Public submissions on proposed amendments to the *Poisons Standard*

Subdivision 3D.2 of the *Therapeutic Goods Regulations 1990* (the Regulations) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the *Therapeutic Goods Act 1989* (the Act) to amend the current *Poisons Standard* and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice. Such a notice relating to the scheduling proposals initially referred to the March 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #20), the Advisory Committee on Chemicals Scheduling (ACCS #19), and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #15), was made available on the TGA website on 22 December 2016 and 3 February 2017, closing on 10 February 2017 and 3 March 2017 respectively.

Public submissions received on or before these closing dates (10 February 2017 and 3 March 2017) are published here in accordance with regulation 42ZCZL of the Regulations. Also in accordance with regulation 42ZCZL , the Secretary has removed information that the Secretary considers confidential.

Under regulation 42ZCZN of the Regulations, the Secretary, after considering the advice or recommendation of the expert advisory committee, must (subject to regulation 42ZCZO) make an interim decision in relation to the proposed amendment. If the interim decision is to amend the current *Poisons Standard*, the Secretary must, in doing so, take into account the matters mentioned in subsection 52E(1) of the Act (including, for example, the risks and benefits of the use of a substance, and the potential for abuse of a substance) and the scheduling guidelines as set out in the *Scheduling Policy Framework for Chemicals and Medicines* (SPF, 2015), available on the TGA website.

Under regulation 42ZCZP of the Regulations, the Secretary must, among other things, publish (in a manner the Secretary considers appropriate) the scheduling interim decision, the reasons for that decision and the proposed date of effect (for decisions to amend the current *Poisons Standard*, this will be the date when it is expected that the current *Poisons Standard* will be amended to give effect to the decision).

Also in accordance with regulation 42ZCZP of the Regulations, the Secretary must also invite the applicants and persons who made a submission in response to the original invitation under paragraph 42ZCZK(1)(d), to make further submissions to the Secretary in relation to the interim decisions by a date mentioned in the notice as the closing date, allowing at least 10 business days after publication of the notice. Such a notice relating to the interim decisions of substances initially referred to the March 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #20), the Advisory Committee on Chemicals Scheduling (ACCS #19) and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #15) was made available on the TGA website on 17 May 2017 and 15 September 2017, closing on 31 May 2017 and 3 October 2017 respectively. Public submissions received on or before these closing dates will be published on the TGA website in accordance with regulation 42ZCZQ.

Privacy statement

The Therapeutic Goods Administration (TGA) will not publish information it considers confidential, including yours/other individuals' personal information (unless you/they have consented to publication) or commercially sensitive information. Also, the TGA will not publish information that could be considered advertising or marketing (e.g. logos or slogans associated with products), information about any alleged unlawful activity or that may be defamatory or offensive.

For general privacy information, go to https://www.tga.gov.au/privacy. The TGA is part of the Department of Health and the link includes a link to the Department's privacy policy and contact information if you have a query or concerns about a privacy matter.

The TGA may receive submissions from the public on a proposed amendment to the Poisons Standard where there has been an invitation to the public for submissions on the proposal in accordance with the Therapeutic Goods Regulations 1990. These submissions may contain personal information of the individual making the submissions and others.

The TGA collects this information as part of its regulatory functions and may use the information to contact the individual who made the submissions if the TGA has any queries.

As set out above, the TGA is required to publish these submissions unless they contain confidential information.

If you request for your submission to be published in full, including your name and any other information about you, then the TGA will publish your personal information on its website. However, if at any point in time, you change your mind and wish for your personal information to be redacted then please contact the Scheduling Secretariat at medicines.scheduling@health.gov.au so that the pubic submissions can be updated accordingly.

Please note that the TGA cannot guarantee that updating the submissions on the TGA website will result in the removal of your personal information from the internet.

Please note that the TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.

[redacted]

The Secretary,
Scheduling Secretariat
GPO Box 9848
Canberra A.C.T. 2601

Public Comment Submission to the Proposed Amendments to the Poisons Standard Joint ACCS/ACMS meeting, March 2017

Dear Sir / Madam,

[redacted] wishes to provide comment on the following substances following the notice published on 22 December 2016, for consideration at the March 2017 meeting of the ACMS and ACCS:

- Anise alcohol,
- Anethole,
- Benzyl salicylate,
- Cinnamaldehyde
- Sodium α-olefin sulfonates and Sodium alkyl sulfates,
- Ethyl hexanediol and
- Climbazole.

Anise alcohol, Anethole, Benzyl salicylate and Cinnamaldehyde

[redacted] does not support the proposed Schedule 6 entry for these substances and suggests an Appendix B entry, as has been previously considered for other flavour/fragrance ingredients used in cosmetic and household hygiene products with low acute toxicity and low public exposure.

Sodium α-olefin sulfonates and Sodium alkyl sulfates,

[redacted] does not support the scheduling of surfactants for the purpose of personal and domestic hygiene. Surfactants for cleaning the body or domestic surfaces have been in market for decades with ingrained consumer use patterns regarding appropriate management of these chemicals.

Addressing the Sodium α-olefin sulfonates and Sodium alkyl sulfates proposal. We believe a generic surfactant entry does not consider the differing performance characteristics the length of the alkyl chain can provide to the discrete surfactant. We do not support the grouping of a C12–C18 Alkyl length as being appropriate. The surfactant industry places significant attention and investment in the delivery of softer [less irritating] surfactants to the consumer which can use the differing performance characteristics provided by virtue of the differing alkyl chain lengths do so. A generic entry for surfactants is contrary to this activity and diminishes efforts to formulate products that deliver softer benefits to the consumer.

Furthermore. Concentration levels of certain cleaning products for Sodium alkyl sulphates can be in the order of up to 60% meaning that products sold internationally without restrictions on surfactant content require distinct and separate labelling for products.

Ethyl hexanediol

[redacted] supports a Schedule 6 entry with low concentration cut offs for cosmetic and domestic use.

Climbazole

[redacted] does not support the amendment of the current Scheduling entries for Climbazole. If the scheduling committee wishes to proceed with amending the current entry, alignment with EU restrictions is likely to be achievable within the cosmetics industry with appropriate implementation times. Considerations should be given to any potential domestic product use.

We thank you for this opportunity to provide comments. If you have any queries, or for more information, please do not hesitate to contact me.

