9 January 2015

Review of Medicines and Medical Devices Regulation Secretariat
Department of Health
MDP 67
GPO Box 9848
CANBERRA ACT 2601

Via email: medicines.review@health.gov.au

Dear Sir/Madam

RANZCO Submission – Review of Medicines and Medical Devices Regulation

The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) appreciates the opportunity to provide comments in response to the Expert Panel Review of Medicines and Medical Devices Regulation in Australia.

RANZCO's mission is to drive improvements in eye health care in Australia, New Zealand and the Asia Pacific region through continuing exceptional training, education, research and advocacy. Underpinning all of RANZCO's work is a commitment to: best patient outcomes; providing contemporary education, training and continuing professional development; evidence based decision making; collaboration; and collegiality. RANZCO also seeks to educate the general public in all matters relating to vision and the health of the human eye and advocates for accessible ophthalmology services for patients.

RANZCO's responses to the questions posed in the discussion paper are set out below - there are some aspects of the paper on which we are unable to comment. The College's primary interests in relation to the regulation of therapeutic goods relate to patient safety, timely patient access to medicines, stable supply, appropriate red tape for use of unapproved products and incentives for sponsors to register medicines for niche ophthalmic indications.

CHAPTER 4 - Regulation of Prescription medicines

RANZCO supports proposals for fast tracked approvals where assessments of medicines not registered on the Australian Register of Therapeutic Goods (ARTG) have already been undertaken by the United States Food and Drug Administration (FDA) and/or European Medicines Agency (EMA). The College agrees that assessment by the Therapeutic Goods

The Royal Australian and New Zealand College of Ophthalmologists ACN 000 644 404
94 - 98 Chalmers Street, Surry Hills NSW 2010 Australia
T 61 2 9690 1001 F 61 2 9690 1321 E ranzco@ranzco.edu
ranzco.edu

Administration (TGA) in such circumstances is unnecessary, duplicative and creates a barrier to timely patient access.

Theme 1 - Duplication of regulatory processes

Issue 1

In terms of the mechanisms to ensure rigorous assessment of medicines as proposed on page 17 of the discussion paper, it is sensible to set transparent criteria which overseas regulators would be assessed against before being designated as a 'trusted overseas regulator'. The criteria should capture the rigour of existing FDA and EMA drug and device approval processes which assess applications against robust clinical trial evidence and manufacturing standards.

If any 'trusted overseas regulator' approves a drug it should be approved in Australia. Conflicting assessments by regulators who satisfy the criteria for being a 'trusted overseas regulator' should not trigger TGA assessment - this may defeat the purpose of determining a regulator as 'trusted'.

In the interests of efficiency, RANZCO believe a TGA review may not be necessary in all circumstances where a trusted regulator rejects an application for a medicine registered in Australia. As proposed in the discussion paper, the TGA should assess whether a review is needed or not in light of the reasons why the application was rejected and whether these are relevant to quality, safety and efficacy in the Australian context. Aspects of safety, quality and efficacy could also be considered as part of scheduling discussions rather than via a full assessment of the application.

TGA review of any safety warning issued by a 'trusted overseas regulator' for an Australian approved drug should be mandatory.

Issue 2

RANZCO is supportive of requiring sponsors to submit Australian specific Module 1 of the Common Technical Document (CTD) as described on page 18 of the discussion paper). There are important benefits for clinicians as it provides valuable prescribing information for prescribers and patients, country specific details for labelling, and dosing instructions which should be consistent with the Australian context.

The Royal Australian and New Zealand College of Ophthalmologists ACN 000 644 404
94 - 98 Chalmers Street, Surry Hills NSW 2010 Australia
T 61 2 9690 1001 F 61 2 9690 1321 E ranzco@ranzco.edu
ranzco.edu

Issue 3
RANZCO agrees that where an application is changed (e.g. contains additional indications to that approved overseas) the TGA should limit reviews to only those aspects of the application that are different, to avoid duplication of assessment. The scope of a review of a changed medicine should be dependent on the change and its impact on safety, quality and efficacy.

With regard to accelerated approval processes, we believe the TGA should exercise its own caution in relation to conditional/provisional approvals. As these approvals are based on more limited clinical data, the TGA should undertake its own assessment and as a result impose the most suitable marketing conditions and provisions for the Australian context.

Theme 2 - Lack of flexibility required to facilitate early access to innovative products

RANZCO agrees with sentiments that Australia should implement accelerated approval programs. The process is welcome given the abundance of niche indications in ophthalmology. RANZCO is unable to compare and comment on the costs and benefits of the EU and FDA programs.

