IVD Australia Submission on New Therapeutic Goods Order: *Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies*

IVD Australia is pleased to offer the following comments in response to the request by the TGA for comments on the New Therapeutic Goods Order: S*tandards for minimising infectious disease transmission…….*

IVD Australia endorses, in principle, the proposed TGO as we believe that this Order will formalise the extent of testing required to be performed on human blood and blood components, human tissues and human cellular therapies.

IVD Australia further believes that Table 4 of Schedule 5 also assists in clarifying those assays that are importance in protecting the blood supply and thus delineates those assays that should be appropriately regulated as Class 4 assays under the soon to be introduced IVD Regulations.

There are a number of technical comments that IVD Australia would offer concerning this draft TGO however.

1) There is no definition of the term “virological” although the definition of “microbiological” specifically excludes viruses. Virological testing is however referred to in Schedule 4, Clause 8.

2) Schedule 4, Clause 9 refers to the archiving of donor serum / plasma until, at a minimum, the time of transfusion or implantation of the blood or tissue. IVD Australia believes that this minimum time should be at least 3 months post transfusion or implantation.

3) Schedule 4, Clause 12 should read “Documentation of the tests performed, test modifications, analyses and any anomalies **are** required to be appended to the donor record in addition to the test results.

4) IVD Australia is also concerned that the TGO refers to the use of commercial IVDs for post mortem samples without indicating that it the responsibility of the end-user to confirm that the IVD has been of manufacturers do include post-mortem samples in the validation many do not and hence the IVD may not have been validated for such samples. Thus the use of these IVDs may represent an “off-label” use by the Laboratory for such samples.

PO Box 298, Parramatta CBD BC, NSW 2124
Phone: 0403 345 678 Fax: 02 8004 8103 E-Mail: drpjharman@tpg.com.au

Once again IVD Australia is pleased for the opportunity to comment on this important draft TGO. Please feel free to contact the undersigned if you require further information.

Dr Peter Harman,
Chief Executive Officer

2nd February 2010

Comments given above were compiled based on feedback provided by members of IVD Australia and represent a collective submission for that purpose. IVD Australia is the peak representative body of manufacturers and sponsors of *in vitro* diagnostic products supplied to clinical pathology laboratories in Australia.