Title	Productivity Commission Issues Paper July 2016: Consumer Law Enforcement and Administration
Department	Productivity Commission
Date of submission	30 August 2016

Relationship to previous/ongoing decisions/consultations	Productivity Commission Issues paper: 15 July 2016 The Commission will seek further information and feedback following release of a draft report: due November 2016 Productivity Commission Research report: due March 2017 In parallel with CAANZ review Issues Paper: 27 May 2016
Result of consultation	In progress and ongoing

Submission type	Response to Issues Paper

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1 Recommendation(s)

It is recommended that:

i) the Government's impending implementation of the Expert Panel's recommendations from the Review of Medicines and Medical Devices Regulation, including the advertising of therapeutic goods reform, be considered inline with recommendations for further remodelling of the multiple regulatory model.

2 Executive summary

2.1 CMA appreciates the opportunity to comment on aspects of the multiple regulator model for enforcing the Australian Consumer Law (ACL) and how it is operating at present. This submission provides comment on potential challenges and suggestions on how the model or operation could be improved.

2.2 CMA supports the examination of how effectively the multiple regulator model provides a national consumer protection framework, the role of specialist safety regimes in protecting consumer safety and their interaction with ACL, and the extent to which responsibilities of the different specialist regimes and ACL regulations are delineated.

2.3 The Therapeutic Goods Administration (TGA) and Food Standards Australia New Zealand (FSANZ) are two such specialist safety regimes the terms of reference explicitly mention the commission should consider.

2.4 In terms of specialist regulatory regimes, it should be noted that the medicines regulator is about to embark on the implementation of a wide-ranging series of expert recommendations 'Expert Panel Review of Medicines and Medical Devices Regulations' (MMDR) on the regulatory framework, including complementary medicines and the framework for advertising therapeutic goods. As such, CMA will be particularly keen to review the Commission's draft report and research report once published, and with consideration of the potential impacts on the future regulation of complementary medicines.

3 Response to Information Requests

3.1 *Information request*: The Commission would welcome comprehensive information on the specialist consumer safety regulatory regimes that lie outside the ACL and the regulators responsible for administering those regimes in and across jurisdictions.

Some specialist regimes, such as that for therapeutic goods, operate under a single specialist national regulator responsible for enforcement, while others such as FSANZ operate its food enforcement capabilities via state and territory agencies. This may be a reflection of an historical approach to governance, the community risks associated with the

products as well as varying resource availability. However, as the study highlights, differences in design and applications across different regimes, and interaction with ACL, pose some significant challenges in assessing the effectiveness and possible solutions to emerging trends.

The Therapeutic goods regulatory regime offers a relatively clear example of the need for regulation. Medicines, including complementary medicines, defined as such in the *Therapeutic Goods Act 1989*, are novel consumer goods in that they involve consumers intentionally introducing these substances into their bodies.

Australia is one of the few countries in the world that not only regulates prescription and pharmacy medicines but also regulates 'complementary medicines' as therapeutic goods. Complementary medicines, which include vitamin, mineral and herbal products, are in many countries classified as foods or dietary supplements, and therefore would be subject to lower regulatory and manufacturing quality controls than medicines.

In Australia, as medicines have evolved so to have their regulation, principally around the three primary pillars of:

3.1.1. their quality;

3.1.2. their safety; and

3.1.3. their efficacy (performance).

The regulation of therapeutic goods became integrated as a major component of Australia's National Medicines Policy. With this, risk appropriate regulation was refined with the level of regulation of each of the classes of therapeutic goods being commensurate with the risk they represent. Therapeutic goods on the market in Australia are required to be manufactured to an appropriate quality, and while no therapeutic good can be considered risk free, when used as intended the benefits of any product should outweigh the risks associated with its use (McEwen, September 2007).

To be included in the Australian Register of Therapeutic Goods (ARTG), higher risk products must demonstrate that they are effective in treating the conditions for which they are approved. These higher risk products include registered prescription, non-prescription and registered complementary medicines (AUST R number outlined on labels). Lower risk products such as listed medicines need only demonstrate that they are of acceptable quality and do not present significant safety risks (AUST L number on labels).

The TGA actively monitors the quality, safety and performance of therapeutic goods when they become available to consumers to ensure the on-going compliance of the products with TGA's regulatory requirements, and has an on-going program of verifying the suitability of manufacturers to produce therapeutic goods for supply in Australia. The TGA also actively monitors unlawfully supplied products and takes appropriate regulatory action where these are identified. There are several different sources of risk that can arise in relation to therapeutic goods—they can be product risks (risks that are inherent to the product), compliance risks (risks occurring from products failing to meet requirements), and unlawful

products (risks of unauthorised products) where a uniformed risk-based compliance framework is applied (Therapeutic Goods Administration, June 2013).

The national system continues to mature into an internationally harmonised regulatory system reflecting the increasing globalisation of markets. Today, the focus on international harmonisation and cooperation in therapeutic goods regulation is continuing under ongoing reforms such as the MMDR.

3.2 *Information request*: What challenges do product complexity and bundling, and overlapping regulation, pose for ACL regulators, specialist safety regime regulators, businesses and consumers? What are some examples of particular concerns? How significant are these challenges? Does the availability of alternative avenues for regulating particular products assist ACL or specialist regulators in protecting consumers?

3.3 The Issues Paper mentions the emerging growth of 'bundled' products and the online international nature of markets as presenting potential issues and challenges.

- The food-medicine interface area offers a number of examples where the overlapping of regulation and international nature of the market can pose significant challenges. With the increase in online sales, for example, the premarket safety aspects of the Australian medicine regulations may be skipped altogether with the purchase of goods from overseas websites, meaning the consumer may end up with an inferior product that has not been through equivalent safety or quality screening. In such a common circumstance, the lack of a domestic 'supplier' of the product makes it difficult for regulators to address concerns through current enforcement tools.

- To the extent that the food-medicine interface issue poses challenges with regard to the appropriate regulatory framework that may be applied in a case by case scenario, CMA understands that officials in regulators of specialist safety regimes do communicate and cooperate with other specialist safety regulators or with ACL regulators where required on matters of safety. There may also be this crossover on other relevant matters, albeit on an irregular or informal basis, particularly where matters of food regulation may not be deemed as an immediate safety concern.

- Further, in 2014 the Therapeutic Goods Administration published the food-medicine interface guidance tool to assist manufacturers and importers of products to understand whether certain products are regulated as therapeutic goods or as food due to the different regulatory requirements that apply.

- Multiple regulator model complexities: products that are subject to specialist safety regulation are also subject to general consumer protection. It is acknowledged that many consumer products are potentially subject to regulation by a number of regulators and particular safety issues could be dealt with by more than one regulator. For example, recalls of therapeutic goods are dealt with by the TGA and notices of some recalls may also appear on the ACCC's Product Safety Australia website. Further, the *Therapeutic Goods Advertising Code 2015* provides that the advertising of medicines in Australia promotes the quality use of therapeutic goods, is socially responsible, truthful, appropriate and not misleading. The ACCC also protects consumers from false or misleading claims about products or services. A threshold question is: how significant or problematic are the challenges posed by the multiple regulator model and is significant remodeling required?

3.4 CMA suggests that the upcoming implementation of the Government's recommendations to the advertising of Therapeutic Goods reform be considered inline with recommendations for the further remodelling of the multiple regulatory model.

Yours sincerely,

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