Australian Government
Department of Health
Therapeutic Goods Administration

New pathways for evaluation of substances for use as ingredients in sunscreens

October 2019

TGA Health Safety Regulation

Contents

Introduction

This paper describes the details of new assessment pathways for the evaluation of new substances proposed for use as ingredients in listed sunscreens (new sunscreen ingredients).

This approach would involve adoption of the evaluation pathways that apply to applications for new substances proposed for use as ingredients in listed medicines (listed medicine ingredients).

The anticipated benefits of this approach for industry are:

- improved assessment timeframes and predictability
- legislated timeframes for applications according to a set of risk-based application categories
- a pre-determined fee structure for the level of evaluation that the application requires.

Implementation of this approach will streamline TGA's assessment processes and improve timely access to sunscreen products for consumers.

Background

Review of Medicines and Medical Devices Regulation

The Government accepted a suite of recommendations from the Review of Medicines and Medical Devices Regulation (MMDR review) to improve the way the TGA assesses listed medicine ingredients. These include:

- continuing to evaluate ingredients for use in listed medicinal products and to develop a framework to broaden the range of acceptable sources of evidence for assessing these substances (Recommendation 35)
- allowing the use of reports from comparable overseas regulators for the assessment of new ingredients, new registered medicines and products assessed through the new listing pathway (Recommendation 36).
- introducing legislated timeframes for screening and evaluating complementary and ingredient assessments (Recommendation 41)
- expanding review and appeal rights for persons who apply to have a new substance permitted for use in listed medicines (Recommendation 47)
- providing incentives for industry, such as market exclusivity for new ingredients approved for use in listed medicines (Recommendation 50).

A number of business process improvements were also implemented to support these reforms, including new risk-based application categories and a revised fee structure.

Having considered the consultation outcomes on the Low Risk Products Review, the Government also agreed to streamline the regulatory requirements for sunscreens by developing a new, more transparent and predictable pathway for approval of new ingredients for sunscreens based on use of overseas reports (Recommendation 14 refers). To do this, the intention is to extend the application categorisation framework for listed medicine ingredients and the framework for the COB report-based process to the assessment of new listed medicine ingredients.

There are separate application pathways for listed medicine and sunscreen ingredients

For a new ingredient to be permitted for use in listed medicines, the applicant must submit a new ingredient application under section 26BE of the *Therapeutic Goods Act 1989* (the Act). Once the ingredient is determined to be safe, it is included in the Permissible Ingredients Determination and may be used in any listed medicine.

Applications under section 26BE of the Act have four available application categories (depending on the level of assessment required) with associated fees and legislated timeframes; and review and appeal rights. These applications can be submitted by an online lodgement portal.

Unlike other ingredients in listed medicines, currently, applications for the evaluation of a substance for use as an ingredient in **sunscreens** are made under regulation 16GA of the Therapeutic Goods Regulations 1990 (the Regulations). This application pathway:

- does not have legislated timeframes
- does not have different application categories
- does not have review and appeal rights.

As this application pathway does not have the same legislative underpinning as other ingredient applications, the evaluation timeframes and fees are based on the number of pages of data submitted for evaluation and can be unpredictable and may not be an accurate reflection of the effort or risk associated with the evaluation.

There are disparities in data requirements for listed medicine and sunscreen ingredients

Applications for new listed medicine ingredients require submission of data in accordance with Part C of the Australian Regulatory Guidelines for Complementary Medicines (ARGCM). The main parameters considered in the evaluation are **quality and safety**:

- The quality aspects (such as: chemical identity, manufacturing process, process controls and stability) are evaluated for the purpose of characterising the substance (identifying the physical and chemical properties). Where there is a default standard for the substance, the quality of the substance is assessed against that standard. Where there is no default standard applicable to the substance (USP-NF, BP or Ph Eur monographs), a TGA compositional guideline[1] is required.
- The safety evaluation determines whether the toxicological profile of the substance meets the requirements for the purpose for which it is to be used and is, therefore, considered safe to be used as an ingredient in listed medicines.

In contrast, applications for new sunscreen ingredients (excipient and active) require submission of a similar set of **safety data only** (**Attachment A**) in accordance with the Australian Regulatory Guidelines for Sunscreens (ARGS).

The quality of sunscreen ingredients is not assessed as this is not currently a requirement in the ARGS. However, the applicant is required to hold quality data similar to that submitted for listed

[1] A compositional guideline is a summary of descriptions, tests and appropriate acceptance criteria (which are numerical limits, ranges or other criteria) that define the characteristics and specify the composition of an ingredient permitted for use in listed medicines.

medicine ingredient applications (**Attachment B**). In addition, excipient and active sunscreen ingredients that are not the subject of default standards are **not** required to have a compositional guideline.

Description of the application pathways for approval of new sunscreen ingredients

We intend to align application pathways, submission requirements and business processes for sunscreen ingredients with those of other listed medicine ingredients, which are submitted under section 26BE of the Act.

Implementation of a single, streamlined process, will:

- bring consistency to the evaluation and approval process of these substances
- provide greater transparency and predictability of the regulatory process.
- Provide more timely market access for new sunscreen ingredients.

This will result in the following changes to the applications for new sunscreen ingredients.

Application categories for evaluation of sunscreen ingredients

Consistent with the arrangements in place for new listed medicine ingredients, applications for evaluation of sunscreen ingredients will be categorised into four application levels (IN1-IN4) as defined in regulation 2 of the Regulations (see **Table 1** below). These categories differ in the amount and type of information we will need to review, the degree of scrutiny necessary before the substance can be made available in Australia and the assessment timeframe.

Using the existing IN1-IN4 application categories for sunscreen ingredient applications will bring consistency to the way all ingredients for use in listed medicines are assessed. This will also enhance predictability and transparency to the sunscreen sector by providing legislated timeframes and fees associated with the safety and quality evaluation of sunscreen excipient and active ingredients as outlined below.

Table 1: Application categories for assessment of new substances

Category	Description	Evaluation and application requirements
IN1	• Evaluation of **safety and quality**[2] based on evaluation reports from a COB.	• Supporting information to demonstrate that report(s) from a COB meets all information required to demonstrate the **safety** and **quality** of the substance.
IN2	• Evaluation of **safety** based on evaluation reports from a COB.	• Supporting information to demonstrate that report(s) from a COB meets all information required to demonstrate **safety** of the substance.

[2] For new active sunscreen ingredients, SPF, broad spectrum performance, water resistance and stability testing data will be covered by the quality assessment.

Category	Description	Evaluation and application requirements
	• Independent evaluation **quality** by the TGA.	• All information required to demonstrate **quality** of the substance to be submitted for evaluation by the TGA.
IN3	• Evaluation of **quality** based on evaluation reports from a COB; or a monograph contained in a default standard. • Independent evaluation of **safety** by the TGA.	• Supporting information to demonstrate that report(s) from a COB or a monograph contained in a default standard meet all information required to demonstrate **quality** of the substance. • All information required to demonstrate **safety** of the substance to be submitted for evaluation by the TGA.
IN4	Full independent evaluation of safety and quality by the TGA.	• All information required for an application for evaluation of the substance (safety and quality data) to be submitted for evaluation by the TGA.

Proposed changes to submission requirements

To align the submission requirements for sunscreen ingredients and listed medicine ingredients, the following changes are proposed.

1. A framework for the use of reports from comparable overseas bodies (COBs) will be implemented

Under the application categorisation framework there will be increased flexibility and transparency for applicants about the types of information from COBs that can be used to support their applications and to what degree the evaluation fees and/or timeframes are reduced.

Applications may be evaluated in one of three ways:

1. *Evaluation based solely on the use of COB reports*: Applicants provide evaluation report(s) and a complete data dossier for the same substance from a COB that meets all data requirements for safety and quality (i.e. IN1).
2. *Mixed evaluation*: Applicants can provide a combination of COB report(s) that meet data requirements for safety or quality in combination with evidence for an independent evaluation of the missing parameter by the TGA (i.e. IN 2 or IN3).
3. *Full independent evaluation* of all parameters (quality and safety) by the TGA (IN4).

Applications for new sunscreen ingredients submitted through the COB report-based process (IN1, IN2 or IN3) will need to follow the requirements in the Guidance on using Comparable Overseas Body reports (See agenda item 3.3).

2. Applicants will be required to submit quality data for evaluation

As part of this proposal, we will look to revise the data requirements for sunscreen ingredient to align with the requirements for new listed medicine ingredients provided in Part C of the ARGCM.

As part of this revision, quality data for both active and excipient sunscreen ingredients will be required to be submitted for evaluation. It is proposed that quality requirements for

complementary medicine ingredients outlined in **Attachment B** will be required where appropriate. Quality may be established using a report from a COB (see above).

Further consultation on these requirements will be undertaken as part of the revision of the ARGS (see below).

This is not expected to present significant issues for applicants—the current ARGS (section 8, Manufacture and quality control) and section 40(4)(a)(i) of the Act already requires the manufacturer to ensure the quality of the of the finished product and also that of the active ingredients and excipients used in its manufacture and ensure compliance with any applicable standards.

Introducing these changes will:

- bring consistency to the submission requirements for all substances intended for used in listed medicines; and thereby ensure all ingredients listed on the Permissible Ingredients Determination have been subjected to the same level of evaluation
- allow approved substances to be used in other topical products, subject to any restrictions.

3. A TGA compositional guideline will be required

Consistent with the arrangements in place for new listed medicine ingredients, where there is no default standard applicable to a new sunscreen ingredient (USP-NF, BP or Ph Eur monograph), it is proposed that a TGA compositional guideline will be required. Compositional guidelines will be used for approved excipient or active ingredients.

Compositional guidelines assist sponsors to:

- understand the specific nature of the ingredient that has been approved for use
- determine whether their material conforms to the requirements for that ingredient minimise any risk associated with the ingredient by complying with the parameters of the specification

Ingredient applicants are responsible for providing a draft compositional guideline in their submission dossier. Refer to ARGCM Part C, Compositional guidelines for complementary medicine substances for more information.

Pre-market assessment process

It is proposed that all new substance applications made under section 26BE of the Act, including new sunscreen ingredients, will follow the same assessment process as outlined in Figure 1. Lower application categories will have shorter assessment timeframes due to the reduction in information to be evaluated.

Figure1: Proposed pre-market assessment process

These phases are described in detail in How to apply for evaluation of a substance for use in listed complementary medicines in Part C of the ARGCM.

Introducing these changes will:

- bring consistency to the assessment process for all substances intended for used in listed medicines and improve procedural fairness safeguards
- ensure applications of comparable quality are received
- help support improved assessment timeframes.

To align the assessment process for new sunscreen ingredients with the process for new listed medicine ingredients, the following changes to the premarket assessment process are proposed.

1. Legislated assessment timeframes

Regulation 16GI of the regulations provides for legislated timeframes for applications submitted under section 26BE of the Act. The same legislated timeframes would also apply to applications for new sunscreen ingredients. Implementing legislated timeframes will improve predictability, and thereby allow sponsors to better plan the roll-out of new products to the market.

The timeframes shown in **Table 2** below align with the risk-based application categories as outlined in **Table 1** above.

Table 2: Application categories and legislated assessment timeframes (in working days)

Application category	Screening[3]	Total evaluation time
IN1	40	70
IN2	40	120
IN3	40	150
IN4	40	180

Within 40 working days of receiving an application, the TGA delegate of the Secretary will notify the applicant in writing of whether the application has or has not been accepted for evaluation.

[3] Please note that the screening phase is not included in the legislated timeframe.

The timeframes for the evaluation of a substance will:

- commence only once an application is accepted for evaluation and the evaluation fee has been paid
- apply to working days only and exclude public holidays and weekends
- exclude the time when the evaluation clock has stopped (for example: the time taken by the applicant to provide responses to formal requests for information; or when the applicant and TGA agree to a mutual stop clock).

If the Secretary does not make a recommendation within the evaluation timeframe, the TGA must refund 25% of the prescribed application fee.

2. Application and evaluation fees

Consistent with the arrangements in place for new listed medicine ingredients, the inefficient and complex page count structure[4] for evaluation fees for new sunscreen ingredients will be replaced with an application fee and an evaluation fee. These fees are provided in Schedule 9 of the Regulations.

IN1-IN4 application categories (see Table 1) have fees that reflect the amount of work required to complete the relevant applications and evaluations. The fee structure, as presented in **Table 3**, was introduced in March 2018 for applications for new complementary medicine ingredients.

The following principles were applied:

- **Application fees** cover the administrative costs associated with an application and are applicable to all application types.
- **Evaluation fees** cover the cost of assessing the supporting information for application types requiring evaluation of data. The evaluation fee is payable when the applicant has been notified of the TGA's acceptance of the application but will be invoiced upfront for administrative efficiency.[5]

The fee structure will also ensure that our fees are aligned with the costs of providing evaluation services. Information on the approach to the calculation of these fees are provided in the TGA's Cost Recovery Implementation Statement (CRIS) version 1.4 published in June 2018.[6]

Table 3: Application categories and legislated assessment timeframes (in working days)

[4] Applicants for evaluation of substances for use as ingredients in sunscreens are currently required to self-determine the appropriate evaluation fee based on the total page count of safety data in their application. Administrative and quality data are currently excluded.

[5] Note that where an application does not proceed to evaluation, the evaluation fee is not payable and any evaluation fees paid, or part thereof, will be refunded to the applicant.

[6] The public consultation paper Business process improvements supporting the complementary medicines assessment pathways published in September 2017. The consultation paper included draft application and evaluation fees for applications for new substances, assessed listed medicines and registered complementary medicines.

Application Category	Application fee	Evaluation fee	Item in Schedule 9, Part 4
IN1	$1,090	$14,600	Items 28 and 29
IN2	$1,090	$14,600	Items 30 and 31
IN3	$2,880	$23,800	Items 32 and 33
IN4	$2,880	$23,800	Items 34 and 35

3. Review and appeal rights for applications

After considering an application made under section 26BE of the Act, the Secretary may:

- make a recommendation that the Minister include the substance in the Permissible Ingredients Determination (successful applications)
- refuse to make a recommendation (rejected application).

Consistent with the arrangements in place for new listed medicine ingredients, applicants requesting an evaluation of a new sunscreen ingredient will be able to request a review of the Secretary's decision about that application under section 60 of the Act if they are not satisfied with the decision. Applicants can request a review of rejected applications and restrictions placed on the use of the ingredient.

4. New online application portal and workflow management system

Under the proposed approach, all applications for evaluation of substances for use in sunscreens will be lodged using the TGA Business services (TBS) portal using a new application and workflow system.

The online application process provides more streamlined application lodgement and invoicing process. Applicants will also be able to view the status of their application through the portal and upload their dossier directly.

Implementation plan

Given the amount of change that will occur to implement new assessment pathways for sunscreen ingredients, we are proposing a four-phased approach to implementation (see Figure 2).

Phase 1 – Establish business process changes

The listed medicine ingredient pathways are already available to sunscreen ingredient applicants to use if they choose to do so. Applicants will continue to have the option to use the

current page count-based pathway (under regulation 16GA) until 1 May 2020. However, applicants choosing to use the page count-based pathway will not have access to:

- application categories with legislated submission requirements and timeframes
- set fees
- the ability to use reports from COBs depending on application category selected

From 1 May 2020, applicants will only be able make submissions for the evaluation of new sunscreen ingredient under the IN1-IN4 application categories.

Phase 2 – Revision of guidance

During the second phase of implementation, the TGA will revise the ARGS. This will include

- Correcting inconsistencies with legislation and other guidance materials, particularly in relation to labelling and advertising requirements. Specific issues are listed in **Attachment C**.
- Specifying the quality data requirements for both active and excipient sunscreen ingredients to align with the requirements for new substances for use in listed complementary medicines provided in Part C of the ARGCM.

Phase 3 – Phase out 'old' pathway

The page count-based pathway will be progressively phased out between November 2019 and 1 May 2020. Applications on hand will progress as usual.

Phase 4 – Completion

It is anticipated that all applications for sunscreen ingredients will be made under the new approval pathway from 1 May 2020.

Figure 2: Key points in implementation timeline

Phase 1: Establish business changes	Phase 2: Update guidance	Phase 3: Phase out old pathway	Phase 4: Completion
November 2019	**November 2019 – February 2020**	**November 2019 - 1 May 2020**	**1 May 2020**
1. Application and process changes published on TGA website? 2. COB guidance material and list published.	3. Update the ARGS: • Correct inconsistencies in the ARGS • Align quality requirements in ARGS with those in the ARGCM	5. 'Old; submission pathway phased out.	6. All submissions to be made through the new approval pathway.

Attachment A: Comparison of ARGS and ARGCM safety requirements for pre-market assessment

Therapeutic Goods Administration

Requirements	ARGS		ARGCM	
	Active	Excipient	Active	Excipient
Ingredient characterisation				
• Australian Approved Name (or proposed name) and any synonyms	✓	✓	✓	✓
• Identification of excipient in International Cosmetic Ingredient Dictionary (ICID)	N/A	✓	N/A	N/A
• Assurance not within Annex II to the EEC Directive 76/768	✓	✓	N/A	N/A
• IUPAC name	✓	✓	✓	✓
• Chemical structure	✓	✓	✓	✓
General Description				
• Propose intended health or therapeutic use	✓	N/A	✓	N/A
• Population, formulation, route of administration, dosage	✓	✓	✓	✓
Literature search	×[7]	×	✓[8]	✓
History and pattern of human use				
• History and human exposure	×	×	✓	✓
• Current domestic and international regulatory status	✓[9]	✓	✓	✓
Biological Activity				
• Pharmacodynamics	×	×	✓	✓
• Pharmacokinetics (ADME)	✓	✓	✓	✓
• Interactions	✓	✓	✓	✓
Photostability				
• UV absorption	✓	✓	N/A	N/A
Toxicology				
Acute Toxicology	✓	✓	✓	✓
Repeat-dose Toxicology	✓[10]	✓	✓	✓
Local tolerance/other toxicity	✓	✓	✓	✓
Genotoxicity	✓	✓	✓	✓
Reproductive toxicity	✓	✓	✓	✓
Carcinogenicity	✓	✓	✓	✓
Other toxicity studies/toxicokinetics				

• antigenicity, immunotoxicity, mechanistic studies, dependence, metabolites and impurities	×	×	✓	✓
• oral and dermal bioavailability	✓	✓	✓	✓
• percutaneous absorption test	✓	✓	✓	✓
Clinical trials (safety issues)				
• Controlled or epidemiological studies	×	×	✓	✓
Adverse reactions				
• Including nature, severity and frequency	×	×	✓	✓
Substances of human or animal origin				
• eg clearance of risk for transmissible spongiform encephalopathy	×	×	✓	✓

[7] This requirement is not directly specified in the ARGS, although it is assumed a literature search will have been undertaken. We propose to directly specify this requirement in the ARGS.

[8] Systematic literature search strategy to reflect totality of available evidence.

[9] Evidence of approval by overseas regulators/agencies or in use within market-approved products overseas.

[10] At least 3 months of animal data.

Attachment B: Comparison of ARGS and ARGCM quality requirements for pre-market assessment

Requirements	ARGS[11]		ARGCM	
	Active	Excipient	Active	Excipient
Definition of substance			✓	✓
Identification of excipient in International Cosmetic Ingredient Dictionary (ICID)	N/A	✓	N/A	N/A
Assurance not within Annex II to the EEC Directive 76/768	✓	✓	N/A	N/A
IUPAC name	✓	✓	✓	✓
Chemical structure	✓[12]	✓	✓	✓
General physiochemical properties	All information listed below must be held by the manufacturer, but is not required for pre-market assessment[13]			
- appearance, melting point, solubility, etc	×	×	✓	✓
Manufacturing details				
- manufacturer's details	×	×	✓	✓
- description of manufacturing process development, process and process controls	×	×	✓	✓
- control of raw materials, critical steps and intermediates	×	×	✓	✓
- process validation and/or evaluation	×	×	✓	✓

[11] Quality data is not required to be submitted for pre-market assessment of sunscreen ingredients; however, it is the responsibility of the manufacturer of the finished product to ensure the quality of the product and also that of the active and excipient ingredients used in its manufacture. Section 40(4)(a)(i) of the Act requires the manufacturer to ensure that the product complies with any standard applicable to the product.

[12] The information listed under chemical structure in the ARGCM (chemical identity/structure; molecular formula and mass; CAS registry number for the substance and/or known components) is likely to be provided on request, but is not specifically listed as in the ARGCM.

[13] Many of the chemicals used as active or excipient ingredients in sunscreens are the subjects of monographs in the USP-NF (generally under their International Non-proprietary Names [INNs]), BP, Ph Eur and USP-NF. Ingredients that are not the subject of a monograph in the BP, Ph Eur or USP-NF must be controlled by appropriate quality control specifications that control and ensure their identity, relevant physical and chemical properties, and purity using validated test methods. Compositional guidelines are used for approved active or excipient ingredients for use in complementary medicinal products where there is no default standard recognised in the Act. We propose to extend this requirement to active and excipient ingredients for use in sunscreen products.

Requirements	ARGS[11]		ARGCM	
	Active	Excipient	Active	Excipient
Characterisation				
- elucidation of structures and other characteristics	×	×	✓	✓
- impurities and incidental constituents	×	×	✓	✓
- residual solvents	×	×	✓	✓
- incidental metals and non-metals	×	×	✓	✓
- pesticide residues and environmental contaminants	×	×	✓	✓
- other organic or inorganic impurities or toxins	×	×	✓	✓
- microbiological standard	×	×	✓	✓
Control of substance				
- default standard or compositional guideline with justification of tests and limits	×	×	✓	✓
- specification with justification	×	×	✓	✓
- analytical procedures with validation data	×	×	✓	✓
- batch analysis	×	×	✓	✓
Reference standard				
- authentication of reference materials	×	×	✓	✓
- profile chromatogram for herbal materials	×	×	✓	✓
Container closure system				
- storage conditions	×	×	✓	✓
Stability data throughout storage period	×	×	✓	✓

Attachment C: Labelling and advertising issues

Labelling issues		
Source of information	**Requirements for 'Directions for use'**	**Issues**
ARGS (main text)	… the product should be applied to the skin in generous amounts over all of the exposed areas 20 minutes before sun exposure, it should be reapplied every two hours or more often when sweating, and should be reapplied after swimming or towelling	The 'Directions for use' are inconsistent between the ARGS and Sunscreen standard, and within the ARGS
ARGS Labelling Checklist (Appendix 1)	.. the product should be applied in generous amounts over all of the exposed areas 15 to 20 minutes before sun exposure, and again after swimming or towelling	
Sunscreen Standard	… apply generously to the skin 20 minutes before skin exposure, then reapply frequently, and after swimming or towelling; or words to this effect	
Source of information	**Requirements for 'Warning statements'/purpose**	**Issues**
ARGS (main text) and Labelling Checklist (Appendix 1)	If a sunscreen has an SPF 30 or higher and it provides broad spectrum protection the label is permitted to include claims … provided the label also highlights the need for avoidance of prolonged exposure to the sun and the importance of wearing protective clothing, hats and eyewear	This is listed as a statement of purpose of the product, not as a warning statement
Permissible Ingredients Determination	Avoid prolonged exposure in the sun (or words to this effect)	Specific requirement to be printed on the label
	Wear protective clothing - hats and eyewear when exposed to the sun	
Source of information	**Requirements for 'Dose Form'**	**Issues**
ARGS (main text)	.. the name of the dose form, for example, '*cream*' or '*lotion*'	- The example dosage forms are not consistent - The terminology used is inconsistent: dosage vs dose
ARGS Labelling Checklist (Appendix 1)	.. the name of the dose form, (for example, 'cream', 'lotion', 'stick')	
TGO 69 s3(2)(e) and TGO 92 s8(1)(d)	… the name of the dosage form	
Source of information	**Requirements for 'Terms'**	**Issues**
ARGS/checklist	The use of the term 'sunblock' is not acceptable as part of a product name (or elsewhere on the label)	The prohibited terms are not consistent.

Sunscreen standard	Terms 'sunblock', 'waterproof' and 'sweat proof' shall not be used	
Source of information	**Requirements for 'text height'**	**Issues**
ARGS main text	The height of letters with ascenders or descenders is not less than 1.5 mm (except for the AUST L or AUST R number, which may be 1 mm high)	- The Sunscreen Standard specifies a text height for the words 'water resistant'. This is not mentioned in the other documents. - TGO 92 specifies different text heights are acceptable for small containers.
ARGS Labelling Checklist, Appendix 1	The height of letters with ascenders or descenders is not less than 1.5 mm (except for the AUST L number, which may be 1 mm high)	
The Sunscreen Standard	Water resistant primary and secondary sunscreen products may be labelled as 'water resistant' provided that the words 'water resistant' appear on the main label … in letters no larger than those used for the labelled SPF	
TGO 69 s3(b)	In the case of the registration or listing number, not less than 1 millimetre height as required by regulation 15(1)(b) and (c); and in all other cases in letter height of not less than 1.5 millimetres.	
TGO 92 s10(5)(b)	If the sunscreen preparation is enclosed in a container with a capacity of not more than 25 millilitres, it shall be sufficient if: the sun protection factor is displayed in a text size of not less than 1.5 millimetres; and all other information is displayed in a text size of not less than 1.0 millimetres.	
Advertising issues		
Source of information	**Requirements for 'Directions for use'**	**Issues**
ARGS (main text) and Labelling Checklist (Appendix 1)	If a sunscreen has an SPF 30 or higher and it provides broad spectrum protection the label is permitted to include claims … provided the label also highlights the need for avoidance of prolonged exposure to the sun and the importance of wearing protective clothing, hats and eyewear	- There are inconsistencies with the wording describing sun exposure. - Although the Sunscreen Standard example is a direction of use for the label, this refers to 'skin' exposure, not 'sun' exposure.
Therapeutic Goods Advertising Code 2018 s27(2)	Prolonged high-risk sun exposure should be avoided	
	Frequent re-application or use in accordance with directions is required for effective sun protection	
Sunscreen Standard	… apply generously to the skin 20 minutes before skin exposure, then reapply frequently, and after swimming or towelling'; or words to this effect	

Permissible Ingredients Determination	Avoid prolonged exposure in the sun (or words to this effect)	
	Wear protective clothing - hats and eyewear when exposed to the sun	

Version history

Version	Description of change	Author	Effective date
V.1	Original publication	Complementary & OTC Medicines Branch	October 2019

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TGA Reference: D18-10490721

Complementary and OTC medicines Regulatory and Technical Forum

Item No. 2.7
ComTech 4
Date: Tuesday 29 October 2019

Subject: **Sunscreen pathways and guidance**

Speaker s22 **(Business Improvement and Support Section)**

ISSUE

To:

- Advise members of the TGA's intention to implement changes to the way sunscreen ingredients will be assessed. These changes will coincide with the publication of the list of comparable overseas bodies (COBs).

OUTCOME SOUGHT

That members:

- **NOTE** that we plan to implement new assessment pathways for the evaluation of sunscreen ingredients by adopting the existing application categorisation framework for listed medicine ingredients and the framework for the COB report-based process to the assessment of new sunscreen ingredients.
- **NOTE** that the Australian Regulatory Guidelines for Sunscreens will be revised to ensure consistency with the legislative requirements and the requirements for listed medicine ingredients set out in the Australian Regulatory Guidelines for Complementary Medicines (ARGCM).

BACKGROUND

- The Government accepted a suite of recommendations from the Review of Medicines and Medical Devices Regulation (MMDR review) to carry out further reviews of the regulation of 'low risk' products (Recommendations 14 and 23).
- Having considered consultation outcomes on these recommendations, The Government also agreed to streamline the regulatory requirements for sunscreens by developing a new, more transparent and predictable pathway for approval of new ingredients for sunscreens based on use of overseas reports (Recommendation 14 refers).
- In May 2018, the TGA introduced a suite of reforms to to improve the way the TGA assesses substances for use in listed medicines in response to the MMDR which address these objectives.

KEY CONSIDERATIONS

- Details of the proposal were discussed at Comtech in September 2018. Full details of the proposal are provided in Attachment 1.

ATTACHMENTS

Attachment 1: New pathways for evaluation of substances for use as ingredients in sunscreens discussion paper, D19-6131949

Complementary and OTC medicines Regulatory and Technical Forum

Item No. 2.5
ComTech 5
Date: 17 June 2020

Subject: **New evaluation pathway for new sunscreen ingredients**

Speaker s22 [redacted]

ISSUE

To:

- Address feedback from industry regarding the TGA's intention to transition the evaluation of sunscreen ingredients to the s.26BE regulatory pathway, which is consistent with all other ingredients intended for use in listed medicines.
- Assure industry that any changes will be subject to a fair and reasonable transition period.

OUTCOME SOUGHT

That members:

- **NOTE** that the TGA has considered feedback received from industry about transitioning the evaluation of sunscreen ingredients to the s.26BE regulatory pathway.
- **DISCUSS** the TGA's proposals for progressing this reform.

BACKGROUND

- The Government accepted a suite of recommendations from the Review of Medicines and Medical Devices Regulation (MMDR review) to carry out further reviews of the regulation of 'low risk' products (Recommendations 14 and 23).
- Having considered consultation outcomes on these recommendations, the Government also agreed to streamline the regulatory requirements for listed medicine ingredients by developing a new, more transparent and predictable pathway for approval of new ingredients for sunscreens based on the use of overseas reports (Recommendation 14 refers).
- In May 2018, the TGA introduced a suite of reforms to to improve the way the TGA assesses ingredients in response to the MMDR, which address these objectives.
- In December 2019, the TGA published a list of Comparable Overseas Bodies (COBs). Reports from COBs on this list can be used to support applications for registered complementary medicines, assessed listed medicines and ingredients for use in listed medicines.

- The implementation of these reforms has paved the way for the TGA to transition the evaluation of sunscreen ingredients away from the historical (reg.16GA) regulatory pathway to the s.26BE pathway. This will bring evaluations of sunscreen ingredients in line with all other ingredients intended for use in listed medicines.

KEY CONSIDERATIONS

- Details of the proposal to transition to the s.26BE regulatory pathway were presented at ComTech 4 in October 2019.
- Industry were provided an opportunity to provide feedback regarding this proposal. All feedback was received by 29 February 2020.
- The TGA has addressed industry concerns and feedback in the discussion paper provided in Attachment 1.

ATTACHMENTS

Attachment 1: Transitioning sunscreen ingredients to the s.26BE regulatory pathway: Discussion paper (D19-6522153)

Australian Government
Department of Health
Therapeutic Goods Administration

Transitioning sunscreen ingredients to the s.26BE regulatory pathway: Discussion paper

TGA Health Safety Regulation

Contents

Introduction

At the last ComTech meeting (27 October 2019), the TGA tabled a proposal to transition the assessment of sunscreen ingredients away from the existing historical pathway afforded by regulation 16GA (reg.16GA) of the *Therapeutic Goods Regulations 1990* (the Regulations) to a new contemporary pathway for all listed medicines (under section 26BE [s.26BE] of the *Therapeutic Goods Act 1989* [the Act]). This transition will align the assessment of all ingredients for use in listed medicines under the one efficient and contemporary pathway that is subject to best-practice regulatory guidelines.

This paper addresses some of the concerns raised by industry in an out-of-session meeting and in formal feedback regarding the proposal.

Sunscreens and the Listed Medicines framework

Sunscreens are regulated as medicines under the TGA's Listed Medicines regulatory framework. The TGA acknowledges that the regulation of sunscreens in Australia is more stringent than it is in some European countries. However, given their importance in preventing skin cancer in the Australian context, their regulation as medicines in Australia is commensurate of the risks posed to public health (see below for further information).

Requirements of for listing sunscreens

At the time of listing a sunscreen on the ARTG, a sponsor certifies that their product meets all applicable legislative requirements, which includes certification that the product:

1. only contains low-risk ingredients selected from the permissible ingredients list pre-approved by the TGA
2. makes certain therapeutic claims selected from the exclusive list of pre-approved 'permissible indications' for listed medicines. Those claims are listed below and are restricted for use with only sunscreen products.

With the exception of sunscreen products, listed medicines must not refer to any serious form of a disease, disorder or condition, including on the label and through any advertising or product communication that is undertaken, and can only make certain low-level general health and health maintenance therapeutic claims selected from the exclusive list of pre-approved 'permissible indications' for listed medicines.

As sunscreens are a primary preventative measure against skin cancer for all Australians, section 27 of the Therapeutic Goods Advertising Code (No. 2) 2018 (the Advertising Code) allows sunscreens to make higher level therapeutic claims relating to sunburn and skin cancer, even though neoplastic disease is generally considered a prohibited representation under section 30(b)(i) of the Advertising Code[1]. Indications permitted for use on sunscreen products include:

- Can aid in the prevention of premature skin aging

[1] Section 30(b)(i) of the Advertising Code defines representations that regard the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to, neoplastic disease as a prohibited representation.

- Can aid in the prevention of solar keratosis
- Can aid in the prevention of sunspots
- May assist in preventing some skin cancers
- May reduce the risk of some skin cancers.

3. is manufactured in accordance with the principles of Good Manufacturing Practice (GMP) by pre-approved manufacturers.

With regard to GMP, all sunscreen products released on the Australian market must be manufactured according to the principles of GMP as described in the Sunscreen manufacturing: Demonstrating compliance with the PIC/S guide to GMP, PE 009-13. In essence, this document states that all sunscreen products released on the Australian market must be manufactured by pre-approved manufacturers who should:

- hold a certificate of analysis from the manufacturer of the raw material for all ingredients used in medicinal products (**active and excipient**).
- be able to demonstrate that ingredients (**active and excipient**) meet the requirements outlined in a default standard (BP, USP, Ph. Eur.) if available, and if not, that they meet the requirements of an established specification, which is similar to a compositional guideline[2].
- generate and hold Product Quality Reviews (PQRs) relevant to the specific manufacturing step they are undertaking. PQRs verify the consistency of the manufacturing process and verify the appropriateness of the current specifications for the starting material and the finished product.
- test active ingredients in finished products using validated, stability-indicating methods.

TGA's GMP inspectors have advised that it is the responsibility of the medicinal product manufacturer to hold evidence that ingredients used in a product meet the requirements of a default standard, or the established specification. This evidence may be in the form of the certificate of analysis provided by the ingredient manufacturer, or the ingredient may be tested upon receipt at the medicinal product manufacturing site. In addition, the inspectors have confirmed that the quality of excipient ingredients are not tested in the final product.

Sunscreens have a different risk profile compared to other listed topical medicines

Sunscreens play an important role in the Australian context, and as such, the TGA considers that the public health risks posed by sunscreens are not analogous to other listed topical products.

Australia has one of the highest UV radiation levels in the world, with approximately two out of every three Australians being diagnosed with skin cancer before the age of 70[3]. Skin cancer prevention initiatives implemented by the Australian Cancer Council and State and Federal

[2] A compositional guideline is a summary of descriptions, tests and appropriate acceptance criteria (which are numerical limits, ranges or other criteria) that define the characteristics and specify the composition of an ingredient permitted for use in listed medicines. See also Appendix A for more information.

[3] Staples MP, Elwood M, Burton RC et al, Non-melanoma skin cancer in Australia: the 2002 national survey and trends since 1985. Med J Aust. 2006. 184(1):6-10.

Health agencies have successfully improved people's sun protection behaviours[4], especially in terms of reducing the incidence of melanoma and increasing skin cancer survival rates[5,6].

Although sunscreens do not relieve or treat any kind of skin condition *per se*, applying sunscreens is one of the primary preventative measures encouraged by these Government agencies and various not-for profit groups involved in sun protection. For example, the SunSmart Program recommend that these products be applied liberally every two hours to any skin not covered by clothing on days when the UV index is 3 or above[7]. This applies to infants over 6 months old, children, adults, pregnant/lactating women and the elderly. Unfortunately, although consumers are familiar with sunscreens, up to 85% of Australians do not apply sunscreen correctly[8].

Noting this and taken together with the lifelong use of sunscreen products, their recommended frequency of use, the quantity required for effective protection, and the wide target population, the risks associated with sunscreens cannot be considered analogous to the risks posed by other topical products, such as nappy rash barrier creams. Indeed, the important function of sunscreens in the Australian context is unique; therefore, regulating these as therapeutic products is commensurate with the potential risks posed by ineffectual or unsafe products.

Transitioning to s.26BE pathway – why now?

As part of the MMDR reforms, the Government accepted recommendations to review the regulation of low-risk products, which included sunscreens. Having considered the consultation outcomes on the Low Risk Products Review, which concluded that sunscreens should remain regulated as medicines, the Government agreed to streamline the regulatory requirements for sunscreens by developing a new, more transparent and predictable pathway for the approval of new sunscreen ingredients. The implementation of MMDR reforms for listed medicines (application categorisation framework for listed medicine ingredients and the Comparable Overseas Bodies [COB] report-based framework) has paved the way for the TGA to transition the evaluation of all listed medicine ingredient applications, including sunscreen ingredients, away from the historical (reg.16 GA) regulatory pathway to the more contemporary s.26BE pathway.

The reg.16GA 'new substances' provision was the only legislative pathway for the evaluation of listed medicine ingredients until the new evaluation route via s.26BE became fully effective with application categories and legislative timeframes in March 2018. The assessment pathway (under s.26BE) for new ingredients for use in listed medicines allowed approved ingredients to

[4] Langbecker D, Diaz A, Chan RJ et al. Educational programmes for primary prevention of skin cancer. Cochrane Database Syst Rev. 2018 (3): CD011061. Published online at doi: 10.1002/14651858.CD011061.pub2

[5] McCarthy WH. The Australian experience in sun protection and screening for melanoma. J Surg Oncol. 2004 ;86(4):236-45.

[6] Montague M, Borland R and Sinclair C. Slip! Slop! Slap! and SunSmart, 1980-2000: Skin cancer control and 20 years of population-based campaigning. Health Educ Behav. 2001. 28(3):290-305.

[7] Sunscreen fact sheet, Sunsmart, https://www.sunsmart.com.au/downloads/resources/info-sheets/sunscreen-info-sheet.pdf. Accessed 9 December 2019.

[8] Almost half of Australians confused about sunscreen. 20 October 2019. Cancer Council. https://www.cancer.org.au/news/media-releases/almost-half-of-australians-confused-about-sunscreen.html. Accessed 18 March 2020.

be entered on the Permissible Ingredients Determination (the 26BB list) – a pre-approved list of low-risk ingredients that are legally allowed to be used in listed medicines.

Advantages of the contemporary s.26BE pathway

Applications for new ingredients made under the contemporary s.26BE pathway can be assessed via four different application categories (depending on the level of assessment required), which can be submitted via an online lodgement portal. Each category has a specific fee and legislated timeframe. Ingredients that are determined to be safe and of satisfactory quality are included in the Permissible Ingredients Determination and may be used in any listed medicine. Benefits of the s.26BE pathway that are not available under the historical reg.16GA pathway include:

- certainty about the evaluation time with legislated timeframes according to risk-based application categories
- pre-determined fees based on the application category
- greater efficiency through the use of reports from comparable overseas bodies (COBs)
- review and appeal rights

Advantages of these benefits are discussed in more detail below.

The evaluation of sunscreen ingredients via the s.26BE pathway

Despite the introduction of this new evaluation pathway, applicants for new sunscreen ingredients have continued to use the historical reg.16GA pathway. A significant factor contributing to the continued use of the reg.16GA pathway can be linked to the guidance provided in the 2012 Australian Regulatory Guidelines for Sunscreens (ARGS), which is now considerably outdated. Several aspects of these guidelines are misleading with regard to sunscreen ingredient evaluations. For instance, the ARGS notes that **safety data only** must be submitted as part of an application for evaluation. Quality data is not required to be submitted, but the ARGS does note that manufacturers must hold the relevant quality data demonstrating compliance with any applicable standards. The ARGS also contains several errors, the most notable being the safety requirements for excipient ingredients presented in Table 4 and section 10.7. The TGA would like to clarify that the requirements listed in Table 4 are applicable to both **active and excipient** ingredients.

A comparison of the reg.16GA and s.26BE pathways

The dichotomy between the two ingredient pathways (reg.16GA and s.26BE) in terms of the clarity of the data requirements and evaluation processes is not efficient, transparent or consistent with best-practice regulation. The use of a single regulatory pathway under s.26BE for all evaluations of new listed medicine ingredients irrespective of their type or how they are intended to be used will unite this fragmented evaluation process[9].

[9] As with all other listed medicine ingredients approved for inclusion in the s.26BB permissible ingredients list, this will not be applied retrospectively. Only applications for new excipient or active ingredients for use in sunscreen products will be subject to evaluation under the s.26BE pathway.

From a business process perspective, it is inefficient to operate two distinct pathways for a single subset of listed medicine ingredients. Generally, the TGA receives 8 applications for sunscreen excipient ingredients per year via the reg.16GA pathway; however, this number is decreasing, with only 2 applications received in 2019. The last active sunscreen ingredient submitted under the reg.16GA pathway and evaluated by the TGA was tris-biphenyl triazine in 2015. While the figures are comparable to those submitted via the s.26BE pathway, the type of applications were different. During 2016-2019, the TGA received applications for 29 active ingredients (~7 applications/year) intended for use in listed medicines. Some of these applications also sought approval for use of the ingredient as an excipient in other listed medicines in the same application.

Under the s.26BE pathway, all applications for new ingredients for use in listed medicines (excipient and active), including those ingredients intended for dermal application, will require evaluation of both quality and safety data. Approved ingredients can then be included in the s.26BB permissible ingredient list and used in a listed product. At the ingredient evaluation stage, the TGA ascertains whether an ingredient is manufactured according to an appropriate standard and is safe for its intended use. Where a default standard does not exist for a new ingredient, then a compositional guideline must be developed as per current best-practice regulatory guidelines. These requirements apply to both active and excipient ingredients (see Part C of the Australian Regulatory Guidelines for Complementary Medicines [ARGCM]). Many ingredient manufacturers will hold relevant quality data to satisfy this assessment, as per GMP requirements.

The transitioning of new sunscreen ingredients to the s.26BE pathway is timely, given the FDA's concerns about the toxicity of common active sunscreen ingredients. In February 2019, the FDA reported that new scientific evidence suggests that some sunscreen ingredients are readily absorbed through the skin; hence, their safety is inconclusive and warrants further investigation. Noting this and the importance of sunscreens in the Australia context, assessment of the quality and safety data of all new sunscreen ingredients before being formulated into final products is appropriate and is consistent with the existing regulatory framework for all listed medicine ingredients.

The TGA is closely following the FDA's activities and any regulatory changes they may propose, and plans to act on any new information that arises. The TGA has also started an audit on all active sunscreen ingredients on the Therapeutic Goods (Permissible Ingredients) Determination (Permissible Ingredients Determination) to ensure the relevant safety data is available. This is especially applicable to 'grandfathered' ingredients, for which safety data might have been limited.

During 2020, the TGA will phase out the historical reg.16GA pathway. From 2021, all applications to evaluate sunscreen ingredients must be made under the s.26BE pathway.

Legislated timeframes according to risk-based application categories

There is no legislated timeframe for applications that are submitted for evaluation under reg.16GA. Maximum legislated timeframes for evaluation of ingredient applications submitted via the s.26BE pathway range from 70-180 days depending on the application category (with up to 40 days pre-evaluation screening time). Historically, timeframes under the reg.16GA pathway were variable, and have extended well beyond the maximum timeframes legislated for other listed medicine ingredient evaluations. Over the last 4 years, only 26% of the applications for excipient sunscreen ingredients submitted via the reg.16GA pathway were approved under 70 days (equivalent to the legislated IN1 evaluation timeframe) and approval times for 22% of applications exceeded the 180 days legislated for the IN4 pathway. The remaining applications fell within the IN2-IN4 timeframes.

The legislated timeframes associated with the s.26BE pathway (Table 1) represent the maximum length of time allowed for an evaluation; shorter timeframes may occur depending on the quality of the submission. The fixed evaluation timeframe of the s.26BE pathway for new sunscreen ingredients should not, as some have suggested, have any more of an impact on the number of new products released on the market than that of the non-legislated variable evaluation timing of the old reg.16GA pathway.

Table 1: legislated timeframes under the s.26BE pathway

Application Category	Screening[10]	Total Evaluation Time
IN1	40	70
IN2	40	120
IN3	40	150
IN4	40	180

A pre-determined fee structure based on application category

Despite contrary assertions by one industry member, the costs incurred by the sunscreen industry for approval of new ingredients and, therefore, products are similar regardless of regulatory pathway. One particular stakeholder has asserted that it will cost industry at least $20K (excipient) or $50K (active) for an approval of a new sunscreen ingredient if they were to use the s26BE pathway. The TGA refutes these costs and provides that:

(1) The costs associated with an assessment of a new ingredient evaluation via the s.26BE pathway is between $15,690 to $26,680 (new excipient or active depending on the application category), and apart from the yearly CPI increases, this cost has not changed for new listed medicine ingredients.
(2) Under the reg.16GA pathway, the costs associated with assessment of a new ingredient are dependent on the page count of the clinical or toxicological data submitted to support the application[11]. These fees are not dissimilar to those available under the s.26BE pathway:
    a. $10,700: 0-50 pages
    b. $13, 800: 50-250 pages
    c. $18,800: 250-500 pages
    d. $24,900: 500-1000 pages
    e. $37,400: 1000-2000 pages
    f. $49,800: 2000-3000 pages
    g. $74,700: >3000 pages
(3) The introduction of the s.26BE pathway has not changed the fee requirements associated with listing an actual sunscreen product (or any other listed medicine product) in the

[10] The screening time is not included in the legislated timeframe.

[11] Fees are providing in Schedule 9, part 2, sections 7A and 7B of the Regulations.

ARTG or the annual fees associated with maintaining the product listing in the ARTG. The current fee to list a new product is $840 and the annual charge for listed medicines is currently $1,140, noting that these are subject to yearly CPI increases.

(4) Further, arguments that it will cost more to market a sunscreen product in Australia than it does in Europe because of the proposal to change regulatory evaluation pathway of ingredients to the s.26BE are clearly spurious. Considering the differences in regulatory approaches to sunscreens that exist between Australia (listed medicine) and Europe (cosmetic), it comes as little surprise that the cost of marketing a sunscreen also differs between these jurisdictions. The higher cost of marketing sunscreens in Australia is proportionate with the higher-level evaluation required for therapeutic products and is commensurate with the risk that sunscreens pose if found to be ineffective in the Australian context. This is appropriate and consistent with the Australian Government's public health policies.

From a legal perspective, the ability to group excipients into the one submission for a single evaluation is not possible under the s.26BE pathway, although this is available under the reg.16GA pathway. From a technical perspective and noting the recent safety concerns for some sunscreen ingredients recently raised by the FDA, evaluating new ingredients separately and on an individual basis before being included in the Permissible Ingredients Determination is appropriate and commensurate of the risks.

Using reports from COBs to support applications under the s.26BE pathway

Establishing a list of comparable overseas bodies (COBs) from which to leverage relevant evaluation reports to enhance assessment efficiency of, and access to, new sunscreen ingredients was a strongly supported outcome of the 2017 consultation into the future regulation of low-risk products recommended by the MMDR. A list of COBs and the reports they generate that are suitable for use in relevant listed medicine evaluations was published on the TGA website in December 2019.

Safety reports

The TGA specifically identified two COBs from which reports may be used to support safety evaluations of ingredients for use in sunscreens: the CIR and SCCS[12]. However, industry has expressed concerns that they will not be able to obtain an un-redacted report from these COBs to support their applications for excipient ingredients. The TGA acknowledges that the final redacted reports only will be available from these COBs and is generally satisfied that these will be suitable to support the safety evaluations of excipient ingredients (see also The impact of the animal testing ban on safety evaluations). The TGA will clarify this point in the next update of the COB guidance.

[12] In the EU, the Scientific Committee on Consumer Safety (SCCS) undertakes safety evaluations on active and non-active (excipient) substances intended for use in cosmetics, which includes those intended for use in sunscreens[12]. Following evaluation, these substances may appear in Annexes II – VI of the EU Regulation 1223/2009/EC. This includes lists of substances that are restricted or prohibited in cosmetic ingredients, and lists of colourants, preservatives and UV filters allowed in cosmetic products.

The impact of the animal testing ban on safety evaluations

Industry have raised concerns about the impact the European animal ban will have on their ability to generate a data package that meets the TGA's requirements for safety for new sunscreen ingredients.

The European Union (EU) banned the testing of cosmetic products in animals in 2004. This ban was extended to include ingredients intended for use in cosmetics on 11 March 2009 and it is now compulsory to use validated alternative replacement methods (see EU Regulation 1223/2009/EC). In line with the EU, Australia recently (12 March 2019) passed the Industrial Chemicals Bill 2017, which will come into effect on 1 July 2020. The Industrial Chemicals Bill 2017 will ban testing in animals of industrial chemicals that have an intended end use solely in cosmetics.

There have been major advances in alternative testing methods and new validated methods are regularly incorporated into the Scientific Committee on Consumer Safety Notes of Guidance document. The TGA considers these SCCS Notes as part of its evaluations. Additionally, the TGA follows the EMA Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches, which describes the criteria for regulatory acceptance of an alternative testing approach. As per international best regulatory practices, the TGA can accept safety reports based on these new validated methods, and indeed the TGA has accepted several alternative test methods during past evaluations (Appendix B).

Quality reports

Why is quality data required in addition to safety data?

The basic prerequisite for the evaluation of any ingredient starts with an assessment of an ingredient's quality information (the physical and chemical properties of an ingredient) and is one of the three cornerstones of any risk assessment for all medicines (the others being efficacy and safety assessments).

Under the s.26BE pathway, both the quality and safety data of an ingredient are evaluated before it can be approved for use in listed medicines. The quality evaluation aims to fully characterise an ingredient on which the safety evaluation is based, and includes information on impurities, manufacturing, batch analysis and process controls. Specifically, quality information is important as it ensures that:

- Any impurities are readily identified and do not inadvertently increase an ingredient's toxicity profile. Adhering to manufacturing controls helps to identify and minimise impurities. Impurities may be present themselves as a result of the starting ingredients, the manufacturing process, ingredient degradation over time or an interaction with the sunscreen product's container.
- The ingredient's physical and chemical properties, e.g. particle size and partition coefficient (measure of lipophilicity or hydrophobicity), are well described. This information can highlight the potential for an ingredient to be absorbed by the skin (dermal absorption) and its subsequent distribution throughout the body. Considering the FDA's recent report that some sunscreen ingredients are readily absorbed through the skin and may not be safe, this quality data will be required in support of the safety of new sunscreen ingredients in Australia.
- The ingredient's stability is also considered (e.g. photo/heat degradation) to determine whether a product will remain efficacious and safe across its shelf life. This is especially relevant to sunscreens, which are regularly exposed to the sun and hot environments.

In contrast, under the historical reg.16GA pathway, quality data were not submitted by the applicant and hence a quality evaluation as outlined above was not undertaken for sunscreen ingredients. However, as mentioned earlier, the manufacturer is legally obliged to hold this information. Despite the absence of a formal dossier containing quality data, the TGA would undertake a limited preliminary quality assessment of any ingredient submitted via the reg.16GA pathway based on the public information available before completing the safety review[13]. The reasons for undertaking a quality evaluation outlined above demonstrate that the historical approach taken under reg.16GA is neither best practice nor consistent with the quality evaluation performed as part of the s.26BE pathway for all other listed medicine ingredients.

Provision of quality reports

Industry has asserted that it has not been asked to provide quality data in the past and that it will be difficult to source and/or expensive to obtain the quality data that the TGA requires to support ingredient applications made under the s.26BE pathway due to the manufacturer holding this information.

From the TGA's perspective, it is hard to judge the veracity of this assertion given that most of the ingredient applications received over the last four years were manufactured according to a default quality standard, and compliance with this standard ascertained during a GMP audit of the manufacturer. Some of this manufacturing quality data should be submitted as part of the s26BE applications to allow for ingredient characterisation. Additionally, and importantly, quality data is required to be submitted for all other listed medicine ingredient applications (with the exception of FFPI ingredients) and it is not appropriate for ingredients of sunscreens to meet a lesser standard particularly since sunscreens pose a higher health risk to consumers compared to other listed medicines if they are ineffectual.

In the TGA's experience, a good working relationship with the ingredient or product manufacturer will assist in the provision of quality data. Given that sunscreen ingredients are often manufactured according to a default standard, and under these circumstances, the submission of information such as a certificate of analysis to demonstrate that the ingredient meets this standard is straightforward.

In the absence of suitable information to define the quality of an ingredient, such as a COB report or certificate of analysis demonstrating that the ingredient meets a default standard, applications for sunscreen ingredients will need to be submitted through the IN3 and IN4 pathways so that the TGA can undertake an independent quality assessment.

Some limitations of COB reports for quality characterisation

While specific quality reports for particular ingredients are limited internationally, the TGA is generally satisfied that the SCCS *safety* reports are suitable to support the majority of quality parameters required in an application to evaluate an excipient ingredient; however, additional information will be required to address some of the issues indicated above:

- details about the manufacturer, the manufacturing process and process controls
- batch analyses results
- justification for the compositional guideline, if the ingredient is not the subject of a default standard.

[13] For simple chemical ingredients, this information would include the molecular formula, molecular weight, Chemical Abstracts Service (CAS) Registry Number, applicable default standard and any nominated characterised constituents or similar information to demonstrate identity.

The TGA will clarify this in the next update of the COB guidance.

Where data gaps or limitations are identified within a COB report, such as when new safety has been generated since the finalisation of a COB evaluation report, then further clarification may be sought from the sponsor. Depending on the data provided a change in application type maybe required.

Other evaluation reports

One stakeholder suggested that the TGA consider recognising ingredients listed on the Australian Inventory of Chemicals (AICS), or that are available for use in the EU or US for cosmetic purposes, as acceptable for inclusion on the Permissible Ingredients Determination.

While other evaluation reports and assessment can be used (and have been used) as supporting information, the exposure associated with the use of a particular ingredient in a medicine is often different to that of cosmetics or chemicals; therefore, independent evaluations of the safety and quality of those ingredients in the context of medicinal use is required. This is one of the reasons why, at this time, evaluations undertaken only by the listed COBs are considered suitable for the shortened listed medicines ingredient evaluation pathways (IN1 and IN2).

