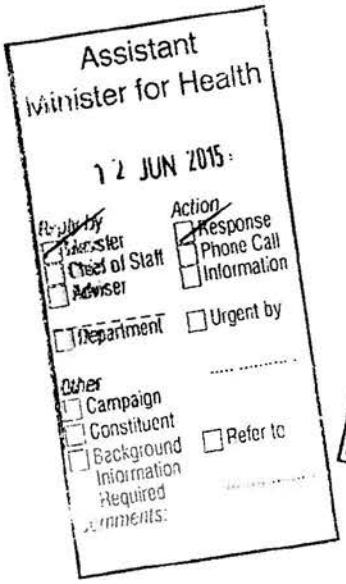
Australian Dental Industry Association | ADIA



Ref: 11.11.14K — 9 June 2015

Sen. Hon. Fiona Nash
Assistant Minister for Health
PO Box 6100 – The Senate
Parliament House
CANBERRA ACT 2600

Dear Minister

RE: TGA Fees & Charges – Senate Estimates Hearing (2 June 2015)

As the peak business organisation representing manufacturers and suppliers of dental products, the Australian Dental Industry Association (ADIA) takes this opportunity to provide clarity on evidence presented to the estimates hearing of the Senate Community Affairs Legislation Committee held on 2 June 2015 (copy attached). The issue concerns the Low Value Turnover charges exemption scheme administered by the Therapeutic Goods Administration (TGA).

ADIA is concerned that the evidence presented to the committee by the TGA may give the impression that the reform, intended to reduce compliance costs, may result in a reduction in fees for small businesses in the dental industry when this is not the case.

The TGA maintains the Australian Register of Therapeutic Goods (ARTG), which is a list of medicines and medical devices that can be lawfully supplied in Australia, and the TGA levies a charge to businesses to place a product on the ARTG. A business can apply for an exemption to this charge if the value of products sold is fifteen times or less the charge that would have been payable to the TGA; however, the threshold where a business is eligible to claim an exception for the charge will drop to $0 from 1 July 2015. Recognising that the proposed reform will increase the charges paid by businesses to place products on the ARTG, the TGA is proposing an arbitrary fee reduction of around 5% for some charges; however this does not take into account the significantly increased ARTG charges that many small businesses in the dental industry will pay.

During the Senate hearing, Sen. Jan McLucas asked whether these reforms would result in "a reduction of fees". In response the TGA National Manager, Adj. Prof. John Skerritt, answered that the reforms are a "reduction to our [the TGA's] base charge". This response may give the impression that the reforms will result in an overall reduction in TGA charges, a conclusion which cannot be readily substantiated. The reduction in TGA base charges for listing some classes on medical devices on the ARTG is likely to increase overall TGA revenue as the changes will see an increase in the number of ARTG entries that will now attract charges.

Australian Dental Industry Association Limited
ABN 32 003 314 396
National Office: GPO Box 960, Sydney, NSW, 2001
Government Affairs: GPO Box 1, Canberra, ACT, 2601
e: national.office@adia.org.au www.adia.org.au
t: 1300 943 094 f: 1300 943 794

The challenge is that the TGA's own assessment, conducted at the request of ADIA, is an increase of around 30% in the charges paid to the TGA by the small businesses that sell dental products. That this assessment was not referenced in the Regulatory Impact Statement (RIS) is of concern insofar as regulatory reform is being progressed based on an incomplete analysis.

Given that the RIS did not the adverse cost impacts on small business in the dental industry as identified by the TGA, ADIA believes that a more comprehensive review of the proposal is merited. If, as there is reason to believe, the proposal will adversely affect small business the changes should not be proceeded with in the current form.

It is noted that ADIA has yet to receive a response to our letter dated 8 May 2015 which requested a comprehensive review of the changes, we look forward to your advice concerning this matter at your earliest convenience.

Yours faithfully

Troy R Williams FAIM MAICD
Chief Executive Officer

Encl.

