



Australian Consumer Law Review
The Treasury
Langton Crescent
PARKES ACT 2600

Email: ACLReview@treasury.gov.au

Dear Madam/Sir

Accord provides the following comments to the Australian Consumer Law (ACL) Interim Report, October 2016. This is further to our submission to the Issues Paper released in March of this year.

Accord's views have not significantly altered from those expressed in our first submission. We find the Interim Report disappointing in that while it provides a summary of the submissions received, little has been expressed regarding the future direction for reform. Instead, it would appear we have been given a further opportunity to provide comment on issues raised in the first round of consultation.

Accord's specific concerns are provided in the attached document.

We look forward to working constructively with government in articulating its risk appetite commensurate with business practices and international trends.

The contact officer for this submission is Ms Dusanka Sabic, Accord's Director Regulatory Reform. Should you have any questions in relation to the matters raised please do not hesitate to contact her at 02 9281 2322, 0422569222 or dsabic@accord.asn.au.

Yours sincerely

A handwritten signature in black ink, appearing to read "Bronwyn Capanna", with a long horizontal flourish extending to the right.

Bronwyn Capanna
Executive Director

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Products for healthy living and a quality lifestyle

2.2 Product Safety

2.2.3 General safety provision

Accord remains of the view that a general safety provision is not required under the ACL. The current law provides consumers with redress if the goods have a safety defect or if their safety is not such as consumers are generally entitled to expect. We feel that this together with the range of product safety and product liability provisions covered under the ACL does not warrant a general provision. Furthermore, Australia provides a range of specialist safety regimes for therapeutic goods, food and agvet products. If a general provision was to be introduced then the current regime of general and specific safety regimes as well as commonwealth and jurisdictional regimes would need to be streamlined into one overarching scheme.

2.2.10 Mandatory reporting requirements

31 Should the mandatory reporting trigger be clarified?

Accord supports a change to the current circumstances under which mandatory reporting is triggered. As advised previously, the current trigger for product safety mandatory reporting under the ACL is inconsistent with other adverse event reporting requirements in Australia and internationally. Under the ACL, all participants in the consumer goods supply chain are required to provide written notification within a mandatory 48 hour notification period of becoming aware of consumer goods which may have caused death, serious injury or illness. Serious injury is defined as one which resulted in the supervision of a qualified doctor or nurse. This definition of serious injury or illness sets a much lower threshold (and therefore a much higher reporting burden) when considered alongside the definition used in other comparable jurisdictions such as:

- Therapeutic Goods Administration (TGA):
serious adverse events, such as those suspected of causing:
 - *death*
 - *danger to life*
 - *admission to hospital*
 - *prolongation of hospitalisation*
 - *absence from productive activity*
 - *increased investigational or treatment costs*
 - *birth defects (medicines).*
- New Zealand:
Serious reactions include those that are fatal, life-threatening, disabling, incapacitating, or which result in or prolong hospitalisation (medicines).
- EU:
any serious risk, including the effects of which are not immediate, requiring rapid intervention by the public authorities (GPSD Article 2 (d)).

- Canada:
An occurrence in Canada or elsewhere that resulted or may reasonably have been expected to result in an individual's death or serious adverse effects on their health, including serious injury (consumer goods).

Recommendation 1

Change the threshold for mandatory reporting of consumer goods to include: *Serious injury is defined as one which may have caused death or hospital admission.*

32 Should the current timeframe for making a mandatory report be extended?

The current process does not allow for an adequate risk assessment of the serious injury prior to notification and is inconsistent with the approach required from suppliers in consideration of determining whether to undertake a voluntary recall. The requirement to provide written notification within a mandatory 48 hour notification period of becoming aware of consumer goods which may have caused death or hospitalisation is consistent with international practices. What is inconsistent is the lack of opportunity for the supplier to undertake a risk assessment and put forward to the regulator a proposed course of action.

