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Device Reforms
Medical Devices Branch
Therapeutic Goods Administration
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Dear Sir/Madam,

Consultation Response: Proposed new medical device classification for substances introduced into the body via a body orifice or applied to the skin

ASMI is pleased for the opportunity to respond to this consultation and the extent to which the incorporation of the EU classification rule 21 will be appropriate in the Australian regulatory context, to further enhance the smooth functioning of the medical devices market while also achieving high standards of quality, safety and performance.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. More information about ASMI and our membership is available on our website.

We take a keen interest in this consultation because the majority of ASMI's ordinary members market products currently regulated as Class I devices which will be impacted by this proposed reclassification. Members also market medicinal products which may fit the description in the consultation paper of *borderline products,* where it is not clear whether a given product is a medical device or a medicine.

We hope the comments we provide below to this consultation are helpful to this reform's effective implementation. Should you require clarification of the detail provide don't hesitate to contact me.

Yours faithfully

[redacted]

Harmonisation

We note that this consultation is undertaken as part of addressing MMDR recommendation 20 - *that the regulation of medical devices, wherever possible and appropriate, align with the European Union (EU) framework including the classification of medical devices*.

ASMI supports efforts toward international harmonisation of regulation and it is anticipated that this proposal in the longer term will have benefits for consumers, the industry and the regulator. To achieve those benefits in the immediate term however represents significant cost and regulatory burden to the industry. This burden includes the human resource requirements, submission and audit costs and time to establish the revised higher classification requirements to now support existing products, and the reapplication and assessment of the new data package to allow for the re-inclusion of the device in the ARTG at the revised classification. With the TGA 100% cost recovered the only real way to reduce the burden for the industry is to provide a sufficient timeframe over which the revised classification can practically be achieved, and the significant costs amortised.

We believe there is a need to first understand how Rule 21 will be interpreted in EU and then with that clarity, undertake further consultation on the transition implications. The EMA is yet to provide an update to the Guidance document - Classification of Medical Devices - MEDDEV 2.4/1, nearly 2 years after the EU MDR legislation was introduced. It would undermine the intent of alignment with the EU MDR, to commence the transition with an Australian specific interpretation for applying the rule.

In principle, before implementation of such a significant and costly transition can commence, it is critical there is clarity of requirement and process provided through guidelines and educational sessions. Members have stressed the importance of clarity of requirement in the ARGMD and provision of educational workshops. With the potential expense and resource intensive nature required for of this reform, coupled with the current lack of access to TGA Medical Device advice, it would could be a catastrophic for a company during this reclassification, if an application was to be determined to be incorrectly classified, or not to be a medical device.

The term 'convergence' rather than 'harmonisation' has also come into common parlance in recognition that adoption of regulation from other jurisdictions needs to consider the impacts within the existing local regulatory framework and its resultant local market and be appropriately accommodated. We were therefore pleased with the language used in describing the consultation's aim as to "consider introducing a new medical device classification rule, which is appropriately tailored for the Australian regulatory context". Additionally, the Australian market is relatively small within the global context, therefore strict alignment can create barriers. Alignment with the EU can also result in divergence from the regulation of other major trading partners e.g. North America. This may prove problematic especially in relation to borderline products. As a small market, a level of flexibility may need to be maintained. It is also important that Australian regulation remains aligned with the even smaller market of New Zealand to ensure that economies of scale can be achieved across the Tasman via provision of the same product in both markets. We request that TGA maintain a dialogue of medical device reforms with Medsafe as they are concurrently introducing their new Therapeutic Products legislation.

The longer-term goals of alignment with the EU MDR need to be ensured by addressing 'Australian specific' requirements within the *Therapeutic Goods (Medical Devices) Regulations 2002*. For example, the current lack of a process for inclusion of new substances on the list of substances excluded from the Special rule described under Schedule 2, section 5.5. Until this is addressed

consistently with the EU MDR, devices composed of a substance of microbial origin (like Xanthan Gum – produced by bacterial fermentation, and commonly used in cosmetics, foods and some OTC medicines), will be classified Class III in Australia but Class IIa or Class IIb in the EU without good reason. The implication of this inconsistency translates to a need for an Australian specific Class III data package for the device, however in reality the expense of undertaking this exercise is unlikely to be justified for the Australian market. Additionally, the classification of devices which include a highly refined substances of microbial origin as Class III does not appear to commensurate with risk that such substances pose. The Industry would welcome a review of the risk that highly refined substances of microbial origin pose when included in medical devices and the consideration of treating these substances in a consistent manner with the EU.