Review and repeal rights of s.26BE pathway

Internal review under s.60 of the Act is available to applicants in relation to any decision relating to listing, registration, variation or cancellation of a therapeutic good (among others); however, this does not extend to the evaluation of new ingredients submitted under the reg.16GA pathway.

Applicants requesting an evaluation of a new sunscreen ingredient under s.26BE of the Act will be able to request a review of the Secretary's decision about that application under s.60 of the Act if they are not satisfied with the decision.

This will apply to situations where the Secretary has:

- Refused the application (rejected application).
- Proposes restriction(s) on the use of the ingredients that differ to those requested or agreed to by the applicant. In this situation, the Secretary would refuse to make a recommendation and the applicant would be eligible for review and repeal rights.

Updates to the ARGS

At the last ComTech meeting, the TGA flagged its intention to update the Australian Regulatory Guidelines for Sunscreens (ARGS, 2012) and to give further consideration to:

- Reinstating the table of approved active ingredients or coming up with an alternative
- Discontinue duplicating the legislative requirements for listed medicines (as they apply to sunscreens) in the ARGS, due to inaccuracies resulting from outdated legislation, and include reference to the relevant information and legislation, such as:
  - Current labelling requirements, TGO 69 will be replaced by TGO 92 in September 2020
  - Therapeutic Goods (Permissible Ingredients) Determination
  - Therapeutic Goods (Permissible Indications) Determination
  - Reference to current advertisement requirements

- Reflect any changes to the AS/NZ 2604:2012 Sunscreen standard that is under review.
- Include reference to Part C of the ARGCM that outlines the quality data requirements for all listed medicine ingredients, including sunscreen ingredients.

Appendix A – Compositional Guidelines

Below are a series of questions about compositional guidelines posed by industry along with the TGA's responses.

1. How long does it take to have a new compositional guideline (CG) approved?

Compositional guidelines (CGs) are submitted by the applicant as part of evaluation of a new substance application under s.26BE of the Act. CGs include a list of specifications for appropriate characterisation of a new substance and more details of tests and criteria can be found in the CG template published on the TGA website. CGs are only required for substances that do not have a default monograph in the BP, USP-NF and Ph. Eur. The timeframes that currently apply for IN4 application category will apply which is, 180 working days for evaluation and 40 working days for screening.

2. What processes (if any) are in place to change/update a compositional guideline?

CGs are not regularly amended as they are established specifications that characterise the substance at the time a new substance is approved for use in listed medicines. It is normal that there will be improvements in testing methods as equipment and technology advances. As such, a manufacturer/sponsor can justify any deviations from the CG without needing to update the CG. As long as there is a sound scientific and validated justification that ensures the ingredient is still the same as what was approved, then this approach is suitable.

3. What processes are in place to consult on new compositional guidelines, or is it a 'first in best dressed' situation for the applicant to have the ingredient evaluated?

As mentioned earlier, CGs are part of an application under s.26BE to characterise the ingredient that the TGA approves for use in listed medicines. If a new compositional guideline is required, that is likely to mean the proposed ingredient is something different than what has been previously evaluated and approved. In this case, a manufacturer/sponsor can apply for a new ingredient.

4. How is anticompetitive behaviour discouraged? Industry say that a compositional guideline could be used to exclude certain raw material suppliers from the Australian market.

Refer to answer for point 2. Deviations from the compositional guideline are possible where the sponsor can justify, and provide scientific/validated justification that demonstrates and ensures the same ingredient is manufactured as was approved. Furthermore, a successful applicant for a new permitted ingredient may have exclusive use of that ingredient for a 2-year period. During the specified exclusivity period the use of a protected ingredient in a listed medicine is restricted for use only to the ingredient applicant and other persons nominated by the applicant. At the end of the exclusivity period, the exclusive approval will revert to a general approval and any sponsor can include the ingredient in their listed medicine included in the ARTG.

Appendix B – alternative test methods accepted by the TGA for safety evaluations

The TGA has accepted the following test methods that are alternatives to animal testing methods:

- *in vitro* assays using mammalian cells expressing the hERG K+ channel to assess potential QT prolongation [ICH S7B]
- *in vitro* electrophysiology studies using cardiac cells or preparations to assess potential effects on cardiac repolarisation [ICH S7B]
- *in vitro* studies using bacterial, yeast, animal or human cells to assess potential genotoxicity [ICH S2(R1)]
- *in vitro* studies using mouse 3T3 cells to assess potential phototoxicity [ICH S10]
- *in vitro* studies using skin and eye preparations to assess local tolerance [EMA/CHMP/SWP/2145/2000 Rev. 1]
  - Cytotoxic effect on the EpiOcular™ cornea epithelial model (*In vitro* eye irritation)
  - Hen's egg test (*In vitro* eye irritation)
  - Skinethic reconstructed human epidermis (*in vitro* skin irritation)
  - Human reconstructed epidermis; Episkin™ model (*in vitro* skin irritation)
- *In vitro* molecular methods (Deep sequencing or high-throughput sequencing) replacing existing neurovirulence test.

Australian Government
Department of Health
Therapeutic Goods Administration

Complementary and OTC Medicines Regulatory & Technical Forum (ComTech)

DRAFT Record of outcomes

Video Conference – 17 June 2020

Contents

Participants

Cheryl McRae (Chair)	Assistant Secretary, Complementary and OTC Medicines Branch (COMB) Health Products Regulation Group (HPRG), Department of Health
s22 [redacted]	

Health Products Regulation Group (HPRG), Department of Health representation:

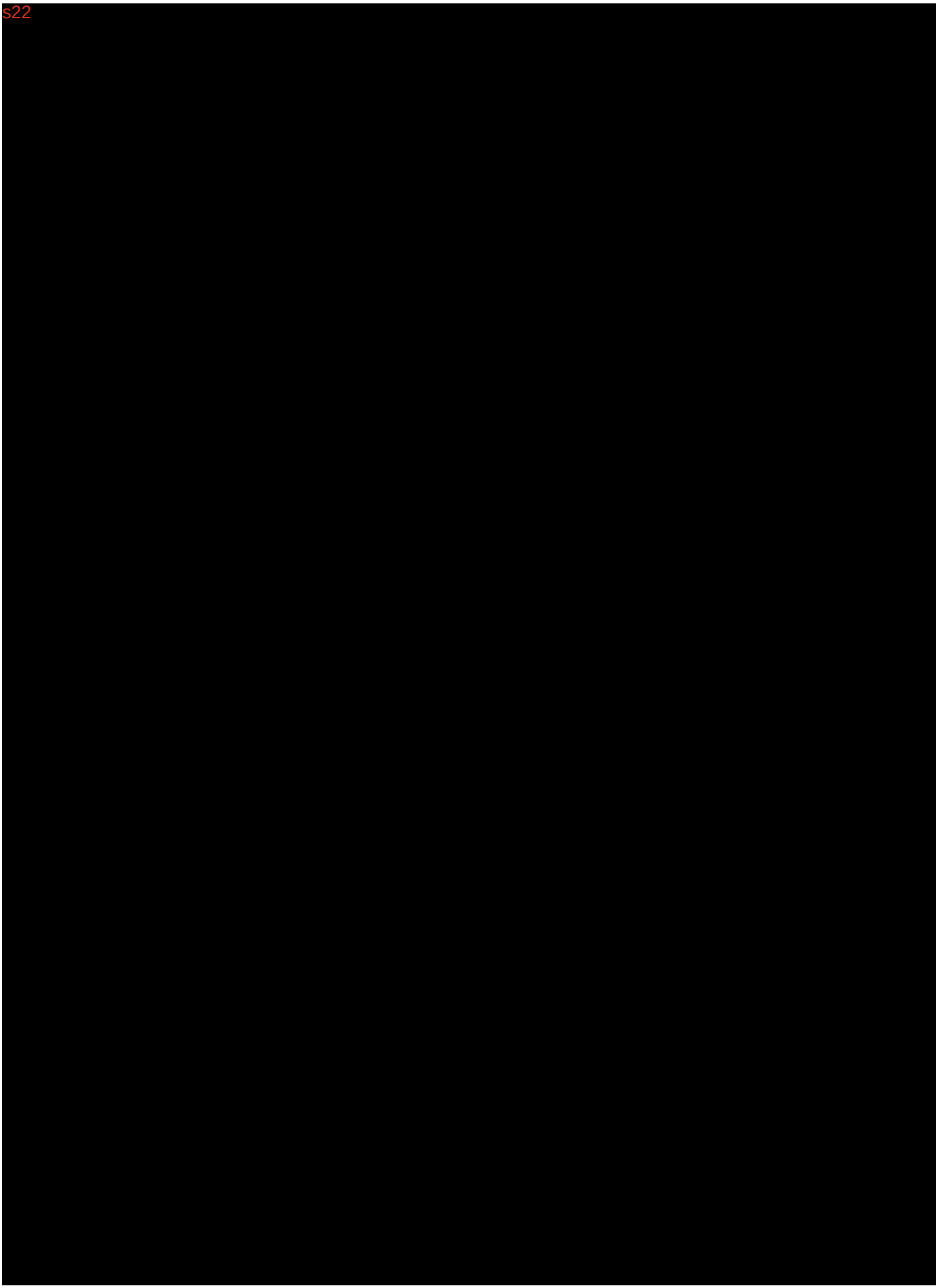
s22 [redacted]		Item 2.1
		Items 2.3, 2.5
		Item 2.2
		Item 2.4
		Item 2.6
Lisa Kerr	Assistant Secretary, Laboratories Branch	Item 2.6
s22 [redacted]		Item 2.6
		Item 2.6
		Secretariat

Item 1 Administrative items

s22 [redacted]

Item 2 New Business

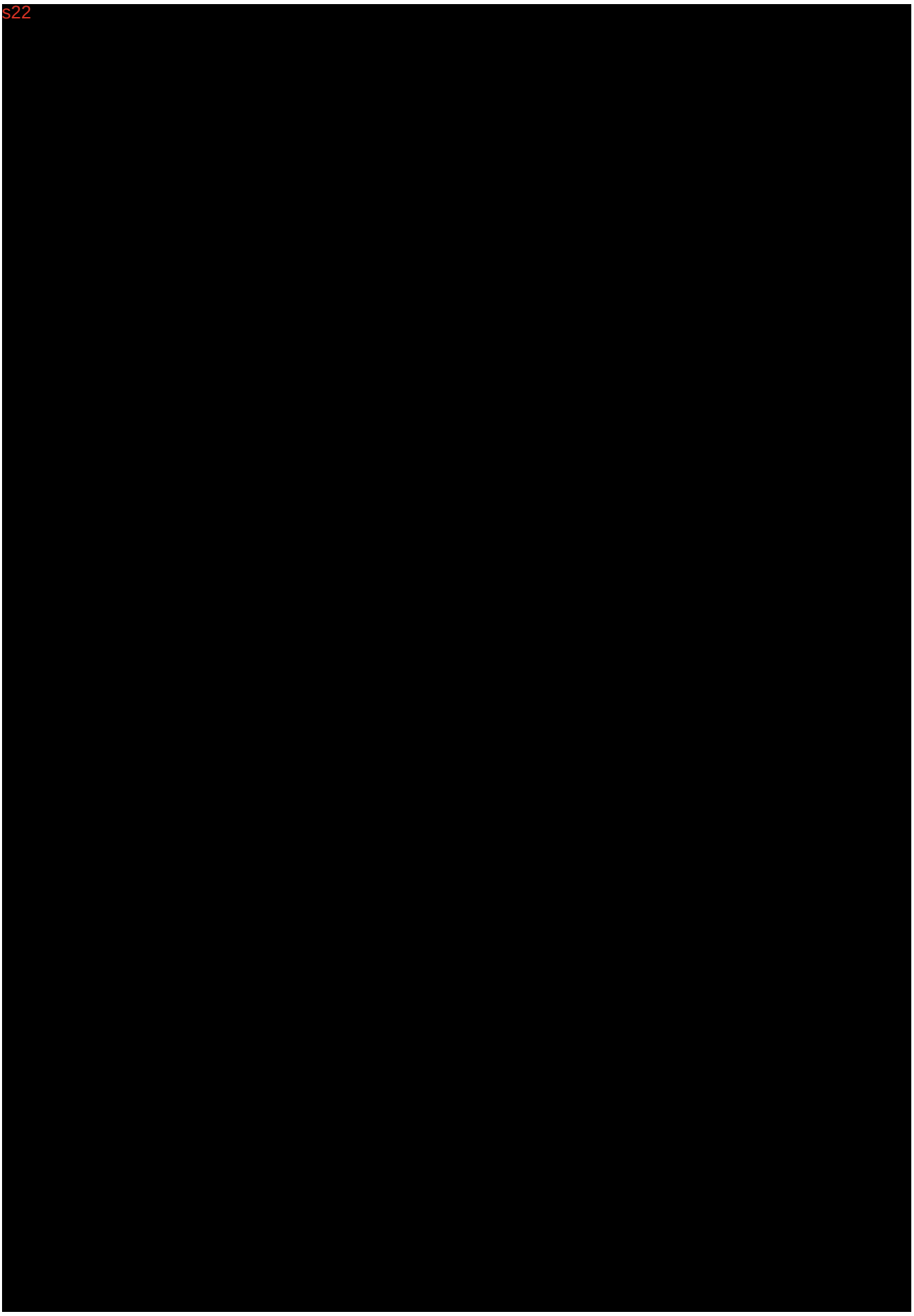
s22



s22

[redacted]

s22



s22 [redacted]

2.5 New ingredients for sunscreens and the listed medicine application pathway

TGA introduced the agenda item, and thanked members for providing feedback on the proposal to transition sunscreen ingredients from the regulation 16GA pathway through to the section 26BE pathway. TGA explained that the feedback received so far has been quite detailed and has outlined some significant issues, which will be assessed going forward. TGA explained that while they stand by the objectives of the proposal, given the issues raised further consideration is required to address these. s47 [redacted]

s47 [redacted]

TGA noted that there are some intersecting projects that may impact on this proposal, such as the development of the mandatory requirements and updating the ARGS. Hence, it may be prudent to wait until these projects are further developed before progressing this proposal.

s47 [redacted]

TGA clarified that the basis for sunscreens being considered higher risk is related to products being sun protective. TGA also clarified that it is not the intention to restrict products coming onto the market.

s47 [redacted]

Action items:

s47 [redacted]

s22 [redacted]

s22

s22

3. Verbal updates

s22

s22 [redacted]

s22 [redacted]

The Chair declared the meeting closed at 2.20 pm

Therapeutic Goods Administration

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Australian Government
Department of Health
Therapeutic Goods Administration

Complementary and OTC Medicines Regulatory & Technical Forum (ComTech)

DRAFT Record of outcomes

Video Conference – 23 November 2020

Contents

Participants

Cheryl McRae (Chair)	Assistant Secretary, Complementary and OTC Medicines Branch (COMB) Health Products Regulation Group (HPRG), Department of Health

s22 [redacted]

Health Products Regulation Group (HPRG), Department of Health representation:

s22 [redacted]	Items 4.3, 4.4, 4.8, 4.10, 4.11
	Item 4.1
	Items 4.5, 4.6, 4.9
	Items 4.7, 4.12
	3.1
	4.1
	4.2
	2.1
	Secretariat

Item 1 Administrative items

s22 [redacted]

Item 2 TGA Wide Update

s22

Item 3 New Business

s22

s22

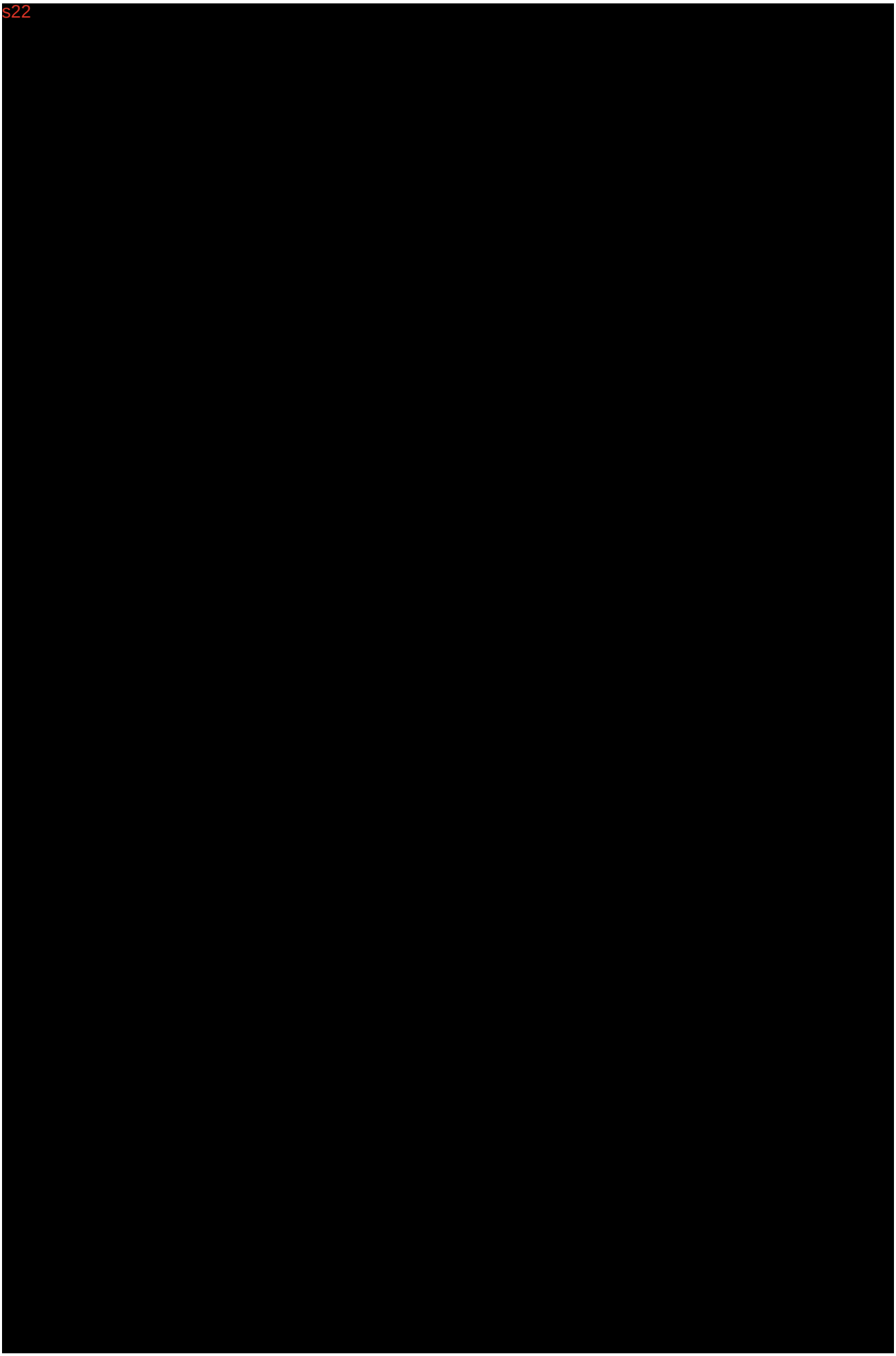
[redacted]

Item 4 Updates

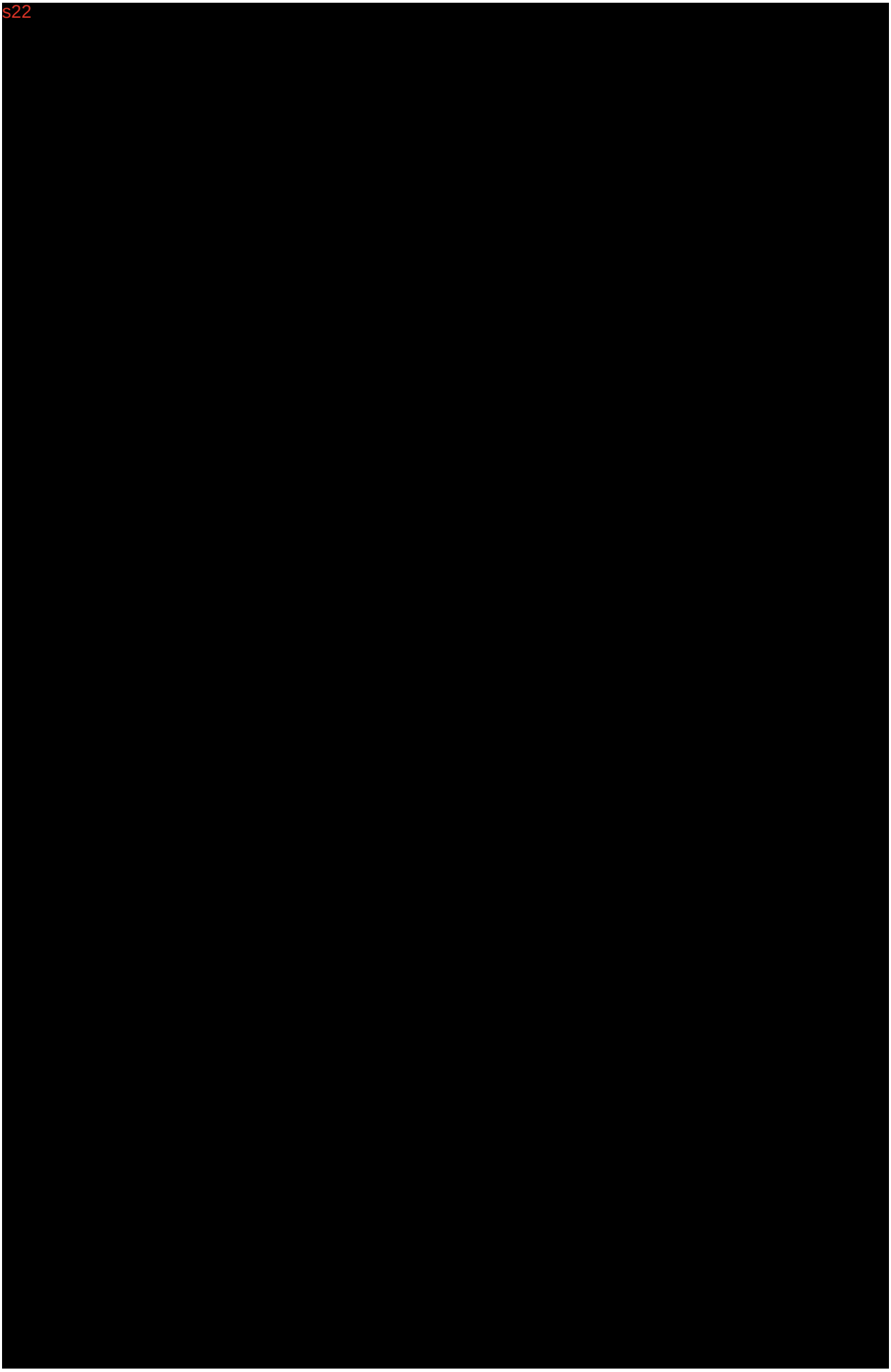
s22

[redacted]

s22



s22



s22

[redacted]

s22

[redacted]

s22 [redacted]

4.9 ARGS

The TGA provided an update on the Australian Regulatory Guidelines for Sunscreen, s47 [redacted]

s47 [redacted]

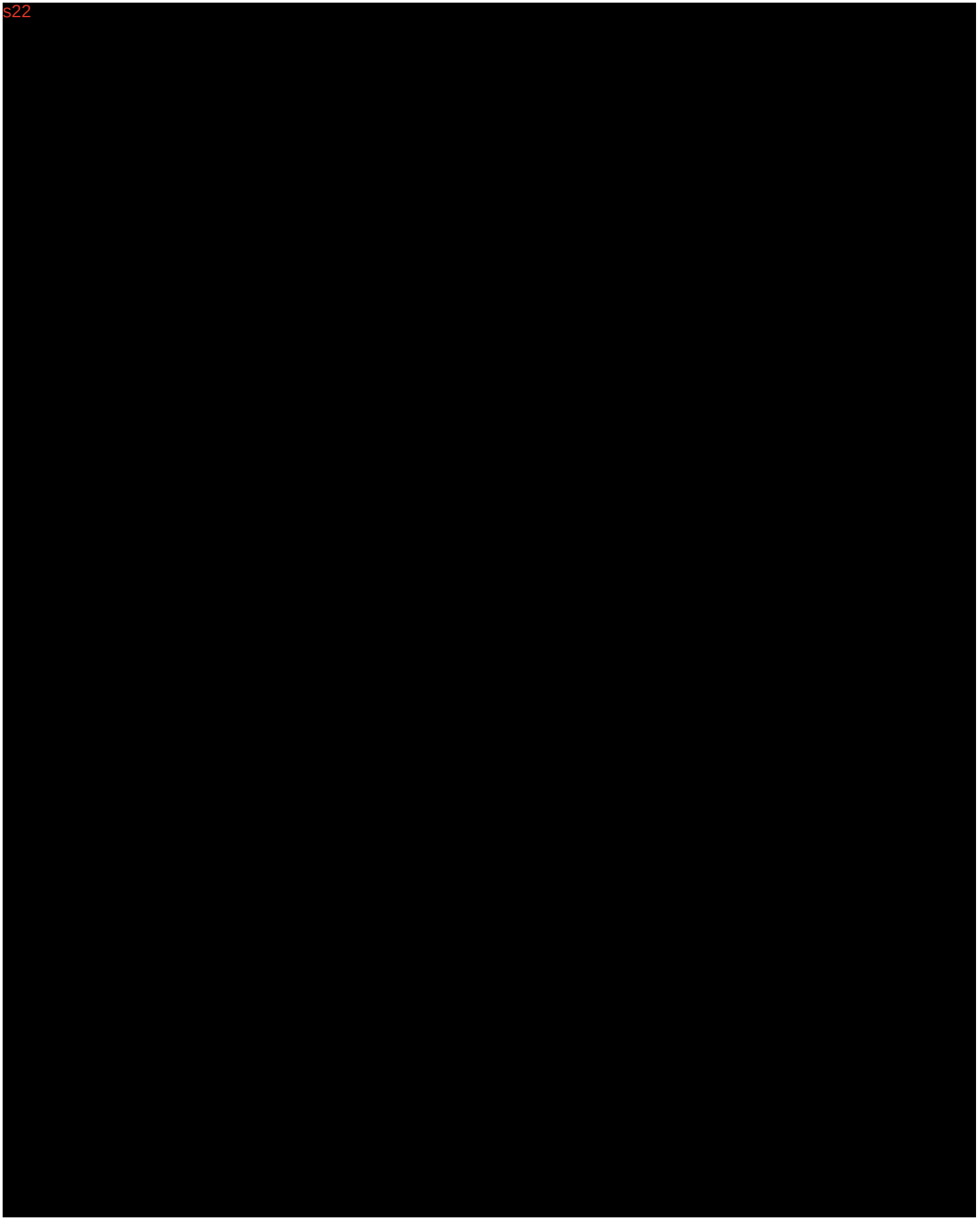
The TGA confirmed that it would like to receive feedback as early as possible (by mid-December) in order to be able to discuss the issues in early January.

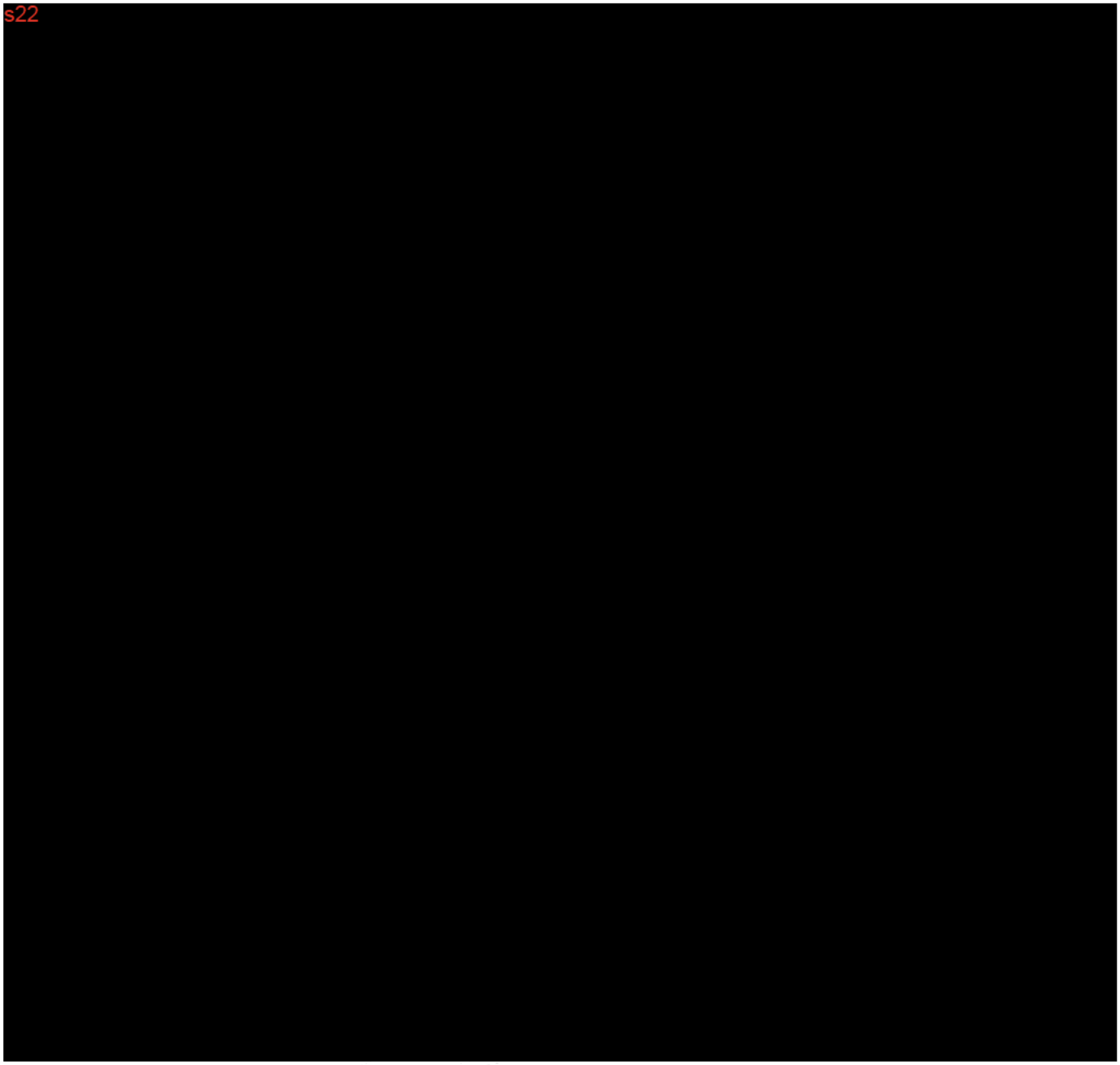
s47 [redacted]

Action Items

s47 [redacted]

s22





All members noted the update.

The Chair declared the meeting closed at 2.00 pm.

Therapeutic Goods Administration

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Australian Government
Department of Health
Therapeutic Goods Administration

Complementary and OTC Medicines Regulatory & Technical Forum (ComTech)

Record of outcomes

Meeting 7 – 1 April 2021

Contents

External Participants

Participant	Organisation
s22 [redacted]	

TGA Participants

Name	Position	Item
Cheryl McRae (Chair)	Assistant Secretary, Complementary and OTC Medicines Branch (COMB)	Items 1.1, 1.2
s22 [redacted]		Items 2.2, 2.6, 2.8
		Items 2.7, 2.8, 2.10
		Items 2.5, 2.11
		Item 2.4, 2.9
Lisa Kerr	s22 [redacted]	Item 2.12
s22 [redacted]		Item 2.12
		Items 2.1, 2.3

Item 1 Administrative items

s22 [redacted]

s22 [redacted]

Item 2 New Business

2.1 Australian Regulatory Guidelines for Sunscreens

The TGA discussed proposed updates to the Australian Regulatory Guidelines for Sunscreens (ARGS). s47 [redacted]

- **Phase 1:** The TGA hopes to publish Phase 1 updates by the end of April. This update will focus on correcting all out-of-date links and references to incorrect legislation. The TGA has taken this opportunity to restructure the document and add new content, for example, information about the permitted indications, which came into effect after the ARGS was published in 2012.

- **Phase 2:** The TGA hopes to publish Phase 2 updates early in the second half of 2021.This will incorporate changes to reflect the updated Australian/New Zealand Standard 2604:2012 (the Sunscreen Standard), which is due to be published in June 2021. The TGA is aware that the *Therapeutic Goods Regulations 1990* and the Therapeutic Goods (Excluded Goods) Determination will need to be amended to adopt the updated standard; however, is currently seeking legal advice about the timing of these amendments and what transition arrangements can be put in place.
- **Phase 3:** The publication date is yet to be confirmed, but this update will incorporate the mandatory requirements for new ingredients once this work has been finalised.

The TGA noted that some feedback has not been incorporated in the Phase 1 update, specifically:

- The Bibliography has been removed and hyperlinks have been provided throughout the document. The TGA hopes to list all resources on a linked webpage as it is easiest to have all resources listed in one place for ease of updating.
- Appendix 1 (labelling checklist) has been removed due to inconsistent and duplicative information both within the document and with external information.

The TGA also noted that it intends to create a feedback form similar to that designed for the Australian Regulatory Guidelines for Listed Medicines and Registered Complementary Medicines (ARGLMRCM). Feedback can be provided at any time, and the TGA can then address any issues raised in a subsequent update.

s47 [redacted] he TGA noted that sponsors should refer to the Therapeutic Goods (Permissible Ingredients) Determination (the Permissible Ingredients Determination), as this contains the most current information. However, as sunscreens are a unique product type and there are limited active ingredients restricted for use in sunscreens, the TGA agreed that the list in the ARGS could be amended. The TGA noted that the list will also have a caveat indicating that the information in this table was correct as of a specific date, and that sponsors should not rely on this as the current information and refer to the current Permissible Ingredients Determination.

s47 [redacted]

Action items:

- The TGA to reinstate the percentage limits in the table of active sunscreen ingredients and to include a caveat referring sponsors to refer to the Permissible Ingredients Determination for current information.
- s47 [redacted]

s47 [redacted]

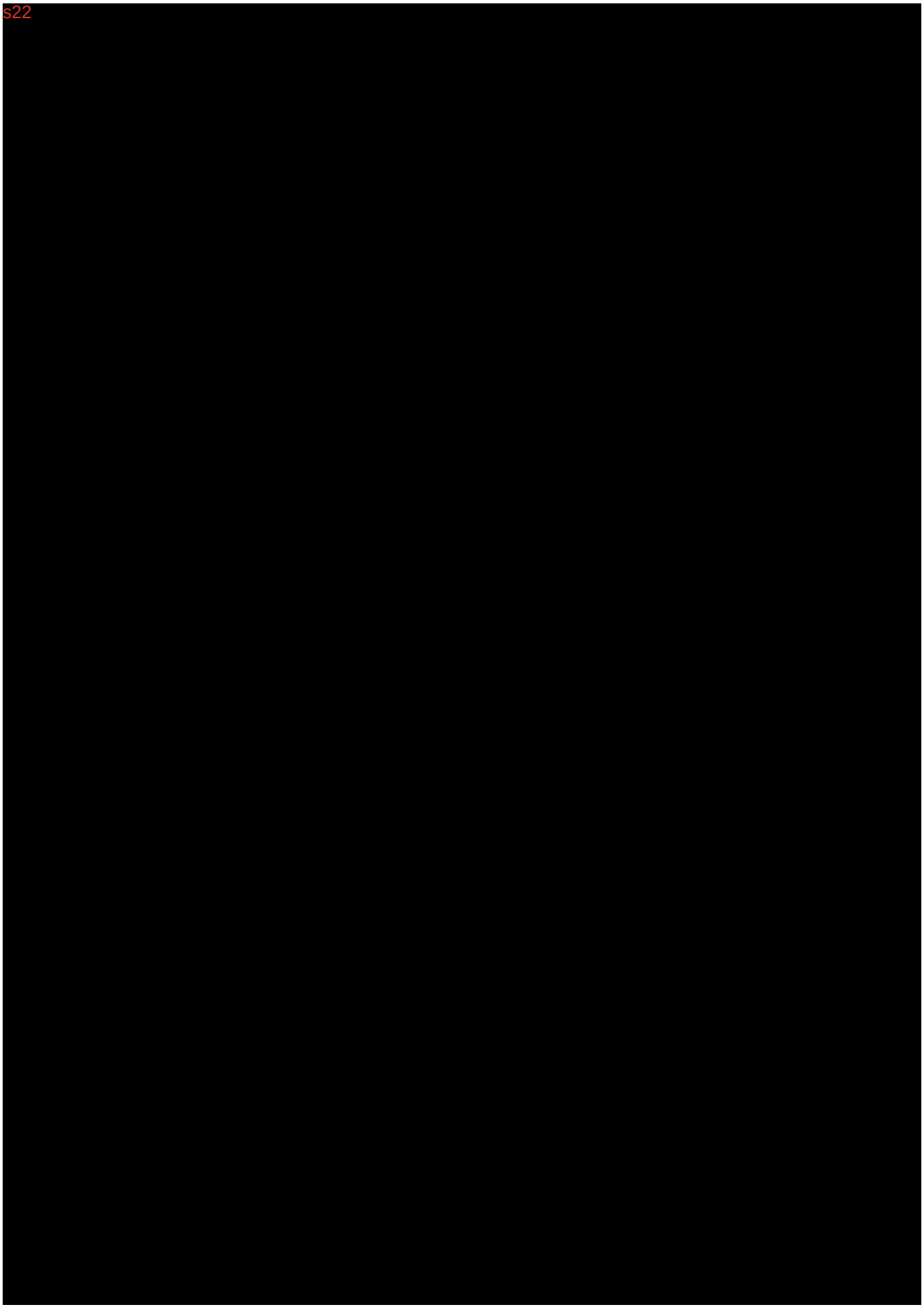
s22

[redacted]

s22

[redacted]

s22



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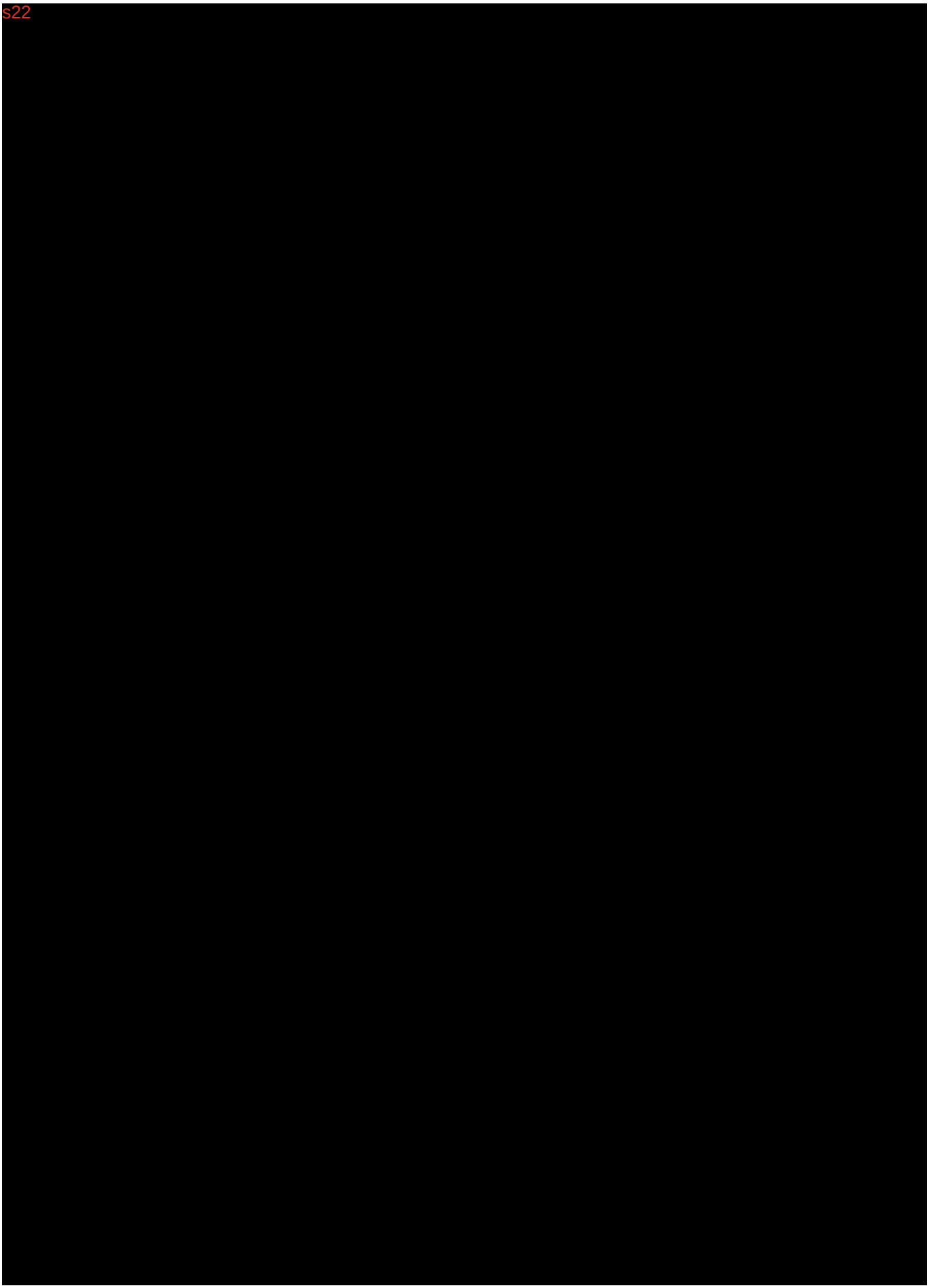

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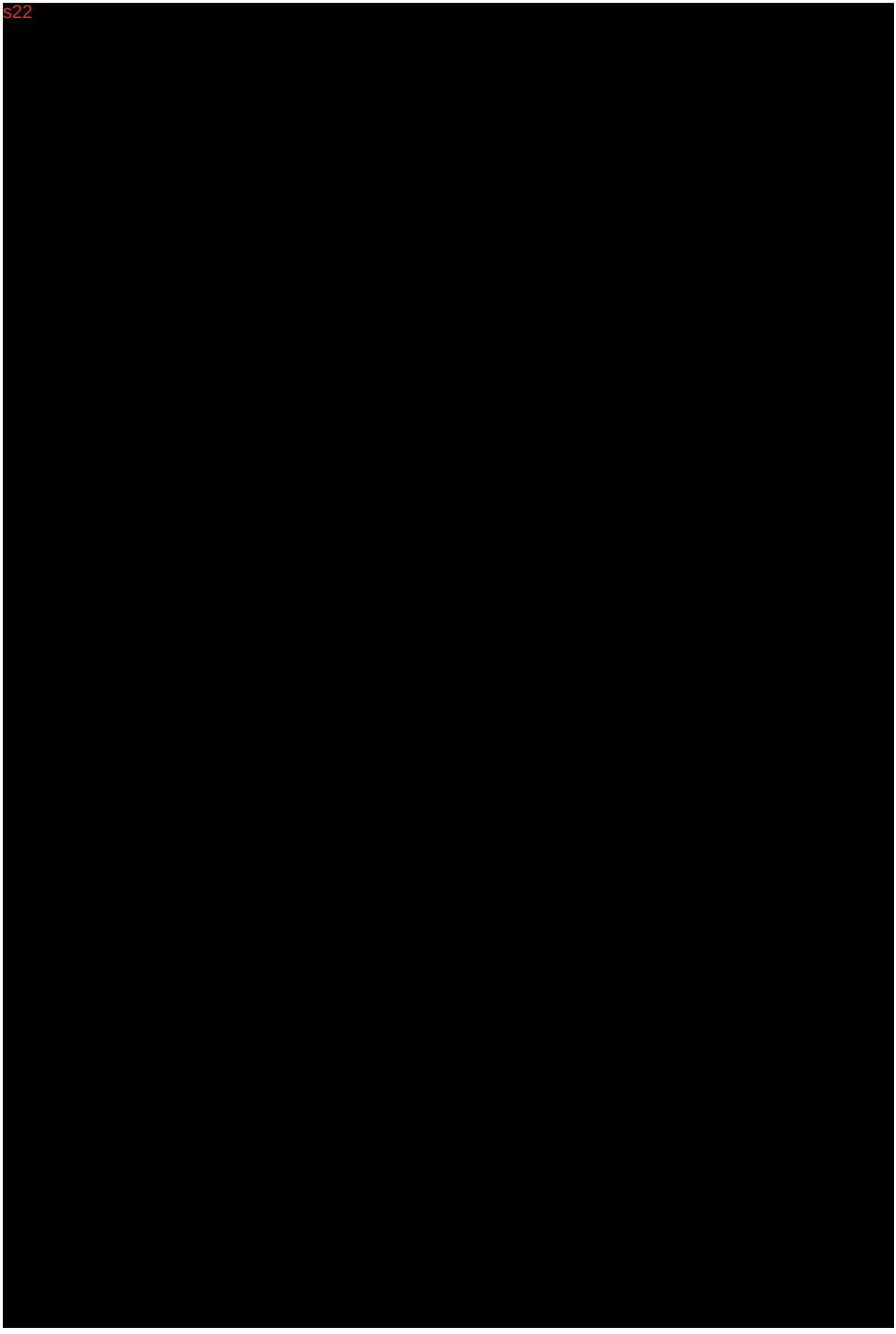
[redacted]

s22

[redacted]

s22



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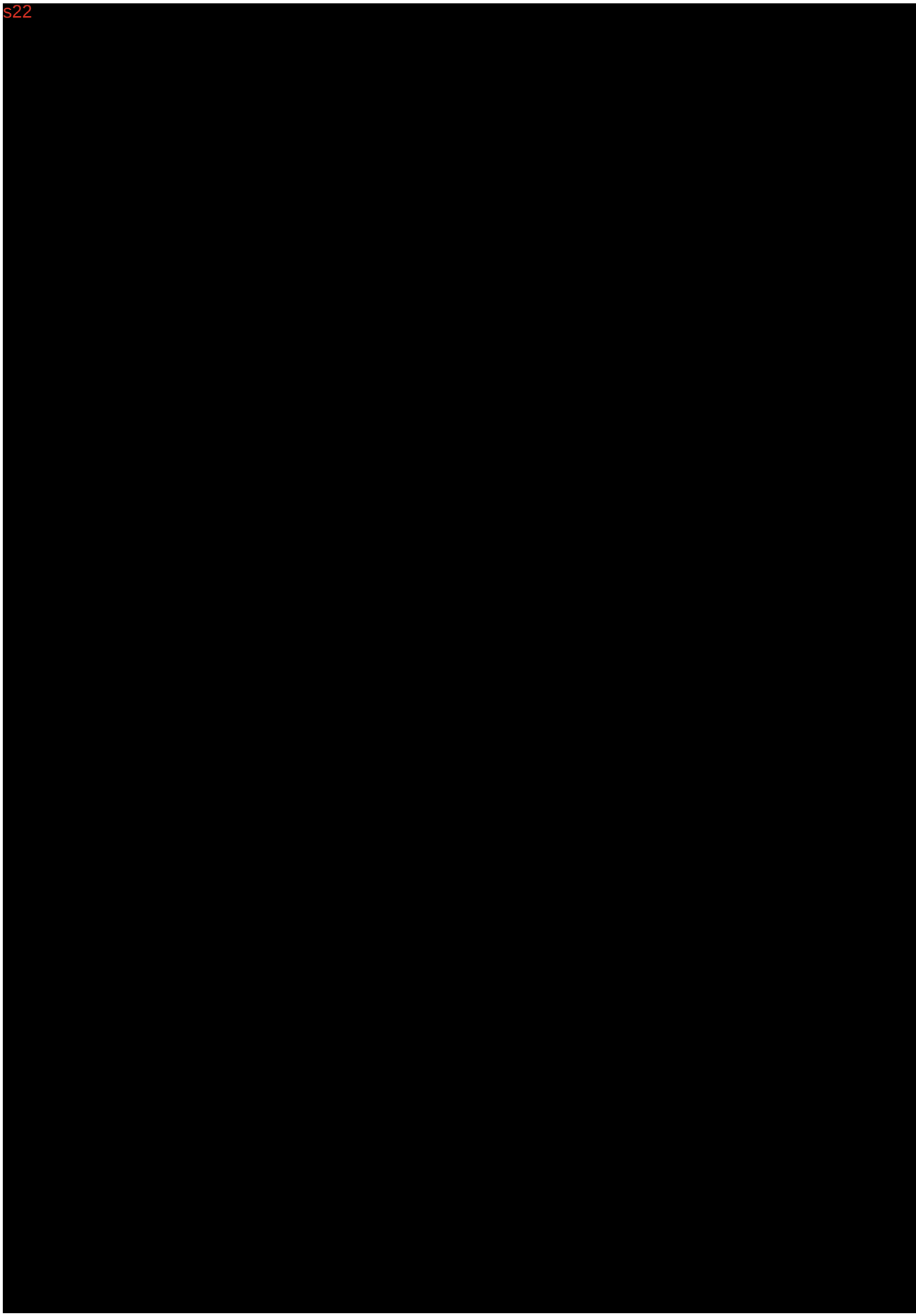

s22

[redacted]

s22 [redacted]

Additional business: *For noting*

The Chair reiterated due dates for feedback:

- ARGS, 22 April
- Data protection, 15 April
- Market exclusivity, one month.

The meeting was declared closed at 2:50 pm.

Therapeutic Goods Administration

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Complementary and OTC medicines Regulatory and Technical Forum

Item No. 2.1

ComTech 7

Date: 1 April 2021

Subject: ***Australian Regulatory Guidelines for Sunscreens***

Speaker s22 [redacted], Business Improvement and Support Section

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ISSUE

- To provide an update on the TGA's revisions to the Australian Regulatory Guidelines for Sunscreens (ARGS).

OUTCOME SOUGHT

That members:

- **NOTE** that the TGA has considered feedback received from ComTech members in December 2020 and January 2021.
- **NOTE** that the TGA intends to update the ARGS using a phased approach.
- **NOTE** that the TGA intends to publish the first phase amendments to the ARGS by the end of April 2021.

BACKGROUND

- The ARGS has been updated twice since it was initially published in October 2012. The most recent revision in 2019 replaced the table of active ingredients (Table 3) with a link to the Therapeutic Goods (Permissible Ingredients) Determination. Prior to this, revisions made in 2016:
  - reflected changes in the Therapeutic Goods Regulations 1990 by removing reference to sunscreens with a claimed SPF of <4 that contain certain human or animal-derived ingredients
  - included reference to the recently made Therapeutic Goods (Permissible Ingredients) Determination No.1 of 2015
  - added one new active ingredient (tris-biphenyl triazine), which was removed in the 2019 revision along with other active ingredients.
- The pending April 2021 revision of the guidelines will update the following references to legislation and guidance material:

  - the labelling requirements (TGO 69 has been replaced by TGO 92)
  - reference to the Therapeutic Goods (Permissible Indications) Determination
  - references to the current Therapeutic Goods Advertising Code
  - remove reference to the Cosmetics Standard 2007
  - remove reference to the Industrial Chemicals (Notification and Assessment) Act 1989
  - Reference to the current Therapeutic Goods (Excluded Goods) Order
- Other general updates in the April 2021 revision include:
  - Removing information duplicated from legislative instruments (as they apply to sunscreens) and including hyperlinks instead. This will prevent the ARGS from containing inaccurate and inconsistent information due to reference to outdated legislation.
  - Removing section 12 (Bibliography) and instead providing hyperlinks to the relevant documents within the main body of the text.
  - Removing Appendix 1 (Labelling checklist) to prevent duplicating information. In addition, some of the information in this checklist is inconsistent with (a) the information contained in the main body of the text, (b) the Sunscreen Standard and other sources of regulatory information (i.e. the Labelling Order).
  - Restructuring the guidance document to make it clearer and flow more logically; this will involve moving information between sections.
  - Updating the regulatory categories of sunscreens section to reflect changes in the way cosmetic sunscreens are regulated due to the introduction of the Therapeutic Goods (Excluded Goods) Determination 2018.
- The ARGS will be further updated using a phased approach.
  - The TGA is currently working jointly with an industry working group to clarify and develop mandatory safety and quality data requirements for active and excipient ingredient applications intended for use in listed medicines. When finalised, these requirements will be incorporated as appropriate into the ARGS.
  - The Australian/New Zealand Sunscreen Standard (AS/NZS 2604:2012) is currently being updated, and it is anticipated that the updated version will be published in June 2021. The TGA will revise the ARGS to indicate that there is a new Sunscreen Standard available, and to list any changes that have been made during the update.
  - The ARGS may be updated in one or two phases depending on whether the finalisation of the ingredient application data requirements coincides with or is close to the publication of the updated Sunscreen Standard.

KEY CONSIDERATIONS

- A marked-up version of the ARGS with an outline of the proposed changes was circulated to ComTech members on 6 November 2020.
- CHPA provided feedback in December 2020 (Attachment 1).
- In January 2021, Accord indicated that their feedback was largely consistent with that provided CHPA.

- The TGA has considered this feedback. Comments and the TGA's responses have been incorporated into the revised version of the ARGS (Attachment 2).

ATTACHMENTS

Attachment 1: Marked-up version of the ARGS including CHPA's comments, D20-3998138.

Attachment 2: Revised version of the ARGS, D20-650852.

