

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2016 - 2017, 1 March 2017

Ref No: SQ17-000393

OUTCOME: 5 - Regulation, Safety and Protection

Topic: TGA Drug warning labels

Type of Question: Written Question on Notice

Senator: Di Natale, Richard

Question:

How can the department and Minister guarantee that medications are safe, when basic safety information is missing?

Answer:

Comprehensive medicine safety information is available in Product Information (PI) and Consumer Medicine Information (CMI) to all Australian consumers including packages, website information and other means such as mobile apps. Information on CMIs is readily available on the Therapeutic Goods Administration (TGA) website.

The PI contains comprehensive safety information about the medicine and is approved by the TGA at the time of registration and as a result of a comprehensive evaluation of quality, safety and efficacy. The PI contains safety information identified during the evaluation and contains the known contra-indications, precautions, drug interactions and adverse events associated with the product identified during clinical trials or in post market use.

There is constant monitoring of product safety by the TGA once medicines are available in Australia and any new safety information is added to the PI. This is also approved by the TGA.

A Consumer Medicines Information (CMI) document is written by the pharmaceutical company responsible for the medicine and is based on the information contained in the PI document. CMIs are written in less technical language in order that a consumer may easily understand the information contained in the document. The TGA reviews the CMI as part of the registration process for a medicine and when there are major updates to product usage (such as with an approval for a new patient group).

CMI content is defined by regulations and includes:

- Name of the medicine;
- Names of the active and inactive ingredients;
- Dosage of the medicine;
- What the medicine is used for and how it works;
- Warnings and precautions, such as when the medicine should not be taken;

- Interactions the medicine might have with food or other medicines;
- How to use the medicine properly;
- Side effects;
- What to do in the case of an overdose;
- How to store the medicine properly;
- Name and address of the sponsor; and
- Date the CMI was last updated.

The CMI does not contain all safety information but essential information for the consumer with necessary prompts to consult their health care professional. The more extensive PI contains comprehensive safety information about the medicine and there is an expectation that the prescriber will explain the risks and benefits to the patient, including any specific information of relevance to that particular patient from this document.

The CMI and PI are available in different formats to patients including in some medicine packages, websites, mobile apps and other forms.