IVD AUSTRALIA

Response to the Therapeutic Goods Administration Consultation Paper:

"Low Value Turnover Exemption Scheme "

May 2014

PO Box 298, Parramatta CBD BC, NSW 2124
Phone: 1300 483 287 Fax: 02 8004 8103 E-Mail: info@ivd.org.au

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Executive Summary

IVD Australia is pleased to be asked to comment on the Consultation Paper from the Therapeutic Goods Administration regarding the Review of the Low Value Turnover (LVT) Exemption Scheme.

As the peak body responsible for manufacturers and sponsors of *in vitro* diagnostic (IVD) products in Australia, IVD Australia represents companies supplying products valued at over $750,000,000 per annum and that are presently covered by over 1200 ARTG inclusions.

On balance, IVD Australia recommends that the TGA and Government adopt Option #5 and scrap the LVT Exemption Scheme altogether.

IVD Australia does not believe that IVD sponsors currently obtain, or will obtain, significant benefit from the LVT Exemption Scheme. The benefits of the Scheme in its present form go to a small group of large companies, and the Scheme adds significantly to the overall level of Annual Charges for all therapeutic goods.

While the benefit to accrue to Medical Device inclusions from abandoning the LVT Exemption Scheme is less than that for Medicine sponsors, there is still significant benefit. Clearly, if all sponsors remove all products that have previously qualified for LVT from the ARTG, then the expected reductions in Annual Charges will not eventuate. However IVD Australia does not believe that this will occur and if even 25% are retained then all sponsors will benefit.

IVD Australia believes that the LVT Exemption Scheme has moved significantly from its original purposes of supporting Australian manufacturers of small volume products, small startup companies, herb growers and small medical device manufacturers.

The full cost recovery nature of the TGA means that all sponsors pay higher than necessary annual charges to support the LVT Exemption Scheme where the benefits seem to predominately accrue to a select group of sponsors. IVD Australia believes that this is neither fair nor equitable.

IVD Australia does not believe on balance that there will be significant benefits for IVD sponsors in adopting any of the other Options presented in the Consultation Paper and hence is supportive of Option 5.

IVD Australia will continue working with the Government, the Department of Health and the Therapeutic Goods Administration to foster a regulatory framework for *in vitro* diagnostics that, while providing the level of safety and reassurance required by the Australian community, imposes as far as possible "*light touch"* regulation on manufacturers and sponsors of *in vitro* diagnostic (IVD) medical devices.

About IVD Australia

IVD Australia is the peak body representing sponsors and manufacturers of *in vitro* diagnostics based in Australia.

In vitro, literally "*in glass*", diagnostics (IVDs) comprise the instruments, reagents and consumables that are used to perform laboratory based pathology tests requested by General Practitioners, specialist Physicians or other healthcare professionals.

These pathology tests are generally performed in accredited Public and Private pathology laboratories across Australia, but IVDs also include over-the-counter tests such as blood glucose meters for diabetes testing, home pregnancy tests and point-of-care (PoC) IVDs used in general practice and healthcare clinics to measure parameters such as INR or HbA1c.

Supply of all IVD products in Australia is regulated for the Government by the Therapeutic Goods Administration (TGA).

IVD Australia was formed in July 2009 and currently represents Australian manufacturers, multi-national and local distributors of IVDs, as well as regulatory consultants working in the IVD sector. Our 55 members supply *in vitro* diagnostic products in Australia valued at over $750,000,000 per annum and they employ around 2000 people across Australia.

As the IVD regulations are still in transition, and may continue in this mode for at least another 12 months, most IVDs are exempt from annual charges, and hence the LVT Exemption Scheme only presently applies to existing Registered and Listed IVDs. However IVD Australia believes that it is important to make our views know to the TGA as Annual Charges will certainly apply from 2015/16 onwards and will represent a significant cost burden on the sector.

General Comments on the Proposal

IVD Australia thanks the Therapeutic Goods Administration (TGA) for the opportunity to comment on the Consultation Paper "***Review of the Low Value Turnover (LVT) Exemption Scheme"***.