Australian regulatory guidelines for sunscreens

Version 1.2, August 2019

Contents

Commented [s22.]: Propose restructuring as follows:

1.Introduction
2.The Australian and New Zealand Sunscreen Standard
2.1updates to the AS/NZ Sunscreen Standard
2.2 legislative changes stemming from the new Standard
3.Regulatory categories of sunscreens
3.1sunscreens regulated by the TGA
3.2Excluded sunscreens
3.3Exempt sunscreens
4.Listing process
4.1Listed therapeutic sunscreens
4.1.1Permitted indications
4.2Registered therapeutic sunscreens
4.3Responsibility of sponsors to report adverse reactions
5 Labelling and advertising
6. Changes to sunscreens
6.1 Changes to active ingredients
6.2 changes to excipient ingredients
6.2,1 Deletion or addition of excipient ingredients
6.2.2 Deletion or addition of fragrance or colour
6.2.3 Quantities of excipient ingredients
6.2.3 Changes that may affect SPF properties
6.3 Other changes
7. Permitted ingredients
7.1 Permitted active ingredients
7.2 Permitted excipient ingredients
7.3 Nanoparticles in sunscreens
8. New ingredients
8.1 New ingredients
8.2 Safety test guidelines
9. Safety data requirements for new ingredients
9.1 Safety data requirements for new excipients
9.2 Justification for not providing particular studies
9.3 Related studies
9.4 alternative test methods accepted by the TGA
9.5 Alternative sources of data
10. Quality data requirements for new ingredients
10.1 Photostability
11. Manufacture and quality control
11.1 Manufacture
11.2 Quality control – manufacturing
11.2.1 Default standards
12. Reproducibility of SPF test results
12.1 In vivo SPF testing protocol
12.2 Validity of in vivo SPF testing results
12.3 Retesting sunscreens
13. Stability testing
13.1 Stability testing results
13.2 Establishing stability before market approval
13.3 Confirming stability and shelf life
13.4 Stability protocol requirements
13.5 Shelf life determination
14 Glossary of terms and abbreviations

Commented [s22.]: We note the following new items for which there was no advice of proposed content:

12.3 Retesting sunscreens

1. Introduction

These Guidelines replace Chapter 10, 'Sunscreens', in the *Australian Regulatory Guidelines for OTC Medicines* (ARGOM) published in 2003. They have been produced by the Therapeutic Goods Administration (TGA) in consultation with the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the pharmaceutical and cosmetics industries.

The first draft of these Guidelines was published on the TGA web site in May–June 2010 for stakeholder and public consultation. The preparation of the finalised Guidelines has taken into account the comments received as a result of the consultation and also the changes to the Australian and New Zealand Sunscreen Standard (see below).

These Guidelines describe the regulatory requirements and standards for sunscreens and their ingredients in Australia as at the date of publication.

Many of the terms, such as therapeutic sunscreen, cosmetic, cosmetic sunscreen, primary sunscreen, secondary sunscreen, sun protection factor (SPF) referred to in these Guidelines are defined in section 11 'Glossary of terms and abbreviations'.

The legislation (Acts and regulations), standards and other relevant regulatory documents (Therapeutic Goods Orders, codes, etc.), referred to in these Guidelines are listed along with their sources in section 12 'Bibliography' at the end of the document. Sunscreens classified as therapeutic goods are, unless exempt, required to be included in the Australian Register of Therapeutic Goods (ARTG) maintained by the TGA before they can legally be marketed in Australia. To be listed, sunscreens must comply with the Australian and New Zealand Sunscreen Standard *AS/NZS 2604 Sunscreen products—Evaluation and classification* in force at the time of listing.

A new Australian and New Zealand Sunscreen Standard, *AS/NZS 2604:2012* which replaces the previous Standard *AS/NZS 2604:1998* has been developed by the Standards Australia and Standards New Zealand in consultation with stakeholders and the public. This was published on 30 May 2012. The Standard and the International Standards Organisation (ISO) standards to which it refers are available for purchase from SAI Global through its web site.

AS/NZS 2604:2012 includes the following significant changes from the previous Standard:

- Adoption of the *ISO 24444:2010 in vivo* test procedure for determining SPF. This is essentially the same as the *in vivo* test procedure in *AS/NZS 2604:1998*, but includes statistical criteria for acceptance of the test results. In most cases the SPF test results obtained according to *AS/NZS 2604:1998* would comply with *ISO 2444:2010*.
- Increase of the maximum SPF that may be claimed on the label of a sunscreen product from SPF 30+ to SPF 50+. A claim of SPF 50+ is allowed only if the mean SPF test result is 60 or higher.
- Limiting of the permitted SPF claims to 4, 6, 8, 10, 15, 20, 25, 30, 40, 50 and 50+ (depending on the SPF test result). Note that a claim of SPF 30+ is not permitted under *AS/NZS 2604:2012*.
- Changing of the SPF ranges for categorisation of protection as 'low' (SPF 4, 6, 8 or 10), 'medium' or 'moderate' (SPF 15, 20 or 25), 'high' (SPF 30, 40 or 50) or 'very high' (SPF 50+).
- Adoption of the *in vitro* test procedure in *ISO 24443:2012* for determining broad spectrum performance. The criteria for broad spectrum performance determined using this test procedure are significantly more stringent than the criteria in *AS/NZS 2604:1998*, and many products complying with that standard would not comply with *ISO 24443:2012*.
- Making 'broad spectrum' performance mandatory for all primary sunscreens and for those secondary sunscreens classified as 'therapeutic sunscreens' and regulated by the TGA.

Commented [s22] Remove mention of ARGOM NICNAS now AICIS

Commented [s22] No longer relevant, suggest removing.

Commented [s22] Given we are implementing the next update to AS/NZS 2604, we suggest deleting the first sentence and amending the 2nd.

Commented [s22] Propose adding the following:
These will be further updated following the publication of the new the Australian and New Zealand Sunscreen Standard (see section 2 The Australian and New Zealand Sunscreen Standard).

Commented [s22] Suggest removing Bibliography and use hyperlinks instead.

Commented [s22] While the bibliography requires updating, it does provide reference to a point in time and what has and has not been considered. Hyperlinks to other requirements that may be updated to new information without the sponsor knowing can be just as problematic as an out of date bibliography.

Commented [s22] This will change with the introduction of the new Sunscreen Standard.

Propose adding the following: A new Australian and New Zealand Sunscreen Standard has been developed by Standards Australia and Standards New Zealand in consultation with stakeholders and the public. This will replace Standard *AS/NZS 2604:*2012 and is expected to be published in mid 2021.
Until the new Standard is published, all sunscreens must adhere to *AS/NZS 2604:2012*

Suggest creating a new section for discussion about the Sunscreen Standard with subheadings for Updates to the AS/NZ sunscreen standard and Legislative updates stemming from the new standard. This will break this section up so it is easier to read.

Commented [s22] Accept, recognising that wording will be dependent on the timing of ARGS update relative to the new Standard.

- Making 'broad spectrum' performance mandatory for cosmetic sunscreens with SPF30 or higher and optional for cosmetic sunscreens with SPF less than 30.

In recognition of this new Standard, Item 7 of Part 1 of Schedule 4, Item 8(g) of Schedule 5, and Item 14 of Schedule 7 of the *Therapeutic Goods Regulations 1990* (the Regulations) have been amended to require sunscreens products listed in the ARTG as from 10 November 2012 to comply with *AS/NZS 2604:2012* rather than *AS/NZS 2604:1998*.

However, regulation 49 of the Regulations allows products listed prior to that date (that come within Item 7 of part 1 of Schedule 4 or are able to be marketed in Australia because they are exempt under Item 8(g) of Schedule 5 of the Regulations) to continue to comply with *AS/NZS 2604:1998*.

Sponsors may make changes to those products (for example, changes to labels or sites of manufacture) provided the changes do not make the product a new product requiring a new listing in the ARTG.

A proposed change to a product will create a new product if it is of the kind referred to in s.16(1A) of the Act (different active ingredients, different quantities of active ingredients or different dosage form) or in regulation 11 of the Regulations (different name, different indications, different excipient or changes are made to or in relation to any restricted ingredients).

If a new listing is required because of such a change, the product concerned will need to comply fully with *AS/NZS 2604:2012*.

Commented [s22]: Suggest adding a link to section 6 Changes to Sunscreens

Commented [s22]: Agree

At the time the 2012 guidelines were published the majority of sunscreens listed in the ARTG carried claims of SPF30+ and provided broad spectrum protection.

An SPF30+ sunscreen may have originally produced an SPF test of 40 or higher and, therefore, could potentially carry a claim of SPF 40, SPF 50 or SPF 50+ allowed under *AS/NZS 2604:2012*. In most cases the SPF test results (and water resistance test, if relevant) obtained previously would have complied with the statistical requirements of *AS/NZS 2604:2012* and retesting for these parameters would not be necessary. Any such product would, however, need to be retested according to *AS/NZS 2604:2012* and *ISO 24443:2012* for compliance with the requirements for 'broad spectrum' performance. If any such product passed the broad spectrum test, the product could be renamed and relabelled accordingly in compliance with *AS/NZS 2604:2012*. Prior to release into the Australian market it would need to be relisted in the ARTG as a new product with a new AUST L number.

If, on the other hand, the product failed the broad spectrum test in *AS/NZS 2604:2012*, it may be possible for it to be reformulated (for example, by adjusting the quantities of the active ingredients within the allowed limits or adding other approved active ingredients) in order to pass the test. The reformulated product would then need to be retested for SPF (and water resistance, if relevant), renamed and relabelled in full compliance with *AS/NZS 2604:2012* and these Guidelines, and listed in the ARTG as a new product with a new AUST L number. Depending upon the degree of reformulation required, new stability data may also need to be generated to support the shelf life claimed for the reformulated product.

2. Therapeutic sunscreen or cosmetic sunscreen?

Commented [s22]: Suggest rewriting and combining this section with Section 3.

2.1 Therapeutic sunscreens

For the purpose of these Guidelines, sunscreens that are regulated as therapeutic goods under the Act and the Regulations and are not classified and regulated as cosmetics (see subsection 2.2) are referred to as 'therapeutic sunscreens'. Included in this category are:

- primary sunscreens with SPF 4 or more
- secondary sunscreens – except those regulated as cosmetics (see subsection 2.2)
- primary or secondary sunscreens with SPF 4 or more that contain an insect repellent
- sunscreens that are exempt from being listed under the Act because they come within the exemption in Item 8(g) of Schedule 5 of the Regulations.

2.2 Cosmetic sunscreens

Commented [s22]: These now fall under the Excluded sunscreens category.
Legislative updates required. Clarify which products fall under this category.

Commented [s22]: Agree

Some products contain an ingredient with sunscreening properties but the primary purpose of the product is neither sunscreening nor therapeutic. These products are regulated as cosmetics by the National Industrial Chemicals Notification & Assessment Scheme (NICNAS) rather than by the TGA as therapeutic goods. In accordance with the *Therapeutic Goods (Excluded Goods) Order No. 1 of 2011*, these products are not regulated under the Therapeutic Goods legislation and are not required to be included in the ARTG. For the purpose of these Guidelines such products are called 'cosmetic sunscreens'. They may also be referred to as 'excluded' sunscreens.

A cosmetic sunscreen product must meet the definition of a cosmetic under the *Industrial Chemicals (Notification and Assessment) Act 1989* and any requirements set out in the current *Cosmetics Standard* and *NICNAS Cosmetics Guidelines*. Requests for regulatory information and enquiries about cosmetic products should be directed to NICNAS.

Section 5 of the *Industrial Chemicals (Notification and Assessment) Act 1989* defines a cosmetic as follows:

Commented [s22]: Propose not duplicating definition here and providing hyperlink to the legislation instead.

Commented [s22]: The Name of the Act has changed - Industrial Chemicals Act 2019

ARGS serves as the most complete guidance for explaining Australian sunscreen regulation to those unfamiliar with our complex requirements.

Like the definition of a 'medicine', the definition of a Cosmetic doesn't change with great regularity, both residing in an Act Only d, changed in the new Act as follows:
"a substance or preparation prescribed by the rules for the purposes of this paragraph."

We suggest maintaining the definition here.

'Cosmetic means:

a. substance or preparation intended for placement in contact with any external part of the human body, including:
   i. the mucous membranes of the oral cavity; and
   ii. the teeth;
   with a view to:
   iii. altering the odours of the body; or
   iv. changing its appearance; or
   v. cleansing it; or
   vi. maintaining it in good condition; or
   vii. perfuming it; or
   viii. protecting it; or
b. substance or preparation prescribed by regulations made for the purposes of this paragraph; but does not include:
c. therapeutic good within the meaning of the Therapeutic Goods Act 1989; or
d. a substance or preparation prescribed by regulations made for the purposes of this paragraph.'

The current *Cosmetics Standard* and the associated *NICNAS Cosmetics Guidelines* should be consulted for guidance on the conditions applying to the following secondary sunscreen products for them to be regulated as cosmetics rather than therapeutic goods:

a. Make-up products for the face and nails:

- tinted bases or foundation (liquids, pastes or powders) with sunscreen
- products (tinted or untinted) intended for application to the lips with sunscreen.

b. Skin care products:

- some moisturising products with sunscreen for dermal application, including anti-wrinkle, anti-ageing and skin whitening products
- some sunbathing products (for example, oils, creams or gels, including products for tanning without sun and after sun care products).

The *Cosmetics Standard* and *NICNAS Cosmetics Guidelines* include specific requirements regarding the presentation and labelling of cosmetic sunscreen products. Sponsors are responsible for ensuring that such products comply with those requirements. Failure to comply with those requirements may make the product concerned a therapeutic good that must be listed or registered in the ARTG.

Other mandatory requirements applying to the labelling of all cosmetic products are set out in *Cosmetic & toiletries ingredient labelling* published by the Australian Competition & Consumer Commission (ACCC).

Commented [s22] Needs updating

Commented [s22] Agree
Cosmetics Standard to EGD
NICNAS to AICIS
Cosmetic & toiletries ingredient labelling to Consumer Goods (Cosmetics) Information Standard 2020

3. Regulatory categories of sunscreens

Most therapeutic sunscreens marketed in Australia are currently defined as 'listable' therapeutic goods which means that they must be 'listed' in the ARTG. Other sunscreen products must be 'registered' in the ARTG, while others are exempt from registration or listing (see below). General information on listing and registration of therapeutic goods is available on the TGA Internet site. The current regulation of the various categories of sunscreens is summarised in Table 1 below and explained in the text that follows.

Table 1. Summary of the current regulation for the various categories of sunscreens.

Product category	Sub-category	Currently regulated by:
Listable sunscreens	• Primary sunscreens carrying SPF claims of at least SPF 4 and not greater than SPF 50+ • Secondary sunscreening products that meet the definition of a therapeutic sunscreen (See subsections 2.1 and 3.2)	Listing in the ARTG under s.26A of the Act
Registrable sunscreens	Sunscreens that make therapeutic claims other than sunscreening and/or reduction of risk of skin cancer, solar keratosis, sunspots or premature ageing. (See subsection 3.3)	Registration in the ARTG under s.25 of the Act
Exempt sunscreens	Primary sunscreens with an SPF less than 4 and not containing ingredients of human or animal origin. (See subsections 2.2 and 3.1)	Exempt from the requirement of listing or registration in the ARTG
Cosmetic sunscreens (Excluded sunscreens)	Some secondary sunscreens that are excluded from regulation by the TGA but meet the definition of a cosmetic. (See subsection 2.2)	Regulated by NICNAS and the ACCC as cosmetics and not regulated under the Act

Commented [s22] Table needs updating

Commented [s22] For each regulatory product category, it might be helpful to address each of the relevant AS/NZS 2604 Categorisation Table headings to avoid any ambiguity.

3.1 Exempt sunscreens

A therapeutic sunscreen product is 'exempt' under Item 8(g) of Schedule 5 of the Regulations if:

- the SPF established by testing according to *AS/NZS 2604:2012* is less than 4, and
- the label claims comply with *AS/NZS 2604:2012*, and
- the product does not have an indication for the treatment of a serious disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the *Therapeutic Goods Advertising Code*.

Commented [s22] Legislative update required

Commented [s22] Agree

Exempt therapeutic sunscreens do not require registration or listing in the ARTG, but are treated as therapeutic goods in all other respects and must comply with all relevant parts of the Therapeutic Goods legislation, including relevant standards such as the Labelling Order (Therapeutic Goods Order No. 69, and amendments) and the *Therapeutic Goods Advertising Code*.

3.2 Listing of therapeutic sunscreens

The majority of therapeutic sunscreen products require listing in the ARTG in accordance with Item 7 of Part 1 of Schedule 4 of the Regulations.

Information on the listing process using the TGA's Electronic Listing Facility (ELF) and details of what information needs to be provided for listed products are provided in the *Electronic Listing Facility (ELF) User Guide*.

Under Item 7 of Part 1 of Schedule 4 of the Regulations, sunscreen products are eligible for listing where they come within the following description:

> 'Sunscreen preparations for dermal application (other than preparations for the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code), if:
>
> a. the claimed sun protection factor has been established by testing according to the method described in Standard *AS/NZS 2604:2012*, as in force from time to time; and
>
> b. the performance statements and markings on the label comply with that Standard; and
>
> c. the sunscreen preparation only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act; and
>
> d. if a determination under paragraph 26BB(1)(b) of the Act specifies requirements in relation to ingredients being contained in the sunscreen preparation—none of the requirements have been contravened

The SPF of therapeutic sunscreens must be determined by testing on human skin in accordance with the sunscreen standard *AS/NZS 2604:2012* which references the International Organisation for Standardisation procedure *ISO 24444:2010 Cosmetics – Sun Protection test methods – In vivo determination of SPF (Sun Protection Factor)*.

Note that, where *in vivo* SPF test results have been produced using the US FDA static SPF test procedure described in *FDA Sunscreen Drug Products for OTC Human Use: Final Monograph*, the individual SPF results may be used to calculate the mean SPF and the label SPF provided they meet the statistical criteria set out in *ISO 24444:2010* as referenced in *AS/NZS 2604:2012*.

Therapeutic sunscreen products may only contain active sunscreening ingredients that are included in the list of sunscreening agents permitted as active ingredients in therapeutic sunscreens (see subsection 9.1) and are within the maximum concentrations stated in the list.

Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure that the finished product is safe for its intended purpose.

Sunscreen products that make therapeutic claims other than sunscreening (for example, reduction of free radicals in or below the skin, or claims relating to reduction of UV induced immune suppression) and/or contain active therapeutic ingredients that are not included in the list of sunscreening agents permitted as active ingredients (see subsection 9.1) are not 'listable sunscreen preparations' and must be registered in the ARTG as OTC or prescription medicines depending on the active ingredients contained and therapeutic claims made (see subsection 3.3 for registration of therapeutic sunscreens). Subsection 4.1 lists the therapeutic claims permitted for listed sunscreens.

Commented [s22] Legislative update required.

Commented [s22] Agree

Commented [s22] Propose making the listing process a new section, discussing how to list and register sunscreens.

Propose to add a new subheading for permitted indications. Suggest moving information about the indications from labelling and advertising section here.

Commented [s22] Sounds acceptable will review in the proposed draft.

Commented [s22] Requires updating – 2 new parts to this item need to be added (parts e and f)

Commented [s22] Agree

sunscreen preparations for dermal application, if:

(a) the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:2012, as in force from time to time; and

(b) the performance statements and markings on the label comply with that Standard; and

(c) the sunscreen preparation only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act; and

(d) if a determination under paragraph 26BB(1)(b) of the Act specifies requirements in relation to ingredients being contained in the sunscreen preparation—none of the requirements have been contravened; and

(e) the sunscreen preparation only has indications that are covered by a determination under paragraph 26BF(1)(a) of the Act; and

(f) if a determination under paragraph 26BF(1)(b) of the Act specifies requirements in relation to the indications—none of the requirements have been contravened

Commented [s22] Suggest moving yellow section to the Reproducibility of SPF test results section.

Commented [s22] ISO 24444 now requires data to be reported in a **standardised Normative** format. This should be explicitly stated in the ARGS. This should apply to both the static and water resistance data.

With regards the 2nd paragraph – we suggest that this practice will no longer appropriate with the adoption of ISO 24444:2019 into AS/NZS 2604.

The current AS/NZS 2604:2012 provides the details for calculation of the mean SPF and all details for reporting. This detail will now reside in ISO 24444:2019. Therefore to comply with AS/NZS 2604: 2021 once adopted into the TG Regs this ...

Commented [s22] Propose to rewrite with reference to the Permitted Ingredients Determination.

Commented [s22] Suggest also including that - Cosmetic sunscreens may include UV filters to achieve an SPF. Colour/tinted cosmetics may contain may achieve an intrinsic SPF by the presence of ingredients like iron oxides.

Commented [s22] Propose moving to section on reproducibility of SPF test results.

Commented [s22] Suggest this statement is more related to the safety of the finished formulation product and development pharmaceutics. i.e. that the formulation is rational.

3.3 Registration of therapeutic sunscreens

Sunscreens that are not 'listable', 'exempt' or 'cosmetic' (excluded) are evaluated by the TGA for quality, safety and efficacy as registered therapeutic goods under section 25 of the Act.

Data to support the quality, safety and efficacy of such products are required as detailed under the relevant chapters of the *Australian Regulatory Guidelines for OTC Medicines* (ARGOM).

Products in this category include:

- products that contain a sunscreen active ingredient that is not included in the list of sunscreening agents permitted as active ingredients (see subsection 9.1)
- products that make any therapeutic claims other than the sunscreening claims permitted under section 4 'Labelling and advertising', or that are for the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 of the *Therapeutic Goods Advertising Code*
- products that contain substances that are scheduled in the SUSMP
- products that contain a sunscreening active ingredient combined with a claimed therapeutic active ingredient that is not a permissible active ingredient in a listed medicine in accordance with section 26BB of the Act
- products that are not otherwise 'listable', 'exempt' or 'excluded'.

Commented s22 Remove

Commented s22 The TGA should also provide clarity of the regulatory pathways. E.g. if a new sunscreen active or an excipient was either scheduled or not approved for inclusion in 26BB – could an application for specific uses be made via the OTC section provided indications were OTC appropriate.

Where indications relate to restricted or prohibited representations this type of product would need to be evaluated as a prescription medicine.

By providing clarity it avoids awkward applications. Removal of reference to ARGOM only creates greater ambiguity. If not ARGOM what? ARGCM or ARGPM?

Lack of information leaves ambiguity.

Commented s22 Legislative updates required

Commented s22 Agree

3.4 Responsibility of sponsors to report adverse reactions

It is a standard condition of listing or registration of a medicine that the sponsor has an appropriate system of pharmacovigilance and that the sponsor reports to the TGA adverse reactions experienced by users of the sponsor's products. This requirement applies to sponsors of therapeutic sunscreens.

Details of the TGA's requirements for pharmacovigilance and the reporting of adverse reactions can be found on the TGA Internet site.

Commented s22 Add hyperlink to Pharmacovigilance website.

Commented s22 Agree – requires updating.

4. Labelling and advertising

The labelling and advertising of therapeutic sunscreen products included in the ARTG must comply with the relevant requirements of each of the following:

- the Labelling Order, Therapeutic Goods Order No 69 (or any subsequent order amending or replacing TGO 69)
- the *Therapeutic Goods Advertising Code* (as updated from time to time)
- the Australian/New Zealand Standard *AS/NZS 2604:2012 Sunscreen products – Evaluation and classification*
- the current edition of *Required Advisory Statements for Medicine Labels* (RASML).

A check list is provided at the end of this document (Appendix 1) to assist sponsors in designing their sunscreen labels in accordance with the requirements of the documents listed above. However, the check list is not exhaustive and sponsors are responsible for ensuring that their labelling complies with all of the relevant legislative requirements.

TGO 69, the *Therapeutic Goods Advertising Code* and the RASML do not apply to cosmetic sunscreens.

4.1 General

As required by sections 2 and 3 of the Labelling Order (TGO 69), the label (or labels) must:

- be printed on or firmly and securely attached to the container
- be unlikely to become detached or defaced or illegible during use
- be positioned so that it will not be damaged or removed when the container is opened
- not be obscured by any other label or object
- be printed in English
- be printed in lettering that is clear, distinct and legible, and the height of letters with ascenders or descenders is not less than 1.5 mm (except for the AUST L or AUST R number, which may be 1 mm high).

As prohibited by section 4 of the *Therapeutic Goods Advertising Code*, the labelling must be free from claims, statements or pictures that:

- are likely to arouse unwarranted and unrealistic expectations of the product's effectiveness
- are false, unbalanced, unsubstantiated, misleading or likely to mislead the user
- abuse the trust or exploit the lack of knowledge of consumers or contain language that could bring about fear or distress
- encourage or are likely to encourage inappropriate use
- indicate or imply that the product is infallible, unfailing, magical, miraculous, or effective in all cases
- indicate or imply that the product cannot cause harm
- indicate or imply that other competitor products are harmful or ineffectual

Commented [s22] Legislative updates required

Commented [s22] Agree

Commented [s22] When updated to AS/NZS 2604:2021 may need to highlight the changes to labelling in the standard.

Commented [s22] Remove

Commented [s22] Agree – RASML is irrelevant

Commented [s22] Suggest removing Appendix 1 – this has some information that is inconsistent with the main body of the ARGS.

Commented [s22] Members advise this checklist as it is very helpful to Sponsors - especially overseas manufacturers (after corrections made). Instead the necessary corrections need to be made.

Commented [s22] Remove

Commented [s22] Agree or could provide the Cosmetic & toiletries ingredient labelling to Consumer Goods (Cosmetics) Information Standard 2020

Commented [s22] Suggest not duplicating information in the legislation, as this is a source of inconsistency within the ARGS. Provide a hyperlink to the relevant legislation only.

Commented [s22] Agree that reiterating the TGO and the TGAC is not helpful.

- indicate or imply that the product is endorsed by any government agency, hospital or other facility providing healthcare services, individual healthcare professional or group of healthcare professionals.

Therapeutic sunscreens that are 'listable' are permitted to carry the following coded indications provided that the sunscreen meets the requirements of *AS/NZS 2604:2012* for the indications designated:

1. A broad spectrum sunscreen with an SPF of 30 or higher is permitted to carry the following indications:
   - 'May assist in preventing some skin cancers.'
   - 'May reduce the risk of some skin cancers.'
   - 'Can aid in the prevention of solar keratoses.'
   - 'Can aid in the prevention of sunspots.'
2. A broad spectrum sunscreen with an SPF of 4 or higher is permitted to carry the following indication:
   - 'Can aid in the prevention of premature skin ageing.'

In principle, indications considered appropriate for listed sunscreens are those that can be used safely and effectively without the intervention of a healthcare practitioner. For medicines generally this includes diseases, disorders or conditions that are normally of a benign or self-limiting nature that the average consumer can be expected to evaluate or diagnose accurately. Some indications that relate to a serious disease condition, ailment or defect such as skin cancer are restricted except those allowed above which have been approved by the TGA for therapeutic sunscreens.

The Act requires that, at the time of listing a medicine in the ARTG, a sponsor must certify that it holds the information or evidence to support indications and claims made in relation to the product. All indications and claims must be capable of substantiation – that is, evidence held by the sponsor must adequately demonstrate all indications and claims made for the product are true, valid and not misleading.

Listed medicines are not subject to pre-market evaluation for efficacy at the time of listing. However, data supporting the indications may be requested by the TGA for review after listing of a medicine. Hence, the TGA may request copies of labelling and the results of pre-market SPF, broad spectrum performance, water resistance or stability testing. If requested, it is expected that this information will be available and can be provided to the TGA within a reasonable time of the request.

Therapeutic sunscreens may also carry justified non-therapeutic claims (for example, 'contains Vitamin E', 'contains aloe vera', 'moisturising', 'antioxidant', 'free radical barrier') and information to support such claims may be requested by the TGA for review. If the certification by the sponsor that it holds this information or evidence is incorrect, the TGA can cancel the listing of the product from the ARTG.

The labelling may also carry company logos, other symbols and consumer information provided these do not create confusion for Australian consumers and they do not conflict with the requirements of the Therapeutic Goods legislation, the Labelling Order, the Sunscreen Standard or the Advertising Code.

If the formulation includes a proprietary ingredient, the sponsor should check with the manufacturer or supplier of the proprietary ingredient to ascertain that it does not contain any specified excipients that must be declared on the labels in accordance with TGO 69.

Commented s22 Propose moving this information to the new subsection on permitted indications under the listed sunscreens section.

Commented s22 Agree.

Commented s22 Suggest moving to section about listed sunscreens

Commented s22 Agree

Commented s22 Move this paragraph to proposed subsection about permitted indications.

Commented s22 Disagree – these are not indications these are cosmetic claims. Suggest they should remain within the general labelling section. Keep this para
And the next 2 paras together.

Commented s22 Move these 2 paragraphs to top of section.

Commented s22 Agree

4.2 Labelling of immediate container and primary pack

As required by subsection 3(2) of the Labelling Order and section 7 of the Sunscreen Standard *AS/NZS 2604:2012*, the main label on the container and the main label of the primary pack (for example, carton), if any, must contain all of the following information:

- the product name

  Note: The use of the term 'sunblock' is not acceptable as part of a product name (or elsewhere on the label). The term is a misnomer because sunscreens filter to varying degrees but do not completely block the sunburning radiation.

- the name of the dose form, for example, 'cream' or 'lotion'
- the sun protection factor (SPF) of the product preceded by the expression 'Sun Protection Factor' or 'SPF' marked in durable and legible characters and in such colour or colours as to afford a distinct contrast to the background colour and in letters not less than 1.5mm in height

  Note: A category description may also be given, for example, 'low / medium or moderate / high / very high protection'.

- [if relevant] the water resistance of the product (in hours or in minutes) established in accordance with *AS/NZS 2604:2012*

  Note: The use of the terms 'waterproof' and 'sweat proof' are not acceptable. Sunscreens may be water resistant but none are completely waterproof, and even those with a high water resistance rating will gradually wash off the skin when immersed in water for long enough or through perspiration.

- the statement 'broad spectrum' in letters not larger than those used for the SPF provided that the product meets the criteria of broad spectrum protection from UV (or UVA and UVB) light as defined and measured by *AS/NZS 2604:2012*
- the net quantity of the goods (by volume in mL or weight in g)
- the ARTG listing number preceded by 'AUST L' or registration number preceded by 'AUST R'.

  Note: If the container is packed in an outer carton the listing or registration number must be on the main label of that carton and may be, but is not required to be, on the container as well.

All of the following information must be included either on the main label or on a rear or side panel [see subsection 3(3)(c) of the Labelling Order]:

- the names of all sunscreening active ingredients expressed using Australian Approved Names (AAN)

  Note: International Nomenclature of Cosmetic Ingredients (INCI) names may also be included in addition to (but not as a substitute for) the AANs.

- the proportions of those ingredients either expressed as a percentage in terms of w/w or w/v or expressed as a weight in a stated weight or volume of the product using metric units of measurement (for example, mg/g or mg/mL).

All of the following information must be included somewhere on the label(s) or container:

- the recommended storage conditions 'store below 25°C' or 'store below 30°C', as applicable
- the batch or lot number of the product, preceded by the batch number prefix using one of the formats specified in subsection 2(1) of the Labelling Order

Commented [s22] Propose not duplicating this information from the legislation and Sunscreen Standard as this is a source of inconsistency. Provide hyperlinks instead.

Commented [s22] Agree

- the expiry date of the product preceded by the expiry date prefix 'Expiry Date', 'EXPIRY DATE', 'Expiry', 'EXPIRY', 'Expires', 'EXPIRES', 'Exp. Date', 'EXP. DATE', 'Use before', 'USE BEFORE', 'Use By', 'USE BY', 'Exp', or 'EXP'

  Note: Terms such as 'Best by' or words to this effect are not acceptable.

- if relevant, the presence in the product (preceded by the word 'contains') of any ingredient listed in the First Schedule to the Labelling Order, including:

  – benzoic acid, calcium benzoate, potassium benzoate or sodium benzoate

  Note: If the product contains more than one of these substances, they may be grouped under the term 'benzoates'.

  – ethanol (if > 3% v/v)

  – hydroxybenzoate ester(s) (for example, ethyl, methyl, propyl, sodium ethyl, sodium methyl, sodium propyl hydroxybenzoate)

  Note: If the product contains more than one of these substances, they may be grouped under the term 'hydroxybenzoates'.

  – peanuts and peanut products (for example, peanut oil, arachis oil)

  – sorbic acid or potassium sorbate

  Note: If the product contains more than one of these substances, they may be grouped under the term 'sorbates'.

  – sulfite, metabisulfite and bisulfite salts and sulfur dioxide

  Note: If the product contains more than one of these substances, they may be grouped under the term 'sulfites'.

  – tartrazine or 'tartrazine CI 19140'

  – any other antimicrobial preservative(s)

- a statement of the purpose or purposes of the product

  Notes:

  a. The purpose of the product can generally be made obvious by it being called a 'sunscreen' or 'moisturiser with sunscreen' or 'moisturiser' with an SPF stated on the label.

  b. If (and only if) a therapeutic sunscreen has an SPF of 30 or higher and it provides broad spectrum protection, the label is permitted to include a representation to the effect that the product 'may assist in preventing some skin cancers' or 'may reduce the risk of some skin cancers' provided the label also highlights the need for avoidance of prolonged exposure to the sun and the importance of wearing protective clothing, hats and eyewear (see Gazette notice of 25 September 2002). Other acceptable related claims are 'can aid in the prevention of solar keratoses' and 'can aid in the prevention of sunspots'.

  c. Any broad-spectrum sunscreening preparation with an SPF of 4 or higher may also make the claim 'can aid in the prevention of premature skin ageing' or words to that effect.

  d. The labelling of therapeutic sunscreens may also carry justified non-therapeutic claims.

- directions for use of the product

  Note: The directions for use for a primary therapeutic sunscreen should include statements to the effect that the product should be applied to the skin in generous amounts over all of the exposed areas 20 minutes before sun exposure, it should be reapplied every two hours or more often when sweating, and should be reapplied after swimming or towelling. The labelling must not contain a claim (for example, 'all day protection') that indicates or implies that the product does not need to be reapplied at regular intervals.

- required warning statements as included in the RASML

  Note: The labels of both primary and secondary therapeutic sunscreens should include warning statements to the effect that the product should be kept out of the eyes and should not be used on broken, damaged or diseased skin. Spray-sunscreens should also include a warning not to inhale the product.

  Primary therapeutic (but not secondary) sunscreen products should also include warning statements to the effect that prolonged exposure to the sun should be avoided, and it is important to wear protective clothing, hats and eyewear when exposed to the sun.

- the name and address of the sponsor or Australian supplier of the product.

  Note: An Australian contact telephone number may also be included.

4.3 Minimum requirements for small containers

In accordance with subsection 3(11) of the Labelling Order, if the immediate container has a capacity of 20mL or less AND the container is enclosed in a primary pack (for example, carton), the primary pack labelling must include all of the information listed above and the labelling on the container must include at least the following information:

- product name (in full or in abbreviated form if there is insufficient room for the full name)
- name of the dosage form
- quantity of product in the container
- batch or lot number preceded by the batch number prefix
- names and quantities of all active ingredients in the product. If there is insufficient room, this information about active ingredients is only required on the label of the primary pack.

4.4 Nanoparticles in sunscreens

Nanoparticulate titanium dioxide and zinc oxide are commonly used in sunscreens. The labels of therapeutic sunscreens are not required to declare the particle sizes of ingredients.

The TGA's policy on the safety of nanoparticulate ingredients in sunscreens is available from the TGA Internet site.

Commented s22 Propose to move this information to the permitted ingredients section and to update information.

Commented s22 Agree

4.5 Advertisements for therapeutic sunscreens

Advertisements for therapeutic sunscreens are required to comply with the Therapeutic Goods Advertising Code.

Commented s22 Propose removing this, as it is mentioned at the beginning of this section.

Commented s22 Agree

5. Reproducibility of SPF test results

Commented [s22]: Propose moving this section towards the end of the ARGS (immediately before the Stability testing section)

Commented [s22]: This very detailed commentary was written by [s22] after reviews of lab results from the then 2 Aust based test labs. [as [s22] recalled, 1,000+ data points and not including data from overseas testing].

Further advice on the planned detail for the proposed heading Retesting of Sunscreens is requested.

The in vivo testing of the SPF of a sunscreen product according to the procedure in *ISO 24444:2010* and *AS/NZS 2604:2012* produces a reasonable estimate, but not a highly accurate and precise measure, of the true SPF of the product applied to the skin at a rate of 2 mg/cm2. The test data exhibit a considerable inherent variance which needs to be taken into account when interpreting the test results and labelling of the product, and also needs to be taken into account when interpreting the results of any subsequent retesting of the product.

The test procedure in *ISO 24444:2010* and referenced by *AS/NZS 2604:2012* requires the product to be tested on a minimum of 10 subjects and for the arithmetic mean, standard deviation and 95% confidence interval (95% CI) for the mean to be calculated using the formula $95\%\ CI = m \pm t.s/\sqrt{n}$, where:

'n' is the number of individual SPF data,

'm' is the arithmetic mean of those data,

't' is the value of Student's t for n-1 degrees of freedom and p=0.05 (double sided), and

's' is the standard deviation of the test data.

There is a 95% probability that the true SPF of the product lies somewhere within the 95% CI.

For the test to be considered valid, the 95% CI must fit within ± 17% of the mean and, if not, the product must be tested on further subjects (up to a maximum of 20) until the 95% CI based on the data for all subjects does fit within ± 17% of the mean. If testing on 20 subjects does not bring the 95% CI within ± 17% of the mean the whole test must be rejected. In practice, use of more than 10 subjects would be necessary only if the coefficient of variation (CV = s/m) is greater than 24%, and testing on 20 subjects would only fail if the CV was greater than 37%.

Statistical analysis of the SPF test data submitted to the TGA over recent years in support of SPF claims made for a large range of sunscreen products has shown that the data typically exhibit a relative standard deviation (RSD) or coefficient of variation (CV) in the range 5–20%. Only rarely is the CV less than 5% or greater than 20%. Thus, in the majority of cases, testing on 10 subjects would yield a 95% CI well within the ±17% limits and testing on additional subjects would not be required.

Subsequent retesting of a sunscreen is likely to yield a mean SPF anywhere within the 95% CI from the original testing of the product or even a few SPF units beyond either end of that 95% CI. Consequently, if the original test result was close to the lower limit for a particular SPF claim allowed by the Standard, the retest result could be lower than that lower limit and appear to cast doubt on the validity of the labelled SPF claim. However, it would be necessary to retest the product several times and obtain consistently low mean results before any conclusion could be drawn about the labelled SPF being unjustified.

6. Changes to sunscreens

Commented [s22]: Propose adding information about what constitutes a propose change (section 16(1A) of the Act and regulation 11 of the Regulations.

Commented [s22]: Agree,

Details of the requirements and procedures for making changes to the ARTG record of listed therapeutic goods are provided in the ELF User Guide.

6.1 Changes to active ingredients

The addition to or deletion of an active ingredient to a product or a change to the quantity of such an ingredient creates a new therapeutic good requiring an application to be made for a new entry in the ARTG (see subsections 16(1) and 16(1A) of the Act and regulation 11 of the Regulations). If successful, a new AUST L or AUST R number will be assigned to the new product.

6.2 Changes to excipients

Commented [s22]: Propose creating subheadings to break this section into smaller parts. No new content planned though.

Commented [s22]: Agree – Assume the proposed new heading 'Changes that may impact SPF properties' is intended to highlight the information of the last paragraph.

The identities of excipients in a sunscreen product and the quantities of 'restricted ingredients' are required to be included in the ARTG record for the product.

Deletion or addition of excipients in a therapeutic sunscreen (other than the permanent removal or addition of a fragrance or colouring agent) creates a new therapeutic good requiring an application to be made for listing or registration in the ARTG as a new product. If successful, a new AUST L or AUST R number will be assigned to the new product.

If the excipient to be added or removed is a fragrance or colouring then, notwithstanding that a new therapeutic good is created, the new product can retain the same AUST L or AUST R number under the *Therapeutic Goods (Groups) Order No. 1 of 2001* (the Grouping Order) provided the new formulation is intended to replace the existing formulation. However, an electronic application must be submitted to change the formulation recorded in the ARTG

Quantities of excipients other than restricted excipients are not required to be included in the ARTG record for listed sunscreens.

Where a change is to be made to the quantity of a restricted excipient and grouping applies in accordance with the Grouping Order subsection 5.1(a)(i) and (ii) and (b) an electronic application must be lodged to change the formulation details recorded in the ARTG. When grouping does not apply, such a change will require a new product application and a new AUST L or AUST R number.

Sponsors should recognise that the SPF and other physical properties of a sunscreen are affected not only by the active ingredients, but also by the base. Therefore, qualitative or quantitative changes in the excipients may adversely affect the SPF. Testing of a changed formulation to confirm its SPF or stability may be required if the changes are likely to affect the emulsion properties or the adhesion of the product to the skin in a way that could alter its sun protection properties.

6.3 Other changes

Changes to the ARTG details of a sunscreen product must be approved by or notified to the TGA (using the ELF system in the case of a listed sunscreen). Whether or not grouping applies, a change to the product name requires approval.

7. Stability testing

7.1 Stability test requirements

Therapeutic sunscreens marketed in Australia must be labelled with an 'expiry' or 'use by' date. That date must be supported by experimental data that support the shelf life of the sunscreen product in the container intended for marketing (or at least a container made of the same materials and with similar shape, size and wall thickness to that of the market container) under the recommended storage conditions (that is, 'Store below 25°C' for product to be stored in air-conditioned premises or 'Store below 30°C' for product to be stored at room temperature). The data must substantiate the physical, chemical and microbiological stability of the product for at least the claimed shelf life.

Sponsors of all therapeutic sunscreen products are expected to have performed stability testing on each product to at least the standard set out in these Guidelines. The claimed shelf life and storage conditions for each product should be derived from the results of the stability testing on that product. Generation of adequate stability data to support the assigned shelf life for a therapeutic sunscreen is the responsibility of the sponsor.

While the stability data supporting the shelf life of a sunscreen product are not required to be submitted to the TGA at the time of listing, they may be requested for review by the TGA at any time. Sponsors should, therefore, ensure that the data are available in a form suitable for submission to the TGA if and when requested.

Stability testing guidelines for sunscreens, *Guidelines for Stability Testing of Sunscreens April 1994*, were developed by the Australian industry peak bodies and accepted by the TGA. They are now incorporated below with some minor amendments to improve clarity and consistency with the stability guidelines for medicines adopted by the TGA (see ARGOM chapter on Quality). This section (7) now supersedes the *Guidelines for Stability Testing of Sunscreens April 1994*.

7.2 Establishing stability before listing or registering

Prior to listing and market launch, the shelf life must be established with real time testing for the whole of the required shelf life or with adequate certainty using accelerated testing (that is, 6-9 months at 10°C or 15°C above the stated maximum storage temperature – see Table 2) or justified on the basis of supporting stability data for a closely related formulation.

Pre-listing or pre-registration stability testing should be carried out using at least two batches of the formulation intended for marketing manufactured in a manner that closely mirrors the production-scale manufacturing process. A formulation very similar, but not identical, to that intended for marketing formulation may be used provided any differences are very minor and unlikely to affect the physical, chemical or microbiological stability or in-use performance of the product.

The batches tested in stability studies may be pilot-scale but should have been manufactured in a manner sufficiently similar to that of commercial production scale batches that they adequately reflect the properties of the product intended for the market.

7.3 Confirming stability and shelf life

If the shelf life assigned at the time of listing is based on data generated using pilot-scale batches and accelerated studies, the shelf life should subsequently be confirmed by real time studies covering the whole of that shelf life using at least two production-scale batches stored at the

Commented [s22] Propose to move this section to the end of the guidance and to present it slightly differently.
Propose adding a new paragraph about the EMEA/CPMP/ICH guidelines that the TGA follows, which provide direction on the design and conducting of stability studies.

Commented [s22] These sunscreen requirements for stability should remain. They are practical for the seasonality of the product, effective with storage temperature conditions that adequately stress an emulsion for Australian conditions. For years (decades now) they have provided acceptable stability shelf life prediction and ongoing stability confirmation for sunscreens in the Australian market. With the following key comments:

a. Extrapolation from accelerated data needs at least 4 time points. This key detail was omitted when the details were transferred from the original Industry Guidelines for Stability Testing of Sunscreens 1994.

b. See comments inserted below at section 7.4 on preservative efficacy.

It must be recognised that Sunscreens are seasonal consumer products, with category buyers demanding new products in ranges each year. In the majority of markets the products are cosmetics. The strict application of ICH Stability requirements for sunscreens creates unnecessary regulatory costs for the product. It increases the cost of sunscreens for the Australian public, and creates regulatory barriers for import of OS products and export of Australian products.

Commented [s22] Propose changing heading to establishing stability before market approval

Commented [s22] Agree

maximum recommended storage temperature. These production scale batches should be tested initially at manufacture and then annually until the end of the shelf life.

7.4 Stability protocol requirements

Physical testing should include at least the following quality parameters: appearance, emulsion stability, absence of crystallisation, odour, viscosity, compatibility with the immediate container and the condition of the inside surface of the container in contact with the product.

Chemical stability testing should include: pH (if water is the continuous phase) and the content of each of the active ingredients assayed using a validated, stability-indicating analytical procedure (for example, HPLC). Active ingredients should remain within the limits 90% to 120% of label claim.

Overages of active ingredients in the formulation are acceptable provided they do not result in concentrations exceeding the limits provided in subsection 9.1.

For water-containing sunscreens, microbiological stability should be confirmed by means of preservative efficacy testing at the start and end of accelerated stability testing and at the end of the shelf life during the subsequent real-time stability testing.

The temperature of storage used in stability studies should be controlled, monitored and logged to ensure the integrity of the results.

The frequency of testing for accelerated studies should be adequate to allow regression and statistical analysis to support extrapolation of the data. Appropriate testing time points would typically be 0, (1 or 2), (3 or 4), (5 or 6), 9 and 12 months (followed by 24 and 30 months, depending on the shelf life required to be justified).

The accelerated stability data should only be extrapolated as in subsection 7.5 if their accuracy, reproducibility and fit around a straight time-line are adequate. A minimum of 4 time-points with a reasonably even spread over the time period concerned are needed for meaningful line-fitting and 95% confidence interval calculations.

Commented [s22] Also insert another sentence " It may be useful to monitor chemical stability of preservatives during stability using a stability-indicating validated method.

This sentence also didn't transfer from the original Guidelines into ARGS.

Commented [s22] Using a minimum of 4 data points.

7.5 Shelf life determination

For a product exhibiting no discernible changes or trends, a 2-year shelf life for storage conditions of 'store below 30°C' (that is, storage at room temperature in Australia) may be supported by stability data covering 6 months storage at 40°C, and a 3-year shelf life for storage conditions of 'store below 30°C' may be supported by data covering either 9 months at 40°C or 6 months at 45°C.

A shelf life of greater than 3 years should be supported by data from storage at 40°C covering at least half of the shelf life (for example, 2.5 years accelerated data would be required to support a 5-year shelf life).

For a product exhibiting no discernible changes or trends, a 2-year shelf life for storage conditions of 'store below 25°C' (that is, the product should be stored in air-conditioned premises) may be supported by stability data covering 6 months storage at 35°C, and a 3-year shelf life for storage conditions of 'store below 25°C' may be supported by data covering either 9 months at 35°C or 6 months at 40°C.

A shelf life of greater than 3 years should be supported by data from storage at 35°C covering at least half of the shelf life.

Generally, the maximum shelf life permitted for any therapeutic good is 5 years.

Table 2. Shelf life Prediction from short-term testing at elevated temperatures

Temperature above labelled storage conditions	Time period	Test time points	Possible shelf life prediction
+10°C	6 months	0, (1 or 2), (3 or 4), 6 months	2 years
+10°C	9 months	0, (1 or 2), (3 or 4), (5 or 6), 9 months	3 years
+15°C	6 months	0, (1 or 2), (3 or 4), 6 months	3 years

Commented s22 Propose moving this table to section about establishing stability before listing or registering.

Commented s22 Agree

8. Manufacture and quality control

8.1 Manufacture

In accordance with Part 3-3 of the Act and Part 4 of the Regulations, manufacturers of 'listed' or 'registered' therapeutic goods destined for the Australian market or for export from Australia to an overseas market must be licensed or approved by the TGA and must also comply with manufacturing principles as determined by the Minister. These manufacturing principles are set out in the TGA's requirements for good manufacturing practice (GMP).

Where an Australian manufacturer is nominated in an application to list or register a sunscreen, that manufacturer must be licensed by the TGA to manufacture such products and must comply with the TGA's GMP requirements as relevant to sunscreens. Where the product is imported, each nominated overseas manufacturer is expected to comply with a code of GMP equivalent to that applying to Australian manufacturers and the TGA must have issued a GMP clearance for that manufacturer.

Further information on licensing or approval of manufacturers is available on the TGA Internet site.

8.2 Quality control

It is the responsibility of the manufacturer of the finished therapeutic product to ensure the quality of the product and also that of the active ingredients and excipients used in its manufacture.

Section 40(4)(a)(i) of the Act requires the manufacturer to ensure that the product complies with any standard applicable to the product.

In accordance with the definitions in section 3 of the Act, the default standards applying to therapeutic goods registered or listed in the ARTG are the *British Pharmacopoeia (BP)*, *European Pharmacopoeia* (Ph Eur) and *United States Pharmacopeia-National Formulary* (USP-NF). Other standards in addition to the pharmacopoeia that apply to sunscreens include relevant Therapeutic Goods Orders made under section 10 of the Act (for example, TGO No. 69 for labelling and TGO No. 77 for microbiological quality).

This means that if there is a monograph for a finished product in one (or more) of the BP, Ph Eur and USP-NF, then the sponsor must ensure that the product will comply with the specifications in that monograph (or at least one of those monographs).

Sunscreen finished products are not the subject of a monograph in the BP, Ph Eur or USP-NF and therefore must to be controlled, instead, by appropriate "in house" quality control specifications that control and ensure their identity and relevant physical, chemical and microbiological properties. Test methods must be validated, as appropriate.

Therapeutic sunscreen products in all categories are required to comply with the relevant requirements of sections 8 and 9 of *Therapeutic Goods Order No. 77 Microbiological Standards for Medicines*.

Sunscreen manufacturers are responsible to ensure that batches of product released to the market comply with their specifications.

Subsection 13(5) of the Act requires that, when a finished product is not the subject of a monograph in the BP, Ph Eur or USP-NF, but any of its ingredients is the subject of a monograph in one or more of those pharmacopoeia, that ingredient must comply with at least one of the monographs concerned, unless the Minister has issued an order determining that this

Commented [s22] Propose moving this section so it comes after the safety and quality of ingredients sections.

Also propose to clarify ingredient and product quality requirements – ingredient quality in separate section.

Commented [s22] Will discuss as part of the Mandatory Requirements Working Group.

Commented [s22] Add hyperlink

Commented [s22] Agree

Commented [s22] Suggest adding the word manufacturing to the heading.
Suggest adding text about the GMP requirements. Provide link to GMP and PIC/S guide for sunscreens

Commented [s22] Suggest instead to move the first two paras up under 8.1

Agree it will be very useful to provide the link to the PIC/S Guide for Sunscreens.

Commented [s22] Suggest adding that the manufacturer must hold evidence that ingredients (active and excipient) used in a product meet the requirements of a default standard, or the established specification.

Commented [s22] This is already clearly stated in the requirements for Release for Supply.

Commented [s22] Suggest creating a new subheading called default standards.

Commented [s22] Legislative updates required

Commented [s22] Agree

Commented [s22] Suggest creating a new subheading called default standards and finished products

Commented [s22] Perhaps with subheadings Starting Materials Specicifct5ions and Finished Products Specifications

Commented [s22] Legislative update

Commented [s22] Agree

Commented [s22] Suggest creating a new subheading called default standards and ingredients.

Commented [s22] Pharmacopoeial and non-pharmacopoeial may be useful delineations.

requirement does not apply to the goods concerned. Note that, as at the date these Guidelines were published, no such order exempting sunscreens had been issued by the Minister.

Many of the organic chemicals used as active ingredients in sunscreens are the subjects of monographs in the USP-NF (generally under their International Non-proprietary Names [INNs]) while the inorganic substances titanium dioxide and zinc oxide are the subject of monographs in each of the BP, Ph Eur and USP-NF.

Many of the excipients (including solvents) used in sunscreen products are the subjects of monographs in one or more of the BP, Ph Eur and USP-NF.

Ingredients that are not the subject of a monograph in the BP, Ph Eur or USP-NF must be controlled by appropriate quality control specifications that control and ensure their identity, relevant physical and chemical properties, and purity. Test methods must be validated, as appropriate.

9. Permitted ingredients

9.1 Sunscreening agents permitted as active ingredients

The only sunscreening active ingredients permitted in therapeutic sunscreens are those included in the Therapeutic Goods (Permissible Ingredients) Determination. Sponsors should consult the Determination for restrictions applying to each ingredient. The labelling must include the Australian Approved Name (AAN) for each active sunscreening ingredient.

Sponsors wanting to market a therapeutic sunscreen product containing a sunscreening active ingredient which is not on the list of permitted substances in therapeutic sunscreens must submit data to establish the safety and efficacy of the ingredient under its proposed conditions of use (see section 10).

9.2 Excipients

Only those excipients approved by the TGA for use in topical medicines may be used in therapeutic sunscreens. In some cases the TGA has set limits on the amounts of such ingredients and sunscreens must comply with those limits. For more information on the substances that may be used in Listed medicines supplied in Australia and the restrictions applying to their use, please consult the Therapeutic Goods (Permissible Ingredients) Determination.

Commented [s22 redacted] Suggest adding text that sunscreens can only contain low-risk ingredients from the Permitted Ingredients Determination, which may be used in other topically applied medicines. Also propose adding a link to the ARGLMRCM for more information.

Commented [s22 redacted] Agree
As previously expressed we need to reintroduce the Permitted Active Ingredients Table, their synonyms, and limits of usage. It is critical that there is a positive list of approved actives for Australia. Both Australian and OS parties should not need to search the permissible ingredients determination, to try to detect which Sunscreen actives are or are not approved in this market. The risk of the needing to update such a table is low as new sunscreen actives are not added very frequently, and existing actives have not historically been subject to frequent change.

Commented [s22 redacted] Change to quality, the TGA does not evaluate efficacy of ingredients. The efficacy aspect referred to evaluation of UV spectral characteristics of active ingredients. We consider this to be a quality aspect.

Propose to add links to safety, quality and manufacture sections.