COMMONWEALTH OF AUSTRALIA

Proof Committee Hansard

SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Estimates

(Public)

TUESDAY, 2 JUNE 2015

CANBERRA

BY AUTHORITY OF THE SENATE

[PROOF COPY]

SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Tuesday, 2 June 2015

Members in attendance: Senators Bernardi, Carol Brown, Di Natale, Leyonhjelm, Marshall, McLucas, Moore, Peris, Polley, Reynolds, Ruston, Seselja, Siewert, Smith, Waters, Xenophon.

Senator McLUCAS: Of those two types of international visits, which—although you cannot really answer that question because the second lot are variable.

Prof. Skerritt: They are both variable because, of course, we do GNP inspections on demand from a company that wants to get a product onto the Australian market or when their current inspection period might reach that three or four years and there needs to be a reinspection.

Senator McLUCAS: This is a different issue, but once again still with the TGA. Could you remind the committee about the low value turnover exemption scheme?

Prof. Skerritt: Certainly. The low value turnover scheme is being replaced with the annual charge exemption scheme or the ACE scheme. The reason for the replacement of the scheme is the old scheme was tremendously unpopular. I guess you could call it a masterpiece in the creation of red tape. It required companies large and small, and it was a particular burden on small and medium sized enterprises, to have to do a detailed return of their turnover for each and every product that they had that was under a limit of 15 times the annual charge. I should add that following advice from the National Audit Office they could not even submit this return themselves, even if they were a medium sized company that employed a couple of accountants. They had to pay an external accountant to go and submit and certify that return. They also had to make an application for exemption at $155 per product. You can imagine that starts to add up with large numbers of products.

It was a very cumbersome scheme and highly unpopular across the overwhelming majority of industry and especially small and medium sized industries. We have replaced that, starting in July, with another scheme which is essentially an exemption. It is a zero turnover scheme. Under that scheme no application fee is required for products. Products will be automatically exempted until the turnover continues. You will not need an accountant and it will be done through online self-service.

For products that are low in turnover but are still important on a public health basis, if it can be shown that they would otherwise not be financially viable, you can apply for an exemption and one of our clinicians will look at that and say, 'Yes, this is important from a public health basis.'

Senator McLUCAS: The Australian dental industry is one group that is affected by the change. What other organisations?

Prof. Skerritt: All of our sponsors are affected. The vast majority of medical devices are represented by other groups such as MTAA and AusBiotech and, of course, medicines; whether or not they are represented by Medicines Australia, with the over-the-counter medicines, complementary medicines or the generic medicines industry. This affects all of our products.

Senator McLUCAS: In your view, what is the response from industry to the abolition of the—

Prof. Skerritt: There has been overwhelming and strong support for it. **The Australian Dental Industry Association wrote to us about five particular companies and asked us to run the figures. When we ran the figures those five particular companies that they expressed concerns about indicated that they would be between $1,000 and $14,900 worse off** if none of their products received the public health exemption—that is an 'if'. We do not know because what we are expecting is that a number of products will either receive a public health exemption or they may say, 'We're selling two of these and there's lots of other companies in the market.' They may make a decision to take a product after market. The other thing that has been done for medical devices is a five per cent decrease in the base charges for class 2 devices and above.

What we have undertaken to do, because this scheme is actually costing TGA $2.4 million this financial year, is we have decreased our charges almost across-the-board. For example, for a generic chemical medicine, of which there are many other copies on the market and meets other criteria, there is a 23 per cent reduction in charges. I mentioned a five per cent reduction in base charges.

We will monitor the overall impact of this scheme. We will monitor how it goes after the first year. We need to do that every year in the context of going to government for approval of our annual fees and charges. That ledger will be open to all industry associations and I imagine, if there are particular industry sectors that, for unexpected reasons, have been very seriously affected by this, that is a discussion that we will have with the minister in the context of discussing what fees we would set for next year.

CHAIR: I will have to go to some other senators. If there are further questions I will come to you, Senator McLucas.

Senator McLUCAS: Can I have one question to finish?

