



Submission on the Exposure Draft of the Security Legislation Amendment (Critical Infrastructure) Bill 2020

27 November 2020

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CONTEXT AND BACKGROUND

The National Pharmaceutical Services Association (NPSA) welcomes the opportunity to provide feedback on the Exposure Draft Security Legislation Amendment (Critical Infrastructure) Bill 2020 (the Bill) as this is an important development that impacts the entire medicines supply chain.

In developing our response, the NPSA has enlisted subject matter expertise from each of our member businesses. We have focussed our responses on identifying and constructively establishing broader industry impact to assist Government in their efforts to strengthen Australia's security and economic resilience.

The NPSA strongly recommends drawing upon the experiences of their sector and their members proven track record. Given there has been no failure in the system to date, we recommend Government moves very cautiously and actively works with our members to understand the unintended consequences this draft legislation could have on their day-to-day operations and the reliable access to medicines that all Australians experience every day.

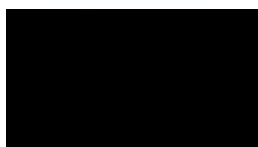
To that end, NPSA welcomes the chance to be part of a broader consultation focussing on ensuring that any legislative frameworks are fit for purpose and do not add unnecessary or costly regulatory burden or through unintended consequence, diminish what is already an agile and responsive medicines supply chain.

NPSA members as full line medicine wholesalers are charged with the obligation to provide timely and equitable access to medicine
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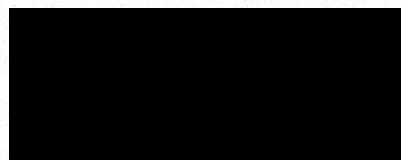
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We look forward to being a ci
contribute along with other r

Executive Approval of this st



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ABOUT THE RESPONDENTS – NPSA’S EXPERIENCE IN MANAGEMENT OF CRITICAL INFRASTRUCTURE

Established in 1976, the National Pharmaceutical Services Association (NPSA) is the peak industry body representing full-line pharmaceutical wholesalers in Australia (Australian Pharmaceutical Industries, National Pharmacies, Sigma and Symbion).

NPSA member companies provide a vital part of Australia’s complex health infrastructure. They are the link between the manufacturers of medicines and community pharmacy. They distribute medicines that are relied upon by millions of Australians through community and hospital pharmacies where they are dispensed to patients.

Our critical work as medicine distributors involves:

- Ensuring Australians enjoy equity of access to medicines with next day, if not same day, delivery,
- Providing facilities for rapid supply of urgent and emergency medication for patients via pharmacy,
- Providing supply chain redundancy for manufacturers, pharmacies and patients when medicines are in short supply due to supply shortages, natural disasters or epidemics,
- Maintaining quality, safety and efficiency standards within a compliant supply chain from medicine manufacturers through to pharmacies,
- Keeping medicines supply affordable for the community and for Government and
- Manual tracking, tracing and recall of medicines on behalf of manufacturers

To support this work, we have invested more than \$500M over the last 10 years to improve the efficiency, safety and security of the medicine distribution systems we operate.

We deliver this critical national infrastructure through a 3,400 strong workforce in 34 distribution centers supported by a national transport network moving 24 hours a day, 7 days a week to 5,800 community pharmacies and hospital pharmacies throughout Australia enabling 300 million medicines to be dispensed each year. This is in addition to some 100’s of millions of pharmacy and medical products.

This critical infrastructure has also been partially funded by the Australian Government through the Community Service Obligation (CSO) contracts which recognise the importance of the just-in-time supply chain across all of Australia and the need to ensure that delivery can occur regardless of the geographical or other barriers.

Our members have been consistently and reliably fulfilling their obligations to Government since the CSO was introduced in 2007 through the CSO Operational Guidelines which require the establishment of ongoing review of business continuity plans that cover IT platforms, critical warehousing and distribution technologies and systems including ordering portals.

