Response ID ANON-3NHQ-DDK2-Y

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-12 15:48:52

Introduction

1 What is your name?

Name:
Dr Roy J Hardman

2 What is your work title?

Work title:
Managing Director

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Right Time Business Pty Ltd

5 What is your company/organisation address?

Please provide the business address of your company or organisation.:

[redacted]

6 Which industry do you work in, or represent?

Please state the industry that you work in, or are representing in your submission.:
Medical Devices Regulatory Agent

7 Are you responding:

On behalf of an organisation

Exclusion

8 Do you agree with the rationale for the proposed exclusion of products?

Yes

If you answered 'no' to the above question, why do you disagree with the rationale for the proposed exclusion of the products listed?:

9 Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA?

No

Please explain your response, including by providing examples that illustrate and/or support your position.:

The risk is that the respective manufacturer will not manufacturer a quality product. The manufacturer will need to substantiate that their device is manufactured to a standard accepted by the TGA. This would need to be supplied to the TGA so that an exemption number be issued to the manufacturer. This would enhance the supply and manufacture of a quality-based system that is compliant with a low risk device. Also allowing the market to understand that the TGA has issued an exception number to substantiate the device.

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

Ensure your answer directly addresses (1) why the products pose no, or insignificant, levels of risk or (2) why the product does not meet the definition of a medical device. :

Yes, the TGA needs to clearly define what is a raw material with respect to 3D printing materials and those considered as borderline devices as per previous guidelines.

Exemption

11 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 the consultation paper?

No

If you answered 'no' to the above question, please explain why it is that you disagree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched medical devices?:

Yes, this is agreed as long as the device is manufactured by a registered practitioner who is trained to produce such devices that are low risk. This can be a Laboratory Technician, A Dentist, A dental laboratory managed by a qualified person who is registered to produce devices.

12 Can the risks posed by Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in the consultation paper be adequately managed if they are exempted from inclusion in the ARTG?

No

Please explain your response, including by providing examples that illustrate and/or support your position.:

Yes, they can be a risk, however, if the respective manufacturer has submitted the devices overview as per previous comment to the TGA under a guidance notification and received an exception number that needs to be placed on the device produced, then the risk is minimised.

13 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?

Ensure your answer directly addresses 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.:

Yes: raw material supply to produce a device, aligners and minor adjustment devices that are patient specific, low risk and maintained and monitored by a dental health professional.

Alternative conformity assessment procedures

14 Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medical devices when produced under the circumstances listed in the consultation paper?

No

If you answered 'no' to the above question, please explain why you disagree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medical devices?:

Yes, this is agreed, however the materials used to produce these devices need to be included on the register. This is a case that a device classified as a class IIa is being manufactured to be a crown, guide, bridge ect as a result of customizing a material that is currently included on the ARTG. To customise a device to make a crown bridge or other prosthesis used in the mouth during a dental treatment or to have a device surgically in place for greater than 30 days is a form of customization and not a single device entity. This will reduce regulatory burden. Once again if an exception number is issued by the TGA to substantiate this position it would ensure only qualified persons produce such customisation of materials.

15 Do you agree that the risks associated with the Class IIa patient-matched medical devices when produced under the circumstances listed in the consultation paper could be adequately managed through the proposed alternative conformity assessment procedure?

No

Please explain your response, including by providing examples that illustrate and/or support your position.:

Yes, it is agreed, however, it is imperative that the devices to be produced need to be substantiated with a self-declaration new template from the TGA that is registered and that the TGA issue a registered number prior to distribution for a small fee so that the quality management and essential principals are adhered to.

16 Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate?

Please ensure that your answer directly addresses what measures are in place to manage the risks associated with the devices.:

Technically a long-term denture, plate, expansion device, are all patient matched devices are fabricated from a resin base or a thermal formal resin. These materials need to be included on the register as per those used for aligners, with the understanding that these materials are once again being customized to for the end device used. If they are manufacturer within the regulatory guidelines and an exception is issued, or the alternative conformity assessment is accepted, then a registered number can be issued and substantiate the deice category for a manufacturer.

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

Please outline your reasoning.:

Yes, patient superstructure, patient reconstructed jaws, all these are manufactured from materials that need to be placed on the ARTG prior to being used to produce a patient matched device. Once aging a case of customization. If registered in a much simpler format and a minor fee paid it will reduce the regulatory burden and satisfy the industry plus the TGA's requirements for a device that meets the intended use by the manufacturer

Alternative approaches we should consider

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

If applicable, please write your response in the text box below.:

Please refer to the following as per discussions with laboratory owners and dentists.

