Supporting Nurse Practitioners through advocacy resources, networking and professional development

Australian College of Nurse Practitioners response to:

AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH
Therapeutic Goods Administration

Potential refinements to the new regulatory framework for personalised medical devices

[redacted]

14th July 2021

Australian Government Department of Health
Therapeutic Goods Administration
Personalised Medical Devices Team

By email: personalisedDevices@health.gov.au,
personaliseddevices@tga.gov.au.

Dear Personalised Medical Devices Team,

Thank you for the opportunity to provide a response to proposed refinements to the regulation of personalised medical devices.

The Australian College of Nurse Practitioners (ACNP) is the national peak organisation for Nurse Practitioners, advancing nursing practice and consumer access to health care. We actively seek opportunities to contribute to improvements to safety, quality and access to health care.

Please see below for comments relating to the consultation from the Australian College of Nurse Practitioners.

EXCLUSIONS

1. **Do you agree with the rationale for the proposed exclusion of products? If not, why not??**
   ACNP Response – Yes, we agree

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.**
   ACNP Response – Yes, the considerations for/against exclusion are appropriate, especially in regard to the potential for harm, or where other regulatory controls exist.

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
   ACNP Response – None we are aware of

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?**
   ACNP Response –Yes

[redacted]

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.
   ACNP Response –Yes, provided if there is a change in alternative mechanisms for oversight that the exemption can be reviewed

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.
   ACNP Response – none we are aware of

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?**
   ACNP Response – Yes

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?**
   ACNP Response – Yes, provided again, that there is a process to follow should the alternative mechanisms change, or the circumstances supporting the self-assessment and declaration change.

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?**
   ACNP Response – None we are aware of

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?**
    ACNP Response – None we are aware of

[redacted]

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?**
ACNP Response –No

Thank you again for the opportunity to participate in this vitally important review. I would be happy to discuss our responses further, and we look forward to participating in any further consultation.

Yours sincerely

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[redacted]
Australian College of Nurse Practitioners
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