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Pathology Technology Australia

Response to TGA Consultation Paper on Fees and Charges 2023-24

It is very clear from many perspectives that the TGA is under-funded. However, placing a greater burden on the industry to fund the TGA is problematic, as we submit below.

The members and management at Pathology Technology Australia (PTA) express our grave concerns regarding the proposed increase in fees and charges imposed on the industry to pay for digital transformation, program implementations, new building fit out and to subsidise 50% of public good activities at the Therapeutic Goods Administration (TGA).

TGA's funding model has been controversial both locally as well as internationally over the years (https://www.kickstartqueensland.com.au/audit/scathing-review-of-the-tga/, https://amp.theguardian.com/australia-news/2017/nov/08/therapeutic-goods-administration-rejects-claims-it-is-too-close-to-medical-industry), recovering even more from the industry will only exacerbate distrust in the public eyes and attract more scrutiny about conflict of interest.

The Australian pathology technology (IVD) manufacturing and supply sector is already facing significant challenges to market access and business sustainability (in this highly competitive and low margin market). The proposed increase in fees and charges will exacerbate these challenges, limiting access to new, innovative, and frequently life-saving pathology tests. This technology is essential for good health in Australia. More than 70% of all diagnosis and patient management decisions depend on pathology technology, as do 100% of all cancer diagnosis.

As a society, we have a duty to ensure that all Australians have equitable access to high-quality healthcare, and increasing the fees and charges for TGA submissions will impede this objective. Australia already lags many other developed nations for access to cutting-edge diagnostic technologies in genomics and point of care testing. We simply cannot afford to put up more barriers to access that will further widen this gap.

Australia is one of the lowest cost healthcare environments in the world and we constitute less than 2% of the global health technology market. Over 95% of all IVD technology used in Australia is imported, mostly from North America and Europe. Importers and suppliers of IVD's have been very successful in securing supply certainty from manufacturers, despite the very low returns achievable here. However, recently we have seen suppliers make decisions not to import and launch new or improved technology in Australia due to the barriers to entry and low return on sales (see the case studies in this response).

More than 98% of all pathology testing is taxpayer funded, (approximately) 65% via the MBS and 35% via State and Territory health budgets. Increasing fees and charges can only lead to 2 possible outcomes: increased costs to the taxpayer, or reduced access to vital technology.

The proposed increase in fees will disproportionately affect smaller suppliers and emerging pathology test developers. Local innovation companies, integral to our sovereign, high tech manufacturing capability, will be hard hit by these fees and charges, driving more of them offshore. This seems at odds with recent government initiatives which are promotion the funding of innovations in certain sectors including medical sciences.

The TGA has significant public health obligations and as such should be funded proportionally from the public purse. Public funding of like services in comparable economies ranges from 35 to 100%. The expectation that the TGA is only 8% publicly funded is completely out of step with international trends and counter to the best outcomes for public health in Australia.

We call on you to consider the broader implications of this proposal and to exclude pathology technology (IVDs) from these proposed increases. It is crucial that Australia prioritises equitable access to healthcare, especially in a sector as vital as pathology testing. We must ensure that Australia closes the technology gap (we have to comparable economies) to again be at the forefront of innovative and cutting-edge diagnostic technology. IVD technology in genomics, point of care testing and digital pathology will deliver better patient outcomes at a lower total cost, improving access and equity to healthcare for all Australians.

Case Study 1 – Supplier of critical infectious diseases tests

A mid-size Australia IVD Technology company, operating for 30 years, employs 14 skilled specialists and imports tests and control samples for rare infectious diseases such as Japanese Encephalitis Virus (JEV), Zika Virus, Chikungunya Virus, Yellow fever and others. In many cases they are the only supplier of such tests and the controls (used to determine if the tests have performed correctly). Their European manufacturer participates in world vigilance to look out for the next pandemic causing virus.

The demand for these products is low but the need for them is critical to lab services at VIDRL and PathWest, to name two. This company's TGA fees have increased 30% in the last 5 year, making these low volume products (commercially) marginal at best. The proposed fees and charges increase will mean these critical products will be unsustainable. This company has already decided not to import and register 5 infectious diseases tests requested by key Australian labs, due to the high costs and low returns.

Further erosion of the company's profitability might see them shut down their Australian business.

Case Study 2 – Lessons from the European regulatory changes

A high-quality manufacturer of critical IVD tests has reduced their portfolio by more than one third and increased prices by up to 70% related to the increased complexity and cost of product registration in Europe. Important technology that has been safely used for many years will now not be available.

Of critical importance to Australia is that some of these products are important control samples that are needed to verify that the tests have worked as intended. The increased TGA fees and charges will make these products even more unaffordable in Australia. Reduced availability of these controls will slow or stop the introduction of (sometimes) esoteric tests which require them.

Products that have achieved IVDR should not be subject to further assessment or fees and charges in Australia.

Case Study 3 – Autoimmune Encephalitis will remain difficult to diagnose

A rare but extremely debilitating disorder, Autoimmune Encephalitis, can be treated if diagnosed early. It strikes women more than men and people between the ages of 18 and 50 years. Patients often require long hospital and ICU stays and suffer psychotic delusions, anxiety and insomnia. New technology to diagnose this disease is available but will very likely not be available in Australia due to the high cost and complexity of registration and the low volume of sales.

https://www.mayoclinic.org/medical-professionals/neurology-neurosurgery/news/autoimmune-encephalitis-paving-the-way-to-better-outcomes/mac-20523925

Summary

While PTA acknowledges that TGA needs a sustainable financial model, our members are not supportive of the substantial increases in fees proposed in this consultation document, as the means to achieve this model. Increasing TGA fees and charges will effectively cost taxpayers more, deliver poorer healthcare outcomes and increase total healthcare costs. We will see reduced market choice and some critical tests might be removed from the market completely. There is a potential for serious impact to patient management in Australia. We will see companies possibly withdraw from Australia. As a nation we will be less prepared for the next serious infectious disease or pandemic. There is no upside to increasing fees and charges for IVDs, only downside; the illusion of cost recovery will be quickly obliterated.

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