The Australasian College of Dermatologists – Submission to the Therapeutic Goods Administration

Consultation: Changes to accessing unapproved therapeutic goods through the Authorised Prescriber (AP) and Special Access Schemes (SAS)

March 2017

The Australasian College of Dermatologists welcomes the findings of the Review of Medicines and Medical Devices Regulation (MMDR Review) and applauds the Therapeutic Goods Administration (TGA) on its plans to implement Recommendations 24 – 26. Briefly, these recommendations relate to improving the access to unapproved therapeutic goods by a) establishing a notification process for certain Special Access Scheme (SAS) Category B goods, supported by transparent criteria for identifying suitability; b) establishing an integrated, online system to manage SAS notifications, approvals and reporting; and c) reducing the role of the TGA in assessment of Authorised Prescriber (AP) Scheme applications.

The College is of the view that the proposal for implementation of these recommendations is sound. The current application processes are ponderous and can create unnecessary administrative delays in patient management. Given that many SAS-B applications are for the renewal of previous applications or are for therapeutic goods which commonly receive approval through this scheme, a means of streamlining access is in the interest of patients, health care professionals and regulators. A notification system for SAS-B would seem appropriate for therapeutic goods that meet the proposed criterion.

In response to the specific questions outlined in the Consultation paper, the College is pleased to provide the following feedback.

Is the proposed criterion suitable for identifying unapproved therapeutic goods that are suitable for notification? Are there any amendments to the proposed criterion that would enhance the process?

The proposed criterion of '*Unapproved Therapeutic Goods that have an established history of use for a given indication/intended purpose*' appears appropriate for identifying unapproved therapeutic goods and their indications that are suitable for notification. With respect to how this criterion could be met, further information should be provided regarding the definition of 'significant safety concerns' (page 7). Thalidomide is an example of a medication with an adverse safety profile, but with appropriate monitoring and registration of providers, it can be appropriately prescribed to patients where there is an otherwise unmet need.

The proposed minimum details to be included on the list of medicines and biologicals should also ideally list trade name and manufacturer, in addition to the name of the active ingredient, indication/s and dosage form.

Correspondence with stakeholders and craft groups regarding suitable therapeutic goods is recommended. The College looks forward to reviewing the list of possible medicines for

dermatological use, which could include thalidomide (SAS-B), fumaric acid esters (SAS-B) and clobetasol propionate (AP). The proposed system has the potential to improve access to 'older' drugs that have been utilised in a small number of patients – in dermatology this would include thalidomide and fumaric acid esters; AP status for agents such as clobetasol (approved in many jurisdictions, but not Australia); new agents being evaluated and already approved by FDA or EMEA, such as ixekizumab; or approved agents for new indications, such as adalimumab for hidradenitis suppurativa.

The statement on Page 7 of the Consultation paper '…TGA would determine which goods to include on the notification listing based on the agreed criterion. This decision will not be appealable' appears severe, especially in light of the previous statement on Page 6: 'this list can be updated periodically...as needed in a timely manner.' However the College deems it acceptable that manufacturers should not be able to appeal any decision.

There is some concern that the TGA is abdicating responsibility as evidenced by the comment 'The TGA presumes that prescribers of unapproved therapeutic goods have appropriate knowledge…and are therefore in the best position to understand all relevant literature and the needs of the patient. The prescriber is responsible for prescribing the therapeutic goods and has a responsibility to ensure that goods prescribed to the patient have a favourable risk/benefit profile.' It is beyond expectation that an individual clinician will have the resources to undertake the type of review of all relevant literature – preclinical and clinical – which would be a reasonable undertaking by the TGA.

In addition to publishing the notification listing on the TGA website, how else could we make stakeholders aware of what therapeutic goods are on the SAS Category B notification list / changes to the SAS B scheme / roles and responsibilities for the Authorised Prescriber Scheme?

Communication of any change relating to notification listings and changes to SAS-B and AP can be undertaken by direct mail / email through AHPRA and medical colleges to their membership.

There is some additional concern that shifting of responsibility to medical colleges will occur as highlighted in the following statement on Page 8:

'The TGA will no longer need to approve the clinical justification for use of products, instead we will rely on the HREC/college expertise, which will improve the efficiency of the scheme. TGA assessment of the AP application will be limited to:

- ensuring that no other available goods on the register could act as an alternative; and
- confirming HREC or specialist college endorsement is provided, including a declaration that all necessary documentation has been reviewed; and
- there are no safety concerns with the product.'

It is unclear how compliance would be monitored in this case and while efficacy will be improved for the TGA, the potential for additional burden on colleges and HRECs should be considered.

What information is required to assist in complying with the SAS and AP Schemes? Would it be useful to have a standardised template for reporting to assist in complying with the TGA requirements?

A standardised reporting template would assist with compliance. Further information and clarification is sought on the proposed process for monitoring of compliance, which should provide feedback and guidance and not be punitive. Prescribers should be informed if they fail to adhere to guidelines.

What are your views about moving solely to an online system for SAS and AP Scheme applications and notifications? Is there a time by which you think a paper-based system would no longer be needed? Would integration into existing clinical software systems (such as prescribing and dispensing) be an important element of the new process?

An online system is welcomed, although there will be times and circumstances where such a method will not be applicable and retention of the paper-based system as a back-up should be considered. Incorporation / integration with existing clinical software systems, particularly prescribing software, is to be welcomed however as there are multiple systems the feasibility of this task should be fully assessed.