Yours sincerely,

[unsigned for electronic submission]

[redacted]

10 February 2017

[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.scheduling@health.gov.au

Dear Sir/Madam

Public Comment Submission to the March 2017 joint meeting of the Advisory Committee on Medicine Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 22 December 2016 inviting public submissions, with respect to certain substances, addressing a matter raised in s.52E of the *Therapeutic Goods Act 1989.*

Accord Australasia Limited is the peak national industry association that represents the hygiene, cosmetic & specialty products industry.

Accord wishes to provide information on the following substances for consideration at the March 2017 meeting of the ACMS/ACCS:

- Anise alcohol
- Anethole
- Sodium α-olefin sulfonates and sodium alkyl sufates
- Benzyl salicylate
- Cinnamaldehyde
- N-(alkylamino)cyclohexylbenzamides

Please see the attached submission for details.

Also attached is a document on the international risk management system for fragrance substances, the basis of which are the International Fragrance Associating (IFRA) standards, which we reference in our submission.

With regard to implementation dates, it is important to recognise that an adequate transition period of at least 12 months must be allowed for any labelling changes and/or reformulation that may be required where no immediate risk has been identified. To our knowledge, there is no evidence to suggest immediate action is required for the risk management of these substances.

We look forward to further advice from the ACMS, ACCS and the Delegate. Should the Committees or the Delegate require any additional information from Accord at this stage please do not hesitate to contact me on [redacted].

Yours Sincerely

[unsigned for electronic submission]

Rachael Linklater
Science & Technical Regulatory Associate

10 February 2017

Accord Australasia Limited [redacted]

ACCS/ACMS joint meeting: March 2017

Anise alcohol

Anise alcohol is a flavour/fragrance material and an International Fragrance Association (IFRA) standard exists for the substance. The IFRA standard restricts the use of anise alcohol in products to between 0.04% and 2.5% depending on the intended use of the product[1]. There are no concentration restrictions on products with no intended skin contact or incidental skin contact. As IFRA explains, the negligible skin contact from these types of products means there is no justification for a restriction of the concentration of this fragrance ingredient in the finished product as the concern with this substance is based on the skin sensitisation potential.

In cosmetic products in the EU, there are no restrictions on the concentration of this substance that may be used in products. The EU Cosmetics Regulation does require products containing anise alcohol to disclose this information by including *"anise alcohol"* in the ingredient list on the product label if the concentration in the finished product is greater than or equal to 0.001% in leave-on products, and greater than or equal to 0.01% in rinse-off products.

We note that in the pre-meeting notice these EU label disclosure thresholds have been described as concentration restrictions, which is incorrect.

Typically product fragrances are identified in ingredient lists on labels as *"fragrance"* or *"parfum"* and individual fragrance components are not disclosed unless mandated as described above. This approach has been taken to ensure that those individuals that are allergic to the ingredient can avoid the products.

To date, neither the scheduling committee nor the Delegate has recommended scheduling of fragrance ingredients that have not been considered to pose a special risk e.g. the scheduling of citral based on its high frequency/volume of use *combined* with sensitisation potential. Even in these cases, the scheduling decisions aligned with the controls imposed by the International Fragrance Association (IFRA) through their standards.

Industry is committed to compliance with the international risk management measures as set out in the IFRA standards for fragrances.

Given the history and approach to scheduling of fragrances with similar hazard profiles in the past and noting that there is an international standard that applies to fragrances that companies internationally comply with, we do not believe that scheduling of anise alcohol is required.

[1] http://www.ifraorg.org/view_document.aspx?docId=23569

ACCS/ACMS joint meeting: March 2017

Anethole

Anethole is a flavour/fragrance material used in cosmetic and domestic products.

Anethole is not listed in the EU Cosmetics Regulation, therefore there are no restrictions on the concentration of this substance that may be used in cosmetic products marketed in the EU.

In the US anethole is listed in the Substances Generally Recognised as Safe (GRAS) list for human consumption[2].

There is no IFRA standard available for this substance, though we note that anethole is the main component of anise, star anise and fennel oils.

Anise oil was previously considered for scheduling by the NDPSC in 2000 and was included in Schedule 5 (based on the work of the Essential Oils Working Party) with an exemption for preparations containing <50% oil based on oral toxicity concerns.

Anise oil and star anise oil were further considered by the NDPSC in 2004, as both contained the same principle constituent. A separate entry for star anise oil was included in Schedule 5 consistent with that for anise oil.

Fennel oil was considered by the ACMS in November 2016 based on another of its components – methyl chavicol, which is an isomer of anethole. The interim decision on fennel oil proposes a Schedule 5 entry for fennel oil with exceptions for medicines for human therapeutic use with packaging and labelling requirements and for preparations containing 5 per cent or less of methyl chavicol, in line with the entry for basil oil. No consideration was given to the anethole content.

Consideration of this substance is very complex given all of the interrelated substances that do not appear to have been considered by the applicant. We suggest that further investigation and consideration of this substance (and related isomers), particularly its presence in other naturally derived substances be carried out. This information should then be provided for further consultation to inform any scheduling consideration. Regulatory treatment must be consistent across all current uses (both therapeutic and cosmetic/domestic) and all related existing schedule entries. A piecemeal approach is not acceptable to industry and is not good regulatory practice.

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2 http://www.femaflavor.org/sites/default/files/linked_files/Newberne%20et%20al.%2C%201999%20%28trans-anethole%29.pdf

ACCS/ACMS joint meeting: March 2017

Sodium α-olefin sulfonates and sodium alkyl sulfates

Accord has long opposed scheduling of individual surfactants through the Chemical Scheduling process. It is out of step with international requirements. As far as we are aware, no other advanced economy has placed restrictions on commonly used surfactants.

When sodium lauryl sulfate (SLS) was first scheduled, it was our understanding that all current uses of the surfactant were excluded from scheduling, noting that SLS is in wide use, and has been used without raising significant health concerns over the history of its use. However, the wording of the lauryl sulfates schedule entry meant that some imported cosmetic products required separate labelling for the Australian market, and created an unintended negative consequence for products that had been safely used in Australia, and continue to be used globally without concern.

For cosmetic use, these substances are available without restriction in the EU, and the US CIR report[3] for sodium α-olefin sulfonates concluded that they are safe for use in rinse-off products at any concentration, and at concentrations up to 2% in leave-on products.

