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SUBMISSION

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Consultation: Proposed changes to the regulation of exempt medical devices and exempt Other Therapeutic Goods

AMA response to TGA consultation

By email: devices@tga.gov.au

Introduction

The AMA is pleased to provide input to this consultation regarding proposed options for improvement to the current regulation of exempt medical devices and Other Therapeutic Goods (OTGs).

We commend the initiative to re-examine current arrangements for exempt medical devices and OTGs in response to external stakeholder feedback and a noted increase in the use of exemptions.

Consumer safety in the use of therapeutic goods must always be the key driver to implementing appropriate regulation that operates as intended. A robust regulatory framework should also pre-empt and mitigate against the risk of users misapplying or intentionally circumventing the system to remove barriers to manufacture and supply without adequate justification.

Among the issues cited in this consultation, the AMA considers identifying and engaging with sponsors of exempt therapeutic goods to be instrumental to ensuring both consistent regulation and to safeguard consumer safety in the instances exemptions are applied. The proposed changes acknowledge the importance of engaging with sponsors as agents who can contribute to building transparency and assurance in the regulation process.

It is appropriate to inquire on these measures now, acknowledging the anticipated increase to the use of exemptions in the context of a changed medical device regulatory framework. With this understanding of the economic conditions likely to stimulate increased utilisation of exemptions by smaller medical device manufacturers in particular, the AMA agrees the proposed changes are appropriate to build greater consistency and agility to the existing regulatory framework.

Proposed Options

The AMA supports and endorses the proposed measures, which the consultation demonstrates will contribute to a more consistent approach to obtaining and maintaining the data necessary to manage

effective regulation of exempt medical devices and exempt OTGs. The proposed changes effectively extend the regulatory obligations incumbent upon sponsors and suppliers while aligning with the legislated responsibilities of the TGA as the regulating body for exempt devices and OTGs under the *Therapeutic Goods Act 1989.*

These changes uphold the principle of exemption in the cases where pre-market approval by the TGA and/or Australian Register of Therapeutic Goods (ARTG) inclusion for a therapeutic good is not practical, while minimising sponsor's arbitrary exclusion and the risks that may pose to effective regulation.

1. Require notification of supply

The AMA broadly agrees that notifications to the TGA should be required for exempt devices and OTGs as an appropriate measure to enable the regulation of exemptions. The use of a uniform platform as a means for collecting notification data from sponsors is an effective approach to more consistent, current data. The targeted information to be collected regarding notification of supply is also relevant and appropriate to the purpose of regulation.

2. Publish information about supply

The AMA broadly agrees that information about exempt devices/OTGs required to notify the TGA of supply should be made publicly available. The changes proposed effectively enshrine transparency in the regulation of exempt medical devices and exempt OTGs. Public visibility of exempt goods and their sponsors should enable stakeholders like healthcare providers and sponsors alike to perform due diligence in ensuring compliance. We approve the information to be published under this measure is suitably aligned with the information supplied for medical devices listed in the ARTG.

3. Provision of information and samples

The AMA broadly agrees that sponsors of medical devices exempt under Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* and all OTGs exempt under Schedule 5 or Schedule 5A of the *Therapeutic Goods Regulations 1990* should be required to provide information about their product and/or a reasonable number of samples to the TGA upon request.

The AMA considers extending the TGA's authority to request further information and samples from sponsors registered under these arrangements to be proportional with the automatic conditions applicable to those items under the ARTG. It is also justified as an essential means of fulfilling the TGA's obligation to conduct post market activities to assure safety, quality and performance standards for exempt medical devices.

Exclusions

The AMA agrees with the application of the proposed changes to exemption categories detailed under Appendix A. We also note it is reasonable to exclude transitioning patient-matched medical devices from the requirement to publish, given they will be published once incorporated within the ARTG.

The AMA agrees with the exemption categories the TGA proposes be excluded from the outlined changes, both under the notification and publication requirements.

We note some particular categories captured in Appendix B and the appropriate grounds upon which they should not be effected:

- Special Access Scheme, supported by clinical justification through the medical practitioner or other health practitioner
- Devices/OTGs imported for the purpose of personal, singular or non-commercial use, such as the Personal importation scheme
- Samples of devices for particular uses like demonstration, audit, assessment already covered under TGA audit requirements
- Devices/OTGs to which a Prescription Medicines Authorisation applies, such as vapes and associated products
- Those devices/OTGs which are not made available to the public or to health providers, such as in-house IVD medical devices, and
- Those which feature as a limited exemption to address a time-sensitive supply issue or service persons visiting Australia for a limited time, such as a national or international sporting event.

We also note these measures uphold protection of individuals' private information and apply consistency between the requirements of publication only in cases where exempt goods warrant notification to the TGA.

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