Therapeutic Goods Administration Consultation Paper: Options for the future regulation of "low risk" products

Australian Competition and Consumer Commission Submission

May 2017

Executive Summary

This submission sets out the ACCC's role in relation to consumer protection and product safety and provides the ACCC's response to the Therapeutic Goods Administration (TGA) consultation paper on options for the future regulation of "low risk" products.

The ACCC notes that of the options proposed throughout the consultation paper, one is full exclusion from the *Therapeutic Goods Act 1989* with the outcome that these products would be regulated solely as consumer goods and "would fall under the auspices of ACCC and not a specialist regulator".

While this is ultimately a matter for government, the ACCC:

- is concerned with expectations raised in the consultation paper; there is a misapprehension the ACCC would be able to provide the same level of regulatory oversight as the TGA does presently
- considers it is not sustainable to remove or reduce a specialist regime and expect the same level of attention and expertise from a generalist regulator, and
- is not in a position to step in where another regulator has resource constraints or makes a different assessment of priorities given our broad consumer and competition remit.

1. The role of the ACCC

The Australian Competition and Consumer Commission (ACCC) promotes competition and fair trading in markets to benefit consumers, businesses and the Australian community. Our primary responsibility is to ensure that individuals and businesses comply with the *Competition and Consumer Act 2010* (the CCA) which includes the Australian Consumer Law (the ACL).

The ACCC's role is critical in making markets work by:

- maintaining and promoting competition and remedying market failure by preventing anti-competitive mergers, stopping cartels and intervening when misuse of market power is identified
- protecting the interests and safety of consumers and supporting a fair marketplace by addressing misleading behaviour, removing unsafe goods and tackling unconscionable dealings
- driving efficient infrastructure through industry-specific regulation and access regimes.

In relation to consumer protection, the ACCC's role is twofold – we seek to ensure consumers can confidently participate in markets and consumer goods are safe.

Our role in relation to consumer protection

To ensure that consumers can confidently participate in markets, the ACCC administers and enforces both the general and specific protections of the ACL so that businesses trade fairly and do not mislead consumers. This includes enforcing the general protections of misleading or deceptive conduct and unconscionable conduct, and specific protections of false or misleading representations and unfair contract terms.

In addition, the ACCC administers ACL rights and remedies relating to consumer guarantees (e.g. rights to a refund, repair or replacement where a good fails to meet a statutory

guarantee), and unsolicited consumer agreements (e.g. protections where a consumer enters an agreement with a door-to-door seller or telemarketer, including disclosure requirements for traders and cooling off rights for consumers).

The ACCC also undertakes compliance and education programs with consumers and businesses in relation to their rights and responsibilities under the ACL.

Whole of economy regulation

The ACCC is a whole of economy regulator, applying the consumer protection provisions in the ACL to address systemic and economy-wide problems. As a whole of economy regulator, we are responsible for all sectors of the Australian economy, ranging from agriculture to telecommunications, from construction to retail. While many of these sectors also have specialist regulators, the ACCC's role across the economy is focused on ensuring compliance with the ACL.

The breadth of the ACCC role means we receive over 250 000 contacts each year ranging from consumer complaints about false advertising, small business complaints about misuse of market power and community reports of unsafe products, injuries or illnesses. However, the ACCC only has capacity to deliver approximately 30 cases in court each year across all the obligations provided for by the CCA (including competition law, regulated infrastructure and industry codes) and the ACL.

To decide where to allocate our finite resources most effectively, the ACCC takes a risk-based approach to enforcement, compliance and education, allocating resources to the issues of greatest risk of consumer detriment. Our Compliance and Enforcement Policy[1] is used to prioritise matters and select the most appropriate response. We prioritise matters based on:

- a series of priority factors (indicators of matters that will, or have the potential to, result in widespread consumer detriment and therefore we will prioritise them whether or not the conduct occurs in a priority area) and
- a series of priority areas (areas of the economy in which we are taking a more detailed interest). These priority areas are reconsidered annually.

Our role in relation to consumer product safety

The ACCC's role in relation to consumer product safety is to identify unsafe or potentially unsafe consumer goods and product-related services, prevent or stop their supply and remove them from the market.

The scope of the ACL is that of all 'consumer goods', being those goods that are intended to be used, or of a kind likely to be used, for "personal, domestic or household use".[2]

There are over 15 000 types of products available in Australia, with the ACCC responsible for a number of classes of goods including toys, clothing, furniture, novelties, gardening equipment, phones and cameras to name just a few.

We focus on identifying and addressing safety hazards in consumer goods using an intelligence-led approach to assess current and emerging safety risks. To do this we review a range of data sources to identify issues that may present a safety concern, including

[1] See ACCC (2017) Compliance and Enforcement Policy, available at: https://www.accc.gov.au/publications/compliance-and-enforcement-policy.

