TGA CONSULTATION: COMPLAINTS HANDLING

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TGA CONSULTATION: COMPLAINTS HANDLING

There are a number of concerns with this TGA proposal:

1. **Triaging**

   Key terms are not defined but the process appears to prioritise physical harm over economic harm and other forms of consumer detriment.

2. **Complaint priorities**

   Complainants apparently will not be informed as to the priority TGA officers assign their complaint: low, medium, high and critical.

3. **Transparency**

   Even if a complainant submits a detailed complaint alleging specific breaches of the Therapeutic Goods Advertising Code 2018, it is unclear if these specific allegations will be forwarded to the advertiser responsible.

   In addition, if the TGA finds additional breaches of the Code when assessing the complaint, it is unclear if these will also be communicated to the advertiser, let alone the complainant.

   Regardless of priority, there apparently will be no information published on what alleged Code breaches were determined by the TGA to be justified or not justified.

   For low priority cases, no details of who is responsible for the advertisement will be disclosed.

   For low and medium priority cases, it appears up to the complainant to check if a “regulatory obligation notice” or an "acceptable response" achieved compliance.

   For high and critical priority cases, no information will be provided to the complainant and the public until a final outcome is achieved; if this involves Court action, this may take years.

   It is important for educating complainants, advertisers and the industry that details of specific Code breaches upheld or rejected by the TGA be published, as has been the practice of the CRP. This is also crucial for monitoring the performance of the TGA.

4. **Time taken to close complaints**

   These statistics will be meaningless because compliance is not routinely checked.

5. **Monitoring and trend analysis**

   Post-marketing compliance data must be broken down into targeted and random reviews, categories of products, and the most non-compliant companies named.

6. **The TGA website advertising hub**

   This site is a work-in-progress. Although it shows promise, we have provided feedback on many concerns.

7. **Conclusion**

   We reiterate the point made in other submissions; unless the TGA accepts that consumer protection is an equal objective to industry assistance, and gains the will to act, a revised Code and complaint system (including increased penalties and sanctions) will have no more impact than the current dysfunctional system.

Background

The concept of the TGA taking over the Therapeutic Goods Advertising Complaint System to provide a single, more efficient, complaint body with powers to apply timely and meaningful sanctions for regulatory violations is excellent.[1] However, the TGA's proposed implementation leaves a lot to be desired.

Issues

1. Triaging

This process is said to depend on an assessment by TGA officers as to whether the advertisement is likely to (my emphasis):

- Cause **public harm**;
- Impact of the advertising on the ability of consumers to **safely and appropriately use** the goods for their intended purpose;
- the **frequency and likely impact of the non-compliant advertising and its influence on other advertisers to the detriment of consumers**, and
- the advertisers' awareness of their advertising obligations (**previous upheld complaints?**).

Our concern about these triaging criteria is that the key terms used are not defined and the process appears to prioritise physical harm over economic harm and other forms of consumer detriment.

For example, does consumer detriment include consumers being misled by advertising into:

- Purchasing a more expensive product when more cost-effective alternatives are available (the ACCC Nurofen case)[2]?
- Purchasing an ineffective product, for example Brauer[3] or Owen homeopathics[4] hay fever products instead of an effective registered product available at pharmacies containing fexofenadine hydrochloride[5]?
- Forsaking evidence-based action because of misleading claims, for example neglecting a healthy diet and instead consuming heavily advertised multi-vitamin supplements[6]?

Senior TGA staff have said that their charter does not extend to protecting consumers from their own stupidity or gullibility. Yet apparently "stupid" choices can be rational decisions when vulnerable consumers are misinformed by misleading and deceptive advertising.

For example, how many people would be seduced by the promotion of black salve if there was full disclosure that it is not effective for treating cancer and it destroys normal tissue? How many parents would administer homeopathic (or other traditional) medicines to their children if there was full disclosure that there is no scientific evidence that these products work?

