ACVM expectations of hormonal growth promotant (HGP) sellers with an approved operating plan

ACVM guideline

1. Background

Hormonal growth promotants (HGPs) are a group of veterinary medicines that pose unique risks to New Zealand's trade in primary produce. While it is legal to administer HGPs to beef cattle in New Zealand, certain overseas countries have banned their use. As New Zealand exports 80% of its beef produce, it became necessary to develop regulatory controls to ensure HGP-treated beef is not sent to markets that only accept non-HGP animal products.

To ensure the above, MPI employs a two-pronged strategy:

- Apply the provisions under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 to impose conditions of registration that obligate sellers of HGPs to comply with certain requirements.
- Apply the provisions under the Animal Products Act to issue the Animal Products (Regulated Control Scheme – Hormonal Growth Promotants) Notices.

This document is about the controls applied to HGPs through the provisions of the ACVM Act.

2. Approved operating plan required for selling HGPs

Those in the supply chain of HGP distribution and sales must have an HGP seller operating plan (OP) approved under section 28 of the ACVM Act. This requirement applies to:

- registrants
- importing agents or freight forwarders
- distributors/wholesalers/retailers (supplying directly to veterinary practices only)
- New Zealand GMP approved manufacturers (if the manufacturer is subject to the GMP Programme an OP in this format is not required. HGP processes will be audited as part of their biennial GMP inspection).

3. HGPs have the same registration conditions as restricted veterinary medicines

HGPs are restricted veterinary medicines (RVMs). Therefore, they have the same registration conditions. This means the two conditions that relate to the sale of RVMs also apply to HGPs.

Condition 69	The product must be sold only by either: 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 a person specified to sell the product or similar products in and acting in accordance with a relevant operating plan approved under section 28.
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.

4. Operating plan

In the case of RVMs that are not HGPs, the "**relevant** operating plan approved under section 28" referred to in Condition 69 will mean the approved Operating Plan for Sellers of Restricted Veterinary Medicines. In the case of HGPs, the "**relevant** operating plan

approved under section 28" referred to in Condition 69 will mean the approved Operating Plan for Sellers of Hormonal Growth Promotants.

The OP describes procedures from the point of importation/procurement of the HGP stock to the point of transfer of the HGP stock to the authorising veterinarians or to other owners of approved HGP seller operating plans. A template for the operating plan is available on our website.

The HGP seller OP will replace the previous requirement for HGP registrants and distributors to comply with the *ACVM Standard for Distributors of Hormonal Growth Promotants*.

5. Information requirements for HGP sellers OP similar to RVM sellers OP

The information requirements for completing an HGP sellers OP are similar to that required for the RVM sellers OP. The key feature that distinguishes the HGP seller OP from the RVM seller OP is that the former requires selling of HGPs only to veterinary practices or to entities having an approved HGP seller OP (or a GMP approved audited system for manufacturers).

The HGP must not be handed over to an end user. The Animal Products (Regulated Control Scheme – Hormonal Growth Promotants) Notice 2012 requires that HGPs be administered to animals only by a competent person or a person acting under the direct supervision of a competent person. Operationally, this is interpreted to mean that an end user will not be issued with a veterinary authorisation for independent purchase of the HGP.

The competent person, or the person acting under the direct supervision of the competent person, will maintain secure control of the HGP at all times for administration to the end user's animals. The ACVM Group and the New Zealand Standards Group of MPI have made the above arrangement to ensure that the risks associated with the sale and use of HGPs are adequately managed.

Another feature of the HGP seller OP is the requirement to include the orange HGP-specific ear tags when fulfilling orders for HGPs.

6. Certificate of compliance

A certificate of compliance, valid for three years, will be sent to all owners of approved HGP seller OPs.

7. OP to be audited every three years

To ensure that the approved OPs reflect current practice, that they meet the requirements of the ACVM Act, and that the OPs are being appropriately implemented, MPI will conduct desktop audits every three years. For New Zealand GMP approved manufacturers with an approved HGP seller OP, the HGP processes will be audited as part of their biennial GMP inspection. HGP sales and distribution records will be required for completing the audits.

8. Charges for approving and auditing OP

There is a fee for the approval of the HGP seller OP and for approval of any subsequent amendments made to the plan. The fee will be at the normal MPI hourly rate, with one hour charge as the minimum.

Charges will also apply for the desktop and on-site audits. Fee details are available on the website.

If you have questions or are unsure as to whether you need an MPI-approved operating plan for selling HGPs, contact us (approvals@mpi.govt.nz).