Medical Colleges can play a role in alerting prescribers to provisional approval and its implications. Existing TGA mechanisms that assist with recalls could manage withdrawals of provisionally approved medications.

Theme 3 - Regulatory requirements are not commensurate with risk

Issue 3
The practice of ophthalmology is at present markedly reliant on the availability and timely access to unapproved medicines through the TGA's Special Access Scheme (SAS) and Authorised Prescriber Scheme (APS). This arises primarily because the cost of registering a product is in the vicinity of several hundreds of thousands of dollars. This is appropriate for products which will make significant profit, however it is prohibitive for some others, such as many ophthalmic drugs which apply to niche indications. There are often multiple drugs for niche indications but they are not financially viable for sponsors to get registered. Sometimes the best drug for a particular indication is unavailable in Australia.

RANZCO has recently worked with the TGA to create clinical practice guidelines for the use of triamcinolone, due to the high volume of requests under the SAS for the supply of preservative free triamcinolone (Triesence) being received by the TGA. Between 1 January 2013 and 18

The Royal Australian and New Zealand College of Ophthalmologists ACN 000 644 404
94 - 98 Chalmers Street, Surry Hills NSW 2010 Australia
T 61 2 9690 1001 F 61 2 9690 1321 E ranzco@ranzco.edu
ranzco.edu

November 2013, the TGA received and approved 1904 SAS (Category B) applications for triamcinolone, in anticipation of 2150 applications for the full 2013 calendar year.

Other ophthalmic products with high numbers of SAS applications for the full 2013 calendar year (the TGA's predicted numbers are in brackets) were: riboflavin eye drops - all strengths and suppliers combined (950); cyclosporine ophthalmic emulsion (560); dexamethasone eye drops (400); sodium chloride hypertonic ophthalmic solution (360).[1]

Whilst the APS reduces the administrative burden on both the ophthalmologists and the TGA (as compared to the SAS) to access triamcinolone; RANZCO recognise there is the risk that a product could, in effect, achieve de-facto marketing approval, which would remove any incentive for the sponsor to seek registration of the unapproved product.

RANZCO acknowledge that the SAS was set up for experimental drugs use and not the high volume of applications received for ophthalmic drugs, and would be very interested to participate in any discussions advocating an avenue for drugs for niche indications to be affordably registered, particularly so that costs are not unfairly passed on to patients.

The current situation results in an excessive paperwork burden on ophthalmologists as well as the TGA. It would be worthwhile for the TGA to implement electronic approvals and any other similar efficiencies, particularly where the prescribing risk for the unapproved medicine is low. The proposal of an online portal and use of smartforms on page 30 of the discussion paper would be welcome.

Issue 4

In the interests of improving medication safety and encouraging transparency, RANZCO are supportive of enhancing post-marketing surveillance through the analysis of existing data sets and the development of new data sets. The Fight Retinal Blindness! audit set in Australia and the American Society of Retinal Specialists Therapeutic Surveillance Committee's collection of post-marketing data are useful examples. .

<u>Theme 5 - Overly burdensome processes</u>

Issue 1

RANZCO Fellows find the paperwork relating to SAS and APS approvals (as described above at Theme 3) most burdensome.

[1] Email correspondence between RANZCO and the TGA, 18 December 2013

The Royal Australian and New Zealand College of Ophthalmologists ACN 000 644 404
94 - 98 Chalmers Street, Surry Hills NSW 2010 Australia
T 61 2 9690 1001 F 61 2 9690 1321 E ranzco@ranzco.edu
ranzco.edu

The TGA website is also difficult to navigate and should be revised to be more intuitive. Many links either indirectly lead to valuable information or directly lead to old/archived information.

Issue 2
RANZCO believe current regulatory requirements, cost and timeframes act as a disincentive to the registration of additional indications for medicines. One avenue that should be explored is to enable Medical Colleges to submit literature-based submissions with the TGA's assistance and advice.

CHAPTER 5 – Regulation of Generic medicines and Biosimilars

The RANZCO responses provided above in relation to determining trusted overseas regulators etc. are applicable to those repeated questions in this chapter.

The barriers for generic companies to enter the Australian market should be reduced. Ophthalmologists in Australia currently have a very limited antibiotic range available due to shortage issues and vulnerabilities built into the regulatory system. This could be alleviated if there were incentives in place for generic companies to supply niche presentations, instead of focussing on high volume products as they do presently. This would also increase the alternatives available when recalls or shortages effect the market. Currently a shortage event means patients don't have access to any alternative, or are relying on small manufacturers who are unable to match supply with demand.

