



Australian Government

Department of Health
Therapeutic Goods Administration

Instrument under the *Therapeutic Goods Act 1989*

**Arrangement under section 7C of the *Therapeutic Goods Act 1989*
for use of computer programs to make decisions**

I, Natasha Cole, First Assistant Secretary, Regulatory Practice and Support Division, a delegate of the Secretary of the Department of Health for the purposes of section 7C of the *Therapeutic Goods Act 1989* (the Act):

ARRANGE under subsection 7C(1) of the Act for the use of the computer program known as TGA Business Services to make decisions for the Secretary as specified below:

Cancellation of an entry

- (a) decisions under paragraph 30(1)(c) of the Act to cancel the registration or listing of therapeutic goods if the person in relation to whom the goods are included in the Australian Register of Therapeutic Goods (the Register) requests in writing the cancellation of the registration or listing;
- (b) decisions under paragraph 32GA(1)(d) of the Act to cancel the entry of a biological from the Register if the person in relation to whom the biological is included in the Register requests in writing the cancellation of the entry of the biological from the Register;
- (c) decisions under paragraph 41GL(d) of the Act to cancel the entry of a kind of medical device from the Register if the person in relation to whom the kind of medical device is included in the Register requests in writing the cancellation of the entry of the kind of device from the Register;

Revocation of cancellation of entries upon request

- (d) decisions under subsection 30A(1) of the Act to revoke the cancellation of a registration or listing of therapeutic goods;
- (e) decisions under subsection 32GD(1) of the Act to revoke the cancellation of a registration or listing of therapeutic goods

- (f) decisions under subsection 41GLA(1) of the Act to revoke the cancellation of an entry of a kind of medical device;


Revocation of cancellation of entries – payment of annual charge

- (g) decisions under subsection 30AA(1) of the Act to revoke the cancellation of a registration or listing of therapeutic goods;
- (h) decisions under subsection 32GDA(1) of the Act to revoke the cancellation of an entry of a biological from the Register;
- (i) decisions under subsection 41GLB(1) of the Act to revoke the cancellation of an entry of a kind of medical device;

Transfer or assignment of business

- (j) decisions under subregulation 10AB(7) of the *Therapeutic Goods Regulations 1990* (the Regulations) to amend the Register to change the person in relation to whom therapeutic goods are registered or listed, if a 'notifying person' within the meaning of subregulation 10AB(5) notifies the Secretary of an event under paragraph 10AB(5)(b) and any further information requested by the Secretary under subregulation 10AB(6) is provided;
- (k) decisions under subregulation 10F(7) of the Regulations to amend the Register to change the person in relation to whom a kind of medical device is included, if a 'notifying person' within the meaning of subregulation 10F(5) notifies the Secretary of an event under paragraph 10F(5)(b) and any further information requested by the Secretary under subregulation 10F(6) is provided;
- (l) decisions under subregulation 10H(7) of the Regulations to amend the Register to change the person in relation to whom a biological is included, if a 'notifying person' within the meaning of subregulation 10H(5) notifies the Secretary of an event under paragraph 10H(5)(b) and any further information requested by the Secretary under subregulation 10H(6) is provided;

This approval has effect from 16 July 2018.


Natasha Cole
Delegate of the Secretary

12 July 2018