Commented [s22 redacted] OK

Commented [s22 redacted] Propose to add new text about submitting data to establish safety and quality if the ingredient is not on 26BB

Propose to add links to safety, quality and manufacture sections.

10. New ingredients

The information below should be read in conjunction with the guidelines for the approval of new substances given in the ARGOM section on applications for new substances.

10.1 Naming of new substances

A 'Proposed Name for a Chemical Substance Used in a Therapeutic Good' application form needs to be submitted to the TGA to enable the establishment of an identity and an appropriate 'Australian Approved Name' (AAN) for the substance. Information on the naming of substances and applying for an AAN can be found on the TGA Internet site.

There are no fees for the AAN applications and approval of ingredient names (at the time of publication). However, fees will apply to the evaluation of the data for the new substance and for the listing or registration of the product as specified in the summary of fees and charges available from the TGA Internet site.

10.2 New active ingredients

Sponsors wishing to market a product containing an active ingredient which is not on the Therapeutic Goods (Permissible Ingredients) Determination must submit data to establish the safety and efficacy of the ingredient under its proposed conditions of use.

10.3 Safety data requirements for new actives

Table 3 below lists the topics of relevant guidelines for the types of safety data that are usually required for a new sunscreen active ingredient or new excipient (see also new excipient section).

The list of relevant European Union (EU) 'non-clinical' guidelines that have been adopted by the TGA can be found on the TGA Internet site. They are not detailed in this Sunscreen Guideline document because there are frequent changes and sponsors should, therefore, consult the current list on the TGA Internet site. These EU guidelines relate to sunscreens because sunscreening products (as defined earlier in this Guideline) are treated as therapeutic goods in Australia.

The intention in listing relevant guideline topics is not to set absolute requirements but to assist sponsors in assessing the type and depth of information needed to support an application with the understanding that primary sunscreen products are treated as therapeutic goods in Australia as opposed to 'cosmetics' in Europe.

If a particular guideline is not applicable or other data are available that adequately address the same criteria, alternative approaches based on adequate scientific justification will be considered by the TGA during evaluation of the application, or pre-submission. Relevant human studies are acceptable in the assessment of potential skin irritation and sensitisation using the repeat 'insult patch test' or other relevant validated tests.

Commented [s22] Propose to separate this into a section about new ingredients and a section about safety data requirements for new ingredients. We anticipate that the section about safety data requirements for new ingredients will be updated in the future to reflect the mandatory requirements for topical ingredients.

We also propose to create a new section called quality requirements for new ingredients. Details about the quality requirements are lacking in this current version of the ARGS. This section will be updated in the future to reflect the mandatory requirements for topical ingredients.

Commented [s22] Change to link in ARGLMRCM

Commented [s22] Remove heading

Commented [s22] Provide link to relevant website

Commented [s22] Provide link

Commented [s22] Propose to create a new heading for new ingredients only. Have dot points for active and excipients.

•**New text for New active ingredients:** In general, these will be present at significant concentrations in therapeutic sunscreen products to be efficacious, and may be expected to interact with human tissues and physiological systems topically (skin, eyes and mucosal surfaces) and systemically (if they penetrate the skin and move into the systemic circulation).

New general text: The safety data for new ingredients need to be comprehensive to ascertain both the short-term (acute) and long-term (chronic) effects on human health and safety from exposure to these ingredients. This is important, given that sunscreen products will be used by people of all ages (infants, children, adults and the elderly); genders (including women of childbearing potential); and could be readily anticipated to be used frequently (daily).

Commented [s22] Propose to change the word efficacy to quality. The efficacy aspect referred to evaluation of UV spectral characteristics of active ingredients. We consider this to be a quality aspect.

Commented [s22] Propose to create a new section for the safety data requirements of new ingredients. This would come before the section on Safety data requirements for new ingredients.

Commented [s22] Propose to create a new heading called safety test guidelines and put this information under it.

Commented [s22] OK

Table 3. Safety data normally required for a new sunscreen active ingredient or excipient

Requirements
Photostability • UV absorption spectra
Acute toxicity (oral and dermal; animal data)
Local tolerance: • skin irritation (animal data and/or human repeat insult patch test - HRIPT • phototoxicity (animal and/or human data) • eye irritation (animal *in vivo* or *in vitro* test)
Allergenicity: • skin sensitisation (animal data and/or HRIPT) • photosensitisation (animal and/or human data – HRIPT)
Toxicokinetics: • oral and dermal bioavailability • ADME (absorption, distribution, metabolism and excretion) studies Note: An *in vivo* determination of dermal and oral absorption is needed to establish systemic exposure via both routes and to enable interpretation of the toxicity studies.
Repeat dose toxicity (oral and dermal) at least 3 months
Genotoxicity: • *In vitro* bacterial (Ames) assay • *In vitro* mammalian cell line assay • *In vitro* and *in vivo* chromosome aberration assay Note: Genotoxicity *in vitro* testing in bacterial, mammalian cell lines, and chromosome aberration assay should include photomutagenicity arm.
Reproductive toxicity Notes: a. For assessment of developmental and fertility effects. b. Endocrine disruption potential needs to be addressed. This could be examined during the repeat-dose toxicity and/or reproductive toxicity studies.
Carcinogenicity Note: *In vivo* carcinogenicity and photocarcinogenicity bioassays or a justification for not providing these studies (see below).

Commented [s22]: Remove from table as this is a quality requirement.

Commented [s22]: Add 'this can be addressed with information obtained from repeat-dose toxicity studies

Commented [s22]: Add 'inhalation toxicity data may be required if the product is used in a spray dosage form.

Commented [s22]: Remove

Commented [s22]: Add Refer to ICH guidelines.

Requirements
Interaction potential Note: Since sunscreen formulations usually contain more than one active ingredient, data on the potential for interaction of the new substance with other UV filters will usually need to be provided.

More details on different safety tests for chemicals for pharmaceutical use can be found at the Internet sites of the following organisations:

- The European Medicines Agency (EMA)
- The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- The Organisation for Economic Co-operation and Development Guidelines for the testing of chemicals (section 4: Health Effects).

More details on different safety tests for chemicals that are for cosmetic sunscreens used in Europe can be found in The SCCS's *Note for Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 7th Revision 14 December 2010 SCCS/1416/11*.

Commented [s22 redacted] Move to proposed new section on safety test guidelines

Commented [s22 redacted] Needs updating

10.4 Justification for not providing particular studies

In circumstances where particular tests specified in the table above (TGA-adopted European guidelines) are not feasible or appropriate, sponsors should submit a justification for not including these tests in the dossier which is based on sound scientific argument.

In the case of *in vivo* carcinogenicity bioassays, a justification for not including long-term studies could be based around the following issues as they apply to the ingredients or product:

- the expected pattern of use
- results of *in vitro* and *in vivo* genotoxicity assays
- lack of similarity to other molecules with known carcinogenic activity
- low persistence in the skin
- low or no *in vivo* dermal absorption
- lack of photosensitisation or phototoxic potential
- proven photostability
- lack of possible adverse effects on the skin (change to epidermis/dermis)
- length of submitted *in vivo* repeat dose toxicity studies
- lack of adverse activity in local tolerance studies (skin irritation and skin sensitisation).

10.5 Related studies

Other studies that are not currently referenced in EU guidelines may be useful in supporting particular applications. Reference to these studies is included only as a guide. They will not be relevant in all cases, nor should they be seen as a complete list of relevant studies. Examples

Commented [s22 redacted] Propose to add a new section after this one called Alternative test methods accepted by the TGA.

Major advances in alternative testing methods and new validated methods have been implemented following the introduction of animal testing bans for cosmetic ingredients in Europe and Australia (see the Industrial Chemicals Act 2019). The TGA follows the EMA Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches, which describes the criteria for regulatory acceptance of an alternative testing approach. In addition, the TGA will accept validated test methods that are alternatives to animal testing methods from the following sources:

- OECD Test guidelines for the Chemicals
- The European Commission's Tracking System for Alternative methods towards Regulatory acceptance (TSAR)
- The European Commission's science and knowledge service

Commented [s22 redacted] Very useful

include the following studies and referenced Internet sites which may be useful in providing information on the potential of a substance to cause tumours in people:

- studies using appropriate and validated transgenic animal models to test exposure to the substance; information on transgenic models can be found on the OECD or European Centre for the Validation of Alternative Methods (ECVAM) internet sites
- *in vitro* human dermal cell cultures exposed to the substance
- *in vitro* human dermal tumour cell cultures exposed to the substance.

Additionally, the following references may be useful when investigating the use of ingredients with a potential for skin corrosion/irritation:

> Non-animal testing strategies for assessment of the skin corrosion and skin irritation potential of ingredients and finished products; M K Robinson *et al; Food and Chemical Toxicology*, 40(5), pp 573–592, 2002.
>
> OECD/OCDE, test number: 431 (April 2004) OECD Guidelines for the testing of chemicals; *in vitro* skin corrosion: human skin model test.

10.6 UV spectral characteristics

In addition to the requirements stated in the ARGOM chapter on Quality, sponsors should provide data to establish the UV absorption range of the new substance enabling confirmation of UVA/UVB absorption profile. Data addressing the potential for physical interaction with other commonly used sunscreening agents should also be provided.

Commented [s22 redacted] Move to new section called Quality data requirements for new ingredients and rename photostability

10.7 New excipients

Where a therapeutic sunscreen contains an excipient ingredient which is not in any product currently included in the ARTG for supply in Australia, the excipient must be assessed for use by the TGA. The following information is required as a minimum:

Commented [s22 redacted] Propose to move this so that is comes before the justification for not providing particular studies and related studies.

- naming and identification of an ingredient name as an Australian Approved Name (AAN) - this may be finalised while the safety data are being evaluated
- identification of the excipient as a substance included in the Personal Care Products Council International Cosmetic Ingredient Handbook (Dictionary) (the page number and reference should be quoted). There is also an on line subscription service known as wINCI that provides an electronic version of INCI monographs
- assurance that it does not appear in Annex II to the EEC Directive 76/768 list of substances which must not form part of the composition of cosmetic products
- documentary evidence that the excipient has been approved by the appropriate regulatory agency in Sweden, Canada, USA, UK or the Netherlands; or evidence that there have been marketplace sales of comparable products containing the excipient in one of those five countries for at least two years
- acute oral toxicity study
- skin irritation study – animal or alternative study such as HRIPT
- sensitisation study – skin, animal and/or (preferably) HRIPT.

Commented [s22 redacted] These 2 dot points refer to quality requirements, and will fall under the proposed new section about quality requirements for new ingredients.

The following additional studies may be requested in individual cases where concern becomes evident at the time of evaluation:

- *in vitro* mutagenicity (for example, an Ames test or other validated alternative test)
- eye irritation study (animal *in vivo* or *in vitro* test)
- *in vitro* or *in vivo* percutaneous absorption test.

All of the above information should be submitted for safety evaluation of the new substance for use in therapeutic sunscreens. Additional studies may be requested in individual cases where concerns become evident at the time of evaluation.

Once the substance is approved (and an AAN has been assigned), it will thereafter be able to be used in other therapeutic sunscreens without the need for further evaluation, but only up to the safety limit that has been approved. Any increase in that safety limit requires submission and approval of a formal application. The substance may also be able to be used in other topically applied medicines (subject to any conditions or limitations) without the need for further evaluation. However, additional data may be required if the characteristics of the substance are considered to change in different formulations or patterns of use in new products or if the substance is to be used outside the stated conditions and/or limitations.

Alternative sources of data on the safety of the excipient will be considered. For example, if the excipient has been assessed by NICNAS or by the US Cosmetic Ingredient Review (CIR) group, the review document may be sufficient in itself. Copies of CIR reviews are available from the Internet site www.cir-safety.org. Copies of NICNAS reviews may be available from the supplier of the excipient.

Required study reports should be submitted in full as well as in summary form (as described in the ARGOM Chapter on Applications). Simple summaries or synopses of studies without the full study reports are not acceptable for assessment.

All studies submitted must be in English or be provided with an accompanying English translation.

The EU guidelines that have been adopted by the TGA for therapeutic goods should be referred to for detailed guidance on the appropriate tests and how they should be conducted. Studies can be rejected as 'invalid' if appropriate and scientifically robust methodology is not followed (for example, low animal numbers, lack of or inappropriate controls).

Proper and comprehensive identification of the substance(s) being tested in all studies is required; laboratory codes, trade names and synonyms must be linked to the substance identified in the new substance application form for the AAN.

Concentrations of the new substance used in all studies must be clearly and unambiguously stated. The intended final concentration of the new excipient in therapeutic goods to be marketed in Australia must be stated; this allows a comparison to establish that the submitted studies were conducted at concentrations to support the proposed levels to be used in marketed goods.

Where a substance is present in the product with the listed purpose of excipient, no therapeutic claims can be listed against its presence.

If a substance with a known active function is classified as an excipient, evidence of excipient function and purpose will be required.

Furthermore, a justification must be provided for the inclusion of that substance as an excipient at a concentration in excess of the concentration typically used for its role as an active

Commented [s22 redacted] Propose to move this to the beginning of the permitted ingredients section and to add a reference to the ARGLMRCM.

Commented [s22 redacted] Create a new heading: Alternative sources of data

Commented [s22 redacted] Move these 2 paragraphs to beginning of section about Safety data requirements for new ingredients. Remove reference to ARGOM.

Commented [s22 redacted] Move this paragraph to new section about Safety test guidelines.

Commented [s22 redacted] Move this and the next paragraph to the beginning of the section about Safety data requirements for new ingredients.

Commented [s22 redacted] Move these paragraphs to the dot point about new excipient ingredients and reword.

ingredient. If that concentration is above the approved safety limit for use in listed products, then the product with that concentration of the substance must be registered.

The concentrations of excipients with a known active function in the formulation must be below the concentration associated with its established active function. If the excipient concentration is above the minimum threshold of active function then the substance should not be classified as an excipient in the product but, instead, should be classified as an active substance in the product and it will be evaluated as an active component of the product. In this case a therapeutic sunscreen containing that substance must be listed or registered on the ARTG.

11. Glossary of terms and abbreviations

Commented [s22]: Updated to reflect legislative changes and to remove ARGOM

Commented [s22]: Will a 'hover' glossary be available?

Note: Where relevant, references to particular definitions are provided in brackets (...)

ACCC means the Australian Competition and Consumer Commission.

Active ingredient (in relation to a sunscreen) means an active substance included in a sunscreen to protect the skin from ultraviolet (UV) radiation. It is an ingredient in a therapeutic good's formulation that is responsible for its physiological or pharmacological action (see regulation 2 of the Regulations).

Antimicrobial preservative means an ingredient added to a product to inhibit the growth of micro-organisms in the product. (TGO 69).

ARGOM means the Australian regulatory guidelines for OTC medicines

ARTG means the Australian Register of Therapeutic Goods

AS/NZS 2604:2012 means the Australian and New Zealand Standard for Sunscreen Products (2012 edition)

Australian Approved Name (AAN) – The approved name applied to a therapeutic substance, as outlined in the *TGA Approved Terminology for Medicines*, which includes: Approved Biological Substance Names (ABNs); Approved Chemical Substance Names; Approved Herbal Names (AHNs); and Approved Herbal Substances (AHSs).

Batch number means a number, or a combination of numerals, symbols or letters, which is given by a manufacturer to a batch of goods, to uniquely identify that batch and from which it is possible to trace that batch through all stages of manufacture and distribution (TGO 69).

Batch number prefix means the prefix which precedes the batch number and clearly indicates that the number is the batch number. Examples of acceptable batch number prefixes include 'Batch Number', 'BATCH NUMBER', 'Batch No.', 'BATCH NO.', 'Batch', 'BATCH', 'B', '(B)', 'B/N', 'Lot Number', 'LOT NUMBER', 'Lot No.', 'LOT NO.', 'Lot' or 'LOT'; or words or symbols to this effect.

Broad spectrum product means a sunscreen product which has been shown, using the in vitro test method defined in *AS/NZS 2604:2012* to provide protection from the sun's terrestrial UVA and UVB rays (*AS/NZS 2604:2012*).

Category description means the designation of the level of protection given by a grouping of label sun protection factors (*AS/NZS 2604:2012*).

Container means an article (for example, bottle, jar, tube, sachet) that immediately covers the goods, and includes an ampoule, blister pack, bottle, sachet, dial dispenser pack, strip pack, syringe, tube, vial, wrapper or other similar article, but does not include an article intended for ingestion (TGO 69).

Cosmetic (For the full definition, see subsection 2.2.)

Cosmetic sunscreen product means a product containing a sunscreening ingredient that is regulated as a cosmetic by the *Industrial Chemicals (Notification and Assessment) Act 1989* and by the Cosmetics Standard and is not a therapeutic good (see subsection 2.2).

Excipient ingredient (in relation to a sunscreen) means an ingredient of a sunscreen other than an active ingredient. Excipient ingredients may have multiple uses such as fragrance, preservative and/or solvent.

Excipient mix is a Proprietary Ingredient formulation comprised of a mixture of excipient ingredients that may be used in a therapeutic good. Examples include emulsifiers and anti-oxidants.

Excluded sunscreen means a sunscreen product that is not regulated under the *Therapeutic Goods Act 1989* (see the *Therapeutic Goods (Excluded Goods) Order No. 1 of 2011*).

Exempt sunscreen means a sunscreen product that is regulated under the Act but is not required to be registered or listed in the ARTG (see Item 4(g) of Schedule 5 of the Regulations).

Expiry date means the date (month and year) after which the goods should not be used, being a date not more than five years after the date of manufacture (TGO 69).

Expiry date prefix means the prefix which precedes the expiry date, and clearly indicates that the following information is the expiry date. Examples of acceptable prefixes include 'Expiry Date', 'EXPIRY DATE', 'Expiry', 'EXPIRY', 'Expires', 'EXPIRES', 'Exp. Date', 'EXP. DATE', 'Use before', 'USE BEFORE', 'Use By', 'USE BY', 'Exp', or 'EXP' but terms such as 'Best by' or words to this effect are not acceptable (TGO 69).

Fragrance (or perfume) means a substance whose primary purpose is to alter the smell of a therapeutic good.

Ingredients of human or animal origin are those derived directly from a human or animal source. They are also listed in the Regulations.

INCI means International Nomenclature Cosmetic Ingredient.

INN means International Non-proprietary Name.

Label means a display of printed information upon, or securely affixed to, the container and any primary pack containing the goods (TGO 69).

Label Sun Protection Factor (SPF) means the SPF indicated on the label.

Letter height means the height of upper case (capital) letters or lower case letters having an ascender or descender, unless otherwise stated (TGO 69).

Listing or registration number means the combination of numbers, symbols and letters assigned to the goods by the TGA under section 27 of the Act (TGO 69).

Medicine means a therapeutic good that is represented to achieve, or is likely to achieve, its principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal (see subsection 3(1) of the Act).

Minimum Erythemal Dose (MED) means the lowest dose of ultraviolet radiation that produces the first perceivable unambiguous erythema with defined borders appearing over most of the field of UV exposure 16-24 hours after UV exposure (*AS/NZS 2604:2012*).

New substance is an ingredient (chemical, herbal or biological) that is currently not used in a medicine for supply in Australia, or is proposed for a new route of administration to the previous use of the ingredient. This ingredient may or may not have an Australian Approved Name.

NICNAS means the National Industrial Chemicals Notification and Assessment Scheme.

Primary pack, in relation to therapeutic goods, means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers (see subsection 3(1) of the Act).

Primary sunscreen product means a product which is represented as being primarily to protect the skin from ultraviolet radiation (*AS/NZS 2604:2012*).

Principal or main label means (a) where there are two or more labels or two or more portions of a single label — that label or portion of the label where the product name is more or most conspicuously shown; or (b) where the product name is equally conspicuous on two or more labels or portions of a label — each such label or portion (TGO 69).

RASML means Required Advisory Statements for Medicine Labels.

Secondary sunscreen product means a product that is represented as having a primary purpose other than sun protection whilst providing some protection of the skin from ultraviolet radiation (*AS/NZS 2604:2012*).

Sun Protection Factor (SPF) means the arithmetic mean of all valid individual SPF values obtained from all subjects in the test (*AS/NZS 2604:2012*). See also, Minimum Erythemal Dose (MED).

SUSMP means the *Standard for the Uniform Scheduling of Medicines and Poisons* (previously called the *Standard for the Uniform Scheduling of Drugs and Poisons* [SUSDP]).

TGO 69 – see the Labelling Order.

The Act means the *Therapeutic Goods Act 1989*.

The Labelling Order means Therapeutic Goods Order (TGO) No. 69 – **General requirements for labels for medicines** (or any subsequent order amending or replacing TGO 69).

The Regulations means the *Therapeutic Goods Regulations 1990*.

Therapeutic good includes a good that is represented in any way to be, or that is, whether because of the way in which the good is presented or for any other reason, likely to be taken to be for therapeutic use or for use as an ingredient or component in the manufacture of therapeutic goods (subsection 3(1) of the Act).

Therapeutic sunscreen product means a primary or secondary sunscreen product that meets the definition of a therapeutic good rather than the definition of a cosmetic (see subsection 2.1).

Therapeutic use means use in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals, or influencing, inhibiting or modifying a physiological process in persons or animals (subsection 3(1) of the Act).

Topical – for sunscreen use means applied to a certain area of the skin for a localised effect.

TSEs means transmissible spongiform encephalopathies.

Ultraviolet radiation (UV) means the terrestrial solar ultraviolet radiation in the range 290–400 nm. Ultraviolet radiation A (UVA) is the terrestrial solar ultraviolet radiation in the range 320–400 nm and ultraviolet radiation B (UVB) is the terrestrial solar ultraviolet radiation in the range 290–320 nm.

UV filter, for the purposes of these Guidelines, means a substance that is exclusively or mainly intended to protect the skin against certain UV radiation by absorption, reflection or scattering of UV radiation.

Water resistant product, for the purposes of these Guidelines, means a sunscreen product which has been shown after designated periods of water immersion, using in vivo Sun Protection Factor test methods to provide protection against certain of the sun's UV rays (*AS/NZS 2604:2012*).

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Appendix 1: Labelling checklist

Note: This check list is not mandatory. It is designed to assist sponsors in designing their labels for therapeutic sunscreens in accordance with the TGA's requirements. It is not exhaustive. Sponsors are reminded that they are responsible for ensuring that their labelling complies with all of the relevant legislative requirements. These labelling requirements do not apply to those secondary sunscreen products categorised as cosmetics.

General	
Is/are the label (or labels):	
• printed on or firmly and securely attached to the container?	
• printed on or firmly and securely attached to the container?	
• unlikely to become detached or defaced or illegible during use?	
• positioned so that it will not be damaged or removed when the container is opened?	
• not obscured by any other label or object?	
• printed in English?	
• printed in lettering that is clear, distinct and legible, and the height of letters with ascenders or descenders is not less than 1.5 mm (except for the AUST L number, which may be 1 mm high)?	
As prohibited by the Therapeutic Goods Advertising Code section 4, is the labelling free from claims, statements or pictures that:	
• are likely to arouse unwarranted and unrealistic expectations of the product's effectiveness?	
• are false, unbalanced, unsubstantiated, misleading or likely to mislead the user?	
• abuse the trust or exploit the lack of knowledge of consumers or contain language that could bring about fear or distress?	
• encourage or are likely to encourage inappropriate use?	
• indicate or imply that the product is infallible, unfailing, magical, miraculous, or effective in all cases?	
• indicate or imply that the product cannot cause harm?	
• indicate or imply that other competitor products are harmful or ineffectual?	

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General	
• indicate or imply that the product is endorsed by any government agency, hospital or other facility providing healthcare services, individual healthcare professional or group of healthcare professionals?	

Labelling of immediate container and primary pack	
Does the main label contain the following information:	
• the product name? Note: The use of the term 'sunblock' is not acceptable.	
• the name of the dose form, (for example, 'cream', 'lotion', 'stick')?	
• the sun protection factor (SPF) of the product preceded by the expression 'Sun Protection Factor' or 'SPF'? Note: A category description may also be given, for example, 'low/moderate or medium/high/very high protection'.	
• the fact that the product provides 'broad spectrum' protection from UV light (in letters no larger than the SPF)?	
• [if relevant] the water resistance of the product (in hours or minutes)? Note: 'sweat proof' and 'waterproof' are not acceptable claims.	
• the contents of the container (volume in mL or weight in g)?	
• the ARTG listing or registration number preceded by 'AUST L' or 'AUST R'? Note: If the container is packed in an outer carton the listing number must be on the main label of that carton and may also be but is not required to be on the container.	
Is the following information included either on the main label or on a rear or side panel:	
• the names of all active ingredients expressed using Australian Approved Names AND the proportions of those ingredients either expressed as a percentage in terms of w/w or w/v or expressed as a weight in a stated weight or volume of the product using metric units of measurement (for example, mg/g or mg/mL)?	
Is the following information included somewhere on the label(s) or container:	
• the batch or lot number of the product preceded by the batch number prefix using one of the formats specified in TGO 69 s2(1)?	
• the recommended storage conditions?	

Labelling of immediate container and primary pack	
• if relevant, the presence in the product of benzoates, hydroxybenzoate ester(s), sulfites, or any other antimicrobial preservative(s), sorbates, ethanol (if >3% v/v), peanuts or peanut products (for example, peanut/arachis oil), or any other ingredient included in Schedule 1 of TGO 69?	
• required warning statements? Note: The label for a primary sunscreen should include warning statements to the effect that: prolonged exposure to the sun should be avoided, it is important to wear protective clothing, hats and eyewear when exposed to the sun, and the product should be kept out of the eyes.	
Is the following information included somewhere on the label(s):	
• a statement of the purpose or purposes of the product? Notes: 1. The purpose of the product is generally made obvious by it being called a 'sunscreen'. 2. If a sunscreen has an SPF of 30 or higher and it provides broad spectrum protection the label is permitted to include claims that the product may assist in preventing some skin cancers or may reduce the risk of some skin cancers provided the label also highlights the need for avoidance of prolonged exposure to the sun and the importance of wearing protective clothing, hats and eyewear. 3. Any broad spectrum sunscreen may also carry a claim that it can aid in the prevention of premature skin ageing. 4. Sunscreens may also carry justified non-therapeutic claims.	
• directions for use of the product? Note: The directions for use for a primary sunscreen should include statements to the effect that the product should be applied in generous amounts over all of the exposed areas 15 to 20 minutes before sun exposure, and again after swimming or towelling. An indication should also be given of how frequently the product should be re-applied during prolonged exposure to the sun.	
• the name and address of the sponsor or Australian supplier of the product? Note: An Australian contact telephone number may also be included.	

Special requirements – small containers	
If the immediate container has a capacity of 20mL or less AND the container is enclosed in a primary pack (for example, carton):	
• Does the primary pack labelling include all of the information listed above?	
• Does the labelling on the container include at least the following information: – the product name (in full or in abbreviated form if there is insufficient room for the full name)? – the name of the dosage form? – the quantity of product in the container? – the batch number preceded by the batch number prefix? – the names and quantities of all the active ingredients? Note: If there is insufficient room, the information regarding active ingredients is only required on the label of the primary pack.	

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Office of Medicines Authorisation	10/10/2012
V1.1	Updated to reflect the changes to the *Therapeutic Goods Regulations 1990* by removing references to sunscreens with a claimed SPF of <4 that contain certain human or animal derived ingredients Updated the relevant sections by including reference to the recently made Therapeutic Goods (Permissible Ingredients) Determination No.1 of 2015. Updated the table listing the permitted active ingredients by adding the newly approved sunscreen active Tris-biphenyl triazine	Complementary & OTC Medicines Branch – OTC Medicines Evaluation	22/01/2016
V1.2	Updated to remove Table 3 – Permitted active ingredients for therapeutic sunscreens and replace with links to the Therapeutic Goods (Permissible Ingredients) Determination	Complementary and Over the Counter Medicines Branch	30/8/2019

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Australian Government
Department of Health
Therapeutic Goods Administration

Australian regulatory guidelines for sunscreens

Version 2, July 2021

TGA Health Safety Regulation

Contents

Part A – General information about the regulation of sunscreens

Introduction

The Australian Regulatory Guidelines for Sunscreens (ARGS; the Guidelines) describe the regulatory requirements and standards for sunscreens (and their ingredients) regulated as **therapeutic goods** in Australia by the Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act 1989* (the Act) as at the date of publication.

For the purpose of these Guidelines, sunscreens that are regulated as therapeutic goods under the Act are referred to as '**therapeutic sunscreens**'. Unless excluded, therapeutic sunscreens include:

- **Primary sunscreens:** Products that are used primarily for protection from UV radiation.
- Some **secondary sunscreens***:* Products with a primary purpose other than sun protection, but which also contain sun screening agents.

Many secondary sunscreen products, such as cosmetic sunscreens, are not considered to be therapeutic goods and are 'excluded' from therapeutic goods legislation.

Sunscreen and insect repellent combination products

Therapeutic sunscreens that also make insect repellent claims must comply with all legislative requirements as for any other therapeutic sunscreen.

In addition, all insect repellents for human use must comply with any requirements of the Australian Pesticides and Veterinary Medicines Authority (APVMA). Refer to APVMA more information.

Many of the terms referred to in these Guidelines, such as 'therapeutic sunscreen', 'cosmetic', 'primary sunscreen', 'secondary sunscreen', and 'sun protection factor' (SPF) are defined in Glossary of terms and abbreviations.

The Australian/New Zealand Sunscreen Standard

The Australian/New Zealand Sunscreen Standard (AS/NZS) 2604 Sunscreen products — Evaluation and classification [as referenced in the *Therapeutic Goods Regulations 1990* (the Regulations) and in the Therapeutic Goods (Excluded Goods) Determination 2018 (Excluded Goods Determination); herein referred to as the **Australian Sunscreen Standard**] details the procedures for testing the performance of all sunscreen products (including therapeutic sunscreens) in Australia. It also provides labelling requirements that need to be applied along with all other applicable legislation relating to labelling for therapeutic sunscreens.

The Australian Sunscreen Standard classifies sunscreens as primary or secondary sunscreen products and further describes them based on their performance e.g. SPF; broad spectrum [protects against the sun's ultraviolet A (UVA) and ultraviolet B (UVB) rays]; and water resistance claims. Table 1 provides the category descriptions based on the SPF for sunscreens.

These categories and performance are reflected in the indications that therapeutic sunscreens can make (refer to the Indications permitted for use in listed therapeutic section).

Table 1. Sunscreen category descriptions based on SPF

SPF	SPF claim on label	Description/Level of protection
0-4	NA	NA
4-14	4, 6, 8,10	Low protection
15-29	15, 20, 25	Medium or moderate protection
30-59	30 ,40, 50	High protection
60 or higher	50+	Very high protection

Regulatory categories of sunscreens

In Australia, unless exempt, therapeutic sunscreens must be listed or registered in the Australian Register of Therapeutic Goods (ARTG) before they can legally be marketed in Australia (refer to Medicines and TGA classifications for more information on listed and registered therapeutic goods). Other sunscreens are **exempt** from therapeutic goods legislation or **excluded** from the requirement to be in the ARTG.

Sunscreens not required to be included in the ARTG

Excluded sunscreens

Many **secondary** sunscreen products are not considered to be therapeutic goods and are '**excluded**' from therapeutic goods legislation under the Excluded Goods Determination, for example: cosmetic sunscreens. Refer to table 2 for details of these product types.

Excluded products are not required to be included in the ARTG and are not required to comply with standards applicable to therapeutic goods. These products may fall within the definition of a '***cosmetic***' as defined in the Industrial Chemicals Act 2019 (refer to Glossary of terms and abbreviations).

For information on the regulatory requirements for these products refer to:

- The Australian Industrial Chemicals Introduction Scheme which is responsible for the manufacture and importation of industrial chemicals including ingredients used in cosmetic sunscreens.
- The Australian Competition and Consumer Commission which is responsible for product safety and labelling standards for consumer products including cosmetics.
- The Consumer Goods (Cosmetics) Information Standard 2020 which sets out the mandatory requirements applying to the labelling of all cosmetic products.

This category of sunscreen product will not be considered further in these Guidelines.

Exempt sunscreens

Item 8(g) of Schedule 5 of the Regulations 'exempts' certain therapeutic sunscreens from the requirement to be included in the ARTG – refer to table 2 for details of these product types

While 'exempt' therapeutic sunscreens do not need to be included in the ARTG, these products are considered to be therapeutic goods and therefore must comply with all relevant legislative requirements for therapeutic goods. These include relevant standards such as the most current Labelling Order (Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines) and Advertising Code.

This category of sunscreen product will not be considered further in these Guidelines.

Sunscreens required to be included in the ARTG

Sunscreens classified as therapeutic goods are, unless exempt, required to be included (listed or registered) in the ARTG before they can be marketed legally in Australia.

To supply a therapeutic good in Australia, you must have:

- your own ARTG entry for that therapeutic good; or
- retail arrangements with a sponsor who has an ARTG entry for that therapeutic good.

Listed therapeutic sunscreens

The majority of therapeutic sunscreen products fall under the listed medicines framework and are included in the ARTG in accordance with section 26A of the Act and Item 7 of Part 1 of Schedule 4 of the Regulations. More information about the requirements for listed therapeutic sunscreens can be found in Part B – Information for Listed therapeutic sunscreens.

Registered therapeutic sunscreens

Therapeutic sunscreens that are not exempt or not eligible to be listed in the ARTG require inclusion in the ARTG as registered therapeutic goods under section 25 of the Act. As such, these products must be evaluated for suitability as either over-the-counter (OTC) registered medicines or prescription medicines. Further information can be found in the Australian Regulatory Guidelines for OTC Medicines (ARGOM) or the Australian Regulatory Guidelines for Prescription Medicines, respectively.

Table 2 provides a summary of the current regulation for the various categories of sunscreens.

Table 2. Summary of the current regulation for the various categories of sunscreens

Sunscreen category	Required to be in ARTG?	Product type
Excluded sunscreens	**No** Excluded from therapeutic goods legislation under the Excluded Goods Determination.	Excluded sunscreens are **secondary** sunscreen products that are used, advertised or presented for supply in the following ways: • products intended for application to the lips with sunscreen if the **SPF is 4 or more**

Sunscreen category	Required to be in ARTG?	Product type
		• tinted bases and foundations (such as liquids, pastes or powders) with sunscreen if the **SPF is 4 or more** • moisturising skin care products for dermal application (including anti-wrinkle, anti-aging and skin whitening products), in a pack size no larger than 300mL or 300g, with sunscreen if the **SPF between 4 and 15** • sunbathing skin care products (such as oils, creams, gels, tanning products without sun, and after-sun care products), in a pack size not larger than 300mL or 300g, with an **SPF between 4 and 15** Excluded sunscreen products must: • meet the requirements set out in the Australian Sunscreen Standard, including the performance requirements for a broad-spectrum product • not contain any substances included in Schedules 2, 3, 4 or 8 of the Standard for the Uniform Scheduling of Medicines and Poisons
Exempt sunscreens	**No** Exempt [under item 8(g) Schedule 5 of the Regulations] from the requirement to be included in the ARTG	A therapeutic sunscreen is considered 'exempt' from the requirement to be included in the ARTG if: • the SPF established according to the Australian Sunscreen Standard **is less than 4** • the label claims comply with the Australian Sunscreen Standard • the product does not have an indication for the treatment of a serious disease, condition, ailment or defect as specified in the most current Advertising Code • the product does not contain ingredients listed in Item 8(g) of Schedule 5 of the Regulations, such as ingredients that are from humans, or particular organs from cows, sheep, goats or mule deer. Note: if the sunscreen contains one of these ingredients, it is not exempt from the requirement to be included in the ARTG

Sunscreen category	Required to be in ARTG?	Product type
Therapeutic sunscreens	**Yes** Required to be listed (under s.26A of the Act) or registered (under s.25 of the Act) in the ARTG	Non-exempt therapeutic sunscreens that are required to be included in the ARTG include: • **primary** sunscreens carrying SPF claims of more than **SPF 4** • some secondary sunscreens (i.e. those secondary sunscreens that are not excluded from therapeutic goods regulation by the Excluded Goods Determination) such as sunbathing and moisturising skin care products with an SPF of over 15 **Listed therapeutic sunscreens** Therapeutic sunscreens may be listed in the ARTG if they: • only make therapeutic indications that are permitted for use in listed medicines(see Ingredients permitted for use in listed therapeutic sunscreens) • only include ingredients that are permitted for use in listed medicines(see Indications permitted for use in listed therapeutic sunscreens) **Registered therapeutic sunscreens** Therapeutic sunscreens require registration in the ARTG if they: • contain an ingredient that is not a permitted ingredient in a listed medicine; and/or • carry higher-level therapeutic indications than those permitted for use in listed medicines

Legislative requirements for all therapeutic sunscreens

To be included in the ARTG, sunscreens must comply with the Australian Sunscreen Standard and with any relevant requirements as prescribed by the Act. General information on how to list or register a therapeutic good can be found in Part B of this document (listed therapeutic goods), and on the TGA website.

There are legal requirements that apply to all therapeutic goods. It is the responsibility of the sponsor to review the relevant regulatory guidance and ensure their product meets all relevant legal requirements. It is also important to note that sponsors have ongoing responsibilities and legal obligations. For more information, refer to Overview of supplying therapeutic goods in Australia on the TGA website.

Requirement to report adverse reactions for therapeutic sunscreens

It is a standard condition of listing or registration of a medicine in the ARTG that the sponsor has an appropriate system of pharmacovigilance and that the sponsor reports to the TGA adverse reactions experienced by users of the sponsor's products. This requirement applies to sponsors of all therapeutic sunscreens.

Details of the TGA's requirements for pharmacovigilance and the reporting of adverse reactions can be found on the TGA's Pharmacovigilance responsibilities of medicine sponsors website.

Labelling and advertising requirements for of therapeutic sunscreens

The labelling and advertising of therapeutic sunscreens must comply with the relevant requirements of each of the following:

- the most current version of the Labelling Order
- the most current version of the Advertising Code
- the Australian Sunscreen Standard

Non therapeutic claims for therapeutic sunscreens

Therapeutic sunscreens may also carry non-therapeutic claims, providing they are truthful and not misleading, such as:

- cosmetic claims, such as 'moisturising', 'antioxidant', 'free radical barrier'
- insect repellent claims
- content claims, such as 'contains Vitamin E', 'contains 30% more'

The sponsor must be able to substantiate these claims. If the certification by the sponsor that it holds this information or evidence is incorrect, the TGA can cancel the listing of the product from the ARTG. All insect repellents for human use must comply with any requirements of the APVMA. Refer to APVMA more information.

The labelling of therapeutic sunscreens may carry company logos, other symbols and consumer information provided that these do not create confusion for Australian consumers and they do not conflict with the requirements of the Australian Sunscreen Standard or relevant Therapeutic Goods legislation, such as the current Labelling Order and Advertising Code.

If the formulation includes a proprietary ingredient, the sponsor should check with the manufacturer or supplier of the proprietary ingredient to ascertain that it: does not contain any specified excipients that must be declared on the labels in accordance with the most current Labelling Order; and all components in the proprietary ingredient comply with the Permissible Ingredients Determination.

The Labelling Order and the Advertising Code do not apply to **excluded** sunscreens. Rather, mandatory requirements applying to the labelling of all excluded sunscreens that are considered to be cosmetic products are set out in the Consumer Goods (Cosmetics) Information Standard 2020.

Part B – Information for listed therapeutic sunscreens

Legislative requirements for listed therapeutic sunscreens

At the time of listing a sunscreen in the ARTG, a sponsor must certify that their product meets all applicable legislative requirements, which includes certification that the product:

- Only makes certain therapeutic claims selected from the Therapeutic Goods (Permissible Indications) Determination (Permissible Indications Determination), an exclusive list of indications that have been pre-approved by the TGA (see Indications permitted for use in listed therapeutic sunscreens section in this document) and complies with any requirements associated with those indications.
- Only contains low-risk ingredients selected from the Therapeutic Goods (Permissible Ingredients) Determination (Permissible Ingredients Determination), a list of ingredients pre-approved by the TGA (see Ingredients permitted for use in listed therapeutic sunscreens section in this document) and complies with any requirements associated with those ingredients. Information about the data required to support the safety and quality of sunscreen ingredients can be found in the Safety data requirements for new ingredients for use in listed therapeutic sunscreens and Quality data requirements for new ingredients for use in listed therapeutic sunscreens respectively.
- Complies with any applicable standards, including:
  - the claimed SPF of the therapeutic sunscreen must have been established by testing according to the method described in the Australian Sunscreen Standard
  - the performance statements and markings on the label comply with the Australian Sunscreen Standard

Listed medicines are not subject to a pre-market evaluation of efficacy at the time of listing. However, data supporting the indications may be requested by the TGA for review after listing of a medicine. The TGA may request copies of labelling and the results of pre-market SPF, broad-spectrum performance, water-resistance or stability testing. It is expected that this information will be available and can be provided to the TGA within a reasonable time of the request.

Information on the listing process using the TGA's Electronic Listing Facility (ELF) and details of what information needs to be provided for listed products are provided in the Application and submission user guide: Listed and assessed listed medicines.

Indications permitted for use in listed therapeutic sunscreens

Listed therapeutic sunscreens are only permitted to carry indications that are specified in the Permissible Indications Determination, which is maintained by the TGA (see Appendix 1).

In principle, indications that are considered appropriate for listed therapeutic sunscreens are those that can be applied to products that can be used safely and effectively without the intervention of a healthcare practitioner. Indications permitted for use in listed medicines can relate to diseases, disorders or conditions that are normally of a benign or self-limiting nature that the average consumer can be expected to evaluate or diagnose accurately.

However, as sunscreens are a primary preventative measure against skin cancer for all Australians, in the interests of public health, the TGA has allowed listed therapeutic sunscreens

to make higher level therapeutic claims relating to sunburn and skin cancer as provided below, even though neoplastic disease[1] is generally considered a prohibited representation under the Advertising Code.

In addition, the sunscreen must meet the requirements of the Australian Sunscreen Standard.

1. A broad spectrum sunscreen with an SPF of 30 or higher is permitted to carry the following indications:
    - 'May assist in preventing some skin cancers.'
    - 'May reduce the risk of some skin cancers.'
    - 'Can aid in the prevention of solar keratoses.'
    - 'Can aid in the prevention of sunspots.'
2. A broad spectrum sunscreen with an SPF of 4 or higher is permitted to carry the following indication:
    - 'Can aid in the prevention of premature skin ageing.'

The Act requires that, at the time of listing a medicine in the ARTG, a sponsor must certify that they hold the information or evidence to support indications and claims made in relation to their product. All indications and claims must be capable of substantiation – that is, evidence held by the sponsor must adequately demonstrate all indications and claims made for the product are true, valid and not misleading. Information to support such claims may be requested by the TGA for review. If the certification by the sponsor that it holds this information or evidence is incorrect, the TGA can cancel the listing of the product from the ARTG.

Therapeutic sunscreens that make therapeutic indications other than sunscreening (for example, reduction of free radicals in or below the skin, or claims relating to reduction of UV-induced immune suppression) and/or contain active therapeutic ingredients that are not included in the Permissible Ingredients Determination, do not fit the criteria of a listed therapeutic sunscreen product. Such products must be included in the ARTG as an OTC or prescription registered therapeutic sunscreen, depending on the active ingredients it contains and therapeutic claims made (see Registered therapeutic sunscreens subsection in this document).

Appendix 1 provides a list of indications permitted for use in listed therapeutic sunscreens at the time of publication.

Ingredients permitted for use in listed therapeutic sunscreens

Listed sunscreen products may only contain low-risk ingredients selected from the Permissible Ingredients Determination, a list of ingredients that have been approved by the TGA. Sponsors should consult the Permissible Ingredients Determination for restrictions applying to each ingredient in their product. The product's label must include the Australian Approved Name (AAN) for each active ingredient.

If your product contains an ingredient that is not on the Permissible Ingredients Determination, you will need to submit an application to have the safety and quality of the substance evaluated under its proposed conditions of use; please refer to the Applying for a new ingredient to be

[1] Paragraph 30(b)(i) of the Advertising Code defines representations that regard the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to, neoplastic disease as a prohibited representation.

used in listed therapeutic sunscreens, Safety data requirements for new ingredients for use in listed therapeutic sunscreens and Quality data requirements for new ingredients for use in listed therapeutic sunscreens sections in this document for more information on new ingredients.

Ingredients permitted for use in listed therapeutic sunscreens, that are not restricted to use in sunscreens only, may also be used in other topically applied medicines (subject to any conditions or limitations) without the need for further evaluation. However, additional data to ensure the continued safety of use may be required if the characteristics of the substance are considered to change in different formulations or patterns of use in new products, or if the substance is to be used outside the stated conditions and/or limitations. For example, if a substance has been limited for use in a particular dosage form, such as a cream/lotion, then an application to vary the Permissible Ingredients Determination would be required to provide further safety information that supports its use in an alcohol base.

Active ingredients permitted for use in listed therapeutic sunscreens

A list of active ingredients restricted for use in sunscreen products can be found in Appendix 2. In general, these will be present at significant concentrations in therapeutic sunscreens to be efficacious, and may be expected to interact with human tissues and physiological systems topically (skin, eyes and mucosal surfaces) and systemically (if they penetrate the skin and move into the systemic circulation).

Excipient ingredients permitted for use in listed therapeutic sunscreens

Only excipients approved by the TGA for use in topical medicines may be used in therapeutic sunscreens. Excipient ingredients are not generally considered to be 'inert' and may have effects on human health and safety, even though no therapeutic claims can be listed against their presence. In addition, these ingredients may sometimes make up a significant proportion of the sunscreen. Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure that the finished product is safe for its intended purpose.

If a substance with a known active function is classified as an excipient, evidence of excipient function and purpose will be required. Furthermore, a justification must be provided for the inclusion of that substance as an excipient at a concentration in excess of the concentration typically used for its role as an active ingredient. If that concentration is above the approved safety limit for use in listed products, then the product with that concentration of the substance must be registered.

The concentrations of excipients with a known active function in the formulation must be below the concentration associated with its established active function. If the excipient concentration is above the minimum threshold of active function then the substance should not be classified as an excipient in the product but, instead, should be classified as an active substance in the product and it will be evaluated as an active component of the product.

Nanoparticle ingredients in sunscreens

Nanoparticulate titanium dioxide and zinc oxide are commonly used in sunscreens; however, other ingredients may be used in nanoparticle form if they have been specifically evaluated and approved by the TGA. The labels of sunscreens are not required to declare the particle sizes of ingredients.

The TGA actively monitors local and international research on nanoparticles in sunscreens. A literature review by the TGA on the safety of titanium dioxide and zinc oxide nanoparticles in sunscreens was first published in 2006, and is regularly updated.

Applying for a new ingredient to be used in listed therapeutic sunscreens

The information below should be read in conjunction with the guidelines for the approval of new substances provided in the Applications for new substances in listed medicines: Australian regulatory guidelines and Information required in an evaluation of a substance for use in listed medicines: guidance for sponsors.

A 'Proposed name for a chemical substance (AAN) used in a therapeutic good' application form needs to be submitted to the TGA to enable the establishment of an identity and an appropriate '**Australian Approved *Name***' (AAN) for the substance. Information on the naming of substances and applying for an AAN can be found on the TGA approved terminology for therapeutic goods webpage.

There are no fees associated with AAN applications and approval of ingredient names. However, fees will apply to the evaluation of the data for the new substance and for the listing or registration of the product as specified in the TGA's Schedule of fees and charges webpage.

General requirements for new ingredients for listed therapeutic sunscreens

Sponsors wishing to market a product containing an active or excipient ingredient that is not on the Permissible Ingredients Determination (see Ingredients Permitted for use in listed therapeutic sunscreens) must submit data to establish the safety and quality of the ingredient under its proposed conditions of use. Please refer to Information required in an evaluation of a substance for use in listed medicines: guidance for sponsors for further information.

The safety data for new ingredients need to be comprehensive to ascertain both the short-term (acute) and long-term (chronic) effects on human health and safety from exposure to these ingredients. This is important, given that sunscreen products will be used by people of all ages (infants, children, adults and the elderly); genders (including women of childbearing potential); and could be readily anticipated to be used frequently (daily).

Once the substance is approved, and an AAN has been assigned, it may thereafter be able to be used in other therapeutic sunscreens without the need for further evaluation, but only up to the limit that has been approved. Sponsors wishing to increase the limit imposed by the TGA will need to submit a separate application for further safety evaluation.

Scientific guidelines for ingredient testing for listed therapeutic sunscreens

The TGA closely aligns its regulatory approaches to therapeutic products with those of comparable international regulatory counterparts wherever possible. The list of relevant guidelines that have been adopted by the TGA can be found on the TGA's International scientific guidelines adopted in Australia webpage. These guidelines are not detailed in this document because they are subject to frequent changes. Therefore, sponsors should consult the current list on the TGA website.

The EU guidelines that have been adopted by the TGA for therapeutic goods should be referred to for detailed guidance on the appropriate tests and how they should be conducted. Studies can be regarded as 'invalid' if appropriate and scientifically robust methodology is not followed (e.g. low animal numbers, lack of or inappropriate controls).

The intention in listing relevant guideline topics is not to set absolute requirements but to assist sponsors in assessing the type and depth of information needed to support an application with

the understanding that primary sunscreen products are treated as therapeutic goods in Australia as opposed to 'cosmetics' in Europe.

- Details on different safety tests for **chemicals for pharmaceutical use** can be found on the websites of the following organisations:
  - the European Medicines Agency (EMA)
  - the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
  - the Organisation for Economic Co-operation and Development Guidelines for the testing of chemicals (section 4: Health Effects).
- Details on different safety tests for **chemicals that are for cosmetic sunscreens used in Europe** can be found in the:
  - Scientific Committee on Consumer Safety's (SCCS) The SCCS notes for guidance for the testing of cosmetic ingredients and their safety evaluation 10th Revision (SCCS/1602/18.)

If a particular guideline is not applicable or other data are available that adequately address the same criteria, alternative approaches based on adequate scientific justification will be considered by the TGA during evaluation of the application, or during a pre-submission meeting. Relevant human studies are acceptable in the assessment of potential skin irritation and sensitisation using the repeat 'insult patch test' or other relevant validated tests.

Safety data requirements for new ingredients for use in listed therapeutic sunscreens

Safety data that is required for a new active or excipient ingredient for use in listed medicines, including sunscreens, are included in Table 3 below.

Required study reports must:

- be submitted in full as well as in summary form: simple summaries or synopses of studies without the full study reports are not acceptable for assessment
- be in English or be provided with an accompanying certified English translation.

Proper and comprehensive identification of the substance(s) being tested in all studies is required. The CAS number, laboratory codes, trade names and synonyms must be linked to the substance identified in the new substance application form and the 'Proposed name for a chemical substance (AAN) used in a therapeutic good' application form.

Concentrations of the new substance used in all studies must be clearly and unambiguously stated. The intended final concentration of the new substance in therapeutic goods to be marketed in Australia must be stated as this allows a comparison to establish that the submitted studies were conducted at concentrations to support the proposed levels to be used in marketed goods.

Table 3. Safety data required for new active or excipient sunscreen ingredients

Requirements	
TOXICOKINETICS	
• oral and dermal bioavailability • ADME (absorption, distribution, metabolism and excretion) studies Note: An *in vivo* determination of dermal and oral absorption is needed to establish systemic exposure via both routes and to enable interpretation of the toxicity studies.	
TOXICITY	
Acute toxicity	• Oral and dermal; animal data • This can be addressed with information obtained from repeat dose toxicity studies
Repeat dose toxicity	• Oral and dermal (at least 3 months) • Inhalation toxicity data may be required if the product is used in a spray dosage form
Genotoxicity	• *In vitro* bacterial (Ames) assay • *In vitro* mammalian cell line assay • *In vivo* chromosome aberration assay • Genotoxicity *in vitro* testing in bacterial, mammalian cell lines, and chromosome aberration assay should include a photomutagenicity arm
Carcinogenicity	• Refer to ICH guidelines • *In vivo* carcinogenicity and photocarcinogenicity bioassays or a justification for not providing these studies (see Justification for not providing particular studies to support the safety of new ingredients for use in listed therapeutic sunscreens section)
Reproductive toxicity	• For assessment of developmental and fertility effects
Local tolerance	
• Skin irritation (animal data and/or human repeat insult patch test - HRIPT) • Phototoxicity (animal and/or human data) • Eye irritation (animal *in vivo* or *in vitro* test) • Skin sensitisation (animal data and/or HRIPT) • Photosensitisation (animal and/or human data – HRIPT)	

Requirements
Interaction potential
• Since sunscreen formulations usually contain more than one active ingredient, data on the potential for interaction of the new substance with other UV filters will usually need to be provided.

Safety data requirements for new excipients for use in listed therapeutic sunscreens

Where a therapeutic sunscreen contains an excipient that is not in any product currently included in the ARTG for supply in Australia, the excipient must be assessed for use by the TGA. The following information is required as a minimum:

- acute oral toxicity study – this can be addressed with information obtained from repeat-dose toxicity studies
- skin irritation study – animal or alternative study such as HRIPT
- sensitisation study – skin, animal and/or HRIPT.

The following additional studies may be requested in individual cases where concern becomes evident at the time of evaluation:

- *in vitro* mutagenicity – for example, an Ames test or other validated alternative test
- eye irritation study – animal *in vivo* or *in vitro* test
- *in vitro* or *in vivo* percutaneous absorption test
- assurance that it does not appear in Annex II to the Regulation (EC) No. 1223/2009 list of substances that must not form part of the composition of cosmetic products
- documentary evidence that the excipient has been approved by the appropriate regulatory agency in Sweden, Canada, USA, UK or the Netherlands; or evidence that there have been marketplace sales of comparable products containing the excipient in one of those five countries for at least two years.

All of the above information should be submitted for a safety evaluation of the new substance for use in therapeutic sunscreens. Additional studies may be requested in individual cases where concerns become evident at the time of evaluation.

Justification for not providing particular studies to support the safety of new ingredients for use in listed therapeutic sunscreens

In circumstances where particular tests specified in Table 3 above are not feasible or appropriate, the sponsor should submit a justification based on sound scientific argument for not including these tests in their dossier.

