Submission for proposed refinements to the regulation of personalised medical devices

14 July 2021

1. Executive Summary

Gadens is pleased to have the opportunity to make a submission in response to the questions raised in the *Proposed refinements to the regulation of personalised medical devices* consultation paper (**Consultation Paper**).

Gadens is supportive of the proposed refinements to the *Therapeutic Goods (Medical Devices) Regulations 2002* (**Regulations**) under the *Therapeutic Goods Act 1989* (Cth) (**Act**).

We make the following comments and recommendations in respect of the mechanisms for refinements raised in the Consultation Paper:

(a) Gadens agrees that products that do not meet the definition of a medical device should be excluded from compliance. However, in relation to products that meet the definition of an accessory, we consider it reasonable that the assessment for significant harm should be clarified to include an objective criteria. Further, in relation to products that meet the definition a medical device but is predominantly used for cosmetic purposes, the test for predominant use needs to be clarified.

(b) We recommend that the TGA consider other exemptions based on principles such as public health risk of products and the intended use of products.

(c) We recommend that the purpose and intent of an alternative conformity assessment procedure be clarified to ensure that this does not lead to confusion as to which alternative conformity assessment procedure would apply.

Any defined terms used in our submission have the meaning given in our submission or are otherwise defined in the Consultation Paper.

2. Exclusion

The TGA proposes to exclude products from regulation:

(a) if the products do not meet the definition of a 'medical device';

(b) if the products meet the definition of an 'accessory' but do not pose significant harm to an individual, including due to inappropriate use of the products; or

(c) if the products meet the definition of 'medical device' but are predominantly used for cosmetic purposes and do not present a risk of harm.

Through the proposals, the TGA intends to reduce the regulatory obligations on manufacturers of these types of products.

Gadens agrees that products that do not meet the definition of a medical device should be excluded from compliance, and the relevant manufacturers should not be unnecessarily burdened with the procedural requirements of registering their product with the Australian Register of Therapeutic Goods (**ARTG**).

We are also of the view that the TGA consider other principles-based factors to exclude certain other products. In particular:

(a) In relation to products that meet the definition of an accessory being excluded from compliance, we consider it reasonable that the assessment for significant harm should be clarified to include an objective criteria to enable manufacturers to undertake an effective self-assessment.

(b) In relation to products that meet the definition of a medical device but are predominantly used for cosmetic purposes being excluded from compliance, we think the assessment for 'predominant use' should be clarified to enable manufacturers to undertake an effective self-assessment.

We also recommend that the TGA consider other principles to exclude products, such as:

(a) the complexity or simplicity of use of the products;

(b) the information available on the market regarding the products; and

(c) the familiarity of consumers with the products or the sophistication of consumers in relation to particular types of products.

3. Exemption

The TGA proposes to exempt products from regulation if these are classified as Class I non-sterile, non-measuring patient-matched medical devices where risk can be adequately managed through:

(a) the product is manufactured by a trained, accredited professional; or

(b) there are alternative mechanisms of oversight for the manufacture and use of the product.

The current exemptions system contained in Schedule 4 of the Regulations relies on classification of medical devices contained in Schedule 2. For example, Gadens have identified the following Items in Schedule 4 which rely extensively on definitions in Schedule 2:

(a) Item 1.1: IVD medical device, Class 4 IVD medical device, Class AIMD medical device, Class III medical device, Class 3 IVD medical device, Class IIb medical device, Class 2 IVD medical device, and Class IIa medical device; and

(b) Item 2.10: Class 1, Class 2, and Class 3 in-house IVD medical device.

These exhaustive exemptions present particular issues for new or emerging medical technologies not expressly addressed or contemplated by the Regulations. For example, an exemption in Item 1.1 covers a swathe of medical device in those Classes where the quantity of the product imported does not exceed an amount in a given period. While this may potentially create a wide net for exempt products (for example, products used to store blood or modify the composition of blood), the Classes are based on the product's specific applications and may exclude future products if they do not meet these strict criteria or products that otherwise were not contemplated in the Regulations.

Exemptions should be determined by the risk products pose to consumers. This is recognised in Section 3.3(b) of the Regulations where the Classes of products referred to in Schedule 2 are categorised based on their public health risk.

In addition to the reference to Class I non-sterile, non-measuring patient-matched medical devices, Gadens proposes that the TGA consider other exemptions based on principles such as:

(a) Public health risk of the products. For example, if the products is likely or reasonably likely to lead to adverse health consequences.

(b) The intended use of the products. For example, whether the intended use of the products falls into a category which might reasonably place public health at risk.

The inclusion of principles-based exemptions could benefit consumers and manufacturers through:

(a) clear principles-based regulations reduce regulatory 'grey areas' leaving manufacturers unsure of their obligations; and

(b) streamlined access to low risk evidence-based products.

4. Alternative conformity assessment procedure

The TGA proposes to allow products to be subject to an alternative conformity assessment procedures. In particular, the TGA proposes that Class II patient-matched devices may be subject to an alternative conformity procedure, such as:

(a) alternative mechanisms of oversight for the manufacture and an alternative of the product; and

(b) the manufacturer undertakes a self-assessment declaration that they meet the regulatory requirements.

We query how likely this would impose additional compliance burden on the industry, noting that this approach would still require a manufacturer to prepare/hold technical documentation, hold evidence that the device meets the Essential Principles, and establish post-market monitoring, reporting and corrective action system. If a product does not fall within the lower risk categories allowing for an exclusion or exemption, the purpose and intent of an alternative conformity assessment procedure would need to be clarified. Otherwise, this would likely lead to confusion as to which alternative conformity assessment procedure would apply.

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