AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

TRIM: D19-29755

Adjunct Professor John Skerritt
Deputy Secretary
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

John

Dear Professor Skerritt

Therapeutic Goods Administration consultation on increased online access to ingredient information

I am writing in regards to the Therapeutic Goods Administration's consultation on increased online access to ingredient information (August 2019).

The Australian Commission on Safety and Quality in Health Care (the Commission) welcomes the opportunity to participate in this important consultation. The Commission supports initiatives for improved medicines information to support safer, informed, and shared decision making.

In response, the Commission supports Option 1A*: Publish names of excipients except those used in flavour or fragrance proprietary ingredient mixes.* The Commission also recommends the TGA consider including allergy and substance warnings at least on the public view of the Australian Register for Therapeutic Goods, and ideally on labelling for the following:

- If known allergic substances are used in flavour or fragrance proprietary ingredient mixes
- If known allergic substances are used in proprietary ingredient mixes and only trade name or proprietary name is published (as proposed in Option 1B).

The Commission can assist the TGA in disseminating changes through the Commission's communication channels. I enclose the Commission's full response to the consultation for your consideration (**Attachment 1**). The Commission believes that increased online access to ingredient information will empower consumers and health professionals, and has the potential to minimise unnecessary medication-related harm.

If you have any questions regarding the consultation feedback, please contact:

Mr Christopher Leahy
Director, eHealth and Medication Safety
Christopher.Leahy@safetyandquality.gov.au (02) 9126 3600

Yours sincerely

[redacted]

Adjunct Professor Debora Picone AO
Chief Executive Officer

3 October 2019

Attachment 1 – TGA consultation on increased online access to ingredient information - Response from the Australian Commission on Safety and Quality in Health Care, October 2019.

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

TRIM: D19 - 29610

October 2019

TGA consultation on increased online access to ingredient information

Response from the Australian Commission on Safety and Quality in Health Care

Executive Sponsor

[redacted]

Program Director

Mr Chris Leahy, Director, eHealth and Medication Safety

Project Manager

[redacted]

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Authorised for release:

[redacted]

…… (3/10/19)

Adjunct Professor Debora Picone, AO

Chief Executive Officer

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Summary

The Therapeutic Goods Administration (TGA) proposes the names of excipient ingredients used in therapeutic goods are published in the public view of the Australian Register for Therapeutic Goods (ARTG). The Australian Commission on Safety and Quality in Health Care (the Commission) supports the TGA's initiative to publish excipient ingredient information on the ARTG for all therapeutic goods. Increased accessibility to excipient ingredient information will assist consumers and health professionals to make safer and more informed decisions in a timely manner.

Introduction

On 29 August 2019, the TGA published a public consultation paper, increased online access to ingredient information (**Appendix A**).

In response, the Commission supports Option 1A: Publish names of excipients except those used in flavour or fragrance proprietary ingredient mixes.

The Commission also recommends the TGA consider including allergy and substance warnings at least on the public view of the ARTG, and ideally on labelling for the following:

- If known allergic substances are used in flavour or fragrance proprietary ingredient mixes
- If known allergic substances are used in proprietary ingredient mixes and only trade name or proprietary name is published (as proposed in Option 1B).

Context

Excipient ingredients are the inactive ingredients used in medicines to improve absorption, stability, taste or appearance. Excipient ingredients do not have any therapeutic effect. However, excipient ingredients have the potential to cause allergic reactions in sensitive individuals. It is imperative that consumers and health professionals have access to excipient ingredient information to make an informed decision about medicines.

In Australia, for prescription medicines, names of excipient ingredients are included in the medicine's Product Information (PI) document and in the Consumer Medicine Information (CMI) leaflet. PIs and CMIs can also include proprietary ingredient mixes listed by their trade or proprietary name and sometimes the names of ingredients used in the proprietary ingredient mix.

For non-prescription medicines, excipient ingredients are not always published, and most non-prescription medicines do not have a PI or CMI document. Instead consumers rely on a time-consuming process of contacting TGA or the company supplying the medicine to check whether a particular ingredient is present in that medicine. The TGA proposes to make excipient ingredient information for all medicines easily available to the public by listing it through the ARTG.

Background

Drug allergy prevalence and the number of hospital presentations related to drug allergies are increasing in Australia.[1,2,3] Around 43% of Australians aged 50 years and older take five or more medicines, including non-prescription medicines.[4] Non-prescription medicines such as omega-3 marine triglycerides, glucosamine, aspirin, and calcium were among the most commonly taken medicines in those aged 50 years.[4] As excipients have the potential to

cause adverse reactions[5,6], it is imperative to have all excipient ingredient information readily available to consumers and health professionals.

