MMDR consultation: Reforms and Operations
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

29 March 2017

Dear Sir/Madam

Medicines Australia welcomes the opportunity to provide comment on the proposals presented in the Therapeutic Goods Administration (TGA) consultation paper, *Consultation: Changes to accessing unapproved therapeutic goods through the Authorised Prescriber (AP) and Special Access Schemes (SAS).* Our detailed feedback and responses to the questions posed in the Paper follow below.

Our submission has been prepared with the expert input of Medicines Australia's Regulatory Affairs Working Group (RAWG). Members of RAWG are selected for their regulatory experience and industry knowledge, and bring a whole-of-industry perspective to the consideration of regulatory issues that stand to impact to our sector.

We would be happy to provide further comment on any aspect of our response (below).

Special Access Scheme Category B (SAS B) proposals

Medicines Australia and its member companies are broadly supportive of the proposals contained in the consultation paper that are aimed at enabling patient access to certain unapproved therapeutic goods via the SAS B access pathway through a notification scheme.

Medicines Australia agrees with the TGA's stated position, viz. that unapproved therapeutic goods should only be accessed in exceptional circumstances where goods on the ARTG are not clinically suitable for a patient. We also support the approach taken by the TGA, to put patients' interests first, by enabling rapid access to certain unapproved medicines where circumstances warrant.

We agree that the proposed criterion for including a particular medicine on the list of unapproved therapeutic goods is suitable, and we further agree that the factors to be considered in determining whether to include a medicine on the proposed list are appropriate.

We note the TGA proposal to initiate the process for listing an unapproved good as notifiable under SAS Category B, which will need to be enabled by legislative changes. In this case,

Sponsors should be given sufficient advance notice of a TGA decision to include a medicine on the proposed SAS Category B notification list, so that Sponsors can respond to any potential increase in demand for a medicine being supplied under the existing SAS Category B approval pathway.

Proposed on-line system

Concerning the questions on process improvements, we would wish to encourage the TGA to adopt an online scheme with standardised e-forms to support all aspects of management of the proposed system (application and reporting). In an ideal world this online system would be made available at the same time as the proposed changes to the scheme are implemented, but we would not wish for it to hold up the implementation of the other proposed changes, as this would delay the beneficial impact of the proposals on prescribers and patients.

We would urge the TGA to consult often and closely with all stakeholders, including Sponsors, in the design and implementation of an online system. An online system should minimise the need for health practitioners to repeatedly apply to the TGA for approval. In addition, the system should also benefit Sponsors by reducing the unnecessary administrative burden of processing SAS requests, in order to allow prompt supply and better reporting.

To further reduce unnecessary regulatory burden for Sponsors, the online scheme should be able to be used to support real time notification of supply decisions and eliminate the current six (6) monthly report requirements. From a Sponsor perspective, this would simplify logistics. For example, it would close off actions as part of the initial supply process rather than retrospectively creating a six monthly report. From a benefit/risk perspective, this means that if there were a major safety issue or recall etc., the TGA would have immediate visibility of parties who have received supplies rather than having to contact Sponsors to request that information.

The system would also, ideally, allow prescribers to directly send requests to Sponsors for supply consideration via an alert to a company email or via the eBS portal, for instance. If designed appropriately, Sponsors and the TGA will benefit from access to a common archive of SAS requests and supply decisions. The ability for Sponsors to generate reports of requests and supply should also be included as a feature of any new system.

In relation to the question posed in the paper regarding the on-line system being exclusively on-line, we note that not all Australians can access the internet quickly and efficiently and we therefore suggest that the TGA consult closely with other relevant Australian government departments, and the Australian Digital Health Agency.

We welcome the commitment in the paper to conduct further targeted consultation regarding the on-line system, and we look forward to being involved in it.

Comments on the plan to communicate changes and some practical considerations

The TGA has sought suggestions on additional measures to make stakeholders aware of the SAS Category B notification scheme, as well as therapeutic goods on the list. Whilst we support the proposal to streamline access to these SAS Category B medicines, we are mindful of the high number of requests already received by the TGA (>20,000 per year) and the potential impact that a broad communication plan by TGA may have on the uptake of the scheme by a wider group of prescribers. We recommend that the TGA confer with Sponsors, state health systems and prescriber bodies/colleges to ensure that any communication around the changes do not inadvertently trigger a sudden increase in demand for an unapproved good through the SAS, or place any undue administrative burden on Sponsors.

Also, as the proposed changes will significantly transform the way existing users operate, the need for effective change management, training and on-going support to ensure a seamless transition should not be underestimated. Medicines Australia would recommend the TGA incorporate learnings from the successful rollout of the Medicines Shortages Initiative, which is also based on an electronic portal. The rollout included training and roadshows conducted by the TGA to raise awareness with stakeholders and this approach worked well.

Thorough testing of the new on-line system by all stakeholders before the system goes live is critical, especially with the volumes of transactions that will occur. The difficulties experienced with the introduction of the on-line CTN serve to highlight the challenges of change management when moving from a well-established system with a diverse set of stakeholders into an on-line environment.

Authorised Prescriber Scheme

Medicines Australia supports the TGA proposals to modify assessment of Authorised Prescriber applications, as to some extent this will result in a similar approach to the one already adopted by the TGA in relation to engagement in clinical trials in Australia. We are also supportive of the proposed changes in the duration of the AP approval, acknowledging the reduction in regulatory burden on applicants.

Medicines Australia would be happy to share with the TGA the opportunity to consult with the MA/MTAA (Medical Technologies Association of Australia) R&D Task Force which comprises a number of clinical trials experts drawn from across the clinical trials sector. This would be one way to ensure that TGA guidance and communication in this area and the role of the colleges and HREC's (Human Research Ethics Committee) is appropriately considered.

Compliance framework

We agree that an enhanced compliance framework will be critical to the effective implementation of the proposed changes to the SAS and AP schemes. We note that the TGA claims to have received a number of notifications under SAS Category A, for which it states the SAS Category B approval pathway may been more appropriate. This highlights the need for robust compliance measures to be built into the proposed system to ensure that:

1. the appropriate SAS route is used by prescribers and

2. unapproved medicines are supplied by Sponsors in accordance with legal requirements.

We agree that a standardised template, as proposed in the consultation paper, should help prescribers and sponsors comply with their statutory and regulatory requirements. The new system should also be capable of validating SAS requests from prescribers to ensure they use the correct SAS pathway. To effectively achieve this, we again recommend that the TGA consult closely with stakeholders on the design, pre-production testing and comprehensive planning of implementation of the online system.

Concluding comments

Medicines Australia supports the proposed changes to the SAS and AP Schemes to streamline access to unapproved therapeutic goods and create efficiencies for all stakeholders, to ensure patients gain timely access to potentially life-saving and/or life-changing medicines. We strongly recommend establishing a dedicated consultative group of external stakeholders to assist the design and be involved in pre-production testing to ensure the new framework and online system meets the needs of all stakeholders. The system should also be piloted to ensure it does not shift unnecessary administrative burden to any particular group of stakeholders. An enhanced monitoring and compliance framework will also help ensure that patient access under the SAS proposals meets all statutory requirements.

We would welcome the opportunity to be included in any further and ongoing TGA consultations on the SAS and AP Schemes.

Yours sincerely

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