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Levant Section Middle East Branch Department of Foreign Affairs and Trade RG Casey Building, John McEwen Crescent Barton ACT 0221

Dear DFAT

Feasibility study on strengthening trade and investment with Israel: Submission by the Medical Technology Association of Australia

Background

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

MTAA members provide all of Australia's healthcare professionals with essential product information, continuing education and training to ensure safety and to optimise the effective use of medical technology. Our members design, manufacture and circulate virtually every medical product used in the management of disease, disability and wellness in Australia.

Response

MTAA and its membership supports a bilateral economic relationship with Israel for the purposes of advancing medical technology in Australia and thereby providing access for Australians to novel medical technologies.

The Australia / Israel tax treaty, enacted in 2019 removed the greatest barrier to trade and investment with Israel. With this in place, the MTAA recognises that Israel is a 'start-up nation' with 20 of the 350 multinational research and development centres focused on medical technology.¹ While engagement between the Israeli and Australian medical technology sectors has historically been low, the sectors are potentially complimentary with significant room for further collaboration. For this reason, MTAA would welcome improving trade and investment pathways, including through a free trade agreement, from a medical technology perspective.

Israel has a particularly strong start-up culture including in medical technology. However, the next stages of pre-commercialisation are less successful there: from clinical trials to meeting regulatory standards to manufacturing / conformity assessment, distribution and procurement pathways. Whereas Australian companies, facing similar challenges, are more skilled at navigating these pathways.

¹ Deloitte Consulting & Deloitte Catalyst, Startup Nation: The Future of MedTech is Underway in Israel, (2021)

In programs where there are joint interests, there has been little uptake and few success stories, eg. Victoria's VISITS program <u>https://business.vic.gov.au/grants-and-programs/the-victoria-israel-science-innovation-and-technology-scheme-visits</u>.

As an example, one field that is well-suited and potentially 'ready' for synergistic trade and investment is the 3D printed medical devices, as they can be produced quickly, are lightweight and readily customisable. R&D in this area in Israel is growing at a rapid pace, with novel applications, fast-iteration innovations in printer design and diversity in biocompatible materials. Australia is considered a world leader in the regulation of 3D printed medical devices. In fact, our regulatory processes have been adopted by the International Medical Device Regulators Forum (IMDRF) that seeks to harmonise device regulation worldwide. It is expected that the EU and the UK will adopt these standards. Therefore, Australia could be a potential target for clinical research, early registration and launch of Israeli technology, potentially in conjunction with Australian partners. This may enable partnerships that launch technology in other major markets.

Thus, a unique and complementary opportunity exists for Australia and Israel, at least in the short term. This provides an incentive to file for inclusion on the ARTG with the TGA prior to filing in the EU or the USA (typically, FDA approval in the US is sought prior to a TGA application because of shorter completion times).

In order to attract a meaningful cohort of Israeli startup companies to Australia, any trade and investment arrangements between Israel and Australia would need to:

- 1. Provide the right visa and personal tax settings to enable start-ups (incentivised by stock options) to move back and forth between the countries;
- 2. Ensure that FIRB approval process is favourable (ie. lower thresholds for Israel as is the case with the UK and the USA). The current FIRB process is deemed too slow to be attractive to investors;
- 3. Seek where possible aligned regulatory processes and mutual recognition between the TGA and AMAR, so as not to duplicate processes that are essentially equivalent.

In short, MTAA is very supportive of DFAT improving trade and investment between the two countries and looks forward to further consultation on these issues. Please contact Merrilyn Clancy, Senior Policy Officer, via email <u>mclancy@mtaa.org.au</u> for any further information.

Yours faithfully

lan Burgess Chief Executive Officer