Therapeutic goods and use of human embryos or human embryonic stem cells or material derived therefrom

Sponsor Declaration

In relation to this submission, I certify that to the best of my knowledge:

A i The goods that are the subject of this submission are/are not (delete whichever is not applicable) manufactured using a human embryo or human embryonic stem cell, or other material sourced from a human embryo or human embryonic stem cell;

ii The draft PI and CMI do/do not (delete whichever is not applicable) include a statement that human embryos or human embryonic stem cells or any other material sourced from a human embryo or human embryonic stem cell were used in the manufacture of the therapeutic good.

B i Information included in this submission does/does not (delete whichever is not applicable) refer to the use of human embryos, human embryonic stem cells (or materials sourced from human embryos or human embryonic stem cells) in research undertaken in the development of the medicine.

If this answer is affirmative, list references[1] below:

ii The draft PI and CMI do/do not (delete whichever is not applicable) include a statement that human embryos, human embryonic stem cells (or materials sourced from human embryos or human embryonic stem cells) were used in research undertaken in the development of the medicine.

Signature:		Date:	/ / dd mm yy
Name: (please print)			
Position/ Relationship to Sponsor:			

(Declaration must be signed by an authorised officer of the company)

[1] Cross-referencing to documents should be made by referring to the CTD module, volume and tab identifier