For sodium alkyl sulfates (C12-18) – this captures a wide range of chain lengths, with irritancy potential highest for shorter chain lengths, while longer chain lengths may not be irritants at all. The NICNAS IMAP report relies heavily on read across from data on C12 alkyl sulfate to justify the proposal for scheduling of all alkyl sulfates. These shorter-chain length "lauryl sulfate salts" are already in Schedule 6 (with exceptions). The HERA report for alkyl sulfates[4] indicates the alkyl chain length is important for considering skin and eye irritancy and that higher C16 and C18 chain lengths are much less irritating than the C12 chain length. It is not therefore not appropriate to consider one schedule entry to cover this range of substances.

Accord does not support the scheduling of sodium α-olefin sulfonates and sodium alkyl sulfates, as we do not believe that scheduling of this surfactant will lead to a better risk management outcome. We believe that the risks of surfactants are already well managed. The public have a good understanding that surfactant based products such as shampoos, soaps and detergents are irritating to skin and eyes and will wash their hands and rinse their eyes in case of accidental contact, without being prompted by the label. In fact, if accidental eye contact did occur, attempting to read any instructions on the product label may prove to be problematic.

However, if the Committee believes that these surfactants require scheduling controls, this should be considered in the context of the lauryl sulfates entry. As SLS is known to be one of the harshest surfactants in use, we would expect to see higher concentration cut-offs for these less hazardous substances. In order to ensure regulatory consistency we would also expect the same understanding used when considering SLS to be applied, in that all current uses of the surfactant were excluded from scheduling.

We also request that any scheduling decision include an adequate transition period of at least 12 months to allow for any labelling changes that may be required. Any changes would affect products currently in the Australian market with an established history of safe use. To our knowledge, there is no evidence that would suggest immediate action is required for the risk management of this substance.

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[3] http://online.personalcarecouncil.org/jsp/CIRList.jsp?id=2202

[4] http://www.heraproject.com/files/3-hh-04-%20hera%20as%20hh%20web%20wd.pdf

ACCS/ACMS joint meeting: March 2017

Benzyl salicylate

We note that the scheduling proposal for benzyl salicylate is based on the substance's skin sensitisation potential.

Benzyl salicylate is a flavour/fragrance material and an IFRA standard exists for the substance. The IFRA standard restricts the use of benzyl salicylate in products to between 0.5% and 12.8% depending on the use of the product[5]. There are no concentration restrictions on products with no intended skin contact or incidental skin contact. As IFRA explains, the negligible skin contact from these types of products means there is no justification for a restriction of the concentration of this fragrance ingredient in the finished product as the concern with this substance is based on the skin sensitisation potential.

In cosmetic products in the EU, there are no restrictions on the concentration of this substance that may be used in products. The EU Cosmetics Regulation does require products containing benzyl salicylate to disclose this information by including "benzyl salicylate" in the ingredient list on the product label if the concentration in the finished product is greater than or equal to 0.001% in leave-on products, and greater than or equal to 0.01% in rinse-off products.

We note that in the pre-meeting notice these label disclosure thresholds have been described as concentration restrictions, which is incorrect.

Typically product fragrances are identified in ingredient lists on labels as "fragrance" or "parfum" and individual fragrance components are not disclosed unless mandated as described above. This approach has been taken to ensure that those individuals that are allergic to the ingredient can avoid the products.

To date, neither the scheduling committee nor the Delegate has recommended scheduling of fragrance ingredients that have not been considered to pose a special risk e.g. the scheduling of citral based on its high frequency/volume of use combined with sensitisation potential. Even in these cases, the scheduling decisions aligned with the controls imposed by the International Fragrance Association (IFRA) through their standards.

Industry is committed to compliance with the international risk management measures as set out in the IFRA standards for fragrances.

Given the history and approach to scheduling of fragrances in the past and noting that there is an international standard that applies to fragrances that companies internationally comply with, we do not believe that scheduling of benzyl salicylate is required. Addition to Appendix B (Substances considered not to require control by scheduling) would be consistent with other fragrance allergens with similar hazard profiles previously considered for scheduling.

[5] http://www.ifraorg.org/view_document.aspx?docId=23153

ACCS/ACMS joint meeting: March 2017

Cinnamaldehyde

Cinnamaldehyde is a flavour/fragrance material and an IFRA standard exists for the substance. The IFRA standard restricts the use of cinnamaldehyde in products to between 0.02% and 0.4% depending on the use of the product[6]. There are no concentration restrictions on products with no intended skin contact or incidental skin contact. As IFRA explains, the negligible skin contact from these types of products means there is no justification for a restriction of the concentration of this fragrance ingredient in the finished product as the concern with this substance is based on the skin sensitisation potential.

In cosmetic products in the EU, there are no restrictions on the concentration of this substance that may be used in products. The EU Cosmetics Regulation does require products containing cinnamaldehyde to disclose this information by including "cinnamaldehyde" in the ingredient list on the product label if the concentration in the finished product is greater than or equal to 0.001% in leave-on products, and greater than or equal to 0.01% in rinse-off products.

We note that in the pre-meeting notice these label disclosure thresholds have been described as concentration restrictions, which is incorrect.

Typically product fragrances are identified in ingredient lists on labels as "fragrance" or "parfum" and individual fragrance components are not disclosed unless mandated as described above. This approach has been taken to ensure that those individuals that are allergic to the ingredient can avoid the products.

To date, neither the scheduling committee nor the Delegate has recommended scheduling of fragrance ingredients that have not been considered to pose a special risk e.g. the scheduling of citral based on its high frequency/volume of use combined with sensitisation potential. Even in these cases, the scheduling decisions aligned with the controls imposed by the International Fragrance Association (IFRA) through their standards.

Industry is committed to compliance with the international risk management measures as set out in the IFRA standards for fragrances.

The scheduling decisions for the derivatives amyl and hexyl cinnamaldehyde were published in September 2016, with both substances being included in Appendix B - Substances considered not to require control by scheduling.

Given the history and approach to scheduling of fragrances in the past and noting that there is an international standard that applies to fragrances that companies internationally comply with, we do not believe that scheduling of cinnamaldehyde is required.

[6] http://www.ifraorg.org/view_document.aspx?docId=23297

ACCS/ACMS joint meeting: March 2017

_N_-(alkylamino)cyclohexylbenzamides

We are currently unaware of any non-medicinal uses of these opioid substances, and will await further information in order to assess the impact of this proposal on our members.

