



# Consultation: Increased online access to ingredient information

Due 10 October 2019

## **Mylan in Australia**

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**Alphapharm Pty Ltd (Trading as Mylan Australia)**

**ABN** 93 002 359 739

**Mylan Health Pty Ltd**

**ABN** 29 601 608 771

**Meda Pharmaceuticals Pty Ltd (A Mylan Company)**

**ABN** 59 155 308 679

[www.mylan.com.au](http://www.mylan.com.au)



## INTRODUCTION

The Mylan group of companies, Alphapharm Pty Ltd and Mylan Health Pty Ltd (herein referred to as ‘Mylan’), has been supplying medicines in Australia since 1982. We are the leading supplier of medicines by volume to the Pharmaceutical Benefits Scheme (PBS), with about one in six PBS prescriptions dispensed with a Mylan medicine.

Mylan offers locally a broad range of branded, generic and over the counter products - more than 800 individual formulations - and is one of the largest pharmaceutical manufacturers in the country. Last year, our internationally-accredited manufacturing plant at Carole Park, Queensland, produced over 3 billion doses of oral solid dose medicines, more than half of which was exported to about 40 countries.

Mylan also has interests in medical devices.

## GENERAL COMMENTS ON THE CONSULTATION

Mylan values this opportunity to provide comment on the proposed *increased online access to ingredient information*.

### **Mylan Comments:**

The availability of ingredient information for therapeutic goods compared with that for cosmetics and foods in Australia is very different. Consumers needing or wanting ingredient details of lower risk therapeutic goods must approach suppliers or the TGA, unless that information is otherwise provided in the public domain. Current practices in other similar jurisdictions (Canada, New Zealand, US, EU & UK) demonstrate greater transparency.

Australian consumers seek greater transparency and understanding of medicine ingredients, be they active or excipients. Many medicines have Product Information (PI) and Consumer Medicine Information (CMI) documents and the active and excipient ingredients are listed therein.

Closer harmonization of information accessibility across product categories to reduce consumer concerns relates more to some Over-The-Counter (OTC) and Complementary medicine products, each being widely distributed and easily purchased through pharmacies, and, in many cases via supermarkets and health food shops.

The time-consuming nature of enquiries, to either TGA or sponsor companies, from the general public, is also an important aspect which the outcomes from this consultation may address.

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## TGA Questions and Mylan responses

### *Question 1.*

Which is your preferred option? (1A; 1B; or 2)

Why?

### *Mylan Response 1:*

Mylan prefers Option 1A, that is to:

- publish the names of excipients except those used in flavor or fragrance proprietary ingredient mixes

Reasons:

- Closer alignment of accessibility of therapeutic goods ingredient information with those of food and cosmetics makes sense for consumers, and for improvement of public health.
- The information is already available to consumers if they ask specific questions of the TGA or sponsors, and many suppliers provide those details on line.
- Greater transparency of ingredients information, without mentioning quantities except for an active ingredient, does not increase risk of exposure of formulations or particular IP

### *Question 2.*

What are the risks and benefits (e.g. commercial, consumer safety, innovation) for each of the options proposed?

### *Mylan Response 2:*

#### Option 1A:

- a. Commercial risks & benefits

No additional commercial risks are foreseen provided formulations (that is, ingredient quantities) and manufacturing processes remain confidential. The names of ingredients are already available to consumers from suppliers, or the TGA, without provision of quantities or manufacturing processes.

Benefit: Potential enhancement of Australian suppliers' reputations for information transparency.

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Benefit: Potential reduction in resource expenditure answering consumer enquiries, though this may be counter-balanced to some extent by increases in enquiries, whether from consumers or health care professionals, for quantities of particular excipients in the goods.

b. Consumer safety risks & benefits

With ingredient information for therapeutic goods aligned with that for cosmetics and food labelling practices consumers will have the increased transparency they seek to support their safety. The information being more readily available will help to serve their medical needs and reduce concerns. Consumers will be able to exercise informed choice to a greater degree. With ingredient details more easily accessed by consumers their time will be saved and enquiries to TGA and to sponsors will be reduced. Consumers may feel more confident and in control of their choices when purchasing and using therapeutic goods. For health care professionals the availability of details to this level will assist them in managing patients.

c. Innovation risks & benefits

No innovation risks or benefits are foreseen because the ingredient information is already available, without detailing quantities and manufacturing processes.

**Question 3.**

If Option 1A or 1B is implemented, are you interested in collaborating with us to help communicate this information to consumers?

**Mylan Response 3:**

Mylan is prepared to consider assisting communication to consumers about increased transparency of medicine ingredients' information.

**Conclusions**

Greater alignment across product categories (cosmetics, food, medicines) to ensure appropriate information is accessible to the general public will provide benefits for public health and wellbeing.

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