



THE HON CATHERINE KING MP
Parliamentary Secretary for Health and Ageing

MEDIA RELEASE

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TGA applies stricter regulation to joint implants

Hip, knee and shoulder joint implants will be reclassified as high risk, Class III medical devices from 1 July 2012, the Parliamentary Secretary for Health and Ageing, Catherine King, announced today.

"This new classification will bring greater rigour to the way the Therapeutic Goods Administration (TGA) assesses these devices before they can be used in Australia," Ms King said.

"It will also ensure an improved level of monitoring is undertaken once the product is on the market, and will allow easier product recall.

"This change will also allow better identification of these products on the Australian Register of Therapeutic Goods (ARTG) as they will now be included as individual products rather than allowing a number of products to be included on the ARTG under a single entry.

"Overall it will better assure the safety, quality and performance of joint replacement devices."

Ms King said the reclassification is in response to recommendations of the Health Technology in Australia review and following concerns over the quality of some hip replacement implants that have needed to be recalled in recent years.

"There has been widespread stakeholder consultation and I believe all parties see the need for closer scrutiny of joint replacement devices," Ms King said.

People wanting to manufacture or supply new hip, knee and shoulder joint implants will need to apply for inclusion on the Australian Register of Therapeutic Goods (ARTG) as Class III medical devices.

Manufacturers and suppliers of existing hip, knee and shoulder joint implants will have two years to transition these to be reclassified as Class III medical devices.

The TGA is writing to affected organisations to provide details of the new arrangements, including that some fees and charges will be waived to facilitate the transition.

Further general information on the reclassification of hip, knee and shoulder implants, is available in the [medical device section of the TGA website](#).

For more information:

- [Implementation commences 1 July 2012 to reclassify hip, knee and shoulder joint implants](#)
- [Increasing scrutiny of hip, knee and shoulder joint implants](#)
- [Regulation impact statement for reclassification of hip, knee and shoulder joint implants](#)

**For more information, contact the parliamentary secretary's office
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