It is agreed that there is a need for regulatory accountability with in the dental laboratory and prosthesis industry. However, as our industry sector only purchased materials that have been registered for importation and included on the register of therapeutic goods in accordance with the essential principals and fit for purpose they have already undergone substantial ISO manufacturing standards there is very little requirements to introduce over and above this an ISSO compliance onto laboratories as this has already been assessed by the Therapeutic Goods Administration (TGA) in Australia. The only time ISSO compliance is needed is when exporting overseas which the vast majority of dental laboratories and Dental Surgeries are not involved with. I believe that if a company is looking at exporting they should be supported in this endeavour by our department of trade and industry. AUS Trade.

Point [1] Register the systems used in a lab or surgery i.e. my laboratory has 2 systems .System [a[Zirkonzahn system using all materials included on the register of therapeutic Goods with TGA in Australia. The materials already have the parameters in my system to use these ZirkonZahn materials in my System. Just one registration needed as there is no need for compliance through the expensive manufacturing ISSO compliance that will cost approx. $100000 –$200000 as i.e. ZirkonZahn already have these registrations on their products and therefore no need to duplicate and commit the industry to increased regulatory and cost burden.
System[b] Asiga printing system which uses a number of different materials. The materials are already included on the register of therapeutic goods with TGA and in addition the system still has all the parameters to print the material correctly. The material must be listed in the printers software and must be noted on the registered printers software . Again there is no need to have additional ISSO accreditation is nebulous and a substantial cost burden.

With both these system examples the records of what has been produced/manufactured can be kept for 7 years as the software already stores how and what was made and what material was used .This is much simpler than a lot of GDMN codes for every single restoration.
There would be a requirement to register each system and the system should be registered at a Class 2a level so approx. $1500 a system which is consistent with current class 2a registration charges.

The second way of TGA compliance in laboratories and dentist whether its a small lab in a dentists surgery or a large commercial concern is to charge a fee per patient if already using TGA registered materials.
An of example $5 per patient this would be charged in a similar a manner as GST and must be always charged on top of whatever the dentist or lab fees are.
This is to stop Labs and surgery's using we don't charge for tga rego as a sales technique .
This has its advantages as the lab and dentist must have this registration for them to be TGA compliant and also insured. This also stops tax evasion through doing cash only jobs.
You can have a tiered system class 1a i.e. $2 per patient not per unit. class 2a $5 per patient not per unit as this would be much fairer on the patient as any cost would be passed on to the patient anyway regardless of the method of registration .
The other advantage of this is if a dentist or lab brings in work from overseas they would need to not only register with TGA registration for each material they are using in the finished appliance but also pay the patient registration fee . This levels the playing field for suppliers who have already paid for TGA registration of the materials they are selling in Australia. This would also stop businesses bringing in unregistered materials and hiding behind the fact another company has already paid to import said material .There would be requirement from all involved to keep batch numbers to prove they a using registered materials .

In conclusion both ways of maintaining compliance have their merits and can both exist together the second method can also be used where you may only make a certain appliance a few times a year and none of the systems you have can do this and must be hand made for example you can then go ahead and make the appliance pay your rego fee for which ever Class it is and then not have to worry about paying a large fee for something that may only cost be charging $100 .

I think if we go down the path of ISSO compliance the cost will be so large that the cost of dentistry will increase by a considerable amount and will also be used to eliminate smaller more bespoke operators who will not be able to spread the cost of ISSO compliance because they make far fewer appliances.

Required final step - Publishing my response

19 Do you consent to the Department collecting the information requested in Citizen Space about you, including any sensitive information, for the purposes of this consultation?

I consent

20 I consent to the submission made by me being published on the Department's website, and accessible to the public, including persons overseas, in accordance with the following preference:

Publish response, including both my name and organisation's name

21 If there are specific answers you have provided that you do not wish to be published, please indicate these below.

Please state below any specific questions that you do not wish to have your answers to published.:
No

22 May we contact you for further information or to seek feedback about how the consultation was undertaken?

Yes

23 By making a submission, I acknowledge that:

I acknowledge the above