In reviewing the Consultation Paper, IVD Australia acknowledges that most IVD inclusions on the Australian Register of Therapeutic Goods (ARTG) are currently exempt from the payment of annual charges. In fact, under the Transition arrangements, the only products on which annual charges are levied are those remaining registrations and listings that were obtained prior to July 1st 2010 as "other therapeutic goods". At present this seems to cover about 100 - 120 remaining ARTG inclusions. In the Table (Table 2) setting out the Annual Charges and LVT exemptions for the 2012-13 Year, there were only 682 products classified as "Other Therapeutic Goods" that were subject to annual charges. As this includes products such as disinfectants, condoms and tampons, IVDs probably only made up 20% of these inclusions.

However once the Transition period ends on 30th June 2014 then all IVD inclusions will attract annual charges. There are several unknowns around how large this number will be however.

Firstly, it is currently proposed that the Transition be extended to 30th June 2015 for included commercial IVDs. At present there are over 1400 inclusions under the new Framework. However the current application rate would indicate this is likely to grow to over 2000 by the new proposed end of the Transition (30th June 2015).

Secondly, the level of Annual Charge for an IVD inclusion has not yet been set. Discussions in the past have indicated that the TGA propose to set the fee for an IVD inclusion at the same level as that of a Class II medical device; viz. currently $920. At this level, without allowing for LVT reductions, the IVD sector would be paying close to $2,000,000 in annual charges. This is a significant cost on the sector which is already under significant cost pressure.

Indeed the TGA itself is already aware that there will be a significant number of commercial IVDS that will not be transitioned to the new Regulations. Manufacturers and sponsors have already taken the decision to not include products because of the cost of pre-market approval, and the substantial ongoing cost of inclusion. This particularly applies to Class 4 immunohaematology products as these incur significant inclusion costs and annual charges. For example, to get an inclusion for Duffy, Kell and Kidd antisera will cost a minimum of $15,000 and subsequently an annual charge of close to $1,000. Total sales for all these products for most sponsors will not exceed $6,000 - 10,000 per annum and hence the cost of including and maintaining the products on the ARTG will greatly exceed any profit to be made from the sale of the products for a significant period (5-10 years). Hence commercial considerations may restrict the eventual total number of IVD inclusions.

Another issue for IVD products is that most of them are grouped on the ARTG under a GMDN collective term and hence in Class 2 or even 3 there may be 10 - 20 or even more products in a single inclusion. The combined sales of all of these products are therefore likely to exceed the Annual Turnover Limit of fifteen times the Annual Charge (expected to be close to $15,000) and thus the inclusion will not qualify for LVT Exemption. For this reason IVD Australia does not believe that the LVT Exemption Scheme in its present form will be of much benefit to IVD sponsors.

An additional barrier to take-up of the LVT Exemption Scheme lies in its complexity for small business. It is expensive and time consuming for small business to get the necessary declarations from their accountant and then to complete the application forms. With only two months following the end of a Financial Year to get the necessary paperwork together and then make the application, small business may not feel it is worth the trouble to apply, especially if an application for a particular inclusion covers multiple products.

If the LVT Exemption Scheme is to be retained, IVD Australia would also recommend scrapping of the Cap on Applications Fees. This cap, set at 100 applications, is only of benefit to the largest companies, and hence, by limiting the overall TGA revenue from LVT Application fees, serves only to increase the Annual Charges for all sponsors.

IVD Australia is clearly concerned that the current scheme derives from the situation in 1990 following formation of the TGA, and presently does not seem to have clear objectives. However the Scheme does clearly benefit some sponsors at the expense of others. As the paper indicates, small businesses that have small numbers of entries do not appear to benefit from the scheme. However it should be noted there are also large business who do not benefit, particularly in the medical device sector, as the grouping of products within ARTG entries means that often the turnover of the combined group exceeds the LVT threshold. We would certainly favour any scheme that removes the cross subsidization of Annual Charges by small companies. Similarly, medical devices as a group do not seem to benefit greatly from the operation of the scheme, probably again due to the grouping of products.

