Complementary Healthcare Council of Australia



Technical Alert

Therapeutic Goods Amendment Bill (2013 Measures No.1)

Dear Member,

The Therapeutic Goods Amendments (2013 Measures No. 1) Bill 2013 makes a number of amendments to the *Therapeutic Goods Act* 1989 (the Act). The Bill has been introduced to Parliament for a second reading and will be referred to the Senate Community Affairs Legislation Committee for report in June 2013. The CHC has been invited by the Community Affairs Legislation Committee to make a submission outlining the impacts of this Bill on industry.

The purpose of the Bill is to make a number of important changes that aim to streamline and improve the operation of the regulatory scheme across all therapeutic goods under the Act. Many of the changes standardise or replicate existing regulatory requirements so that common regulatory rules and processes apply to all classes of therapeutic goods.

Measures in the Bill include:

1. A power for the Minister for Health to exclude products from the definition of 'therapeutic goods' and thus remove them from regulation under the Act. For example; food where therapeutic claims are made and are not otherwise excluded. Such a determination would be required to be tabled before Parliament and would be disallowable.

2. A new provision enabling specific power for the secretary of the department of health to remove products which are not, or are no longer 'therapeutic goods' from the Australian Register of Therapeutic Goods (ARTG). It will also allow the Secretary to remove a product that may have come within the definition when it was included but no longer does so, for instance where claims about its therapeutic use are no longer being made. Such a decision will be subject to both internal review and review by the Administrative Appeals Tribunal (AAT).

3. Clarify the source of the power for the Secretary to approve product information (PI) under section 25AA of the Act.

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Other amendments

The Schedules make a number of other amendments to the Act, including:

4. Providing that the Secretary may suspend or cancel the registration or listing of therapeutic goods where the presentation of the goods is not acceptable or, in the case of listed goods, is unacceptable. For instance where its presentation (name, labelling, packaging of the goods and any advertising or other informational material associated with the goods) no longer reaches an acceptable standard, but only after giving the sponsor the opportunity to make submissions (subject to internal review and review by the AAT).

5. Providing that the Secretary may cancel the registration or listing of therapeutic goods where a sponsor does not respond to a request from the Secretary under section 31 of the Act to provide specified information or documents about those goods.

6. Giving the Secretary the option of publishing information about various regulatory decisions made under the Act (including suspension and cancellation of goods from the Register) on the Department's website rather than in the Gazette.

7. Giving the Secretary the power to require in particular circumstances (for instance where therapeutic goods have been suspended or cancelled from the Register, or where the Secretary has come to the view that the safety, quality, efficacy/performance, or presentation of therapeutic goods, is unacceptable), the sponsor of those therapeutic goods to provide information about the goods to the public or to a class of persons such as health care professionals or patients, and to give to the Secretary information about persons to whom the goods have been supplied.

8. Modifying the definition of a kit in section 7B of the Act to encompass kits containing (among other things) only one registered or listed therapeutic good, or a biological combined with other items (provided they are for use as a unit); and

9. Introducing an offence where a sponsor provides information that is false or misleading in a material particular in relation to a request under section 9D of the Act for a variation to an entry on the Register.

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Amendments in the Bill will ensure that the secretary can request sponsors of all classes of lower-risk therapeutic goods (CMs, biologicals and medical devices) to provide information and documents relating to any of the certifications made for the good. This requirement acknowledges that lower-risk products are included in the ARTG and available for supply in Australia without pre-evaluation by the TGA.

A copy of the Bill, Explanatory memorandum and 2nd reading speech are available here.

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