The purpose of the Therapeutic Goods Advertising Code[7] is to ensure that consumers are not misled or deceived by unethical advertising to allow them to make informed choices on the basis of accurate

[1] https://www.tga.gov.au/consultation/consultation-complaints-handling-advertising-therapeutic-goods-public
[2] https://www.accc.gov.au/media-release/accc-targets-alleged-false-and-misleading-nurofen-claims
[3] https://shop.brauer.com.au/collections/allergy-relief/products/brauer-hay-fever-o-s-20ml
[4] https://www.owenhomoeopathics.com.au/product/homeopathic-hay-fever-complex/
[5] https://telfast.com.au/antihistamines/telfast-120mg/
[6] https://swisse.com/en-au/products/vitamins-supplements/mens-health/swisse-mens-ultivite
[7] https://www.tga.gov.au/sites/default/files/draft-therapeutic-goods-advertising-code-guidance-2018.pdf

information about the quality, safety and efficacy of the product. The latter is also the object of the *Therapeutic Goods Act 1989,*[8] which the TGA is tasked with upholding.

We are concerned that some senior TGA staff apparently want to abdicate their responsibilities in this area. We have opposed the suggestion that the TGA should exclude so-called "low-risk" products, such as vitamins and homeopathic medicines, from the TGA's regulatory responsibility.[9] We are especially concerned that the TGA has yet to publish public submissions to this consultation, or its own conclusions, despite the consultation closing on 12 May 2017.

We agree with the submission the ACCC kindly provided us; it is the TGA's responsibility as a specialist regulator to be responsible for the regulation (including consumer protection) of all therapeutic goods. The ACCC does not have the expertise or resources to take over of the regulation of these areas (see appendix).

2. Complaint priorities

Following assessment, the TGA says complaints will be triaged into one of four priority categories; low, medium, high and critical. From the pyramid on page 11:

"Low priority advertising breaches (low priority cases)" are defined as:

- One-off breach not considered serious in terms of being misleading as to the contents, identification or use of the goods.

  Yet 88% of 109 complaints found justified by the Complaint Resolution Panel (CRP) in 2016-17[10] were found to breach s. 4(2)(c) of the 2015 Code, "Must not mislead or be likely to mislead".

"Medium priority advertising breaches (medium priority cases)" are defined as:

- On-going breaches despite the advertiser having been made aware of their obligations but not likely to lead to unsafe or inappropriate use of the goods.

  Yet 22% of 109 complaints found justified by the CRP in 2016-17 were found to breach s.4(2)(i) of the 2015 Code, "Must not claim that goods are completely safe, harmless, or free of side-effects" and 9% breached s.4(2)(f) of the 2015 Code. "Must not encourage excessive or inappropriate use of the advertised product".

"High priority advertising breaches (high priority cases)" are defined as:

- Continued advertising breaches (despite previous warning),

  Pharmacare Laboratories provides an ongoing example which the TGA has so-far failed to address.[11]

- Advertising prohibited or restricted representations likely to impact on consumers ability to safely or effectively use the product,

  60% of 109 complaints found justified by the CRP in 2016-17 were found to breach s.5 of the 2015 Code. "Prohibited or restricted representations".

[8] https://www.legislation.gov.au/Details/C2017C00226

[9] https://www.tga.gov.au/consultation/consultation-options-future-regulation-low-risk-products

[10] http://www.tgacrp.com.au/wp-content/uploads/CRP-complaints-summary-1-Jul-2016-to-30-Jun-2017-including-graphs.pdf

[11] http://www.tgacrp.com.au/complaint-register/?_search=Pharmacare

- Mass advertising, or the potential to influence others in the industry, to the detriment of consumers.

  What about 110,000 Chemist Warehouse sample packs containing Swisse Magnesium, etc., distributed to children and adults at the MCG and AFL Grand Final Footy Show at the Rod Laver Arena; complaint sent to the TGA in October 2017, still without an outcome?

"Critical advertising breaches (critical priority cases)" are defined as:

- "Extensive or targeted advertising directed to vulnerable groups"

  Kids' vitamin gummies are a continuing example about which the TGA has done nothing: these products are unhealthy, poorly regulated and exploitative.[12]

- "Advertising that is likely to lead to "harm or injury if the claims are relied upon", or

  Advertisements for Black salve are a nice example of physical harm and injury.

