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Consultation: Options for the future regulation of "low risk" products

Dear Madam/Sir

Unilever Australasia is an international manufacturer and marketer of home and personal care products and is a market leader in many grocery categories in Australia and New Zealand. Our well known brands include: Domestos, Dove, Jif, Omo/Persil, Rexona, Tresemmé and Vaseline. Our home and personal care products are used every day by millions of people around the world. Consumers trust us to provide them and their families with products that are suitable for use.

We fully support the concept of appropriate levels of regulation for the potential risks to consumer rights and consumer and environmental safety, while minimising bureaucratic and cost burdens on both regulators and industry. We also support alignment of Australian regulations against current international best regulatory practices to promote exchange of innovation and goods between Australia and its trading partners.

Will are pleased to be given the opportunity to comment on;

- **Nappy Rash Creams,**
- **Antiperspirants,**
- **Disinfectants,**
- **Other low risk registered non-prescription (OTC) medicines and**
- **Sunscreens**

Nappy Rash Creams

Option 3 – Exemption from listing in the ARTG – supported
Option 4 – Review of registered nappy rash active ingredients – supported

As these products are for use by a vulnerable consumer group we would support further review of this area leading to a two-stream approach, reflecting the fact that there are two distinct product sub-groupings in this category. Products containing anti-fungal and anti-bacterial agents which are intended to treat skin

infections, and those topical creams which protect from/prevent mild nappy rash through providing topical moisturisation and skin barrier benefits. We would support two different levels of regulation under option 3 based on a combination of ingredients and claims but do have reservations as to where these products will fall in advertising and manufacturing requirements.

Further clarity could be delivered to separate these two groups via a monograph or other guidance material specifying permitted intended purpose and area of application claims. Alternatively placing Nappy Rash creams into the excluded goods order in a manner that clearly defines the scope of entry would facilitate the consistent presentation of topical barrier creams for the prevention and or treatment of Nappy Rash.

Antiperspirants

Option 2 – Exclude antiperspirants from the regulatory framework - supported

We would support the inclusion of all topical antiperspirants in the current Excluded Goods Order as there is no health risk to the consumer from non-performing products. Our experience is that consumers quickly self-regulate non-performing products by refusal to repeat purchase, with associated loss of brand credibility and revenue.

We believe the inclusion of the words "...and topical antiperspirants" in the current Deodorant entry will be sufficient to allow for innovation and to bring this category into regulatory alignment with the majority of other countries around the world.

Hard surface disinfectants

Option 2 – Streamline the regulatory framework for hard surface disinfectants - supported
Option 4 – Approval process for new ingredients - supported

The proposal to streamline the regulatory framework by moving currently "registered" products to "listed" and "listed" to exempt is supported provided performance requirements between the separate categories (household/hospital grade) are retained.

While clear guidance to industry regarding permissible claims and performance requirements is acknowledged and desired, we feel a monograph style system is not appropriate. Monographs, while clear are prescriptive and can result in stifling newer and potentially safer/more environmentally friendly innovative products due to restrictions on permissible ingredients.

A revised TGO 54 would be a preferred alternative to new monographs, with the addition of information such as clarified definitions including "hospital grade" and performance requirements to demonstrate efficacy for specific claims for "listed" products.

Other low risk registered non-prescription (OTC) medicines

Option 2 – Review of eligibility of active ingredients to become Listable - supported

We would support Option 2, review of eligibility of active ingredients to become listable. In particular we would propose a review of the status of anti-dandruff shampoos, acne treatments, anti-septic mouth washes and desensitising toothpastes against international regulations using the same rationale as for antiperspirant products i.e. that non-performance does not present a health risk, and that international markets have been shown to effectively self-regulate based on product performance.

Sunscreens

Option 2 – Streamline the regulatory pathways for sunscreen regulation – supported
Option 5 – New ingredient approval process – supported
Option 4 – Creation of a GMP standard for primary sunscreens – supported

We would support combination of the streamlining of the regulatory pathways for sunscreen regulation as outlined in Option 2 with the international ingredient recognition process of Option 4 to facilitate rapid introduction of ingredients approved in other markets.

We would like to thank the TGA for the opportunity to comment and remain engaged and willing to participate in the development of any potential guidance materials for industry that arise from this consultation.

<Unsigned for email transmission>

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Unilever Australia Limited

12th May 2017