Therapeutic Goods (Excluded purposes) Specification 2010[1]

Therapeutic Goods Act 1989

I, SARAH JANE HALTON, Secretary to the Department of Health and Ageing, make this Specification under section 41BEA of the *Therapeutic Goods Act 1989*.

Dated 30 June 2010

SARAH JANE HALTON
Secretary to the Department of Health and Ageing

1 Name of Specification

This Specification is the *Therapeutic Goods (Excluded purposes) Specification 2010*.

2 Commencement

This Specification commences on 1 July 2010.

3 Definitions

In this Specification:

Act means the *Therapeutic Goods Act 1989*.

IVD medical device for self-testing has the meaning given by the Dictionary in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

serious disease has the meaning given by the Dictionary in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

4 Excluded purposes

(1) This section applies to a kind of IVD medical device for self-testing.

(2) For section 41BEA of the Act, each of the following purposes mentioned for a device is specified for paragraph 41FD (ia) and subsection 41FF (1A) of the Act, unless the device is also to be used for another purpose, including a purpose mentioned in subsection (3):

(a) to test specimens from the human body for the presence 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).

(3) Subsection (2) does not apply to the device if it is also to be used for any other purpose including any of the following purposes:

(a) for testing for a disease or condition as part of a public health screening program sponsored by the government of the Commonwealth or a State or Territory;

(b) for self-testing to monitor a diagnosed disease or condition;

(c) for export only.

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003.* See http://www.frli.gov.au.

Federal Register of Legislative Instruments F2010L01889