OUR TRACK RECORD IN MANAGING CRITICAL INFRASTRUCTURE DURING CRISES

NPSA members have a long history of successfully managing the supply of medicines and medical products during national and state-based crisis situations. The security, redundancy and contingency planning we have in our business systems supports our day-to-day operations standing up as critical infrastructure during these crises.

In 2019 and 2020 NPSA members faced an extenuious set of challenges involving bushfires, floods and the COVID-19 pandemic. NPSA members worked tirelessly 24/7 to ensure that Australians, particularly those worst affected by these disasters, continued to have access to their medicines and medical products. During the bushfires and floods, this involved NPSA members chartering planes and helicopters, , partnering with Government agencies, organizing special freight deliveries and even employing locals to drive medicines to locations not accessible by normal transport vehicles to ensure that Australians continued to have access to their medicines.

When Australia's COVID-19 response emerged, this work took on an unprecedented scope and complexity and our members systems and capabilities were able to surge to respond.

The scale of the demand during this period is evidenced in the medicine deliveries during March 2020, which were at record levels (up 70%). During March and April 2020, NPSA member companies distributed more than 70 million PBS medicines during a six-week period. This included more than one million flu vaccine doses, equivalent to the number of doses supplied to community pharmacy for the entire 2019 season.

To respond to this demand for medicines and pharmacy products, our members worked with local and overseas suppliers to secure additional stock. It was an hour-by-hour proposition but showed that open communications and collaboration across the supply chain in combination with our robust management of systems data and reporting with appropriate escalation, backups and contingency systems could maintain access to medicines and medical products for all Australians without concern.

We did this while operating under the Biosecurity Act requirements for social distancing and cleaning to keep our workers and the community safe.

Additionally, in early March following a rapid increase in consumer and pharmacy demand, the NPSA was proactive in initiating the adjustment to the Government's CSO Deeds and requesting the implementation of measures to help manage the volatile early response to the pandemic and preserve medicine for broad based availability where needed across Australia, in line with the National Medicine Policy objective. We were keen to voluntarily work with Government to manage this issue together – as one supply chain.

In addition, NPSA secured ACCC authorisation to allow our members to share data in order to collaboratively manage demand and prevent stockpiling induced shortages.

Just as in the bushfires immediately preceding the COVID-19 response, we were proactive in volunteering information and data to Government individually and once the ACCC authorisation was in place coordinated as a sector to proactively report and provide data to Government

This authorisation further assisted NPSA members in implementing Government-supported restrictions on medicines and to further ensure that any medicines or products in high demand were not stockpiled but available to be distributed equitably across the community to those who needed them most, including small and rural pharmacies.

Additionally, the medicines supply chain from manufacturer to wholesaler to pharmacy typically carries 4 – 5 months inventory based on normal demand to provide a buffer against abnormal demand surges.

Our experience as critical health infrastructure providers is that the existing regulations, contracts and business-based systems we have in place, combined with our individual and collective commitment to the health of Australians in times of crises delivers a robust and responsive system that all levels of government can rely upon and do rely upon. We do our job, and we do it well.

This existing system and infrastructure have been proved more than capable of withstanding bushfires, drought, cyber risk and the COVID-19 pandemic. We are naturally concerned that proposed interventions add a layer of complexity and cost that are unnecessary and put at risk the streamlined safe and secure delivery of medicines the Government expects and Australians rely upon.

We appreciate that the global environment is ever changing from a security threat perspective – and our member businesses are in lock step with those changes and have continued to invest over the last 10 years more than \$500 M in upgrading and improving their operating systems including anticipating and responding to any potential risk to the safe and secure supply of medicines. As public companies, cyber security is considered and dealt with as a key business risk with all of our members having cyber-security plans and controls in place.

COMMENTS ON THIS PROPOSED BILL

NPSA assumes based on its reading of the *Security Legislation Amendment (Critical Infrastructure) Bill 2020* (Bill) that its members will be captured under the expanded definition of critical infrastructure. In this context, the following is a summary of NPSA's comments on the Bill.

