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AMA submission – TGA proposal for expedited pathways for prescription medicines

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

Under the current regulatory framework for the approval of prescription medicines, medical practitioners can focus on treating patients, confident that the medicines they prescribe 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.

The AMA's comments below are provided in this context.

Priority Review pathway

The AMA does not have concerns about the proposed Priority Review pathway which would prioritise the evaluation of novel prescription medicines that have a complete data dossier with a view to reducing the timeframe for a registration decision. The medicines submitted for registration under this pathway are underpinned by the usual standards of evidence.

Provisional Approval pathway

The AMA understands this pathway aims to allow seriously ill patients access to novel prescription medicines which have early promising data.

Given the higher risks inherent in early approval of these medicines, the AMA supports the proposed restrictive criteria for accepting an application under this pathway, that is, that the medicine would: treat life threatening or seriously debilitating diseases or conditions; address an unmet clinical need; and potentially provide a major therapeutic advantage.

The AMA has no comments to make on the application process itself, including the administrative aspects of the process, the publication of TGA decisions, the proposed exit triggers from the registration process, fees/charges, appeal avenues, etc. These are matters of interest primarily to sponsors.

However, the AMA does have concerns about what will happen after a medicine is granted Provision Approval, given the much higher risks involved in prescribing these medicines and the higher onus this will place on medical practitioners making decisions about appropriate and safe treatments.

The consultation paper only flags the possibility of 'enhanced post-market reporting and compliance measures' in passing on page 16 in one sentence under the section *Legislative and regulatory amendment*. There is also mention here that additional public consultation on the provisional approval pathway will be undertaken in 2017 prior to legislative changes. Perhaps post-market issues will be explored and proposals developed to deal with them at that time, but it is not clear from the consultation paper.

Considerable additional thought needs to be given to the following issues.

- How will the 'provisional registration' status of new medicines be clearly communicated to prescribers and patients so that they are fully informed about the inherent higher risks? - Will this be communicated on the medicine label, PI and CMI, and in other ways?

- Will the TGA actively, rather than passively, monitor 'provisional registration' medicines post-market? Will feedback from prescribers about adverse reactions and outcomes be actively sought?

- How will information collected post-market by the TGA about these medicines, such as reports about adverse reactions, be effectively communicated in a timely way?

- What processes will the TGA put in place to effect a withdrawal of Provisional Approval? What information/events would trigger a withdrawal, and how would the TGA manage this?

- How will patient expectations/confidence be managed if a Provisionally Approved medicine is withdrawn from market?

It would be useful for the TGA to describe how these issues are dealt with in Europe, the US and Canada where some form of conditional approval system is already available.

Expert advice

The consultation paper advises that TGA decisions will be informed in part by expert advice provided by an Advisory Committee for Medicines and a specialist advisory group. Given this, it is important that the composition of these groups is finalised and made public as quickly as possible so that we can be confident that they have a sufficient breadth and depth of expertise, for example, in day-to-day clinical practice as well as in pharmacology and research.

Post-implementation review

The AMA fully supports a review of the new pathways, once they are implemented. It is also important that the review does not only consider the administrative aspects of the application/registration process and the impact on sponsors.

A review should also evaluate the impact of the new approval pathways on prescribers and patients, and the effectiveness of post-market monitoring and compliance processes in providing early access to new medicines while minimising harm to patients.

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