  However, does "harm" include economic harm from being "ripped off" by misleading and deceptive claims, or harm from consumers forsaking evidence-based treatments because they are attracted to more heavily, cleverly marketed products advertising false hope?

  Complementary medicines used for menopausal symptoms are a nice example.[13]

- "Advertising that undermines accepted public health messages".

  Advertisements for homeopathic immunisation are a nice example.

  But what about advertisements for multi-vitamins that undermine public health messages about the importance of eating a balanced diet containing fruit and vegetables?

It will be important that the resources noted on page 16 (11. Education and guidance) contain examples of complaints that the TGA has triaged into the above categories.

Our own view is that the majority of complaints likely to be submitted will be of "high" or "critical" priority if properly assessed by the TGA.

We are concerned that complainants apparently will not be informed as to the priority TGA officers assign their complaint.

3. Transparency

We have extensive concerns about this area.

First, even if a complainant submits a detailed complaint alleging specific breaches of various section of the Therapeutic Goods Advertising Code 2018, it is unclear if these specific allegations will be forwarded to the advertiser responsible.

In addition, if the TGA finds additional breaches of the Code when assessing the complaint, it is unclear if these will also be communicated to the advertiser, let alone the complainant.

Instead, for low and medium priority cases it appears that only a non-specific "regulatory obligation notice" or "warning letter" will be sent.

We reiterate that it is crucial for educating complainants, advertisers and the industry that details of specific Code breaches upheld or rejected by the TGA (determinations) be communicated and

[12] https://theconversation.com/kids-vitamin-gummies-unhealthy-poorly-regulated-and-exploitative-76466
[13] https://www.mja.com.au/journal/2015/203/3/use-complementary-and-alternative-medicines-menopausal-symptoms-australian-women

published, as has been the practice of the CRP. This is also crucial for monitoring the performance of the TGA.

Second, we comment on the different case priorities the TGA proposes to assign.

"Low priority cases"

Complainants who send a valid complaint will apparently receive an email with a case identification number. However, it appears that the complainant **will NOT be told the priority level their complaint has been assigned to.**

The complainant may find some information about their complaint in TGA bi-annually statistics: the case identification number, date received, date completed and the "outcome"; that is, a "regulatory obligation notice" was sent.

There apparently will be NO information published on:

- **The product involved;**
- **What alleged Code breaches were determined by the TGA to be justified or not justified?**
- **If the "notice" achieved compliance? Although the TGA says some targeted post-marketing reviews may be done on such cases.**

Why should the complainant have to follow up if compliance has been achieved; why not the TGA in all cases?

"Medium priority cases"

An acceptable response to a warning letter appears to be merely a statement from the sponsor that the alleged breach has been responded to.

Once again, NO information is provided on:

- **What alleged Code breaches were determined by the TGA to be justified or not justified?**
- **Whether the sponsor achieved actually compliance?**

For medium priority cases, the details published in bi-annually statistics appear to be the case identification number, the therapeutic good involved, the responsible entity, the date the complaint was received, date warning letter sent and the "outcome" (that is, the sponsor said problem fixed or, if no response was received, the complaint was escalated).

Experience with the current CRP shows that many sponsors will assert they will fix the problem, but then don't; alternatively, they may correct the breaches pointed out, but then create new ones!

In short, monitoring compliance is essential; trusting sponsors is naive!

High and critical priority cases

In these cases, the TGA state they will determine the most appropriate regulatory tools to be used.

Once again, NO information is provided on what alleged Code breaches were determined by the TGA to be justified or not justified.

The TGA notes that matters that require court action can take some time to properly investigate and assemble, for example for criminal prosecutions. Outcomes that are dependent on court decisions either civil or criminal can, according to available court resources, take longer to resolve and close. In these cases, the TGA will report on outcomes when the matter is finalised.

At this time, the details of the responsible entity, the case identification number, date received, date completed, the therapeutic goods involved, the compliance action/s taken, and the outcome will be published.

This means that it may be several years before a final outcome is achieved. In the interim, apparently the complainant and the public will not be informed that this advertising has been assigned a high or critical priority level, what the problems are, nor what action is in train.

