

Technical Alert

Changes to Nappy Rash products

Formation of the Naturopathic Council of Australia

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From 1 January 2020, [some nappy rash products will become exempt](#) from regulation under the Therapeutic Goods Act, from any requirement to be entered on the ARTG and from any requirement to be made under GMP.

This regulatory change will apply to listed medicines and Class I medical devices which are indicated for nappy rash symptoms, **via a barrier effect only**.

The exemption will **not apply** to nappy rash preparations:

- That are also indicated for other skin conditions, such as eczema, psoriasis and dermatitis,
- Where relief of nappy rash symptoms are provided by another mechanism, and
- Those nappy rash preparations that are registered medicines.

Background

The history of this changes arises from MMDR recommendations to review the [regulation of low risk products](#). Consequent to consultations in 2017, the TGA announced in December 2018 the regulatory changes to nappy rash products.

How will exempt products be regulated?

To exempt devices, a declaration will be made under section 41BD(3).

For listed medicines, eligible nappy rash products will become exempt from the requirement to be entered into the Register (part 3-2 of the Act), and exempt from having to be made in accordance with GMP standards (part 3-3). However as these products will still fall under the oversight of the TGA, they will still be subject to [controls and standards](#) of listed medicines, such as acceptable presentation and safe for its intended purpose. For further information about exempt complementary medicines go [here](#) on the TGA website.

Formation of the Naturopathic Council of Australia

A new co-ordinating body to represent the naturopathic profession has recently been formed: the [Naturopathic Council of Australia \(NCA\)](#).

The NCA will

- provide a united voice on important issues affecting naturopaths in Australia and will be a go-to organisation for external stakeholders.



- be a coordinating body on key issues affecting the naturopathic profession such as registration, education standards and private health insurance rebates.

The NCA formalises, and builds on the efforts of its current members, who have been collaborating on many years:

- [Naturopaths and Herbalists Association of Australia \(NHAA\)](#)
- [Complementary Medicine Association \(CMA\)](#)
- [Australian Register of Naturopaths and Herbalists \(ARONAH\)](#), and
- [Endeavour College of Natural Health \(ECNH\)](#).

Each of these members are also members of the World Naturopathic Federation (WNF), with CMA being gold sponsors of the WNF in the [non-profit section](#). The NCA also looks forward to welcoming future Australian WNF member organisations should they choose to contribute to the shared vision and mission.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.

ENDS