[redacted]

From: [redacted]
Sent: Tuesday, 19 September 2017 1:43 PM
To: [redacted]
Cc: SKERRITT, John; KELLY, Larry; MCDONALD, Mark
Subject: ERIC Paper - Specific policy proposals for the future regulation of 'low risk' products [SEC=UNCLASSIFIED]
Attachments: ERIC paper - Specific policy proposals - Low risk products 22 September 2017.tr5

[redacted]

Please find attached the ERIC Paper - Specific policy proposals for the future regulation of 'low risk' products.

The paper was circulated to Larry, Adriana and business area Branch heads last week

s22(1)

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Expert Review Implementation Committee (ERIC)

Meeting: 22 September 2017

Agenda Item X: Specific policy proposals for the future regulation of 'low risk' products.

Sponsor: Dr Mark McDonald, Assistant Secretary, Complementary and OTC Medicines Branch

Recommendations:

That ERIC:

1. **ENDORSES** the specific policy proposals for 'low risk' products
2. **ENDORSES** the next step of seeking Ministerial approval of the specific policy proposals.

Purpose:

To seek ERIC endorsement of the specific policy proposals for the future regulation of 'low risk products' and the proposed next steps for this project.

The range of low risk products is quite broad, and pending policy approval for particular changes, their implementation would need to be prioritised. It is proposed that reforms to s22(1) regulation of products such as s22(1) aromatherapy and be carried out first - s22(1)

Background:

The Government accepted the recommendations from the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) to carry out further reviews of the regulation of 'low risk' products (MMDR recommendations 14, 23 and 48). It is noted that while the MMDR has been described as a program of reduction of "unnecessary regulation" or of "red tape", the review of low risk products is one of the few MMDR work programs that has this as an overt consideration.

In conducting these further reviews and developing the public consultation paper 'Options for the future regulation of 'low risk' products', the TGA Regulatory reforms team engaged TGA stakeholders as well as conducted external meetings with other APS agencies (ACCC, APVMA and FSANZ).

A facilitated internal workshop was held on 26 October 2016 to demonstrate and validate a tool to help objectively define 'low risk' products which allowed the scope of the review into low risk products to be defined. Targeted industry consultation was conducted in November and December 2016 with ADIA, MTAA, Accord Australasia, ASMI, CMA and representative sunscreen manufacturers.

COMB, MDB, MQB and PSAB were consulted on the proposed options for products in their respective areas.

