



Submission

The Therapeutic Goods Amendment (2016 Measures No.1) Bill 2016

Day Hospitals Australia does not have any major concerns relation to the Therapeutic Goods Amendment (2016 Measures No.1) Bill 2016.

However with reference to the third summary point in the explanatory memorandum, which relates to the enabling of Australian “notified Bodies” there are some words of caution that should be noted.

Day Hospitals Australia would like to emphasize that risk management strategies should be in place with respect to the selection of “notified Bodies”.

Criteria for qualification, as a one of the nominated new Notified Bodies, must guarantee transparency of the assessment process, ensuring no conflict of interest with respect to the medical device, the manufacturing process and the safety of the product.

It would be concerning for example, if a body that is designated as a Body which is permitted to undertake conformity assessments was under the control/direction of one or more manufacturers.

Thank you for the opportunity to provide comment on the Therapeutic Goods Amendment.

Yours faithfully

Jane Griffiths
Chief Executive Officer