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18 October 2024

Chief Financial Officer
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Submission by email only: costrecovery@apvma.gov.au

Dear Sir/Madam,

Re: Consultation Paper: Cost Recovery Implementation Statement (CRIS) 1 July 2025-30 June 2026

Thank you for the opportunity to provide comment on the Consultation Paper: APVMA Cost Recovery Implementation Statement (CRIS) 1 July 2025-30 June 2026.

Animal Medicines Australia (AMA) is the industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. They are the local divisions of global innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's $34 billion livestock industry and the $33 billion pet industry. Our members represent more than 90% of registered veterinary medicine sales in Australia.

AMA recognises the APVMA as a trusted, independent and best-practice regulator of pesticides and veterinary medicines, where decisions are based on scientific evidence and risk analysis, and whose decisions are respected by government, industry and the community.

Industry accepts the need to contribute to an efficient and effective regulatory system. However, the cost of animal health innovation continues to increase, creating challenging circumstances for companies to recoup high research and development costs within short data protection periods. High registration fees and unique registration requirements for a small market may create barriers that limit the availability of veterinary products. AMA seeks to ensure that its contribution to regulatory functions supports rigorous, science-based assessments whilst

maintaining incentives for industry to bring innovative new products and technologies to the Australian animal health market.

AMA's priority is to ensure that this CRIS will deliver:

(i) **Predictability and consistency** in assessments and decision-making,
(ii) **A return for the increased contribution** to the APVMA regulatory system by animal health companies, and
(iii) **Equity** so that all beneficiaries of the regulatory system make a contribution to its operation.

Predictability and consistency

Predictability and consistency in decision-making drives efficiency and reduces costs for both the regulator and applicants/registrants. Highly predictable outcomes facilitate applicants supplying all required data for a positive APVMA decision. This avoids applicants dedicating time and resources on applications that will not meet APVMA requirements. Similarly, APVMA will not waste assessment resources on applications that will not be approved. Decision timeframes are also critical as new products being introduced to the Australian market may be coordinated with release in other overseas markets. Confidence in the ability of the regulator to deliver its regulatory decisions on time helps to balance the higher risks of investing in a small market. Higher fees may be partially offset with surety on timeframes to support market entry.

Return on contribution

AMA members seek to ensure that should increased resourcing for the regulatory system be required, that this delivers a corresponding increase in regulatory performance. Improved guidance materials and additional information on what will (and will not) be acceptable to the APVMA when assessing applications will improve the quality of applications received, minimising wasted assessment resources.

Equity

The costs of regulation should be equitably distributed across all those who benefit from that regulation. AMA considers that a number of key APVMA responsibilities (especially some post-registration monitoring, compliance and enforcement functions) deliver considerable public good and may be more appropriately funded through government appropriations.

AMA members also seek to ensure that where increased resourcing is required, that no registrant, or class of registrants, is unfairly required to contribute in excess of their market competitors.

Best Practices in Cost Recovery

AMA supports an independent regulator that is appropriately resourced to deliver high quality, timely, rigorous and accurate assessments efficiently and whose decisions are based on scientific evidence and risk assessment. AMA notes and supports the critical importance of independence of the regulator.

AMA expects that a CRIS will adhere to government policy and guidelines for efficient and effective cost recovery:[1,2]

- The regulatory system should be appropriately resourced to enable efficient recovery of the costs of regulation from the regulated community.
- Registrants should not be liable for costs over and above the efficient administration of the regulatory scheme.
- The core principles of cost recovery policy should be (1) efficiency and effectiveness; (2) transparency and accountability, and (3) stakeholder engagement.[3]
- Operational efficiencies directly affect the cost base of APVMA's operations and must be considered when developing the cost model.
- Any increases in fees and charges must be justified. Stakeholders should be able to scrutinise the assumptions underpinning the costing model, and given appropriate and sufficient opportunities to do so.
- Increases in fees should only be considered after all requirements of the Australian Government Cost Recovery Guidelines have been met and increased operational efficiencies have been achieved.
- Changes should have appropriate lead-times before they commence.