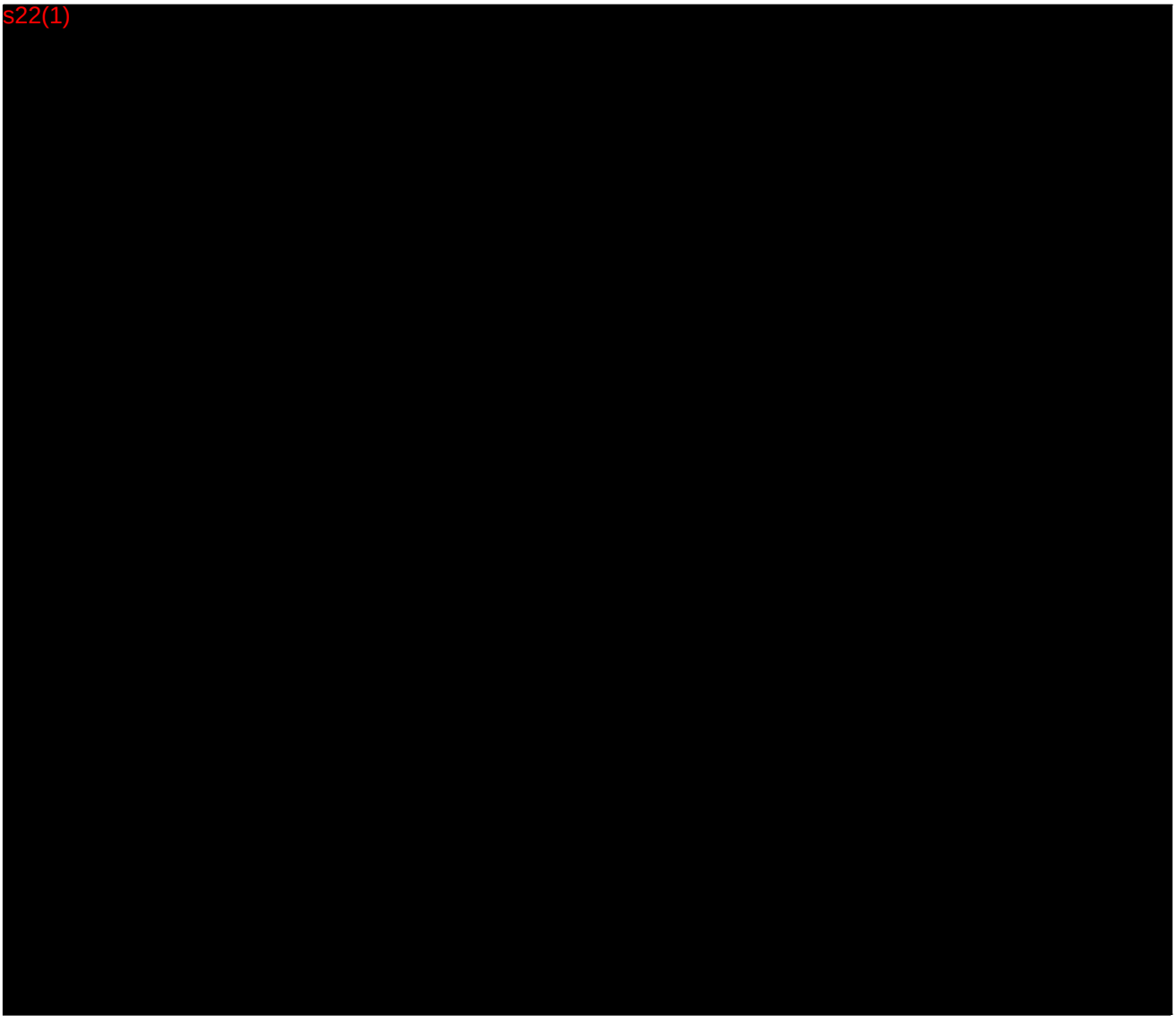
The public consultation paper was published on the TGA website for six weeks (31 March – 12 May). In addition, key stakeholders were also specifically invited to comment. These stakeholders include peak industry bodies (e.g. MTAA, ACCORD, ASMI, CMA, ADIA and Australia sunscreen manufacturers) and health professional interest groups (e.g. the Australian Medical Association, Royal Australasian College of General Practitioners and the Australasian College of Dermatologists). 1028 submissions were received for the public consultation.

Internal working groups were established to facilitate the development of consolidated TGA positions for the specific policy proposals.

Specific policy proposals

These specific policy proposals have been endorsed by COMB, MDB, MQB and PSAB.

s22(1)



Pages 4-18 inclusive exempt in full under section 22(1) of the FOI Act

s22(1)

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Aromatherapy products (essential oils)

