



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



THE OVERSEAS GMP SCHEME

Overseas Manufacturers of Veterinary Chemical Products

Guidelines and Requirements for Providing Evidence of GMP Compliance

4th Edition

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INTRODUCTION

All veterinary products registered for use in Australia must be manufactured in sites that are compliant with standards equivalent to the ***Australian Code of Good Manufacturing Practice for Veterinary Chemical Products***. Evidence of GMP compliance must be submitted with all new product applications or when an application to vary a manufacturer is submitted.

The registration details of all imported veterinary products include conditions that require registrants to maintain current evidence of GMP compliance. This evidence must be submitted to the APVMA within ten days of receiving a request for submission.

1 GENERAL REQUIREMENTS FOR DOCUMENTARY EVIDENCE

1.1 Quality of documentation

1. Certificates must be either original or a copy of the original certificate certified by the issuing authority or a notary public.
2. Certified copies must be fully legible and complete.
3. Faxed, photocopied, scanned or emailed copies are not acceptable.
4. Bilingual certificates are acceptable provided one of the languages is English.

1.2 Validity of documents

5. Where possible, documentation should generally be from a government authority that is recognised by the APVMA. Recognised Authorities are the APVMA, TGA, and appropriate government authorities from the EC (established members), USA, Canada, Switzerland, Norway, Lichtenstein, Iceland and New Zealand.
6. Generally, documentation from non-government inspection bodies is not accepted as primary evidence of GMP compliance.
7. Certificates and audit reports are only accepted for three years after the date of the last inspection or until the expiry date shown on the certificate (whichever is earlier).
 - If a certificate states that it is valid for more than three years after the date of inspection, it will only be accepted for a maximum of three years after the last inspection date.
 - If a certificate has an expiry date less than three years after the inspection date, it will only be accepted until the stated expiry date.
8. There must be no qualifying statement on a certificate that renders it invalid (e.g. a statement that 'the certificate is issued for the Government of the UK and must not be used for any other purpose').

1.3 Information contained in the documents

9. The name and street address of the manufacturer on the certificate must be identical to that shown on the application form for registration of a relevant product.
10. The scope of the certificate or audit report must cover the type of product to which the application relates and the relevant steps of manufacture.
11. Where no satisfactory documentary evidence of compliance can be provided, overseas manufacturing facilities will need to be audited by an APVMA-authorized auditor.

2 INTERNATIONAL AGREEMENTS

2.1 Mutual Recognition Agreements with EC and EFTA

The Commonwealth of Australia has entered into two Mutual Recognition Agreements on Conformity Assessment (MRAs) that include veterinary chemical products. These are with the European Union (EC) and the European Free Trade Association (EFTA). For further information about Mutual Recognition Agreements, please see the APVMA's website at <http://www.apvma.gov.au/consultation/international.php>

The APVMA will accept Certificates of GMP Compliance issued under the provisions of an MRA by recognised authorities in those countries. Currently, the recognised countries are:

Austria	Greece	Netherlands
Belgium	Iceland	Norway
Denmark	Ireland	Portugal
Finland	Italy	Sweden
France	Liechtenstein	United Kingdom
Germany	Luxembourg	Spain

The scope of the MRA does not cover audits by recognised EC authorities outside their own countries. However, these may be considered on a case-by-case basis.

2.2 Memorandum of Understanding with New Zealand

The APVMA has a memorandum of understanding with the New Zealand Food Safety Authority's Agricultural Compounds and Veterinary Medicines Group (ACVM) which facilitates mutual recognition of Certificates of GMP Compliance between the two countries. Australia will recognise Certificates of GMP Compliance for facilities in New Zealand that are audited by this authority.

3 GUIDELINES FOR ACCEPTABLE SOURCES OF EVIDENCE

This guideline provides information on the sources of evidence of GMP compliance from different countries. Decisions often need to be made on a case-by-case basis due to differences in individual circumstances and the underlying legislation in different countries. The flexibility provided by this approach is often beneficial to applicants. For example, where the local authority may not be recognised, an audit report by a local authority or inspectorate may be acceptable as part of a documentary package.

Although the MRA with the EC and EFTA are the only formal treaties of mutual recognition, some other regulatory authorities are recognised as having standards equivalent to the Australian Code of GMP for Veterinary Chemical Products.

Please contact the GMP Section if you require further clarification about these guidelines.

4 ACCEPTABLE EVIDENCE OF GMP COMPLIANCE

4.1 Evidence from recognised EC and EFTA Countries

Sterile and non-sterile medicinal products, vaccines and other immunobiologicals, ectoparasiticides, medicated stock feeds, premixes and supplements

Under the terms of the MRA, evidence should be in the form of a Certificate of GMP Compliance of a Manufacturer. See http://www.apvma.gov.au/supply/veterinary/gmp_overseas.php for the standard format of a certificate. If there is an expiry date indicated on the certificate, the certificate will only be valid for the time period nominated (provided this is less than three years from the date of the last inspection).