The costs of registration and market entry are already high in comparison to market size, which has a disproportionate impact on innovation and can discourage the introduction of innovative new veterinary products to Australia. Our industry supports a regulatory system that recognises and reflects the unique challenges posed by the Australian animal health operating environment.

APVMA situation

AMA notes the circumstances of the APVMA as outlined in the CRIS but seeks further clarification on the underpinning assumptions:

- **Transparency in calculations**

The CRIS document would benefit from additional detail on the calculations of workload associated with each application type, which underpins the proposed fee changes in the CRIS. AMA notes that the comparison of regulatory timeframes alongside the work tasks associated with each application type is central to cost recovery calculations. It is unclear how timeframes have been determined, nor their appropriateness to complete the tasks required. AMA notes that some item types with similar timeframes appear to have different amounts of associated assessment.

- **Levy income projections**

The key sensitivity in the CRIS modelling is the projection of environmental conditions for the next few years. After several years of positive agricultural conditions associated with successive La Niña events, ABARES has forecast 'worsening' farming conditions to come, which is projected to

[1] Australian Government Cost Recovery Policy | Department of Finance
[2] Australian Government Charging Policy | Department of Finance
[3] Australian Government Cost Recovery Policy | Department of Finance

result in a decrease in sales levy income. The projected decline in levy revenue seems excessive and may be reliant on indicators with more relevance to crop protection products rather than veterinary medicines. Predictions of levy revenue by sector may lead to lower estimates of deficit in the cost model.

While AMA accepts that veterinary medicines represent the smaller proportion of APVMA's regulated industry, some moderation of projections to reflect that veterinary medicines are not all agricultural products may be warranted.

- **IT improvements**

AMA notes that IT improvements in the 2025-26 CRIS have been limited to 'securing the system' and no improvements to user interfaces or internal file management systems are intended. AMA notes the significant investment in IT reforms at APVMA with limited improvements from an industry perspective. Whilst industry acknowledges and supports necessary improvements in system security, further IT projects should be deferred until a comprehensive evaluation of previous projects is undertaken and a clear pathway to achieving the desired IT improvements is identified.

Scenario Analysis

The CRIS provides three scenarios, all of which include considerable increases to application fees and annual registrations for registrants. Scenario 3 also proposes an adjustment to the sales levy. AMA acknowledges that the CRIS proposes realigning fees to more closely reflect the intended 40/60 fee/levy split. This results primarily in fee increases, although there are some fee decreases.

Further opportunities for operational changes to deliver greater efficiencies would be welcomed and supported by AMA. For example, the reduction of manual handling tasks, increased use of international data and technical assessments, and the provision of clear guidance materials would provide workflow efficiencies and deliver timeframe improvements. Properly scoped and implemented, AMA notes that these may be cost-neutral by reducing unnecessary and inefficient work flows.

Scenario 1

Of the three options presented, Scenario 1 is *conditionally* preferred by AMA. Scenarios 2 and 3 each involve additional cost recovery for investments in resourcing and infrastructure that, at present, require further scoping to determine whether they offer significant regulatory performance improvements.

It is noted that Scenario 1 is intended to deliver higher revenue for the APVMA but provide the same level of service in response. Industry could support some fee increases if there were clear benefits for registrants in terms of timeframe reductions and improved guidance material.

AMA would welcome consideration by the APVMA of additional measures that could be implemented to improve regulatory system performance. AMA has identified three options for efficiencies that collectively, if implemented, would support improved operational efficiencies and regulatory outcomes, as well as create benefits for registrants that offset the additional costs from higher fees.

AMA would welcome further negotiations and consultations with the APVMA to consider how these efficiencies can be implemented.

