



26 November 2020

Department of Home Affairs
Australian Government
CANBERRA ACT 2601

Dear Sir/Madam,

**MSD AUSTRALIA RESPONSE TO THE SECURITY LEGISLATION AMENDMENT
(CRITICAL INFRASTRUCTURE) BILL 2020**

MSD Australia welcomes the opportunity to respond to the Security Legislation Amendment (Critical Infrastructure) draft Bill 2020.

2020 has firmly showcased the need for government and enterprise to recognise the interdependencies and inherent vulnerabilities that exist across key infrastructure assets and systems in Australia. In a world where volatility, uncertainty, complexity and ambiguity are now the norm, MSD Australia applauds this initiative as we believe it seeks to provide a framework to help protect the critical capabilities that underpin our society in what has become a highly interconnected world.

MSD Australia wishes to provide feedback on two main points in relation to the proposed bill amendment, firstly the selection criteria for assets deemed Critical Infrastructure and secondly the proposed provisions for government assisted powers in the event of a cyber incident.

Critical Infrastructure Criteria Clarification (Health Care and Medical Sector)

The expansion of scope for what is deemed critical infrastructure is welcomed. The expanded scope that now encompasses communications, data storage and processing, defence, financial services, food and grocery, higher education and research, healthcare, transport, energy, space technology and water and sewerage is both broad reaching and comprehensive. We at MSD Australia, as an innovative biopharmaceutical company, are proud of our heritage of bringing innovative medicines to those that need them the most, whether it be human or animal, for over 125 years. It is our view that the scope of these proposed amendments would see MSD Australia be both a consumer and possible provider of assets and systems impacted by the proposed amendment. As a consumer of these assets we believe the proposed bill

amendment provides enhanced confidence in the services we rely on to conduct business.

Being categorised within the health sector scope, it is in the best interests of our patients and the commercial viability of our organisation to ensure that we have strong resilience plans in place to ensure the supply of our life saving medicines. From a human health perspective, MSD Australia primarily imports finished pharmaceutical products from manufacturing plants around the world. Whilst we welcome the intention of the proposed bill amendment we also believe that existing provisions already exist to ensure appropriate resiliency protocols are in place. Should the supply of pharmaceutical products be included in scope of the proposed bill amendment it is our position that the Therapeutics Goods Act (1989) adequately encompasses the principles by which the proposed bill amendment seeks to address. Furthermore, we believe the strict auditing practices conducted by the Therapeutic Goods Administration agency already address many of the objectives of the proposed bill amendment. It is our belief that the recognition of these practices should provide assurances to the Department of Home Affairs that effective resiliency practices are being observed.

From an animal health perspective MSD Australia is proud to manufacture animal health vaccine products in our Bendigo Victoria plant. As stated in the explanatory document, the proposed bill amendments are purposefully vague when defining what might be in scope for healthcare services. The explanatory document(162) refers to “the production of medical products that support the provision of health care services” however it fails to identify whether this refers directly to human or animal health manufacturing production. It is our position that clear guidance be provided to assist with the determination of whether such facilities could and should be included within the scope of this proposed bill amendment. Furthermore, it is important to recognise the manufacture of animal health products is overseen by the Australian Pesticides and Veterinary Medicines Authority or APVMA. Similar to the Therapeutic Goods Administration, the APVMA have in place existing protocols to ensure appropriate controls are in place for the safe and efficacious manufacture of animal health products.

In summary we believe that the proposed bill amendment in relation to risk management (Part 2a -Critical Infrastructure Risk Management Programs) would be seen as duplicative in effort to both the Therapeutic Goods Administration and APVMA obligations.

Government Assisted Powers in relation to Cyber Security

In today’s interconnected world we all benefit from the advances and rapid adoption of technology. The convenience of online banking, the freedom to remotely work from home and the ability to visit a physician virtually are small examples of how technology continues to modernise and simplify our world. Governments and

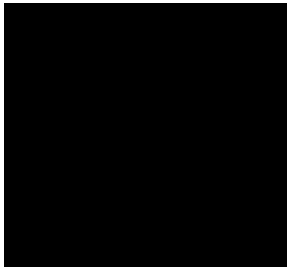
enterprise alike are rapidly adopting technology as a new means to reach their customer base and offer services and solutions that only a few years ago we would never have been dreamed of. Unfortunately, the rapid adoption of technology has also attracted unwanted attention in the form of cyber threats both locally and abroad.

MSD Australia applauds the attention that the proposed bill amendment places on adequate cyber security measures to guard and protect against cyber actors. The provisions laid out in the proposed bill amendment outlines the authority for government agencies to assume control should they deem a particular incident to be outside the control of the organisation in question.

MSD Australia, as a subsidiary of Merck & Co, Kenilworth, New Jersey, USA, leverages globally hosted systems and equipment which is outside the control of agents representing MSD Australia. It is unclear how said powers would and could be enacted against a foreign corporation in this situation. Furthermore, it could be assumed that many of organisations in scope of the proposed bill amendment would fall into this category and therefore be in a similar situation. It is our belief that further effort is required to ascertain the scope of government assisted powers.

Thank you again for the opportunity to provide feedback on this very important topic.

Yours sincerely,



Michael Azrak
VP & Managing Director
Australia & New Zealand