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Manufacturing Quality and Licensing (MQL)
Australian Pesticides and Veterinary Medicines Authority (APVMA)
By email only: mls@apvma.gov.au

Dear Manufacturing Quality and Licensing team,

Re: Proposed changes to the overseas GMP compliance assessment fee process

Thank you for the opportunity to provide feedback on the proposed changes to the overseas GMP compliance assessment fee process.

Animal Medicines Australia (AMA) is the peak industry body representing the leading animal health companies in Australia. AMA member companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products that prevent, control and cure disease in the livestock, companion animal and equine sectors. AMA member companies represent more than 90% of Australian sales of registered veterinary medicines.

AMA welcomes the opportunity to assist the APVMA in supporting regulation that is effective, efficient, proportionate and fit for purpose, and consistent with the government principles of best practice set out in the Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies[1] and the Australian Government Guide to Regulatory Impact Analysis[2]. These principles highlight the need for genuine, meaningful and timely consultation with stakeholders to improve policy decisions, minimise the impact of regulatory changes and generate superior regulatory outcomes.

In the last few years, AMA has appreciated the willingness of the APVMA to consult with industry to develop regulatory solutions that are mutually acceptable to both the regulator and the regulated community. On this occasion, there was no consultation with industry prior to informing registrants of the proposed changes to the overseas GMP compliance assessment process. AMA welcomed

[1] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standards Setting Bodies (pmc.gov.au)
[2] Australian Government Guide to Regulatory Impact Analysis | OBPR (pmc.gov.au)

APVMA's responsiveness to the issues that we raised, and postponed implementation of new measures subject to further industry consultation.

AMA is pleased to provide the following comments in relation to the proposed changes to the overseas GMP compliance assessment fee process.

The role of GMP

Veterinary chemicals sold in Australia must be manufactured in accordance with Good Manufacturing Practice (GMP). GMP ensures that veterinary chemical products are safe, reliable and effective for their intended purpose with the use of consistent manufacturing processes, where every step of manufacture must meet a certain standard, and effective quality control processes to confirm the finished product continues to meet that standard, before it is released for supply to the market.

The production of veterinary chemical products involves multiple steps, including the analysis of starting materials, formulation, processing, packaging, labelling and stability testing. These steps may occur at different sites. Every site must be registered and regularly assessed for compliance with GMP standards.

Registrants may register multiple sites for a particular step in the manufacturing process for a product as security against disruption, such as alternate analytical test sites, formulating or packaging sites. This allows registrants, if-and-when required, to quickly move a particular step in the manufacturing process to a registered alternative or back-up site without requiring additional assessment by APVMA.

Registration holders must pay an annual GMP compliance fee for each overseas site of manufacture on their registrations ($1000 per site per annum). Regulation 71A(3) allows that if the same site of manufacture is used for multiple products, the fee is only payable once. Registration holders have also previously been able to provide a Statutory Declaration notifying the APVMA that an overseas site of manufacture listed on their registration was not used in that financial year, and the overseas GMP compliance assessment fee for the unused site was then waived.

Proposed change

AMA understands that from the commencement of financial year 2023-24, it will no longer be possible to submit a Statutory Declaration identifying unused overseas sites of manufacture. Registration holders will be required to pay the overseas GMP compliance assessment fee for all sites listed on their registration, irrespective of use (although Regulation 71A(3) would still apply).

AMA has been given two rationales for the proposed change:

1. APVMA has always been authorised to cost recover the overseas GMP compliance fee for all sites on a registration, but had not done so previously. It is not clear whether this was an oversight, or if a deliberate decision had been made in the past (to not charge), nor why this fee is now to be charged.
2. APVMA has noted that during the process to generate overseas GMP compliance fee invoices each year, more than 40% of the preliminary invoices are returned with Statutory Declarations to remove inactive sites from the final invoice. Processing this volume of declarations and re-issuing the associated invoices places a considerable burden on APVMA resources.

Impact of proposed change

Alternate and back-up sites on a product registration are a critical safeguard for the animal health industry. This was highlighted during the COVID-19 pandemic, when the flexibility to quickly move manufacture from one registered site to another registered site in response to sudden disruptions in supply chains and workforces, allowed veterinary chemical companies to maintain continuity of supply of essential veterinary medicines in the midst of considerable disruptions to global supply chains.

