

MEDIA RELEASE

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“IVD Australia disappointed by TGA Blueprint”

IVD Australia today expressed its disappointment in the lack of commitment shown by the Government to increasing the level of ethical standards in the promotion of health sector products.

In acknowledging the release of the document entitled “TGA Reforms: A blueprint for the TGA’s future” the Chief Executive Officer of IVD Australia, Dr Peter Harman, noted that “IVD Australia fully supported the Trimmer Committee’s recommendations regarding the implementation of reforms on the promotion of therapeutic goods. It is very disappointing that the Government has chosen not to take up all the recommendations and has failed to extend them to all parties in the wider health sector.”

“This will continue the situation of an uneven playing field where companies who chose the ethical and responsible path are at a disadvantage to those who do not”, he said.

“IVD Australia is also concerned that the costs of including IVDs on the ARTG will rise under the ‘Blueprint’ proposals. Australian sponsors bear the full costs of the TGA, unlike other jurisdictions such as the USA which is less than 35% cost recovered. IVD sponsors are already incurring large increases in costs to include IVD products on the ARTG and further increases will mean that even more products will not be supplied in Australia post the July 1st 2014 IVD Transition date”, he added.

“IVD Australia does however welcome the commitment to increased transparency regarding the regulatory processes of the TGA. We have been working with the TGA and other stakeholders to introduce a number of reforms to the regulation of medical devices, including IVDs, which were well underway before the release of this Response. These will assist consumers to better understand exactly which products are included on the ARTG.”

IVD Australia is the industry Association representing companies who manufacture and supply in vitro diagnostics in Australia. In vitro, literally “in glass” diagnostics (IVD’s) comprises the instruments and reagents that are used to perform pathology tests requested by General Practitioners or specialist Physicians. These are generally performed in accredited Public and Private pathology laboratories across Australia, but IVD’s also include over-the-counter tests such as blood glucose meters for diabetes testing and home pregnancy test kits. Supply of these products is regulated for the Government by the Therapeutic Goods Administration. IVD Australia represents over 60 multinational and local importers as well as Australian manufacturers of IVDs. IVD Australia members currently supply products valued at over \$800,000,000 pa and they employ 2000 people across Australia.

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