s47C

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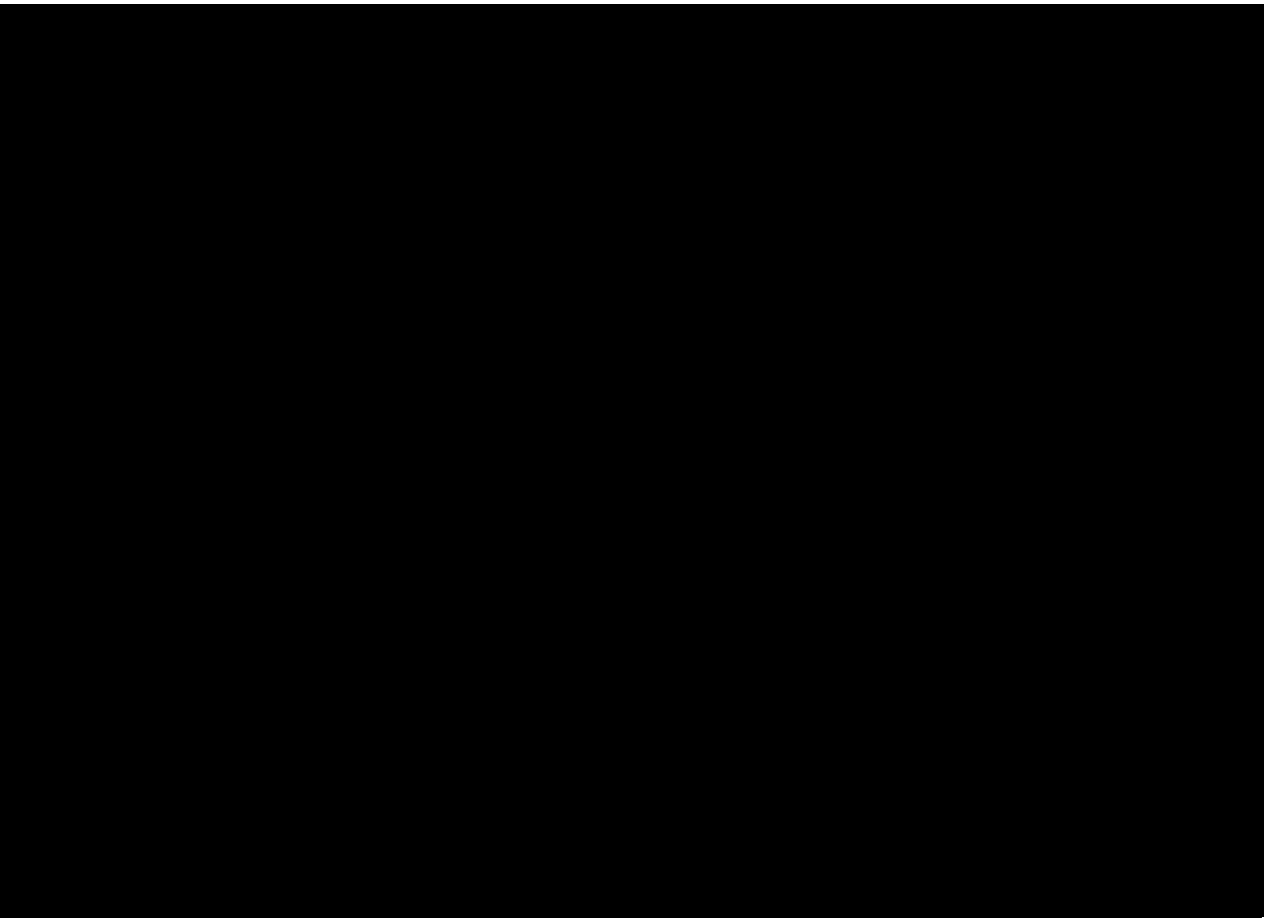
In Australia, the purpose of a product containing an essential oil determines which part of government regulates it. That is, if the product makes only cosmetic claims the chemicals within the oil are regulated by NICNAS, but if the product makes a therapeutic claim it would be considered a therapeutic good and regulated by the TGA. Like all products, general safeguards under Australian Consumer Law also apply.

Currently products solely containing essential oil(s) that are considered to be therapeutic goods must list their product in the ARTG prior to supply and must comply with statutory requirements including: Mandatory quality standards (such as the British Pharmacopoeia), the Poisons Standard, and Therapeutic Goods Orders on Medicines Labelling (TGO 92) and Child Resistant Packaging Requirements for Medicines (TGO 80).

Essential oils that are supplied solely as starting materials to practitioners are generally exempt from the requirement to be included on the ARTG and the requirements of GMP unless they are pre-packaged for therapeutic purpose or formulated as a dosage form.

