s 22 [redacted]

From: FOI Requests
Subject: FW: Questions
Attachments: Questions.docx

From: s 22 [redacted]@pmc.gov.au>
Sent: Tuesday, 23 March 2021 4:21 PM
To: s 22 [redacted]@pmc.gov.au>; s 22 [redacted]@pmc.gov.au>
Subject: Questions [SEC=OFFICIAL]

OFFICIAL

Questions

- What are the implementation timings?
- What are the challenges engaging with states and territories?
- Who are the key stakeholders?
- What is the view of the regulator?
- How can the Taskforce support this work?
- What the business benefits of the work?
- What are the social and economic benefits?

Opportunities

Following up an opportunity from DAWE about potentially observing international standards in relation to agricultural and veterinarian chemicals as a way for Australian businesses to access the latest chemical technology and processes in an affordable and timely way.

If we could identify a strong economic and social benefit, business impact it's worth supporting but as a deep dive

Risks and Sensitivities

This is more about streamlining the chemical registration process rather than removing duplication in Cth and State/Territory legislation.

Implementation pathway is unclear given that implementing this change is reliant on other reforms that have not yet been implemented or agreed and so the proposal is still fairly conceptual.

Compelling end user impact, strong alignment with reform rationale such as EVs and allowing international regulation to reduce the need for local, rigorous

Attendees

Julia Gaglia, Agvet Chemicals and Forestry Branch

s 22 Agvet Chemicals Legislation

s 22, Director, Agvet Chemicals Policy

s 22, Director, Overseeing the AgChem work

LICENCING TO ACCESS INTERNATIONALLY REGISTERED PRODUCTS

The independent review of Australia's regulatory system for pesticides and veterinary medicines (PVMs) has identified measures to remove unnecessary or duplicative regulation. One measure that would lend itself to a deep dive is licencing of internationally registered products for use in Australia.

What is the specific irritant from the perspective of business?

In advanced economies such as Australia, the USA, Canada and Europe, regulators approve PVMs based on a scientific assessment of a product and each of its proposed uses (e.g. each of the crops or animals it is used on and the pests and diseases it treats). These assessments consider matters such as the safety of the product for humans, animals, plants and the environment – and in many cases their effectiveness. The regulatory charges in Australia for these assessments are broadly comparable to those overseas; however, our market is much smaller. As a result, the economic viability of registering both products and uses is generally lower in Australia than overseas, and access to the Australian market is not always a priority for multinational chemical companies. This means that Australian agricultural producers and other users of PVMs often miss out on timely access (and sometimes any access) to new PVMs, and particularly PVM uses, compared to their overseas counterparts. This puts our producers at a competitive disadvantage compared to their overseas counterparts. Importantly, most of the assessments performed by Australian and comparable overseas regulators consider essentially the same matters.

The problem of PVM access was one of the major concerns raised by stakeholders during the review. Chemical users, particularly primary producers, have long seen it as a critical shortfall.

What is the possible reform?

The proposed reform would improve timely access to PVMs and their uses by leveraging approvals from comparable international regulators. This would involve a licensing scheme to allow importers and manufacturers, and potentially grower groups and other users, to supply certain internationally-registered PVMs in Australia subject to transparent conditions to manage any risks and requirements that are unique to Australia.

Importantly, the comparable international regulator will have conducted most of the risk assessment and approved the appropriate risk management controls. The licensee would develop a risk management plan to address any unique Australian risks and regulatory requirements (such as use in the Great Barrier Reef catchment and meeting Poisons Scheduling requirements). This plan would be assessed and approved (or rejected) by the Australian regulator, without the need for detailed scientific assessment of a full data package, as happens now. Risk management plans would also be subject to periodic audit by the regulator.

Sensitivities

The proposal is unique and innovative, however there is growing community concern about the use of chemicals in food production and the environment.

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Stakeholder concerns about the proposal centred on three areas:

- the potential impact on local chemical manufacturers and suppliers, including of generic versions of products
- reduced oversight by the Australian regulator (i.e. reliance on international regulatory decisions)creating reputational risk for Australian chemical companies and traded Australian produce
- that overseas assessments would not necessarily be applicable to Australian situations and how unique Australian circumstances would be managed.

These concerns are understandable given the significant change that the reform would represent. However, the proposal contains protections to ameliorate relevant concerns. For example:

- The regulator would assess and approve the risk management plans that address unique Australian circumstances, and periodically audit the licensee to ensure their suitability and compliance with the plan. Coupled with administrative, civil and criminal penalties, the pathway will have considerable rigour.
- The dual requirements for both international registration and active risk management by the licensee (with oversight by the regulator) will ensure the products are safe and suitable for use in Australia.
- These requirements will operate in parallel with obligations for work health and safety, dangerous goods, poisons, fair trading, gene technology, biosecurity and other complementary state and territory agriculture, health, and environmental laws.
- The proposal to make risk management plans publicly available would help provide confidence that all risks have been identified and are being satisfactorily managed.
- The licensing scheme would complement, not replace, the current registration scheme which would continue to be available through the APVMA. Both pathways would result in a safe and effective product being accessible in the Australian market.
- Some stakeholders have suggested that Australian-based producers of generic pesticide and veterinary medicine products would be disadvantaged by a licensing scheme as there may be no registered products to reference (generic products are registered on the basis of chemical similarity to a registered product). However, the proposal provides for internationally-registered generic products to be supplied under licence, and the future-state regulatory system could potentially provide for products supplied under licence to be referenced.

