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**Consultation: Scope of regulated software-based products**
**Pathology Technology Australia – May 2020**

## ***Executive Summary***

Pathology Technology Australia recommends the lightest of regulatory touches for software-based products regarding in vitro diagnostic applications. This recommendation is based firmly in the TGA principle, described in the consultation outline, of reducing unnecessary regulatory burden;
– by not regulating products where there is no a risk to safety (a no-harm principle)
– by not regulating twice (that is, where suitable frameworks for product or system oversight are already in place).

From the perspective of Pathology Technology Australia and its members, the current regulations are effective, providing safety and efficacy commensurate with the much lower risk profile associated with IVDs. We recommend minimal changes to existing classifications if any and suggest further consultation with the IVD sector at this early stage. Laboratory Information Management Systems (LIMS/LIS) and Middleware software, that do not recommend a diagnosis or treatment decision and that do not message IVD instruments should be exempt.

In addition to the above measures, it is recommended that the TGA continue with its recognition of comparable overseas regulators in terms of conformity assessment and validation or verification of software intended actions. This will also allow TGA to fast-track approvals in Australia by continuing to recognize international approvals from these countries (particularly where regulatory review by one or more agencies has already taken place). Given the predominance of medical devices originating from these markets, the TGA's regulatory burden would be lessened, allowing the Administration to focus on software as medical devices whose classification may differ between jurisdictions.

## ***Justifications***

IVD software devices, like almost all other IVD devices, are not intended for use by the consumer and have multiple layers of controls, process and oversight before they lead to an action taken that affects a patient. These controls are not only built in by the IVD manufacturer, but also the regulations associated with clinical laboratories (e.g. ISO 15189 and NPAAC guidances). Therefore, the risk of harm to the patient is low. As such, we recommend that IVD software devices be principally managed via post market surveillance.

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The current guidance provided to industry supporting IVD regulation and application is summarised in short at the end of our response. Software already has a risk-based approach as does all IVD regulation, and for example, only software that is separate from an instrument **and** where its intended purpose is to determine a high risk/high classed diagnostic, requires higher classification.

Clarity however is sometimes difficult when it comes to Laboratory Information Management Systems (LIMS/LIS). Further industry discussion needs to be held around distinctions between a basic LIS, Clinical LIS, enhanced LIS and Middleware applications.

Aside above, the following factors are some of the key reasons why we take this approach:

Software devices are increasingly complex and diverse in their coding, their interconnectivities and their data presenting and storage options, requiring skilled and experienced experts to write, maintain, train and use. Additional complexities include the presence of multiple and widely distributed LIS locations and workstations, sometimes accessing different levels of functionality. More extensive use of the lower levels of the GDMN codes might be useful in aiding classification.

IVD software that complies with IEC 62336 and 62304 will be able to demonstrate compliance to Australia's Essential Principles. The Verification and Validation reports and other common deliverables can be made available for review by the TGA based upon risk classification, but since the majority of these products are manufactured overseas, the recognition of international approvals should be utilized wherever possible (as previously discussed.)

Software devices benefit from frequent updates and enhancements which are often loaded automatically once the user has accepted its implementation. Monitoring updates and related releases would be an unreasonable burden on Manufacturers, Sponsors and the TGA. This should already be managed within the Quality Management System of the Manufacturer and through their agreement with the Sponsor. Many software updates are typically enhancements that have been developed and optimised in conjunction with active and professional customer feedback. Post-market monitoring is likely to be the most effective means for the Manufacturer, Sponsor and the TGA to determine that the software medical device is operating as intended in the field.

There will be an increasing demand for software with self-learning and Artificial Intelligence capabilities. It is expected that these will be constantly changing based on software outputs, inputs and the environment that they operate in. Regulation of

such software will need to be based on the IEC 62336 and 62304 standards, including a demonstration that it meets the intended use statement together with robust post market surveillance.

***Summary***

In summary, we must reinforce that IVD Software, as with most IVD devices, are not intended for use by the consumer and have multiple layers of controls, processes and oversight between the software output and an action being taken to a patient. This is significantly different to that of the focus of the SaMD Consultation being the broader medical device arena.

Pathology Technology Australia and its members recommend that IVD software devices are kept out of these SaMD consultations until discussions between the TGA and the IVD industry are finalised.

Pathology Technology Australia and its members certainly wish to engage but we respectfully suggest that this is not a great time for the TGA or local Manufacturers and Sponsors to find the bandwidth to give this topic due process.

***Follow Up Discussion Topics***

From an industry and end user perspective, we are generally happy with the way things stand now; we understand the regulations and their requirements/expectations, and we think it works well for IVD software.

Our Members would be interested in further discussions with the TGA in relation to LIS/LIMS devices; their definitions, purpose and classifications accordingly. We note that LIS functionality can vary greatly within a single product (via "bolt on" option) and between products requiring system communications and interactions.

LIS can also range from basic In/Out functionality, through to functions that take the place of a device operator; from making decisions to enacting requests for repeat tests, reflex tests and diluted tests and so on. Current GMDN-CT selections in Australia identifies guidance on some of these complexities however can still be considered ambiguous. We feel these are some of the opportunities for clarity and guidance without necessarily needing to change regulation.

Further discussion on Clinical Decision Support software would be of benefit, along with further clarification of some conflicting advice on software used to generate companion diagnostics results.

Acknowledgement of current IVD Software guidelines in summary format:

Aside Regulation 3.3(5) Principles for applying the classification rules in the Regulation and Schedule 2A IVD Classification Rule 1.6 w*e wish to highlight below the GMDN/CT and Class Guidance on Software and useful Web supporting material*. It is the regulation of common and not so common "Clinical LIS" systems having only one mention in the GMDN Software Class guidance document where the industry would likely benefit from greater guidance.

https://www.tga.gov.au/publication/software-vitro-diagnostic-medical-devices-ivds

***Software IVDs***

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| L1CT (Class 1 IVDs) | **CT944 Software IVDs**<br>Software that has been developed for the purpose of being incorporated into an IVD or that is intended for use as an IVD in its own right. Software systems may be an integrated collection of items which include computer programs, procedures and any associated documentation and data.<br>All analytes as represented in Level 2 software collective terms. |
| L2CT (Class 2 & 3 IVDs) | **CT1250 Analyser software IVDs**<br>Software that is intended to be incorporated into an IVD analyser to establish or supplement operational functions which may include the processing of specimens, generation of data, interpretation, storage, display and/or reporting of results obtained from a clinical laboratory specimen.<br>Laboratory analyser software |
| L2CT (Class 2 & 3 IVDs) | **CT910 Interpretive software IVDs**<br>An interpretative software algorithm intended to be applied to a clinical result or set of results obtained through testing in order to identify and/or formulate additional clinical information which may then be used to guide patient management.<br>First trimester screening assessment trisomy 21 (Down syndrome) risk software. |
| L2CT (Class 2 & 3 IVDs) | **CT1251 Laboratory information system IVDs**<br>Software that is intended to be used either as an independent system or incorporated into an existing network to establish or supplement the functions of a clinical laboratory information system including the generation of data, interpretation, storage, and/or reporting of results obtained from a clinical laboratory specimen.<br>Clinical laboratory information system software, Blood bank laboratory information system software. |

**About Pathology Technology Australia**

Pathology Technology Australia Ltd is the peak industry body representing manufacturers and importers of technologies, vital to testing patient samples in the clinical laboratory, in hospitals and in the community.
This technology enables more than 500 million tests to be performed in Australia every year. With an aging population and increasing disease chronicity, pathology technology will play an increasingly important role in providing high quality, accessible and affordable healthcare services in Australia's future.