For a voluntary recall, a supplier is obliged to notify the Commonwealth minister within two days of recalling consumer goods. However, a supplier can undertake an adequate risk assessment and develop a risk management strategy prior to notification of the action and also has 10 days in which to provide a copy of the notice to the Commonwealth minister following the recall.

The TGA recommends immediate notification of adverse events or reactions, but allows up to 15 calendar days for reporting. The TGA's reporting requirements are aligned with those of the EU and USA. There is an inconsistent reporting treatment for consumer and therapeutic goods in Australia, with the more onerous requirements for consumer goods, those products usually deemed safer in the market place. There appears to be little understanding of proportionate risk management by the ACCC in carrying out its product safety function.

The TGA also makes a distinction between serious adverse reactions and significant safety issues. A significant safety issue is considered to be an unexpected adverse event or reaction which does not meet the test for serious. Any significant safety issue identified by the sponsor must be reported to the TGA within 72 hours. The 72-hour clock starts from the time of awareness of the issue by any personnel of the sponsor¹. This is considered to have occurred when the sponsor's review and analysis have been completed and a conclusion is drawn that a significant safety issue exists, or when the sponsor becomes aware of the actions of an overseas regulatory agency.

Similarly, the EU General Product Safety Directive (GPSD) allows for a risk assessment and provides a methodological framework for facilitating consistent risk estimation and evaluation. In Canada suppliers have 10 days in which to provide a written report to Health Canada which includes measures proposed to be taken with respect to the products.

A sponsor is a person or company who does one or more of the following:

- exports therapeutic goods from Australia
- imports therapeutic goods into Australia
- manufactures therapeutic goods for supply in Australia or elsewhere
- arranges for another party to import, export or manufacture therapeutic goods.¹

In Accord's response to the Issues Paper we recommended that following a mandatory reporting incident, suppliers should be allowed 10 days in which to undertake an adequate risk assessment and develop a risk management strategy prior to notification of the proposed action to the ACCC. The 10 days was based on the practice by a comparable trusted international regulatory agency, i.e. Health Canada, in line with the government's Adopting Trusted International Standards policy.

The Interim Report notes the importance of balancing the needs of industry to collect and report meaningful information with the needs of the regulator to quickly identify and address safety risks. Where a longer period is provided by other regulatory frameworks, such as the 15-day period by the TGA this is balanced with a requirement for suppliers to immediately notify the regulator of the incident. Accord supports this balanced approach between notification, risk assessment and reporting.

Recommendation 2

Accord supports an increase to the current mandatory reporting timeframe to 15 days which includes immediate notification of the incident i.e. within 48 hours, followed by a report.

Other issues - Enforceable undertakings

In our submission to the Issues Paper we raised concerns regarding the application of enforceable undertakings. Section 87B provides a mechanism for the ACCC and a company under investigation for a contravention of the Act to agree on a public undertaking to cease the alleged conduct. The issue with this type of undertaking is that under the *Competition and Consumer Act 2010* (CCA) an agreement to S87B is an admission of guilt by the company. An admission of guilt is a deterrent to accept this form of remedy under the ACL.

Under Australia's Model Work Health and Safety (WHS) legislation, an enforceable undertaking is not an admission of guilt. The company enters into a relationship with the regulator in much the same way as a S87B undertaking but there is no admission of guilt. Enforceable undertakings can provide an effective and timely mechanism to address a breach and should be encouraged as a way to resolve issues. There is a greater likelihood of take-up and better compliance outcomes particularly for small business if there is no admission of guilt. S87B of the CCA should be consistent with the Model WHS legislation as it is applied in the states and territories. At the very least an analysis of the application of the two systems should be undertaken with a view to determining the optimal system, particularly for SME's.

Recommendation 3

Amend the *Competition and Consumer Act 2010* so that S87B enforceable undertakings are not an admission of guilt on the part of the party entering into the enforceable undertaking.