EXPLANATORY STATEMENT

Therapeutic Goods (Excluded Purposes) Specification 2010

Section 41BEA, Therapeutic Goods Act 1989

OUTLINE

The Therapeutic Goods (Excluded Purposes) Specification 2010 is a Specification made by the Secretary to the Department of Health and Ageing under section 41BEA of the *Therapeutic Goods Act 1989* (the Act). This Specification only applies to a kind of in-vitro diagnostic medical device for self-testing (IVD medical device for self-testing).

An IVD medical device for self-testing is an IVD medical device intended to be used in the home or similar environment by a lay person, or in the collection of a sample by a lay person and if that sample is tested by another person, the results are returned directly to the person from whom the sample was taken without the direct supervision of a health professional who has formal training in a medical field or discipline to which the self-testing relates.

This Specification sets out those purposes (excluded purposes) for which a kind of IVD medical device for self-testing may not be used. Each of the excluded purposes mentioned for the kind of device in the Specification is specified for paragraph 41FD (ia) and subsection 41FF(1A) of the Act. Paragraph 41FD(ia) requires that an applicant seeking to include a kind of medical device in the Australian Register of Therapeutic Goods (the Register) certify that a device of that kind is not to be used exclusively for one or more of the excluded purposes specified in the Specification. In addition, the Secretary to the Department of Health and Ageing (or her delegate) is prohibited from including a kind of device in the Register, if the Secretary is satisfied that the kind of device is to be used exclusively for one or more of those excluded purposes specified in the Specification.

This Specification commences on 1 July 2010.

BACKGROUND

The *Therapeutic Goods Act 1989* provides for the establishment and maintenance of a national system of controls relating to the quality, safety and efficacy of therapeutic goods that are used in Australia or exported from Australia.

The new regulatory framework for IVD medical devices under Chapter 4 of the *Therapeutic Goods Act 1989* will commence on 1 July 2010. The IVD medical devices framework includes the regulation of IVD medical devices for self-testing (also known as Home Use IVD's under Part 3-2 of the Act). As part of the framework certain IVD medical devices for self-testing must not be included in the Register if they are used exclusively for one or more of the purposes identified as "excluded purposes" in a Specification made by the Secretary under section 41BEA of the Act. This Specification will enable that part of the framework to be operational for the purposes of preventing the supply of specific categories of IVD medical devices for self-testing.

Section 41BEA of the Act provides that the Secretary may, by legislative instrument, specify purposes relevant to paragraph 41FD(ia) and subsection 41FF(1A).

Subsection 41FF(1A) provides that the Secretary must not include a kind of device in the Register if the Secretary is satisfied that the device is to be used exclusively for one or more of excluded purposes specified under a Specification made under section 41BEA of the Act.

Paragraph 41FD(ia) requires an applicant for inclusion of a kind of medical device in the Register to certify that devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BEA. Subsection 41FF(1A) therefore authorises the Secretary to refuse to include a kind of medical device in relation to a person if she is satisfied that the medical device is to be used exclusively for one or more of the excluded purposes specified in the instrument made under section 41BEA.

THE SPECIFICATION

Each of the following purposes is an excluded purpose specified for paragraph 41FD(ia) and 41FF(1A) of the Act:

(a) to test specimens from the human body for the purposes of, or exposure to, pathogenic organisms or transmissible agents, including agents that cause notifiable infectious diseases;
(b) genetic testing to determine the presence of, or predict susceptibility to diseases in humans;
(c) to diagnose, aid in diagnosis or indicate the presence of a serious disease or condition, such as cancer or myocardial infarction;
(d) to test for the presence of markers that are precursors to a serious disease or condition such as Pap smear tests (marker for cervical cancer) or prostate specific antigen tests (marker for prostate cancer).

The effect of the Specification is to prevent a kind of IVD medical device for self-testing that is to be used exclusively for one or more purposes specified in paragraphs (a) to (d) above to be included in the Register. However, if the IVD medical device is to be used for other purposes in addition to those purposes specified in paragraphs (a) to (d), or for purposes that are not mentioned in paragraphs (a) to (d), then the Secretary may include the kind of device in the Register.

CONSULTATION

A regulation impact statement was completed as part of the overall IVD medical devices framework. Consultation was extensive on this framework and the requirements for IVD medical devices for self-testing were part of this consultation. There was overall support for the new IVD medical devices framework.

During consultation with the Department of Health and Ageing an issue in relation to the risk of “off label use” in regard to 4(3)(b) was raised. Whilst “off label use” is a possibility this would be the same for many IVDs or medical devices. The Therapeutic Goods Administration does not regulate the user however the TGA can ensure labelling is specific about “off label use”.

A Preliminary Assessment on the impact of this Specification on business was carried out and shows that it is of low impact.