About the IFRA Standards[7]

The IFRA Standards form the basis for the globally accepted and recognized risk management system for the safe use of fragrance ingredients and are part of the IFRA Code of Practice. This is the self-regulating system of the industry, based on risk assessments carried out by an independent Expert Panel.

The Expert Panel is made up of renowned independent experts from the fields such as dermatology, toxicology, pathology and environmental sciences. Their role is to evaluate the data on a fragrance ingredient to see if it supports the current use level, to make sure that there is no risk for the consumer. In cases where the safety assessment does not support the current use, the Panel instructs IFRA to issue a Standard either restricting or banning a material.

The Standards amount to 186 substances which have been either banned or restricted in their use in fragrance products. All members of IFRA are required, as a condition of membership, to observe the IFRA Code of Practice. The fragrance industry spends approximately $8 million (annually) in joint research on the safety of fragrances, and much more at the individual company level.

IFRA provides information on the exposure situation (usage concentration, variety of use, volume of use), chemical composition as well as the olfactory profile and olfactory potential (importance) of a fragrance ingredient to the Research Institute for Fragrance Materials (RIFM), the scientific arm of IFRA. RIFM then prepares comprehensive dossiers on the materials including all available safety data and, if necessary, initiates and organizes any missing safety studies on the fragrance ingredient.

The Standards are established according to the following process:

1. IFRA provides information on the exposure situation (usage concentration, variety of use, volume of use), chemical composition as well as the olfactory profile and olfactory potential (importance) of a fragrance ingredient to RIFM;

2. RIFM prepares a comprehensive dossier on the material including all available safety data and, if necessary, initiates and organizes any missing safety studies on the fragrance ingredient;

3. The RIFM Panel of independent experts, evaluates the data to see if it supports the current use level, to make sure that there is no risk/danger for the consumer; if the safety assessment does not support the current use, the Panel instructs IFRA to issue a Standard*;

4. IFRA prepares a Standard in accordance with the Panel's instructions and conclusions;

5. The draft Standard is consulted with the IFRA membership and stakeholders for a period of about a month, to ensure that IFRA/RIFM are aware of all data on the material and to provide holders of additional data that might alter the outcome of the Panel's risk assessment with the opportunity to share those with IFRA/RIFM;
6. If no additional information is received via the Consultation phase, the final Standard is published in a notification procedure as part of an “Amendment to the IFRA Code of Practice”.

* The final decision on the content of the Standard is solely in the hands of the Expert Panel, not IFRA or RIFM.

[7] http://www.ifraorg.org/en-us/about-the-standards#.WJ0QUW996os

[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.scheduling@health.gov.au

Dear Sir/Madam

Public Comment Submission to the March 2017 joint meeting of the Advisory Committee on Medicine Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 3 February inviting public submissions, with respect to certain substances, addressing a matter raised in s.52E of the *Therapeutic Goods Act 1989.*

Accord Australasia Limited is the peak national industry association that represents the hygiene, cosmetic & specialty products industry.

Accord wishes to provide information on the following substances for consideration at the March 2017 meeting of the ACMS/ACCS:

- Resorcinol

Please see the attached submission for details.

Accord is an interested party and stakeholder with regard to the nominated substance and would appreciate being advised of the Committee's considerations and the Delegate's interim decision, with the opportunity for further submission, if appropriate.

We look forward to further advice from the ACMS, ACCS and the Delegate. Should the Committees or the Delegate require any additional information from Accord at this stage please do not hesitate to contact me on [redacted].

Yours Sincerely

[unsigned for electronic submission]

Rachael Linklater
Science & Technical Regulatory Associate

3 March 2017

Accord Australasia Limited [redacted]

ACCS/ACMS joint meeting: March 2017

Resorcinol

Accord has no objections to aligning the scheduling controls for this substance when used in hair dyes with those in the EU. We note that resorcinol is included in Annex III of the EU Cosmetics Regulation[1], allowing its use:

- As a hair dye substance in oxidative hair dye products and in products intended for colouring eyelashes with an in-use concentration (after mixing under oxidative conditions) not exceeding 1.25%. Eyelash products containing this substance are restricted to professional use only.
- In hair lotions and shampoos with an in-use concentration not exceeding 0.5%.

We note that resorcinol is used in topical therapeutic goods in Australia and overseas, and under the TGA is currently:

- Available for use as an Active Ingredient in Biologicals, Export Only, Over the Counter, Prescription Medicines; and
- Available for use as an Excipient Ingredient in: Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, Prescription Medicines.

It is also permitted for use in OTC products in North America and Canada.

As therapeutic goods are subject to a higher level of regulatory control regarding their safety (as compared to consumer products), and given the regulatory status of resorcinol overseas for use in OTC products, we do not believe that therapeutic uses should be captured in any new schedule entry for resorcinol.

We note that the derivative 2-methylresorcinol was considered for scheduling in 2016, with the final decision to include the substance in Schedule 6 with exceptions for hair dye preparations.

In line with recent decisions on hair dye ingredients, Accord proposes the following schedule entry:
Schedule 6 - New Entry

RESORCINOL in cosmetic preparations, **except**:

a. in oxidative hair dye preparations containing 1.25 per cent or less of resorcinol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements:

   KEEP OUT OF REACH OF CHILDREN, and

   WARNING - Hair colourants can cause severe allergic reactions.

   Written in letters not less than 1.5 mm in height; or

b. in oxidative eyebrow/eyelash colouring products containing 1.25 per cent or less of resorcinol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements:

[1] http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=84332

KEEP OUT OF REACH OF CHILDREN, and

FOR PROFESSIONAL USE ONLY, and

WARNING - Hair colourants can cause severe allergic reactions.

Written in letters not less than 1.5 mm in height.

c. In hair lotions and shampoos containing 0.5 per cent or less of resorcinol when the immediate container and primary pack are labelled with the following statement:

CONTAINS RESORCINOL

With regard to implementation dates, it is important to recognise that an adequate transition period of at least 12 months must be allowed for any labelling changes and/or reformulation that may be required where no immediate risk has been identified. To our knowledge, there is no evidence to suggest immediate action is required for the risk management of this substance.

[redacted]

The Secretary
Medicines and Poisons Scheduling
Office of Chemical Safety (MDP 88)
GPO Box 9848
CANBERRA ACT
2601

03/02/2017

Dear Sir/Madam,

RE: Comments on Proposed amendments referred by the Delegates to the joint advisory committees on Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling (ACMS)

[redacted] would like to provide comments on the proposed amendments referred by the Delegate to the Committee of Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling (ACMS).

