Public Pathology AUSTRALIA

21 December 2018

Att: Ms Breanna Gallagher
IVD Reforms, Medical Devices Branch
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Therapeutic Goods Administration
Department of Health
devicereforms@tga.gov.au

Dear Ms Gallagher

Regulation of IVD Companion Diagnostics

Thank you for the opportunity to comment on the proposal for the regulation of In Vitro Diagnostic (IVD) companion diagnostics dated October 2018 (the CDx Proposal).

Background & Scope

Public Pathology Australia (PPA) represents the government owned and operated pathology services across Australia (see www.publicpathology.org.au).

PPA recognises that the main focus of the CDx Proposal is on those products that are marketed commercially with claims around being essential for the safe and effective use of a new medicine or biological.

PPA members also use laboratory developed or "in-house" companion diagnostic tests which are treated differently under the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG) compared to the commercial IVD medical devices. These in-house companion diagnostic tests are typically provided within immunology and genetics (molecular) departments within pathology providers. PPA makes this submission as the regulation of commercial companion diagnostic tests may have an impact on the future regulation of in-house companion diagnostic tests as stated on p19 of the CDx Proposal.

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Submission

PPA is in favour of the introduction of a legal definition for IVD companion diagnostics and a regulatory approach that ensures these devices are subject to an appropriate level of premarket scrutiny prior to commercial supply in Australia. PPA is in favour of the Proposals 1- 8. However, the application of these recommendations to in-house companion diagnostics as identified in Proposal 9 must be further explored. This is necessary in order to strike an appropriate balance between meeting a need, fostering innovation and improvements in clinical safety under the National Pathology Accreditation Advisory Council (NPAAC) framework.

Proposal 1 - Definition
The proposed definition of IVD companion diagnostics is appropriate as it is harmonised with global definitions whilst still being tailored to the *Therapeutic Goods Act 1989* (the Act). PPA agrees with the need for the two caveats listed on p12 of the CDx Proposal, being IVDs to match donor blood, tissue or organs with a potential recipient and IVDs to monitor treatment.

Proposal 2 - Essential for the safe and effective use
The meaning of "*essential for the safe and effective use*" is clear, being for the purposes of labelling the medicine / biological therapeutic good in product Information (PI) and consumer medicines information (CMI) as illustrated on p13.

Proposal 3 – Class 3 classification
Companion diagnostics should be classified as Class 3 IVDs under Schedule 2A of the *Therapeutic Goods (Medical Devices) Regulations 2002* to ensure appropriate and consistent regulation of IVD companion diagnostics.

Proposal 4 – Compulsory audit
It should be made clear that a compulsory audit of all IVD companion diagnostic tests prior to inclusion on the ARTG is limited to commercial companion diagnostics as in-house IVDs do not need to be included on the ARTG. In-house IVDs are regulated by the (NPAAC) Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (IVDs) (Fourth Edition 2018) and subject to National Association of Testing Authorities (NATA) assessments.

Proposal 5 - Identification
Regulation 1.6 should be amended to require a unique product identifier as a characteristic for identification of all commercial IVD companion diagnostics in applications for inclusion on the ARTG.

Proposal 6 - Fees
Fees should be commensurate with cost recovery for assessment. There should be fee reductions for abridged assessments.

Proposal 7 & 8 - Transition
An appropriate transition process and timeframe is necessary to meet the new requirements.

Proposal 9 - Inhouse IVDs
The principles behind regulation of commercial IVD companion diagnostics are sound. In-house IVDs are regulated under the TGA within the NPAAC framework. NPAAC requirements have been progressively reviewed to reflect clinical risk parameters.

Compliance of in-house IVD companion diagnostics must strike an appropriate balance between meeting a need, fostering innovation and improvements in clinical safety under the NPAAC framework.

PPA is not aware of any patient safety issues that would justify the need for in-house IVD companion diagnostics to comply with the clinical evidence and analytical performance requirements applicable to all IVD companion diagnostics. However, a literature review should be undertaken by the TGA in order to make an evidence-based assessment of the need for higher regulation of in-house IVDs prior to seeking feedback on this matter.

Should this review indicate a need for change, a targeted consultation process engaging the providers of in-house companion diagnostic tests (represented by their industry associations such as Public Pathology Australia) and regulatory bodies (National Association of Testing Authorities (NATA), the Royal College of Pathologists of Australasia (RCPA) and the National Pathology Accreditation Advisory Council (NPAAC)) is the best approach to ensure that in-house IVD companion diagnostic tests will be being adequately assessed.

PPA trusts that these comments are of assistance. For any points of clarification or further information, please contact PPA's CEO Jenny Sikorski on 0466 576 221, ceo@publicpathology.org.au.

Yours sincerely

Dr Michael Whiley
President