediary);
n) name of staff member who released the order.

8 Operating an independent warehouse

(1) If you operate as an independent warehouse (that stores RVMs) and your procedures and controls are not covered or included in a seller's operating plan, or you perform this activity for more than one seller, you must have your own approved operating plan to cover your activity including receipt of inward goods, security and storage, release and dispatch.

(2) Use the guidance in Part 5 as to what should be in the operating plan in regard to the scope of your activity.

9 Selling/supplying RVMs for export

(1) Sale/supply of RVMs outside New Zealand (i.e. export only) is a particular activity that should be specified in the operating plan as a secure activity isolated from supply in New Zealand. The operating plan should specify how the RVMs will be isolated from ones that will be sold in New Zealand and how they will be controlled until export.

(2) Because the processes are basically the same, except for those preventing diversion into the New Zealand market, use the guidance in Part 5 as to what should be in the operating plan in regard to the scope of export only sale/supply