Senator David Pocock, in his role as a participating member of the Senate Finance and Public Administration References Committee, has asked that the following written questions on notice be put to Pathology Technology Australia for response.

Responses to the above questions are sought by **COB Friday, 24 May 2024**.

1. We've heard the government talk a lot about procurement reform and a Future Made in Australia, but I was shocked to find out that to be an Australian company you just need an ABN. Would you support redefining SME in the rules as a sovereign Australian firm, meaning the company is not a subsidiary of a foreign company, is headquartered in Australia and is at least 51 per cent Australian owned and governed by a board of at least 51 per cent Australian directors?

PTA

There may be more to this question than intended. It might also be true that firms can create an Australian ABN and also claim innovation tax credits of 42.5%. Be that as it may, care needs to be given when considering the three factors listed as defining an Australian SME. For example, there may be companies that meet the 51% ownership and director test but for practical reasons need to headquarter offshore. On balance we support the 51% ownership and governance tests and this test being applied to companies accessing the innovation tax credit.

2. To help boost the development of sovereign tech, would you support redefining 'value for money' in the procurement rules to capture 'retained economic benefits' like whether or not a supplier is paying corporate tax in Australia, is a truly sovereign Australian firm, is building local jobs, skills and IP and is investing in local infrastructure and/or capabilities?

PTA

We fully support the concept of retained economic value that covers a wide range of economic values. To be effective there needs to be an economic multiplier factor accepted by commonwealth and state procurement authorities. This factor needs to be sector specific and built in an Australian context. Our own organisation has raised this with DISR and offered to coordinate an arm's length study of the value of high-tech manufacturing in the medical technology sector. We understand that government procurement authorities are not permitted to include indirect economic value in procurement decisions. In our opinion, medical technology and healthcare are fundamentally a national security issue and decisions on sovereign manufacture and supply should be outside FTA considerations. We strongly urge this inquiry to recommend a broader consideration of economic value to facilitate development of a strong sovereign medical technology manufacturing sector on national security grounds. In particular, manufacture and commercialisation of genomic and point of care testing technology, that we are so good at developing.

3. Do you believe the existing Commonwealth Procurement Rules are being complied with consistently across all government departments and agencies?

PTA

We don't have visibility across such a broad range of departments and services. In terms of health procurement, we did see some increased government procurement of Australian technology during the COVID-19 pandemic. However, Australian producers of world class technology were very often bypassed for imported products. Many of these Australian products are very well accepted in North America and Europe.

4. Would you support the establishment of a platform for sovereign Australian startups, defined as firms with 2-20 employees, to showcase their capabilities to the government in a more agile 'sandbox' environment outside of the standard procurement process?

PTA

In general, we agree. We suggest 2 to 50 employees might be more realistic for high-tech medical device start-ups. The issue remains that Australia needs to be the first customer and not the last. If this mechanism results in purchase orders, then great.

5. How can grants and other R&D funding be better connected with the procurement system? Is there a need for greater connectivity between the end of the grant process and the start of the procurement process so the government makes use of more of the products it's funding? If so, what could that look like?

PTA

Yes, completely agree. This is a complex topic that needs a broader treatment. The ADAPT report (funded by DISR) and completed by MTPConnect and PTA (and was included as part of our written response to this inquiry) addressed this topic in part. For this proposal to be fully effective, R&D for diagnostic devices needs to be guided by an overarching diagnostic strategy and roadmap. In brief, such a strategy could identify high priority, unmet health needs and direct R&D, manufacturing and commercialisation in that direction. This would increase the end-to-end success rate and value for money.

Not to over emphasis the point, Australia spends about $6.1 billion per year on medical R&D, this puts us into the top 5 nations globally for innovation. The tragedy is that, from a diagnostics perspective, virtually none of that flows back to benefit Australia in any way – no patient benefit, taxpayer benefit, no new employment and no development of sovereign high tech manufacturing capability.

A properly constructed diagnostics strategy and roadmap, guided by an expert advisory board, including industry representatives, and linked to downstream regulatory, MBS funding and government procurement strategy would deliver far better taxpayer benefits and yield better outcomes all round.

In addition to our responses above, and with the indulgence of this Senate Committee we provide the following summarised perspectives:

- 97% of Australia's IVD - diagnostic devices - are imported.
- It is unlikely that Australia will compete effectively with global manufacturers for the high volume IVD – diagnostics device- manufacturing. However, we have the strong capability to be world's best in a few key areas such as genomic and point of care testing. Establishing this kind of stronghold will provide Australia with bargaining chips at the trade table should global supply tighten.
- In the event of a significant and prolonged geopolitical supply shock our health system is a small step from systemic failure which would place the lives of Australian at risk within 4/6 weeks. This is not news. It is ongoing:
    - In mid-2022, there were only 15 epidural kits available in Victoria at one stage
    - In 2019 Australia was within two weeks of running out of safe blood to use for transfusion services due to a hold-up at the border of tests to screen blood supplies for HIV.
- This issue is neither a health system nor a trade issue, but a national security issue. Which is exactly the attitude the taken by the USA government. Reference the US invoking the Korean War "Defence Production Act" of 1950 during the COVID-19 pandemic.
- We note the Treasurer's recent statements calling for the "fusion of Australia's international and domestic ends and the integration of the government's economic and strategic ends".
- We believe this goal can be achieved by better alignment between national security and national procurement.
- We note that:
    - Successive Aust govts have supported innovation via the R&D tax rebate. 42.5c in every $1 spent in R&D is paid for by Australian taxpayers.
    - So Australian innovators identify problems facing taxpayers, and the taxpayer funds the development of solutions that solve these problems.
    - However, under the current system and in the biotech/medtech sector - while the taxpayer supports the development of the solution – the Australian Government is rarely, the first customer for that solution.
- We recommended that the Australian Government should follow the lead of Governments such as the USA, China and Japan by identifying those solution in the supply chain that are of national interest and:
    - Preference local producers/suppliers over offshore suppliers of every solution that falls within the realm of being a national security risk.
    - Introduce a program similar to the US RADX program to support the creation of solutions that respond to problems that fall within the national security risk realm.
    - Preference locally developed solutions that are funded through the Australian R&D process over offshore developed solutions by linking the R&D tax rebate to procurement decisions.
    - Commit to preferencing Australian companies if that company can provide the same solution at the same price.
    - Change procurement policies to clearly state that all suppliers must legally provide Government with their best price (like the US policy), agreeing not sell the same product cheaper elsewhere.
- We point out that for too long the Australian Government has relied on grants as a mechanism to effect change.
    - Grants have a place, mostly in supporting pure research.
    - Australian medtech developers and innovators do not favour grants.
    - Innovators and those commercialising Australian innovation require orders, future orders, a commitment from a customer.
- There needs to be better recognition that the IVD - diagnostic devices - market is almost 100% taxpayer funded and that Federal, State and Territory governments make up around 40% of the customer base.
- The Australian Government should be the first customer for Australian innovation not the last.
- If the problems we solve through our innovation are compelling enough to receive 41.5% in the dollar R&D tax rebate, if they are compelling enough for the first customer to be the Australian Government, then they are compelling enough to be scaled globally.