Anise alcohol, benzyl salicylate, cinnamaldehyde

These ingredients are commonly used as components of fragrances for cosmetic leave on and rinse off products such as mouth washes, cleansers, body washes.

These fragrance components are used in a number of [redacted] cosmetic products in varying concentrations as outlined below:

Anise alcohol
- leave on up to 0.0009%,
- rinse off up to 0.002%

Benzyl salicylate
- leave on up to 0.20%
- rinse off 0.20%

Cinnamaldehyde
- leave on up to 0.002%
- rinse off up to 0.04%

As these ingredients are covered under the IFRA standard with appropriate concentration cut offs applied, we propose that they are included in Appendix B of the SUSMP (substances considered not to require control by scheduling). This is consistent with other fragrance allergens with similar hazard profiles previously considered for scheduling.

We refer the committee to the ACCORD submission

[redacted]

[redacted]

Sodium α-olefin sulfonates and sodium alkyl sulfates

These are classes of commonly used surfactants in cosmetic products such as body washes and facial cleansers. Sodium C14-16 Olefin Sulfonate is commonly used by [redacted] in a number of cosmetic products at varying concentrations up to 14% in rinse off products and up to 0.3% in leave on.

The US CIR report for sodium α-olefin sulfonates concluded that they are safe for use in rinse-off products without a concentration cut off, and at concentrations up to 2% in leave-on products.

It is not appropriate to consider one schedule entry to cover this entire range of surfactants. The proposal captures a wide range of chain lengths, with irritancy potential highest for shorter chain lengths, while longer chain lengths may not be irritants at all.

Additionally, consumers understand how to appropriately use surfactants ie not for use in the eye. These types of products have an established history of safe use, and are used in appropriate concentrations globally in common personal care products such as facial cleansers and scrubs.

We propose that these types of surfactants not be scheduled when used in cosmetic products such as body washes and facial cleansers as they have a long history of safe use.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Advisory Committee on Medicines Scheduling
Department of Health
MDP 71
GPO Box 9848
Canberra ACT 2601
medicines.scheduling@tga.gov.au

Re: Proposed amendments to the Poisons Standard (Medicines)
Dihydrocodeine:
To reconsider whether the Schedule 2 and Schedule 3 entries for dihydrocodeine should be amended or deleted, in view of the recent reconsideration of codeine scheduling

Dear Sir/Madam

There are 7 entries on the ARTG for products containing dihydrocodeine all being single active ingredient formulations. Six of these entries are under the brand “DICODIN” all of which are noted as Schedule 8 (Controlled Drug) medicines.

The ARTG details for the seventh entry, “RIKODEINE”, notes it as a Schedule 3 medicine and it has historically been marketed as such. As this formulation contains no other therapeutically active substance, the correct scheduling, and therefore supply of this product should be as a Schedule 8 (Controlled Drug) medicine in accordance with the requirements of *Poisons Standard November 2016.*

As there do not appear to be any formulations containing dihydrocodeine in combination with another therapeutically active substance on the ARTG, amending or deleting the Schedule 2 and Schedule 3 entries for dihydrocodeine would have no direct or immediate implication, and [redacted] holds no objections to any such proposals. It would be appropriate however, for there to be an immediate review of the ARTG entry for “RIKODEINE” to ensure compliance with the current Poisons Standard.

[redacted]

[redacted]

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **1 medicine** between **01/01/1971 – 19/10/2016**:

- Rikodeine (Dihydrocodeine Tartrate)

Important information

The TGA uses adverse event reports to identify when a safety issue may be present. An adverse event report does not mean that the medicine is the cause of the adverse event. If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. The TGA strongly advises people taking prescription medicines not to change their medication regime without prior consultation with a health professional.

About the Database of Adverse Event Notifications (DAEN) - medicines

- The DAEN - medicines contains information from reports of adverse events that the TGA has received in relation to medicines including vaccines used in Australia.
- The DAEN - medicines does not contain all known safety information about a particular medicine. Please do not make an assessment about the safety of a medicine based on the information in the DAEN - medicines.

The TGA medicine safety monitoring program

More information about the DAEN - medicines and the TGA medicines safety monitoring program is available at:

- About the DAEN - medicines <http://www.tga.gov.au/safety/daen-about.htm>
- Medicines safety <http://www.tga.gov.au/safety/information-medicines.htm>

You are encouraged to report an adverse event suspected of being related to a medicine used in Australia. Reports of adverse events in relation to medicines and vaccines can be reported using the 'blue card' reporting form, by phone and online <http://www.tga.gov.au/safety/problem.htm>.

Other useful sources of information on Australian medicines

More information about a medicine is available from the Product Information (PI) <http://www.tga.gov.au/hp/information-medicines-pi.htm> and Consumer Medicine Information (CMI) <http://www.tga.gov.au/consumers/information-medicines-cmi.htm> leaflet or the labelling of the medicine. Australian Public Assessment Report for Prescription Medicines (AusPARs) <http://www.tga.gov.au/industry/pm-auspar.htm> for some prescription medicines, are also available from the TGA website. <http://www.tga.gov.au>
Your health professional can also provide help and assistance on how to use medicines.
Information on medicines used in Australia is available from NPS MedicineWise <http://www.nps.org.au/>.

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of the adverse events reported to the TGA, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.
To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

Results

Number of reports (cases): 32

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 22

(The TGA thinks there is a possibility that the medicine caused the adverse event)

Number of cases where death was a reported outcome: 0

(These reports of death may or may not have been a result of taking a medicine)

MedDRA system organ class[i]	MedDRA reaction term[ii]	Number of cases[iii]	Number of cases with a single suspected medicine[iv]	Number of cases where death was a reported outcome[v]
Gastrointestinal disorders	Nausea	7	3	0
Respiratory, thoracic and mediastinal disorders	Cough	6	4	0
Skin and subcutaneous tissue disorders	Pruritus	5	2	0
General disorders and administration site conditions	Drug ineffective	5	5	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea	5	4	0
Gastrointestinal disorders	Vomiting	4	3	0
Nervous system disorders	Somnolence	3	2	0
Skin and subcutaneous tissue disorders	Rash	2	1	0
Gastrointestinal disorders	Abdominal pain	2	2	0
General disorders and administration site conditions	Asthenia	2	1	0
General disorders and administration site conditions	Chest pain	2	1	0
Gastrointestinal disorders	Constipation	2	2	0
Nervous system disorders	Dizziness	2	1	0
Skin and subcutaneous tissue disorders	Urticaria	2	2	0
Gastrointestinal disorders	Dry mouth	1	0	0
Gastrointestinal disorders	Dyspepsia	1	0	0
Gastrointestinal disorders	Dysphagia	1	0	0
Renal and urinary disorders	Dysuria	1	1	0
Eye disorders	Eye swelling	1	1	0
Gastrointestinal disorders	Flatulence	1	1	0
Nervous system disorders	Headache	1	0	0
Nervous system disorders	Hypoaesthesia	1	0	0
Metabolism and nutrition disorders	Hypoglycaemia	1	0	0