Efficiency proposals

1. Timeframe reductions

AMA notes inconsistencies in timeframes for several application types. Reductions in timeframes can deliver benefits by permitting applicants to deliver products to market sooner, generating income for the registrant that can offset additional registration costs. For example, a three-month reduction in assessment time by the APVMA on a new product that is expected to deliver $1m in annual sales could be worth $250,000 to the applicant.

Currently, some application types have equivalent assessment timeframes despite requiring less assessment by the APVMA. For example, Items 1, 3 and 4 have 18 month assessment timeframes, and Item 2 is 17 months, yet only Item 1 & 2 require assessment of the active constituent.

AMA members also note that there are opportunities to deliver timeframe improvements through more effective use of international data and technical assessments. Although the ability to include international data in APVMA applications has improved, it has not delivered the expected timeframe savings or reductions in administrative burden. AMA considers that APVMA could deliver efficiencies through greater emphasis on the assessment of any Australia-specific data requirements or unique risks that may be posed with use in the Australian context, rather than repeating the technical assessments of other equivalent, trusted overseas regulators.

AMA proposes a reduction in application timeframes for *some* application types consistent with the analysis provided in *Attachment 1*.

2. Improved guidance materials

AMA considers that improvements in guidance materials could have a significant impact on regulatory efficiency by avoiding the APVMA and applicants dedicating resources to applications that may not meet contemporary standards. Our members have highlighted examples where different perspectives on APVMA requirements have been received from different APVMA officers, including *during the same meeting*. Improved guidance can mitigate this.

APVMA may wish to consider the merits of:

- publishing (in a de-identified and confidential manner) information on frequent issues and trends where applicants have not met APVMA's contemporary assessment requirements. This would include issues identified in PAAs as well as applications;
- clearly identifying when and where APVMA updates its perspectives of current risk assessment requirements;
- providing clear guidance materials to clarify expectations, improve application quality, reduce reliance on PAAs to determine application requirements, and ensure mutual understanding by both regulatory staff and applicants. This includes revision of existing guidance (such as for active ingredient approvals) and creation of new guidance where none currently exists (such as for chemistry and manufacturing changes, antibiotics or expectations regarding documentation for non-assessable changes);

- developing a clear and consistent regulatory approach to emerging technologies, such as nanomaterials, monoclonal antibodies, hemp and cannabis products, and methane inhibitors;
- developing internal guidance and processes to streamline workflows and improve consistency in decision-making;
- greater alignment of APVMA requirements with international standards and guidelines (such as VICH guidelines) and promote more efficient use of international data and technical assessments completed by equivalent trusted regulators; and
- improvements to the user portal and application management systems.

AMA would be pleased to work with the APVMA to identify needs and priorities for updated guidance to ensure that the most pressing needs are identified for action.

3. Avoiding unintended consequences

AMA recognises that the APVMA's activity-based costing (ABC) model has identified significant under-recovery in some application types. Scenario 1 models a 12% increase in application fees to address this. However, these fee changes are not evenly distributed across application types, with some fees effectively doubling (Item 1, 15, Module 3.1) or tripling (Item 11, Module 12.1, PAAs with meetings). In particular, there are significant increases in fees for application types that are predominantly used by companies to bring innovative new veterinary medicines to Australia, being Items 1, 2, 11,15 and level 1 & 2 modules, as well as finalisation modules. A staggered implementation of these fee increases would reduce the disproportionate burden placed on innovative applications.

AMA notes that the PAA fee increases may result in applicants failing to seek advice in order to minimise costs. The significant increases to PAA fees in scenario 1 could discourage use of this important service, and risks the loss of efficiencies associated with better quality submissions and early discussions with the regulator to clarify data requirements.