Specifics of the proposal

The proposal to introduce a **new classification rule** into Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (Australian MD Regulations), would be achieved with wording to align with Rule 21 (Annex VIII, Chapter III) of the EU MD Regulation.

Rule 21 states:

> *Medical device that is composed of a substance or of a combination of substances that is intended to be introduced into the human body via a body orifice* ***or*** *applied to the skin* ***and*** *that is absorbed by or locally dispersed in the human body is classified as:*
>
> - *Class III if the device, or its products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;*
> - *Class III if the device achieves its intended purpose in the stomach or lower gastrointestinal tract and the device, or its products of metabolism, are systemically absorbed by the human body;*
> - *Class IIa if the device is applied to the skin or in the nasal or oral cavity as far as the pharynx, and achieves its intended purpose on those cavities; and*
> - *Class IIb in all other cases.*

Rule 21 is complex to understand and apply within a risk based classification approach. In the absence of an updated Guidance document - Classification of Medical Devices - MEDDEV 2.4/1, it is difficult to understand the extent of the implications. European colleagues advise this has been creating concern delays in implementation.

It will be vital that the guidance is available prior to commencement within this market and that education sessions are provided. We note that the determination of risk class is dependent on:

i) the extent of systemic absorption of the substance (or products of its metabolism) 'by the human body', and whether or not the intended purpose is achieved by the absorption,

ii) the point of introduction or application of the device, but also where the device achieves the intended purpose.

For those of us more familiar with medicines regulation, the definition of 'systemically absorbed' may have a different and broader interpretation in this medical device context than when the same term is applied to a medicine. Similarly the term 'locally dispersed' should be defined for clarity. We therefore recommend definitions for both terms would be useful.

To demonstrate the difficulty of interpretation of Rule 21 we noted in the consultation paper included TGA's example of Eye irrigation solution (eye wash) with a ***current classification*** - *Class I*

Sterile and a ***proposed classification*** *– Class IIb (introduced into the human body via the surface of the eyeball and are absorbed by the human body)*. However, it could also be argued (reading through the rule, noting the 'or' and the 'and') that - the device does not meet the first criteria of Rule 21 – it is not intended to be introduced into the body via the eye (orifice), or to be applied to the skin. Its intended action is on the surface of the eyeball. In this interpretation, Rule 21 does not apply and the Eye wash remains Class I Sterile.

Definitions proposed to be adopted from the EU Regulation as part:

> ***'invasive device'*** *means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.*
>
> *'**Injured skin or mucous membrane**' means an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound.*

There is concern that the proposed definition could impact the classification of medicine applicators and dosing pipettes. These devices would currently be considered Class I but it is unclear whether they may also require reclassification to Class IIa. Again, at this stage there is a lack of clarity around interpreting the classifications.

While the term injured skin is not actually mentioned in Rule 21, it applies within Rule 4 for all non-invasive devices.

This EU definition is quite broad. The wording "pathological change or change following a disease or wound" could be interpreted as including dermatological conditions including inflammatory conditions, infectious conditions, even common skin conditions such as acne or rash where there is some pathological change to the skin. In relation to "mucous membrane" this definition could potentially encompass all manner of conditions including mouth ulcers, inflammation from badly fitting dentures etc. as well as various locations within the body, e.g. bronchial mucosa, oesophageal mucosa.

In adopting these definitions, the TGA should be mindful of the potential applicability to a wide range of products, many of which may currently be regulated as medicines.

Borderline products

ASMI members have products represented on both sides of the medicine/medical device interface. Our concerns therefore extend beyond the consultation's stated proposal, noting a lack of clarity with regards TGA's intention for regulation of borderline products. It is difficult to provide informed comment on the suitability of transition proposals where the extent or scope of the proposal is unclear. It is unclear whether this proposal applies to the reclassification of not only existing Class I devices but also some low risk medicines.

The recent TGA consultation paper on definitions and the scope of the medical device regulatory framework in Australia provided no clarity either. While the consultation paper suggests that the introduction of Rule 21 will apply to products that are already devices, there is no advice of the proposed treatment of borderline products within the Australian regulatory context. However the table of examples of product descriptions with current and proposed classification include some product types which have historically been regulated as medicines by the TGA. Throughout the paper there are different statements which send mixed messages – but none clearly indicating TGA's intent regarding the scope of the change. For example:

"Consequently products that achieve their principal intended action by chemical means (including products that are composed of substances or of combinations of substances), and that are intended for one or more of the medical purposes stated above, may be regulated as medical devices."

