Biotherapeutics Association of Australasia

Tel: (08) 92243124
Fax: (08) 92241420
www.bioaa.org.au
ABN: 170 8789 5485

c/- Royal Perth Hospital
Level 2 North Block RPH
Welling St Campus
Perth, WA 6000

CONSULTATION SUBMISSION

Proposed medical device classification for human cells, tissues and organs storage solutions and IVF media

Thank you for this opportunity to provide feedback on the proposal to classify as medical devices, some of the solutions and media used in the provision of cells and tissues for implant.

The Biotherapeutics Association of Australasia (BAA) welcomes opportunities to provide sector perspective on proposed changes. Unfortunately, on this occasion notification of this consultation was not received and we only became aware of it in early April.

As this proposal does have the potential to significantly and adversely affect a number of cell facilities and tissue banks, we request an extension of time to enable our members to seek clarity and ascertain the potential impact for the biologicals sector. To this end we propose a direct consultation with the Biologicals Sector (tissues, cell therapy and eyes).

On preliminary review we bring to your attention the following points of confusion:

- It is unclear how or if the changes will apply to commercial solutions used just before implantation or administration; an example being PBS/saline.
- With reference to these commercial solutions, will ARTG listing exempt them from having to be classified as a medical device?
- It is unclear if in-house solutions are exempted. However, if they are would they be required to be listed as an IVD?

Yours respectfully
BAA Council