SA Health RSS / RLHN response to the current TGA consultation: Proposed refinements to the regulation of personalised medical devices

The TGA has requested that submissions, consider and respond to the questions below Comments are to be provided on the issues outlined in the consultation paper "CONSULTATION : Proposed refinements to the regulation of personalised medical devices".

The Rural Support Service is a collaboration of the 6 Regional LHNS in SA Health.

Barossa Hills Fleurieu LHN

Eyre & Far North LHN

Flinders and Upper North LHN

Limestone Coast LHN

Riverland Mallee Coorong LHN

Yorke & Northern LHN

The RSS provides Allied Health professional leadership governance and advice to the RLHNS. The RLHNS have commissioned the RSS to respond on behalf of the collective to the current TGA consultation. This advice covers the AH professions of Occupational Therapy(OT), Orthortics and Prosthetics (O&P), Physiotherapy (PT) and Podiatry(POD) working in the above mentioned LHNS

<u>Proposed refinements</u>

1. Products that could potentially be excluded from regulation.

Response:

1. Yes we agree with the rationale for the exclusion of the products as stated based on a no harm principle.
2. Yes The products are low risk and represent 'over the counter products' such as 'bunion pads' which may be dispensed to a client in a healthcare setting that are freely available to purchase in a retail setting pose little or no risk to the consumer. Materials and components which will be incorporated into a patient matched

device and are therefore regulated as part of that device and as such can be excluded in their own right
3. All non-invasive class 1 devices.

Proposed refinement 2:

4. Do you agree with the rationale for the proposed exemption of Class I nonsterile, non-measuring patient-matched devices when produced under the circumstances listed in this consultation paper?

Response:

4. Yes it is reasonable to exclude patient matched devices of Class 1 non-sterile non Measuring if they are produced in a NSQHS accredited organisation. We are assuming that exempt devices will still need to meet the other regulatory requirements / essential principles.

We seek further clarification on the points below'

- For those devices that are manufactured on site for the accredited health service and not manufactured by an AHPRA registered health Professional i.e. an allied health assistant what constitutes 'trained'?
- In this scenario what would the mechanisms of oversight need to be demonstrated?
- For those devices that are manufactured off site from the accredited health service and not manufactured by an AHPRA registered health Professional i.e. an orthotic Lab technician what constitutes 'trained'?
- In this scenario what would the mechanisms of oversight need to be demonstrated?
- Packaging and labelling requirements for items e.g. Foot orthotics. Nil information evident on the TGA website as to what these requirements are.
- Clarification of the information that is supplied to the patient is it purely a product data sheet or is there a requirement for clinical application information in addition to the device data sheet.
- Record keeping and whether current documentation in medical records as part of daily clinical practice is sufficient to meet TGA needs? A challenge for SA Health would be the ability to easily pull this information from existing medical record systems especially for remote sites that are paper based.

- Whether SA Health internal system for adverse event reporting would be sufficient to satisfy TGA requirements or if an alert is required to be embedded in our Safety Learning System reporting to include TGA notification for any adverse events relating to medical devices?

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?

Yes the risks can be managed within an accredited NSQHS organisation.

The RLHNS are supporting that all items created by OT,O&P,PT,&PODs working under SA Health are considered for exemption for the following reasons:

- These Class I non-sterile devices are produced within a health care facility that is accredited against NSQHS standards
- All OT,O&P,PT,&PODs working in SA Health hold a current registration with AHPRA
- OT,O&P,PT,&PODs are working within their scope of practice and clinical training when producing these devices.
- Clinical governance provided through a supervision framework ensures allied health staff are trained and competent in creating these devices.
- The devices are intended to be used by a patient of an SA Health care facility
- SA Health have an internal safety reporting system that enable staff to report any adverse events

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?

Yes - All class 1 devices that are made up of individually exempt parts or components that are already TGA compliant e.g. lower limb prosthesis that are manufactured by Certified Othrotists.

RSS is suggesting as SA Health meets the requirements by TGA in : ensuring the devices are produced by OT,O&P,PT,&PODs who are registered with a accrediting body working within scope of practice in a governance structure that mitigates risks and has documentation structure and a reporting system for any adverse events ; that SA health OT,O&P,PT,&PODs devices be considered for an alternative conformity assessment which would allow items to not require certification for inclusion in the ARTG. Refer to pg 9 and pg 13

Proposed refinement 3.

This section is not relevant for RLHN OT,O&P,PT,&PODs as currently noone utilises Class 11a and above devices.

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

- Clarification on packaging and labelling requirement
- Clarification for LHNs as to the due diligence required to demonstrate suppliers are TGA registered/compliant.
- Clarification on the scope of patient information to be supplied with a device and the recording of the information given to a client.
- Details to be included in records of supply
- Updated safety reporting system within SA Health that could allow ease of data retrieval for any adverse event due to a medical device to be pulled and sent to TGA rather than a duplication of reporting.
- Nil requirement of conformity assessment for each LHN, site or therapist rather one application is required through SA Health