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Medical Devices Reform Unit
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
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Dear Medical Devices Reform Unit Team

Consultation: Proposed changes to medical device essential principles for safety and performance

Thank you for the opportunity to provide feedback to this consultation.

CHP Australia is the leading voice and industry body for **manufacturers and distributors of consumer healthcare products**, which includes non-prescription medicines and lower risk medical devices. We strive to advance consumer health through **responsible Self Care** and were previously known as the Australian Self Medication Industry (ASMI).

Our key priorities for the industry include **improving health literacy, growing the consumer healthcare products industry** and **increasing access to medicines** where appropriate.

We provide responses to each of the consultation questions below.

Providing informed responses to this consultation in the absence of the provision of the outcomes of the many medical device reforms consultations that have been undertaken to date has been somewhat difficult. Impacts are dependent on what the context will be. More constructive information on the financial implications may be able to be provided once a total picture of the reform consultation outcomes are understood.

We hope our comments are helpful and provide a level of insight into the benefits and issues or potential for issues that industry perceive with this proposal. Should you have any queries about the details provided, please don't hesitate to contact me.

Yours sincerely

[redacted]

Questions

1. Do you agree with the proposal to update the Australian Essential Principles to:
   a. align[1] with the IMDRF Essential Principles and Labelling documents?
   b. include relevant additional details captured by the General Safety and Performance Requirements in the EU MD and IVD regulations[2]?

This proposal establishes 'state of the art' medical device/IVD regulation and should future proof Australia's regulatory framework from the need for update for some time.

Members support the proposal to update the Australian Essential Principles.

We note that the consultation paper lists as a benefit of the proposed approach:

> [the] *reduction in unnecessary regulatory burden (time and cost) for manufacturers and sponsors of medical devices*.

As presented in the consultation paper, it is less clear to us whether this approach of establishing the Australian Essential Principles will deliver the harmonisation the industry had anticipated from MMDR recommendation 20, to harmonise with the EU. There is a level of concern that it could, in effect, be creating potential for Australian specific requirements.

Will the time and cost benefits to the industry of harmonisation be realised, or will there be a need to explain the structure/detail of the Australian Essential Principles to suppliers in other jurisdictions and to map them to other's Essential Principles to provide assurance or clarity of equivalency. These types of regulatory differences have historically been the things that have consumed unnecessary time and resource and hence cost burden.

It will be helpful to receive more detail on how the TGA believe the differences from the EU MDR/EU IVDR Essential Principles will translate to reduced regulatory burden. The achievement of these benefits may be better explained and achieved by the provision of guidelines, guidance, tools and templates (see more in Q7).
We were concerned at the proposal to incorporate what is a guidance into the regulations, recognising the challenges of language style. We appreciated the provision of the note that:

> *while it is intended to take the IMDRF documents and EU MD Regulations into account, the Australian legislative instruments are structured differently and there is variation in the legal terminology acceptable in each jurisdiction. It is acknowledged that legislation cannot always be successfully replicated across jurisdictions. When considering the proposed measures, you should assume that in-principle the*

[1] Considering the Australian regulatory and legal context.
[2] As compared with the IMDRF documents.

proposals to align with the IMDRF documents and EU MD and IVD Regulations are in the context of the Australian MD Regulations.

2. Do you agree with the proposal to provide additional clarity regarding expectations for compliance as specified under Proposal 2?

Additional clarity of requirement is always helpful in ensuring the effective inclusion on the register, the manufacture, distribution and maintenance of compliant products.

The information and guidance must be value adding, clear, concise, practical and peer reviewed for its effectiveness prior to introduction. Industry would value the opportunity to support the development of additional clarity by providing feedback to draft guidance and other supporting documents.

3. Do you agree with the proposal to restructure the Essential Principles and Labelling requirements for clarity and readability?

In principle the re-ordering of this information, as has been achieved in the IMDRF guidance, makes sense. The restructure for improved clarity, of the Essential Principles with the separation of those that apply to non-IVD medical devices and those that apply to IVD medical devices.

Grouping all the labelling information is helpful from the perspective of readability. The only concerns we have, as outlined under Q1, are from a harmonisation perspective and what that can mean from a regulatory practice perspective. That is, the need to explain/translate the Australian Essential Principles to other jurisdictions, or the need to transpose information from one jurisdictional format into an Australian format. These impacts might be mitigated to an extent via guidance, tools and templates.

4. Do you agree with the proposal that software medical devices without any physical packaging should include the ARTG number on the electronic label? Are there other devices where the ARTG number should be provided?

We agree with the principle of this approach for software medical devices but do not speak to its practicality, not having expertise in this area.

- The ability to access the ARTG numbers for medical devices generally is important as it can otherwise be difficult for consumers and health practitioners to find a device entry within the ARTG.
- Applying unique Australian specific requirements for a physical label carries significant cost implications to the sponsor in managing a supply chain with unique labels and unique packaging runs for the Australian products.