In the case of *in vivo* carcinogenicity bioassays, a justification for not including long-term studies could be based around the following issues as they apply to the ingredients or product:

- the expected pattern of use
- results of *in vitro* and *in vivo* genotoxicity assays
- lack of similarity to other molecules with known carcinogenic activity

- low persistence in the skin
- low or no *in vivo* dermal absorption
- lack of photosensitisation or phototoxic potential
- proven photostability
- lack of possible adverse effects on the skin (change to epidermis/dermis)
- length of submitted *in vivo* repeat dose toxicity studies
- lack of adverse activity in local tolerance studies (skin irritation and skin sensitisation).

Related studies that may be used to support the safety of new ingredients for use in listed therapeutic sunscreens

Other studies that are not currently referenced in EU guidelines may be useful in supporting particular applications. Reference to these studies is included only as a guide. They will not be relevant in all cases, nor should they be seen as a complete list of relevant studies. Examples include the following studies and referenced websites that may be useful in providing information on the potential of a substance to cause tumours in humans:

- studies using appropriate and validated transgenic animal models to test exposure to the substance; information on transgenic models can be found on the OECD or European Centre for the Validation of Alternative Methods (ECVAM) internet sites
- *in vitro* human dermal cell cultures exposed to the substance
- *in vitro* human dermal tumour cell cultures exposed to the substance.

Additionally, the following references may be useful when investigating the use of ingredients with a potential for skin corrosion/irritation:

- Non-animal testing strategies for assessment of the skin corrosion and skin irritation potential of ingredients and finished products; M K Robinson *et al; Food and Chemical Toxicology*, 40(5), pp 573–592, 2002.
- OECD/OCDE, test number: 431 (April 2004) OECD Guidelines for the testing of chemicals; *in vitro* skin corrosion: human skin model test.

Alternative test methods accepted by the TGA for new ingredients for use in listed therapeutic sunscreens

Major advances in alternative testing methods and new validated methods have been implemented following the introduction of animal testing bans for cosmetic ingredients in Europe and Australia (see the Industrial Chemicals Act 2019). The TGA follows the EMA Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches, which describes the criteria for regulatory acceptance of an alternative testing approach. In addition, the TGA will accept validated test methods that are alternatives to animal testing methods from the following sources:

- OECD Test guidelines for the Chemicals
- The European Commission's Tracking System for Alternative methods towards Regulatory acceptance (TSAR)
- The European Commission's science and knowledge service

Alternative sources of data for listed therapeutic sunscreens

Alternative sources of data on the safety of excipient ingredients will be considered. For example, if the excipient has been assessed by AICIS, the Scientific Committee on Consumer Safety (SCCS), or the US Cosmetic Ingredient Review (CIR) group, the review document may be sufficient in itself. Copies of CIR reviews are available from the Internet site www.cir-safety.org. Copies of AICIS reviews may be available from the supplier of the excipient.

Quality data requirements for new ingredients for listed therapeutic sunscreens

Where a therapeutic sunscreen contains an ingredient (active or excipient) that is not in any product currently included in the ARTG for supply in Australia, the ingredient must be assessed for use by the TGA.

The following information is required as a minimum:

- naming and identification of an ingredient name as an Australian Approved Name (AAN) - this may be finalised while the safety data are being evaluated
- identification of the new ingredient as a substance included in the International Cosmetic Ingredient Dictionary and Handbook published by the Personal Care Products Council, available electronically as wINCI (the page number / reference should be quoted)

Photostability of active ingredients for use in listed therapeutic sunscreens

Sponsors should provide data to establish the UV absorption range of a new active ingredient to enable confirmation of its UVA/UVB absorption profile. Data addressing the potential for physical interaction with other commonly used sunscreening agents should also be provided.

Manufacture and quality control of listed therapeutic sunscreens

Manufacture of listed therapeutic sunscreens

In accordance with Part 3-3 of the Act and Part 4 of the Regulations, manufacturers of '***listed***' or '***registered***' therapeutic goods destined for the Australian market or for export from Australia to an overseas market must be licensed or approved by the TGA. These goods must also comply with manufacturing principles as determined by the Minister. These manufacturing principles are set out in the TGA's requirements for Good Manufacturing Practice (GMP). Guidance specific to sunscreen manufacturing can be found in the Sunscreen manufacturing: Demonstrating compliance with the PIC/S guide to GMP, PE0009-13.

- Where an Australian manufacturer is nominated in an application to list or register a sunscreen, that manufacturer must be licensed by the TGA to manufacture such products and must comply with the TGA's GMP requirements as relevant to sunscreens.
- Where the product is imported, each nominated overseas manufacturer is expected to comply with a code of GMP equivalent to that applying to Australian manufacturers and the TGA must have issued a GMP clearance for that manufacturer.

Further information on licensing or approval of manufacturers is available on the TGA website.

In addition, subparagraph 40(4)(a)(i) of the Act requires the manufacturer to ensure that the product complies with any standard applicable to the product. It is the responsibility of the finished medicinal product manufacturer to hold evidence that ingredients (active and

excipient) used in a product meet the requirements of a default standard, or the established specification as stated in the Release for supply of medicines guidance document.

Quality control – manufacturing of listed therapeutic sunscreens

All sunscreen products released on the Australian market must be manufactured according to the principles of GMP as described in the Sunscreen manufacturing: Demonstrating compliance with the PIC/S guide to GMP, PE 009-13. This document states that all sunscreen products released on the Australian market must be manufactured by pre-approved manufacturers who are responsible for meeting the necessary requirements associated with the raw materials, ingredients and manufacturing process.

Default standards for listed therapeutic sunscreens

Pharmacopoeial Standards

In accordance with the definitions in section 3 of the Act, the default standards applying to therapeutic goods registered or listed in the ARTG include the:

- British Pharmacopoeia (BP)
- European Pharmacopoeia (Ph Eur)
- United States Pharmacopeia-National Formulary (USP-NF).

Non-pharmacopoeial Standards

Other standards that apply to sunscreens include relevant Therapeutic Goods Orders made under section 10 of the Act such as the most current:

- Labelling Order
- Order for Microbiological Standards for medicines

Finished products specifications for listed therapeutic sunscreens

Pharmacopoeial Standards

If there is a monograph for a finished product in one (or more) of the BP, Ph Eur or USP-NF, the sponsor must ensure that the product will comply with the specifications in that monograph (or at least one of those monographs).

Finished sunscreen products that are not the subject of a monograph in the BP, Ph Eur or USP-NF must be controlled by appropriate 'in-house' quality control specifications that control and ensure their identity and relevant physical, chemical and microbiological properties. Test methods must be validated, as appropriate.

Non-pharmacopoeial Standards

Therapeutic sunscreen products in all categories are required to comply with the most current order describing Microbiological Standards for medicines, particularly with regard to the sections regarding the efficacy of antimicrobial preservation of a multidose medicine and microbiological attributes of a non-sterile medicine.

Sunscreen manufacturers are also responsible for ensuring that batches of product released to the market comply with their specifications.

Ingredients specifications for listed therapeutic sunscreens

Pharmacopoeial Standards

Subsection 13(5) of the Act requires that when a finished product is not the subject of a monograph in a default standard, but any of its ingredients is, that ingredient must comply with at least one of the monographs concerned, unless the Minister has issued an order determining that this requirement does not apply to the goods concerned. Note that as at the date these Guidelines were published, no such order exempting sunscreens had been issued by the Minister.

- Many of the organic chemicals used as active ingredients in sunscreens are the subjects of monographs in the USP-NF [generally under their International Non-proprietary Names (INNs)], while the inorganic substances titanium dioxide and zinc oxide are the subject of monographs in each of the BP, Ph Eur and USP-NF.
- Many of the excipients (including solvents) used in sunscreen products are the subjects of monographs in one or more of the BP, Ph Eur and USP-NF.
- Ingredients that are not the subject of a monograph in the BP, Ph Eur or USP-NF must be controlled by appropriate quality control specifications that control and ensure their identity, relevant physical and chemical properties, and purity. Test methods must be validated, as appropriate.

Reproducibility of SPF test results for listed therapeutic sunscreens

The SPF of therapeutic sunscreens must be determined by testing on human skin in accordance with the Australian Sunscreen Standard, which references the International Organisation for Standardisation procedure *ISO 24444 Cosmetics – Sun Protection test methods – In vivo determination of SPF (Sun Protection Factor)* as referenced in the Australian Sunscreen Standard.

In vivo SPF testing protocol for listed therapeutic sunscreens

The *in vivo* testing of the SPF of a sunscreen product according to the procedure in *ISO 24444* referenced in the Australian Sunscreen Standard produces a reasonable estimate, but not a highly accurate and precise measure, of the true SPF of the product applied to the skin at a rate of 2 mg/cm^2. The test data exhibit a considerable inherent variance, which need to be taken into account when interpreting the test results and labelling of the product, and also need to be taken into account when interpreting the results of any subsequent retesting of the product.

Validity of *in vivo* SPF testing results for listed therapeutic sunscreens

The SPF test is considered valid if the 95% CI fits within ±17% of the mean. If this criterion is not met:

- The product must be tested on further subjects (up to a maximum of 20) until the 95% CI based on the data for all subjects fits within ±17% of the mean.
- If testing on 20 subjects does not bring the 95% CI within ±17% of the mean the whole test must be rejected.
- In practice, the use of more than 10 subjects would be necessary only if the coefficient of variation (CV = s/m) is greater than 24%, and testing on 20 subjects would only fail if the CV was greater than 37%.

Statistical analysis of the SPF test data submitted to the TGA over recent years in support of SPF claims made for a large range of sunscreen products has shown that the data typically exhibit a

relative standard deviation (RSD) or coefficient of variation (CV) in the range of 5–20%. Only rarely is the CV less than 5% or greater than 20%.

In the majority of cases, testing on 10 subjects would yield a 95% CI well within the ±17% limits and testing on additional subjects would not be required.

Retesting listed therapeutic sunscreens

Subsequent retesting of a sunscreen is likely to yield a mean SPF anywhere within the 95% CI from the original testing of the product or even a few SPF units beyond either end of that 95% CI.

- If the original test result is close to the lower limit for a particular SPF claim allowed by the Australian Sunscreen Standard, the retest result could be lower than that lower limit and appear to cast doubt on the validity of the labelled SPF claim.
- However, it would be necessary to retest the product several times and obtain consistently low mean results before any conclusion could be drawn about the labelled SPF being unjustified.

Stability testing of listed therapeutic sunscreens

Stability test requirements for listed therapeutic sunscreens

Therapeutic sunscreens marketed in Australia must be labelled with an '***expiry***' or '***use-by***' date. This must be supported by:

- experimental data supporting the shelf life of the sunscreen product in the container intended for marketing (or at least a container made of the same materials and with similar shape, size and wall thickness to that of the market container) under the recommended storage conditions:
  - '***Store below 25°C***' for products to be stored in air-conditioned premise
  - '***Store below 30°C***' for products to be stored at room temperature.
- The data must substantiate the physical, chemical and microbiological stability of the product for at least the claimed shelf life.

Sponsors of all therapeutic sunscreen products are expected to have performed stability testing on each product to at least the standard set out in these Guidelines.

- The claimed shelf life and storage conditions for each product should be derived from the results of the stability testing on that product.
- Generation of adequate stability data to support the assigned shelf life for a therapeutic sunscreen is the responsibility of the sponsor.

- The stability data supporting the shelf life of a sunscreen product are not required to be submitted to the TGA at the time of listing. However, the data may be requested for review by the TGA at any time.

- Sponsors should, therefore, ensure that the data are available in a form suitable for submission to the TGA if and when requested.

The TGA follows the EMA/ CPMP/ ICH guidelines, which provides direction on the design and conducting of stability studies:

- ICH Q1A (R2) Stability Testing Guidelines: Stability Testing of New Drug substances and Products (CPMP/ICH/2736/99)
- Guideline on Stability Testing: Stability Testing of Existing Active substances and Related Finished Products (CPMP/QWP/122/02 Rev 1)
- ICH Q1E Note for Guidance on Evaluation of Stability Data (CPMP/ICH/420/02)
- ICH Q1B Photostability Testing of New Drug substances and Medicinal Products (CPMP/ICH/279/95).

Establishing stability before market approval for listed therapeutic sunscreens

The shelf life of a sunscreen product must be established with real-time testing for the whole of the required shelf life or with adequate certainty before it can receive market approval and be included in the ARTG. This can be achieved by:

- accelerated testing for 6-9 months at 10°C or 15°C above the stated maximum storage temperature (see Table 4)
- providing a justification based on supporting stability data generated for a closely related formulation.

Table 4 shows the shelf life prediction of a sunscreen product from short-term testing.

Table 4. Shelf life prediction from short-term testing of listed therapeutic sunscreens at elevated temperatures

Temperature above labelled storage conditions	Time period	Test time points (months)	Possible shelf life prediction
+10°C	6 months	0, (1 or 2), (3 or 4), 6	2 years
+10°C	9 months	0, (1 or 2), (3 or 4), (5 or 6), 9	3 years
+15°C	6 months	0, (1 or 2), (3 or 4), 6	3 years

Stability testing should be carried out using at least two batches of the formulation intended for marketing that have been manufactured in a manner that closely mirrors the production-scale manufacturing process.

- The batches tested in stability studies may be pilot-scale.
- Pilot-scale batches should be manufactured in a manner sufficiently similar to that of commercial production-scale batches to ensure that they adequately reflect the properties of the product intended for the market.

A formulation that is very similar, but not identical, to that intended for marketing formulation may be used provided any differences are:

- very minor
- unlikely to affect the physical, chemical or microbiological stability of the product
- unlikely to affect the in-use performance of the product.

Confirming stability and shelf life for listed therapeutic sunscreens

If the shelf life assigned at the time of listing in the ARTG is based on data generated using pilot-scale batches and accelerated studies, the sponsor will need to:

- confirm the shelf life using real-time studies that encompass the whole of that shelf life using at least two production-scale batches stored at the maximum recommended storage temperature
- test the production-scale batches initially at manufacture and then annually until the end of the shelf life.

Stability protocol requirements for listed therapeutic sunscreens

The storage temperature used in stability studies should be controlled, monitored and logged to ensure the integrity of the results. Other parameters are described below.

Physical testing of listed therapeutic sunscreens

Physical testing should include at least the following quality parameters:

- appearance
- emulsion stability
- absence of crystallisation
- odour
- viscosity
- compatibility with the immediate container
- the condition of the inside surface of the container in contact with the product.

Chemical testing of listed therapeutic sunscreens

Chemical stability testing should include:

- pH (if water is the continuous phase)
- the content of each of the active ingredients assayed using a validated, stability-indicating analytical procedure (e.g. HPLC).
  - Active ingredients should remain within the limits 90% to 120% of label claim.
  - Overages of active ingredients in the formulation are acceptable provided they do not result in concentrations exceeding the limits provided in the Permissible Ingredients Determination.

Microbiological stability testing of listed therapeutic sunscreens

For water-containing sunscreens, microbiological stability should be confirmed by means of preservative efficacy testing at the start and end of accelerated stability testing and at the end of the shelf life during the subsequent real-time stability testing. It may be useful to monitor chemical stability of preservatives during stability using a stability-indicating validated method.

Accelerated studies of listed therapeutic sunscreens

The frequency of testing for accelerated studies should be adequate to allow regression and statistical analysis to support extrapolation of the data using a minimum of four data points

- Appropriate testing time points are typically 0, (1 or 2), (3 or 4), (5 or 6), 9 and 12 months. This can be followed by further testing at 24 and 30 months, depending on the length of the shelf life that needs to be justified.

The accelerated stability data should only be extrapolated as described in the Shelf life determination for listed therapeutic sunscreens subsection if their accuracy, reproducibility and fit around a straight time-line are adequate.

- A minimum of 4 time-points with a reasonably even spread over the time period concerned are needed for meaningful line-fitting and 95% CI calculations.

Shelf life determination for listed therapeutic sunscreens

Generally, the maximum shelf life permitted for any therapeutic good is 5 years.

The stability data that is required to support the shelf life of a product with no discernible changes or trends is dependent on the labelled storage conditions.

- Products labelled with storage conditions ***'store below 30°C'*** (i.e. storage at room temperature in Australia) require stability data covering:
  - 6 months storage at 40°C to support a 2-year shelf life
  - either 9 months at 40°C *or* 6 months at 45°C to support a 3-year shelf life
  - data from storage at 40°C covering at least half of the shelf life to support a shelf life greater than 3 years (e.g. 2.5 years accelerated data would be required to support a 5-year shelf life).
- Products labelled with storage conditions ***'store below 25°C'*** (i.e. the product should be stored in air-conditioned premises) require stability data covering:
  - 6 months storage at 35°C to support a 2-year shelf life
  - either 9 months at 35°C *or* 6 months at 40°C to support a 3-year shelf life
  - data from storage at 35°C covering at least half of the shelf life to support a shelf life greater than 3 years.

Changing the ARTG entry of listed therapeutic sunscreens

Details of the requirements and procedures for making changes to the ARTG record of listed therapeutic goods, including sunscreens, are provided in the Changing a listed or assessed listed medicine: application levels and change tables document. Note that some changes may be made through a grouping application, which will not require a change to the AUST L number.

Changes to active ingredients in listed therapeutic sunscreens

The addition to or deletion of an active ingredient to a product, or a change to the quantity of such an ingredient, creates a new therapeutic good. Such changes require the sponsor to submit an application for a new entry in the ARTG. Please refer to subsection 16(1A) of the Act and regulation 11 of the Regulations. If the application is successful, a new AUST L or AUST R number will be assigned to the new product.

Changes to excipient ingredients in listed therapeutic sunscreens

The identities of excipient ingredients in a sunscreen product and the quantities of 'restricted ingredients' are required to be included in the ARTG record for the product.

Deletion or addition of excipient ingredients for listed therapeutic sunscreens

Deletion or addition of excipients in a therapeutic sunscreen (other than the permanent removal or addition of a fragrance or colouring agent) creates a new therapeutic good. Such changes require the sponsor to submit an application for a new entry in the ARTG. If the application is successful, a new AUST L or AUST R number will be assigned to the new product.

Deletion or addition of fragrance or colour for listed therapeutic sunscreens

If the excipient to be added or removed is a fragrance or colouring agent then, notwithstanding that a new therapeutic good is created, the new product can retain the same AUST L or AUST R number under the *Therapeutic Goods (Groups) Order No. 1 of 2001* (the Grouping Order) provided the new formulation is intended to replace the existing formulation. However, an electronic application must be submitted to change the formulation recorded in the ARTG.

Quantities of excipient ingredients in listed therapeutic sunscreens

Quantities of excipients other than restricted excipients are not required to be included in the ARTG record for listed sunscreens.

Where a change is to be made to the quantity of a restricted excipient and grouping applies in accordance with the Grouping Order subsection 5.1(a)(i) and (ii) and (b), an electronic application must be lodged to change the formulation details recorded in the ARTG. When grouping does not apply, such a change will require a new product application and a new AUST L or AUST R number will be issued.

Changes that may affect SPF properties of listed therapeutic sunscreens

Sponsors should recognise that the SPF and other physical properties of a sunscreen are affected not only by the active ingredients, but also by the base. Therefore, qualitative or quantitative changes in the excipients may adversely affect the SPF. Testing of a changed formulation to confirm its SPF or stability may be required if the changes are likely to affect the emulsion properties or the adhesion of the product to the skin in a way that could alter its sun protection properties.

Other changes to listed therapeutic sunscreens

Changes to the ARTG details of a sunscreen product must be approved by or notified to the TGA (using the ELF system in the case of a listed sunscreen). Whether or not grouping applies, a change to the product name requires approval.

Glossary of terms and abbreviations

Note: Where relevant, references to particular definitions are provided in brackets (…)

Active ingredient (in relation to a sunscreen) means an active substance included in a sunscreen to protect the skin from ultraviolet (UV) radiation. It is an ingredient in a therapeutic good's formulation that is responsible for its physiological or pharmacological action (see regulation 2 of the Regulations).

AICIS means the Australian Industrial Chemicals Introduction Scheme

ARTG means the Australian Register of Therapeutic Goods

Australian Approved Name (AAN) means the approved name applied to a therapeutic substance, as outlined in the TGA approved terminology for therapeutic goods, which includes: Approved biological names (ABNs); Approved cell and tissue names (ACNs); Approved names for herbal ingredients (AHNs); and Approved herbal substance names (AHSs).

Australian Sunscreen Standard means The Australian/New Zealand Sunscreen Standard (AS/NZS) 2604 Sunscreen products —Evaluation and classification [as referenced in the *Therapeutic Goods Regulations 1990* and in the Therapeutic Goods (Excluded Goods) Determination 2018]

Broad spectrum product means a sunscreen product which has been shown, using the *in vitro* test method defined in the Australian Sunscreen Standard to provide protection from the sun's terrestrial UVA and UVB rays.

Category description means the designation of the level of protection given by a grouping of label sun protection factors (see the Australian Sunscreen Standard).

Container (in relation to therapeutic goods) means the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion (see subsection 3(1) of the Act).

Cosmetic means:

a. a substance or preparation intended for placement in contact with any external part of the human body, including the mucous membranes of the oral cavity and the teeth, with a view to: altering the odours of the body; changing its appearance; cleansing it; maintaining it in good condition; perfuming it; or protecting it.

b. A substance or preparation prescribed by the rules for the purposes of this paragraph, but does not include:

   i. a therapeutic good within the meaning of the *Therapeutic Goods Act 1989*; or

   ii. A substance of preparation prescribed by the rules for the purposes of this paragraph.

   Noting that an ingredient or component of a cosmetic could be an industrial chemical (see section 9 of the *Industrial Chemicals Act 2019*; definition accessed 26 February 2021).

ELF means Electronic Listing Facility.

Excipient ingredient (in relation to a sunscreen) means an ingredient of a sunscreen other than an active ingredient. Excipient ingredients may have multiple uses such as fragrance, preservative and/or solvent.

Excluded sunscreen means a sunscreen product that is excluded from regulation under the *Therapeutic Goods Act 1989* by virtue of the Therapeutic Goods (Excluded Goods) Determination 2018.

Exempt sunscreen means a sunscreen product that is regulated under the *Therapeutic Goods Act 1989* but is not required to be registered or listed in the ARTG (see Item 8 of Schedule 5 of the Regulations).

Fragrance (or perfume) means a substance with a primary purpose to alter the smell of a therapeutic good.

GMP means Good manufacturing practice.

Ingredients of human or animal origin are those derived directly from a human or animal source. These are also listed in Item 8, Schedule 5 of the Regulations.

INN means International Non-proprietary Name.

Label means a display of printed information upon, or securely affixed to, the container, any intermediate packaging and any primary pack containing the medicine (see section 6 of the TGO 92).

Label Sun Protection Factor (SPF) means the SPF indicated on the label.

Listing number means the combination of numbers and letters that are required to be included on the label of therapeutic goods in a manner described in regulation 15 of the Regulations (see section 6 of the TGO 92)

Main label means:

a. where there are two or more labels or two or more portions of a single label — that label or portion of the label where the name of the medicine is more or most conspicuously shown; or

b. where the name of the medicine is equally conspicuous on two or more labels or portions of a label — each label or portion (see section 6 of the TGO 92).

Medicine means therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human (see subsection 3(1) of the Act).

Minimal Erythemal Dose (MED) means the lowest dose of ultraviolet radiation that produces the first perceivable unambiguous erythema with defined borders appearing over most of the field of UV exposure 16-24 hours after UV exposure (the Australian Sunscreen Standard).

New substance is an ingredient (chemical, herbal or biological) that is currently not used in a medicine for supply in Australia, or is proposed for a new route of administration to the previous use of the ingredient. This ingredient may or may not have an Australian Approved Name.

NICNAS means the National Industrial Chemicals Notification and Assessment Scheme.

Primary pack, in relation to therapeutic goods, means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers (see subsection 3(1) of the Act).

Primary sunscreen product means a product which is represented as being primarily to protect the skin from ultraviolet radiation (the Australian Sunscreen Standard).

Registration number means the combination of numbers and letters that is required to be included on the label of medicines in a manner described in regulation 15 of the Regulations (see section 6 of the TGO 92).

Secondary sunscreen product means a product that is represented as having a primary purpose other than sun protection whilst providing some protection of the skin from ultraviolet radiation *(the* Australian Sunscreen Standard).

Sun Protection Factor (SPF) means the arithmetic mean of all valid individual SPF values obtained from all subjects in the test (the Australian Sunscreen Standard). See also, Minimal Erythemal Dose (MED).

TGO 92 means the Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines.

The Act means the *Therapeutic Goods Act 1989*.

The Advertising Code means the most current Therapeutic Goods Advertising Code

The Labelling Order means the most current Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines

The Regulations means the *Therapeutic Goods Regulations 1990*.

Therapeutic goods means goods that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use or for use as an ingredient or component in the manufacture of therapeutic goods (see subsection 3(1) of the Act).

Therapeutic sunscreen means a primary or secondary sunscreen product that meets the definition of a therapeutic good rather than the definition of a cosmetic.

Therapeutic use means use in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or influencing, inhibiting or modifying a physiological process in persons (see subsection 3(1) of the Act).

Topical (for sunscreen use) means applied to a certain area of the skin for a localised effect.

Ultraviolet radiation (UV) means the terrestrial solar ultraviolet radiation in the range 290–400 nm. Ultraviolet radiation A (UVA) is the terrestrial solar ultraviolet radiation in the range 320–400 nm and ultraviolet radiation B (UVB) is the terrestrial solar ultraviolet radiation in the range 290–320 nm.

UV filter, for the purposes of these Guidelines, means a substance that is exclusively or mainly intended to protect the skin against certain UV radiation by absorption, reflection or scattering of UV radiation.

Water resistant, for the purposes of these Guidelines, means a sunscreen product which has been shown after designated periods of water immersion, using in vivo Sun Protection Factor test methods to provide protection against certain of the sun's UV rays (the Australian Sunscreen Standard)

Appendix 1: Indications permitted for use in listed therapeutic sunscreens

Indications permitted for use in listed therapeutic sunscreens at the time of publication are listed in Table 1.

Please note: Table 1 includes only those indications that were included in the Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021. It is the sponsor's responsibility to check the current Permissible Indications Determination to ensure that ingredient information is correct.

Table 1. Indications permitted for use with listed therapeutic sunscreens (as included in the Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021).

Indication	Requirement
Can aid in the prevention of premature skin ageing (sunscreen)	Indication for use in sunscreen products only.
Can aid in the prevention of solar keratosis (sunscreen)	Indication can only be used for sunscreen products with an SPF rating of 30 or higher.
Can aid in the prevention of sunspots (sunscreen)	Indication can only be used for sunscreen products with an SPF rating of 30 or higher.
May assist in preventing some skin cancers (sunscreen)	Indication can only be used for sunscreen products with an SPF rating of 30 or higher.
May reduce the risk of some skin cancers (sunscreen)	Indication can only be used for sunscreen products with an SPF rating of 30 or higher.
SPF 4 Broad spectrum low protection sunscreen	Indication for use in sunscreen products only.
SPF 6 Broad spectrum low protection sunscreen	Indication for use in sunscreen products only.
SPF 8 Broad spectrum low protection sunscreen	Indication for use in sunscreen products only.
SPF 10 Broad spectrum low protection sunscreen	Indication for use in sunscreen products only.
SPF 15 Broad spectrum medium/moderate protection sunscreen	Indication for use in sunscreen products only.
SPF 20 Broad spectrum medium/moderate protection sunscreen	Indication for use in sunscreen products only.

Indication	Requirement
SPF 25 Broad spectrum medium/moderate protection sunscreen	Indication for use in sunscreen products only.
SPF 30 Broad spectrum high protection sunscreen	Indication for use in sunscreen products only.
SPF 40 Broad spectrum high protection sunscreen	Indication for use in sunscreen products only.
SPF 50 Broad spectrum high protection sunscreen	Indication for use in sunscreen products only.
SPF 50 PLUS Broad spectrum very high protection sunscreen	Indication for use in sunscreen products only.

Appendix 2: Active ingredients restricted to use in therapeutic sunscreens

A. Searching the TGA ingredient database

Active ingredients restricted for use in therapeutic sunscreens can be found by searching the TGA ingredient database. This ingredient database is an electronic repository of approved ingredient names for therapeutic substances, and includes the requirements specified for each ingredient in the Permissible Ingredients Determination. The ingredient database also provides additional information for ingredients that is not in the Permissible Ingredients Determination, and allows for searching using:

- CAS numbers (where available); and
- ingredients that are in the Permissible Ingredients Determination, by entering the term 'Listed' and selecting the field 'Listed' (see Figure 1).

Figure 1 - The TGA ingredients database is a public tool to search for ingredients available for selection in therapeutic goods applications. Searches may be performed on CAS Number, or whether they are available for listed medicines (by typing "Listed" and selecting Listed in the dropdown).

From here, the list of ingredients can be exported in excel, xml and HTML formats. At present, restrictions are not visible in the search results table or exported results; however, they can instead be viewed by clicking on the ingredient summary hyperlink in the ingredients database search results (see Figure 2).

Figure 2 – Click on hyperlinks to view restrictions for individual ingredients in the TGA ingredients database.

B. Active ingredients currently restricted for use in therapeutic sunscreens

Active ingredients currently restricted for use in therapeutic sunscreens at the time of publication are listed in Table 1.

Please note: Table 1 includes only those active ingredients that were included in the Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2021. This Determination is updated regularly; therefore, it is the sponsor's responsibility to check the current Permissible Ingredients Determination to ensure that ingredient information is correct.

Table 1. Active ingredients restricted for use in therapeutic sunscreens (as included in the Therapeutic Goods (Permissible Ingredients) Determination [No. 1] 2021)

Australian Approved Name (AAN)	CAS Number	Synonyms	Maximum concentration
aminobenzoic acid	150-13-0	PABA para-aminobenzoic acid	15%
bemotrizinol	187393-00-6	bemotrizinolum	10%
benzylidene camphor sulfonic acid	56039-58-8	alpha-(2-oxoborn-3-ylidene)toluene-4-sulphonic acid	6% (as acid)
butyl methoxydibenzoylmethane	70356-09-1	BMDM 4-tert-butyl-4'-methoxy dibenzoylmethane avobenzone	5%
camphor benzalkonium methosulfate	52793-97-2	N,N,N-Trimethyl-4-(oxoborn-3-ylidenemethyl)anilinium methyl sulfate camphor benzalkonium sulfate	6%
cinoxate	104-28-9	2-ethoxyethyl para-methoxycinnamate cinoxate anhydrous	6%
diethylamino hydroxybenzoyl hexyl benzoate	302776-68-7		10%
dioxybenzone	131-53-3	benzophenone 8	3%

Australian Approved Name (AAN)	CAS Number	Synonyms	Maximum concentration
disodium phenyl dibenzimidazole tetrasulfonate	180898-37-7	1H-benzimidazole-4,6-disulfonic acid, 2,2'-(1,4-phenylene)bis-, disodium salt bisimidazylate	10%
drometrizole trisiloxane	155633-54-8		10%
ecamsule	90457-82-2	terephthalylidene dicamphor sulfonic acid	10%
ethylhexyl triazone	88122-99-0	octyl triazone	5%
homosalate	118-56-9	homomethyl salicylate	15%
isoamyl methoxycinnamate	71617-10-2	amiloxate isopentenyl-4-methoxycinnamate	10%
menthyl anthranilate	134-09-8	menthyl 2-aminobenzoate 5-methyl-2-(1-methylethyl) cyclohexanol-2-aminobenzoate meradimate anthranilic acid, p-menth-3-yl Ester cyclohexanol, 5-Methyl-2-(1-Methylethyl)-,2-Aminobenzoate menthol anthranilate menthyl o-aminobenzoate	5%
4-methylbenzylidene camphor	36861-47-9	3-(4-methylbenzylidene)-dl-camphor enzacamene neo heliopan 1,7,7-trimethyl-3-[(4-methylphenyl)-methylene]bicyclo[2.2.1]heptan-2-one	4%
methylene bis-benzotriazolyl tetramethylbutylphenol	103597-45-1		10%
octyl methoxycinnamate	5466-77-3	ethylhexyl methoxycinnamate octinoxate	10%
octyl salicylate	118-60-5	ethylhexyl salicylate 2-ethylhexyl salicylate octisalate	5%

Australian Approved Name (AAN)	CAS Number	Synonyms	Maximum concentration
octocrylene	6197-30-4	2-ethylhexyl-2-cyano-3,3 diphenylacrylate	10%
oxybenzone	131-57-7	benzophenone 3	10%
padimate O	21245-02-3	ethylhexyl dimethyl PABA 4-(dimethylamino)benzoic acid 2-ethylhexyl ester	8%
PEG-25 PABA	113010-52-9	ethoxylated ethyl 4-aminobenzoate	4%
phenylbenzimidazole sulfonic acid	27503-81-7	2-phenylbenzimidazole-5-sulfonic acid 2-phenyl-5-sulfobenzimidazole ensulizole	4%
polysilicone-15	207574-74-1	diethylmalonylbenzylidene oxypropene dimethicone dimethicodiethylbenzalmalonate diethylbezylidene malonate dimethicone	10%
sulisobenzone	4065-45-6	benzophenone 4	10%
sulisobenzone sodium	6628-37-1	benzophenone 5	10%
titanium dioxide	13463-67-7	E171 titanium dioxide anhydrous	25%
tris-biphenyl triazine	31274-51-8		10%
trolamine salicylate	2174-16-5	triethanolamine salicylate TEA-salicylate	12%
zinc oxide	1314-13-2	pigment white 4	N/A

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Office of Medicines Authorisation	10/10/2012
V1.1	Updated to reflect the changes to the *Therapeutic Goods Regulations 1990* by removing references to sunscreens with a claimed SPF of <4 that contain certain human or animal derived ingredients. Updated the relevant sections by including reference to the recently made Therapeutic Goods (Permissible Ingredients) Determination No.1 of 2015. Updated the table listing the permitted active ingredients by adding the newly approved sunscreen active Tris-biphenyl triazine	Complementary & OTC Medicines Branch – OTC Medicines Evaluation	22/01/2016
V1.2	Updated to remove Table 3 – Permitted active ingredients for therapeutic sunscreens and replace with links to the Therapeutic Goods (Permissible Ingredients) Determination	Complementary and Over the Counter Medicines Branch	30/8/2019
V2	Restructured into Parts A and Part B. Removed Australian Sunscreen Standard specific reference and outdated information. New table with Sunscreen SPF categories. Clarification of sunscreen regulatory categories. New information on indications permitted for use in listed medicines. New subsection on adverse reactions. Removed Bibliography and instead provided hyperlinks in document. Updated Glossary. New information on EMA guidelines. Changed NICNAS to AICIS. New subsection on alternative test methods. Removed reference to RASML. New information on searching the ingredient database. Reinstated the table of active ingredients. Updated links to legislation and guidelines: e.g. Therapeutic Goods Orders; Advertising Code; Excluded Goods Determination, ELF user guide. Removed reference to the Cosmetics Standards and the NICNAS Cosmetic Guidelines. Included links to the *Industrial Chemicals Act 2019* and the Consumer Goods (Cosmetics) Information Standard 2020.	Complementary and Over the Counter Medicines Branch	July 2021

Version	Description of change	Author	Effective date
	Updated EEC Directive reference. Updated the SCCS's Note for Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation to the 10th Revision. Removed duplicative information: definitions, labelling information; labelling checklist. Provided links to: pharmacovigilance website, GMP requirements and guidance; TGA approved terminology, schedule of fees and charges		

Therapeutic Goods Administration

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https://www.tga.gov.au

Reference/Publication # D20-650852

Australian Government
Department of Health
Therapeutic Goods Administration

Complementary and OTC Medicines Regulatory & Technical Forum (ComTech)

Record of outcomes

Meeting 8 – 13 October 2021

Contents

External Participants

Participant	Organisation
s22	

TGA Participants

Name	Position	Item
Cheryl McRae (Chair)	Assistant Secretary, Complementary and OTC Medicines Branch (COMB)	
s22		Items 2.1,2.11
		Item 2.5, 2.10
		Items 2.8, 2.9
		Items 2.2, 2.4, 2.6, 2.7
		Items 2.1
		Item 2.5
		Item 2.12

Item 1 Administrative items

s22 [redacted]

s22 [redacted]

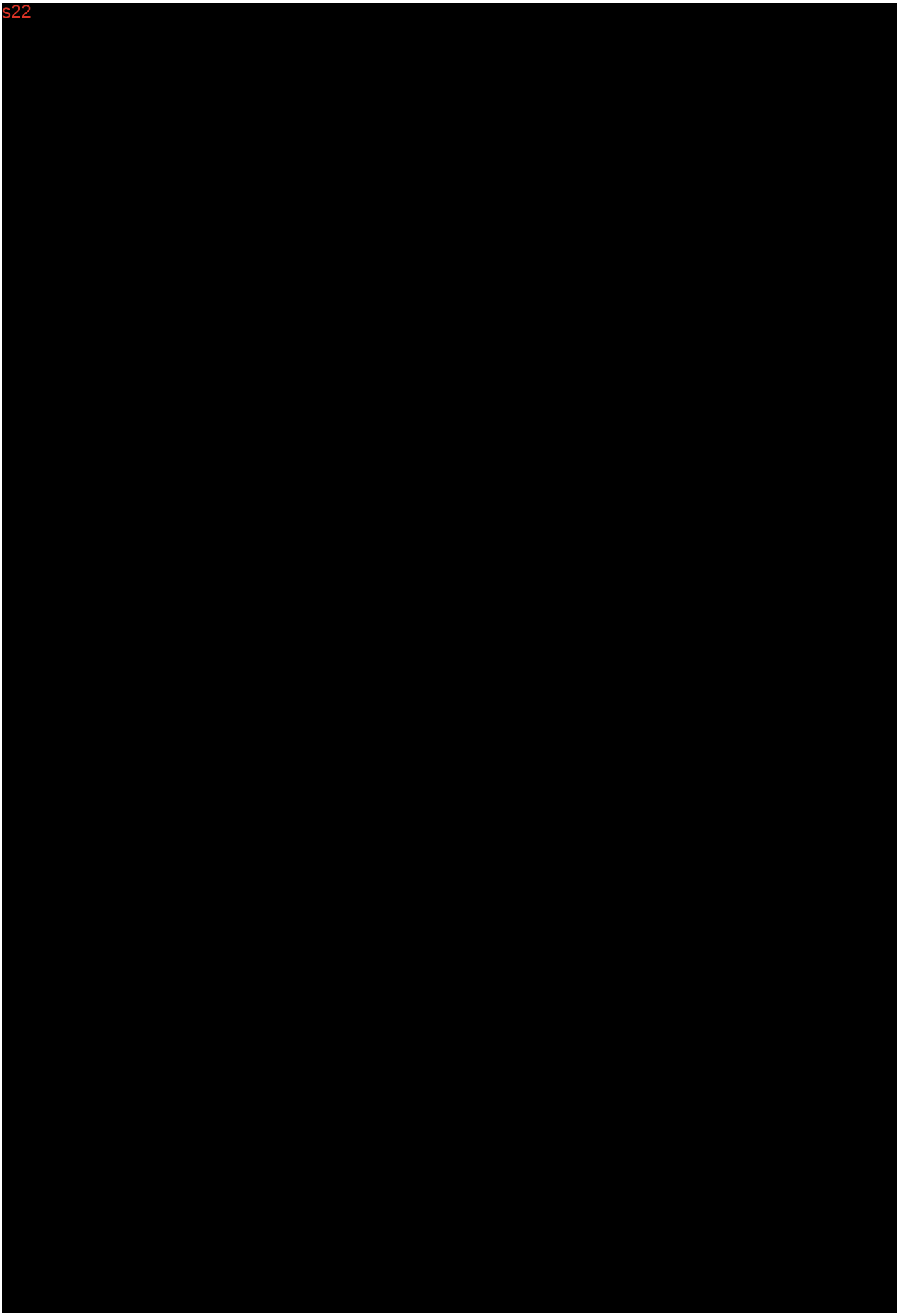
1.3 2021 Consultations

s22 [redacted]

Item 2 New Business

s22 [redacted]

s22



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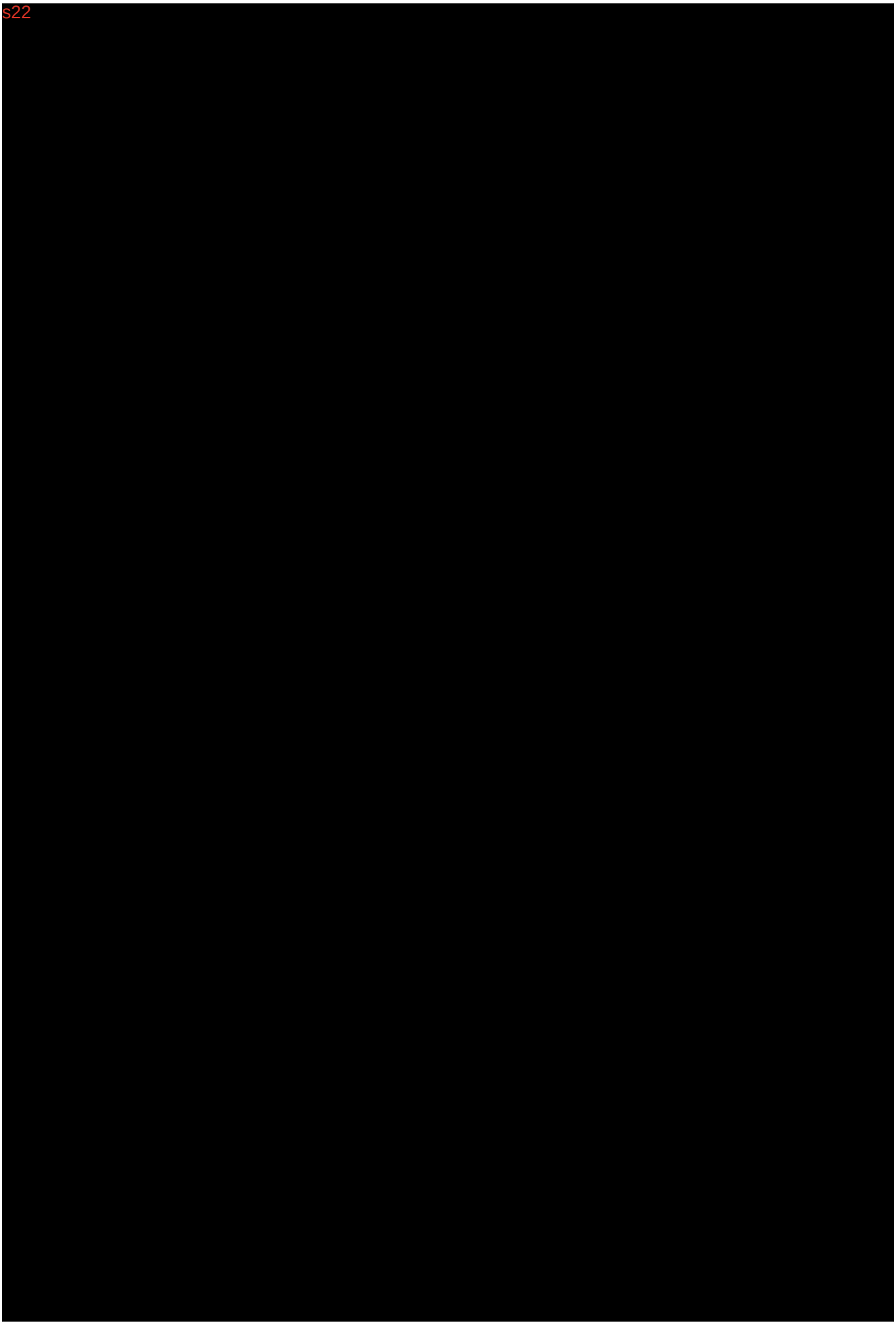

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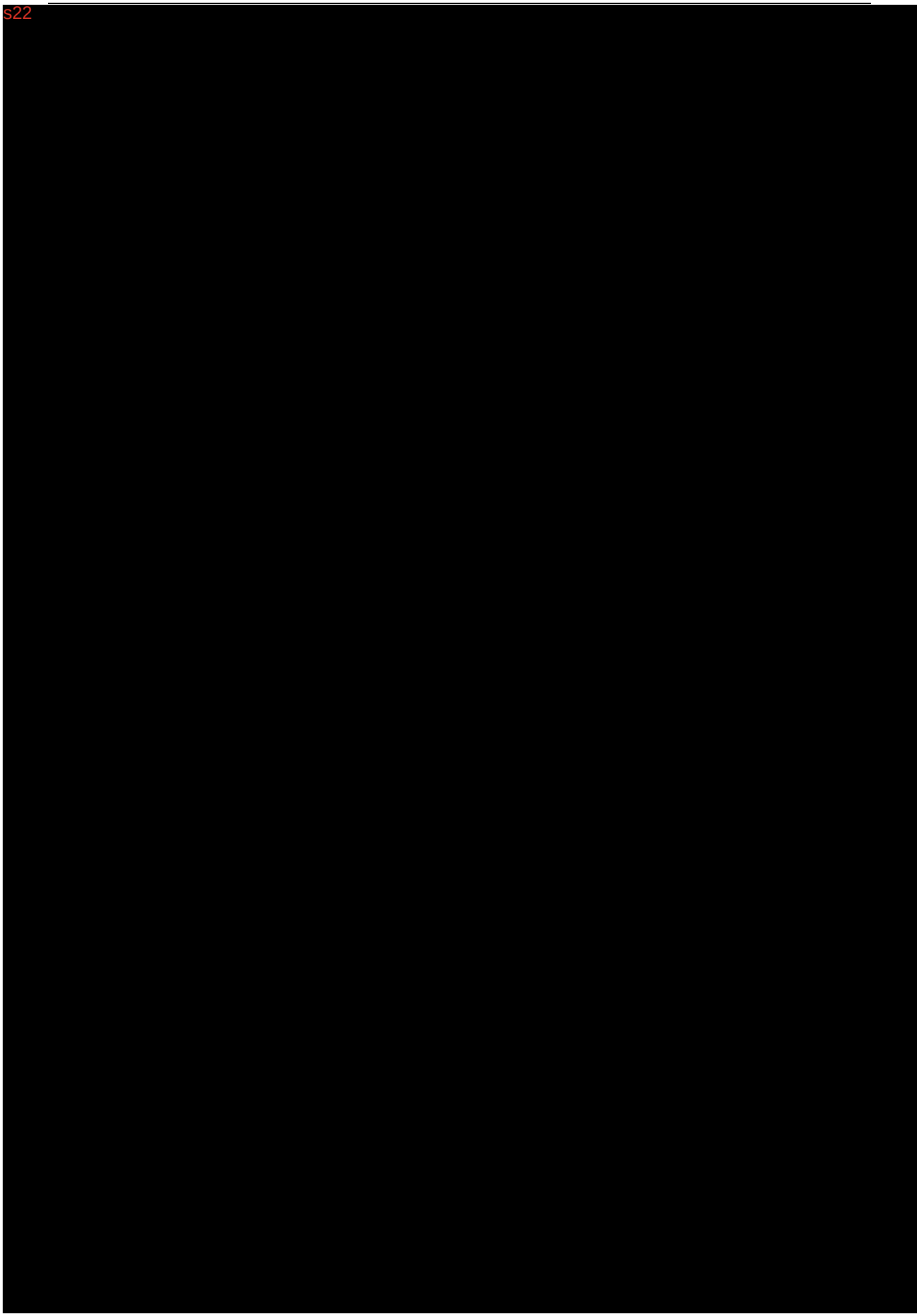

2.7 Australian Regulatory Guidelines for Sunscreens – next steps

The TGA is required to adopt the new AU/NZ sunscreen standard into our legislation for the requirements of the standard to have legal effect. While only recently published, the AU/NZ Sunscreen standard is scheduled to be republished to include the new ISO standard. The TGA advised that it will wait for the final version of the standard to be published before adopting it into our legislation s47 [redacted]

The TGA advised that, when the new standard is published, we will conduct an industry consultation to adopt it into TGA legislation. At this time, consideration will be given to providing a reasonable transition period for products to comply with the new standard. The Chair stressed that the transition period would not be indefinite i.e. there will be no provision for 'grandfathered' sunscreen products.

The TGA advised that it is also aware of other issues in relation to sunscreens which we are monitoring, e.g. FDA work on GRAS ingredients.

s22 [redacted]

s22 [redacted]

2.10 Next steps in relation to the QUT report about efficacy of aerosol sunscreens

TGA is reviewing a report from Queensland University of Technology (QUT) on the delivery of sunscreens via aerosol sprays. The QUT findings are consistent with consumer complaints to the TGA that aerosol sunscreens are ineffective in providing adequate protection (particularly if not applied appropriately).

As part of the recent review of the *Australian/New Zealand Standard AS/NZS 2604:2012 Sunscreen products – Evaluation and Classification*, the TGA proposed labelling changes for aerosol sunscreens to be incorporated into the revised standard. However, although some changes were adopted by the committee, in light of the QUT report and consumer complaints, the TGA is of the view that these changes may not go far enough to ensure effective use by consumers and further regulatory controls and/or post-market evaluation may be required for this class of sunscreen.

The TGA plans to conduct its own testing of aerosol sunscreens to verify QUT's results as well as a compliance review project to determine whether there are product-specific factors that contribute to the efficacy issues observed in the QUT report and described in the consumer complaints. Although consumer education is not the TGA's primary role, the TGA regularly engages with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) and will do so in relation to consumer usage of aerosol sunscreens.

s47 [redacted]

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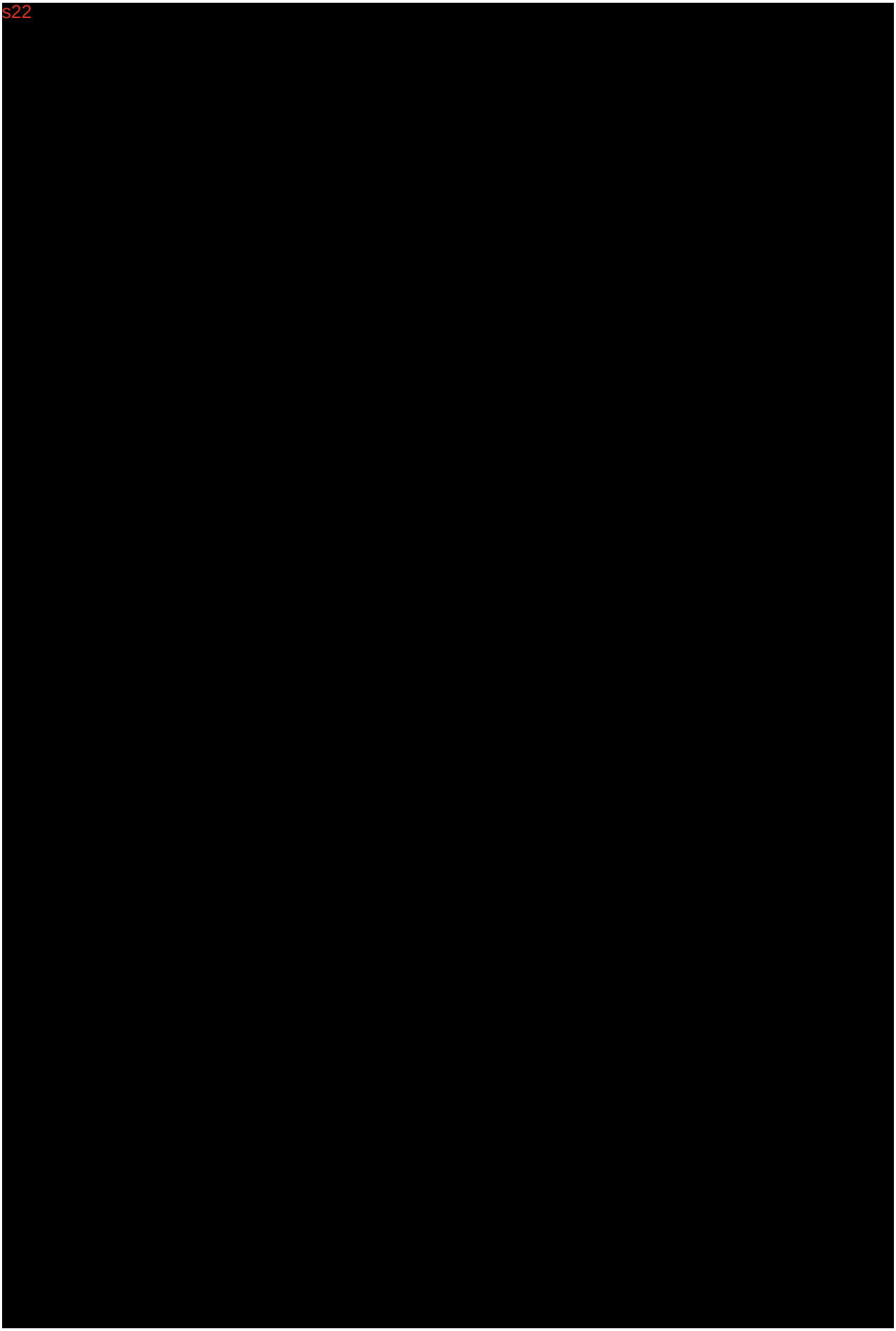

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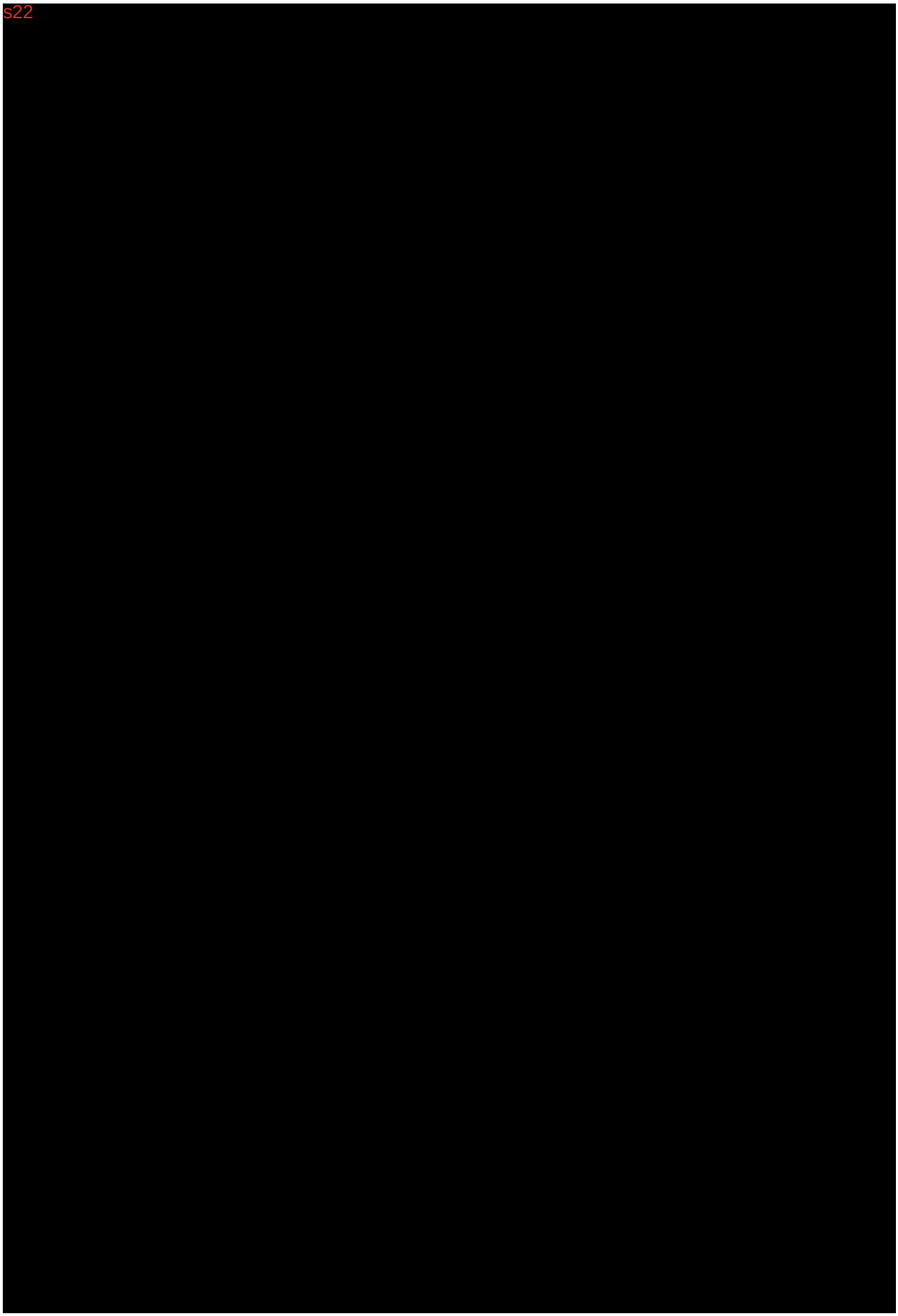

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Additional business: For noting

s22 [redacted]

s22 [redacted]

The meeting was declared closed at 2:50 pm.