Key stakeholders

The key stakeholder groups to which the proposal is relevant include:

- manufacturers and distributors of pesticides and veterinary medicines
- users of pesticides and veterinary medicines (particularly farmers and veterinarians)
- environmental and community groups
- state and territory governments.

Individual chemical companies – both those with an Australian presence and those based entirely overseas – have told us that they would use the licensing pathway to introduce products that are not currently available in Australia (although this support is not universal, particularly among domestically-based companies). A major multinational chemical company with an Australian presence has indicated interest in piloting the scheme to help inform design and implementation.

Some user groups have also expressed interest in utilising the pathway to access uses not currently available to them.

Net benefit

Removal of regulatory duplication, costs, delays and in many cases, administrative burden that arise due to Australian regulatory assessment, will encourage manufacturers and importers to bring more products and uses to Australia and provide more timely access for users. This would provide Australian farmers and other end users with a greater range of pest and disease management solutions. This is important to address trade, safety, resistance and other risks.

The anticipated industry savings for product supply (and extended through to the product users) of not having to navigate the Australian registration system would be considerable. A conservative estimate anticipates industry savings in the order of $5.5 million per year – based on only 14 licences being issued over 10 years. There could be significantly higher industry interest in the approach, in which case the potential flow-on benefits for end users would far exceed this estimate.

In addition, licence holders will not be bound to conform to a 'one-size-fits-all' set of government-delivered tools for managing risks. Instead, licence holders will be able to put forward risk management arrangements that leverage and supplement relevant regulatory arrangements in ways best suited to their business and products. This will result in a more direct relationship between users and product suppliers which may result in a significant cultural shift in terms of shared responsibility, education and transparency. The ability to recognise alternative risk management solutions will also open up innovative approaches to meeting desired regulatory outcomes, including creative new business models for supplying pesticides and veterinary medicines to the Australian market.

There will be costs to participate in the licensing scheme for international products. However, these would be considerably less than Australia's current registration process and allow significantly faster access to much needed products in many cases. The scheme is voluntary (local registration will still be available), and costs therefore will only apply to those who wish to participate.

Licence fees are expected to be in the order of $2,500 per licence with similar costs payable for licence renewals, with any residual scheme costs collected through a levy on products supplied (similar levies apply to registered products). By comparison, the cost to the APVMA for assessing a new product with a new active constituent is in the order of $240,000 which is recovered from industry via upfront fees and levies.

Other factors yet to be considered

The proposal is still high level and conceptual. The ability to implement the measure is closely linked to other review recommendations, including for a single national PVM law at Commonwealth level (currently states and territories control PVM use and may not accommodate the use of products introduced under licence).

The proposal depends on equivalency assessments to determine which comparable international regulators produce equivalent outcomes for which classes of product. The APVMA already engages regularly with its international counterparts and so should have insight into this matter.

The specific administrative details of issuing licences, including any continued role for the states and territories, are expected to be established through the implementation process for the reform.

Primary research of stories from end users (some responses)

In response to the proposal, Ceva Animal Health, a global veterinary medicines company that manufactures in Australia and has a presence in 46 countries (including 25 production sites) said:

'*Ceva has struggled to obtain [Australian] registration for some of their global products which are registered in the EU and the US. Ceva commends the review for recognising that mutual recognition from leading overseas regulators is beneficial and for the proposal of the licensing system to allow sale of products which are approved overseas in Australia under licence*.'

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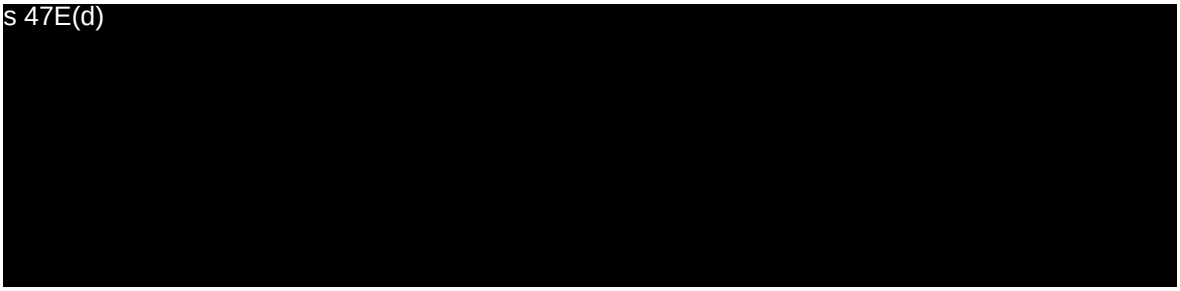

Internationally based companies Andermatt Biocontrol and Marrone Bio Innovations develop low-impact biological pesticides which are not currently available to Australian agricultural producers. Both companies indicated during consultations that they would explore using the licensing pathway to bring products to Australia. These novel products have lower human health and environmental impact than 'traditional' chemical pesticides. The lack of chemical residues in produce treated with these 'biologicals' would also greatly reduce risks to international trade in treated agricultural produce.

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The AgriFutures Australia confidential submission – a compilation of responses gained from grower industry members – included support from the honeybee and pollination industry:

This would help our industry if Varroa mite became established in our country to be able to access acaricides to help keep honeybee hives alive. We currently have a situation in Australia where a chemical used New Zealand for a particular purpose but not registered in Australia for that purpose is permitted in products from New Zealand, under certain trade agreements.

The Tasmanian Farmers and Graziers Association and ACCORD submissions to the draft report also supported the reform.