As we understand the reforms, the UDI code/ UDI database will provide ready access to the ARTG number and entry. Therefore, where allowances are made for device products not to be required to include a UDI code on the label, similar principle based approaches should be considered to allow for access to the ARTG number without creating undue regulatory cost burden. Other 'extended labelling' or digital options might be considered.

5. What financial or other effects—including any that are unintended—do you anticipate the changes to the Essential Principles may have for yourself, your business, and other stakeholders (such as consumers, healthcare professionals, health organisations, industry, etc.)?

In the absence of an understanding of the outcomes of the Medical Devices Reforms consultations held to date, it is very difficult to understand the impacts financially. This is very hard to estimate without clear articulation of what level of change of risk classification will occur and what benefits of harmonisation will be achieved in this approach.

For manufacturers using European EC certificates as conformity assessment evidence to support current ARTG entries, we anticipate the benefit of 'slip streaming' immediately behind the re-certification to the revised EU requirements, costs for addressing any Australian specific requirements and the fees and charges for re-inclusion on the ARTG.

For Australian manufacturers transitioning from the current to the new classifications and applying the revised Essential Principles will take considerable technical and regulatory resource and time before a Technical File could be finalised and submitted to TGA for evaluation.

It is unclear whether the costs of the effort required to re-establish compliance could be easily off-set through price increases or whether those costs would need to be absorbed. The financial impact to consumers and healthcare professionals, health organisations is therefore equally difficult to determine at this stage.

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

The proposed commencement date, November 2020 is not supported. A period of 12 months will be needed to share the updated Essential Principles with Legal Manufacturers prior to the commencement, such that we can ensure that these updated Essential Principles can be met for all new products to be included in the ARTG. The proposed implementation date will be especially problematic for products which are marketed in the EU (under MDD) but are new to Australia, in this circumstance the Legal Manufacturer may not yet be in a position to confirm that they meet the newly proposed Essential Principles.

As previously expressed in earlier responses to the medical device reforms, CHP Australia's members have concerns with the practicality of the transition arrangements.

The TGA are basing the transition period to align with the EU MDR implementation. This alignment is on the basis that medical devices available in Australia are primarily sourced from the EU. The rationale is, given that work that has been in progress for some time in the EU, to bring in similar measures, it will therefore be less burdensome on Australian Sponsors to introduce the proposed changes, as much of the work will have been done already. However, this assumption could have the effect of disadvantaging small Australian Legal Manufacturers who have not been required to consider the implementation of these changes yet. For Australian manufacturers the proposed changes will take time to implement thoroughly. The transition period should give consideration for all manufacturers and not simply be based on the EU MDR implementation timing.

It is notable that issues are being experienced in the EU in terms of transition from the MDD to the new MDR, with the US recently requesting a delay in the MDR/IVDR's implementation timing given the practicalities for the US exporters to comply and the enormous financial implications of not being able to become compliant[3].

Further, the number of Notified Bodies in the EU is currently reducing as some organisations have decided that it is too challenging to operate within the remit of the new MDR, only 2 are currently licenced to operate within the MDR. This restriction presents potential challenges for any Legal Manufacturer needing to transition to the MDR, making changes, or requiring review of a new product as resource for this process and all activities related to it are going to be severely constrained.

We have welcomed the assurances that TGA have provided informally that they will continue to assess the situation and extend the transition period as necessary. Naturally our members would prefer to embark on this project with greater certainty. CHP Australia still believe it would be wiser to wait until the issues currently being experienced in the EU are settled before implementing the changes and amendments to our current systems which relate to the EU system.

[3] https://www.raps.org/news-and-articles/news-articles/2019/8/eu-mdrivdr-us-raises-serious-concerns-urges-3

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

It is currently a laborious task to convert an EU Essential Principles format into the TGA Essential Principles Checklist format.

The proposal to incorporate IMDRF Essential Principles and Labelling documents and the inclusion of the General Safety and Performance Requirements in the EU MD and IVD regulations into the *Therapeutic Goods (Medical Devices) Regulations 2002*, Schedule 1, could thereby be creating a somewhat unique Australian Essential Principles from those listed in EU MDR/ EU IVDR. We therefore question whether this approach:

- will still deliver the benefits of harmonisation to the Australian industry. For example will Australian manufacturers be able to use a common template for the Essential Principles that could be provided to other jurisdictions? Or will we need continue to provide Australian specific templates that differ from the EU format template?
- could require the provision of additional guidance which provides for the explanation of how the Australian Essential Principles have been derived and interprets (maps) the equivalent sections of the EU Essential Principles (and those of other comparable regulators) with the Australian Essential Principles.

We suggest there may be the need for further interpretive guidance to provide clarity of the expectations the new IMDRF labelling requirements in practical terms. For example a query was raised about Appendix 3 (d) "The instructions for use, where relevant, should include a bibliography or references section" - what does "where relevant" mean?

As an outcomes of the changes to the Essential Principles, it appears that the classification rules may also need to be reviewed to ensure that they are aligned to the updated Essential Principles. In particular the classification of products containing highly purified ingredients from microbial origin (e.g. xanthan gum) as it relates to appendix 3, 5.13.3 of the consultation is not aligned with the proposed Essential Principles.