Most veterinary chemical products registered by AMA members have multiple overseas sites of manufacture listed on the registration. It is not uncommon for individual companies to have 30 or more alternative or back-up sites registered across their product portfolio. The proposal to now charge for unused sites of manufacture will have a considerable financial impact on many registrants. Budgets for veterinary chemical manufacturers may be overseen at a global level (especially for large multi-national companies) and prepared several years in advance; sudden changes to expected regulatory costs can be problematic.

AMA notes that this new fee was not foreshadowed prior to its announcement. Registrants only became aware on receipt of a notice (dated 23 March) advising the change, which was to be implemented just 3 months from the date of the notice (1 July, for the 2022-2023 financial year). This change in policy represents a considerable financial impact for both registrants and the regulator, and as such, advance notice and industry consultation should have occurred.

The Australian Government Cost Recovery Guidelines (CRG)[3] states that all stages of the cost recovery process should be underpinned by efficiency and effectiveness, transparency and accountability, and stakeholder engagement. The CRG also states that "each cost recovered activity, regardless of financial value, must be documented in a cost recovery implementation statement (CRIS) before charges commence"[4], particularly if introducing cost recovery for an existing activity that has not previously been cost recovered. Whilst the APVMA already has the statutory authority to charge applicants for its services, and this particular fee change does not require a full CRIS assessment process, that authority does not preclude the APVMA from the requirement to properly consult with affected stakeholders before charges commence.

This policy change will have a significant impact on administrative burden for both registrants and the regulator. In order to obtain an exemption from the overseas GMP compliance assessment fee for an alternative or back-up site of manufacture, registrants will need to formally request that those sites are removed from their registrations by submitting an Item 13A application for a prescribed variation ($175 fee / 1 month timeframe). In the future, if-and-when the registration holder needs to use one of those alternative or back-up sites of manufacture, they will need to submit an Item 13A (for secondary steps of manufacture) or Item 12 application (for primary steps of manufacture; $2000 fee / 3 month timeframe). The timeframe, especially for an Item 12 application, will not allow manufacturers to respond quickly to changes in supply or distribution chains, and will likely result in interrupted supplies and shortages of critically important veterinary medicines.

A flow-on effect of removing the Statutory Declaration mechanism is that registration holders will now need to prepare new applications to add and remove sites of manufacture on an ad hoc basis. This will confer a significant administrative burden throughout the year, for registrants to prepare applications and for APVMA to process those applications. It is possible that the workload generated

[3] Australian Government Cost Recovery Guidelines (RMG 304) | Department of Finance
[4] Australian Government Cost Recovery Guidelines (RMG 304) | Department of Finance

by these applications throughout the year will outweigh the periodic workload of assessing Statutory Declarations.

From the information provided in the proposal, it is unclear if alternative mechanisms have been investigated by the APVMA to address the workload concerns arising from the use of Statutory Declarations. For example, AMA members have noted that the general approach to GMP compliance fee invoices has recently changed. In previous years, Statutory Declarations have been used to declare that a manufacturing site was *not* used in that financial year. However in the last financial year, registrants were instead asked to confirm the manufacturing sites that *were* used. In general, it is easier for registrants to confirm which sites product *is* coming from, rather than sites where product *is not* coming from, particularly where some manufacturing sites on a registration may be protected as CCI. Understanding the impact of this new approach on operational processes and efficiencies could be particularly informative.

The administrative burden of this policy change is greatly complicated by a lack of visibility for registrants on the information held on the Register for their own products, and the issue of invoices that do not identify the manufacturing sites that are being charged for. This makes it extremely difficult for registrants to verify exactly what they are paying for.

Requests to itemise the sites being invoiced have been declined on the basis of Confidential Commercial Information (CCI), where APVMA may be unable to disclose details of some manufacturing sites to some registrants. As a result, APVMA will not release information on sites of manufacture without a formal *Request to release information from the Register* under Regulation 73 of the Agvet Regulations. In order to identify the manufacturing sites on an invoice, registrants must pay $95 per request, plus a further $95 for each additional hour or part thereof after the first hour, to provide the information.

AMA considers that it is inappropriate for a government authority to request payment where it is difficult for the registrant to verify if the charge is correct, without incurring further costs and where there are penalties for failing to pay. To do so is in conflict with the principles of best practice regulation[5], the values of the Australian Public Service[6] and the APVMA's Service Charter[7].