IVD Australia however is not in favour of any option that does not make the scheme simpler, fairer and more transparent.

Specific Proposals to be addressed

Option 1 - retain the LVT scheme in its present form

IVD Australia is not in favour of retaining the LVT Exemption Scheme in its present form.

Given that few if any IVD companies are benefitting from the Scheme, and that it is increasing Annual charges overall, we believe that it either needs significant reform or scrapping altogether.

The current scheme seems to be of most benefit to large medicines sponsors and as such is neither fair nor transparent.

The scheme appears to be of most benefit to companies who don't actually supply particular products in Australia but keep them on the Register "just in case". The current scheme is of little benefit to IVD sponsors who are making very few LVT applications at present due to the low level of registered or listed products that attract annual charges. However IVD sponsors will not generally be able to benefit in future, as the grouping of products mean that there will be few inclusions that fall under the LVT Threshold.

Option 2 - retain the LVT scheme with some amendments.

As indicated previously, IVD Australia believes that the LVT Exemption Scheme either requires changes to make it more transparent, fairer and better targeted to those who need it most or it requires scrapping altogether.

The Consultation Paper suggests under Option 2 that there is a need for clarification of the definition of "turnover" as if this will make a difference to the operation of the Scheme. IVD Australia believes that the definition is clear viz. the sales of the included product or products covered by the ARTG inclusion in the previous financial year. We are not sure how this definition could be amended to make the current scheme either more transparent or fairer.

It is also suggested in this Option that there be the possibility for an extension of the deadline for Lodgement of Applications in order to allow companies to make late submissions. IVD Australia is of the opinion that the current deadline probably disadvantages small companies. Hence if the Scheme is to be retained and the Deadline is to be changed, IVD Australia recommends that the Deadline itself be extended at least for an additional month to 30th September. However, if it is extended even then some sponsor companies will just delay their applications further and pay the late application fee, adding to the administrative burden of the Scheme and increasing the cost to all sponsors.

IVD Australia is also opposed to the option of "self declaration" by small companies. This would leave the Scheme open to companies to declare a lower turnover with little chance of discovery and hence add to the cost of the Scheme for all sponsors. IVD Australia believes that there has to be a positive action by sponsors seeking to take advantage of LVT Exemption by requiring

them to obtain a declaration of turnover from an Accountant or Auditor who has a professional reputation to uphold.

However IVD Australia is supportive of the proposal, if the LVT Exemption Scheme is retained, of removing the Cap of $15,000 for LVT Application Fees. As there is no administrative saving to TGA of large numbers of LVT Exemption applications from any one sponsor company, and as each application has to be assessed independently, capping the Application Fee only disadvantages other sponsors.

Option 3 - replace the LVT Scheme with one that only grants exemptions for Register entries that are not supplied to the Australia market.

IVD Australia believes that there are several issues with a scheme that grants exemption for Register entries that are not supplied to the Australia market.

Firstly, such a scheme is not expected to be of significant benefit to IVD and medical device sponsors due to the grouping of these products. With IVDs, products are grouped under a GMDN collective term and it is unlikely that all products in an inclusion would have zero turnover and hence qualify the inclusion for Zero Value Turnover (ZVT) exemption. The only products that would automatically qualify for ZVT Exemption would be Class 1 IVDs for Export Only.

Of course there could be sponsors who choose to include IVD products on the ARTG when they are not intending to supply them or continue to supply them in Australia. Sponsors may choose to include products for the benefit of simply having an ARTG inclusion that may assist their marketing in other jurisdictions.

However the argument that the reduction (removal) of Annual Charges for ZVT products is justified because of the lack of post market surveillance undertaken by TGA in respect of ZVT products is not supported by IVD Australia. The expectation of overseas regulators, and end users, is that if a product has an ARTG inclusion then it is has been or is supplied in Australia and its post market performance is monitored by TGA. The nuance that a product is on the ARTG but is actually not supplied in Australia is one that would probably escape other regulators and end users, and they would expect that any problems with the product would be able to be identified by TGA.

