Medicines Australia & The Medical Technology Association of Australia

Submission on the Exposure Draft of the Defence Trade Legislation Amendment Regulations

Medicines Australia (**MA**) and the Medical Technology Association of Australia (**MTAA**) welcome the opportunity to comment on the Exposure Draft for the *Defence Trade Legislation Amendment Regulations* 2024 (Cth) (**Exposure Draft**).

The recently passed amendments to the Defence Trade Controls Act 2012 (Cth)(**the Act**) have the potential to negatively impact clinical trials and life science research commercialisation in Australia, and diminish the health and economic benefits they bring. Unfortunately, MA, MTAA, and the broader innovative health sector were not provided ample opportunity to comment on the draft legislation, beyond participation in a round table late in the process.

The amendments to the Act introduced new definitions for *Defence and Strategic Goods List* 2021 (Cth) (**DSGL**), creating complexity, confusion and a risk of unintended non-compliance, potentially resulting in criminal sanctions. The lack of certainty of conducting a clinical trial that will not breach some or all provisions of the Act is likely to discourage future clinical research in Australia. This undermines progress over the past two decades to make Australia a more attractive destination to conduct clinical research.

In this submission, MA and MTAA will outline the key concerns and considerations the pharmaceutical and medical technology industries have relating to the amendments in the Act, and recommendations for the Exposure Draft.

Key Concerns

Complexity and uncertainty with severe consequences for non-compliance

The amendments to the Act significantly expand the range of activities which may be subject to sanction, creating a complex situation for global pharmaceutical and medical technology companies. This poses a real risk of criminal sanctions for innovative medicines and medical technology companies due to the broad scope of their research and development activities.

The expanded definition of DSGL technology means that information generated through research, including clinical trials, may fall under the category of DSGL technology if it is necessary for the development, production, or use of a product listed on the DSGL. This creates uncertainty for companies conducting clinical trials in Australia, as they may inadvertently breach the legislation if their research falls within the scope of the DSGL.

The introduction of the concept of DSGL services further complicates matters, as the provision of advice or support related to clinical trials could be considered DSGL services if the underlying product falls within Part 1 of the DSGL.

Whilst already a pre-existing power, and separate from the recent amendments to the Act and the Exposure Draft, the Government can add items to the DSGL at any time without seeking input on the appropriateness of such additions. An item not initially on the DSGL during a clinical trial may

later fall under the DSGL due to amendments, potentially resulting in a technical breach of the legislation. That means that the primary concern of industry, about retrospective capture of technologies in the DSGL, is already a risk.

Furthermore, the new offences in section 10A will expand criminal offences under the Act to any supply of DSGL technology to a foreign person in Australia, whether or not, for example, that person is a student or employee who is a foreign national (anyone who is not an Australian citizen or permanent resident). The heightened legal risks and potential penalties may further discourage companies from investing in research and development in Australia, fearing legal repercussions and financial liabilities.

There is a general power to prescribe (by regulations) circumstances in respect of which the offences in sections 10, 10A, 10B and 10C of the Act do not apply. The Exposure Draft currently includes a number of exemptions from some or all of these offences. However, multinational companies and Australia's emerging sovereign manufacturers may face challenges in navigating the regulatory landscape and ensuring compliance with the amended legislation.

The lack of clarity in legislative interpretation, even when referencing explanatory or external materials, makes it difficult for companies to make informed decisions whether to invest in research and development activities in Australia. Given the serious consequences of any mistakes, the Exposure Draft should establish clear guidelines and regulations to help companies navigate the regulatory landscape and ensure compliance with the Act. Additionally, any amendments to the DSGL should be subject to consultation with the pharmaceutical, medical technology, and broader life sciences industry.

Lack of clear exemptions for clinical trials

The lack of clear exemptions for clinical trials in the Act and the DSGL could have a significant impact on the clinical trials sector. The definition of "fundamental research" is crucial in determining whether certain activities, such as clinical trials, would be subject to the Act.

The amending Act defines "fundamental research" as *"basic or applied research conducted in circumstances where the results of the research: (a) are intended for public disclosure, or would ordinarily be published or shared broadly; and (b) are not subject to any restrictions on (however imposed) for purposes connected with the security or defence of Australia or any foreign country"*

Based on this definition, it can be inferred that if a clinical trial falls within the scope of "fundamental research," it may be exempt from the provisions of the Act. However, the need for clarity and certainty is important applying the Act to clinical trials, as the definition of "fundamental research" and its interpretation may vary.

