Australian Government

Department of Health

16 February 2017

Consumer Law Enforcement and Administration Study
Productivity Commission
GPO Box 1428
Canberra City ACT 2601

Dear Commissioner Abramson

Department of Health Submission to the Productivity Commission Inquiry into Consumer Law Enforcement and Administration

Thank you for the opportunity to comment on the Commission's Draft Report on *Consumer Law Enforcement and Administration* (the draft report).

Food regulation

The Department of Health thanks the Productivity Commission for the thoughtful discussion of food regulation throughout the draft report, and notes the similarities and some overlap between the food regulatory and consumer protection regimes.

The Department of Health notes the ACCC's discussion of the supply of raw milk in their submission as addressed on page 139 of the draft report which stated that the "concerns about the supply of raw milk were resolved within the food safety regulatory framework but the discussions about the potential application of the ACL nonetheless diverted our resources for several months".

Concerns about the regulation of raw milk arose following report of a rise in the consumption of unpasteurised cow's milk (raw milk) that was sold as 'bath milk' – a cosmetic product labelled 'not for human consumption'. In January 2015, the Ministerial Forum on Food Regulation (the Forum) expressed their extreme concern about the consumption of the product, as people who consume raw milk are at an increased risk of infection causing severe illness and potentially death. At the request of the Forum, a working group was established to look into urgent interim measures to protect public health from the risks associated with the consumption of raw milk. The working group was chaired by the Department of Health and the membership included representatives from FSANZ, the ACCC, the Department of Agriculture and Water Resources, the Department of Industry, Innovation and Science, the Treasury and most jurisdictions.

The working group noted the inconsistencies between the regulation of raw milk in each jurisdiction, and agreed that the best way to address these inconsistencies would be to prevent the supply of raw milk for human consumption through the supply chain. The means to achieve this, however, will vary between jurisdictions and are not being undertaken formally in either the food regulation system or the consumer affairs

system. In particular, the food regulation system cannot address the products when they are labelled as 'not for human consumption'. There remains potential for a similar situation with a different product to occur again.

Therapeutic Goods Regulation

The draft report classifies the Therapeutic Goods Administration (TGA) as a "specialist safety regulator". Chapter 5 – Interaction between specialist safety and ACL regulators – is therefore of particular interest to the TGA.

About the TGA

The TGA forms part of the Department of Health, and is responsible for administering the *Therapeutic Goods Act 1989* (TG Act) and its associated regulations. These create Australia's national framework for regulating the quality, safety, efficacy and timely availability of therapeutic goods used in, or exported from, Australia and to ensure a framework for control of poisons in Australia. The regulatory scheme provides for:

- the marketing approval of therapeutic goods, including medicines, biological products and medical devices;
- the setting of acceptable standards for therapeutic goods;
- the requirement for therapeutic goods to be manufactured in accordance with accept manufacturing principles and practices;
- the monitoring of quality, safety and efficacy/performance of therapeutic goods that are available on the market to ensure ongoing compliance with regulatory requirements;
- sanctions for contraventions of regulatory requirements, including criminal and civil penalties, infringement notices, enforceable undertakings, imposition of conditions, cancellation or suspension (for example, from inclusion in the Australian Register of Therapeutic Goods or of manufacturing licences);
- recall powers for therapeutic goods that present a public health risk (including unapproved and counterfeit goods) or no longer meet other regulatory requirements;
- a framework for regulating the advertising of therapeutic goods to the public; and
- a national framework to control the availability and accessibility of poisons in Australia.

The TGA uses a risk management approach to ensure the quality, safety and efficacy/performance of therapeutic goods. Not all therapeutic goods regulated by the TGA are 'consumer goods' as defined under the *Competition and Consumer Act 2010* (for example, medical devices used in hospitals such as diagnostic imaging devices).

Draft Finding 5.1

The TGA recognises the overlap with the ACCC in the jurisdiction for certain therapeutic goods that are also consumer goods. The TGA can confirm that it has informal arrangements with the ACCC to discuss compliance issues of common interest and to share information on related enforcement activities, particularly in areas of regulatory overlap. Ad hoc communication also occurs in relation to recall actions for certain therapeutic goods and specific complaints that have been received by both agencies. Further, the TGA has procedures in place to redirect complaints that are outside of the organisation's jurisdiction to the appropriate authority. Collectively, these arrangements already implement the "no wrong door approach" (described on page 9 of the report) for consumer complaints about therapeutic goods.

The TGA would be open to more formalised meeting arrangements with the ACCC, including the consideration of a Memorandum of Understanding (MoU), where these arrangements were shown to further improve the constructive and cooperative relationship that currently exists between the two regulators. However, as pointed out in the draft report, an MoU may not be required if the regulatory tools and remedies available to the TGA for contraventions of advertising requirements are broadened and strengthened. The draft Report observed that the shortcomings of the TGA "regulatory toolbox" were discussed in the Review of Medicines and Medical Devices Regulation (MMDR) and, if implemented as recommended and accepted by Government, would address the regulatory gap for the TGA, effectively reducing the possible need for an MOU. The implementation of the powers needed to address the TGA regulatory gap is under way and anticipated to be in place following the required legislative processes.

The proposal for a national database (described on page 9 of the report) for consumer complaints should, if progressed, exclude those complaints handled by existing effective complaint resolution processes managed by national specialist safety regulators such as the TGA. Medicines, biological products and medical devices are not ordinary items of commerce and the regulations governing advertising of these are unique in comparison to other goods and services. Duplicate recording of complaints and outcomes on multiple regulator complaint handling systems would be inefficient and (if published) confusing for consumers, and accordingly highly undesirable.

Draft finding 6.1

The actions of retailers of therapeutic goods, including healthcare practitioners, may not fall within the scope of the TG Act unless they are incorporated entities or are carrying out the retail business across state/territory boundaries. There may be scope to improve consumer redress for the intrastate sale, supply or promotion of unacceptable therapeutic goods by retailers through other mechanisms including a retail ombudsman.

Conclusion

The Department of Health values the engagement of the ACCC and other government agencies when considering complex consumer protection issues like raw milk and therapeutic goods that do not fit neatly into either the food regulation, health regulation or the consumer affairs systems.

My Department would be happy to discuss these issues further with the Productivity Commission should you require any further information. The contact officer for food regulation issues is Ms Elizabeth Flynn, Assistant Secretary, Preventive Health Policy Branch The contact for therapeutic goods issues is Mr Pio Cesarin, Assistant Secretary, Re ulatory Practice, Education and Compliance Branch

Yours sincerely

Martin Bowles PSM
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