Timeshift applications include a mandatory PAA. Timeshift applications can deliver important timeframe savings, but considerably higher PAA costs may outweigh any benefits for applicants. It is noted that the rebate available from PAAs progressing to applications has also increased in line with the application fee increases, but the upfront costs remain considerably higher, with no benefit for applicants if a project does not proceed to an application for registration. AMA would suggest that the fee increases for PAAs are reconsidered to support applicant use and protect the efficiencies that the PAA mechanism delivers to the assessment process.

Scenarios 2 and 3

Scenarios 2 and 3 are not preferred by AMA. Both scenarios project over-recovery of costs in order to create a financial reserve to buffer against future revenue variability, and/or to fund unspecified operational and technical reforms. These endpoints may not be consistent with the government principles for cost recovery, which note that cost recovery charges should be closely linked to a *specified* activity.[4]

CRIS reports prepared by the Therapeutic Goods Administration (TGA) clearly demonstrate where costs are to be recovered from industry to fund specific projects (Figure 1). Similar

[4] Australian Government Cost Recovery Policy | Department of Finance

transparency in APVMA cost recovery proposals would be welcomed when additional funds are sought to support reform activities.

The table below summarises the increase to annual charges in 2023-24 to cost recover digital transformation investment.

Increase to annual charges in 2023-24	Digital Transformation	AEMS	Devices Digitisation	Total Increase
Medicines and biologicals	1.78%	0.46%		2.24%
Medical devices and IVDs	1.78%		1.23%	3.01%
Other annual charges i.e., manufacturing licences, OTGs	1.78%			1.78%

Figure 1. extract from TGA 2023-2024 CRIS[5]

Other issues

Move to annual CRIS cycle

AMA may be able to support some form of annual fee review, *provided* that it does not require greater resources to administer and it does not deliver large variations in fees. Significant engagement with the regulated industry will be required on the scope, process and timeline for an annual CRIS mechanism so that the implications of this policy change can be properly evaluated.

The CRIS notes that an annual CRIS cycle is considered to be 'best practice' as it more closely aligns predicted costs with actual expenditure. However the government cost recovery policy notes that expenses and revenue may be aligned over a longer period to reflect business cycles and external drivers (such as climatic conditions). AMA notes that the TGA reviews its fees and charges on an annual basis for the next financial year. Whilst acknowledging that the drivers of revenue and costs (and their volatility) for TGA and APVMA are different, the TGA model may be instructive for considering how an annual cycle could potentially operate for APVMA.

An annual CRIS cycle is intended to allow APVMA to be more responsive to short-term fluctuations in revenue or costs. Environmental conditions have considerable impacts on the use of agricultural and veterinary products and therefore, on APVMA revenue generated from sales levies. A shorter CRIS cycle may assist APVMA in managing this volatility in levy income.

However it is unclear how these intended benefits could realistically be delivered. There will continue to be a time lag between a change in environmental conditions being reflected in sales volumes, which then flow on to the levies payable. It is unclear how this would be accounted for in an annual CRIS cycle that will, unavoidably, always lag behind the environmental conditions that dictate levy income.

[5] Cost Recovery Implementation Statement 2023-2024 (tga.gov.au)

An annual CRIS cycle risks greater uncertainty and unpredictability for companies. Operational commitments for companies to register new products typically span several budget cycles (years) and predictability of fees is vital for effective and accurate financial forecasting to support current and future registrations. Regulatory budgets are generally set more than 12 months in advance, and company budget cycles may not align to the Australian financial year. Minimal lead-in times and significant changes to projected regulatory expenditure may result in delays to planned market entry and loss of product availability.

In principle, registrants would prefer smaller fee changes more frequently, rather than larger changes less frequently. However, AMA does not support a change to an annual CRIS cycle based on the information presented. AMA would welcome further discussion with APVMA and DAFF on this topic.

A properly funded regulator

AMA recognises the need for APVMA to be appropriately funded so that it can efficiently and effectively execute all of its regulatory and legislative obligations and responsibilities. Industry accepts a cost recovery arrangement to register and market its products in Australia.

