Australian Government

Department of Health and Ageing

Supplementary submission to the Senate Finance and Public Administration Legislation Committee

Inquiry into the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

20 May 2013

Contents

1. Introduction

On 28 February 2013, Senator Di Natale introduced the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill (the Bill) in the Senate. The Bill amends the *Therapeutic Goods Act 1989* (the Act) to create civil penalties related to the provision of payments, services or certain other inducements to medical practitioners by pharmaceutical companies. The Bill also provides for penalties for breaching reporting requirements included in the Bill about certain payments made to or in relation to medical practitioners.

On 21 March 2013, the Senate referred the Bill for inquiry and report. The terms of reference for the inquiry are 'to receive evidence on the need for regulation of pharmaceutical industry conduct with regards to interactions with the medical profession, and the appropriateness of the provisions in the bill that place restrictions on these interactions'.

The Department provided a written submission dated 23 April 2013 which provided information on current Government policy in relation to the promotion of therapeutic goods, national policy on pharmaceuticals, the regulation of the medical profession and the interaction of the proposed amendments with the Act.

Two officers of the Department were witnesses at the public hearing on the Bill conducted by the Committee in Melbourne on 29 April 2013. A number of matters were canvassed in relation to which the officers undertook to provide additional information. This supplementary submission provides that information.

Responses to questions taken on notice are provided separately.

2. Coverage of the Bill

2.1 Definition of "regulated corporation"

The Bill provides for the imposition of civil penalties on registered corporations engaging in particular conduct in relation to registered medical practitioners. It also imposes reporting requirements on regulated corporations, a breach of which can also result in the imposition of a civil penalty.

A "regulated corporation" is defined in proposed section 42DQ as:

(a) a corporation that imports regulated pharmaceutical products into Australia; or
(b) a corporation that manufactures regulated pharmaceutical products in Australia; or
(c) a corporation that supplies regulated pharmaceutical products in Australia.

"Regulated pharmaceutical product" is defined in that section as a medicine that is a listed good or a registered good.

"Listed good" and "registered good" are defined in subsection 3(1) of the Act and refer to goods that are included in the Australian Register of Therapeutic Goods (the Register) under section 26 or section 26A of the Act (listed goods), or under section 25 of the Act (registered goods). Prescription and over-the-counter medicines and some complementary medicines are registered under section 25[1] and the great majority of complementary medicines are listed under section 26A[2].

Under the Act, the company in relation to which the goods are listed or registered under those sections is legally responsible for therapeutic goods. In the case of a prescription or other medicine, this is the company in relation to which the medicine is registered or listed, the name of which is included in the Register entry for the medicine.[3] The company can then supply, or have arrangements with other companies to supply, the approved medicine for the purpose of marketing it in Australia.

The definition of "regulated corporation" in proposed section 42DQ picks up any corporation that "supplies" registered or listed medicines in Australia. "Supply" as defined in subsection 3(1) of the Act has a very wide meaning and includes supply:

- by way of sale, exchange, gift, lease, loan, hire or hire-purchase,
- whether free of charge or otherwise, by way of sample or advertisement or in the course of testing the safety or efficacy of therapeutic goods in persons, and
- by way of administration to, or application in the treatment of, a person.

Apart from this extended meaning, "supply" would also include the sale of the registered or listed medicine whether by an importer, manufacturer, wholesaler or retailer.

While it appears from the Explanatory Memorandum to the Bill (for instance by its reference to "drug companies" and to the "pharmaceutical industry") that its coverage is intended to be limited to companies in relation to which prescription and other medicines are included in the Register, there is an argument that the definition of "regulated corporations" covers a much wider range of companies and could include companies that are involved at any stage in the supply of registered or listed medicines.

It may also, as is suggested in the submission to the Committee from Professor Trewhella on behalf of the University of Sydney, unintentionally capture universities that import registered medicines for medical research.

A definition of "regulated corporation" which refers to corporations "in relation to whom a medicine is listed or registered" may more accurately reflect the intended coverage of the proposed offence and reporting provisions in the Bill.

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1 Registration involves evaluation by the TGA of the medicine by reference to the statutory criteria in section 25 before it is included in the Register.

2 Under section 26A of the Act, low risk medicines are included in the Register without evaluation by the TGA but the applicant/sponsor is required to certify as to a range of matters about the medicine.

3 See for instance, sections 30 and 31 of the Act under which the Secretary can:
- cancel registered and listed medicines from the Register by giving notice to "the person in relation to whom the goods are included in the Register" (s.30), and
- require "the person in relation to whom therapeutic goods are registered" or "the person in relation to whom therapeutic goods are listed" to provide information or documents to the Secretary (s.31).

2.2 Condition of registration

Under the Act, the Secretary of the Department of Health and Ageing can impose conditions on the registration of a registered or listed medicine.

There are a number of possible consequences under the Act if a condition of registration is breached. The Secretary can suspend or cancel the medicine from the Register for a breach of condition (after she has notified the person in relation to whom the medicine is listed or registered of her intention to do so, and given them the opportunity to make submissions)[4]. The Act also makes it an offence for a person in relation to whom a medicine is listed or registered to breach of a condition, with substantial penalties depending on the likelihood of harm or injury resulting from the breach[5]. Finally, the Act provides for substantial civil penalties that can be imposed by a court on a person in relation to whom a medicine is listed or registered for breach of a condition[6].

Thus any company in relation to whom a registered medicine is included in the Register which is subject to a condition risks not only suspension or cancellation but potentially prosecution for an offence or a liability to pay civil penalties.

For some years it has been the practice of delegates of the Secretary to impose the following condition on the registration of prescription medicines (including generic medicines):

> Promotional material (other than Product Information) relating to the registered good must comply with the requirements of the Code of Conduct of Medicines Australia (formerly the Australian Pharmaceutical Manufacturers' Association).

The condition only picks up those requirements in the Code of Conduct that relate to promotional material and only to the extent that they are capable of applying in relation to the promotion of registered medicines.

With the Generic Medicines Industry Association having its own Code of Practice authorised by the Australian Competition and Consumer Commission, the TGA is reviewing the wording of this condition. It is intended that promotional material will need to comply with the specific requirements as recorded in the Medicines Australia Code of Conduct for the product being approved, but consideration is being given to how this is best described in the condition. Revision of the wording will be done in consultation with both Medicines Australia and the Generic Medicines Industry Association and will take account of the work being undertaken by the *Codes of Conduct Advisory Group*.

4 See paragraph 30(2)(c) and subsection 30(3) of the Act.
5 See subsections 21A(5), (6) and (8) of the Act.
6 See subsection 21B(2) of the Act.