The ACCC informs the public when it institutes Court proceedings;[14] why not the TGA?

In summary:

- No complainant will be told the priority level their complaint has been assigned to after triaging.
- Regardless of priority, there apparently will be NO information published on what alleged Code breaches were determined by the TGA to be justified or not.
- For low priority cases, there will be no disclosure of who is responsible for the advertisement.
- For low and medium priority cases, it appears to be up to the complainant to check if a "regulatory obligation notice" or an "acceptable response" actually achieved compliance.
- For high and critical priority cases no information will be provided to the complainant and the public until a final outcome is achieved and, if this involves Court action, this may take years.

In short, the proposed TGA complaint system provides much less transparency that the current CRP system. This is unacceptable.

We are also aware of hundreds of outstanding complaints, sent to the TGA by the CRP, which currently lack a public outcome. The TGA have stated that their current priority is getting up the new Code and complaint system, not dealing with old complaints.

Nevertheless, there is considerable cynicism, based on the above experience, about the TGA's ability (and will) to provide an efficient and transparent complaint system.

We understand that the TGA has prepared a legislative instrument that will facilitate publishing all complaint outcomes: *Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2018*.

We expect that when this latest legislative instrument is enacted, the TGA will at least report the outcome of all complaints forwarded to the TGA by the CRP from December 2017 as a result of the transition from the CRP to the TGA.

This would reassure complainants that the TGA is committed to transparent reporting of complaint outcomes and to community health, wellbeing and consumer protection.

4. Time to close complaints

Time taken to close complaints means the time from when the complaint was received, assessed and triaged to when we assess that no further action is required. These times are our intended timeframes in which to close out matters and depend on the priority given to each accepted case:

Low Priority	Medium Priority	High Priority	Critical Priority
90% in 20 days	90% in 90 days	90% in 90 days	90% in 60 days

[14] https://www.accc.gov.au/media-release/accc-targets-alleged-false-and-misleading-nurofen-claims

On average, the days taken for all complaints handled by the current CRP is 92 days. However, those involving detailed responses from the advertiser and determinations finalised by the Panel can take 6 months or more.[15]

In the new complaint system, the TGA states low priority cases are closed once a regulatory obligations notice to be sent (with no follow-up) while medium and high priority cases receive a warning letter or email / telephone call respectively and are closed on receipt of an "acceptable" response (with apparently no checking that compliance has actually been achieved).

Only in critical priority cases does the TGA state that it is unlikely that these cases would be closed simply by receipt of a response from the responsible entity.

In summary, it appears that in all, except perhaps critical cases, the TGA will close the case without actually checking if compliance has been achieved or not, and without publishing a determination of alleged Code breaches. While this will certainly result in shorter "time taken to close complaints" compared to those of the Panel, the new statistics will be of dubious value.

5. Monitoring and trend analysis

We are concerned about the TGA's ability to perform this task. For example, the TGA has been requested to break down its post-marketing compliance data into targeted and random reviews. This breakdown is NOT present in the TGA's annual performance statistics[16] and half yearly performance snapshots.[17]

Rather the TGA lumps data on compliance breaches for both targeted and random reviews together. This means that if the TGA targets a category of product (such as sunscreens) which have less compliance breaches than other categories (such as herbal or homeopathic products), then the overall compliance rate appears to improve as the latest TGA snapshot showed.[6] This was reported by the media as, "Complementary Medicine Compliance Improves (80% non-compliance drops to 56%)".[18] TGA targets need to be reported publicly, not merely made available for industry to selectively report.

The latest TGA data provided, "Listing Compliance Reviews FY2016-17"[19] has the following problems:

- It gives percentages but not absolute numbers. Good reporting practice means all percentages presented should be preceded by the numbers they represent.
- It has added a new column to the table, "Project" which is not present in the "Annual performance statistics report: July 2016 to June 2017 3.3.2 Compliance reviews".[20] What does this mean? If it's projects mentioned in the annual report that targeted oral probiotics indicated for vaginal conditions and listed medicines with blood glucose and cholesterol indications, what other investigations comprise the "targeted" column?