Certificates are issued by the recognised authorities in each country. For a full list of these authorities, please see http://www.apvma.gov.au/supply/veterinary/gmp_overseas.php

If companies have difficulties with obtaining the correct type of certificate from an authority, please contact the GMP Section who can contact the EC to resolve problems. If delays in auditing schedules cause delays in obtaining a certificate, please contact the GMP section to discuss this. In certain circumstances, the APVMA will consider accepting comparable certificates that contain the same information as a Certificate of GMP Compliance of a Manufacturer. However, the registrant should attempt to obtain the correct version of certificates, in the first instance.

Stock feed additives (such as direct-fed microbials, probiotics and enzymes) and therapeutic pet foods

Manufacturing sites in these countries should be inspected and licensed by a government authority for compliance with manufacturing requirements contained in Regulation (EC) 183/2005.

The evidence sought be a current certificate or other documentation from the relevant government authority from each country which states that the facility has been inspected and complies with Regulation (EC) 183/2005. If this regulation has been transposed into national legislation it must be clear that this relates to Regulation (EC) 183/2005.

These certificates are usually valid for three years from the date of the last inspection or from the date of signing. If there is an expiry date indicated on the certificate, the certificate will only be valid for the time period nominated (provided this is less than three years from the date of signing).

Documentation from non-government authorities such as FAMI-QS inspection bodies or ISO inspection bodies **are not acceptable**.

4.2 Evidence from Switzerland

Switzerland is accepted as having standards equivalent to the Australian Code of GMP for Veterinary Chemical products.

Sterile and non-sterile medicinal products, vaccines and other immunobiologicals, ectoparasiticides, medicated stock feeds, premixes and supplements

The evidence sought should be a Certificate from Swissmedic, the Swiss agency for Therapeutic Products. The certificate should clearly state that the manufacturer is authorised to manufacture veterinary medicinal products (or pharmaceutical products) in accordance with the laws and regulations of the Swiss Confederation. It should also state that the manufacturing plant is regularly inspected and complies with GMP requirements as recommended by the World Health Organisation (WHO) and the Pharmaceutical Inspection Convention (PIC), or other comparable standards.

Stock feed additives (such as direct-fed microbials, probiotics and enzymes) and therapeutic pet foods

Manufacturing sites in Switzerland should be inspected and licensed by a government authority for compliance with manufacturing requirements that are similar to the EC's Regulation (EC) 183/2005, as Swiss Regulations tend to be aligned with EC legislation.

The evidence sought should be a current Certificate or other documentation that states the name and street address of the manufacturing site, and declares that the site is regularly inspected and the products are manufactured in accordance with the requirements of the Swiss equivalent of Regulation (EC) 183/2005.

It will not always be clear from the documentation that the national legislation relates to Regulation (EC) 183/2005. In that case, the manufacturer will need to provide a letter from the Swiss agency confirming that.

4.3 Evidence from New Zealand

The evidence sought should be a current Certificate of GMP Compliance of a Manufacturer issued by the Agricultural Compounds and Veterinary Medicines Group (ACVM) of the NZ Food Safety Authority (NZFSA). This certificate should include details about the manufacturing site, date of last inspection and authorised product types and manufacturing steps.

These certificates are usually valid for three years from the date of the last inspection. If there is an expiry date indicated on the certificate, the certificate will only be valid for the time period nominated (provided this is less than three years from the date of the last inspection).

Some veterinary products in New Zealand are exempt from registration in regulations under the ACVM Act or are specific requirements products (SRP's). SRP's are a class of feed additives which require registration in NZ but not a GMP inspection. In those cases, an audit by an APVMA-authorised auditor will usually be required. An audit by another recognised authority (such as an inspectorate from a recognised EC country) may be acceptable on a case-by-case basis.

4.4 Evidence from the United States

Immunologicals such as vaccines, antisera and other biological products of a therapeutic nature

The required evidence will be a current Certificate of Licensing and Inspection from the US Department of Agriculture (USDA) Centre for Veterinary Biologics. This should state the name and street address of the manufacturing site and that the product and the manufacturing site have been inspected and licensed under the laws and regulations of the USA.

The expiry date listed on these certificates is usually two years, and the certificate is only be acceptable for the time period nominated.

Sterile and non-sterile medicinal products including medicated stock feeds, premixes, supplements and performance enhancing biological products, such as boar taint vaccines and hormones

The required evidence will be a current Certificate to Foreign Government from the US Food and Drug Administration (FDA). This should state the name and street address of the manufacturing site, the products, and a statement that the product and the manufacturing plant which produces it are subject to the jurisdiction of the FDA, the manufacturing plant is subject to periodic GMP-type inspections/audits and the products and the manufacturing plant are in compliance with GMP.