Some historic policy settings used for the framework of APVMA cost recovery are now overdue for review. AMA would welcome the opportunity to discuss the policy settings for APVMA cost recovery, including:

- the 40/60 fee/levy split, and
- the balance between public (i.e. government) and industry-funded contributions.

AMA recognises that the government has a responsibility to provide APVMA with the appropriate and sufficient tools and resources it needs to carry out its job. Cost recovery approaches do risk cost-shifting, with activities that may more appropriately be publicly funded being shifted to a cost recovery framework. AMA considers that targeted investments in APVMA's infrastructure (such as IT systems) and capabilities (like providing in-house auditing), that are necessary to enable the APVMA to efficiently administer its regulatory functions, may be more appropriately publicly-funded.

Many important functions of the APVMA (post-market compliance, chemical review, government reporting obligations, providing policy advice) deliver public goods to provide community assurance on the safety and efficacy of chemicals regulated by the APVMA. These activities are considered to be essential for robust regulation, but do not provide direct benefit to individual registrants. The clear separation of compliance costs from industry funding would support public understanding and perceptions of APVMA's independence. AMA would welcome discussions with APVMA and DAFF on how the costs of these public good activities could be more fairly distributed between the public and industry.

Investments in 'necessary enabling, operational and technical reforms'[6] and cybersecurity upgrades to enable APVMA to do its legislated job more efficiently and effectively may be more appropriately publicly funded.

[6] CRIS, page 20

Greater transparency in determination of timeframes and fees

The determination of timeframes and fees remains opaque to industry. Whilst the CRIS identifies that a Department of Finance ABC model has been used, it does not provide clarity on how much work is required to be completed by APVMA for a specific application type. This makes it difficult to assess if the timeframes and fees assigned are a true reflection of the relative effort involved.

AMA notes that there are significant disparities between the cost of assessment modules, and the Preliminary and Finalisation modules, indicating a mismatch between costs and risk assessment. For example, a minor assessment task to change a site of manufacturing for a compendial active requires a Chemistry – Level 5 assessment (2 month timeframe, $541 fee under Scenario 1). However, when it is paired with the required Preliminary Assessment (no timeframe, $1061 under Scenario 1) and Finalisation modules (2-3 months timeframe, $1624 to $12,014 depending on module), this simple change takes 5-6 months and becomes very expensive.

Similarly, a change in manufacturing site can be processed through an Item 12 or an Item 13a application. Item 12 is a non-technical assessment ($2298 under Scenario 1, 3 month timeframe) and Item 13a Prescribed Variation ($179 under Scenario 1, 1 month timeframe). It is unclear why a *non-technical* assessment is so expensive.

Performance metrics

AMA supports APVMA to undertake further analysis of its 'business-as-usual' operations and workload in order to better determine a sustainable APVMA workforce and appropriate performance metrics for the future. AMA would encourage a focus on operational improvements to deliver efficiency benefits, such as identifying bottlenecks and redundant tasks in internal workflows.

Externally-reported performance metrics should enable the regulated community to assess the efficiency and effectiveness of regulatory activities and the value of their contributions to the regulatory system.

Implementation lead time

AMA notes that the implementation date of the new CRIS is intended to be 1 July 2025. However annual budgets for registrants are often set more than one year in advance and the budgets for 2025-26 have already been confirmed. AMA member companies include the local subsidiaries of major international companies with global operations and headquarters based overseas. They may be required to operate on internal budget cycles that do not align with the Australian financial year and have limited flexibility to make significant changes in their financial forecasts at short notice.

At a minimum, AMA would request that fees are confirmed *at least* 12 months prior to the intended implementation date.

Data protection

Registration of a veterinary medicine and its patterns of use provides the registrant with a period of market exclusivity through the provision of data protection periods. However the length of data protection associated with applications made under section 10 or section 27 of the Agvet Code[7] differs for agricultural products and veterinary medicines, even though the timeframes and fees payable are the same. There is no scientific justification for this disparity, which disproportionately disadvantages the registrants of veterinary medicines. AMA recommends that this disparity is corrected to provide equal data protection for both agricultural products and veterinary medicines.