Therapeutic Goods Administration

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Complementary and OTC medicines
Regulatory and Technical Forum

Item No.2.3

ComTech 8

Date: 13 April 2022

Subject: **Current and upcoming issues relating to sunscreens**

Speaker s22 [redacted]

ISSUE

There are a number of current and upcoming issues related to sunscreens under TGA consideration.

OUTCOME SOUGHT

ComTech to be aware/discuss current and pending issues relating to sunscreens:

- Adoption of latest sunscreen standard (when published)
- Potential safety concerns for some ingredients currently used in sunscreen products
- Efficacy concerns for aerosol sunscreens
- Data requirements and regulation of applications for listed medicine ingredients

ISSUES/KEY CONSIDERATIONS

1. **Adoption of new Australian New Zealand Sunscreen Standard (to be published in 2022) and latest ISO standard testing requirement for sunscreen**
   - Standards Australia have advised the TGA that (sometime in 2022) they will publish a new Australian New Zealand Sunscreen Standard (AS/NZS 2064), which will include a reference the latest ISO testing procedure for sunscreens (ISO 24444, ISO 24443, ISO 16217).
   - When the new standard is published, the TGA will conduct a consultation to adopt the new sunscreen standard in the Therapeutic Goods Regulations.
2. **Safety concern: sunscreen ingredients that are no longer on the US FDA's GRASE list.**
   - The US-FDA published guidance and a proposed rule in 2019 elaborating the requirement for testing and labelling of sunscreens by manufacturers to determine whether a sunscreen active ingredient is generally recognized as safe and effective (GRASE) under the Sunscreen Innovation Act. The rule divided the 16 active ingredients approved in USA into three categories: GRASE and not GRASE (for use in sunscreens because of safety concerns) and not GRASE (for use in sunscreens because additional data needed).
   - In response, the TGA:
     - has begun an audit of its safety data holdings to better understand the safety profile of these ingredients. monitoring consumer complaints and investigation into related sunscreen products
3. **Safety concern; US FDA reports of benzophenone and benzene in sunscreens**
   - Benzene
     - The US-FDA has published information on their website regarding recall of sunscreen

products containing benzene as an impurity.

- Benzophenone
  - Octocrylene is a common ingredient of sunscreens, however, there have been reports from the US-FDA that octocrylene may degrade to benzophenone
- In response, the TGA is investigating the levels and source of both benzophenone and benzene in sunscreen products.

4. Aerosol sunscreens issues

- There have been recent media/external concerns on sunscreen aerosols:
  - Consumer complaints/adverse events (e.g., sunburn) related to aerosol sunscreens.
  - Queensland University raised concerns in 2021 about the efficacy of aerosol sunscreens, primarily due to incorrect consumer application.
  - The Australia Cancer Society released a media statement in early 2022 raising their concerns about the efficacy of aerosol sunscreens due to the effect of wind on their application.
  - The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) have also raised their concerns with the TGA in relation to consumer usage of aerosol sunscreens.
- In response, the TGA is:
  - performing lab testing an aerosol sunscreen compliance review
  - considering whether the labelling requirements for sunscreen aerosols in the current Sunscreen Standard (AS/NZS 2064:2021) (not yet adopted in legislation by the TGA) will adequately address efficacy concerns related to aerosol sunscreens. The label statement is provided below:

    Labelling requirement to include the direction of use of spray for Sunscreen aerosol:

    i. Hold the container 10-15cm away from the body and apply liberally and evenly until the product looks and feels wet on the skin.

    ii. Do not spray directly on the face. Spray on the hand and apply on the face.

    iii. Do not apply product in windy conditions.

    iv. Use in well ventilated area and avoid inhalation.

5. Data requirement for evaluation of new listed medicine ingredients

- The third round of consultation on the mandatory requirements for new ingredient applications closed on 21 February 2022. The TGA is currently reviewing industry feedback and making amendments to the documents.
- At this stage changes to the evaluation pathways for excipient ingredients are not proposed and applicants will continue to be able to apply through either s. 26BD of the *Therapeutic Goods Act 1989* or regulation 16GA for excipients as is currently the case. Information in the ARGS will need to be updated in the future to ensure core information requirements for inclusion of a new ingredient on the Permissible Ingredients Determination are consistent for dermally applied ingredients, noting the ARGS currently specifies that applicants applying for a new listed medicine ingredient consider the Applications for new substances in listed medicines: Australian regulatory guidelines and Information required in an evaluation of a substance for use in listed medicines.

Attachments/ links

1. Sunscreens - ensuring products are effective and safe for the 2021-22 summer
2. Testing for benzene in aerosol sunscreen products being supplied in Australia
3. 'Banana Boat' Sunscreen Sprays SPF 50+ (aerosol sunscreen)

Australian Government
Department of Health
Therapeutic Goods Administration

Complementary and OTC Medicines Regulatory & Technical Forum (ComTech)

Record of outcomes

Meeting 9 - 13 April 2022

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External Participants

Participant	Organisation
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TGA Participants

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		Item 2.7
		Items 2.3, 2.4, 2.5
Nick Henderson	First Assistant Secretary, Medicines Regulation Division	
s22		Item 2.6
		Item 2.2
		Item 2.1
		Item 2.8

Apologies

Participant	Organisation
s22	

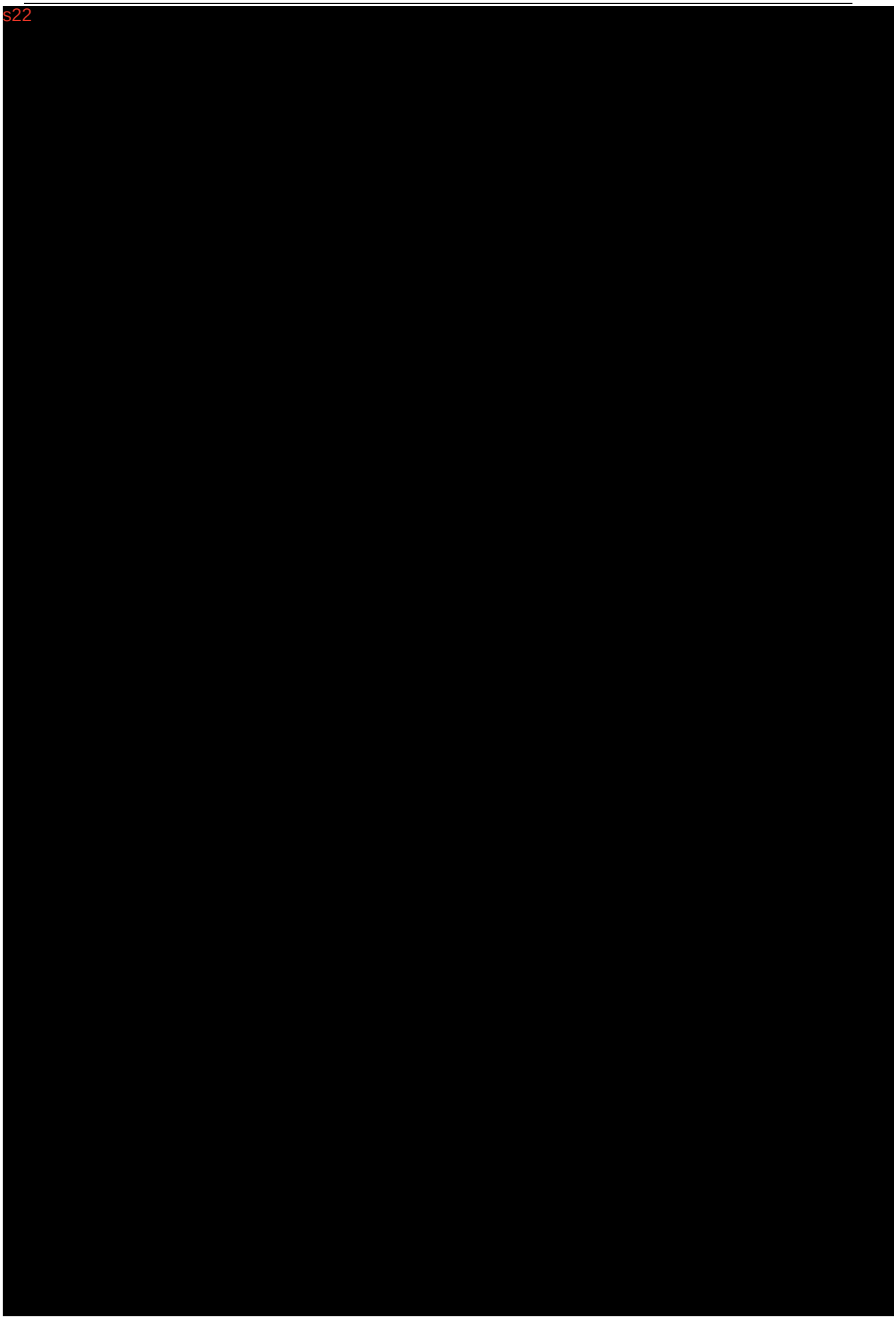
Item 1 Administrative items

s22

Item 2 New Business

s22

s22



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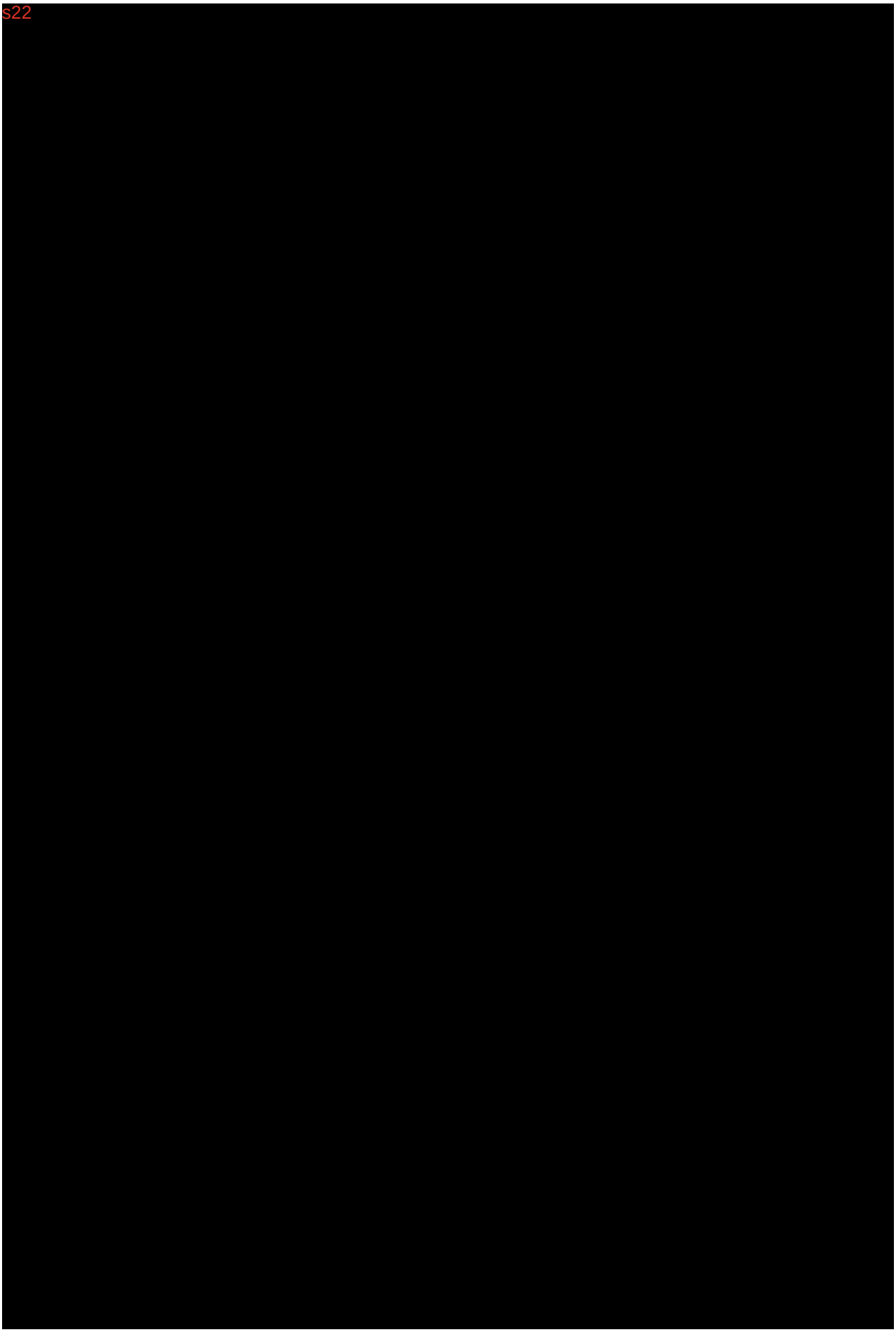

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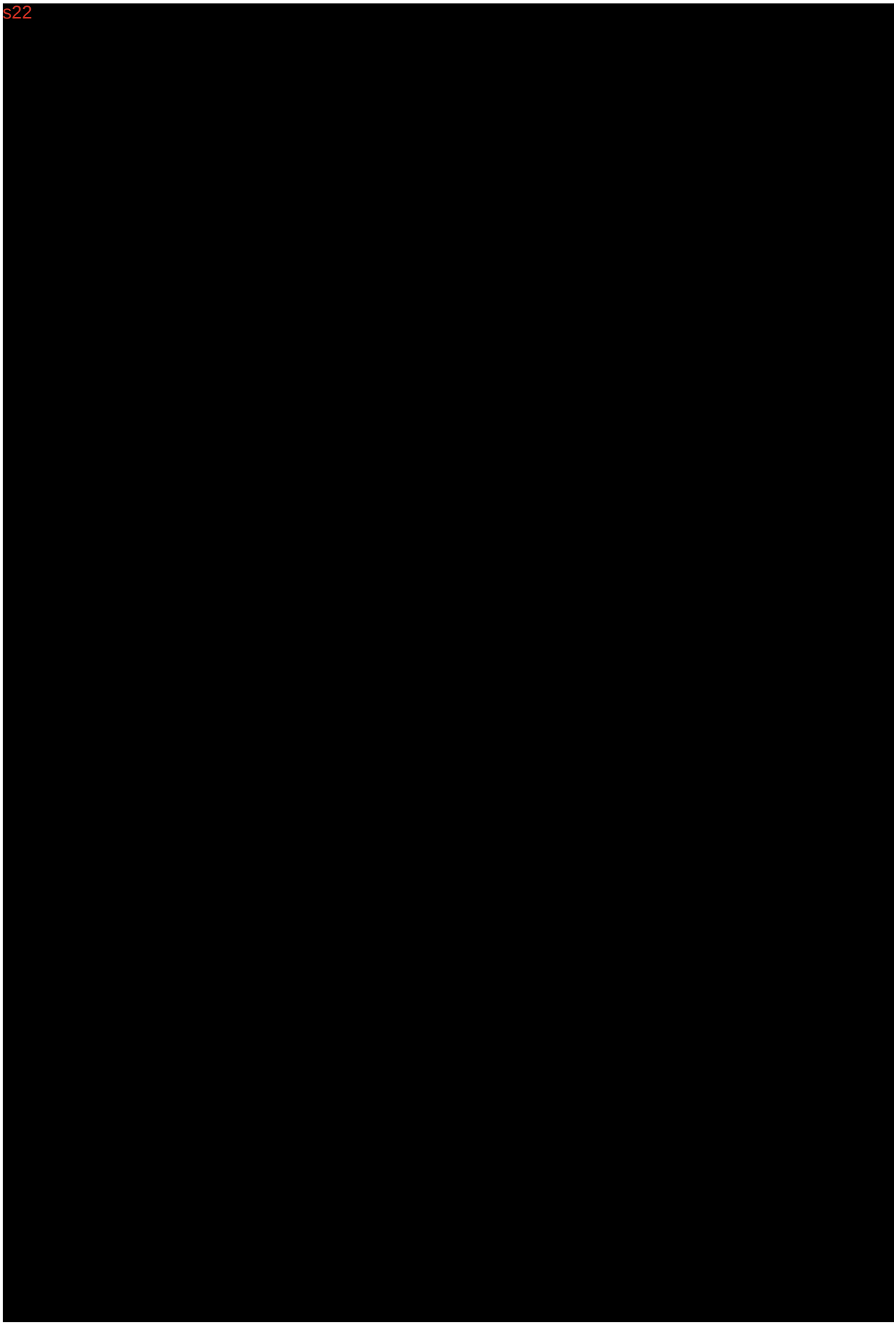

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2.3 Paper: Update on Sunscreen related issues

The TGA provided a verbal update on current and upcoming issues relating to sunscreens and the TGA's response to these issues.

s47 [redacted] The Chair advised that the results are not yet finalised but the TGA will contact individual sponsors as required.

s47 [redacted] he Toxicology section advised that they are in contact with the US-FDA, but the US-FDA is unlikely to release any information for some time. The TGA's current review of sunscreen ingredients is a three-tier approach as follows:

- based on literature surveys zinc oxide and titanium dioxide are considered safe in sunscreens and will not be assessed (noting there may be other concerns relating to titanium dioxide)
- 2 ingredients that US-FDA have removed from GRASE are not sunscreen ingredients used in Australia and will not be reviewed
- seven ingredients are currently being reviewed by the TGA:
    - avobenzone
    - ethylhexyl triazone
    - homosalate
    - octocrylene
    - octinoxate
    - oxybenzone and
    - phenylbenzimidazole sulfonic acid

The TGA's review of the 7 ingredients may take time but may get fast tracked based on information released by the US-FDA.

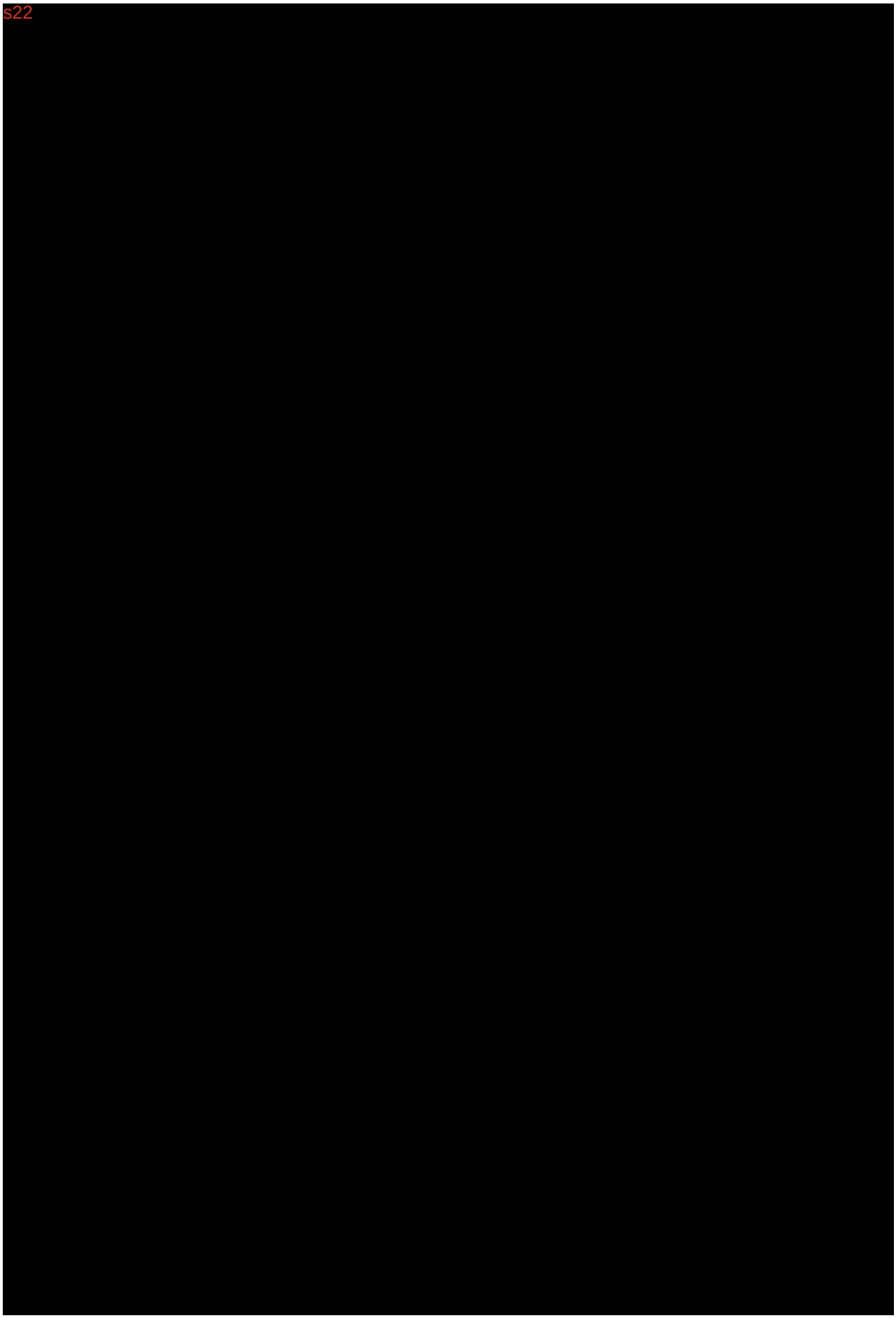
s47 [redacted]

Regarding the data requirement and application pathway discussion, the Chair explained the pathways for Regulation 16GA and section 26 BD of the *Therapeutic Goods Act 1989* are both available for applicants and the data requirement for both pathways are the same. s47 [redacted]

s22

[redacted]

s22



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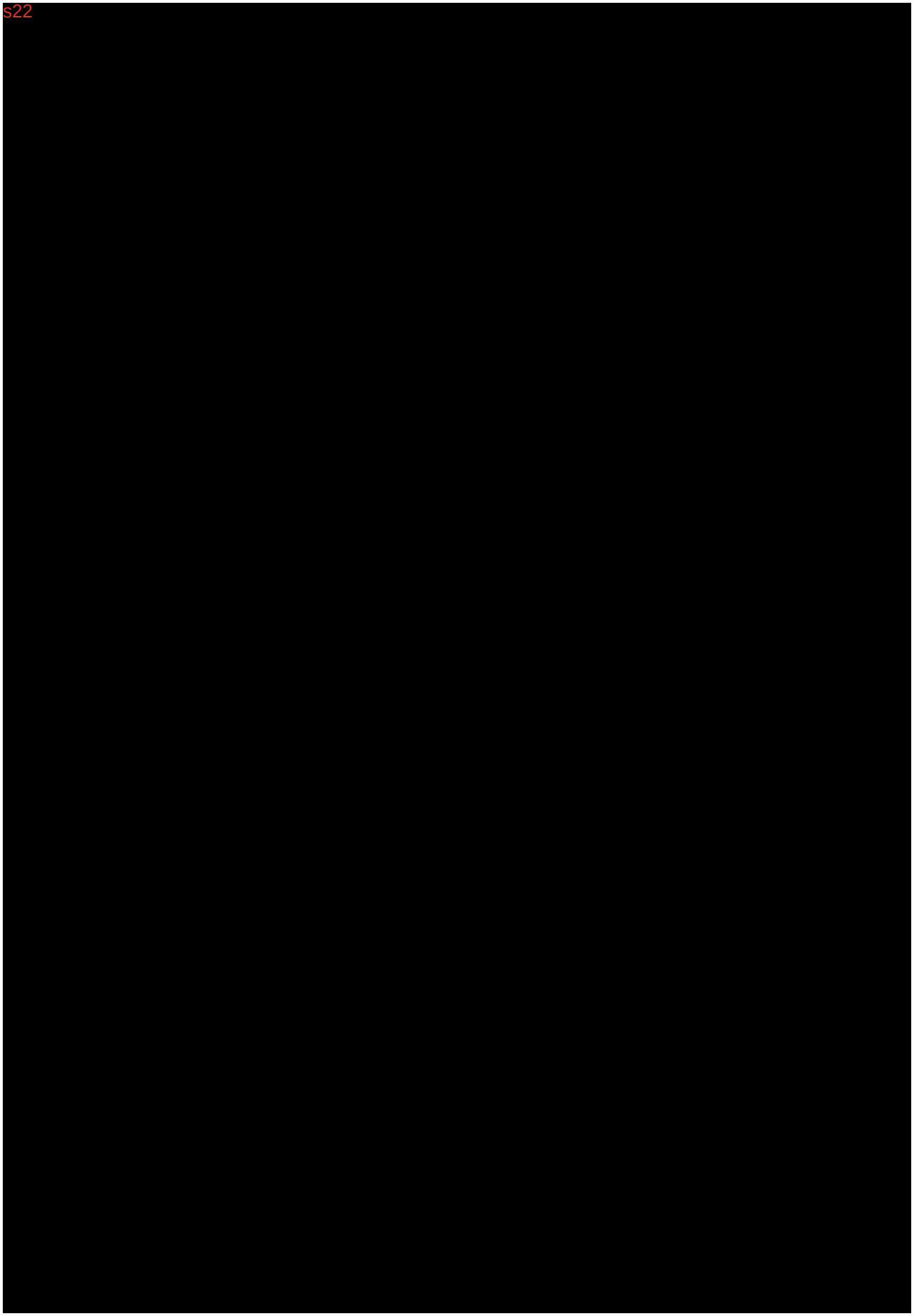

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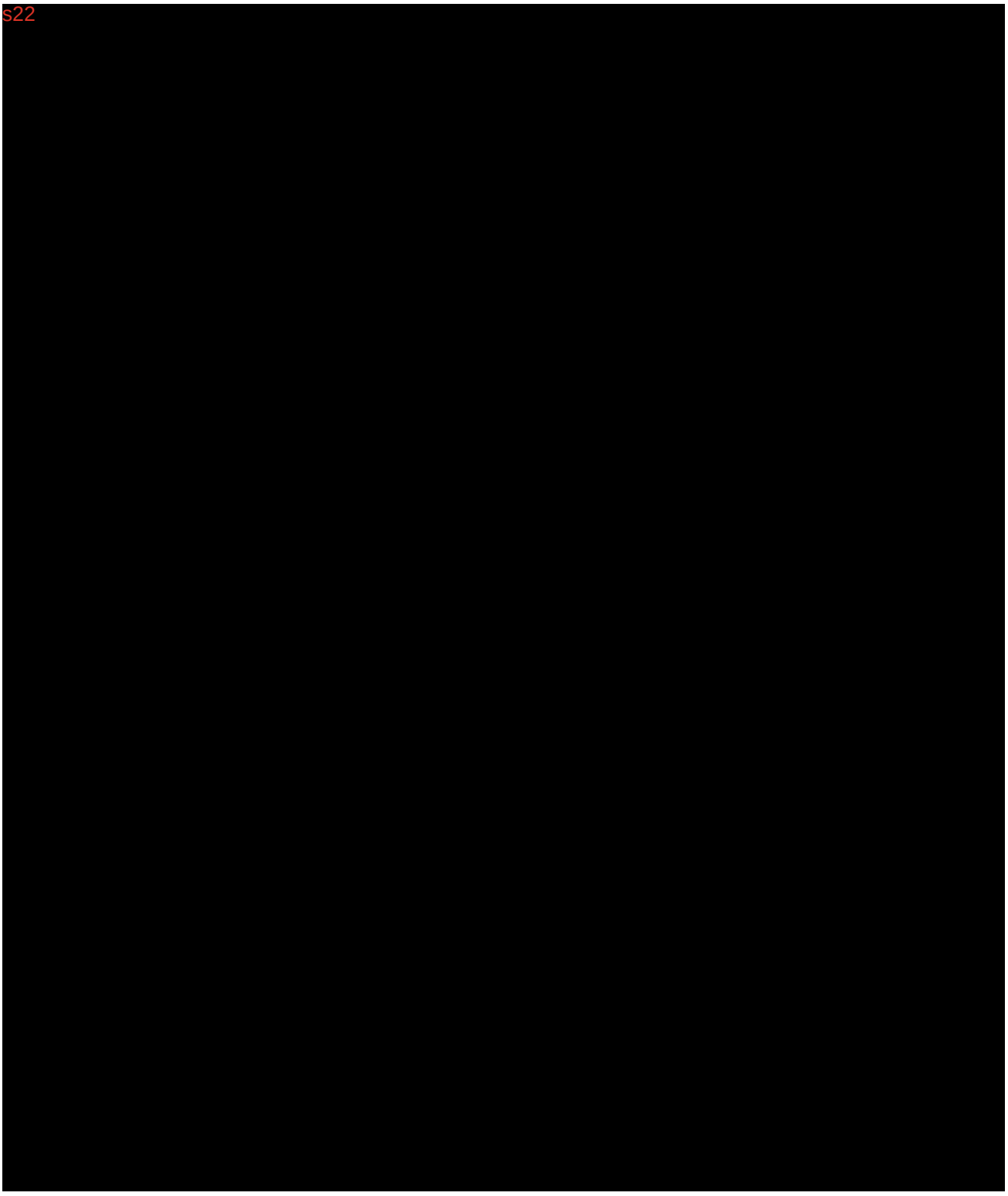

2.9 Additional business: For noting

There was no additional business discussed.

The meeting was declared closed at 2.30pm

Therapeutic Goods Administration

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Email: ComTech.secretariat@health.gov.au Phone: (02) 6289 8347

Complementary and OTC medicines Regulatory and Technical Forum

Item No. …XXX
ComTech 10
Date:

Subject: TGA adoption of the new Australian and New Zealand Sunscreen Standard *AS/NZS 2604 2022 Sunscreen products—Evaluation and classification*.

Speaker s22 [redacted]

ISSUES

1. The TGA intends to adopt the new Sunscreen Standard *AS/NZS 2604 2022* when it is published. An appropriate transition time for industry compliance with the new standard will be provided.
2. At the same time, we propose to remove the category of 'Exempt sunscreens' in the Therapeutic goods regulations 1990.

OUTCOME SOUGHT

Industry to advise of any concerns in relation to the TGA's proposal to adopt Sunscreen Standard AS/NZS 2604 2022 and remove the category of 'Exempt sunscreens'.

ISSUE 1: Adoption of 2022 Sunscreen Standard

BACKGROUND

- The Australian and New Zealand Sunscreen Standard AS/NZS 2604:2012 is the standard currently adopted by the TGA.
- A new Sunscreen Standard, AS/NZS 2604:2021, was published in June 2021. The major changes included in this standard were: adoption of the ISO standards 24444: 2019 and 16217:2020 for determining broad spectrum, sun protection factor and water resistance; and introduction of labelling instructions for the application of aerosol and pump packs (see Attachment 1).
- The TGA did not adopt the 2021 Sunscreen Standard, as we were aware that another version was to be published in 2022. The latest version is currently undergoing consultation, closing 29 September 2022. It is anticipated that the final document will be published shortly after the consultation closes. The major changes in AS/NZS 2604 2022 (refer to Attachment 2) are: adoption of ISO 24443:2021 and a new sunscreen guidance flow chart.

KEY CONSIDERATIONS

- In order for the TGA to adopt the 2022 Standard, references to *AS/NZS 2604:2012* will be replaced with *AS/NZS 2604 2022* in the following legislative documents:
  - Therapeutic goods regulations 1990
    - Schedule 4 Item 7(a)
    - Schedule 5 Item 8(g)(i)(note proposal to remove this altogether)
    - Schedule 7 Item 14(b) (note proposal to remove this altogether)

  - The Therapeutic Goods (Excluded Goods) Determination 2018:
    - Part 4. Definitions
    - Schedule 1 Items 14 and 15
    - Schedule 2 Items 5 and 10
- Adoption of the 2022 standard by the TGA will mean that sponsors of Australian therapeutic products will be required to comply with:
  - ISO standard 24444: 2019 Sun protection test methods- In vivo determination of the sun protection factor
  - ISO 16217:2020 Water immersion procedure for the determination of water resistance
  - ISO Standard 24443:2021 Determination of sunscreen UVA photoprotection in vitro
  - Label instructions for the application of aerosol and pump pack sunscreens.

Attachment 3 outlines the change in requirements for sponsors to comply with the 2022 standard compared to the 2012 standard.

ISSUE 2: Proposed removal of the category of 'Exempt' sunscreens from the Therapeutic Goods Regulations 1990

BACKGROUND

- Schedule 5 Item 8(g)(i) of the Therapeutic Goods Regulations 1990 categorises sunscreens with less than 4 SPF as 'exempt' from the requirement to be included in the ARTG provided they comply with testing and labelling in Sunscreen Standard AS/NZS 2604:2012.
- Schedule 7 Item 14 of the Regulations categorises sunscreens with less than 4 SPF as 'exempt' from manufacturing requirements when tested as described in Sunscreen Standard AS/NZS 2604:2012. Attachment 4 provides the relevant excerpts from the Regulations
- Prior to 2012, the Sunscreen Standard (2604:1998) allowed products to make SPF claims of less than 4. However, since 2012, the Sunscreen Standard does not permit sunscreens to include statements of less than SPF 4 on product labels. That is, since 2012, it is not possible for any sunscreens claiming less than SPF 4 to be compliant with the Sunscreen Standard.
- However, due to concern regarding potential shortage of sunscreens (as a result of the increased testing requirements in the 2012 standard), sunscreens available in the market prior to 9 November 2012 were allowed to comply with the old standard (2064:1998) until such time as they made a change to their product. These transition arrangements were provided in Therapeutic Goods Amendment

Regulation 2012 (No. 3). Excerpt below:

> **49 Transitional**
>
> Despite the amendments made by the *Therapeutic Goods Amendment Regulation 2012 (No. 3)*:
>
> (a) item 7 of Part 1 of Schedule 4, as in force on 9 November 2012, continues to apply in relation to therapeutic goods already included in the part of the Register for listed goods on that date; and
>
> (b) paragraph (g) of item 8 of Schedule 5, as in force on 9 November 2012, continues to apply in relation to goods exempt from the operation of Parts 3-2 and 3-2A of the Act on that date; and
>
> (c) paragraph (b) of item 14 of Schedule 7, as in force on 9 November 2012, continues to apply in relation to therapeutic goods exempt from the operation of Part 3-3 of the Act on that date.

- With the introduction of Permitted Indications in 2018, all listed medicines were required to change their indications to permitted indications and recertify that their goods met all legislative requirements. As there are no permitted sunscreen indications with less than SPF 4, there are no listed medicines in the ARTG with indications of less than SPF 4. That is, all listed sunscreen products now comply with the current Sunscreen Standard adopted by the TGA (2604: 2012).

KEY CONSIDERATIONS

- While no sunscreens listed in the ARTG can have SPF permitted indications of less than 4, 'exempt' sunscreens supplied prior to 2012 can include SPF claims of less than 4 (and not be compliant with the current Sunscreen Standard) due to the indefinite transition arrangements provided in Therapeutic Goods Amendment Regulation 2012 (No. 3).
- As these exempt products are not in the ARTG, the TGA has no visibility of how many, if any, such products remain on the market.
- When the TGA adopts the 2022 Sunscreen Standard we do not intend to include such transition arrangements. All therapeutic products will be required to comply with the latest Sunscreen Standard at the end of a finite, appropriate transition period. We therefore propose, pending legal advice, to delete Schedule 5 Item 8(g)(i) and Schedule 7 Item 14 from the Regulations.

ATTACHMENTS

Attachment 1: Changes to AS/NZS 2604:2021 compared to AS/NZS 2604:2012
Attachment 2: Changes to the AS/NZS 2604:2022 compared to AS/NZS 2604:2021
Attachment 3: Increase in requirements for sponsors for the 2022 Sunscreen Standard compared to the 2012 Sunscreen Standard.
Attachment 4: Excerpts from the Therapeutic Goods Regulations

Attachment 1

Changes to AS/NZS 2604:2021 compared to AS/NZS 2604:2012

(a) This revision completes the transition of methods for determining broad spectrum, sun protection factor (SPF) and water resistance from local Australian and New Zealand test methods to globally written, agreed and published ISO standards for all participating members to adopt.

(b) ISO 24444:2010, *Cosmetics — Sun protection test methods — in vivo determination of the sun protection factor (SPF)*, has been superseded by ISO 24444:2019. The key change is to improve the reproducibility and reliability of this test method. Specific changes include —

(i) replacement of the Fitzpatrick Skin Type for volunteer selection by a colorimetric instrument measurement;

(ii) the addition of three new standard sunscreens P5, P6 and P8 for use with sunscreen tests for SPF 25 and above; and

(iii) photographic examples of erythema responses for grading of results. A sample questionnaire for test subjects is included, removing the need for Appendix E of AS/NZS 2604:2012.

(c) The water immersion procedure for the determination of water resistance now follows ISO 16217:2020, *Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance*. Australia and New Zealand still retain the 4 h water resistance test period and claim, and continue to determine SPF after immersion as the SPF value to use for labelling SPFs.

(d) The new and revised ISO standards include normative requirements for standardized formats for test and results reporting.

(e) Clarification of the definition of the difference between Primary and Secondary Sunscreens. This document now advises taking into account the overall presentation and purpose of a sunscreen when assigning a sunscreen as a primary or secondary sunscreen.

(f) Introduction of instructions for the recommended method of application of sunscreen aerosols and sunscreen spray pump packs to ensure even and generous dosing applied from the correct distance and under optimum conditions while avoiding inhalation.

Attachment 2

Changes to the AS/NZS 2604:2022 compared to AS/NZS 2604:2021

The major changes in the amendment are:

- Incorporation of ISO 24443:2021 Cosmetics -Determination of sunscreen UVA photoprotection in vitro.
- A new attachment of sunscreen guidance flow chart as appendix D.

Section	Changes to the current standard AS/NZS 2604: 2021	Comments
Preface, (b)	Inserted Text: (b): ISO 24443:2012, Determination of sunscreen UVA photoprotection in vitro, has been superseded by ISO 24443:2021 Cosmetics — Determination of sunscreen UVA photoprotection in vitro. The key changes are — (i) the addition of a method for calculation of critical wavelength. (ii) the addition of new sunscreen standards for sunscreen determinations for higher performing broad-spectrum products; and (iii) changes to account for photo-stability of test products by exposing them to specific measured doses of ultraviolet (UV) radiation prior to testing.	• Preface (b) text is addition in the amendments. The inserted text refers to use of new ISO 24443:2021 method and key changes to the updated UVA testing procedure, that was missing in the current standard. • ISO 24443 Determination of sunscreen UVA photoprotection in vitro is one of the testing methods mentioned under section 2. "Normative reference" in the current standard, however it does not provide reference to the new version of ISO method 24443:2021. • In the current standard '*Determination of broad-spectrum performance*' is specified as Appendix C in the current standard. The method reference to ISO 24443 (with no version).
Preface, (h)	(h) Addition of Appendix D, to provide guidance for testing and labelling, including an ordered sequence of questions to help identify whether a sunscreen is a primary	This text is a new addition to the 'Preface' section in the Amendments.
Appendix D	New appendix	The flow chart is a new addition in the amendment as "Appendix D" *Guidance for testing and labelling*. • The flow chat provides informative presentation of the criteria to identify sunscreen as Primary or Secondary sunscreen. • The criteria refer to follow sections in the standard for description (as primary /secondary sunscreen). • There is no obvious change in the requirement for testing and labelling of the sunscreen in the amendments compared to the current standard.

Attachment 3 Increased requirements in ISO standards

Changes in ISO 24443:2021 compared to previous edition of Determination of sunscreen UVA photoprotection in vitro

1. Acceptance of module and introduction of sandblasted PMMA (polymethylmethacrylate) plates, according to specifications described in Annex D.
2. Product application fitted to 1,2 mg/cm² for sand blasted plates.
3. Description of application gesture according to tested products
4. Introduction of a new high UVA PF standard P8 in addition to S2 in the ISO-24443-2012
5. Introduction of critical length calculation
6. Calculation of coefficient 'C' accepted from in vivo screening SPF, with specific conditions based on SEM and percentage of variability and new range proposed from 0,6 to 1,6
7. Pre-Irradiation dose should be limited at a maximum of 36J/cm2 (UVA-PF0 maximum 30)

Additional capabilities – Sandblasted PMMA plates P8 reference standard

Changes in ISO 24444:2019 cosmetic -Sun protection test methods-in vivo determination of the SPF.

Changes in new ISO edition	Previous limit ISO 24444:2010	Current ISO 24444:2019
Definition of minimal erythema response (MED) criteria has been revised.	Lowest dose of ultraviolent radiaiton(UVR) that produces the first percetible unambiguous erythema with define boarders appearing over most of the field of UV exposure, 16h to 24 h after UV exposure	Lowest erythemal effective radiant exposure (Her) that produces the first perceptible unambiguous erythema with define boarders appearing over more than 50% of UV exposure subsite, 16h to 24 h after UV exposure
Selection of test subject	Test subjects included in the SPF test shall be only phototypes I, II or III according to Fitzpatrick[7] or shall have an ITA° value > 28° by colorimetric methods	Test subject shall have ITA° at least 28° by colorimetric method. Colorimetric ITA values and skin colour categories are defined by the colorimetric descriptors of Chardonusing CIE lab colour space (Annex A) (Fitzpatrick skin type selection not included)
Source of ultraviolent radiation Apparatus and material -	The intensity of the beam shall be as uniform as possible. The minimum beam irradiance, at any sub-site, shall be no	Includes more detailed information and limits. Uniformity of beam shall be measured depending on the solar simulator type

Changes in new ISO edition	Previous limit ISO 24444:2010	Current ISO 24444:2019
	more than 10 % lower than the maximum beam irradiance at any sub-site.	using either UV sensitive film or UV sensor method. UV film densitometry: Exposure dose of the UV sensitive film shall be calibrated to achieve film darkening to a density in the mid-range of the scale. Uniformity shall be >90%. UV Radiometer method: UV radiometer sensor used to sample the beam intensity at multiple sites. Multiple output device. New test methods are provided to determine the uniformity of the beam of both large and small beam size solar stimulator. A requirement for uniformity greater than or equal to 90% has been added.
Total Irradiance	Total irradiance shall not exceed 1 600 W/m2. The calibrated critetia for the solar simulator not included.	Total irradiance shall not exceed 1 600 W/m2. The output of the solar simulator shall be measured with broad spectrum sensor (capable of measuring between 280-1600nm) calibrated against the standard reference.
The test subject is based on the individual typology angle (ITA°)	Value characterizing the skin colour of the subject.	Value characterizing the skin colour of the subject as measured by skin contact reflectance spectrophotometer or skin colourimeter. The test subject is based on the individual typology angle (ITA°) with the average of test panel to be within the range 41°-55° with minimum of three subjects with in two of the three ITA° ranges.
		The ITA° is used to define the range of unprotected MED doses for the provisional or the test day unprotected MED determination.
Reference standard sunscreens added to validate SPF test panels	P2, P3, P7. Expected SPF<SPF20 any of the P2, P3 or P7 reference standard can be used. Expected SPF> SPF 20 one of the P2 or P3 standard is used.	Three new reference standard sunscreens (P5, P6 and P8) are added to validate SPF test panels for products with SPF equal to 25 or higher. SPF claim <24: P2 or P3 SPF> 25 but less than SPF 50: P5 of P6 (on at least 5 subjects) and P2 or P3 on remaining subjects.

Changes in new ISO edition	Previous limit ISO 24444:2010	Current ISO 24444:2019
		SPF>50: P8 (on at least 5 subjects) and P2 or P3 on the remaining subjects.
		Sunscreen application procedure has been described in greater detail.
Addition of Annex	- Not present	An informative Annex F is added with photographic examples of erythema responses with guidelines for grading.
	- Not present	The reporting table in Annex G and requirement in Clause 11 have modified to provide more complete information on the results of the testing.
		Bibliography is updated.

Capabilities required: Calibration procedure for Radiometry, densitometry. Reference standard P5, P6, and P8.

Changes to ISO 16217: 2020

The latest version does not have major changes. The process used is mostly described in ISO 24444.

