EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Section 38A Guidelines - Circumstances in which a licence may cover two or more manufacturing sites

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

Section 38A of the *Therapeutic Goods Act 1989*, which came into force on 25 February 2010, authorises the Secretary to make guidelines, by legislative instrument, setting out the circumstances in which a manufacturing licence can cover two or more manufacturing sites (Section 38A Guidelines).

Under section 38(2A) of the Act the Secretary must have regard to the Section 38A Guidelines in making decisions about manufacturing licences. Other provisions that are relevant to the granting, revocation (of existing multi-site) and variation of manufacturing licences include:

- section 37(1B), which allows an applicant for a licence, having regard to the Section 38A Guidelines, to request that a licence cover two or more manufacturing sites that are identified in the application;
- section 38B(3), which requires the Secretary to have regard to the section 38A guidelines in granting new licences as a consequence of the revocation of an old multi-site licence;
- section 40B(1), which allows the holder of a manufacturing licence to apply for a variation of a manufacturing licence so that it covers one or more additional manufacturing sites, if the holder is of the view that having regard to the Section 38A Guidelines, the licence could cover one or more of those additional sites.

The Section 38A Guidelines apply differently depending on whether the licence relates to the manufacture of blood, blood components, plasma, haematopoietic progenitor cells or human tissue, or other therapeutic goods (that are not medical devices). The Guidelines provide that a licence can only cover more than one manufacturing site if certain criteria are met.

Manufacture of therapeutic goods other than medical devices and blood, etc.

Where the particular kind of therapeutic goods being manufactured are not medical devices or blood, blood components, plasma, haematopoietic progenitor cells or human tissue the criteria are that steps of manufacturing for those goods are performed at one site and any other site to be covered by the licence is only used for:

(a) the storage of packaging materials, starting or in-process materials for those goods or the finished goods themselves; or
(b) that kind of storage together with the packing of the goods in packaging not intended to be in contact with the goods ("secondary packaging") and/or the releasing of those materials or the finished goods for supply.

For example, if therapeutic goods of kinds A, B and C are manufactured at site X then it will be open for the Secretary to approve the inclusion in the relevant manufacturing licence sites Y and Z if they are used to store products of the A or B or C kind or to release any of those kinds for supply. However if site Z was also used to store therapeutic good of kind D (which is manufactured at site W), site Z could not be included in the manufacturing licence that covers sites X and Y.

The other criteria are that:

- the manufacturing steps carried out in all the manufacturing sites will be within the defined scope of a single quality system; and
- the TGA is satisfied that all the sites proposed to be covered by the licence can be audited within the relevant on-site period and that once an on-site audit has commenced, the total travel time between all the sites will not exceed 60 minutes.

Manufacture of blood, blood components, plasma, haematopoietic progenitor cells or human tissue

Where the particular kind of therapeutic goods being manufactured are blood, blood components, plasma, haematopoietic progenitor cells or human tissue the criteria are that steps of manufacturing for those goods are performed at one fixed site and any other site to be covered by the licence is only used for:

- where it is a mobile site – for the collection of blood or blood components;
- where it is a fixed site – the storage of starting materials or in-process materials for those goods or the finished goods themselves.

As with the other therapeutic goods, the other criteria are that:

- the manufacturing steps carried out in all the manufacturing sites will be within the defined scope of a single quality system; and
- the TGA is satisfied that all the sites proposed to be covered by the licence can be audited within the relevant on-site period and that once an on-site audit has commenced, the total travel time between all the fixed sites will not exceed 60 minutes.

The same criteria will be relevant if the holder of a manufacturing licence seeks to vary the licence to include additional sites.

BACKGROUND

In August 2009, the *Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009* (the Amendment Act) introduced a range of changes to the Act including, at Schedule 2 to the Amendment Act, a number of changes in relation to the definition of manufacturing premises and sites, manufacturing licences and variations to licences. Schedule 2 of the Amendment Act commenced on 25 February 2010.

As a result of the above changes, an application for a manufacturing licence under section 37 of the Act will generally only relate to one manufacturing site. A licence granted under section 38 will only cover that one site, unless the Secretary exercises a discretion under that section (having regard to the criteria in the Section 38A Guidelines) to allow more than one site to be covered. For each manufacturing site covered by a licence, the Secretary must authorise, in the licence, the holder of that licence to carry out specified steps in the manufacture of specified therapeutic goods at that manufacturing site.

The introduction of provisions for a single licence for each manufacturing site is to ensure that the location and scope of manufacturing may be specifically identified by the licence. A variation to a licence, or regulatory action taken in relation to a licence, is then limited to the affected manufacturing site. The licensing of a single site is consistent with the practice of certifying individual overseas manufacturing sites.

On commencement of the amendments, the Secretary is required to revoke existing multi-site licences and grant new licences taking into consideration the Section 38A Guidelines (section 38B). An applicant for a variation of a licence seeking the addition of one or more manufacturing sites must also have regard to the guidelines under section 38A of the Act.

These changes were to have been included in legislation underpinning the establishment of the proposed Australia New Zealand Therapeutic Products Agency (ANZTPA). However, in July 2007 the New Zealand Government announced that it would not proceed with the necessary legislation in the New Zealand Parliament and further work on ANZTPA was suspended. The Australian Government decided to proceed with amendments relating to, among other matters, the issue of a licence for each manufacturing site.

CONSULTATION

The TGA consulted on the introduction of a provision for a licence for each manufacturing site prior to the introduction of the Amendment Act as part of the consultation for the Australian / New Zealand Therapeutic Products Agency.

Draft guidelines were provided in November 2009 to peak industry bodies and were made available on the TGA website. The TGA sought comment on whether the guidelines sufficiently clarify the circumstances in which a licence may cover two or more manufacturing sites.

Ten comments were received and related to:

- *the travel time between sites* – The time period within which it must be possible to travel between sites for the purpose of an audit was increased from 30mins to 60 mins.

- *a request to allow minor manufacturing steps to be carried out at storage sites* – For manufacturing sites that are used for storage, manufacturers will be also be permitted to undertake release for supply, or secondary packaging, or both, for the materials or products that are manufactured under the licence.
- *clarification of the application of the guidelines to cord blood, haematopoietic progenitor cells and blood storage locations in hospitals* – The guidelines only apply to a person who is required to hold a manufacturing licence and do not create new requirements to hold a licence.
- *clarification of the application of the guidelines to the collection of blood components* – The guidelines were amended to include the collection of blood components from mobile sites.

The Section 38A Guidelines document is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.