"Some of these products may also fall under the definition of a medicine, i.e. these products are so called borderline products (i.e. it is not clear whether a given product is a medical device or a medicine)."

"… products that are not intended to achieve their action in the body by pharmacological, immunological or metabolic means."

"The regulatory pathways for such products are determined based on the product's primary modes of action, their intended uses and manufacturer's claims made regarding product's performance, based on the analysis and scientific evidence."

Although the definition of ***medicine*** in the Act includes "*any other therapeutic goods declared by the Secretary, for the purpose of the definition of* ***therapeutic device****, not to be therapeutic devices",* and section 41 BD (3) of the Act allows the secretary to declare certain goods are not medical devices, it is unclear that TGA has or intends to provide for the option to declare a therapeutic good not to be a medicine but a medical device. Consultation, clarity of process and provision of acceptable transition periods would be critical to TGA creating clearer delineation between medicines and formulated devices. Significant transition periods would be required to reclassify a medicine as a medical device to account for the very different approaches in development of data packages and structure, manufacturing requirements (GMP v Conformity assessment) and labelling requirements and application assessment timeframes between medicines and medical devices.

There are areas of overlap between formulated devices and many current low risk medicines both registered and listed. The examples provided in the consultation paper include sodium alginate based-products for reflux, throat lozenges (which also interface with confectionary) and toothpastes (which also interface with cosmetics). We understand that sunscreens making therapeutic claims in the EU have been regulated as devices. This type of determination would be extremely disruptive to the Australian market and would be inconsistent with the regulation of other major markets.

ASMI members are mindful of the confusing marketplace these interfaces create for consumers with significant differences in labelling requirements dependent on the product's regulation. Low risk medicines have had the advantage of a long history of safe use within the market. With that history, regulatory review and improvement has led to greater consistency of label instructions and effective warning statements. Importantly these products carry an AUST R or AUST L number which provides for easy identification and confirmation on the ARTG.

While this situation of borderline products has historically existed in the Australian market, we observe that we have limited understanding of how consumers navigate the market place or how they perceive similar products on either side of the borderline or their level of understanding of the differences in regulation of these products. Both consumers and health care professionals have been concerned with the difficulty in searching the ARTG for a named device, due to the different requirements. It is also unclear whether pharmacists and other healthcare professionals would be in a position to respond to consumers' questions with an understanding of the classification of devices and the differences in the information provided on the label. There may need to be an assessment of whether HCP education is required, as some products currently presented as medicines may in future be regulated as devices.

On 28 February 2019 the EMA published a news release announcing the First guidance on new rules for certain medical devices. This announcement advises that guidance is still in development for borderline products.

Application of the MDR in the EU is still in quite early stages. The implications of Rule 21 on consistency of regulation of borderline products is unclear, however given that member states will still have the option to classify differently, it is not anticipated to have significant impact on aligning medicines/medical devices interface.

It is unfortunate that the proposed transition in this consultation paper, such that Australia transitions concurrent with the remaining EU implementation period, has not instead proposed to allow time to adjust for any learnings arising from practicalities of the EU experience.

Transitional arrangements

The TGA are proposing a transition period which will align the completion of implementation within a couple of months of that provided within the EU Regulation on medical devices (2017/745). The EU regulation was published in May 2017 allowing Legal Manufacturers and Sponsors a total period of 7 years to prepare for and implement the change and absorb the costs of compliance. Australian Legal Manufacturers and Sponsors have been provided 4 years. This provision appears to assume that the majority of medical devices would be sourced from or supplied to Europe and that Australia will be able to piggy back the EU implementation. Unfortunately, we suspect the reverse may be true and the lack of resource due to EU implementation may hinder the Australian implementation. The TGA should provide a comparable period of time for all activities to be completed and costs to be absorbed.

We suggest that determination of a transition period at this stage may be premature. More time is needed to understand how Rule 21 will be applied in the EU. Greater clarity of TGA's intention for regulation of these devices is required. Until the industry has clarity of these things it is difficult to comprehend the scope of the change and therefore the time necessary to implement.

The proposal for concurrent implementation of the reclassification within the EU's remaining grace period is impractical. Notified bodies are already at capacity addressing the MDR implementation. Global head offices are advising they'll not be able to support the Australian affiliate in that timeframe, that they are already at capacity. We'd recommend a similar total period to that given in the EU of 6-7 years.