The expiry date listed on these certificates is usually two years, and the certificate is only be acceptable for the time period nominated.

This authority does not regulate ectoparasiticides, stock feed additives or therapeutic pet foods.

Products listed above that are either not marketed in the USA or pre-registration

The US Department of Agriculture (USDA) Centre for Veterinary Biologics and the US Food and Drug Administration (FDA) may not issue appropriate certificates for export only products, or before a product is registered in the USA.

Certificates that refer to closely similar products manufactured at the same site may be considered on a case-by-case basis. An audit report from another recognised authority (such as an inspectorate from a recognised EC country) may also be considered on case-by-case basis. Generally, an audit by an APVMA-
authorised will be required to confirm GMP compliance.

Ectoparasiticides

No authorities are recognised.

An audit report from another recognised authority (such as an inspectorate from a recognised EC country) may be considered on case-by-case basis. Generally, an audit by an APVMA-
authorised will be required to confirm GMP compliance.

Stock feed additives, such as direct-fed microbials, probiotics and enzymes, and therapeutic pet foods.

No authorities are recognised.

An audit report from another recognised authority (such as an inspectorate from a recognised EC country) may be considered on case-by-case basis. Generally, an audit by an APVMA-authorized will be required to confirm GMP compliance.

4.5 Evidence from Canada

Immunologicals such as vaccines, antisera and other biological products of a therapeutic nature

Evidence should be sought from the Veterinary Biologics Section of the Canadian Food Inspection Agency. The following documents must all be provided:

- a current Veterinary Biologics Export Certificate, which confirms the product is made in a licensed facility and the product is registered (licensed) in Canada
- a current Veterinary Biologics Establishment Licence, which confirms that the site is licensed and gives details about authorised manufacturing steps
- a copy of the most recent Inspection Report **only if** the Veterinary Biologics Establishment Licence is more than three years old. This will confirm that the site has had a recent inspection.

If the product is **not marketed in Canada** the following documents should be sought:

- a Veterinary Biologics Export Certificate which states the product is for export only and manufactured in a licensed establishment
- a current Veterinary Biologics Establishment Licence, which confirms that the site is licensed and gives details about authorised manufacturing steps
- a copy of the most recent Inspection Report **only if** the Veterinary Biologics Establishment Licence is more than three years old. This will confirm that the site has had a recent inspection.

If these documents cannot be provided, then an audit by an APVMA-authorized is likely to be required.

Sterile and non-sterile medicinal products including premixes and supplements

Evidence should be sought from Health Canada, which is Canada's Department of Health. The following documents must be provided:

- An Establishment Licence which shows the most recent inspection date
- An Inspection Exit Notice for the most recent inspection at the site.

Both these documents are required because the exit inspection notice provides further clarity on the manufacturing activities undertaken at the site.

If these documents cannot be provided, then an audit by an APVMA-authorized is likely to be required.

Ectoparasiticides

No authorities are recognised in these countries.

An audit report from another recognised authority (such as an inspectorate from a recognised EC country) may be considered on case-by-case basis. Generally, an audit by an APVMA-authorized will be required to confirm GMP compliance.

Medicated stock feeds, stock feed additives and therapeutic pet foods, including direct-fed microbials, probiotics and enzymes

No authorities are recognised.

An audit report from another recognised authority (such as an inspectorate from a recognised EC country) may be considered on case-by-case basis. Generally, an audit by an APVMA-authorized will be required to confirm GMP compliance.

4.6 Evidence from all other countries including China, India, Mexico, Brazil, South Korea, Japan, South Africa and Singapore

No authorities are recognised in these countries.

An audit report from another recognised authority (such as an inspectorate from a recognised EC country) may be considered on case-by-case basis.

Generally, an audit by an APVMA-authorized auditor will be required to confirm GMP compliance.

4.7 Testing laboratories

Evidence of GMP compliance should be sought in the first instance from recognised government authorities, as described in the rest of this document.

If evidence cannot be obtained from recognised authorities, the APVMA may consider certification for compliance with the ISO/IEC 17025 Standard (General requirements for the competence of testing and calibration laboratories). The National Association of Testing Authorities, Australia (NATA) has entered into mutual recognition arrangements with national accreditation bodies from a range of countries. These bodies are listed in its publication NATA's Mutual Recognition Arrangements (MRA) Network (see the NATA website, <http://www.nata.asn.au/go/publications>). Only certification for compliance with the ISO/IEC 17025 Standard from the listed accreditation bodies would be acceptable for consideration.