The acceptable time for water immersion is 4hrs as described in the AS/NZS 2604 update

Attachment 4

Excerpts from the Regulations

Schedule 4—Therapeutic goods required to be included in the part of the Register for listed goods

(regulation 10)

Item No.	Therapeutic goods
7	sunscreen preparations for dermal application, if: (a) the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:2012, as in force from time to time; and (b) the performance statements and markings on the label comply with that Standard; and (c) the sunscreen preparation only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act; and (d) if a determination under paragraph 26BB(1)(b) of the Act specifies requirements in relation to ingredients being contained in the sunscreen preparation—none of the requirements have been contravened; and (e) the sunscreen preparation only has indications that are covered by a determination under paragraph 26BF(1)(a) of the Act; and (f) if a determination under paragraph 26BF(1)(b) of the Act specifies requirements in relation to the indications—none of the requirements have been contravened

Schedule 5—Therapeutic goods exempt from the operation of Parts 3-2 and 3-2A of the Act

(subregulation 12(1))

Column 1 Item No.	Column 2 Therapeutic goods
8	the following goods, unless the goods are for the treatment, cure, prevention, diagnosis or monitoring of, or testing susceptibility of persons to, a disease, condition, ailment or defect: (a) homoeopathic preparations more dilute than a one thousand fold dilution of a mother tincture and which are not required to be sterile; and which do not include an ingredient of: (i) human origin; or (ii) animal origin, if the ingredient consists of, or is derived from, any of the following parts of cattle, sheep, goats or mule deer: (A) adrenal; (B) brain; (C) cerebrospinal fluid; (D) dura mater; (E) eye; (F) ileum; (G) lymph nodes; (H) pineal gland; (I) pituitary; (J) placenta; (K) proximal colon;

Column 1 Item No.	Column 2 Therapeutic goods
	(L) spinal cord; (M) spleen; (N) tonsil; (c) unmedicated anti-acne preparations having only a cleansing action or purpose; (d) medicated insect repellents for dermal use if the medication consists solely of an antiseptic having a secondary role in the formulation, except those that are included in a Schedule to the Poisons Standard; (f) disinfectants, except those described in item 16 in Schedule 4; (g) sunscreen preparations for dermal application, if: (i) the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:2012, as in force from time to time; and (ii) the performance statements and markings on the label comply with that Standard; and (iii) the sun protection factor stated on the label is less than 4, unless the preparations include ingredients of human origin, or of animal origin if the ingredient consists of, or is derived from, any of the following parts of cattle, sheep, goats or mule deer: (A) adrenal; (B) brain; (C) cerebrospinal fluid; (D) dura mater; (E) eye; (F) ileum; (G) lymph nodes; (H) pineal gland; (I) pituitary; (J) placenta; (K) proximal colon; (L) spinal cord; (M) spleen; (N) tonsil

Schedule 7—Therapeutic goods exempt from the operation of Part 3-3 of the Act unless supplied as pharmaceutical benefits

(regulation 17)

Column 1 Item No.	Column 2 Therapeutic goods
14	sunscreen preparations for dermal use that: (a) are packaged in containers the labels of which include a statement that the preparations have a sun protection factor below 4 or the equivalent category description; and (b) when tested as described in Standard AS/NZS 2604:2012, as in force from time to time, are established to have a sun protection factor below 4 or the equivalent category description
15	medicated throat lozenges, where the medication consists only of volatile oils and their constituents either alone or in combination with ascorbic acid or its salts

Complementary and OTC medicines Regulatory and Technical Forum

Item No. 4.4
ComTech Meeting 10
Date: 19 October 2022

Subject: s47 [redacted]

Speaker [redacted]

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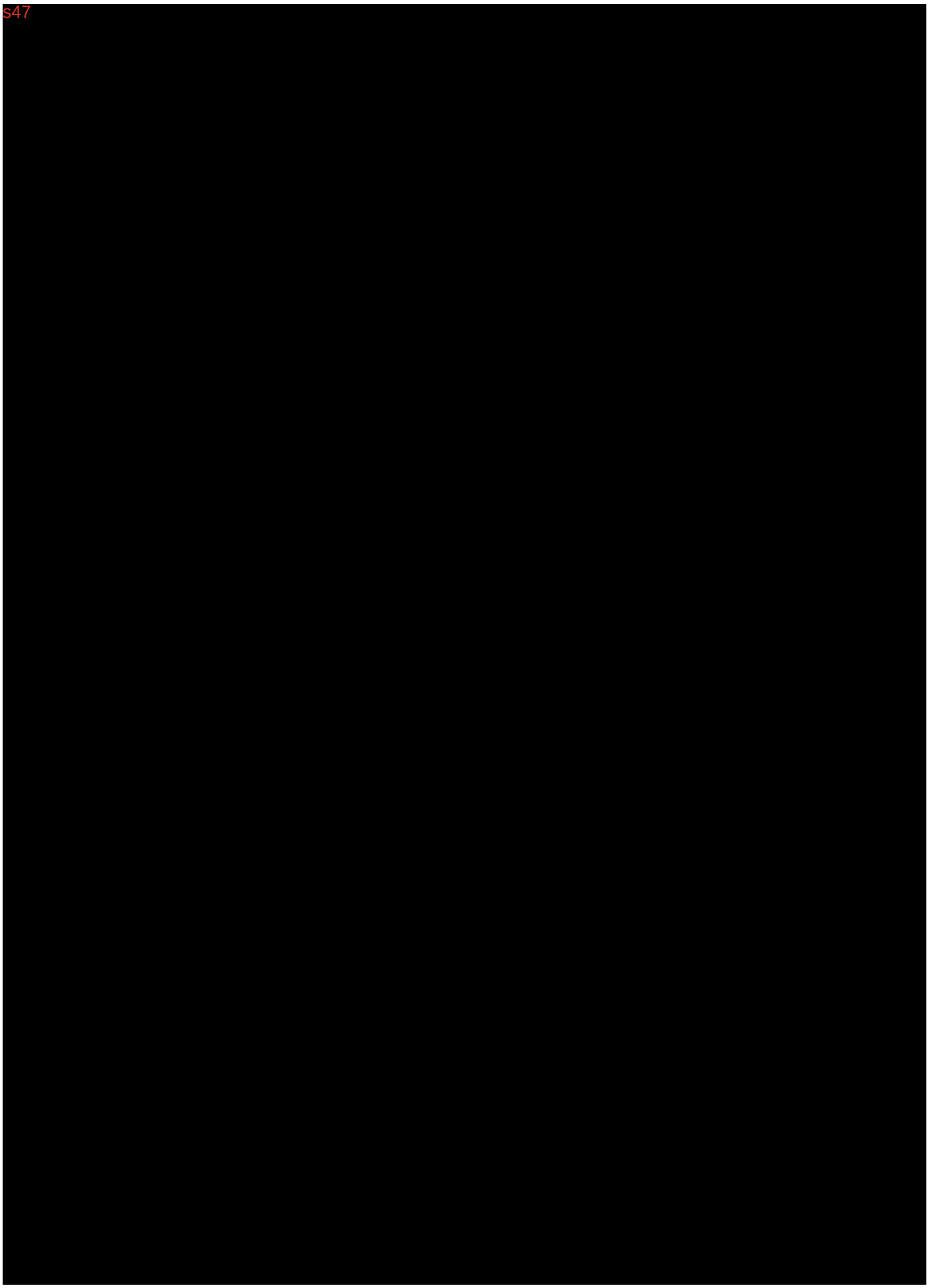
s47 [redacted]

s47

[redacted]

s47



s47

Australian Government
Department of Health
Therapeutic Goods Administration

Complementary and OTC Medicines Regulatory & Technical Forum (ComTech)

Record of outcomes

Meeting 19 October 2022

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External Participants

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s22	

TGA Participants

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		Item 4.7
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		Item 4.6
		Item 4.8
		Item 4.7
		Item 4.5

Apologies

Participant	Organisation
N/A	N/A

1 Administrative items

s22 [redacted]

2 Work plan and action items

s22 [redacted]

2.1 Review of action items from previous meetings

s22 [redacted]

3 TGA and ComTech member verbal updates

The First Assistant Secretary of MRD provided information on senior-level staffing changes for

s22 [redacted]

s22

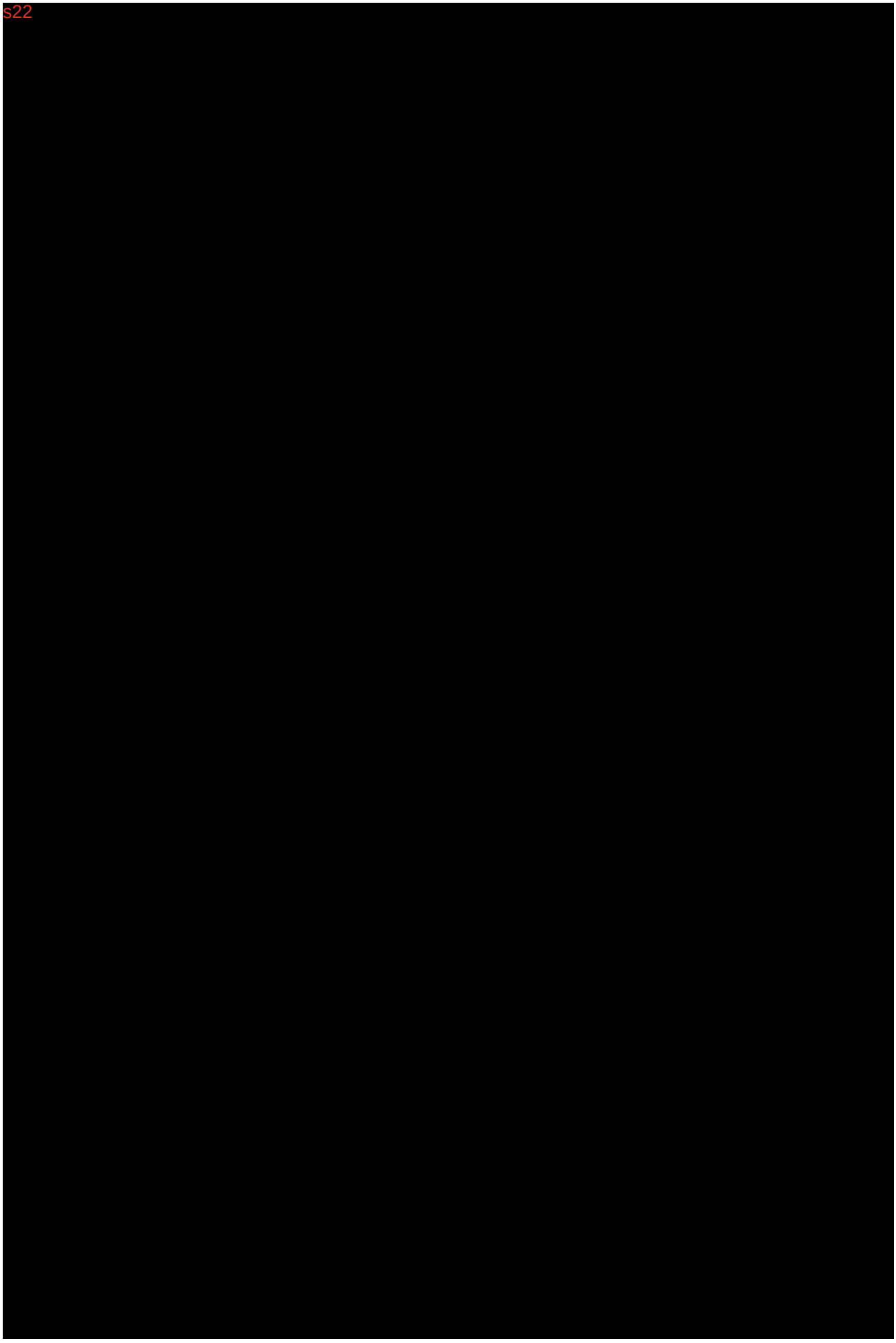
[redacted]

4 Discussion items

s22

[redacted]

s22



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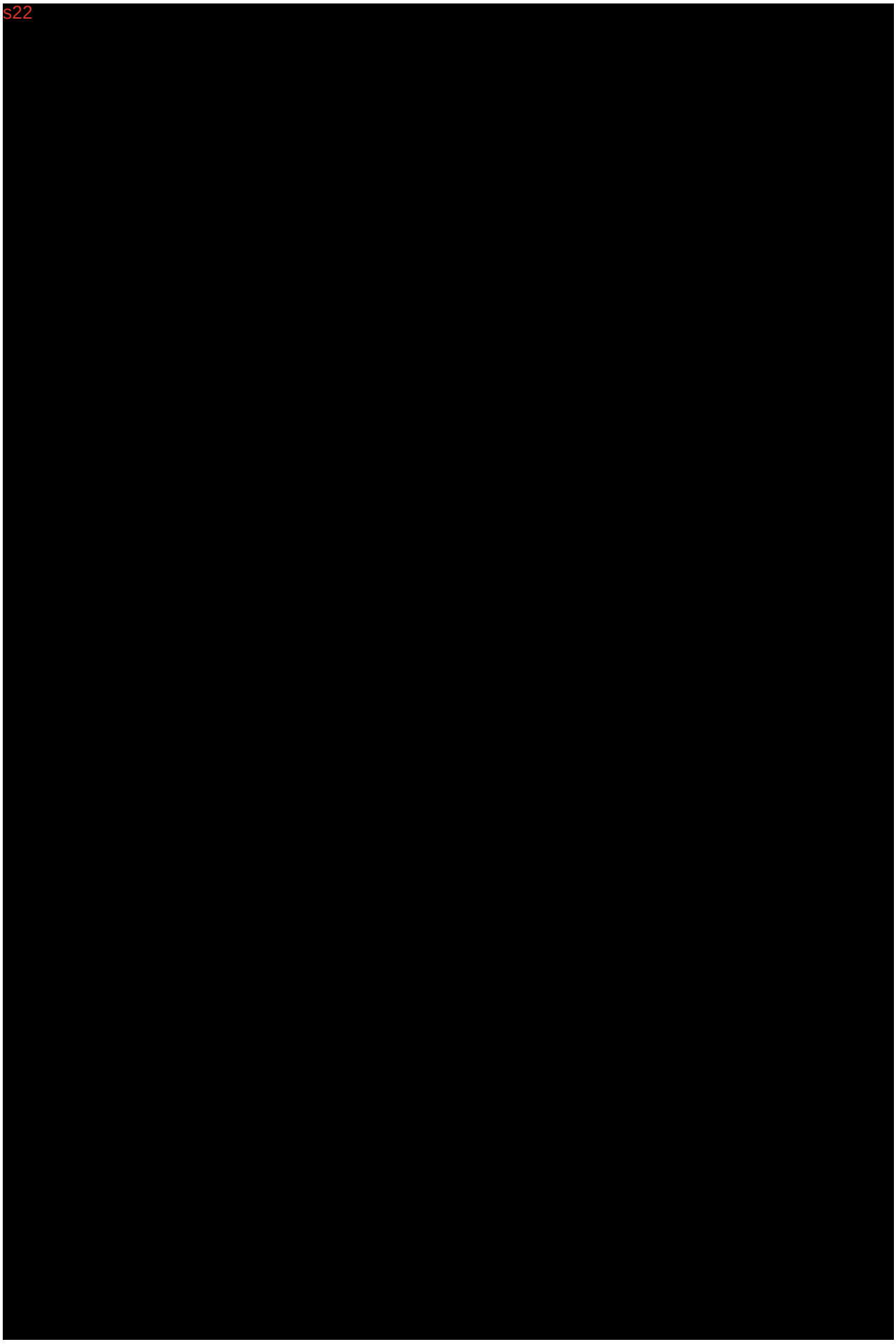

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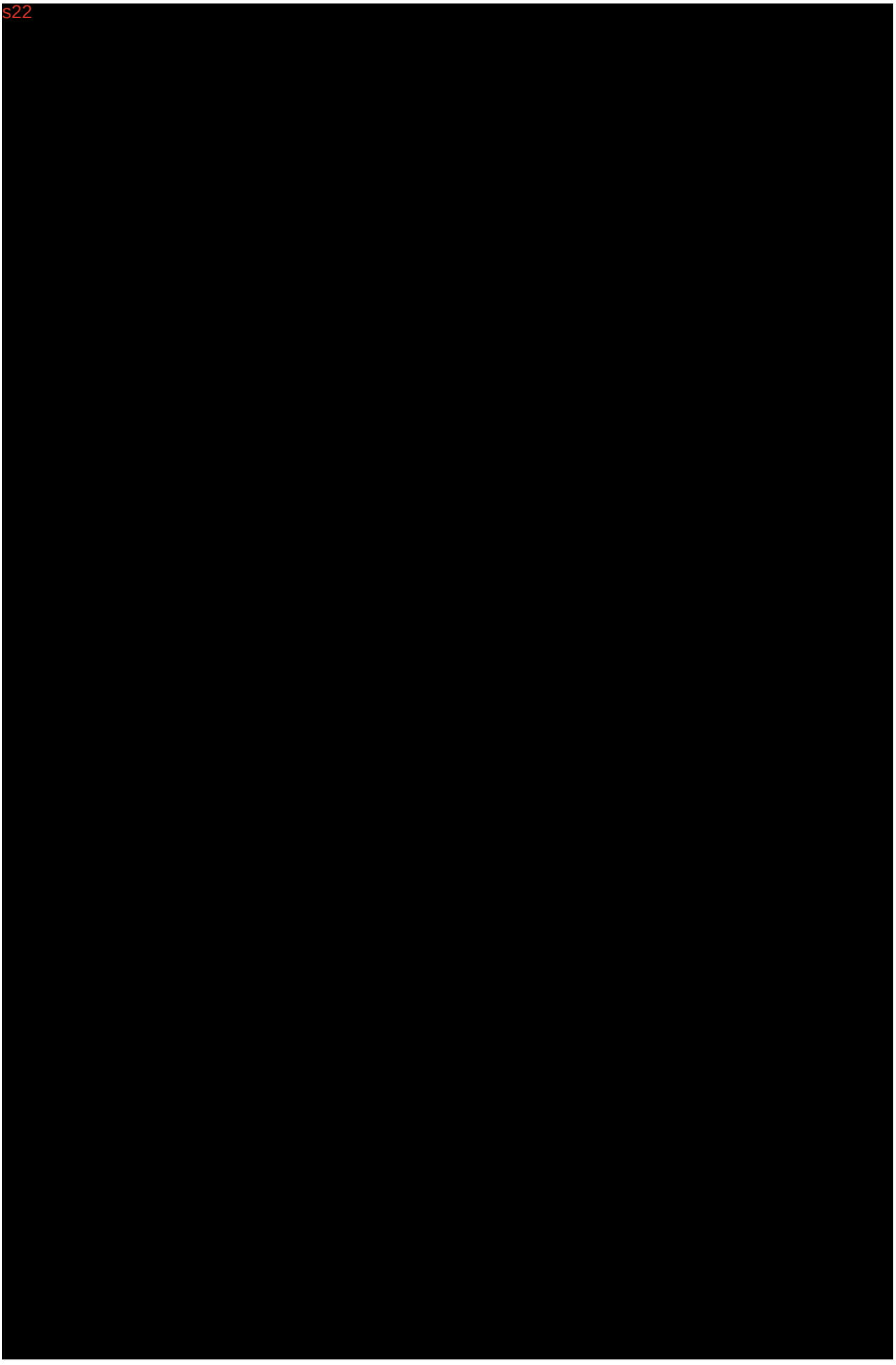
s22



s22 [redacted]

4.4.1 TGA paper: TGA adoption of Sunscreen Standard AS/NZS

The TGA advised that, when published, the new Sunscreen Standard (Amd1 AS/NZS 2604 :2021) will be adopted by the TGA. Public consultation will be required to amend the Therapeutic Goods Regulations 1990 (the Regulations) to adopt the new Standard and an appropriate transition time will be provided for industry to comply with the new requirements. The consultation will commence shortly after the new Standard is published.s47 [redacted]

At the same time, the TGA intends to remove the category of 'Exempt sunscreens' from the Regulations, (which exempts sunscreens with SPF<4 from being required to be in the ARTG), given that such products are not compliant with the current (2012) and the new Sunscreen Standard, which does not permit sunscreen indications of less than SPF4.

4.4.2 s47 [redacted]

s47 [redacted]

s47

s22

s22

[redacted]

s22 [redacted]

4.9 Additional business: For noting

s22 [redacted]

There was no additional business discussed.

The meeting was declared closed at 2.25pm

Therapeutic Goods Administration

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Complementary and OTC Medicines Regulatory & Technical Forum (ComTech)

Record of outcomes

Meeting 3rd May 2023

Contents

External Participants

Participant	Organisation	Item
s22		

TGA Participants

Name	Position	Item
Cheryl McRae (Chair)	Assistant Secretary, Complementary and OTC Medicines Branch (COMB)	Item 2 Item 3
s22		Item 4.1
		Item 4.3 Item 4.6
		Item 4.4
		Item 4.5
		Item 4.7

Apologies

Participant	Organisation
s22	

1 Administrative items

s22 [redacted]

2 Work plan and action items

s22 [redacted]

Action items:

s22 [redacted]

s22 [redacted]

3 TGA and ComTech member verbal updates

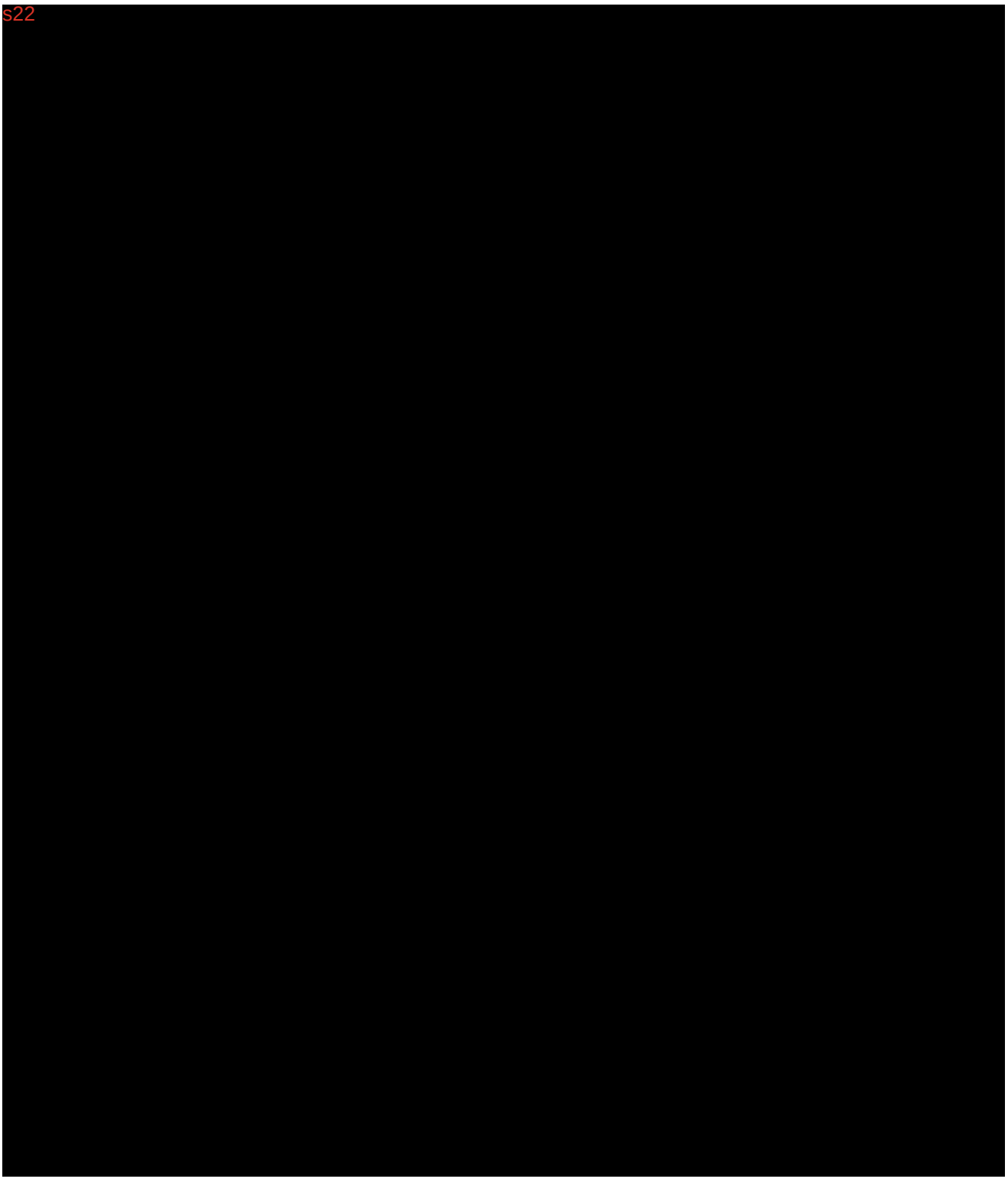
s22 [redacted]

4 Discussion items

4.1 TGA verbal: Update to assessed listed evidence guidelines

s22 [redacted]

s22



s22

4.3 TGA Presentation: Sunscreen issues including TGA adoption of Sunscreen Standard AS/NZS and Toxicology review of sunscreen ingredients

The TGA provided an overview of the current TGA public consultation proposing clarification and updates to the regulation of sunscreens. The potential regulatory clarification and updates include:

1. Adoption of the Australian/New Zealand Standard Sunscreen products - Evaluation and classification AS/NZS 2604:2021 Amd 1:2022 (the 2021 Sunscreen Standard) which specifies the current testing and labelling requirements for sunscreens.

2. Removal of the category of 'exempt' sunscreens and previous transitional arrangements from the Therapeutic Goods Regulations 1990 (the Regulations) which enables sunscreen products with less than SPF4 (that were supplied in the market prior to 9 November 2012) to comply with the superseded Australian/New Zealand Standard Sunscreen products - Evaluation and classification AS/NZS 2604:1998 (the 1998 Sunscreen Standard) and be exempt from the requirement to be included in the ARTG.

3. Clarification on the indications (therapeutic uses) that sunscreens can make. Three options are proposed in the consultation for stakeholder consideration.

If the 2021 Sunscreen Standard is adopted, the TGA advised that this is anticipated to commence 1st January 2024. While this timeline may seem long, the TGA advised that changing legalisation is a lengthy legal process.

The TGA is proposing a staggered transition for industry compliance with the 2021 Sunscreen Standard. A 3-year transition is proposed for all sunscreens to comply with the new ISO Standards testing requirements. Whereas a 1- year transition is proposed for the new labelling requirements for aerosol and pump action sunscreens, as this is a safety issue.

s47 [redacted]

In consideration of indications for sunscreens, the TGA acknowledged that there is an overlap between cosmetic claims and therapeutic indications, advising that, if indications (that could be considered cosmetic indications) are included the Therapeutic Indication Determination that does not preclude them from being used as for a cosmetic product. Pending the outcome of the consultation, clarification will be provided on cosmetic claims and therapeutic indications for sunscreens in the Australian Regulatory Guidelines for Sunscreens (ARGS).

s47 [redacted]

The TGA provided an update on the US FDA 's proposal to remove certain ingredients from the Generally Recognised As Safe and Effective (GRASE) list. To date, there has been no further update from the US FDA. The TGA is conducting its own internal review of the safety of certain sunscreen ingredients, but at this stage, does not have a timeframe of when the review will be finalised. A TGA exposure model is being refined internally which will be utilised in determining the outcomes of the safety review.

In relation to benzophenone impurities in sunscreens, the TGA advised that they continue to test sunscreens in the market for this impurity and will take action if they find that levels are too high.

The TGA is also undertaking a review of the ARGS to reflect the changes in mandatory application requirements for listed medicines and therapeutic sunscreens.

Once the outcome of the sunscreen consultation is realised, further updates to the ARGS will occur as required and will be discussed at future ComTech meetings.

Finally, the TGA advised that future work is planned to review the Excluded Goods Order.

4.4 TGA paper: Promotional listed sunscreens

The TGA presented a paper on promotional listed sunscreens with the same AUST L being presented with different main labels and the potential that this practice is unlawful. The TGA raised concerns that this trend was becoming more prevalent.

s47 [redacted]

One of the concerns raised by the TGA was that consumers could not see the excipient ingredients contained in the sunscreen and that this could be an issue for consumers with sensitivities. s47 [redacted]

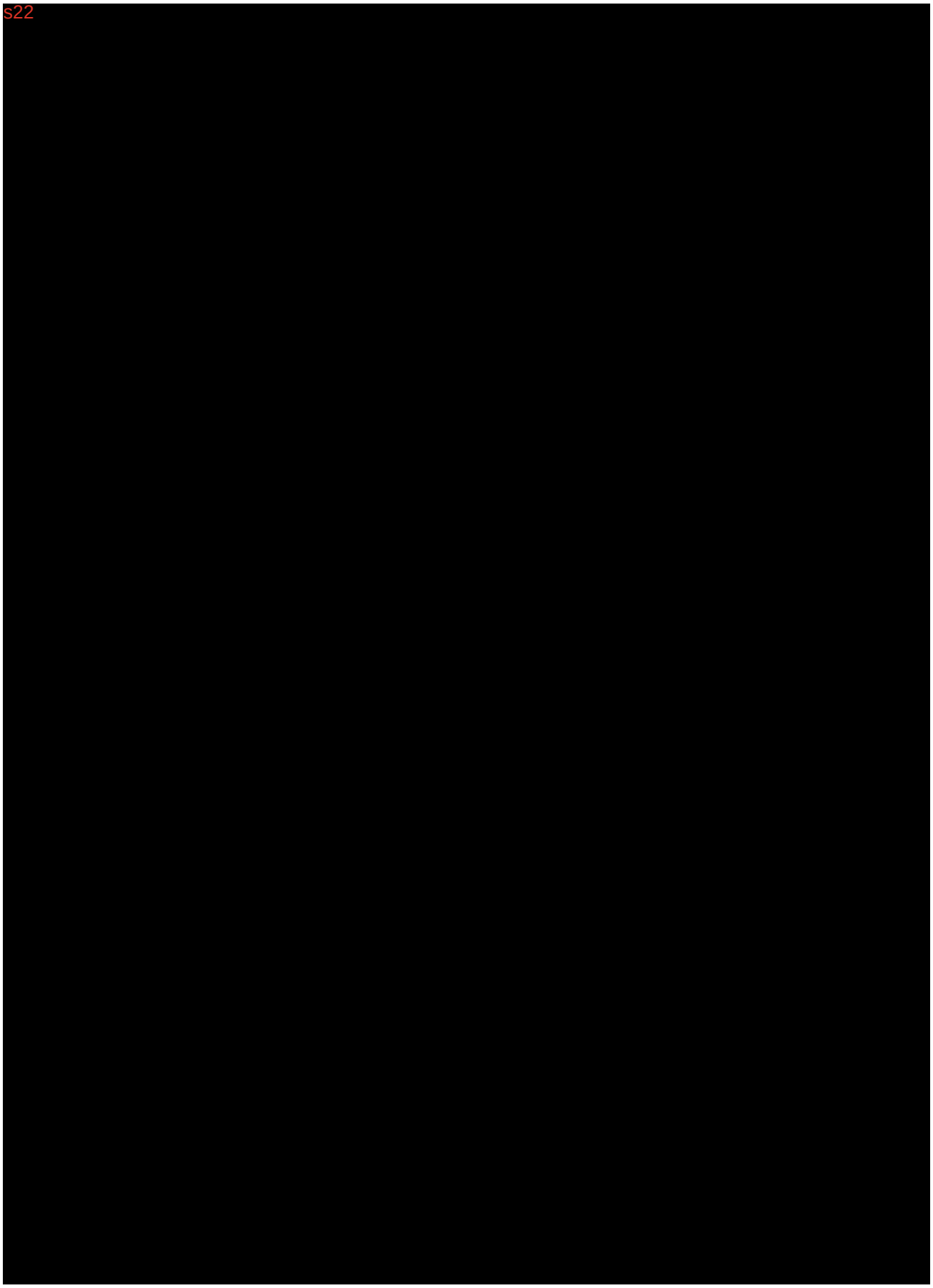
s47 [redacted] he TGA also mentioned that consideration will be given to developing additional guidance for manufacturers, sponsors and distributors.

ACTION items:

- s47 [redacted]
-

s22 [redacted]

s22



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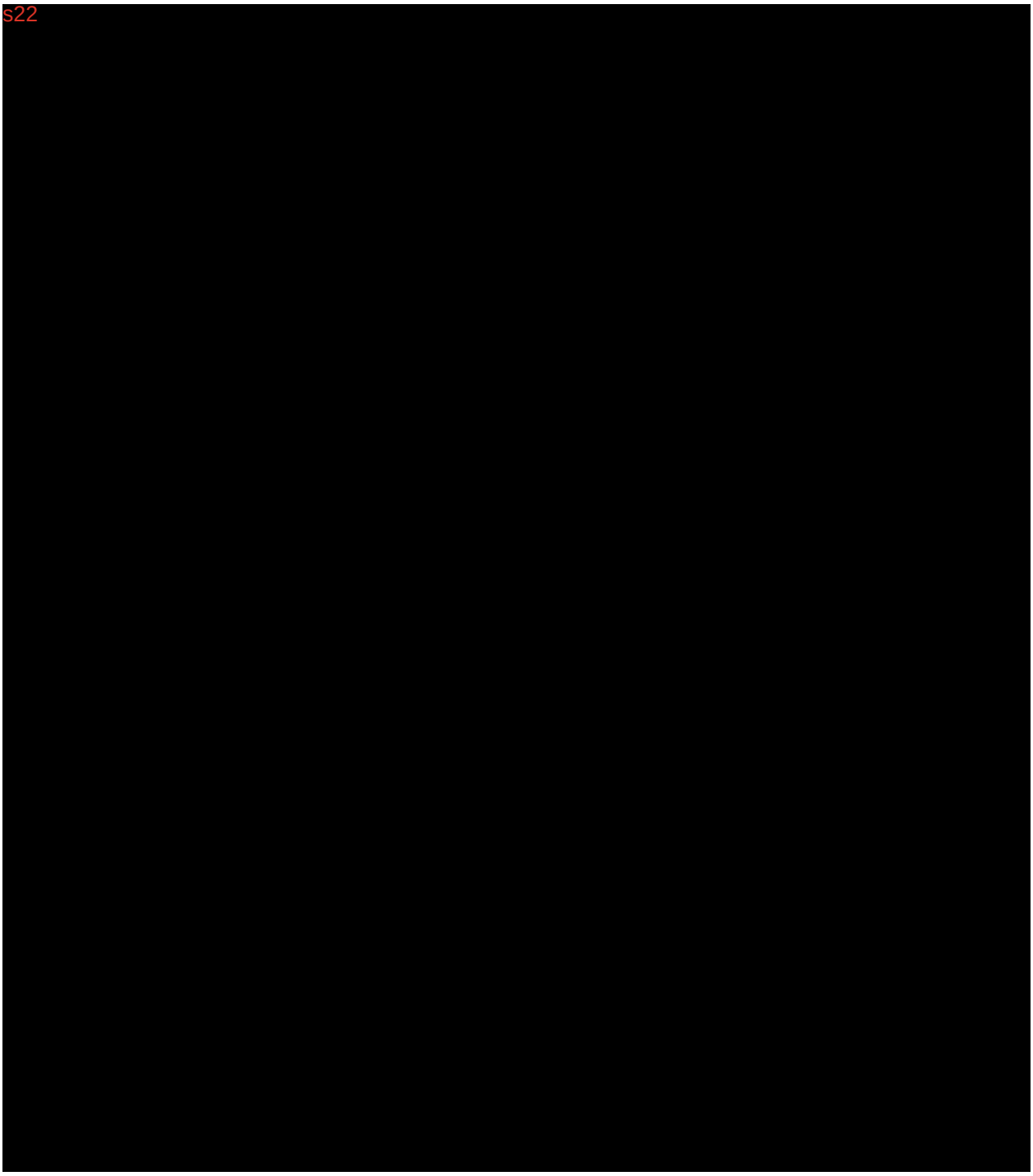

4.8 Additional business: For noting

The Chair thanked the members for their attendance and discussions.

There was no additional business discussed.

The meeting was declared closed at 2.25pm

Therapeutic Goods Administration

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Complementary and OTC medicines Regulatory and Technical Forum

Item No. 4.4
ComTech 11

Date: 3 May 2022

Subject: **Promotional listed sunscreens**
Speaker s22 [redacted]
Assistant Director, Listing Compliance Section

ISSUE

- The Listing Compliance Section (LCS) has observed an increasing number of listed sunscreens (herein after referred as sunscreens) that are used as promotional products for third parties that are not the sponsor. A single listing may then have tens or hundreds of considerably different labels circulating in the Australian market (i.e., in-use labels) at any given time.
- This practice breaches legislative requirements related to the presentation of listed goods and may also breach advertising and manufacturing requirements. This practice also significantly hinders the proper identification of the goods, posing risks to consumers who may want to avoid certain sunscreen formulations as well as adverse event reporting of the correct product.

OUTCOME SOUGHT

That members:

- **NOTE** that the listing of promotional sunscreens is unlawful.
- **NOTE** that the TGA has been and will continue taking enforcement action against this practice.
- **SHARE** information with your members to raise awareness that this is unlawful.
- **DISCUSS**
  - (i) why the practice of listing sunscreens for promotional use is becoming popular amongst sponsors of sunscreens
  - (ii) possible strategies to reduce this issue and improve compliance.

BACKGROUND

- Compliant medicine labels are fundamental for the safe and effective use of listed medicines. In the context of self-selected medicines, the written content and graphical design of a medicine label is crucial for the correct identification and/or discrimination of a particular product. A consistent content and display format helps consumers find the information they need and minimises the potential for confusion and misinterpretation.
- The LCS has noted various cases where sponsors of sunscreens sell their product for promotional purposes through their websites or third-party websites, giving the option to third parties (other entities or consumers themselves) to customise the front panel of the label with any logo/design they want. See attachment 1 for illustrative examples.

- Compliance review of some sunscreen labels have shown that about 80-90% of the area of the front panel consists of information not relevant to the product itself or the sponsor. For example, third party brand logos, brand names, graphic designs and texts, and/or contact details (e.g. phone numbers, addresses and/or websites that are not the sponsor/distributor's details). While the remaining area of the front panel usually includes the name and AUST L of the goods, it is located in a very discrete position and not displayed in a conspicuous manner.

- During our compliance activities, sponsors have revealed and provided evidence outlining that a single listing may have tens or hundreds of significantly different labels at any given time. Concerningly, some sponsors have reported that it is unknown to them how many different labels could be in-use for their sunscreen at a given time.

- In some cases, we have detected differences between back/side labels of the same product across the various labels in relation to declaration of substances, directions for use and advisory statements. This is of particular concern as having accurate and non-confusing information about declarable substances and advisory statements as well as directions for use that align with the AS/NZS Sunscreen Standard are critical to ensuring the safe use of these listed sunscreens.

- Sponsors are knowingly supplying sunscreens with generic labels, with the intention for third parties to add information to these labels. They do not control or restrict the information added by these third parties. Given this is the sponsor's intended business model, they are liable for these third-party modified labels breaching the law.

- Examples of customised front panels of labels for single sunscreens that we have observed include:

    - brand logos/names of skin cancer clinics, dentists, hospitals;
    - brand logos/names of State Governments, councils, members of parliament;
    - brand logos/names of service businesses, banks, insurance companies, schools, colleges (amongst others).

KEY CONSIDERATIONS

Relevant legislative requirements and potential compliance breaches

- The label of a sunscreen, including any statement, pictorial representation or design in it, is covered by the definition of 'presentation' and 'advertise' in section 3 of the Act. It is therefore subject to legislative requirements related to the presentation and advertising of goods listed under section 26A of the Act.
- Having multiple in-use labels for a single sunscreen with vastly different written content, pictorial representations or designs can easily mislead or confuse a reasonable consumer as to the proper identification of the goods. For example, certain texts of the promoted brand/entity/service can be confused and taken to be the name or part of the name of the sunscreen, which is different to name of the sunscreen appearing in the Certificate of the Listing. It can also be hard for consumers to recognise that two bottles with very different

labels are the same product. Therefore, this can result in the following issues for which the sponsor is liable:

  - unacceptable presentation within the meaning of subsection 3(5) of the Act;
  - incorrect certification under paragraph 26A(2)(c) of the Act— that the presentation of the medicine is not unacceptable;
  - be taken to be misleading advertisement under paragraph 8(1)(a) of the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument (the Code);
  - incorrect certification under subparagraph 26A(2)(da)(i) of the Act— that the medicine complies with the applicable provisions of the Code;

- In-use labels containing statements and/or pictorial representations referring to:
  - a government, a government authority, a hospital, a healthcare facility, a current or former health practitioner, a health professional, a medical researcher, and/or an organisation that represents the interests of healthcare consumers (amongst others), can be taken to be an endorsement for the sunscreen. This is not permitted under subsection 24(6) of the Code.
  - the name and contact details of entities that are not the sponsor or distributor of the sunscreen (including phone numbers, physical addresses, email addresses or websites), can be taken to be unacceptable presentation within the meaning of subsection 3(5) of the Act as it can be capable of mislead or confuse consumers as to the proper identification of the goods (e.g. identification for the purposes of recall or reporting issues with the product). Notably, having contact details on the label that are not the sponsor's or distributor's can also breach pharmacovigilance requirements as it may limit the sponsors ability to collect safety information for that therapeutic good (please refer to the Pharmacovigilance Guidelines).

- The LCS has noted that in some instances customised labels are added to the product by third parties and/or the sponsor itself while not being an authorised manufacturer (i.e. not included in the ARTG entry for the goods) and/or not being a GMP licenced or certified manufacturing facility to conduct the manufacturing step of labelling. This may (amongst others) lead to the following issues which the sponsor is liable:
  - incorrect certification under paragraph 26A(2)(h) of the Act— that all the manufacturers of the medicine are nominated as manufacturers in the application;
  - incorrect certification under paragraph 26A(2)(e) of the Act— that if the medicine has been manufactured in Australia—each step in the manufacture of the medicine has been carried out by a person who is the holder of a licence to carry out that step;

  - breach of a condition of listing under paragraph 28(5B)(a) of the Act — that each step in the manufacture of the medicine that is carried out in Australia is carried out by a person who is the holder of a licence to carry out that step;
  - breach of a condition of listing under paragraph 28(5B)(b) of the Act — that each step in the manufacture of the medicine that is carried out outside Australia is the subject of a certification in force under subsection 26A(3) of the Act;

- All the breaches above can result in the cancellation of the goods from the ARTG under section 30 of the Act and constitute offences under various sections of the Act that can lead to financial penalties for the sponsor.

Potential risks of this practice

There are several possible scenarios relating to promotional sunscreens with multiple labels that may pose risks to consumers, for example:

- Certain sunscreen ingredients, such as fragrances (typically not declared on the label), can trigger skin allergies or irritation reactions in some people. For some consumers, the look of a sunscreen is the only discriminatory factor when they want to avoid its use (especially when it has caused them a reaction in the past). A single product with several vastly different labels may impede such discrimination.

- Consumer level recall actions for promotional sunscreens may be significantly more difficult as consumers may be unable to correctly identify the affected product when several different in-use labels are circulating at the same time. Even more so when a sponsor does not know all the labels that have been applied to their product.

- Labels that display the name, logo and/or contact details of an entity unrelated to the sponsor or distributor of the sunscreen, may confuse and/or mislead consumers regarding who they should contact to report an adverse reaction or make a complaint about the product. This significantly hinders a sponsor's ability to fulfill their pharmacovigilance responsibilities.

ATTACHMENT 1

Example of label released for supply

Front Panel

Back Panel

Examples of customised front panel

Example 1

Example 2

Example 3

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Complementary and OTC Medicines Regulatory & Technical Forum (ComTech)

Record of outcomes

Meeting 18th October 2023

Contents

External Participants

Participant	Organisation	Item
s22		

TGA Participants

Name	Position	Item
s22		Item 2 Item 3
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		Item 4.3 Item 4.9
		Item 4.4
		Item 4.8
		Item 4.5
		Item 4.5
		Item 4.6

Apologies

Participant	Organisation
s22 [redacted]	

1 Administrative items

s22 [redacted]

2 Work plan and action items

s22 [redacted]

s22 [redacted]

s47 [redacted]

s22 [redacted]

3 TGA and ComTech member verbal updates

s22

4 Discussion items

s22

s22 [redacted]

4.3 TGA Verbal: Update on Sunscreens issues

The TGA first provided an update on the consultation on proposed clarification and updates to the regulation of sunscreens which closed on 31 May 2023.

In relation to the three proposals that were included in the consultation:

1. Removal of exemption provisions for sunscreens with less than SPF 4: there were no objections to this proposal and ministerial approval has been given. The regulatory amendments are scheduled to commence in January 2024
2. Adoption of the new sunscreen standard: the TGA has received advice from the Office of Impact Analysis that an Impact Analysis is required due to the potential burden to industry and the first draft is currently with the Office of Impact Analysis (OIA). If that all goes well the adoption of the new standard should be implemented in mid-2024
3. Clarification of indications permitted for sunscreens: the majority of consultation responses supported maintaining the status quo, where sunscreens can only use indications permitted for sunscreens. This will be clarified in the next update to the Permissible Indications determination.

s47 [redacted]

Update on Benzophenone safe limit in sunscreens

The TGA provided an update on the Low-negligible risk consultation issue surrounding setting a safe limit for benzophenone in sunscreens – closed 14 September – noting that the consultation responses are currently being reviewed s47 [redacted]

The TGA outlined that the consensus of the responses is that there does need to be a safe level set for benzophenone, however the limit proposed (26 ppm) in the consultation was quite restrictive and further work will need to be done in that space. The TGA noted that there is no rush to set a safety limit and the aim is to keep sunscreens within the low-risk category.

The TGA noted that scientific information relating to dermal absorption of benzophenone is being considered for establishing a more appropriate dermal absorption factor. With regards to an appropriate daily sunscreen exposure rate, however, the TGA noted that the only recommendation for a daily exposure rate currently available is that provided by the Cancer Council and acknowledged that it can be considered to be an overestimation when applying that to daily use for prolonged periods (i.e., 365 days of the year). On the other hand, the Scientific Committee on Consumer Safety (SCCS) prescribes a very different amount of 18g/day. It is important to note that this amount is not a recommendation by the SCCS but is based on habits and practice type data which is very different to recommendations from government and public health organisations in Australia as well as directions for use on Australian products. Moreover, the locations and jurisdictions where that data has been gathered from may not be relevant to Australia so further investigation into a more fit for purpose exposure model for the Australian context is required.

s47 [redacted]

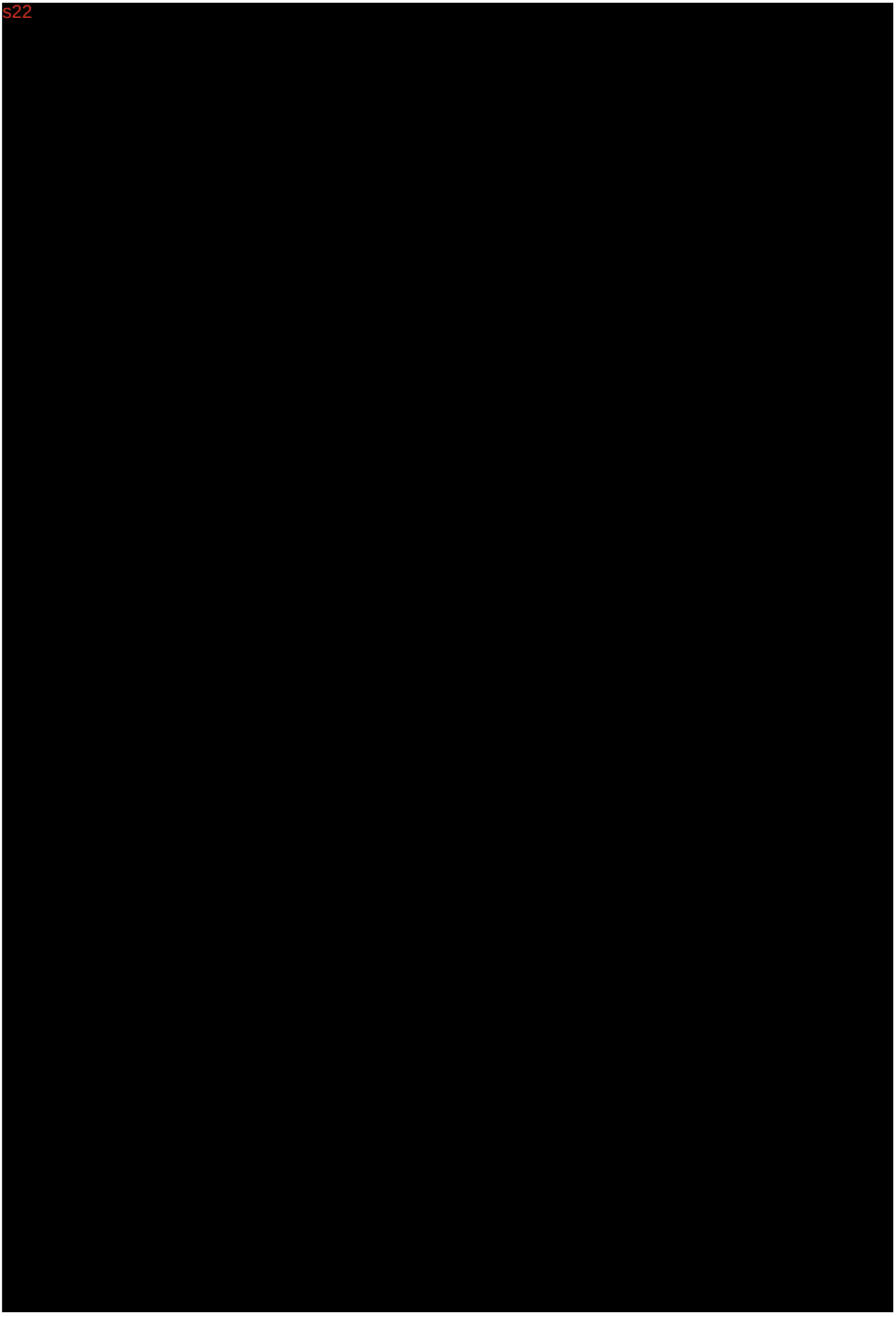
The TGA confirmed that discussions will be had with industry members before a legislated safe limit of benzophenone is established, however noted that the outcome of the Low-Neg risk consultation may need to be deferred as a safe limit cannot be set in the absence of an appropriate daily exposure rate. In terms of the exposure model, s47 [redacted]

ACTION items:

- s47 [redacted]
- TGA to consider options to consult on the exposure model currently being developed by the TGA toxicology section.

s22 [redacted]

s22



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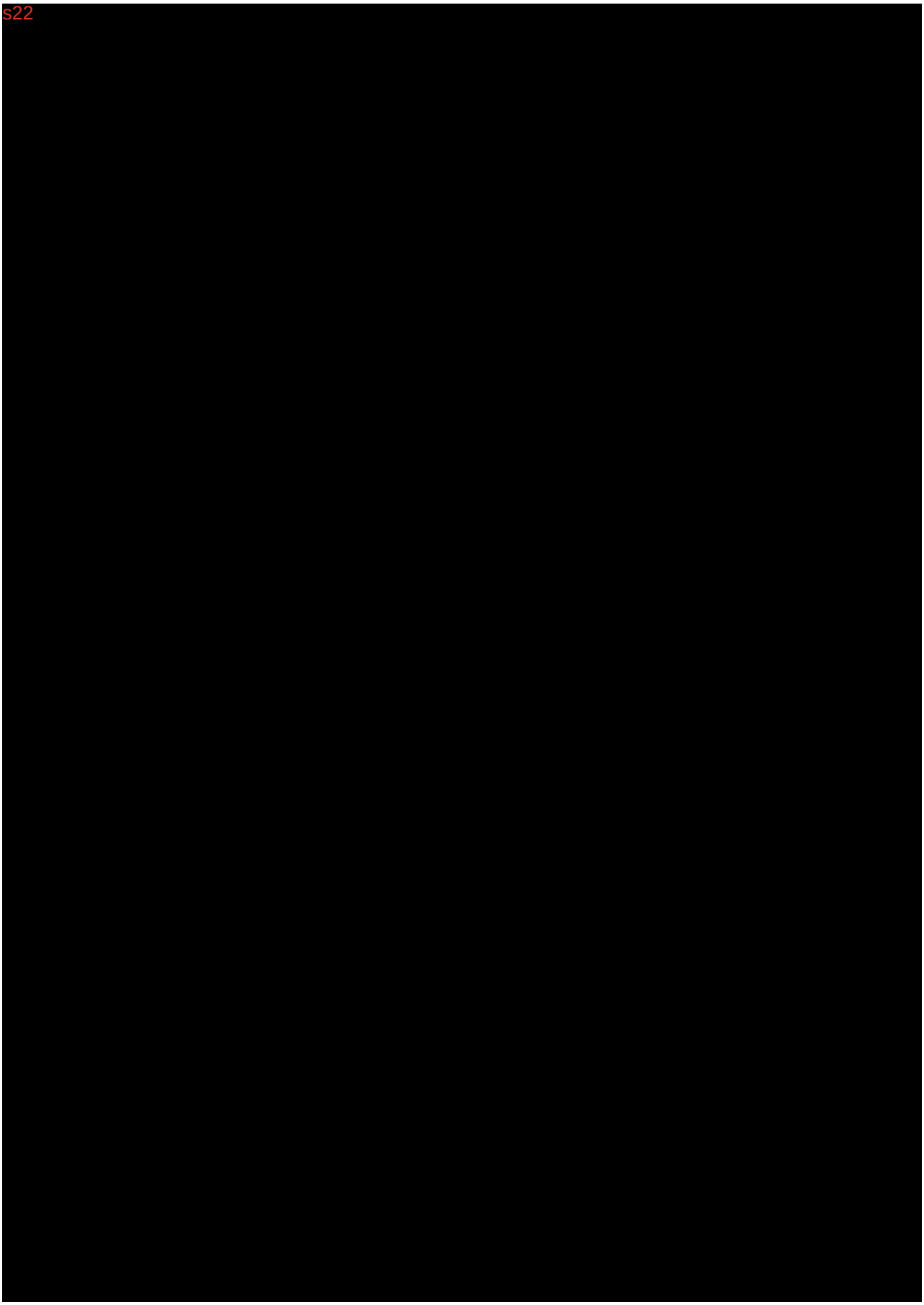

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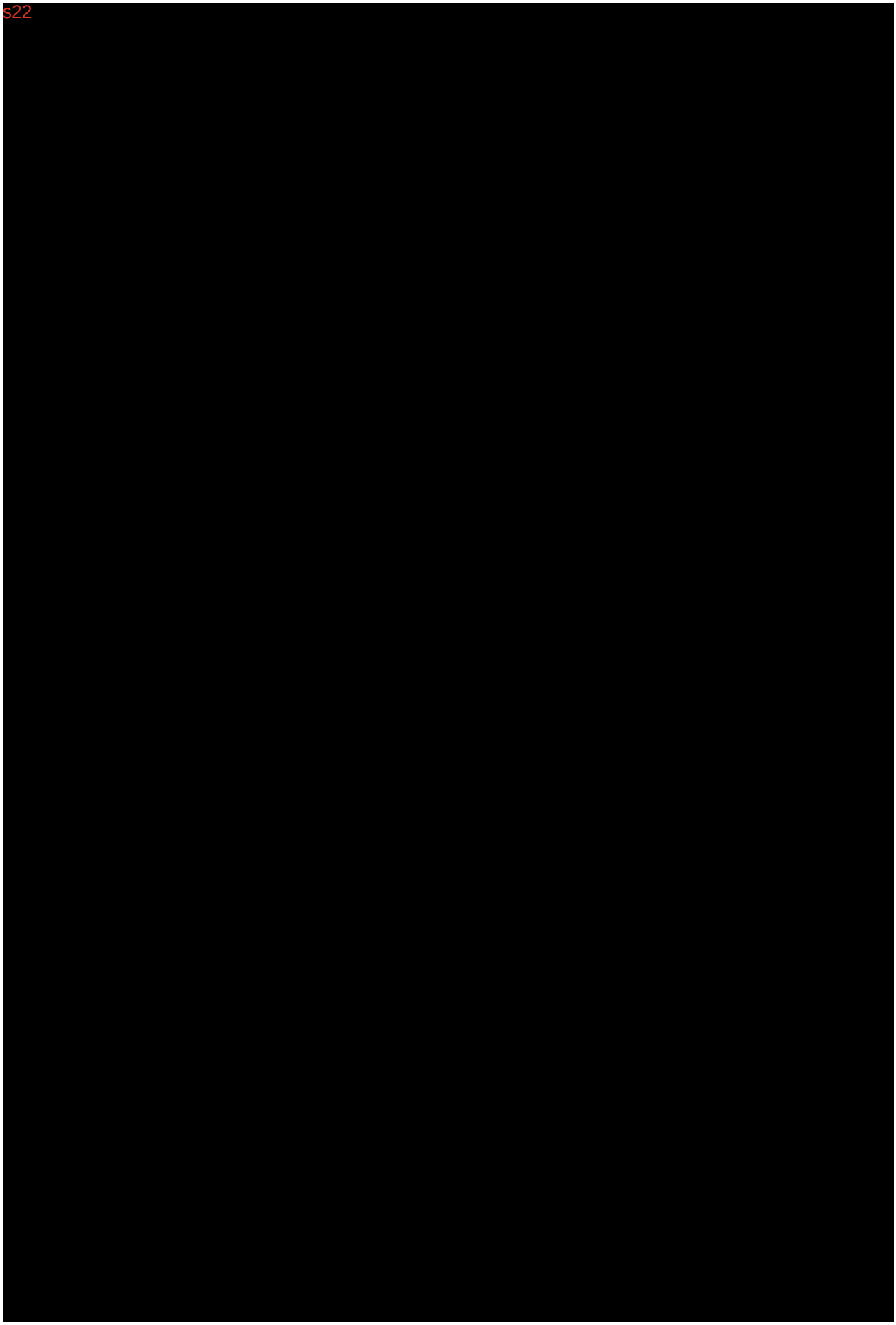

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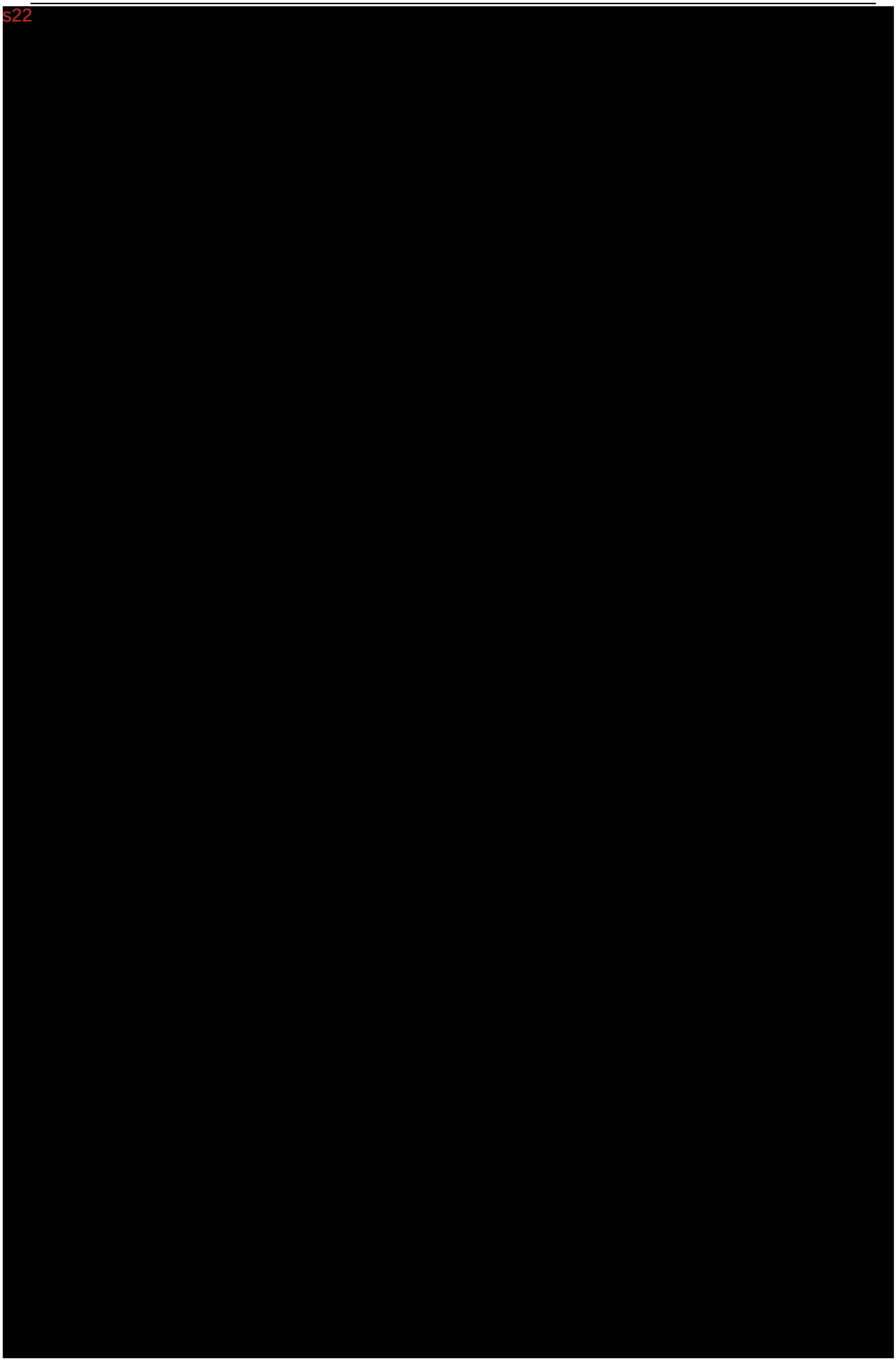

s22 [redacted]