For those non-EU Manufacturers who are required to change their devices from being classified as Class I to Class IIa, Class IIb or Class III, there will be a high burden in terms of:

- resource cost to arrange/prepare the increased documentation requirements (possibly even introduction of a QMS, which members advise is extremely time consuming and may not be completed within the time period afforded)
- increased costs (in terms of TGA fees, annual fees and audit fees)
- tight timelines if technical transfer of products from an existing manufacturer to a new, appropriately certified manufacturer, is required (this can be challenging and time consuming)
- requirement to have a Notified Body perform a Conformity Assessment upon the Technical File for the product
- Availability of Notified Bodies, or the TGA, to conduct conformity assessment processes within the transition period may prove problematic and a rate limiting step. At present TGA

current experiences of timeframes for assessment of a Class III application is greater than 12 months.

An impractical transition period may discourage some Sponsors/Manufacturers from continuing to market their products, disadvantaging consumers. Some Sponsors/Manufacturers may choose to consider if there is an option of presenting borderline products on the other side of a relevant interface (Device/ Medicine, Device/Cosmetic, Device/Food).

It is anticipated that manufacturers currently only certified to manufacture Class I formulated devices would need to achieve conformity assessment to ISO 13485 as part of the reclassification transition. We therefore anticipate the need for a significant level of technology transfer as part of the transition. To support the transition, it may be of assistance to sponsors if the TGA can provide transparency of Australian Manufacturers with CE Certification and conformity to ISO 13485 - Medical device quality management, like the existing provision of details of Australian Licensed Manufacturers within eBS.

The transition period, as outlined in the consultation paper, seems to be structured to encourage Sponsors to leave applying to up-classify their products until the last minute (as any products for which an application is currently under evaluation may continue to be provided under the initial classification until such time as a determination is made). This runs the risk of causing a glut of submissions to be filed with the TGA toward the end of the transition period. Has the TGA considered the potential impact of this in terms of resourcing? Given the potential for an influx of Class III applications, what readiness does the TGA plan to undertake to ensure that applications can be processed in a timely manner and the Sponsors are not further disadvantaged? At a point in time should, sponsors be incentivised (e.g. with return of fees) to withdraw applications which have not yet commenced evaluation and would require immediate reapplication for the new classification in any event?

Many manufacturers of Class I medical devices may not be members of industry associations or in regular contact with the TGA. Direct and broad communication via all relevant media will be important to inform and educate them of the impending changes and the requirement to contact the TGA within the first 6 months of the transition period.

Development of clear guidance, with the provision of clear, appropriate examples, will be vital to support the implementation of these new requirements, to assist Sponsors and Manufacturers in this transition period. It would also be valuable for the TGA to provide appropriate face to face education sessions to afford Sponsors and Manufacturers the opportunity to directly interact with the TGA and understand the consequences and impacts of the proposed changes.

Fees and charges

As previously stated, this reform is very expensive for Sponsors with no commercial benefit other than to continue marketing existing products. With TGA activities 100% cost recovered, they must pay a higher-level application fee and audit assessment fees for the TGA review of a new higher-level classification technical file, to have the product re-included on the ARTG. In addition to the fees outlined above, there will then be ongoing higher annual charges for the life of the product.
This additional, unbudgeted expense may result in some companies deciding not to proceed with reclassification, instead removing their products from the ARTG, possibly disadvantaging consumers.

A reduction or waiving of fees, to incentivise early transition would be welcomed – where the transition period is practical.

Questions of the consultation paper

What impacts—including any that are unintended—do you anticipate the reclassification may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?

ASMI supports efforts toward international harmonisation of regulation and it is anticipated that this proposal in the longer term will have benefits for consumers, the industry and the regulator. To achieve those benefits in the immediate term however, represents significant cost and regulatory burden to the industry. This burden includes the human resource requirements, submission and audit costs and time to establish the revised higher classification requirements to now support existing products, and the reapplication and assessment of the new data package to allow for the re-inclusion of the device in the ARTG at the revised classification.

With the TGA 100% cost recovered the only real way to reduce the burden for the industry is to provide a sufficient timeframe over which the revised classification can practically be achieved, and the significant costs amortised.

More time is needed to understand how Rule 21 will be applied in the EU and greater clarity of TGA's intention for regulation of borderline is required before the extent of this proposal can be quantified and the time necessary to implement determined.

Are there any further issues and questions we should consider when implementing this change (including areas that can/should be clarified in our guidance)?

