PATHOLOGY
TECHNOLOGY
AUSTRALIA

Medical Devices Reform Unit
Therapeutic Goods Administration
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Via e-mail: devicereforms@health.gov.au

Dear Sir/Madam

TGA Consultation: Proposed changes to the medical device Essential Principles for safety and performance

Pathology Technology Australia is grateful for the opportunity to contribute to the above consultation.
We have consulted widely through our member companies to formulate the responses below. At the same time, some members may have chosen to make their own submissions. Even so, the manufacturers, importers and suppliers of IVD devices are aligned on the key points in our contribution.
To summarise our key recommendations:

- We understand that one of the key features of the Essential Principles is to guide design and development with safety, performance, efficiency and clinical utility amongst many manufacturing aspects. The IVD device manufacturers strongly recommend aligning the EPs with Europe's GSPR. Most international manufacturers have already made steps towards such an alignment. With Australia's relatively small market size Sponsors have very little ability to influence manufacturers to add additional steps to their GSPR or to provide additional labeling. If Australia deviates or requires additional inputs, this will add cost, delay introduction of products, or could even result in products being withdrawn from the market. Full alignment will have the benefit of companies establishing one set of technical documents for use globally.

- From a manufacturer's perspective, as far as the clarification and restructure proposal, it would be good to have the Australia EPs follow the same organization/structure as GSPR, so we are not "jumping around" to align EPs with GSPRs. As mentioned above, if the general EPs are sufficient, then manufacturers will not have the need to provide country-specific details in their Technical files As reported by Member companies their Asian based counterparts struggle constantly with additional Labelling and as such offer a smaller portfolio to the market, this is already evident today.

- Inclusion of ARTG number in software or electronic pdf is a burdensome proposal and it is difficult to understand the justification for this requirement. Pathology Technology Australia disagrees with this proposal and suggests that the Device Identifier (DI/GTIN) or UDI be proposed instead as a way to trace. The use of GTIN/UDI increases efficiencies throughout the DoH as other States are already using this in their product traceability systems.

- The current workload for manufacturers globally, with the MDR/IVDR remediations, has completely swamped company resources. The TGA suggestion for a 5 to 6-month window to achieve registration is completely unrealistic. There will be little to no bandwidth within companies to comply and could result in a huge proportion of the submissions made right

on the deadline. We strongly suggest re-aligning the timelines to follow EU MDR/IVDR times by at least 12-18mths.

It's important to point out that additional requirements above and beyond those required for EU compliant products such as the cost of goods (certain low margin goods) will become cost-prohibitive and may be actively withdrawn from the market by sponsors. This reduces choice and range for both customers and patients. All additional country specific requirements incurs a cost to the Sponsor which could potentially increase the final cost of goods. Higher cost products due to requirements for example, over labelling to comply with Australian specific requirements, will impact on customers and potential patients.
The Report of the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) recommending harmonisation has benefits not only for the manufacturer but for which flow directly right down to the patient.
Please see our responses below.

Question No.	**Question**	**Pathology Technology Australia's Response**
Proposal 1 - Incorporation of IMDRF Essential Principles and EU GSPR details		
Do you agree with the proposal to update the Australian Essential Principles to:		
1 a. 1b.	align with the IMDRF Essential Principles and Labelling documents? include relevant additional details captured by the General Safety and Performance Requirements in the EU MD and IVD regulations?	1(a) PTA disagrees with alignment with IMDRF Essential Principles. 1(b) We are open to further consultation on the addition of relevant IMDRF principles regarding safety and performance for in vitro diagnostics (IVD) into the template of the EU IVDR General safety and Performance Requirements (GSPR) framework. Where Labelling may vary this has a significant impact on every country (sharing the product) outside of Australia and as such should be aligned with the largest of trade partners as possible. (refer also to Q5) Commentary: PTA supports international alignment in all scenarios's however through industry contact both local and overseas we are quite aware that IVD Regulation is relatively new and at this point in time heavily biased to the development and compliance with the European IVDR and related GSPR. We would like to draw your attention to the 2015 Report of the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) specifically Recommendation 20 for reforming the therapeutic goods regulatory framework. In particular that Australia's NRA is wherever possible to align with the EU framework.

