The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Excellence in Women's Health

Submission

Potential refinements to the new regulatory framework for personalised medical devices

Thank you for inviting the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) to make a submission to the Department of Health, Therapeutic Goods Administration (TGA) on the *Potential refinements to the new regulatory framework for personalised medical devices.*

RANZCOG is the lead standards body in women's health in Australia and New Zealand, with responsibility for postgraduate education, accreditation, recertification and the continuing professional development of practitioners in women's health, including both specialist obstetricians and gynaecologists, and GP obstetricians.

The *Therapeutic Goods (Medical Devices) Regulations 2002* were introduced in February this year, stipulating a new framework for the regulation of medical devices that are designed and manufactured for individual patients. RANZCOG would like to provide the following specific feedback to the questions raised in the consultation.

Exclusions

1. *Do you agree with the rationale for the proposed exclusion of products? If not, why not?*

   Yes, RANZCOG agrees with the rationale for the proposed exclusion of products.

2. *Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA? Please explain your response, including by providing examples that illustrate and/or support your position.*

   RANZCOG notes that, in a gynaecological context, some of the typical products that are used are a vaginal ring pessary and other intravaginal devices for uterovaginal prolapse and urinary incontinence in women. It is RANZCOG's opinion that such devices need not necessarily be on the ARTG and could be excluded, if the manufacturer provides evidence of safe processes.

   Moreover, monitoring of potential complications is the responsibility of the health provider inserting the product. For instance, complications such as vaginal ulceration may occur as a result of the pressure created by using a device that is too large, particularly if the vaginal mucosa is inadequately oestrogenised e.g. menopause. The appropriate size of the device to be inserted is determined by a practitioner.

3. *Are there further products that meet the principles proposed for exclusion? What are they and why should they be excluded?*

   Please provide an explanation for why:

   - *the product represents no, or insignificant levels, of risk; or*
   - *the product does not meet the definition of a medical device.*

   No other products to be specified.

Exemptions

4. *Do you agree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?*

   Yes, RANZCOG agrees with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices, when produced under the circumstances listed in this consultation paper.

5. *Can the risks posed by the Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in this consultation paper be adequately managed if they are exempted from inclusion in the ARTG? Please explain your response, including by providing examples that illustrate and/or support your position.*

   It is RANZCOG's view that the risks of Class 1, non-sterile, non-measuring devices can be adequately managed, if exempted from inclusion in the ARTG, as the healthcare provider will be aware of the risks. In addition, the risks or complications reflect patient factors e.g. menopausal status, other morbidities and/or the assessment by the practitioner e.g. pessary size, rather than by the product itself. However, the healthcare provider is able to request a product safety recall system, for devices such as vaginal ring pessaries.

6. *Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt? If so, what measures are in place to manage the risks associated* with the devices?

   Please provide details:

   - *describe the specific circumstances that are in place (such as qualifications, accreditation, certification, etc) to ensure that the risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have been met before they are supplied.*

   No, RANZCOG does not have further gynaecological circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempted.

Inclusion in ARTG using alternative conformity assessment procedures

7. *Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?*

   Yes, RANZCOG agrees with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched devices, when produced under the circumstances listed in this consultation paper.

8. *Do you agree that the risks associated with the proposed Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper could be adequately managed through the proposed alternative conformity assessment procedure? Please explain your response, including by providing examples that illustrate and/or support your position.*

   Yes, RAZCOG is of the view that the health practitioners will review, follow-up and medically manage a woman whose complications arise as a result of insertion of a gynaecological device.

   In addition, it is proposed that a safety recall system to be in place or to maintain a log of devices inserted for long-term users.

9. *Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate? If so, what measures are in place to manage the risks associated with the devices?*

   No, RANZCOG does not have further circumstances to specify.

10. *Are there any Class IIa patient-matched devices that should not be subject to an alternative conformity assessment procedure? What are they and why not?*

    No, there are no further Class IIa patient-matched devices to specify.

General question

11. *Are there alternative mechanisms for reducing the regulatory burden for patient-matched medical devices without compromising patient health and safety that you would like to propose?*

RANZCOG is of the view that simple safety mechanisms can reduce regulatory burden e.g.health practitioner logbooks, data bases of patients with long-term devices, or recall systems by practitioners.

Yours sincerely,

Dr Vijay Roach
President