Without explicit carve outs or exemptions for clinical trials, there is uncertainty and ambiguity regarding the application of the Act to research and development activities in the medical and health technology field. The Exposure Draft should provide a clear and comprehensive definition of "fundamental research" and/or clear and explicit carve outs to ensure that legitimate research activities are exempt from the Act's provisions.

Detering clinical trial investment into Australia will negatively impact the health of Australians and the economy

Clinical trials are a fundamental part of the healthcare system. They play a critical role in the research and development of new medicines, vaccines, medical devices, and diagnostics. Clinical trials not only offer patients early access to potentially life-saving treatments at no cost, but they also contribute to the expansion of medical knowledge.[1]

Through R&D and clinical trials, Australia has generated globally transformative medical innovations like the human papillomavirus vaccine Gardasil®, the Cochlear bionic ear implant, and Recell® Spray-On Skin. Industry fears that locally developed world class medical technologies, such as Polynovo's Revolutionary Synthetic Skin Substitutes, may be retrospectively captured by the DSGL.

Beyond health benefits, clinical trials play a pivotal role in the economy of the future, which innovative jobs, exports and productivity will rely. Clinical trials contribute around $1.4 billion to the Australian economy annually, including around $650 million of foreign investment, with Australia attracting trials from around the world.[1] The medtech and biopharmaceutical industries combined contribute $5.5 billion to the economy, $8.2 billion in exports, $2.1 billion in R&D investment, and support upwards of 73,000 jobs in industry and research.[2]

The broad interpretation of the legislative amendments and the uncertainty surrounding their application could discourage future clinical research in Australia. This is a significant concern for MA, MTAA, and the broader innovative health industry that rely heavily on clinical trials to develop and bring new medical treatments to market.

Furthermore, the legislative amendments undermine efforts to make Australia a more attractive destination for global companies to conduct clinical trials. The funding of the National One Stop Shop for clinical trials, announced in the 2024-25 Federal Budget was a result of decades of work and advocacy to streamline clinical trial startup processes. Even the additional process of applying for exemptions would add complexity to a system trying to be more streamlined.

If the legislative amendments create a risk of criminal sanctions for these companies, and/or create excessive administrative burden, it may deter them from conducting clinical trials in Australia, leading to a loss of research opportunities, and a reduction of health and economic benefits. It is, therefore, important that the Exposure Draft provides clarity and guidance on compliance to the Act.

Recommendation

This submission proposes that another exemption should be added in respect of all offence provisions, for circumstances where the DSGL goods or DSGL technology, or provision of DSGL services occurs in relation to a clinical trials which involves a product listed on the Australian Register of Therapeutic Goods or which is, or is proposed to be, the subject of an exemption or approval pursuant to the *Therapeutic Goods Act 1989* (Cth), the *Therapeutic Goods Regulations 1990* (Cth), or to the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth). These are the provisions under which the TGA authorises the conduct of clinical trials in Australia pursuant to its Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) schemes.

MA and MTAA acknowledge the rationale for the amendments to the Act. However, we would like to highlight the potential for unintended consequences for our industry. Future amendments to the Act should involve consultation with the pharmaceutical, medical technology, and broader life sciences industry, and allow adequate time for feedback.

MA and MTAA hope to see specific exemptions for clinical trials in the appropriate instrument, as well as industry consultation becoming a requirement when amendments are made to the DSGL. Our industry looks forward to continuing to work with Defence to ensure a healthy and thriving society, as well as ensuring the security of Australia.

Please do not hesitate to reach out to Medicines Australia or the Medical Technology Association of Australia to discuss any information in relation to this submission.

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About Medicines Australia

Medicines Australia leads the research-based medicines industry of Australia. Our members discover, develop and manufacture prescription pharmaceutical products, biotherapeutic products and vaccines that bring health, social and economic benefits to Australia. Our members invest in Australian medical research and take local discoveries and developments to the world.

About the Medical Technology Association of Australia

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.

[1] MTP Connect. Australia's Clinical Trials Sector Report 2021 [Internet]. Available from: https://www.mtpconnect.org.au/images/MTPConnect_2021_AustraliasClinicalTrialsSectorReport.pdf

[2] MTP Connect. Medical Technology, Biotechnology and Pharmaceutical Sector Competitiveness Plan 2022. [Internet]. Available from: https://www.mtpconnect.org.au/images/2022_MTPConnect_SectorCompetitivenessPlan.pdf