Essential oils are either unscheduled substances or if captured by the requirements of the Poison standard because of their camphor content are scheduled as chemicals in Schedules 5 and 6 which are for substances with a low or moderate potential for causing harm. Schedules 5 and 6 imposes restrictions on the permitted container size as well as requiring other safety devices such as restricted flow inserts and child resistant closures and labelling requirements.

s47C



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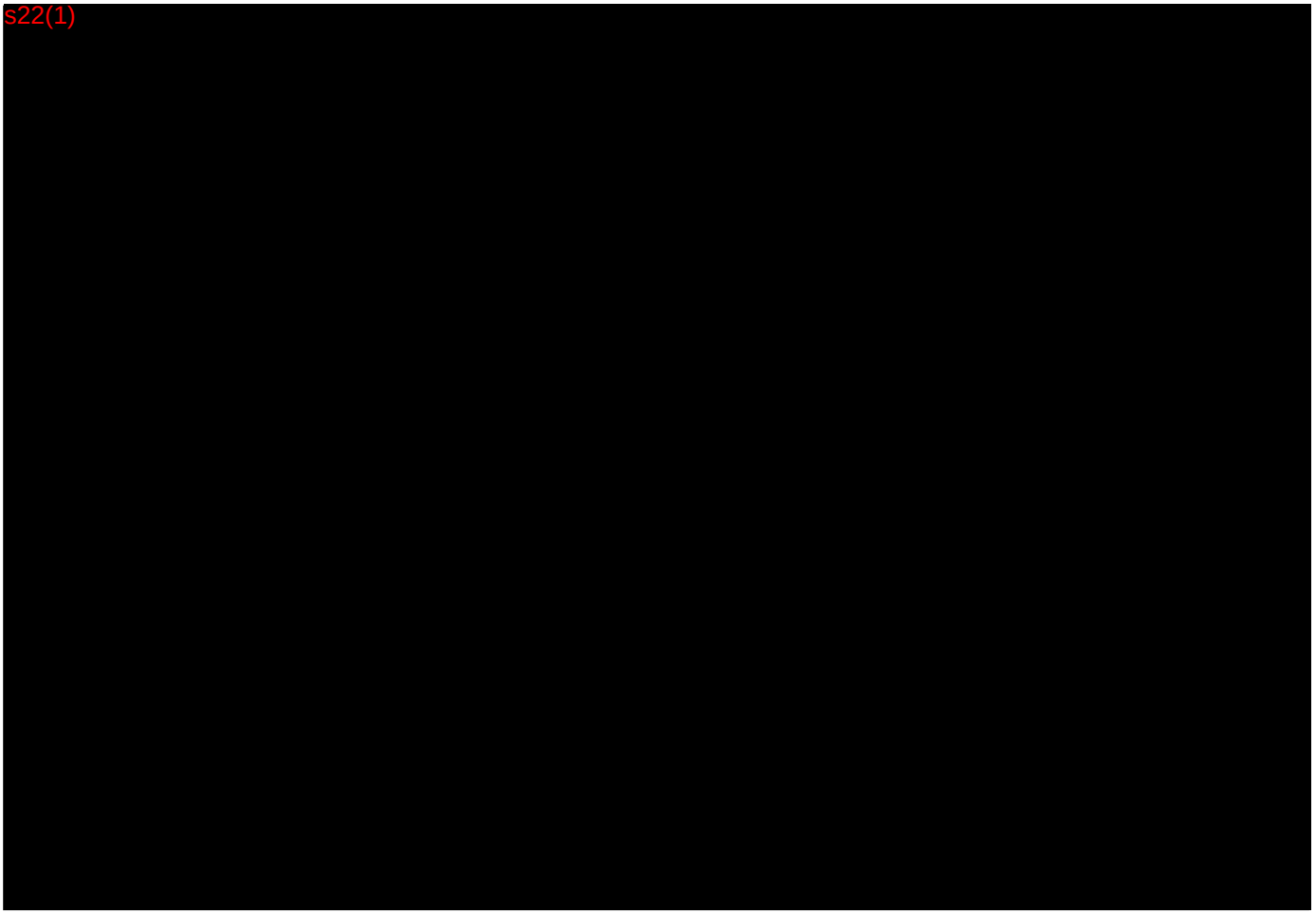

Pages 21-29 inclusive exempt in full under section 22(1) of the FOI Act

Summary of Regulatory changes required to implement proposals

s22(1)

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		Date Cleared:	11 September 2017