

Parliament relaxes Therapeutic Goods Act patent certificates

Federal Parliament has passed a Bill limiting the circumstances in which an applicant for marketing approval of a therapeutic good will be required to file a patent certificate.

22 February 2006

In September 2005 we reported on a proposal to amend the requirements for patent certificates under the *Therapeutic Goods Act 1989*.

The effect of the amendments is to require a Section 26B Certificate to be lodged only where an applicant seeks to rely on data previously submitted by another person as part of that person's earlier application. A typical example of such a situation is an application to register a generic version of an existing drug.

Earlier this month the amendments were passed by the Federal Parliament. The amendments were passed in the form originally proposed, meaning that they will operate as per our earlier report.

The next step is for the amendments to receive Royal Assent, and then for a commencement date to be set. Any applications for marketing

approval lodged after commencement will be subject to the amended requirements.

In other words, an application lodged after commencement will not need to be accompanied by a Section 26B Certificate unless the applicant seeks to rely on data previously submitted by another person as part of that person's earlier application.

A copy of our September 2005 article titled "Proposal to Relax Patent Certificates Under the *Therapeutic Goods Act 1989*" is available on our website under publications.

MORE INFORMATION

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