MedDRA system organ class[i]	MedDRA reaction term[ii]	Number of cases[iii]	Number of cases with a single suspected medicine[iv]	Number of cases where death was a reported outcome[v]
Psychiatric disorders	Insomnia	1	1	0
Gastrointestinal disorders	Lip swelling	1	1	0
Skin and subcutaneous tissue disorders	Rash generalised	1	1	0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	1	1	0
Respiratory, thoracic and mediastinal disorders	Sneezing	1	1	0
Psychiatric disorders	Dependence	1	1	0
Gastrointestinal disorders	Diarrhoea	1	0	0
Musculoskeletal and connective tissue disorders	Pain in extremity	1	1	0
Skin and subcutaneous tissue disorders	Swelling face	1	1	0
Gastrointestinal disorders	Tongue oedema	1	0	0
General disorders and administration site conditions	Pyrexia	1	0	0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	1	0	0
Skin and subcutaneous tissue disorders	Skin burning sensation	1	0	0
Gastrointestinal disorders	Hypoaesthesia oral	1	1	0
Metabolism and nutrition disorders	Decreased appetite	1	0	0
General disorders and administration site conditions	Sensation of foreign body	1	1	0

Footnotes

[i] A description of what, in general terms, was affected by the adverse event, as described by the Medical Dictionary for Regulatory Activities MedDRA (for example 'cardiac disorders')

[ii] A description of the adverse event as defined by MedDRA; these adverse events are grouped by system organ class. You can use the MedlinePlus medical dictionary <http://www.nlm.nih.gov/medlineplus/mplusdictionary.html> to look up terms.

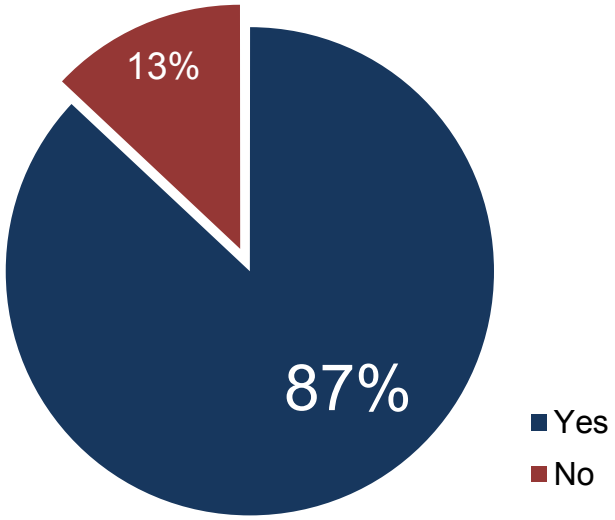
[iii] The number of cases for which each type of adverse event was reported

[iv] Results show where a medicine is the only medicine suspected to be related to the adverse event

[v] These reports of death may or may not have been the result of taking a medicine

The large majority of pharmacists would recommend Rikodeine for cough

Whether pharmacists would recommend Rikodeine for cough



Base: 150 Pharmacists

Q7: Would you recommend Rikodeine for cough?

Reasons why pharmacists would not recommend Rikodeine for cough

"Rikodeine is S3 product and sometimes recommended by doctor or by staff if we know patient"

"Usually wait for GP recommendation. If their cough is that bad, I prefer them to see GP first"

"Drowsiness and addictive properties"

"Too many instances of abuse"

"I see too many people abusing this product and many, particularly Indian/Middle eastern Taxi drivers seem to be addicted, don't know why just an observation"

"Highly addictive, would only recommend if other products had been tried and failed to work"

"Higher potential for abuse. s3 makes it more trouble. more chance of drowsiness."

"Well I don't think it is a yes or no answer. I would if I saw a genuine therapeutic need and cough was keeping up the person at night. Also if no codeine dependency issues are present and no contraindications."

"Even though it is good for dry cough but it is very easy to get addicted"