Registrants are obliged under Section 161(A) to inform the APVMA of any information which contradicts the information held on the product registration. However the restrictions on access to that information associated with CCI make it very difficult for registrants to ensure that the list of sites of manufacture on each product registration is kept current and accurate.

Registrants do not receive a copy of the information entered into the Register, so if an error is made when entering information into the Register, the registrant will not be aware of that error. In order to keep registration information up to date, registrants need to be able to efficiently verify information in the Register against their internal records and confirm that any requested changes to that information have been recorded correctly. Processing errors have significant implications for registrants, especially when that information is used to calculate fees, such as the overseas GMP compliance fee. Some examples noted by AMA members include:

- an incorrect post code was entered for one site, with a second entry made with the correct post code. The exact same site was then counted twice for the overseas GMP compliance fee calculation.

[5] The Office of Best Practice Regulation | OBPR (pmc.gov.au)
[6] APS Values | Australian Public Service Commission (apsc.gov.au)
[7] Service charter | Australian Pesticides and Veterinary Medicines Authority (apvma.gov.au)

- sites have been listed on the Register that should not have been added in the first place as they were not approved during evaluation of the original application to register the product.

It would be helpful if an extract from the Register was provided to registrants following each registration or variation application so that registrants can verify the information is correct and ensure that their internal records match those of the APVMA.

More recently, AMA has become aware of uncertainties and inconsistencies in identifying which manufacturing sites need to be registered, especially testing laboratories that may be used prior to manufacture, or to periodically test finished products as part of ongoing stability monitoring protocols. Testing laboratories are required to meet Good Laboratory Practice (GLP) standards (rather than GMP) which is more appropriate for the testing processes that they carry out. A GMP compliance assessment fee should not be charged for facilities that are required to comply with GLP standards. Clarity on which sites do, or do not, need to be registered is essential, especially when that information is subsequently used to calculate fees for registrants.

AMA has already had some preliminary conversations with APVMA on ways in which the new myAPVMA system may be able to provide summaries or extracts of manufacturing site information from the Register in future. Provision of such capabilities in the new system would be an efficient and effective way to address such issues and AMA members would be pleased to assist with user testing activities.

Summary and Recommendations

Animal Medicines Australia (AMA) supports the implementation of operational processes that are consistent with government principles of best practice regulation and are appropriate, achieveable and effective for the regulated community as well as the regulator.

AMA considers that this proposal does not reflect the principles of best practice regulation. It is likely to confer a regulatory burden on both registrants and the regulator, with no corresponding reduction in risk or improvement in safety, quality or efficacy outcomes. There are also several issues concerning access to manufacturing information and clarity of requirements that underpin this proposal, which must be addressed in order for this policy change to be implemented fairly, equitably and appropriately.

AMA recommends that the APVMA defer implementation of this proposal until critical foundational issues are addressed:

1. The 1 July 2022-30 June 2025 CRIS is published and implemented.

2. Mechanisms are provided to assist registrants in meeting their obligations under the Agvet Code:
    a. A mechanism is provided to assist registrants to efficiently access and verify information held on the Register about their own products. It is anticipated that the new myAPVMA interface could provide such a mechanism.
    b. Written confirmation for each registration and variation processed by APVMA to be provided to allow registrants to confirm changes have been made correctly and support consistency with internal records.
    c. Efficient processes are needed to allow registrants to access alternate sites of manufacture in order to maintain market supply. Such site changes may be time-

critical. The current system directly enables this by permitting unused, but approved, sites of manufacture to remain on registrations without charge.

AMA has already had several constructive discussions with the APVMA on alternative mechanisms that could be used to address these issues, including identifying sites of manufacture on the Register for each product (whilst maintaining CCI), streamlined systems to generate accurate invoices and the importance of retaining flexibility in the GMP system to allow manufacture to move to alternative sites as needed.

The new myAPVMA system could also provide a mechanism to accept and process statutory declarations for inactive sites of manufacture, in line with the current process. This would be an efficient and effective resolution to the resourcing issues noted by APVMA with the current system and would assist registrants to manage globally-integrated business operations to protect market supplies.

AMA looks forward to continuing to work with APVMA to develop and implement efficient and effective operational changes to regulatory processes.

If we can provide any further information, please let me know.

Yours sincerely,

Dr Charmian Bennett

Director of Science and Policy

(unsigned for electronic submission)