CHC Submission on the Trans Tasman Early Warning System

How the process will work in Australia and New Zealand

To:

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Introduction

The Complementary Healthcare Council of Australia (the CHC) is pleased to provide comment on the proposed Trans-Tasman Early Warning System. The CHC supports an early warning system that seeks to improve consumer safety and health outcomes. The early warning of safety signals will assist clinical decision making around the benefits and risks of treatments for individual patients, in particular serious adverse reactions may be mitigated by changes in the use of therapeutic products by health professionals and consumers.

During the 2012 Joint TGA and Medsafe early warning system workshops, the CHC had concerns regarding what particular safety concerns should be included in an early warning system and when and how these safety concerns should be communicated. Overall, the CHC considers that the proposed system offers an appropriate risk management approach to the current therapeutic product vigilance system in Australia. We are supportive of the objective to align early warning regulatory process with New Zealand, where possible.

Specific comments

Sponsor/manufacturer engagement

The Process Flow Chart for the early warning system (page 8) details that after the detection of a safety concern or signal an initial assessment or risk analysis is undertaken. During this phase the process outlines that engagement with the sponsor/manufacturer would occur *if required*. The CHC strongly believe that the sponsor/manufacturer be engaged in the process from the detection of a safety signal and communication be inniated with the sponsor/manufacturer prior to publishing any monitoring communications.

The decision to issue a monitoring communication could be made at the initial assessment/risk analysis step when all safety concerns are considered and when contact has been made with the sponsor/manufacturer, as suggested above. The same should apply for the signal investigation/assessment step, when concerns are deemed to be safety signals the sponsor/manufacturer should be involved in the communication process at the earliest possible stage.

Initial assessment/risk analysis

Safety concerns at this stage of the therapeutic product vigilance system are proposed to include all safety concerns detected by the regulator including those already known, coincidental events and safety signals.

Safety concerns will be considered for a monitoring communication at the initial assessment step if, for Australian products, the product is entered on to the Australian Register of Therapeutic Goods (ARTG) and at least one of the following:

1) The potential safety concern could be serious by international standards and there may be insufficient information to support a review at that time of communication; or

2) There is likely to be an interest in the potential safety concern from consumers, health professionals, government or media; or

3) On advice from an Expert Advisory Committee; including the Advisory Committee on Medical Devices, Advisory Committee on the Safety of Medicines and the Advisory Committee on the Safety of Vaccines.

The CHC recommends that there be communication with the sponsor/manufacturer at the earliest stage and that there is sufficient evidence of the potential serious safety concern to warrant a monitoring communication and further assessment. In cases where the TGA take no further action after a monitoring communication is made the reasons for this should be clearly communicated.

Peak industry associations should also form the criteria for option 2, in being able to make enquires regarding any significant interest in a potential safety concern related to that industry sector. The regulator should also communicate to association bodies any safety signals being investigated and where communication has been made with sponsors/manufacturers in industry.

The CHC recommends, that the TGA seek expert advice from its Committees, including the statutory advisory Committee on Complementary Medicines (ACCM) as part of the process for obtaining independent expert advice regarding complementary medicines that may be considered as a potential safety concern. The ACCM offer a wealth of expertise on matters relating to the inclusion, variation and retention of complementary medicines in the ARTG or any other matters referred to it by the TGA.

Monitoring communication publication

Monitoring communications seek to, among other things, instruct the user to follow the manufacturer's product information or instructions for the medicine. Messages that are communicated to consumers at this early stage need to be very carefully determined so as not to cause consumers to be overly cautious and prematurely stop taking their medicines. The CHC supports the following message, which is outlined in the consumer questions and answers section and the monitoring communications webpages; 'The TGA emphasises that patients should NOT stop using a medicine or medical device subject to a monitoring communication. If you have any concerns with a therapeutic product you are using, please contact your health professional'.

Monitoring communications that have been published to the TGA and or Medsafe websites should include a reminder for interested parties to subscribe to the website update email list, so as to notify those reading the initial communications that a follow up communication or alert could follow and subscribing to these communications will ensure they receive the latest content.

The CHC is appreciative of the opportunity to make this submission. We strongly support a timely, responsive and engaging system for therapeutic product vigilance in Australia and New Zealand.