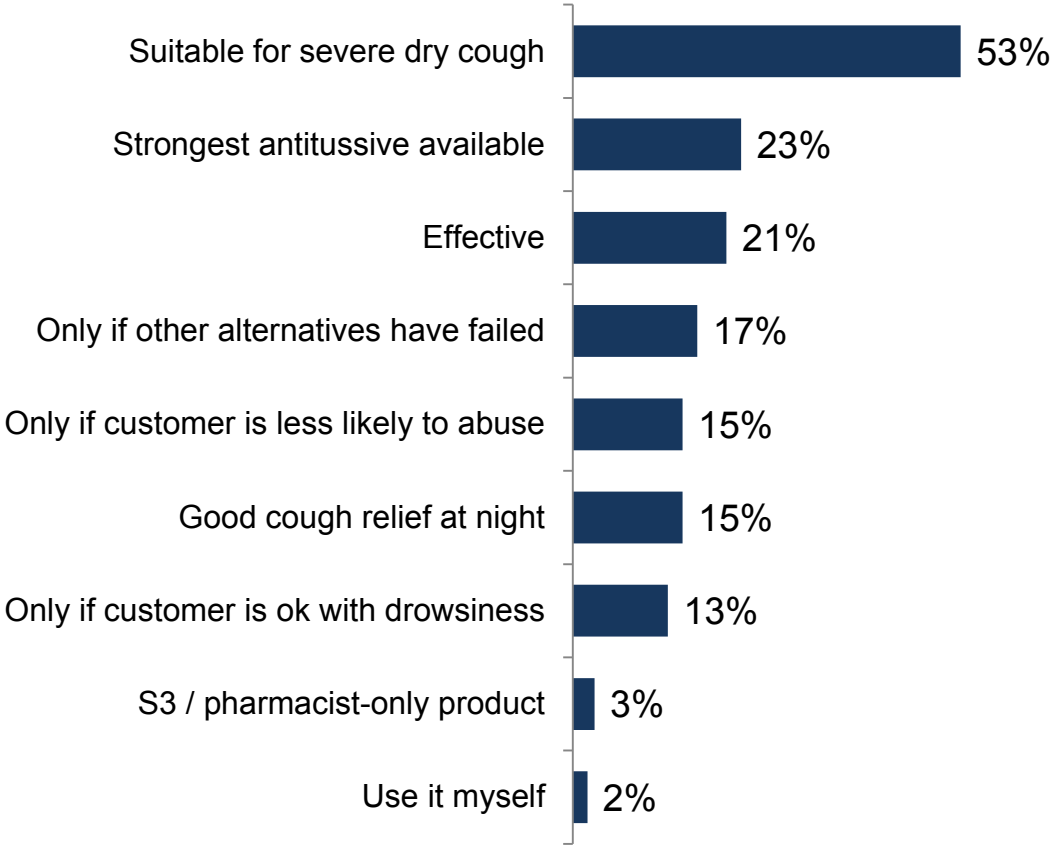
Caution low sample

Base: 19 Pharmacists who would not recommend Rikodeine for cough

Q8: Why would you / would you not recommend Rikodeine?

Pharmacists would recommend Rikodeine primarily due to its suitability for dry cough and potent antitussive – concerns of abuse and drowsiness are also key considerations

Reasons why pharmacists would recommend Rikodeine for cough



"It is the most effective dry cough suppressant"

"I would recommend Rikodeine in cases of stubborn dry cough as it is the strongest cough suppressant over the counter"

"Works very well. Have used it myself. It's potent"

"Best cough suppressant on the market hands down just has the downside of drowsiness, however wonderful at night"

"For more stubborn dry coughs where the OTC medications have proved ineffective I usually recommend Rikodeine however I am careful who I offer this medication to."

"I would only recommend it for short term use for severe stubborn dry coughs or if recommended by the doctor. it is not a product I would suggest first line"

"Only for severe dry cough - not as a first line. It works really well but the re is the potential for abuse"

"The most effective cough suppressant. Would not use if history of dependence"

"Very effective S3 medication, good opportunity for pharmacist involvement for the patient."

Base: 131 Pharmacists who would recommend Rikodeine for cough

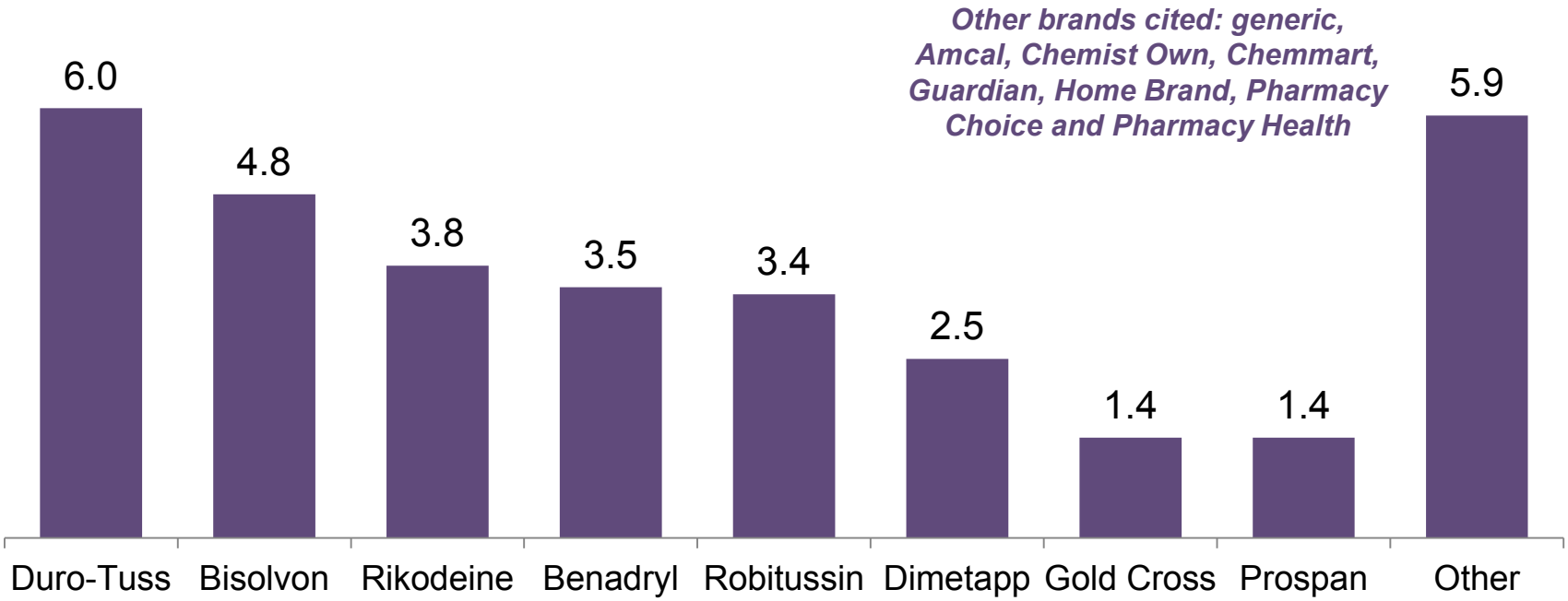
Q8: Why would you / would you not recommend Rikodeine?

Duro-Tuss is the most preferred brand for cough, Rikodeine is also ranked highly vs. majority of other brands

[redacted]

Brand preference: pharmacist recommendation for cough

Average ranking score 1-9



Proportion of pharmacists	Ranked 1st	Ranked 2nd	Ranked 3rd	Ranked 4th	Ranked 5th	Ranked 6th	Ranked 7th	Ranked 8th	Ranked 9th
Duro-Tuss	50%	26%	11%	5%	3%	3%	-	1%	-
Rikodeine	11%	19%	16%	11%	15%	11%	7%	9%	2%

Base: 150 Pharmacists

Q9: Please rank the following brands in order of preference for recommendation to a customer for cough, where rank 1 = most preferred brand.

How to interpret ranking scores:

Ranking scores are derived from actual ranking. A brand gets a score of 9 if ranked 1st, a score of 8 if ranked 2nd and so on.

Thus, the higher the average ranking score, the more preferred the brand is.

