



27 November 2020

Department of Home Affairs

Submitted online

Protecting Critical Infrastructure and Systems of National Significance.
Exposure Draft Security Legislation Amendment (Critical Infrastructure) Bill 2020

Thank you for the opportunity to provide comment on the above Bill.

Consumer Healthcare Products (CHP) Australia is the leading industry voice representing the manufacturers and distributors of consumer healthcare products, including nonprescription medicines.

9 out of 10 Australians use nonprescription medicines regularly¹, including analgesics, hand sanitisers, cold & flu medicines, nicotine replacement therapies, vitamin and mineral supplements, hay fever and allergy relief products, sunscreens and many more.

We note that the proposed regulatory framework would designate both the “health care and medical” sector, and the “food and grocery” sector as critical infrastructure sectors, and therefore subject them both to new sector-specific security obligations.

As Australians access nonprescription medicines from pharmacies, supermarkets, and convenience stores, as outlined in the Exposure Draft, our members are likely to be impacted by the sector-specific standards and obligations for both sectors. It is important to our industry that neither the individual, nor the combined, obligations of the sectors leads to any unnecessary or disproportionate regulatory burden, any unnecessary costs, or any regulatory duplication or any regulatory contradiction.

We have reviewed the exposure drafts and the accompanying explanatory documents and would like to record the following concerns:

- The definition of the “food and grocery sector” and the definitions of “health care”, “health care and medical sector” and “medical supplies” are extraordinarily broad and will likely capture all our members. We were concerned to note, for example, that at paragraph 164 of the Security Legislation Amendment (Critical Infrastructure) Bill 2020 Explanatory Document, that the definition of the health care and medical sector is described as being “intentionally broad”.
- The new obligations will impose significant regulatory burden on our members, despite references to them being a “proportionate” and “risk-based” approach.

¹ Consumer Behaviour Factbook (March 2015) Macquarie University



- Despite their description as “risk-based”, the proposed reforms do not even appear to accommodate the wide range of risks associated with different medicine types (for example the need for resilience in the supply of vaccines and cancer drugs is very different from the need for resilience in the supply of multivitamins, analgesics, hand sanitisers and sunscreens). We were concerned to note the references to “sector-specific” requirements when the sectors we represent will require a nuanced approach across each sector.
- The complex nature of our members’ products (together with the complex supply chains used in their manufacture) mean that a disruption to the supply of active ingredients, excipients or packaging components can have a significant effect. This complexity coupled with the existing high level of regulatory obligations leads members to work towards approving multiple sources of supply to provide greater flexibility and improved resilience. The sort of wide-ranging, and onerous, regulatory framework of the kind proposed is therefore not necessary and not warranted.
- As demonstrated during the current COVID-19 pandemic, our members have been able to maintain supplies of their products (despite unprecedented upsurges in consumer demand). The explanatory documents do not describe any failings in our members’ sectors and do not describe any specific problems that require the introduction of such a widespread and onerous set of legislated requirements.
- As well as failing to describe the need for reform, the explanatory documents fail to disclose whether any non-regulatory options were considered first.
- Of further concern, the new framework does not appear to include any mechanisms for having decisions reviewed, challenged, or scrutinised (and alarmingly describes how the review mechanism under the ADJR Act will be specifically excluded).

In response to those concerns, we propose the following recommendations:

1. All non-regulatory options should be explored and exhausted before any new regulatory framework is imposed.
2. Should it prove necessary to regulate the “health care and medical” sector and the “food and grocery” sector as proposed, then the specific requirements and rules for each sector will need to be co-designed with the whole of industry so as to properly accommodate the diversity of these sectors.
3. In any event, the proposed framework should be revised to include appropriate review mechanisms to ensure good decision making.

We remain available to discuss this response and look forward to participating in the co-design of sector-specific requirements should they prove necessary.



The Consumer Healthcare Products (CHP) Australia contacts for this project are Steven Scarff, Regulatory and Legal Director (email: [REDACTED]) and Sarah Coward, Public Affairs Manager (email: [REDACTED]).

Yours sincerely,

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