CHAPTER 6 – Regulation of Over-the-counter Medicines

<u>Theme 1 - Regulatory requirements are not commensurate with risk</u>

Issue 1
RANZCO supports the use of a formal methodology for assessment of risks and benefits to inform scheduling decisions and improved transparency. It important for observational data to accompany clinical trial evidence as part of this methodology.

Scheduling decisions must also be made with appropriate medical oversight to avoid over-treating of 'suspect' patients, and even more worryingly under-treating others, by non-medical professionals who have had limited/no time in clinics managing patients. This has implications in terms of costs to the patient, healthcare budget and exposure of patients to potential risks of therapy.

The Royal Australian and New Zealand College of Ophthalmologists ACN 000 644 404
94 - 98 Chalmers Street, Surry Hills NSW 2010 Australia
T 61 2 9690 1001 F 61 2 9690 1321 E ranzco@ranzco.edu
ranzco.edu

Scheduling decisions also have drastic implications for supply, and can lead to shortages such as is the current case for chloramphenicol (Schedule 3). Chloramphenicol has been out of stock for a large part of 2014. It is used in most cases in Australia as a prophylactic antibiotic against endophthalmitis, a devastating ocular infection that may follow intra-ocular, surgery or trauma. RANZCO have first-hand experience of the inadequate arrangements presently in place for management and resolution of medication shortages.

The number of patients treated may be small but the risks to patients are high if prescribing is extended beyond the medical workforce.

Issue 2
Refer to RANZCO comments on direct-to-consumer advertising under Chapter 8.

CHAPTER 8 – Framework for Advertising Therapeutic Goods

Issue 1
RANZCO opposes advertising of prescription and Schedule 3 medicines to the general public. The risks created by direct-to-consumer advertising (DTCA) are well-documented.

The Australian Medical Association's position statement on *Direct-to-Consumer Advertising (2007)* states the following risks:

- 'DTCA is unlikely to be broad, balanced and inclusive'
- 'DTCA may be designed to persuade rather than inform', and 'may not provide the necessary balance and objectivity required for consumers/patients to make informed choices'
- There is a 'very real potential for DTCA to undermine patient autonomy and the doctor-patient relationship'
- DTCA 'can create unnecessary stress and worries in otherwise healthy patients, increase demands by patients for medicines that are inappropriate for them, unnecessarily increase healthcare costs, and undermine quality use of medicines.'[2]

Issue 4
RANZCO lodged a complaint in 2013 with the Therapeutic Goods Advertising Code Council regarding online advertisements for eye-drops that purported to treat cataracts and glaucoma. Cataract surgery is the only recognised treatment for cataracts and the eye drops for glaucoma contained no ingredients to lower intra-ocular pressure (IOP) – lowering IOP is the

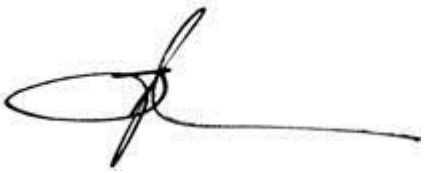
[2] Australian Medical Association (2007) Direct-to-Consumer Advertising <https://ama.com.au/position-statement/direct-consumer-advertising> [accessed 12 December 2014]

The Royal Australian and New Zealand College of Ophthalmologists ACN 000 644 404
94 - 98 Chalmers Street, Surry Hills NSW 2010 Australia
T 61 2 9690 1001 F 61 2 9690 1321 E ranzco@ranzco.edu
ranzco.edu

only recognised way of minimising progressive sight loss caused by glaucoma. The complaint was lodged in July 2013, considered by the relevant TGACC committee in November and the matter closed with RANZCO in July 2014. If the TGACC is ultimately the chosen authority for receiving complaints about advertising and marketing of therapeutic products, its responsiveness must drastically improve in the interests of patient safety. Such advertisements and products dangerously delay the need to seek professional advice and approved treatment.

RANZCO is willing to provide further advice in regards to the issues raised in this submission. Should you require any further information, please contact RANZCO Policy Officer, Ritu Mohan at rmohan@ranzco.edu.

Yours sincerely



Dr Brad Horsburgh
RANZCO President

The Royal Australian and New Zealand College of Ophthalmologists ACN 000 644 404
94 - 98 Chalmers Street, Surry Hills NSW 2010 Australia
T 61 2 9690 1001 F 61 2 9690 1321 E ranzco@ranzco.edu
ranzco.edu