# NRL's response to invitation for comment on "Reforms in the Medical Devices Regulatory Framework: Discussion Paper"

This submission has been prepared by NRL's Director, Ms. Susan Best and NRL's Pre-market Evaluation Team Leader, Dr. Mark Lanigan.

NRL maintains quality in serological testing, particularly for retroviral and other blood borne diseases by virtue of its Pre-market Evaluation and Post-market Monitoring Programmes. NRL has more than 20 years experience in Pre-market Evaluation of *in vitro* diagnostic devices (IVD), either as purely desk-top review of Manufacturer's evidence and/or conducting its own laboratory-based performance testing. Having evaluated an IVD the NRL makes a recommendation to the TGA as to whether the IVD should be included on the Australian Register of Therapeutic Goods (ARTG). Many of the IVDs evaluated by the NRL have already been registered for use in other jurisdictions (e.g. USA, Europe) prior to application for inclusion on the ARTG. This experience has given NRL a valuable insight into the shortcomings of the registration processes of some other jurisdictions and the need for effective and meaningful scrutiny of IVD applications before devices are made available in this country.

NRL seeks to provide input on two of the four proposed changes described in the discussion paper "Reforms in the Medical Devices Regulatory Framework: Discussion Paper".

## Proposals 2A/2C

Based on its considerable experience in evaluating IVDs that have been previously CE-marked, NRL cannot reconcile that accepting conformity assessment from third parties (particularly those from Europe) is consistent with point (c) of Recommendation 8 from the HTA Review.

Australia's thorough and comprehensive pre-market evaluation of HIV and HCV IVDs has ensured that only high-quality devices are allowed to be sold in this country. As it stands currently, automatic acceptance of information of the poor standard often seen in support of CE-marked products would seriously erode the high quality of IVDs in the Australian marketplace, a level of quality that has taken some considerable time to establish.

Only if the quality of information provided by European Notified Bodies is improved dramatically, standardised and monitored could these proposals be of any benefit to Australia and the broader goal of global harmonisation.

With reference to Proposal 2C (ii), there needs to be uniform criteria and guidance for bodies that may become Australian third party assessment bodies, otherwise we will potentially end up with bodies of different standards providing different quality of assessment.

## Proposal 4

Under the previous regulatory framework NRL routinely published the findings of its IVD evaluations for those submissions where a recommendation was made for ARTG inclusion. It is the NRL's experience that the publication of its findings has been useful to the laboratory community in understanding the performance of different products available in the marketplace.

With respect to the performance of an IVD submitted for inclusion on the ARTG it would seem reasonable that TGA might include on its website the type and depth of information similar to that published by NRL. Indeed NRL would welcome the direct linking from the TGA website to findings published on the NRL website if that were deemed appropriate.

Under the terms of its new contract with TGA NRL may only publish the findings of IVD evaluations with TGA's permission; that permission is itself contingent on the IVD Manufacturer/Sponsor in turn granting approval for publication. It is not clear from the Proposal 4 whether TGA will seek approval from IVD Manufacturer/Sponsors before publishing performance information (of the type generated by NRL) nor whether TGA will set any criteria by which it would publish information independent of Manufacturer/Sponsor approval.

It is NRL's experience that Manufacturers/Sponsors may be reluctant to have material published even when the material is largely positive – e.g. where NRL's findings are that an IVD's overall performance is satisfactory but where there might be small ancillary issues that the Manufacturer/Sponsor would prefer to not have disclosed. Moreover, although the NRL has on several occasions recommended that certain IVDs not be included on the ARTG, these IVDs have continued to be sold in countries where they were originally registered (e.g. Europe) and the poor performance of the IVDs has remained hidden from the global community. While this would not appear to directly compromise the quality of IVDs made available in Australia, it does goes against the spirit of global harmonisation.

It is not clear from the Proposal 4 what provisions there will be for a situation where, for example, NRL recommends that an IVD not be included on the ARTG and the Manufacturer/Sponsor (having been informed of the poor performance and the likely consequences) withdraws the application. This is rejection in all but name and unless provisions are made for this kind of situation this a loop-hole could be created whereby publication of poor IVD performance was able to be suppressed.