The Chair thanked the members for their attendance and opened discussion on any further business.

s22 [redacted]

The meeting was declared closed at 3.00pm

Therapeutic Goods Administration

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Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Complementary and OTC Medicines Regulatory & Technical Forum (ComTech)

DRAFT Record of outcomes

Meeting 20th May 2025

Contents

External Participants

Participant	Organisation	Item
s22		

TGA Participants

Name	Position	Item
Avinash Clarke (Chair)	Assistant Secretary (AS), Complementary and OTC Medicines Branch (COMB)	Item 1.1 Item 1.2 Item 2.1 Item 3.1
s22		

1 Administrative items

s22

[redacted]

2 Work plan and action items

s22

[redacted]

s22

[redacted]

s22

s22

4 Discussion items

s22

s22

[redacted]

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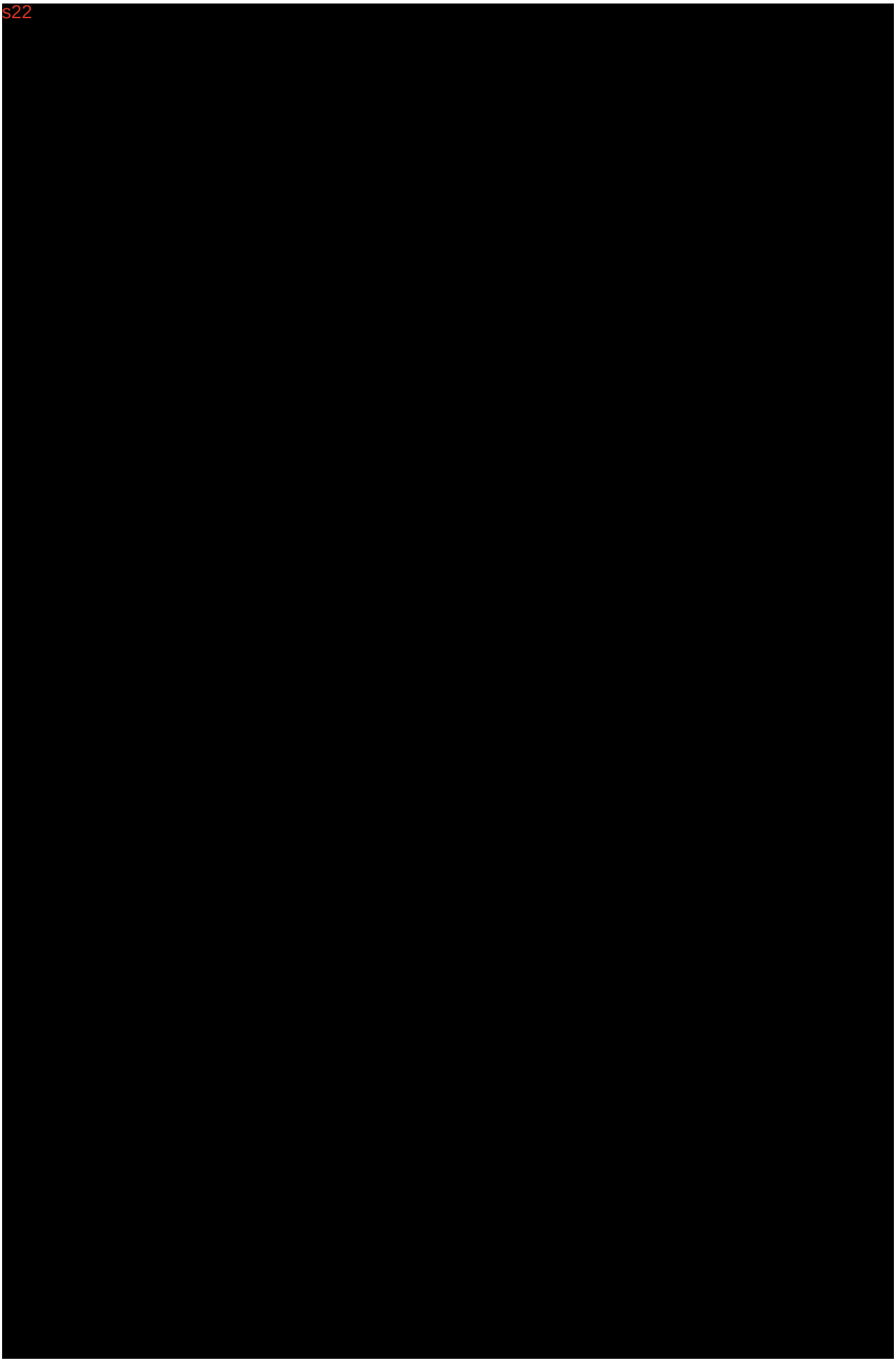

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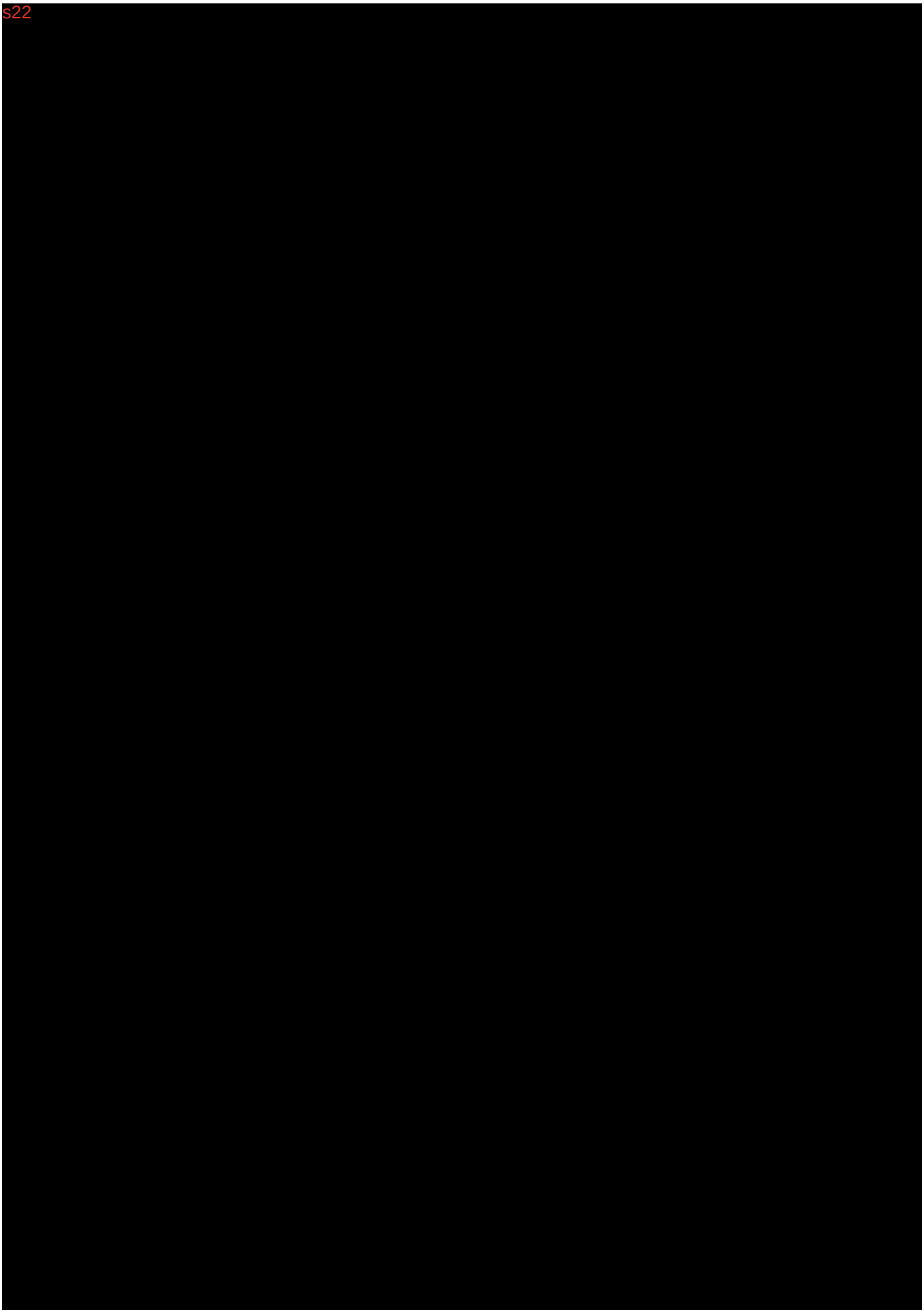

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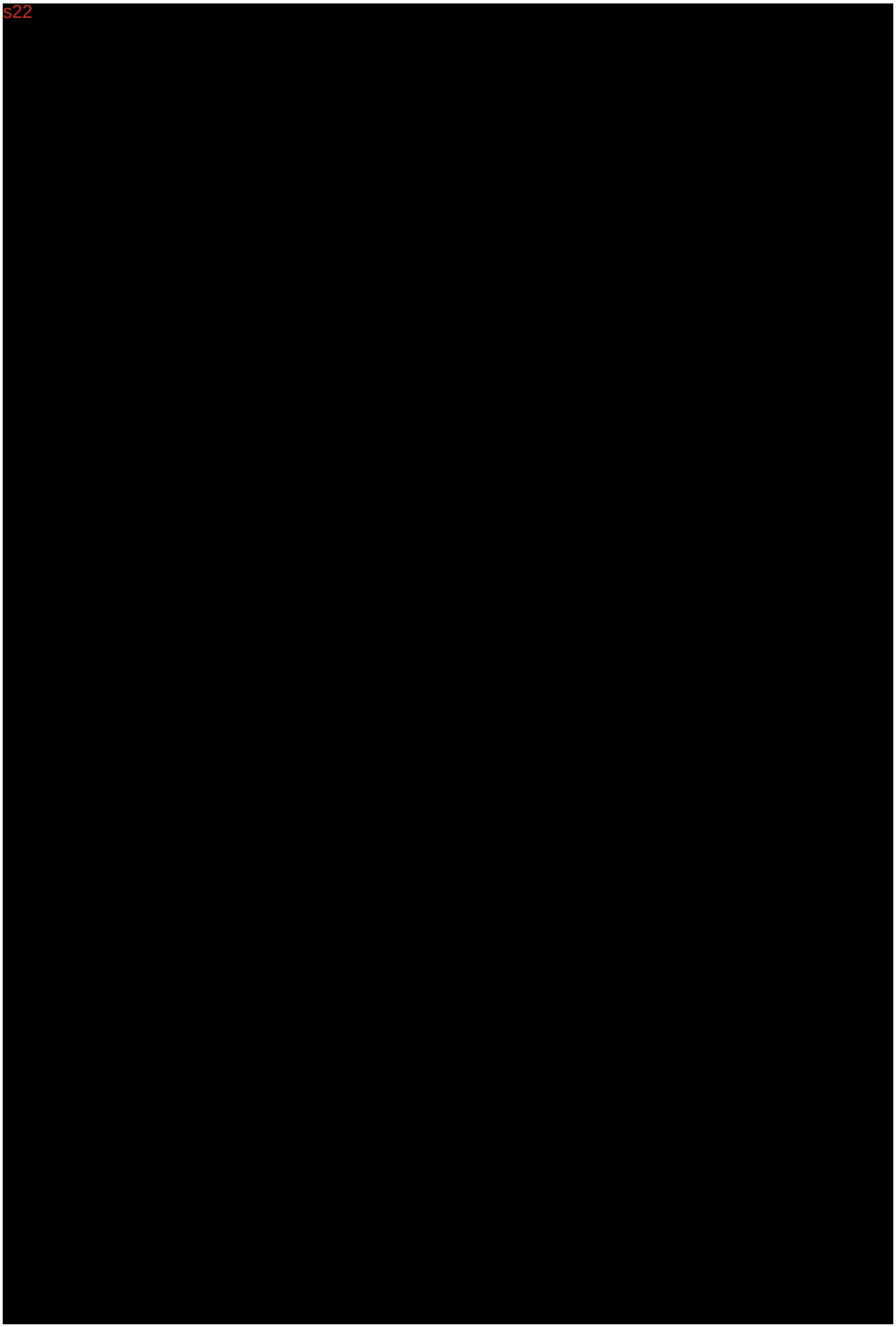

s22

[redacted]

s22

[redacted]

4.10 ACCORD Presentation: Sunscreens work

s47

[redacted]

The TGA reiterated that sunscreens are regulated within the listed medicines regulatory framework and the data requirements for sunscreen ingredients are consistent with all other

topical listed medicine ingredients. Further, recent consideration of the safety of certain sunscreen ingredients, such as benzophenone, reinforces the position that the approval of any new ingredients should be supported by appropriate safety and quality data. Industry replied that sunscreens cannot be tested for unknown factors.

s47 [redacted]

ACTION items:

- s22 [redacted] to send their sunscreen presentation to the ComTech.Secretariat inbox.

s22 [redacted]

s22 [redacted]

The Chair thanked the members for their attendance. The meeting was declared closed at 3pm.

Therapeutic Goods Administration

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Outcome Note

s47 [redacted]

Date: 21 February 2024

Time: 10am to 12 noon

Location: TGA Fairbairn

Purpose of meeting:

s47 [redacted]

- Increase in safety data requirements.
- New quality and compositional requirements.
- Application pathways.

External Participants

Participant	Organisation
s47 [redacted]	

TGA Participants

Name	Position
Nick Henderson	First Assistant Secretary, Medicines Regulation Division
Cheryl McRae	Assistant Secretary, Complementary & Over the Counter medicines Branch
s22 [redacted]	

Discussion

1 Increase in safety data requirements

- Discussion on the increase in safety data requirements did not occur due to lack of time. Discussion on actual data points was deferred to a future meeting.

s47 [redacted]

- TGA response:
  - In a meeting with s47 [redacted] and Deputy Secretary, approx. 3 years ago, the TGA made it clear they were reviewing the requirements for all ingredients to ensure consistency across all evaluations (including for topical sunscreens and listed medicines). There was no undertaking the review would be a clarification of existing requirements only.
  - s47 [redacted]
  - The safety of any ingredient is based on its hazard when exposed to skin, regardless of whether it's intended to be an active or excipient. Safety requirements are lower if not absorbed. The SCCS applies default absorption values if no data is provided, and the FDA has verified that sunscreen active ingredients are absorbed and is calling for further safety data.

2 New quality and compositional requirements

- s47 [redacted]

s47 [redacted]

- TGA response
  - Sunscreens must be manufactured under GMP, which includes having established specifications for each ingredient and validated test methods. This is specified in the sunscreen GMP guidelines. If this is not done for cosmetic ingredients, they would be non-compliant. Validated test methods ensure results are accurate/reliable and were also specified in the previous ARGS. If applicants validate but don't meet the ICH guidelines, they can provide justification.
  - It is not a legal requirement that excipients (raw materials) must be manufactured in compliance with GMP so there is no overlap. This was discussed with TGA GMP inspectors during the industry working group meetings in 2020. s47 [redacted]
  - A basic tenet of GMP is that quality must be built into each batch of product, including knowing the quality of the ingredients and controlling impurities. Carcinogenic impurities such as benzene need to be controlled at the ingredient level because they cannot be identified/tested in the final product if you don't know to look for them. This resulted in a safety recall of sunscreens due to benzene contamination derived from excipients.
  - Premarket quality evaluation establishes what the ingredient is so it can be manufactured under GMP according to what was evaluated/approved as safe.
  - In relation to how the SCCS evaluates active and excipients, a TGA officer stated that the 'SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation' provides that there are basic and minimal quality specifications required to evaluate a cosmetic ingredient. SCCS also requires validated methods. They, like TGA state this is also important for assessing the safety of the ingredient.
  - The TGA acknowledged that many ingredients on the Permissible Ingredients Determination may have been "grandfathered" when the Act came into force. However, new ingredients are required to be evaluated and there is no continuation of the "grandfathering process".
  - Testing and requirements for hazardous impurities are considered based on the quantity of the ingredient applied to the skin in the final product. Applicants justify safety based on the circumstances.
  - The TGA will review whether annotation of 26BB can occur.
- Other specific issues were discussed as provided in the following table:

Table 1: Specific issues raised by industry and TGA response

Specific issues	s47 [redacted]	TGA
Compositional requirements		There are 2 ways of controlling quality for ingredients (including excipients) used in listed products: • Full compliance of the ingredient with a monograph in a default standard

Specific issues	s47	TGA
		• In the absence of a monograph the TGA considers quality of the ingredient. The compositional guideline states what TGA evaluated as being safe and establishes specifications for GMP. This allows market access without requiring premarket evaluation of individual products as is required for other products.
Stability of excipients		This is incorrect. Stability data is not a requirement for dermal excipients and this is specifically not required based on consultation feedback.
Assay of ingredients		Assay is not required if the dermal excipient is only used for its physical properties. This was based on discussion with GMP inspectors about what is required for GMP during consultation workshops and subsequent industry feedback resulting in tailoring of requirements for excipients.
Multi ingredient raw materials		There are some instances where an ingredient can be a mixture of components and the compositional guideline would specify the composition of that ingredient as the name of the ingredient is not sufficient. There is a current sunscreen excipient application like this. However, ingredient pre-mixes are not permitted as individual ingredients for inclusion on the Permissible Ingredients Determination – each ingredient must be approved on its own.

3 Application pathways.

- Discussions on application pathways did not occur due to lack of time and was deferred to a meeting to be scheduled in the future.
- s47 [redacted]
- TGA response:
  - Agreed preference for all ingredient applications to come through s26BB as it had defined timeframes and a legislative process for considering decisions and appeals. The origin for the review of ingredient requirements was the Medicine & Medical Device Regulation Review which recommended addressing significant issues with the

previous r.16GA process that was used for all ingredients and was based on page count, had no timeframes, no appeal rights etc.

Action items

- s47 [redacted]
- The TGA is open to considering amendments, or additions to our guidelines if there are areas that aren't clear, noting specific examples would support this process.
- TGA to investigate how ingredients are currently annotated and investigate whether sunscreen ingredients or dermal ingredients can have specific annotations.
- TGA to hold further workshops to discuss safety data requirements and application pathways noting that there was no time to discuss these issues at the meeting.

From: HENDERSON, Nick
To: s22 [redacted]
Cc:
Subject: FW: Sunscreen working group meeting - next meeting [SEC=OFFICIAL]
Date: Tuesday, 23 July 2024 8:41:49 AM
Importance: High

Hi All

s22 [redacted] has sent through the below ahead of tomorrow's sunscreen meeting. I have added some comments in green I was proposing to go back to her on as an initial response we can talk to further tomorrow. Any further comments you suggest we add? It's great she has provided us their position statement ahead of the meeting and I'd like to get back to her with some comments against he below early this afternoon.

Could I also get a copy of the table that highlights the evidence requirements and splits about excipients. As discussed last week, I'd like to also send this on to s22 [redacted] as I'm keen to work through this table to clarify where their concerns continue to be in relation to regulating excipients in a streamlined way and for us to explain where the lesser requirements are for excipients and what we would expect to see.

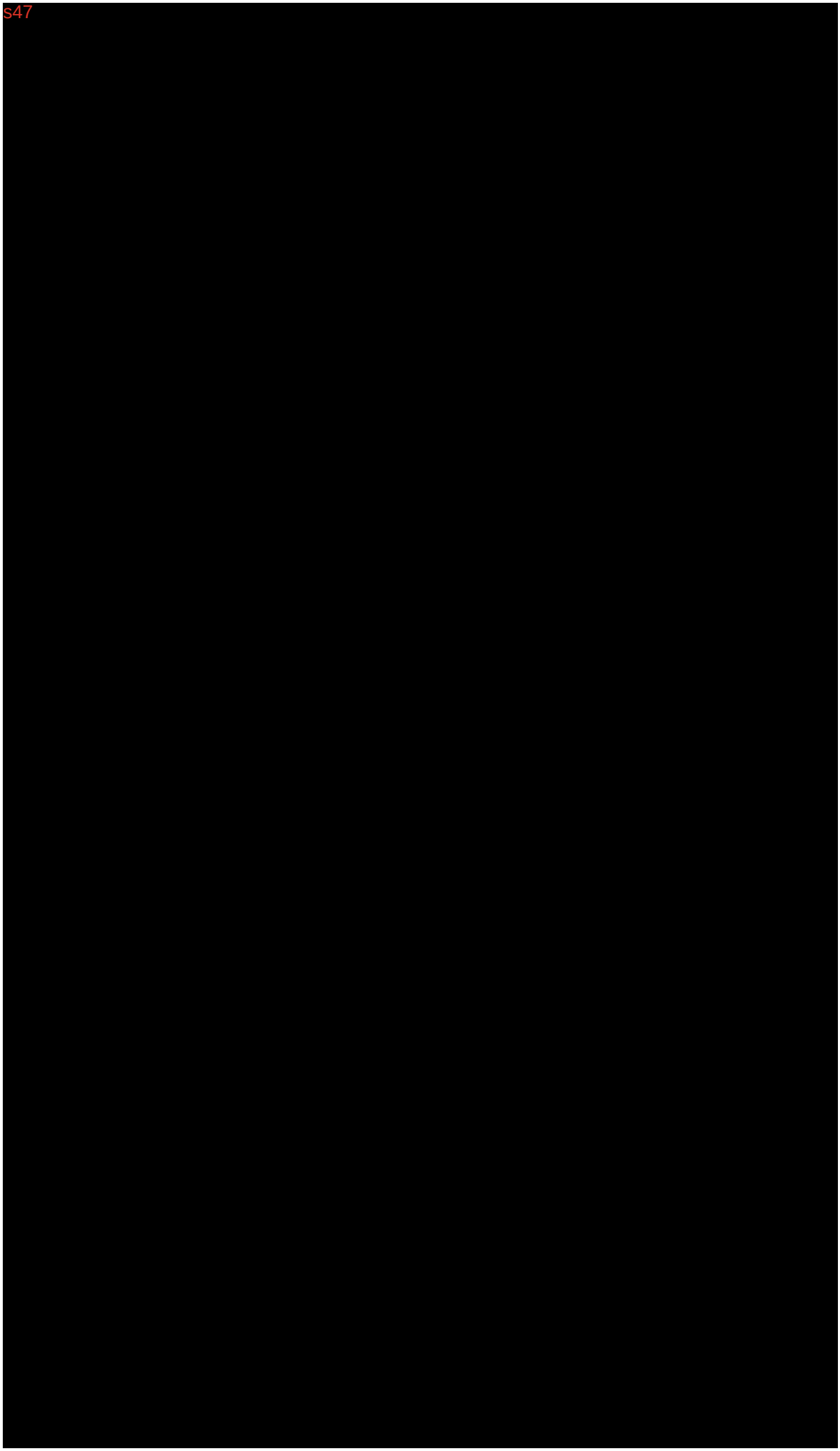
Nick

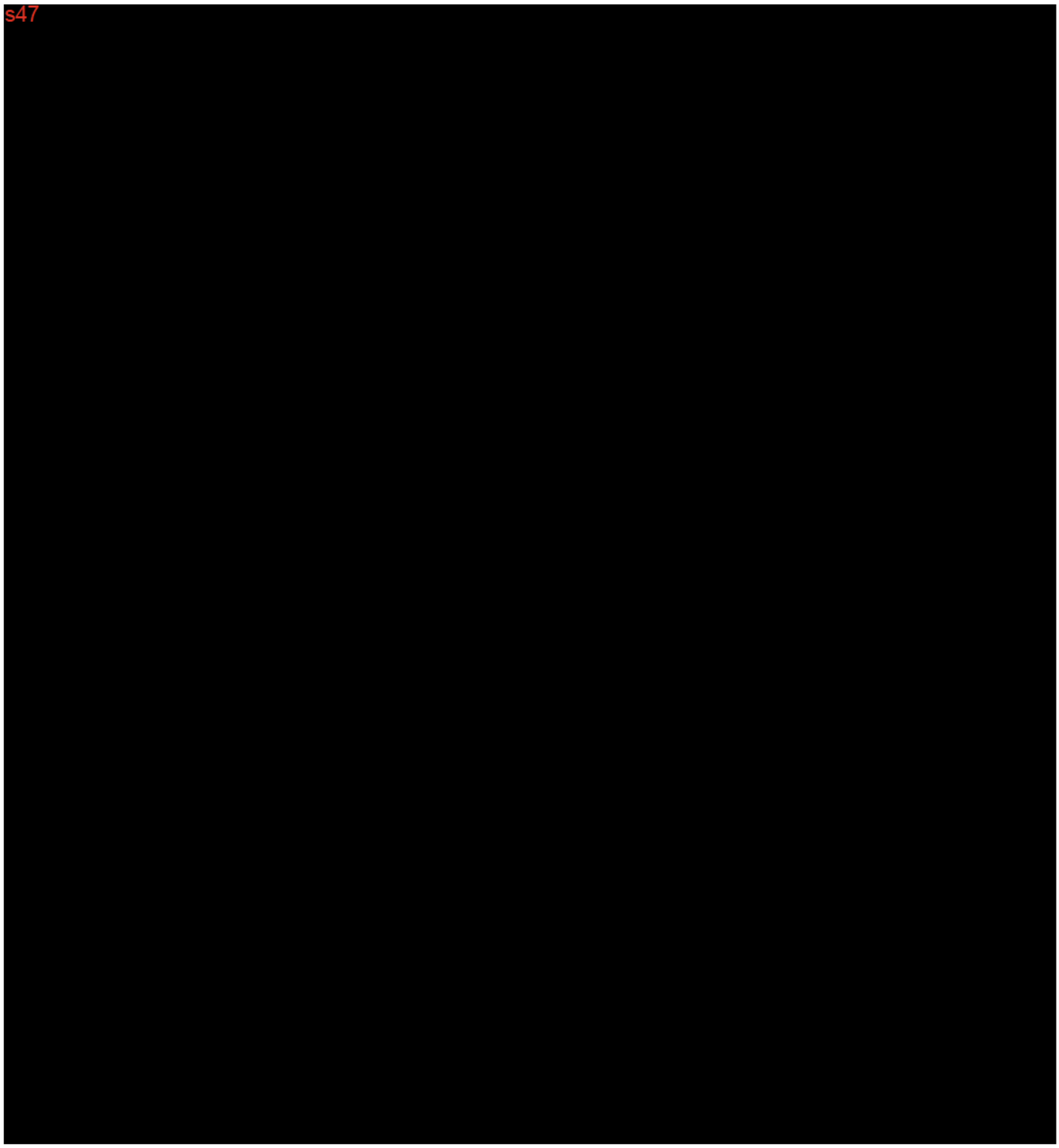
From: s22 [redacted] s47 [redacted]
Sent: Monday, July 22, 2024 4:55 PM
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>
Subject: RE: Sunscreen working group meeting - next meeting
Importance: High

Dear Nick

s47 [redacted]

s47




s47

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Outcome Note

s47 [redacted]

Date: 24 July 2024

Time: 2 to 4 pm

Location: TGA Fairbairn and virtual

Purpose of meeting:

Further the discussions from the first s47 [redacted], including the outstanding issues from the previous meeting and to better understand the respective problems that Industry and TGA face. Also, to discuss the following matters relating to the Australian regulatory guidelines for sunscreens (ARGS):

- Encourage uptake of pre-submission meetings.
- Clarification that pre-market data requirements are not duplicative of GMP requirements.
- Annotations for sunscreen ingredients on the Permissible Ingredients Determination.

External Participants

Participant	Organisation
s47 [redacted]	

TGA Participants

Name	Position
Nick Henderson	First Assistant Secretary, Medicines Regulation Division
s22 [redacted]	

Discussion

The minutes, circulated on 23 July 2024, were accepted with edits on the representation of the SCCS Note of Guidance. The accepted minutes are attached to the email.

s22 and Nick Henderson made opening remarks, both agreeing that we need to first better identify the respective problems for both Industry and TGA and then work together to resolve them:

- Australia has the highest rate of skin cancer in the world. That's why we should all be trying to make sure Australians have access to world class innovative sunscreen products.
- s47
- Simplifying how sunscreens are regulated will give Australians improved ingredients and products, and greater choice, and ideally lead to increased sunscreen use but it was important to balance what is known about ingredients in sunscreens, to ensure they are safe, and that the effectiveness of sunscreens is not reduced.
- Greater choice of sunscreen ingredients would also benefit local formulators and manufacturers, as well as those exporting products.
- s47 It was suggested that TGA's uplift in education and guidance on evidence requirements, such that there has been a perception of increase in requirements from this activity. It would be great to explore this together further.
- Ideally, we should be working together to address these issues, and particularly ensure that the TGA is seen as an enabler of change, and a solution provider, rather than a barrier, at the same time ensuring the regulator does not compromise safety and supports consumer confidence in sunscreens.
- The regulatory system, while recognising the importance of these products as therapeutic goods, should be contemporary, efficient, risk proportionate, cost-effective and ideally internationally aligned where possible, noting the different regulatory treatment here, compared to that of EU.
- The regulatory system and processes should also not confound the issues of other types of therapeutic goods e.g. through inadvertent use of those designed for oral products. Dermal excipients are treated differently in relation to some evidence requirements, and it would be useful to go through these differences to ensure a common understanding of what is required.
- s47
- This being achieved i.e. the requirements being better fit for purpose, enables us to then jointly consider the most appropriate streamlined regulatory process, cost recovery model and application fees, also bettered nuanced between actives and excipients.

s47

The TGA queried if the perceived trend of decrease in sunscreen excipient ingredients available in the Australian market may be confounded by the general decline in numbers of such ingredients being developed in the overseas market. In addition, the TGA was inclined to think that the surge numbers in the 1990s and 2000s could potentially be associated with pre-approval ingredients when the regulatory framework was changed. Industry has responded that in fact there was increasing global innovation in sunscreen.

1 Encourage uptake of pre-submission meetings

- The TGA believes that the ARGS is very well-written, however, not as well-articulated in the application requirements for new substances in listed medicines (ARNS), and this results in the sponsors' perceiving an increase in requirements. The TGA attribute this to the ARNS currently being written to comprehensively cover all possible scenarios, not exclusively for sunscreens.
- To assist in clarifying data requirements for sunscreen ingredients, sponsors are encouraged to take up the option of pre-submission meetings (PSM) that are conducted at no fee, prior to submitting an application.
- The TGA reported that applicants of sunscreen ingredients have had positive engagement with the TGA through PSM or further discussions in putting together their application package.
- A recent example of a sunscreen excipient that made its entry on the Permissible Ingredients Determination is 'D-glucose, polymer with xylitol' (see compositional guideline published on the TGA website). This ingredient is a product of a chemical reaction resulting in an inseparable mixture comprising several components.
- s47 [redacted]

2 Clarification that pre-market quality-related data requirements not duplicative of GMP requirements

- There was discussion of pre-market ingredient evaluation quality-related requirements and perceived overlapped with those of GMP.
- The TGA stated that GMP inspections are designed to verify manufacturing compliance for quality assurance purposes. For a sunscreen manufacturer, amongst other extensive requirements required for an inspection that is undertaken within a short span of time, the majority of excipients are not inspected. Specifications for excipient ingredients are often of very low standard and are meaningless during an inspection, limited to their physical properties. Consequently, new ingredients that have been pre-market assessed with accompanying compositional guidelines have made the inspection more meaningful.
- The TGA confirmed that their priority during audits would not be on low concentration excipients. The example was given that even if the ingredient contained impurities, these would not be at a large enough concentration in the final product to warrant further exploration.
- The TGA also confirmed that the intent of GMP regulation, including audits, is to ensure quality of therapeutic goods.
- In relation to the challenges of obtaining commercially confidential information from manufacturers for commercial reasons - ARNS provide guidance that where a manufacturer is unwilling to supply manufacturing details to the applicant, the information can be supplied directly to the TGA with written authorisation from the applicant. Under the TGA approach to disclosure of commercially confidential information (CCI) policy, the TGA is required to take measures to protect all information, including commercially confidential information.
- s47 [redacted]

- Greater clarification would be useful in relation to:
    - mandatory application elements,
    - mandatory compliance elements, and
    - where justification is possible for quality standards where there is no evidence of safety concerns.

3 Annotations for sunscreen ingredients in the Permissible Ingredients Determination

- An action item from the last s47 [redacted] was for TGA to investigate how ingredients are currently annotated and investigate if sunscreen or dermal ingredients can have specific annotations in the Permissible Ingredients Determination.
- It was confirmed that all new sunscreen ingredients added on the Permissible Ingredients Determination have standard wording, for e.g. the wording will cover the restrictions to be used for dermal route of administration only, to not be directed for use in the eye and broken skin, and a maximum permitted concentration in the medicine.
- The basis for implementing restrictions stems from a toxicological point of view. In general, safety information for sunscreen ingredients for use in the eye and broken skin is not being evaluated. The overarching principle is that in circumstances where the TGA do not have the data or reasons for safety concerns, then TGA restrict the use of the ingredient to where we have sufficient information to establish its safety.
- This ensures that when a sunscreen ingredient is added to the Permissible Ingredients Determination, it cannot be used inappropriately e.g. in an oral dose form complementary medicine, or in excessively high doses.

Action items

- s47 [redacted]
- [redacted]
- Increase clarity of ARGS to ensure that sponsors are better aware what requirements are mandatory and which ‘mandatory requirements’ can be replaced with justifications.
- s47 [redacted]

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Outcome Note: s47 [redacted]

Date: 19 November 2024; 2 to 4pm

Location: TGA Fairbairn/ Microsoft teams

Purpose: s47 [redacted]

Accord Participants

Name	Position
s47 [redacted]	

TGA Participants

Name	Position
Nick Henderson	First Assistant Secretary, Medicines Regulation Division
Avi Clarke	Assistant Secretary, Complementary & Over the Counter medicines Branch
s22 [redacted]	

Discussion points

- s47 [redacted]
- The TGA noted that safety of sunscreen ingredient is another important factor identified. This is achieved by ensuring new ingredients are sufficiently low risk to be used in Australian sunscreens.

Issues with sunscreen ingredient applications

- s47 [redacted]
- The TGA noted and clarified discrepancies in the data presented and relevant contextual considerations.

Applications with multiple ingredients

- This data, in addition to recent applications with large number of excipients grouped as one application, have prompted the TGA to investigate the history of r16GA(1)(b).
- 16GA (1)(b) is tailored to historical grandfathering provision that is no longer applicable. 16GA (1)(b) is applicable to a narrow set of circumstances, however there are currently no conditionally

listed medicines on the ARTG. Advice from TGA's legal team is that applications for multiple ingredients must no longer be accepted unless they meet the provisions of 16GA (1)(b).
- Existing current applications will be completed, as they were accepted on face value in good faith.

Issues with ingredient data requirements

- s47
- [redacted]

Mandatory requirements and ARGS

- s47
- [redacted]

Ingredient application pathways

- In response to s47 query about the FFPI pathway, the TGA acknowledged that the FFPI inclusion process is historical and needs to be reviewed holistically at a future time. That given, the current FFPI process is not proposed to change without further consultation.
- In relation to acceptance of IFRA standard for TGA assessment, the TGA have reviewed IFRA during the MMDR reforms and found that it did not meet the criteria for inclusion on the Comparable Overseas list. However, IFRA standards can be used as supporting information.

Action items

s47 [redacted]

TGA

- Send information clarifying the ineligibility of the 16GA pathway for multiple excipient ingredients in one application.
- Consider future alternative application pathways that may be better tailored for sunscreen excipients under s26BD.
- Update ARGS to:
  - Include examples of appropriate justifications in lieu of data (where acceptable).
  - Further clarify the legal requirements around the CGs. And how they can be used for ingredients manufactured by alternate suppliers, that do not strictly adhere to the CG requirements.
  - Clearly identify the main 'critical' safety studies and quality data that needs to be provided in an application.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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Note for file

Date and time	**Date:** 19 November 2024 **Time:** 2 to 4pm **Location:** TGA Fairbairn/ Microsoft teams
Type of event (e.g. meeting/ telephone conversation)	s47 [redacted]
Topic	Discuss industry issues to application requirements for evaluation of sunscreen ingredients
Participants	**External Participants** Participant: s47F [redacted] — Organisation: [redacted] **TGA Participants** Nick Henderson — First Assistant Secretary, Medicines Regulation Division Avi Clarke — Assistant Secretary, Complementary & Over the Counter medic Branch s22 [redacted]
Key points	**Discussion points** **Disincentives for consumer use of sunscreens**

s47 [redacted]

TGA acknowledge that palatability and aesthetics are factors influencing consumers use of sunscreens. However, another important factor is that consumers want to be confident that ingredients used in sunscreens are safe. That is achieved by ensuring new ingredients are sufficiently low risk to be included in Australian sunscreens

Issues with sunscreen ingredient applications

Decrease in number of ingredients approved

s47 [redacted]

The TGA noted discrepancies in Accord's data compared with TGA records but acknowledged the general downward trend of application approvals. The reason for this would be multifactorial, including: changes in the regulatory framework; potential decrease in development of such ingredients; quality of applicant dossiers etc.

Increased time frame for approval

s47 [redacted]

The TGA noted:

- discrepancies in the data compared to TGA's records
- the data does not detail if the application pathway is s.26BD or r16GA. So far, the TGA has not exceeded any legislative timeframes for s.26BD applications.
- Timeframe can be affected by several factors – the time TGA takes to assess and also time taken by applicants to address request for further information.

Increased application costs

s47 [redacted]

The TGA queried these figures. Currently, the cost for full evaluation under s.26BD is $31,156, while an abridged evaluation under s.26BD is $18,331. Currently the r16GA minimal fee is $12,431 when page count is under 50 pages.

Applications with multiple ingredients

The TGA thanks Accord for putting the data together. This data, in addition to recent applications with large number of excipients grouped as one application have prompted the TGA to investigate the history of r16GA(1)(b).

16GA (1)(b) is tailored to historical grandfathering provision that is no longer applicable. 16GA (1)(b) is applicable to a narrow set of circumstances, however there are currently no provisionally or conditionally listed medicines on the ARTG. Advice from our legal team is that effective immediately,

applications for multiple ingredients must no longer be accepted unless they meet the provisions of 16GA (1)(b).

Any existing applications on hand will be completed, as they were accepted on face value and in good faith.

Ingredients available in Australia compared to overseas

s47 [redacted]

The TGA pointed out that a number of ingredients were included in the permissible ingredients determination, and a number of others were included under different synonyms and different hydration states.

If other ingredients are allowed in Australian cosmetic sunscreens and other jurisdictions, applicants can utilise an AICIS, CIR or SCCS assessment reports for their application to the TGA. Under the COB-based abridged process, AICIS and CIR reports can be used to support the safety of a listed medicine ingredient, while SCCS reports safety and quality.

Issues with ingredient data requirements

Change in data requirements in ARGS v 2.0 (July 2021) vs v 3.0 (May 2023)

s47 [redacted]

The TGA contended that the rationale for aligning data requirements for ingredients was discussed during the targeted consultation process from 2021-2023. The principles of Risk = Exposure x Hazard has been emphasised. If the exposure is negligible (i.e. not absorbed through the skin) x hazard (i.e. does not react with the skin), then the data requirements are lesser.

These considerations were documented in the letter written by Dr Cheryl McRae to ComTech on 14 September 2022, and will be sent as an action item for this meeting.

Based on recent concerns relating to sunscreens, the TGA maintains that the quality of sunscreen ingredients should be established pre-market as this relates to their safety. The importance of appropriate testing at raw material level has also been emphasised, as confirmed by Senior GMP inspector at our last meeting.

Compositional guidelines

The TGA reiterated a compositional guideline is not required if a substance has a monograph in the default standards. All other ingredients need a CG to demonstrate what the TGA has evaluated to be safe and establish the specifications for the purpose of GMP.

The CG, after it has been published, allows for flexibility for sponsors/manufacturers, particularly as methods change or are updated.

The name says nothing of the identity and characterisation of the substance e.g. what does plankton extract mean? Which algae or biological organism is it derived from? Having this described in the CG enables clarity of what has been approved as low risk.

The alternative is that 26BB includes specifications in the specific requirements, which was not considered favourable by all participants.

Need to provide all impurities and incidental components

s47 [redacted]

The TGA stated that impurities of an excipient cannot be identified in a finished product unless they are known at the input stage from the individual ingredients. Examples were provided for benzene, benzophenone, dimethyl sulphate, nitrosamines.

All impurities that need to be considered at the starting material/input stage to be able to be detected or tested for if required in the end product - this prevents recalling products on the market when unsafe levels detected as has been occurring. After the testing is done and shows that the impurities and incidental components are not present, these don't have to be included in the CG and there is no need for batch testing for impurities that are not included in the CG.

Multi-ingredient raw material.

s47 [redacted]

TGA evaluates individual ingredients such that a compositional guideline accompanies each ingredient that has been assessed individually. To have multiple excipients in a raw material mixture constitutes a proprietary formulation, which does not align with the Permitted Ingredients Determination framework.

Mandatory requirements

s47 [redacted]

The TGA advised that the mandatory requirements are non-negotiable but are agreeable to work with industry to clarify in the ARGS guidelines.

Ingredient application pathways

FFPI pathway

s47 [redacted]

The TGA acknowledges that the FFPI inclusion process is historical and needs to be reviewed holistically at a future time. That given, the current FFPI process is not proposed to change without further consultation.

s47 [redacted]

Action items

s47 [redacted]

TGA

Investigate the utility of IFRA standards for pre-market evaluation.
send information clarifying the ineligibility of the 16GA pathway for multiple excipient ingredients in one application.
Consider future alternative application pathways that may be better tailored for sunscreen excipients under s26BD.
Recirculate TGA letter dated 14 September 2022 discussing why each requirement is needed and what sort of justifications may be accepted
Consider the AICIS tiered hazard based assessment approach for excipients which are already available for use in cosmetic products in Australia.
Update ARGS to:

- Include examples of appropriate justifications in lieu of data (where acceptable).
- Further clarify the legal requirements around the CGs. And how they can be used for ingredients manufactured by alternate suppliers, that do not strictly adhere to the CG requirements.
- Clearly identify the main ‘critical’ safety studies and quality data that needs to be provided in an application. E.g. Skin absorption studies/justification to address nil or negligible absorption is critical.

Author details

s22 [redacted]

Draft Agenda

1. **TGA explanation of why multi-ingredient assessment pathway is no longer possible** *(TGA)*

2 s47 [redacted]

3. **Agreed next steps from November 2024 meeting** *(TGA* s47 [redacted]

s47 [redacted]

TGA

- Look into ways to make the Permissible Ingredients Determination more user friendly, potentially including synonyms and CAS numbers
- Send information clarifying ineligibility of the 16GA pathway for multiple excipient ingredients in one application
- Consider future alternative application pathways that may be better tailored for sunscreen excipients under s26BD
- Consider IFRA Standards and how they are used to manage fragrance safety to understand whether they can be adopted for regulatory purposes as it is in other international jurisdictions.
- Update ARGS to:
    - Include examples of appropriate justification in lieu of data (where acceptable).

- Further clarify the legal requirements around the CGs. And how they can be used for ingredients manufactured by alternate suppliers, that do not strictly adhere to the CG requirements.
- Clearly identify the main 'critical' safety studies and quality data that needs to be provided in an application.

4. Actions post November 2024 meeting *(TGA* s47 [redacted]

TGA

- Publication of ASEM consultation outcome
- Publication of ASEM RIS
- Publication of sunscreen actives review
- Draft Australian Regulatory Guidelines for Sunscreens (with a changed name) – changes include inflexible incorporation of ASEM, name change and addition of multiple paragraph seemingly without a specific purpose

s47 [redacted]

5. Other key issues in parallel *(TGA* s47 [redacted]

Meeting Outcome Note

s47 - Sunscreen excipient assessment fees

Date: 12 February 2025

Time: 9.30 am to 11 am

Location: TGA Fairbairn

External Participants

Participant	Organisation
s47	

TGA Participants

Name	Position
Nick Henderson	First Assistant Secretary, Medicines Regulation Division
Avinash Clarke	Assistant Secretary, Complementary & Over the Counter medicines Branch
s22	

Discussion items

- Legal issues relating to the 16GA pathway for new ingredients.
- Applications for multiple ingredients (for sunscreens) under one fee no longer being accepted.
- Data requirements for the different pathways (16GA and 26BD).
- TGA consultation and communication.
- Need for clarity in guidance.
- Project planning required.
- Planning required for potential outcomes of scheduling consideration of active sunscreen ingredients and the downstream effects on sunscreen supply.

Meeting Outcome

1. Agreement that there should be a single pathway for new ingredients to be included in the Permissible Ingredients determination. (currently 16GA is a legacy pathway 26BD is the preferred pathway).

2. TGA to improve industry communication and consultation

    a. Broader communication plan.

    b. Consistent consultation plan and processes to be implemented.

    c. Provide a comprehensive plan of future activities.

3. Future activities

    a. TGA review of activity-based costing

        (i) Will occur as part of the TGA's annual fees and charges review.
        (ii) Submissions should be made through this process.

    b. TGA review of new ingredient application categories
        (i) Further stratification of categories
        (ii) Activity-based costing
        (iii) Potential legislation changes
        (iv) Briefing paper to be provided to s47

    c. Update guidance

        (i) ARGS to remain as guidance for sunscreens
        (ii) Provide links to legislation for sunscreen/application requirements
        (iii) Outline specific data requirements for sunscreen ingredients
        (iv) Outline flexibility – consider providing ASEM Excel spreadsheet as a tool for industry

    d. Discussion and planning for potential scheduling decisions on ingredients

        (i) Prior discussion on any proposed changes
        (ii) Consideration given to market impacts
        (iii) Implementation planning
        (iv) Transition allowance

Action items

s47 [redacted]

TGA to:

- Improve general communication and consultations
- Provide a briefing paper to s47 on the review of ingredient application categories (under 26BD pathway)

- Undertake further review of ARGS in consultation with s47
- Provide plan for future activities related to sunscreens.
- Consider implementation planning and discussions with industry on scheduling changes.

Meeting Outcome Note

s47 [redacted] - Sunscreen excipient assessment fees

Date: 12 February 2025

Time: 9.30 am to 11 am

Location: TGA Fairbairn

External Participants

Participant	Organisation
s47 [redacted]	

TGA Participants

Name	Position
Nick Henderson	First Assistant Secretary, Medicines Regulation Division
Avinash Clarke	Assistant Secretary, Complementary & Over the Counter medicines Branch
s22 [redacted]	

Discussion items

- Legal issues relating to the 16GA pathway for new ingredients.
- Applications for multiple ingredients (for sunscreens) under one fee no longer being accepted.
- Data requirements for the different pathways (16GA and 26BD).
- TGA consultation and communication.
- Need for clarity in guidance.
- Project planning required.
- Planning required for potential outcomes of scheduling consideration of active sunscreen ingredients and the downstream effects on sunscreen supply.

Meeting Outcome

1. Agreement that 16GA is a legacy pathway and 26BD is the appropriate pathway for new ingredients to be included in the Permissible Ingredients determination.

2. TGA to improve industry communication and consultation

    a. Broader communication plan.

    b. Consistent consultation plan and processes to be implemented.

    c. Provide a comprehensive plan of future activities.

3. Future activities

    a. TGA review of activity-based costing

        (i) Will occur as part of the TGA's annual fees and charges review.
        (ii) Submissions should be made through this process.

    b. TGA review of new ingredient application categories
        (i) Further stratification of categories
        (ii) Activity-based costing
        (iii) Potential legislation changes
        (iv) Briefing paper to be provided to Comtech

    c. Update guidance

        (i) ARGS to remain as guidance for sunscreens
        (ii) Provide links to legislation for sunscreen/application requirements
        (iii) Outline specific data requirements for sunscreen ingredients
        (iv) Outline flexibility – consider providing ASEM Excel spreadsheet as a tool for industry

    d. Discussion and planning for potential scheduling decisions on ingredients

        (i) Prior discussion on any proposed changes
        (ii) Consideration given to regulatory impacts
        (iii) Implementation planning
        (iv) Transition allowance

Action items

s47 [redacted]

TGA to:

- Improve general communication and consultations
- Provide a briefing paper to s47 [redacted] on the review of ingredient application categories (under 26BD pathway)
- Undertake further review of ARGS in consultation with s47 [redacted]

- Provide plan for future activities related to sunscreens.
- Consider implementation planning and discussions with industry on scheduling changes.

TGA Use only

Attachment 1: Minutes of meeting

TGA Legal discussion

- 16GA applies to goods already listed- it is a historical pathway that enabled grandfathered products to transition to listed medicines in the ARTG. It is not designed to sit alongside the 26BD.
- New applications should use 26BD pathway- this reflects parliamentary intentions and cancellation pathways under S30 of the Act, whereby products can only include ingredients permitted through 26BD pathway
- In relation to fee waivers- these are generally quite specific and only apply in specific circumstances, not applicable to 16GA pathway

Multiple ingredient applications no longer be accepted

s22

TGA

- This issue has been raised by the TGA on multiple occasions since 2018
- We cannot accept multiple ingredient applications through r16GA(1)(b), but r16GA(1)(a) remains open
- Not a process issue, it is a legal issue.
- Information relating to provisional approvals was removed from guidance
- We genuinely believe this has been communicated to industry

Unreasonable requirements for sunscreen ingredients

s22

s47 [redacted]

TGA consultation and communication

s22 [redacted]

Guidance

s22 [redacted]

TGA

- The Act states that there is a requirement for the Secretary to have regard to the safety and quality of the ingredients and how to achieve this is specified in guidance

Evaluation pathways

TGA

- Undertaking a review of ingredient categories
- Further stratify application categories, look at activity-based costing
- This is a big project if s47 [redacted] is agreeable to the proposed review - requiring legislation changes and guidance update.
- Briefing paper to be provided to s47 [redacted]

s22 [redacted]

Ingredient potential scheduling

s47 [redacted]

s22 [redacted]

TGA

- Scheduling committee welcome information on reformulation, costings etc
- Minister well briefed

From: s47
To: s22 ; CLARKE, Avinash
Cc: s47 s22 ; s47
Subject: RE: s47 [SEC=OFFICIAL]
Date: Tuesday, 1 April 2025 4:20:35 PM
Attachments: image002.png

Hi s22
s47

s47 [redacted]

From: s22 [redacted]@health.gov.au>
Sent: Wednesday, March 26, 2025 10:47 AM
To: s47 [redacted] CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>
Cc: s47 [redacted]
s47 [redacted]
s22 [redacted] s47 [redacted]>; s47 [redacted] s22 [redacted] s47 [redacted]
s22 [redacted]@health.gov.au>; s22 [redacted]
s22 [redacted]@health.gov.au>; s47 [redacted] s22 [redacted] s47 [redacted]
Subject: RE: s47 [redacted] [SEC=OFFICIAL]

Hi s47 [redacted]

Thank you for your update. We acknowledge that there will be feedback and concerns from your member companies, and we will strive to address these as best as we can.

We recommend consolidating relevant questions for discussion at the next s47 [redacted]. We plan to have representatives from the TGA Scheduling and media team present to assist with scheduling-related inquiries and to provide an overview of the public engagement strategy.

We'd appreciate if you could forward on the questions arising from your s47 [redacted] Team meeting, and I will coordinate the next s47 [redacted] with yourselves and s47 [redacted]

Kind regards,

s22

s22
s22 **Complementary Medicines Evaluation Section**
Complementary and OTC Medicines Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Fairbairn, Gulgana Level 1 South East
PO Box 100, Woden ACT 2606, Australia

Gulgana First Aid Officer: On-site Tuesdays and Thursdays

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s47 s22 s47
Sent: Thursday, 20 March 2025 12:32 PM
To: CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>
Cc: s22 @health.gov.au>; s47
s47 s47
s47 ; s47
s22 @health.gov.au>; s22
s22 @health.gov.au>; s47
Subject: RE: s47 [SEC=OFFICIAL]

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Hi Avi,
s47

s47 [redacted]

From: CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>
Sent: Friday, March 14, 2025 11:18 AM
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; s47 [redacted] s47 [redacted] s22 [redacted] @health.gov.au>; s47 [redacted] s47 [redacted] s22 [redacted] s47 [redacted] s22 [redacted] s47 [redacted] s22 [redacted] @health.gov.au>; s22 [redacted] s22 [redacted] @health.gov.au>
Subject: RE: s47 [redacted] [SEC=OFFICIAL]

Hi All,

As discussed – please see a draft project plan around scheduling of sunscreen ingredients. Appreciate any comments/suggestions.

Additionally, we are currently preparing a briefing paper for discussion at ComTech 15 – scheduled for 20 May 2025. We are still at project conceptualisation stage –it will be on further stratification of current IN ingredient application categories under section 26BD, including considering dermal ingredients that are demonstrated to not be absorbed and not react with the skin.

Thanks, Avi

Avinash Clarke
02 5132 1436

From: CLARKE, Avinash
Sent: Monday, 3 March 2025 12:46 PM
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; s47 [redacted] s47 [redacted] s22 [redacted] @health.gov.au>; s47 [redacted] s22 [redacted] s47 [redacted] s22 [redacted] s47 [redacted] s22 [redacted] @health.gov.au>; s22 [redacted] s22 [redacted] @health.gov.au>
Subject: s47 [redacted] [SEC=OFFICIAL]

Hi All,

Apologies for the long delay. Please see attached draft outcomes/action items from last month's s47 [redacted]. We'll also endeavour to set up a future meeting series shortly.

Thanks, Avi

Avinash Clarke
Assistant Secretary
Complementary and Over the Counter Medicines Branch
Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
T: 02 5132 1436 | E: avinash.clarke@health.gov.au

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