Certain excipients in medicines may not be suitable for people suffering from conditions such as coeliac disease and lactose intolerance.[7] The excipient ingredient information will assist consumers in making an informed and safer choice. Given that self-prescribing is a common method of using non-prescription medicines[8], it is more relevant that consumers have easily accessible information on all medicine ingredients.

For health professionals, the excipient ingredient information will assist when ruling out drug allergy and when prescribing new medicines. Incorrect labelling of drug allergy is a patient safety issue that can lead to patients receiving alternative sub-optimal and expensive treatment. Often antibiotic allergies are incorrectly self-reported[9], and this results in patients receiving unnecessary broad-spectrum antibiotics[10,11], which can cause increased adverse effects and antimicrobial resistance.[10] Excipient allergies are frequently overlooked[6,12] when reviewing medicine related allergies. Information on all medicine ingredients will assist making therapeutic decisions and to prevent incorrectly attributing allergy to a drug when another ingredient is responsible.

In countries such as Canada and New Zealand, names of excipient ingredients used in all medicines are available in their online registers. In Australia, the TGA collect and hold full formulation information for all medicines but the names of excipient ingredients are only visible in the internal TGA view of ARTG.

Feedback

Support for the proposed increased online access to ingredient information

Feedback on **Appendix A (Consultation paper)** is provided with consideration of the options proposed by the TGA.

The Commission supports the initiative to improve the visibility and accessibility of excipient ingredient information. The Commission agrees that the information about excipient ingredients will assist consumers in making more informed and safer choices about their medicines.

The Commission supports **Option 1A: publish names of excipients except those used in flavour or fragrance proprietary ingredient mixes**.

The Commission supports the TGA's proposal to add excipient ingredient information to the ARTG public summary for the following therapeutic goods:

- Prescription medicines
- Non-prescription medicines (both registered and listed, including complementary medicines)
- Biologicals (cell and tissue therapies)
- Other therapeutic goods, such as disinfectants and sterilants.

Option 1A provides excipient ingredient information to consumers and health professionals. The publically available information will assist consumers and health professionals in making an informed decision in a timely manner. Easily accessible medicine ingredient information is valuable to consumers who are sensitive to certain ingredients and those suffering from any allergic diseases. The readily available information will also empower consumers and promotes shared decision making with their health professionals.

The Commission does not support Option 1B: Publish names of excipients except those used in any proprietary ingredient mixes. Option 1B is an improvement on existing disclosure. However, it still excludes the name of excipients used in proprietary ingredient mixes. Option 1B limits consumers and health professional's ability to make an informed and safer decision in a timely manner.

The Commission does not support Option 2: Status quo - no action by the TGA to publish excipient names in ARTG summaries.

During the implementation stage, the Commission can assist the TGA in disseminating information through its communication channels.

Further considerations to increased online access to ingredient information

The Commission proposes that the TGA consider including allergy and substance warnings at least on the public view of the ARTG, and ideally on labelling for the following:

- If known allergic substances are used in flavour or fragrance proprietary ingredient mixes
- If known allergic substances are used in proprietary ingredient mixes and only trade name or proprietary name is published (as proposed in Option 1B).

Discussion

Documenting patients drug allergies in the medical record and medication charts are an essential medication safety initiative to prevent patient harm. Drug allergy information is critical when making therapeutic decisions, especially in sensitive individuals. Allergy to excipients is often under-recognised and results in incorrectly attributing allergic reaction to the active ingredient.

The Commission is responsible for the development and support of the National Safety and Quality Health Service Standards including standards for medicines management and quality use of medicines in health services. The Commission is responsible for the stewardship of the National Standard Medication Charts (NSMC), which has the provision for recording drug allergies. The Commission through its NSMC audit and safety initiatives in electronic medication management supports health professionals and health services to continuously improve drug allergy documentation and prevent medication related harm. The Commission's public consultation paper on the third World Health Organization (WHO) Global Patient Safety Challenge – *Medication without harm* also acknowledges the need to improve the information available to patients to facilitate shared and supported decision making.

The TGA's proposal on increased online access to ingredient information will empower consumers and health professionals and has the potential to minimise unnecessary medication-related harm. The Commission supports the TGA's proposal as an important initiative to enhance medication safety. The Commission welcomes further opportunities to review any revisions to the TGA's consultation.

Appendices

A: Therapeutic Goods Administration. Increased online access to ingredient information. Public consultation paper. Version 1.0, August 2019.

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