Dear Dr Lopert

SUBMISSION ON BEHALF OF THE PUBLIC HEALTH LABORATORY NETWORK

PHLN would like to thank Therapeutic Goods Administration for giving consideration to the potential problems associated with the implementation of the TGA-In Vitro Diagnostic medical devices (IVDs) regulations, particularly in relation to the in-house assays.

Australia’s laboratories have expressed significant concerns about the principles that led to these new regulations (see attachment), the process by which they were developed and the potential negative consequences of their implementation. These concerns have particularly related to in house Class 4 IVDs for donor screening and for testing for dangerous and emerging pathogens.

PHLN is pleased to see that the proposals included in this document include options that address these concerns, though we have some reservations related to the costs and the process for evaluation and approval of tests.

1) Issue 1: Timeframe for valid applications for inclusion in the ARTG

This relates only to commercial IVDs and, as such, is not of direct concern to PHLN members. However, we would urge that sufficient time is allowed for commercial manufacturers’ to meet the regulatory requirements. Otherwise there is a significant risk that important diagnostic tests based on commercial assays will be unavailable for an undetermined period of time, which may lead to disruptions to service, increased costs and a decline in quality.

However, PHLN would like to emphasise that the implications of the IVD regulations are still not widely known or appreciated within the pathology community, so that delayed implementation is necessary to allow them to prepare for implementation.

2) Issue 2: Regulatory requirements for Class 4 IVDs

a) Tests based on existing commercial IVDs: cadaveric donor testing
PHLN strongly supports the concerns raised in the background discussion. We have expressed additional concerns that, though one commercial manufacturer is hoping to have their assays validated, that would leave the service dependent on a single manufacturer and their ongoing supply of the tests. Also, for laboratories not already using that manufacturer’s test platform, it would be difficult and expensive to implement. Therefore it is important to ensure that in-house IVDs can be used for this purpose.

Some laboratories have already validated cadaveric assays to current NPAAC/NATA requirements and are providing testing, so it would be sensible to retain that approach under the new regulations. Therefore PHLN supports proposal 2B, which would allow this to occur. Proposal 2A is not preferred because it excludes other Class 4 in-house IVDs

b) De novo Class 4 in-house IVDs

PHLN has previously indicated that the current IVD regulations for Class 4 in-house IVDs would lead to the withdrawal of a number of important tests for which there are no commercial alternatives, including HIV-proviral DNA testing, testing for bioterrorist agents, testing for exotic and emerging pathogens, and nucleic acid testing for organ and tissue donors. These tests would not be able to meet the currently proposed Class 4 conformity assessment process for reasons that have been outlined in previous PHLN correspondence. This would seriously undermine the quality and responsiveness of laboratory services.

Proposal 2B is strongly supported by PHLN and the conditions suggested are supported in principle. Some concern related to the cost and process for implementation is discussed below.

3) Concerns related to implementation of proposal 2B

a) The expected fees associated with the compliance process have not been stated. We note that it is anticipated to be less than a full Class 4 conformity assessment, but could still be substantial for laboratories with many in-house tests. Also we are not yet able to determine the staffing and other resources required for the initial assessment and for maintenance of the approval.

b) The timeliness of the TGA process for approval of Class 4 in-house tests. In house tests are generally developed to meet a current demand, and would usually be implemented shortly after completing the development and validation. Any significant delay beyond that would compromise services. This would particularly apply for tests developed for emerging pathogens where there is an urgent need to deliver tests, and these tests will need to be modified frequently and quickly. Any additional delay would be unacceptable and may need a “pre-approval” process to span the period of test development.

c) Who is going to evaluate the new Class 4 in-house assays, and who will “accredit” laboratories to perform them. Is it intended that a separate process will be in place in addition to the NATA/RCPA assessment and accreditation process? Will the TGA Expert Advisory Group be involved?
d) There has been confusion and mixed messages about the rules and how they will be applied. For example PHLN was involved in a national expert panel convened by TGA, after which PHLN understood that no bacteria would be classified as Class 4. However, it now appears that will not be the case. It is important that the process for assessing and regulating tests is fair, consistent, understandable, and based on the best expert advice available.

4) Proposal 3: Selective performance evaluation of Class 4 IVDs that are submitted for design evaluation

PHLN has no objections to this proposal.

5) Issues 4 & 5

These tests are outside the PHLN remit

The proposals endorsed above, if implemented, will significantly mitigate the potential negative impact of the new IVD regulations on the delivery of diagnostic and public health testing.

While PHLN would prefer a complete review of the IVD regulations and their necessity, if that is not going to occur then we would ask that proposals 1A AND 2b are implemented after addressing the points raised under item (3) above.

Yours sincerely

Prof. David Smith
Chair
Public Health Laboratory Network
3 June 2013

Attachment: Letter from PHLN to Dr Roland Hammett

20101109 PHLN to TGA re IVD Reg.pdf