- There is limited understanding of how consumers navigate the market place or how they perceive similar products on either side of the borderline or their level of understanding of the differences in regulation of these products. Both consumers and health care professionals have been concerned with the difficulty in searching the ARTG for a named device, due to the different requirements. It is also unclear whether pharmacists and other healthcare professionals would be in a position to respond to consumers' questions with an understanding of the classification of devices and the differences in the information provided on the label. There may need to be an assessment of whether HCP education is required, as some products currently presented as medicines may in future be regulated as devices. See more detail under the heading – ***Borderline products***

- Will the implementation provide for Trans-Tasman supply of a harmonised product? Can TGA liaise with Medsafe to ensure it's possible? See more under the heading - ***Harmonisation***

- Before implementation of such a significant and costly transition can commence, it is critical there is clarity of requirement and process provided through guidelines and educational sessions. Members have stressed the importance of clarity of requirement in the ARGMD and provision of educational workshops. With the potential expense and resource intensive nature of this reform, coupled with the current lack of access to TGA Medical Device advice, it could be catastrophic for a company if, during this reclassification, an application was determined to be incorrectly classified, or not be a medical device. See more under the heading - ***Harmonisation***

- The longer-term goals of alignment with the EU MDR need to be ensured by addressing 'Australian specific' requirements within the Therapeutic Goods (Medical Devices) Regulations 2002. For example, the current lack of a process for inclusion of new substances on the list of substances excluded from the Special rule described under Schedule 2, section 5.5. Until this is addressed consistently with the EU MDR, devices composed of a substance of microbial origin (like Xanthan Gum – produced by bacterial fermentation, and commonly used in cosmetics, foods and some OTC medicines), will be classified Class III in Australia but Class IIa or Class IIb in the EU without good reason. The implication of this inconsistency translates to need for Australian specific Class III data package for the product, however reality of the expense of this exercise is unlikely to be justified for the Australian market. Additionally, the classification of devices which include a highly refined substances of microbial origin as Class III does not appear to commensurate with risk that such substances pose. The Industry would welcome a review of the risk that highly refined substances of microbial origin pose when included in medical devices and the consideration of treating these substances in a consistent manner with the EU. See more under the heading - ***Harmonisation***

Do you have any comments/views regarding defining the scope of medical devices that should be covered by the proposed new classification rule?

We believe further clarity is required before we can begin to define the scope of medical devices and possibly medicine which will be covered by the proposed new classification rule. Once there is a level of clarity, further consultation should then be undertaken to confirm the necessary transition. See comments and concerns under the headings ***Specifics of the proposal*** and ***Borderline products***

Do you have any comments/views regarding defining the terms *injured skin or mucous membrane* in the Australian MD Regulations?

This EU definition is quite broad. The wording "pathological change or change following a disease or wound" could be interpreted as including dermatological conditions including inflammatory conditions, infectious conditions, even common skin conditions such as acne or rash where there is some pathological change to the skin. In relation to "mucous membrane" this definition could potentially encompass all manner of conditions including mouth ulcers, inflammation from badly fitting dentures etc. as well as various locations within the body, e.g. bronchial mucosa, oesophageal mucosa.
Our concern is that in application it may set an indistinct and low bar for a term intended to differentiate higher risk.
See more detail under the heading – ***Specifics of the proposal***

Do you have any comments/views regarding the meaning of the term *systemically absorbed* (or *systematic absorption*)? Should this term be clarified in our guidance or defined in the Australian MD Regulations?

The definition of 'systemically absorbed' may have a different and broader interpretation in this medical device context than when the same term is applied to a medicine. Similarly the term 'locally dispersed' should be defined for clarity. We therefore recommend definitions for both terms would be useful.
See more detail under the heading – ***Specifics of the proposal***

If yes, what definition do you propose for the meaning of this term?

We advise that for consistency with the EU it would be good to ensure the Australian interpretation was consistent with the intention of those who drafted the rule.

See more detail under the heading – ***Specifics of the proposal***

Do you have any comments regarding the transitional arrangements proposed in this paper?

We suggest that consideration of a transition period at this stage may be premature. More time is needed to understand how Rule 21 will be applied in the EU. Greater clarity of TGA's intention for regulation of borderline is also required before the industry can understand requirements for transitional arrangements.

The proposal for concurrent implementation of the reclassification within the EU's remaining grace period is impractical. Notified bodies are already at capacity addressing the MDR implementation. Global head offices are advising they'll not be able to support the Australian affiliate in that timeframe, that they are already at capacity. We recommend a similar total period to that given in the EU of 6-7 years.

Many manufacturers of Class I medical devices may not be members of industry associations or in regular contact with the TGA. Direct and broad communication via all relevant media will be important to inform and educate them of the impending changes and the requirement to contact the TGA within the first 6 months of the transition period.

See all comments under the heading - ***Transition***.