It is not clear to NPSA members the basis or event that necessitates the proposed extent of the expansion of the current Act both in terms of its requirements and who they apply to.

We believe that medicine supply is a critical infrastructure component of the Australian health system, but are concerned about its proposed inclusion under this legislation and:

- the extent of powers the proposed Bill provides to the Minister and the bureaucracy,
- the lack of detail contained in the Bill,
- the potential regulatory cost,
- potential for workplace relation disruptions, and
- an absence of appropriate safeguards on powers that would otherwise require voluntary compliance, a warrant or a court order.

Unintended consequences as identified by NPSA members more specifically:

1. There is significant scope for the proposed powers within the Bill to negatively impact NPSA member the operations when persons unfamiliar with our businesses seek to exercise legislative control over our operations noting that our businesses already operate and manage such risk under the CSO Operational Guidelines. The safeguards currently contained in the Bill to protect industry and the community from Ministerial and bureaucratic overreach are inadequate and need to be strengthened.
2. As NPSA members are ASX listed companies, NPSA is concerned that this Bill could have significant impact on costs (capex and operational), for which there is inadequate return.
3. NPSA is of the opinion that too much of the detail remains unknown and that given the scope of the proposed powers, this is an unacceptable risk to Australian businesses and the community. Given this, the Bill should not be put before the Parliament until all significant legislative instruments have been subject to consultation in the same manner as this Bill. It is only through consultation on these instruments that NPSA will be able to assess its true regulatory impact.
4. Given the size of the impact on Australian businesses, a full quantitative regulatory impact statement must be undertaken. This impact statement should be based on the full legislative framework, including legislative instruments, and be subject to industry consultation to ensure accuracy given the breadth of the sectors impacted.
5. The proposed amendments place no requirements on the Minister's decision making, including the weight given to any consultations. As required for the application of some human health powers under the *Biosecurity Act 2015*, the Minister and their delegates should be required to consider decision making principles prior to making certain decisions. Such requirements ensure that the Minister and their delegates must be able to justify their decision making based on relevant considerations.

6. Given the significant scope of some of the proposed powers in the Bill, these should be legislatively limited to ministerial level.
7. Where the Minister is permitted to circumvent consultation processes under the Act, the circumstances under which this can occur should be limited to an 'emergency'. The circumstances as set in s 30AL(3), for example, are too broad. In those instances where a minister seeks to act directly (without consultation), their actions should activate a post-implementation consultation process that should be undertaken within 14 days across relevant impacted industries, sectors and first Ministers. This process should be subject to the decision-making principles referred to in 5 above.

IN CONCLUSION - LESSONS FROM 2019-2020 APPLIED TO THIS BILL

We need to learn from COVID-19 and recognise what worked and what did not. NPSA members consider that our systems worked - what we don't want is in the event of a crisis that our industry whilst on-the-ground managing real time situations is faced with unnecessary additional burden on its operations at critical times

NPSA members are concerned the proposed unprecedented powers that will be available to government ministers and their departments to regulate risk across broad swathes of the economy, determine employee suitability through application of vetting processes and demand and access systems and data, and where failure to do so may result in civil or criminal penalties.

NPSA members believe that the current draft Bill could be a giant leap in regulatory burden for industry, and one for which there is inadequate justification and concerns about bureaucratic overreach on the back of the pandemic.

The Bill includes a range of significant powers that Government departments will be able to exercise over the economy, which will likely include NPSA members. These powers if exercised may threaten our members ability to meet existing service level standards under the CSO Deeds with Government and in turn may impact consumer access to medicines.

NPSA is of the opinion that too much of the detail remains unknown and that given the scope of the proposed powers, that this is an unacceptable risk to Australian business and community.

While we have welcomed the opportunity to review this Bill, NPSA recommends that a similar process should be undertaken with all legislative instruments prior to the Bill being put before Parliament so that industry and the community have an opportunity to properly assess the proposed impacts.

NPSA members stand ready to assist Government to achieve their objectives.