		We understand that one of the key features of the Essential Principles is to guide design and development with safety, performance, efficiency and clinical utility amongst many manufacturing aspects. *If the majority of Conformity Assessment Certifications for the majority of imported IVD's to Australia are compliant to EU IVDR in the future, how are Australian sponsor's, having little leverage from our relatively small trade perspective, going to be able to ask overseas Manufacturer's to bring in additional steps to their GSPR or additional labelling* (where IMDRF currently appears to be clearly over and above reasonable expectation) The time frame for implementation to be after that of the GSPR EU IVDR as the same Manufacturers are currently supporting that incredibly large trade region with significant dossier remediation plans underway. This may well be 12-18mths time period after Nov 2022 (IVDR).
Proposal 2 - Clarification of existing requirements		
2	Do you agree with the proposal to provide additional clarity regarding expectations for compliance as specified under Proposal 2?	PTA has no objection The IVD industry members have no objection with TGA providing additional clarity for IVD, non-IVD and in-house Lab developed tests. However, consultation should be sought in order to ensure prescriptive examples if any are in alignment with the global understandings of our members. The reference to additional clarity are ethics, social factors, public health etc which may well be additional regulation depending on how the plan to implement is to be considered (and we hope with consultation) could be in the form similar to Reg 10 Miscellaneous additional considerations that become country specific where agreeable by public and industry. The requirements of Labelling (refer also Q5) should remain within the EP which is clear to Manufacturer's as primarily their responsibility to provide information about their device and as such will harmonise with our long-standing European trade partners.
Proposal 3 - Restructure for improved clarity		
3	Do you agree with the proposal to restructure the	PTA are in partial agreement

	Essential Principles and Labelling requirements for clarity and readability?	PTA industry members agree with the concept, of a review/restructure of the current Australian EP, *however alignment must be towards the EU IVDR-GSPR* to which Manufacturer's globally are currently assessing and aligning with. Commentary Importantly, clarity within each future Essential Principle must be made for every single line item in relation to its applicability in vitro diagnostics, devices or both. *This is a critical request of our IVD members.* In relation to the minor discussion within the consultation of Proposal 3 around the placement of Labelling in the Regulation, we can only re-iterate Labelling should be aligning with the European guidelines and these should REMAIN within the Essential Principles. Labeling as part of design and development clearly indicates the role of the Manufacturer is to determine and make available "information about the device". There should be little to no additional Australian requirements in either the EP or for example the current Miscellaneous Reg 10 (e.g. 10.2 Sponsor contact details; as an example, having caused incredible angst with the address being included when technology and flexibility should have dictated a simple phone or web contact).
Proposal 4 - ARTG number		
4	Do you agree with the proposal that software medical devices without any physical packaging should include the ARTG number on the electronic label?	PTA does not agree. In relation to consistency with international regulation please note international best practice, appears to be no country specific licence labelling, as neither the European Commission nor the U.S. FDA require manufacturers to include regulatory approval numbers on the device labelling or IFU. With increased digital transformation, the TGA may have the software capabilities to internally identify devices by UDI/Catalogue code identifiers found also on packaging at a later date, this is something we would be supportive of. Another theory presented in this consultation was that labelling virtual SW code or pdf documents is possibly

		simpler than physical packaging or paper instructions for use, however, this is incorrect and much more complicated than face value.
	Are there other devices where the ARTG number should be provided?	No further comments, alternatives to labelling have been proposed.
Proposal 5 – Financial Impact		
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.)?	PTA does foresee a *significant financial impact on the IVD* Sponsor Industry and their overseas Manufacturers if there are as many proposed differences from the EU GSPR (inclusive of labelling) as are being suggested in this consultation document. PTA also foresees *impact to registrations in other countries* when implementing label requirements that do not align with the major trade partners, USA or Europe. When single shared products change label, all regulated countries many of them may be forced into Variation submissions. Commentary Whether locally manufactured or the more common overseas manufactured IVD, there will be significant costs associated with technical file remediation, both in development of a different set of principles for Australia as compared to Europe (in this proposition) and in the development of additional testing protocols and reporting that is likely to be required by different interpretations under IMDRF to EU GSPR. Certainly, it is clear that Labels that do not align globally will require remediation, translations, and cost to other (flow on) international registrations in other countries that are affected by the label changes having shared the same product for distribution Of greater concern is something visible now even for Europe a large trade zone; the ongoing need to rationalise the portfolio and whether it is financially beneficial to perform the remediation effort or better to pull the device from the Australian market or even end-of-life the product entirely. Lastly, even where keeping key products in the marketplace, there will be delays in compliance with the Australian requirements (if they are not aligned)

