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AMA submission – Review of TGA medicines and devices regulations

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The discussion paper released on 21 November 2014 covers a wide range of issues. This submission focuses on issues of most relevance to medical practitioners and their patients.

Independence and scientific rigour

The AMA supports the role of the Therapeutic Goods Administration (TGA), as the regulator of medicines and medical devices in Australia, to ensure that medicines and devices meet appropriate standards for quality, safety and efficacy.

It is important that Australia maintains its own independent regulator of therapeutic products, with local expertise, that is able to resist pressure from industry to approve products for use in Australia without sufficient scientific basis. This ensures medical practitioners can focus on treating patients, confident that the medicines and medical devices they use have passed stringent and independent assessment processes, rather than spend time undertaking their own research to ascertain the validity and scope of industry provided data.

TGA funding and focus

The TGA should receive sufficient funding to undertake quality use of medicines activities that complement its role in regulating the supply of therapeutic products in Australia.

Activities that allow the TGA to better pursue the quality use of medicines and devices should be publicly funded, with cost recovery from industry only applying to the regulatory processes associated with supplying a medicine or device in Australia.

There is a risk that if the current review results in a reduction in regulatory functions, and therefore a reduction in overall funding, the TGA will have insufficient resources to support important quality assurance work. The Government should ensure public funding is committed to these activities.

Access by patients to unapproved medicines under the Special Access Scheme

AMA members have not raised concerns with us about the current process for accessing unapproved medicines for patients.

Post-market vigilance and adverse event reporting

The AMA advocates for a comprehensive product vigilance system in line with international best practice.

The AMA therefore fully supports the range of initiatives implemented by the TGA over the last few years to improve post market vigilance systems, including:

- the ability to send an adverse event report directly to the TGA from their medical software desktop and populate the report using already entered data; and
- an early warning system to improve timely publicly available information about possible concerns about products.

Clinical device registries

The AMA considers the TGA's role in post-market regulation would be substantially strengthened by the introduction of more and relevant sufficiently resourced clinical implantable device registries. There is a clear role for the TGA to work with the specialty medical craft groups to develop or enhance implantable device registries to monitor device performance and to plan clinically appropriate and coordinated responses to device failures to the benefit of the Australian community.

The National Joint Replacement Register (NJRR) is a premium example of a clinical registry that collects and provides high quality data on the performance of joint prostheses, and is internationally renowned.

Implantable devices are likely to always have a failure rate. Clinical registries allow a robust assessment and comparison of devices, both in the short term and over longer time periods. They allow medical practitioners and the TGA to respond appropriately when there is a clear failure of a device that is beyond that of like products.

Clinical registries allow medical practitioners to identify problems early, respond appropriately in a coordinated manner and support clinical decisions about which devices are delivering the best patient outcomes in particular clinical circumstances.

Clinical registries need the capacity to record information to allow registry operators to track devices to individual patients in case device failure rates justify product recalls. We support the work undertaken on behalf of the Department of Health by the Australian Commission on Safety and Quality in Healthcare last year to develop a national patient contact protocol for the recall of high risk devices.

The AMA considers there is a clear role for government to maintain funding to clinical registries that are established and independently operated by the relevant medical specialties as exemplified by the NJRR model. We note that while the Commonwealth's costs of the NJRR are met by a levy on device suppliers, these costs are passed on to patients. We believe this is a cost that it is reasonable for the entire Australian community to share, rather than imposing it on those individuals whose lives have been saved or improved by medical devices.

Accelerated approval programs for higher risk medical devices

The discussion paper queries what additional requirements might be appropriate to alert clinicians to provisionally approved devices (if made available). It would be difficult to adequately manage risks to patients without the establishment of complementary systems such as those described above to monitor performance, and if necessary promptly withdraw devices and contact patients.

Registration of additional and/or different indications (currency of medicine product information)

The AMA has been raising concerns with the TGA about out-of-date medicine product information documentation (PIs) for some time.

The PIs for some medicines have not kept up with national clinical guidelines or established clinical practice based on systematic, evidence-based research, and this can have serious negative consequences for patients.

There is little incentive for sponsors of these medicines to apply to change the indications registered with the TGA, particularly when medicines have gone off-patent. The current regulatory environment, while intending to uphold patient safety, also creates barriers for medicine sponsors to update PIs.

Where evidence supports a change in clinical practice, PIs should be updated in a timely manner in consultation with relevant medical craft groups and pharmaceutical manufacturers.

The AMA acknowledges the TGA's current efforts to identify a range of solutions to address this problem in consultation with key stakeholders. It is important that these efforts continue.

Medicines scheduling and transparency

The AMA recommends medicines should only be up or down scheduled where there is strong evidence it is safe to do so, where there is demonstrated patient benefit and safety in dispensing the medication by this method, and where it would not adversely affect appropriate access to medicine.

The AMA urges that when submissions are invited on these matters being considered by the ACMS, that full information about the proposal or issue is made publicly available – that is, the same information available to the ACMS in making its decisions should be made available to stakeholders to inform their submissions.

It is difficult to develop a relevant submission when there is lack of transparency about the background, rationale and other potentially important evidence supporting the proposal. For example, there was no information released regarding the recent proposal to down-schedule oral contraceptives from Schedule 4 to Schedule 3 on the basis that it was 'confidential'. Information about the originator of the proposal, the basis/evidence on which the proposal was made, and the detail of how the submitter expected supply from pharmacists to be implemented was absent but important for guiding our submission.

Direct-to-consumer advertising and current regulations

The AMA is opposed to the introduction of direct-to-consumer advertising (DTCA) of prescription medicines into Australia.

DTCA of medicines may increase use, but not necessarily effective or rational use in line with quality use of medicines. While DTCA may potentially increase awareness of certain health conditions, medical and health services, and/or health-related treatments, its primary purpose is to increase demand and sales for the advertiser's product. The information provided to consumers/patients through DTCA is designed to persuade, rather than inform. DTCA may not provide the necessary balance and objectivity required for consumers/patients to make informed choices

The AMA notes the discussion about relaxing the regulation of DTCA of Schedule 3 medicines. Many of the concerns about DTCA of prescription medicines also apply to Schedule 3 medicines and there appears to be little benefit in changing current regulations.

The AMA supports the current regulatory framework requiring pre-vetting of medicines advertised directly to consumers.

The AMA's position statement on *Direct-to-consumer-advertising* at https://ama.com.au/position-statement/direct-consumer-advertising provides a more detailed rationale and references to studies supporting our position.

Regulation of low-risk therapeutic goods

The AMA considers that if products are making a therapeutic claim, they should fall under the regulation of the TGA.

The regulation of sunscreens in Australia poses an interesting example. The discussion paper notes that industry stakeholders argue that sunscreens in most overseas jurisdictions are regulated as cosmetics and therefore should not fall under therapeutic product regulation in Australia. However sunscreens in Australia are primarily marketed on the basis that they protect against skin cancer risk - the SPF factor is a key focus of marketing – because it is well documented that the risk in Australia of skin cancers from sun exposure is very high. While consumers in overseas countries may purchase sunscreens primarily for cosmetic purposes, this is not the case in Australia. The sunscreen industry sells sunscreens in Australia based on their therapeutic benefits and therefore should be regulated as such. Consumers should be confident that the products they buy in these circumstances are fit for purpose.

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