CHAIR: Yes, a very quick one to finish and then I will go to Senator Xenophon and Senator Ruston.

Senator McLUCAS: So, full cost recovery for these groups will not be applied because you are saying that there is a cost of $2.4 million?

Prof. Skerritt: No. It is full cost recovery. We believe that we, in that sense, are able to become effective and more efficient. Not only does the current scheme that we are about to replace create a lot of red tape and paper shuffling for companies at the moment but it also creates a lot of checking, paper shuffling and red tape for us. We believe that there can be efficiencies gained for us and also for the regulated industry without any change to the risk profile. That is why we have modelled the $2.4 million reduction in charges.

Senator McLUCAS: So, it is a reduction in fees. I misunderstood.

Prof. Skerritt: It is a reduction to our base charge.

Senator McLUCAS: I understand that. Thank you.

Senator XENOPHON: In response to the question I placed on notice in October last year, SQ14-001248, the TGA stated that the Australian Orthopaedics Association National Joint Replacement Registry reports a low rate of revision for the Birmingham Hip Resurfacing device, the BHR, so it remains available as a surgical option in Australia. I know, however, that the AOANJRR annual report in 2012 identified the BHR as having a higher than expected revision rate—that is at pages 171, 172 and 173—and that it has been re-identified as such in both the 2013 and 2014 reports. It was noted in the 2012 annual report at page 95 that the BHR had a cumulative per cent revision at 11 years of 7.1 per cent while the metal on metal total conventional hip arthroscopy report published by the journal in 2014 identifies a revision rate of 12.1 per cent after 10 years. How does the TGA explain these seemingly contradictory statements?

Prof. Skerritt: I will call Dr Kelly to describe the detail. The information that I have on the data from the AOANJRR on the Birmingham hip replacement is that overall it does not have a revision rate higher than expected. I would also flag that it has not been withdrawn for use in any jurisdiction. As you aware from your earlier question, there has been advice against it through an update of the instructions for use—

Senator XENOPHON: I am happy for you to take this further on notice. I have set out some figures. I have set out the reports. On the face of it, there does seem to be a contradiction between what the TGA has advised and what the journal is reporting.

Dr Kelly: We will take those on notice with your figures. The figures we quote are also from the same source, the joint registry data. I am just wondering whether there is some confusion. There are a number of variants for the Birmingham hip device and I am just wondering whether we are talking about the same particular device.

Senator XENOPHON: And if you could explain that on any answer on notice. I will just continue. The TGA would be familiar with the metal on metal total conventional hip arthroscopy report by the AOANJRR from 2014 which outlines a decline in use and higher revision rates for metal on metal devices. Why is the TGA not placing further restrictions on the use of these devices or withdrawing them completely from the market?

Dr Kelly: I think we have explained this previously. The best advice we have is from the orthopaedic surgeons who analyse the same set of data that you are referring to. We present the information to them. We present the global information for the same types of devices collected across different registries around the world. Their advice remains that a blanket ban on metal on metal hips is not appropriate. They are very suitable for some patients.

Senator XENOPHON: Overall is there a higher rate of revision and complication?

Dr Kelly: Again, it depends on which type of device. There are resurfacing devices and there are total hip replacement devices.

Senator XENOPHON: If you could provide some further details. Finally, has the TGA learned from the lessons of the ASR and are you more cautious about these devices? There are literally thousands of devices approved for use in Australia. Should the TGA be more prescriptive about those approved for use? We have private health funds talking about the money that they fork out which causes increases in premiums because of the rates of revision. It has been a common complaint from private health insurers as well.

Dr Kelly: Hip replacement remains one of the most cost-effective operations in the health system. It is getting the balance right between the safety and the patient benefits. We, following the ASR and through some other factors, reclassified all hip joints so that they now have to go through a higher level of—

Senator XENOPHON: I would be very grateful if you could take on notice the complaints made by private health insurers to say that they think there would be considerable savings if there was some more rigor in terms of the types of devices that are approved and having lower rates of revision. Thank you.