		due to the heavy burden on companies to comply with the MDR/IVDR, which must be acknowledged as being where most companies' efforts are focussed for the next 4-5 years.
Proposal 6 – Transitional arrangements		
6.	Do you have any comments regarding the transitional arrangements proposed in this paper?	6, PTA must strongly recommend the time frames that are often medical device focussed remember that all IVD companies are somewhat a tag along in both the European IVDR running afterwards to the MDR and in Australia's industry experience. Our members would prefer more time (12-18mths) to achieve changes or updated registrations before the four year transition period begins. The entire worldwide industry is swamped with the remediation efforts required for the MDR/IVDR and allowing only 5-6 months after those deadlines to achieve registration is very difficult. Critically, it will likely result in the TGA receiving 90% of applications or updates to conformity assessment as necessary in this last 6month period when Manufacturers have time to refocus following MDR/IVDR deadlines. The 4 year transition period once registration is achieved is fine. Again, this date starting 1-2 years after November 2022 for IVD's, not just 5-6months.
Proposal 7 – Other comments		
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)?	Two key factors to any change in regard to Medical Device Regulation, should be <u>that new or changed text be clear that it relates to IVD's and the IVD implementation time frame be considered</u>. With any future Essential Principles classic Device companies are going to be somewhat more prepared for development and change, whilst IVD products and manufacturers are facing a greater change globally and are unlikely to reflect the same speed of understanding and uptake. Australia is unique somewhat in the combination of classic Devices and IVD's <u>into a single Legislation;</u> this cannot be underestimated in leading overseas Manufacturer's, whom in fact are those responsible for

		complying with much of the requirements, to confusion in overlapped rules, requirements or definitions. As such any future change must take into account clarity in relation to the applicability to in vitro diagnostics: - - Simple examples include greater reference to the "Information provided with a device" versus the introduced term "labelling" and where the definitions for assumed understanding truly sit. - Another example is the Device terminology creeping into shared IVD/MD principles as occurred in the commentary e.g. "t" and "u" of Appendix 1 of the TGA Consultation document where "t" appears for both MD/IVD to the overseas reader, whilst "u" is scoped as discussing IVDs (one noticeable confusion from some member reports was the SSCP point in "t" as the MDR term, for IVDR it is SSP and only for certain classes of devices); - From Appendix 3 from IMDRF and not IVDR/MDR is the mention of Manufacturer Liabilities (general warranties), this would pose a significant rework of labelling as has already been clarified by Australia's ACAC this is a statement to the first Distributor/Sponsor importing the product and not strictly related to an end user, thus nothing to do with instructions for use to an end user. - 5.2.16 Appendix 5 presents another example, the whole paragraph being from the MDR, but it is not in the IVDR as substance content would be described appropriate to the IVD clinical requirement and not like that of a standard device incorporating a biological or medicine. - IMDRF differences from IVDR of interest to be further consulted on if IMDRF labelling 'suggestions' were forced into Australian legislation. From Appendix 5: - 5.3.21 Transport is not in the IVDR; 5.3.24 instructions regarding damages also not in the IVDR; 5.3.25 is not in the IVDR and appears more like a medical device sterilisation suggestion; 5.3.28 relating to significant levels of radiation is not part of the IVDR. <u>these notations above are simply to highlight care needs to be taken in genericising the Essential Principles.</u> Lastly,

		5.2.11 inclusion of the importer or distributor on the product label. This comment by IMDRF has led to many Asian countries employing staff on reduced wages changing the English language to their own non-English language and adding stickers all over the cartons with multiple additional labelling requirements from both the Asian regulators and led by IMDRF over burdensome guidance. This concept should NOT be taken up at all in Australia. As experienced with the Miscellaneous Regulation 10.2 that has been controversial since its inception if a review was to occur it should be in relation to 10.2 providing flexibility for a modern society.