Conclusion

AMA supports APVMA to be appropriately funded in order to efficiently and effectively carry out its legislative obligations and responsibilities. Industry accepts the need to contribute to an efficient and effective regulatory system that is predictable and consistent, equitable and provides a return on increased contributions from industry.

This CRIS presents three scenarios for future cost recovery, all of which include considerable increases in application fees and annual registrations. Scenario 1 is intended to deliver higher revenue for the APVMA but provide the same level of service in response. Scenarios 2 and 3 each involve additional cost recovery for unspecified investment in resourcing and infrastructure.

Scenario 1 is *conditionally* preferred by AMA, but we seek commitments by APVMA to deliver greater operational efficiencies, timeframe adjustments and improvements in guidance material in return.

The proposal to move to an annual CRIS cycle is of interest, but significant further engagement with the regulated industry is required to fully assess the implications of this policy change.

AMA looks forward to continuing to work with all stakeholders to ensure that the APVMA is efficient, effective and sustainably funded.

Please let me know if I can provide further information at any time.

Yours sincerely,

Ben Stapley

Executive Director

[7] Limitation periods – section 34M of the Agvet Code | Australian Pesticides and Veterinary Medicines Authority (apvma.gov.au)

ATTACHMENT 1

Application	Assessment Period (months)	Fee under Scenario 1 ($)	Fee / time comparison	Proposed Assessment Period[8]
Item 1	18	212,987	11,832/month	18 months
Item 2 (example)	17	162,001	9,529/month	17 months
Item 3	18	100,631	5,590/month	12 months
Item 4	18	53,796	2,989/month	8 months
Item 5	8	6,490	811/month	4 months
Item 6	8	6,964	870/month	4 months
Item 17	7	2,231	318/month	3 months
Item 18	7	2,598	371/month	3 months

As a means of comparison, the indicative fee under Scenario 1 is divided by the timeframe to get a unit cost per month.

Item 1 / Item 2 / Item 3 / Item 4

Item 1 is a full assessment of a new product containing a new active ingredient with a timeframe of 18 months. This represents the most complex type of application requiring maximum assessment of all parts. For veterinary products, Item 2 (modular assessment) is used preferentially over Item 1 as applicants only pay for the modules that are relevant to the application. The timeframe for Item 2 is nominally 17 months (length of the longest modular timeframe (13 months), plus 3 months finalisation (Module 11.1) and 1 month preliminary assessment).

Item 2 fees vary depending on the product type and the modules that are applicable. For example, a new veterinary product for a food-producing species with a new active ingredient would typically require modules Preliminary Assessment 1, Chemistry 2.1, Health 3.1, Scheduling 4.1, Residues 5.1, Environment 7.1, Efficacy and Safety 8.1, Finalisation 11.1 and Limits on use of information 12.[9] This example totals $116,501 with current fees, but would increase to $162,001 under Scenario 1.

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[8] Suggested AMA timeframe for adjusted application assessment periods. Timeframe is based on Item 1 as baseline (being highest/ most complex/detailed assessment item). Assessment timeframes for items 3, 4, 5, 6, 17 & 18 reduced to reflect lower quantum of assessment as indicated by application fee. An additional 3 months allowance for Item 3 & 4 reduced timeframe in recognition that comparison of quantum of work between categories is not linear.

[9] For a companion animal product, Residues (module 5) and Non-food trade (module 9) would not be needed, and some modules may be lower tiers (eg: Environment). An additional module (Module 10) is required if the product is an antibiotic or GMO.