It is also important to break down the results for the main categories of products targeted by random reviews: e.g. Vitamins and minerals, Fish oil, Western Herbal Medicine, Chinese Traditional medicine,

[15] http://www.tgacrp.com.au/wp-content/uploads/CRP-complaints-summary-1-Jul-2016-to-30-Jun-2017-including-graphs.pdf
[16] https://www.tga.gov.au/annual-performance-statistics-reports
[17] https://www.tga.gov.au/half-yearly-performance-snapshot-july-december-2017
[18] https://pharmacydaily.com.au/news/cm-compliance-improves/72662
[19] http://www.medreach.com.au/wp-content/uploads/2018/05/TGA-Listing-Compliance-Review-Stats-by-Type-2015-17.pdf
[20] https://www.tga.gov.au/book/export/html/765127

Ayurveda (Indian) medicines, Homeopathic Medicines, Probiotics, Sunscreens and Aromatherapy products.

Finally, it's crucial to report to consumers and health professionals the most non-compliant companies. This will help consumers to select products and health professionals to give advice. It will also provide a stimulus for the named companies to improve.

In the second Civil Society Seminar on, "The Advertising of Therapeutic Goods and Services (and its regulation)"[21] held at Monash law Chambers on Sept 8, 2017, and attended by the TGA's now departed Ross Hawkins, we heard a presentation[22] by Suzanne Crowle, Director of Engagement and Complaints, of NSW Fair Trading.

The NSW Fair Trading Complaints Register provides information about businesses that are the subject of 10 or more complaints received by Fair Trading in a calendar month. It's updated monthly and only includes complaints considered by Fair Trading to have been made by a real person, relating to a real interaction with a business. It provides information about the name of the business; the number of complaints NSW Fair Trading has received about the business in the last month and the product groups complained about.

If NSW Fair Trading can do this monthly, why can't the TGA do it at least 6-monthly?

6. The TGA website advertising hub

We have been involved in user testing of this site for which we had to sign a confidentiality agreement.

The site is a work-in-progress. Although it shows promise, we provided feedback on many concerns.

7. Conclusion

Finally, we reiterate the point made in other submissions; unless the TGA accepts that consumer protection is an equal objective to industry assistance, and gains the will to act, a revised Code and complaint system (including increased penalties and sanctions) will have no more impact than the current dysfunctional system.

[21] http://www.medreach.com.au/?p=2223

[22] http://www.medreach.com.au/wp-content/uploads/2017/09/Crowle-NSW-Fair-Trading-Complaints-Register.pdf

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18 May 2017

Regulatory Reforms Team
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Consultation on options for the future regulation of "low risk" products

The Australian Competition and Consumer Commission (ACCC) provides the attached submission to the Therapeutic Goods Administration (TGA) in response to the consultation paper on *Options for the future regulation of "low risk" products* ('the consultation paper').

The ACCC is concerned that the TGA declaring certain regulated products as "low risk" and excluding them from the TGA's regulatory framework may raise an unrealistic expectation that the ACCC could provide equivalent regulatory oversight through application of the Australian Consumer Law (ACL).

Unlike the TGA, the ACCC is a whole of economy regulator with a broad competition and consumer remit. Our consumer product safety role is to seek to reduce the risk of 'serious injury, illness or death' resulting from the use or foreseeable misuse of consumer goods. This threshold for regulatory intervention differs from that of the TGA, where current post market controls can be triggered by an 'adverse event'.

The ACCC recognises the role of specialist regulators and is unable to increase activity in areas vacated (in whole or in part) by other regulators. We cannot replicate the expertise nor the therapeutic based risk assessments that a specialist regulator like the TGA delivers.

If the TGA dilutes or removes the scope of their specialist regulator activities, the ACCC would be unable to deliver consumer protection in the same way. The identified 'low risk' products may potentially pose a higher risk to consumers if their physical constituents change and specialist regulatory oversight is reduced, leading to a regulatory gap.

Should you have any questions, please contact Tim Grimwade, Executive General Manager, Consumer, Small Business & Product Safety Division on 02 6243 1298.

Yours sincerely

Delia Rickard
Deputy Chair

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

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[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.