Among the choice drivers for cough medicine are efficacy, product range, brand, customer feedback and price

[redacted]

Reasons why brand is most preferred for cough

Duro-Tuss

- Great range of products for various types of cough
- Effective
- Well-known, trusted brand
- Sugar-free
- Packaging
- Pleasant taste
- Reasonable price
- Single ingredient & combination product

Base: 75 Pharmacists who ranked Duro-Tuss 1st

Rikodeine

- Strongest antitussive available
- Most effective
- Excellent for dry cough
- Good brand
- S3 / pharmacist-only product
- Fast-acting
- Positive feedback from customers

Base: 17 Pharmacists who ranked Rikodeine 1st

Bisolvon

- Effective, works well especially for chesty cough
- Prescribed by doctors
- Good expectorant
- Positive feedback from customers
- Reasonable price
- Personal experience
- Sugar-free
- Recognised and trusted brand
- Safe

Base: 24 Pharmacists who ranked Bisolvon1st

Low sample size for other brands (less than 10 responses)

Q10: You have stated that <insert brand ranked 1st in Q9> is your most preferred brand for cough What is your primary reason for this?

Methodology and demographics

All interviews completed between 2/11/2014 and 10/11/2014.

Sample of 150 Pharmacists from Cegedim's panel of healthcare professionals.

Statistically significant differences calculated at 95% confidence level, indicated with ↑ or ↓.

Quota	Sample #	Sample %	Population %
Male	90	60%	69%
Female	60	40%	31%
≤ 50 years	116	77%	67%
> 50 years	34	23%	33%
NSW / ACT	50	33%	32%
VIC / TAS	40	27%	26%
QLD / NT	30	20%	21%
WA / SA	30	20%	20%
Independent	83	55%	56%
Banner Group	67	45%	44%
Total	150	100%	100%

Cochrane Database Syst Rev. 2010 Sep 8;(9):CD007881. doi: 10.1002/14651858.CD007881.pub2.

Interventions for cough in cancer.

Molassiotis A[1], Bailey C, Caress A, Brunton L, Smith J.

Author information

Abstract

BACKGROUND: Cough is a common symptom in patients with malignancies, especially in patients with lung cancer. **Cough** is not well controlled in clinical practice and clinicians have few management options to treat it.

OBJECTIVES: The primary objective of this review was to determine the effectiveness of interventions, both pharmacological and non-pharmacological, (other than chemotherapy and external beam radiotherapy) in the management of **cough** in malignant disease (especially in lung cancer).

SEARCH STRATEGY: Databases searched included: The Cochrane Central Register of Controlled Trials (CENTRAL) and the Database of Abstracts of Reviews of Effectiveness (DARE) (The Cochrane Library issue 4, 2009); MEDLINE (1966 to May 2010); EMBASE (1980 to May 2010); CINAHL (1980 to May 2010); PSYCHINFO (1980 to May 2010); AMED (1985 to May 2010); SIGLE (1980 to May 2010); British Nursing Index (1985 to May 2010); CancerLit (1975 to May 2010). We searched for **cough** suppressants, antitussives and other drugs with antitussive activity as well as non-pharmacological interventions (see Appendices 1-4 for search terms).

SELECTION CRITERIA: We selected randomised controlled trials (RCTs) and clinical trials (quasi-experimental trials, and trials where there is a comparison group but no mention of randomisation) in participants with primary or metastatic lung cancer or other cancers.

DATA COLLECTION AND ANALYSIS: Two review authors independently assessed titles and abstracts of all studies, and extracted data from all selected studies before reaching consensus. A third review author arbitrated with any disagreement. Meta-analysis was not attempted due to the heterogeneity of studies.

MAIN RESULTS: Seventeen studies met inclusion criteria and examined either brachytherapy, laser or photodynamic therapy (eight studies) or a variety of pharmacological therapies (nine studies). Overall, there was absence of credible evidence and the majority of studies were of low methodological quality and high risk of bias. Brachytherapy seemed to improve **cough** in a variety of doses in selected participants, suggesting that possibly the lowest effective dose should be used to minimise side effects. Photodynamic therapy was examined in one study, and while improvements in **cough** were observed, its role over other therapies for **cough** is unclear. Some indication of effect was observed with morphine, codeine, **dihydrocodeine**, levodropropizine, sodium cromoglycate and butamirate citrate linctus (**cough** syrup), although all studies had significant risk of bias.

AUTHORS' CONCLUSIONS:

Format: Abstract

Full text links

Eur Respir J. 1998 Jul;12(1):97-101.

Efficacy and safety of levodropropizine and dihydrocodeine on nonproductive cough in primary and metastatic lung cancer.

Luporini G[1], Barni S, Marchi E, Daffonchio L.

Author information

Abstract

Nonproductive **cough** is a frequent and distressing symptom in patients with lung cancer, and it is not even relieved by palliative chemotherapy. A double-blind, randomized clinical trial regarding the treatment of nonproductive **cough** was performed in 140 adults with primary lung cancer or metastatic cancer of the lungs. The therapeutic efficacy and the tolerability of a 7-day treatment with levodropropizine drops (75 mg t.i.d.) were evaluated in comparison with **dihydrocodeine** drops (10 mg t.i.d.; 7 days). Efficacy was assessed on the basis of **cough** severity scores, number of night awakenings due to **cough**, and overall estimate of antitussive efficacy. Tolerability was evaluated by laboratory results, vital signs and any adverse event occurring during the clinical trial, including presence or absence of somnolence. Subjective **cough** severity was significantly reduced during treatment with either levodropropizine and **dihydrocodeine**, the antitussive effect and its time-profile being similar for both drugs. Also, according to the investigator's evaluation, both levodropropizine and **dihydrocodeine** produced a significant decrease in **cough** severity. Concurrently with the relief of **cough**, the number of night awakenings was decreased significantly by both drugs, with no difference between the two treatments. No change in laboratory test values was considered clinically relevant, and vital signs were not clinically affected. The number of patients reporting adverse events was similar in the levodropropizine (n=6) and **dihydrocodeine** (n=4) group. However, the percentage of patients experiencing somnolence in the group receiving levodropropizine (8%) was significantly lower as compared with that of the **dihydrocodeine** group (22%). These results confirm the antitussive effectiveness of levodropropizine and suggest a more favourable benefit/risk profile when compared to **dihydrocodeine**.

PMID: 9701421

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