Items 3 and 4 have the same 18 month timeframe as Item 1 (and very close to Item 2), yet the unit cost per month is significantly lower. If the fees have been set in proportion to the amount of work required to process a particular application type, then this indicates that less work is required to process an Item 3 or 4 application compared to an Item 1 or 2 application. It is therefore unclear why such a long timeframe has been applied to Item 3 and Item 4.

Item 3 / Item 4

An Item 3 application is for an approved active where there are no registered products containing that active. Scheduling and toxicology assessment is not required as the active is already approved.

Item 4 is for an approved active where there are registered products containing that active. Residues assessment is not required as the active is already approved.

The existence of previously registered products containing that active provides assurance to the APVMA and should enable a determination to be made more quickly (than if there were no examples already in the market).

The timeframe is the same for Item 3 and Item 4 (18 months), yet the comparison shows half the work is required for an Item 4 compared to an Item 3. An Item 4 could therefore have a timeframe roughly half that of Item 3.

Similarly, the comparison for Item 1 against Item 3 and 4 (all with an 18 month timeframe) reveals considerable differences in the unit cost. If the fees have been set according to the work that is required, then the Item 3 timeframe should be roughly half that of Item 1, and the Item 4 timeframe should be roughly one quarter of that for Item 1.

Item 5 / Item 6

Item 5 is an application for a product that is similar to a registered product. Item 6 is for a product that is closely similar to a registered product. Both items have the same timeframe (8 months).

The item descriptors indicate a difference in the data required for Item 5 and Item 6 applications, depending on how similar they are to an already registered product. The degree of difference between the application product and the reference product should be reflected in the amount of work required for APVMA to complete its assessments.

By definition, an Item 5 ('similar') is more different to its reference product than an Item 6 ('closely similar'), so an Item 5 should therefore theoretically require more consideration by APVMA. However the unit cost indicates that an Item 5 requires less work by APVMA than an Item 6.

Item 14 / Item 17 / Item 18

Item 14 (modular), Item 17 and Item 18 are frequently used to make minor changes to a registration, such as an extension of shelf life (Item 17) or minor variation of the active ingredient (Item 18). These changes may only have one small piece of additional data, such as a single additional timepoint in a stability series, a single study to support a new claim, or a reference to an updated pharmacopoeial monograph. A timeframe of 7 months for minor changes such as

these seems excessively long compared to the task required. In reality, the total timeframe for minor changes is 9-12 months after additional time for Preliminary Screening, Finalisation and s161 notices is included.

AMA suggests that minor changes could instead be managed according to the complexity of the change, as illustrated by the tiers of assessment modules where short (2-3 month) modules can be used for minor changes. A tiered approach would deliver welcome timeframe improvements for minor assessment tasks.

Item 24V

Item 24 is a modular application used to vary the relevant particulars for an approved active constituent. It is also used to *remove* manufacturing sites from a pharmacopoeial or non-pharmacopoeial approved active constituent record. This type of application is re-categorized as Item 24V in the portal.

No assessment is needed to *remove* a site of manufacture, meaning that only Module 1.0 ($902) and Module 11.3 Finalisation ($1,730; 2 months) are required. This generates a minimum timeframe of 3 months and fees of $2,632 (which increase slightly to $2,685 under Scenario 1).

This fee and timeframe seems disproportionate to process a simple variation that requires no technical assessment and poses no risks. AMA suggests that removing a site of manufacture from an active constituent record could more efficiently be managed as a Notifiable Variation ($50).

Chemistry modules

There are opportunities for important timeframe improvements in the Chemistry modules, which are particularly long relative to the assessment required. Chemistry module 1.1 is required for new veterinary products with new active ingredients (13 month timeframe). When a s159 notice is issued (which occurs more often than not), an additional 6 months is added to the timeframe, making the module timeframe 19 months. The timeframes for Chemistry variations are relatively long as well compared to the assessment required. AMA would welcome scrutiny of the Chemistry modules in particular to consider the efficiency of assessments and identify more efficient mechanisms to manage chemistry variations.