POSITION STATEMENT – THERAPEUTIC GOODS PACKAGING

Therapeutic goods packaging has additional complexities and requirements that are necessary for the protection of public health and to meet exacting regulatory requirements. These factors must be at the forefront as our industry considers approaches towards more sustainable packaging.

Complementary Medicine Australia (CMA) supports the National Packaging Targets and is committed to supporting industry's transition towards 100% recyclable packaging in formats that make it easy for consumers to recycle and to incorporating recycled content (as feedstock becomes available).

Noting the significance of the challenge to reform the greater recycling markets, infrastructure and systems; product stewardship (where stakeholders across the value chain take financial responsibility for the materials they put on the market) is a necessary driver of change.

Packaging contributes to three central environmental challenges:

- Contribution to landfill
- Greenhouse gas emissions and depletion of natural resources relating to the packaging production, including reliance on fossil fuels for inputs
- Ocean waste and litter as a result of incorrect disposal

Therapeutic goods do not contribute significantly to ocean contamination and litter as they are most frequently consumed in environments where waste disposal is available.

Therapeutic goods packaging has additional functional requirements compared to fast moving consumer goods:

- May support correct dosage and quality use of medicines
- Provides an effective barrier against oxygen and moisture for between 24 and 48 months
- Protects product stability ensuring therapeutic potency and product integrity for the duration of the shelf life

Natural healthcare products have an additional reliance on packaging integrity because formulations don't contain many of the artificial additives that can have a protective effect on the formulation.

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To affirm the shelf life and meet the regulatory requirements for sales in many markets, stability studies need to be undertaken on each product over a multi-year timeframe. Practically speaking, this means that each time a new packaging format is identified that could have improved environmental outcomes, it could take several years for stability to be established and adopted into compliance records.

Australia has a vibrant export market for natural healthcare products, particularly to countries across the Asia region where our high-quality manufacturing standards are well regarded. Transition timeframes for packaging changes need to consider not only Australian regulatory requirements but those of medicines regulators across the region.

Packaging is even more important for the export of medicines to ensure therapeutic potency is maintained throughout transit and throughout the shelf life in countries with high humidity and warmer climates.

Because quality use of medicines requires product use to be spread across an extended timeframe, reduced shelf lives could result in greater product waste, an increase in packaging volumes or incorrect usage.

Learnings from European Union Directive on Packaging and Packaging Waste 20.11.22 (revised):

We note the evolving regulation of packaging in the EU and the recognition that there is need for "*efficient functioning of the internal market for packaged goods, while preventing or reducing the adverse impacts of packaging and packaging waste on the environment and on human health.*"

Accordingly, there are derogations for *"immediate packaging of medicinal products, contact sensitive plastic packaging of medical devices and of in vitro diagnostic medical devices are foreseen until 31 December 2034."*

Understanding the functional and public health role of therapeutic goods packaging, the extended stability testing and regulatory requirements – both domestically and to support Australian exports – **CMA supports a longer pathway for therapeutic goods to comply with National Packaging Targets in Australia and Product Stewardship Schemes.**

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