[2] ACL section 2(1).

mandatory reports of serious illness, injury or death, recalls that have taken place internationally, and information received from the community.

We act on safety risks by advising the Commonwealth Minister responsible for product safety to:

- issue safety warning notices
- ban products (either on an interim or permanent basis)
- impose mandatory safety standards or mandatory information standards, and
- issue compulsory recall notices that require suppliers to recall a product.

These interventions are triggered under the ACL where a consumer good causes 'serious injury or illness' through 'use or foreseeable misuse'. Use and misuse are not defined, but can include both the intended and unintended operation of a product.[3]

Serious injury or illness is defined as an acute physical injury or illness that requires medical or surgical treatment by, or under the supervision of, a medical practitioner or a nurse (whether or not in a hospital, clinic or similar place).[4]

Some of the more common serious injuries and illnesses that fall within the ACCC's remit include laceration, crushing injuries and amputations, ingestions, suffocation and strangulation, eye injuries and concussions.

The breadth of the ACCC's role in relation to consumer goods means that we must prioritise our regulatory interventions based on accepted hazard identification and risk assessment principles. We assess hazards based on the severity of the injury, the probability of the hazard occurring, the potential for consumers to recognise and act to avoid the hazard, and the availability of the product in the market.

In considering potential responses to consumer product hazards the ACCC has regard to government expectations that we not duplicate regulatory oversight. In 2015-16, the ACCC received 3 294 mandatory reports from suppliers. Of these 1 476 were assessed by the ACCC and 1 818 were referred to other regulators. The ACCC also received 671 recall notifications from suppliers, 315 of these were monitored by the ACCC, and 356 were referred to other specialist regulators.

2. The future of "low risk" products

The consultation paper puts forward proposed options for the future regulation of "low risk" products. This follows recommendations of the Expert Review of Medicines and Medical Devices and Regulation to review the range of products currently regulated by the TGA, with a view to these products being regulated under other regulatory frameworks, without undermining public health and safety (Recommendations 14, 23 and 48).

The consultation paper seeks feedback on a number of reform options including an option for the Minister, by legislative instrument, to declare certain "low risk" products are 'excluded goods' and therefore fall outside the TGA's regulatory framework. The consultation paper suggests the outcome from such a step is that these products would be regulated solely as consumer goods and "would fall under the auspices of ACCC and not a specialist regulator".

The ACCC is concerned that, by the TGA undertaking a process whereby the Minister would declare certain regulated products as "low risk" and excluding them from the TGA's

[3] See for example, ACL section 122 and ACCC (December 2015) Product Safety Recall Guidelines, page 6, available at: https://www.productsafety.gov.au/publication/consumer-product-safety-recall-guidelines

[4] ACL section 2(1).

regulatory framework, there is an expectation that the ACCC would be able to provide the same level of regulatory oversight. This expectation is evident in the consultation paper. In particular, the ACCC is concerned that a regulatory gap may emerge for the following "low risk" products if they are excluded from the TGA – ear candles, nappy rash cream, antiperspirants, hard surface disinfectants, sunscreens, tampons and menstrual cups, vitamins and minerals, aromatherapy and homoeopathic products. This gap could emerge if there is significant innovation in product constituents, constituent concentration or manufacturing methods that are not controlled through standards or have not previously been subject to a risk assessment. Further details on these products are provided at **Appendix A**.

While the ACCC is an effective regulator with a broad remit, it is unable to increase activity in areas vacated (in whole or in part) by other regulators. The ACCC cannot replicate the focus and expertise that a specialist regulator like the TGA delivers. If the TGA dilutes or removes their specialist regulator capacity, the ACCC will be unable to deliver consumer protection for these therapeutic goods in the same way.

Parliament has identified enhanced public risk or the need for particular expertise and established specialist regulators such as the TGA. It is not sustainable to remove or reduce this specialist regime and expect the same level of attention and expertise from a generalist regulator. While the ACCC can and does provide strategic interventions in important matters involving therapeutic goods, it is not a substitute for a specialist regulator such as the TGA. For example, medicines and medical devices, whether low or high risk, require expertise and ongoing risk assessments that the ACCC is not able to provide.