Similarly, if a product is manufactured in Australia, but not supplied here (i.e. a Class 1 “export only” IVD), then there is an expectation that, as the regulator in the Country of Origin (COO), TGA will be assessing the product for post market performance. As this product(s) will have zero turnover in Australia and qualify for LVT Exemption under the current definition of turnover and although it may have substantial sales overseas, there will be no post market surveillance in the COO.

IVD Australia notes that there may be some benefit to the community where sponsors of low usage products that target rare assays such as pandemic viruses can have the product included on the ARTG “just in case”. However IVD Australia believes that there will a limited number of these products and, given that they are likely to be Class 3 or 4, the costs of the Application for

Inclusion and Application Audit would be the overarching concern for sponsors rather than the Annual Charge.

On balance, IVD Australia does not support this option. However if it is to be adopted then we would support an Application Fee, supply of appropriate evidence, and the introduction of a ZVT Annual Charge rather than a complete removal of the Annual Charge altogether.

Option 4 - replace the LVT scheme with one that only grants exemptions for Register entries where the sponsor is a small business

IVD Australia does not believe that this option would provide significant benefits to IVD sponsors if adopted.

As discussed previously, IVD inclusions often cover a number of products and it is unlikely that many inclusions, whether from SME sponsors or otherwise, will fall under the threshold for LVT Exemption when the turnover of all products is included.

In addition IVD Australia believes that in general it will only apply to SME's that operate in a single market sector such as IVDs or dental supply or the like. If companies are operating in several market sectors such as dental and medical devices, then turnover is likely to be above that of the Australian Taxation Office's definition of a small business, and hence none of its products would qualify for LVT Exemption under this proposal.

IVD Australia is concerned that, as discussed in Option 3, the removal of the requirement for certification of turnover could lead to false declarations with little likelihood of detection, thus increasing the overall cost for all sponsors.

There are also concerns with the proposal that low volume unique products supplied by medium and large businesses could be captured under the Special Access Scheme (SAS) instead of falling under the LVT Exemption umbrella. This scheme requires the support of a Medical Practitioner and is intended for a "once-off" application or for a restricted number of patients. The Application Fees associated with the SAS program are similar to Annual Charges and there is considerable administrative overhead involved in SAS applications, hence there is little benefit to IVD sponsors in this proposal.

Option 5 - cease the LVT scheme completely

On balance IVD Australia would support this Option.

If Option #5 were to be implemented, then all IVDs sponsors could expect to get lower Annual charges for their inclusions. Whilst it is not clear at present exactly how much of a reduction this would involve for IVD medical devices due to the effect of the current Transition, Table 5 would suggest that, even if 75% of all products currently qualifying for LVT Exemption as “Medical Devices - other than Class 1”, were removed from the ARTG the Annual Charges for this group would fall by 7%. Therefore it could be expected that the Annual Charges for IVD inclusions under the 2010 Regulations would be lower overall. Even a 10% reduction could be expected to save the IVD sector $200,000 to $250,000. Whilst there would be no specific relief for small businesses under this proposal, they would benefit from the overall cost reduction in any case.

IVD Australia also believes that the benefits of the current LVT Exemption Scheme would not be significant for Australia IVD manufacturers, unless their products are “Export only”. While it has been estimated that over 90% of all IVDs manufactured in Australia are exported, Australian manufacturers typically supply a restricted range of products in Australia that could be captured under one or two ARTG inclusions. Thus they tend to focus on the overseas costs of regulation and the need at present to obtain a TGA Conformity Assessment Certificate, rather than the ongoing Annual Charge.

List of Abbreviations and Acronyms

ARTG	Australian Register of Therapeutic Goods
DoH	Commonwealth Department of Health
COO	Country of Origin
IVD	*In vitro* diagnostic
LVT	Low Value Turnover
PoC	Point-of-Care
TGA	Therapeutic Goods Administration
ZVT	Zero Value Turnover