Further, as stated in our submission to the Productivity Commission Study on Consumer Law Enforcement and Administration, the ACCC is not in a position to step in where another regulator has resource constraints or makes a different assessment of priorities given the ACCC's broad remit of national competition and consumer matters. The ACL Review Final Report also recently found that Australia's product safety system is weighted towards reactive post-market controls such as banning or recalling products following an injury, illness or death, with pre-market controls limited to mandatory safety standards or information standards.[5]

The TGA's regulatory framework, on the other hand, has both pre and post-market controls. A number of the "low risk" products listed in the consultation paper currently have a level of information asymmetry and market failure corrected by the TGA's pre-market controls. While the ACCC could address these by investigating misleading claims, if they met priorities, this action relies on consumers identifying a problem with product labelling. However, of course, a consumer may not be aware if a sunscreen or nappy rash cream is making an accurate claim about the efficacy of an active ingredient whereas the TGA may be well placed to do so.

The ACL Review Final Report also found that the ACL, unlike a number of international jurisdictions (including those listed in Appendix 2 of the consultation paper), does not place a clear onus on suppliers to ensure the safety of their products before they enter the market in the form of a general safety provision.[6] Therefore, caution should be drawn when making comparisons between the Australian regime and international regimes, particularly with those jurisdictions that have a general safety provision.

In addition, the legislative triggers for ACCC intervention of 'serious injury or illness' and 'use or foreseeable misuse' mean that incidents that are currently reported to the TGA as 'adverse events' may subsequently be under-reported and under-assessed. For example, a

[5] Consumer Affairs Australian and New Zealand (2017) ACL Review Final Report, page 33 – 47.

[6] Ibid.

reaction to a nappy rash cream would likely fall within the TGA's legislative trigger of 'adverse event', but would unlikely amount to a 'serious injury or illness' under the ACL. As such, the ACCC would be unable to use the product safety provisions to address risks which do not reach its threshold but may still be posed by the nappy rash cream.

While the "low risk" products listed in the consultation may be considered on the lower end of the risk spectrum under the TGA framework, by reference to certain high risk medicine and devices, the ACL's consumer product safety regime is unlikely to offer the same level of regulation for these goods. Therefore, these products may potentially pose a higher risk to consumers where regulatory oversight is reduced or a regulatory gap occurs. This gap may grow as products and ingredients change over time.

Appendix A – Detailed list of "low risk" products

The ACCC is concerned that by excluding the following "low risk" products from the TGA regulatory framework there is an expectation that the ACCC would provide the same level of regulatory oversight:

Product	ACCC's role
Ear candles	The ACCC's consumer protection role does not extend to assessing the efficacy of medical treatments such as ear candling. As an agency it does not hold the specialist knowledge required to evaluate this type of practice or associated health claims.
Nappy rash products	The ACCC observes that users of nappy rash products are babies and infants who are still developing their physiology, and are therefore vulnerable consumers. Should these products be regulated solely as consumer goods under the ACL, potential regulatory intervention would only be triggered by serious illness or injury in addition to the ACCC's broader role in respect of misleading conduct or misrepresentations.
Antiperspirants	Should the TGA deregulate antiperspirants, these products would be subject to predominantly post-market product safety controls under the ACL. The ACCC would only be able to intervene for product safety matters where a serious illness or injury has occurred. Oversight of ingredients for example, including potential substitution, would not be captured.
Hard surface disinfectants	If commercial entities or hospitals, rather than consumers, were to purchase these products they would not be consumer goods and would not fall within the ACCC's product safety remit. Where they do meet the definition of a consumer good, their regulation would be post-market and only triggered by serious injury or illness.
Sunscreen	Should sunscreen be de-regulated by the TGA, the ACCC's regulatory oversight would not extend to the accuracy and efficiency of SPF claims. Regulatory intervention would only be possible when the usage of this good involves serious injury or illness. Other forms of less serious harm would not be captured, and may leave Australian consumers vulnerable given the information asymmetry in the market for these types of products.
Tampons & menstrual cups	The consultation paper states that if tampons were excluded from the regulatory framework they would still be required to meet the Australian Standard (AS 2869:2008). However, currently the Australian Standard is a voluntary standard. In order for tampons to be required to meet the standard, it would need to be declared by the Commonwealth Minister as an enforceable standard under section 105 of the ACL. Tampons would only be captured by the ACL's product safety regime should use of a tampon product trigger serious injury or illness post-market.
Vitamins	The ACCC has taken action in relation to misleading claims around vitamins (see *ACCC v Reckitt Benckiser*). However the ACCC's jurisdiction for these products in respect of product safety does not extend to pre-market controls. Regulatory intervention would only be possible with serious injury or illness.
Homoeopathic and aromatherapy products	If homoeopathic and aromatherapy products were deregulated under the TGA, the ACCC would only be able to step in to address seriously misleading claims that fall within priorities and serious injuries or illnesses. Lower level adverse events or reactions would not fall within the product safety provisions of the ACL. Further, the ACCC does not have the scientific expertise or pre market regulatory tools to assess the ingredients of homeopathic products before they enter the market.