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Dear Sir/Madam

EBR Consultants welcomes the opportunity to comment on the proposed changes and its comments represent a combination of our views as well as those of our clients.

####**Comments on the Proposed Reforms to the Medical Device Regulator Framework**

COMMENTS ON RECOMMENDATIONS

1. Recommendation 8
    a. Although the TGA should be the sole agency responsible for assessing safety, quality and efficacy it must take into account the work already done by recognised European Notified Bodies. The GHTF process is supposed to deliver to the medical device industry portability of approvals over the whole range of device classifications. In this way the TGA is still the main organisation but does so with a light tough for those products which have already been reviewed.
    b. It is essential for the Australian industry to be able to choose a Notified Body which can provide the services it requires but we note that this proposal is also running very late and should have been finalised by now.

   c. It seems ironic that the HTA review specified that the TGA should "reduce unnecessary regulatory burdens" and the TGA then use the report to justify increasing the regulatory burden.
   d. The TGA is already examining higher risk medical devices with more rigour so what aren't they currently doing that needs to be changed.
2. International situation
   a. The reference to the 2008 European commission's proposals suggests that the process is in crisis, it is not.
   b. Why are we making reference to the 510k process when it has never been part of the modern device regulations? This is purely a USA issue.
   c. The concerns regarding the performance of Notified Bodies were taken from a 2004 report which looked at Notified Bodies performance in 2003. We need objective evidence from the EU in regards to their current performance as the 2004 report is out of date and out of tough.
   d. The lack of oversight is not the responsibility of either the industry or the Notified Bodies; it is the poor performance of the Competent Authorities. Perhaps the TGA should only recognise those Notified Bodies who are being overseen by "competent" Competent Authorities. The industry must not be burdened with additional regulation because of the failures of the various Competent Authorities.

<u>COMMENTS ON THE PROPOSALS</u>

Proposal 1.

1. The reclassification of some devices from IIb to III should be done product by product and not, for example, if it is a natural articulating surface.
2. Identify the root cause of the reason for the rate of revisions being higher than for total joints. Is it because some patients should never have been given a total hip in the first place or is it a matter of surgical skill. It is not unreasonable to change the classification because of post market information but it should be the correct reason.
3. The TGA should give a guarantee that these proposed changes will not impact the turnaround time for reviews.
4. The TGA needs to articulate precisely how will this impact the "level playing field".
5. The recognition of 3rd party assessment bodies is taking to long, at the rate it is we will not see this happen until 2015.

Proposal 2.

1. Again the TGA needs to give the industry assurance that the mandatory application audits will not slow up the application process.
2. The confidence building period should be short as we have been doing this for some years.
3. The TGA should give us some more details about this as I am not sure how being on the MRA list will be different in regards to safety and quality than not being on the list. Do we know if any costs are associated with being on the MRA list?
4. It is not clear if TGA has a role in designating CAB's via the MRA.
5. Under what circumstances will the TGA refuse Supply if the MRA is used?, could the TGA please clarify this.

Proposal 3.

1. Why do we need the ARTG to be enhanced and as a result, the definition of a "kind of medical device" needs to be changed. How does having this additional information add to the safety or quality of a device?
2. This proposal looks very much like revenue raising dressed up as safety and quality. Is this the first step in getting an ARTG for all devices?
3. If a sponsor has deliberately misused this process to put a device on the market then there are plenty of ways of dealing with this without passing on extra regulations and costs to the industry.
4. If this change is accepted then under no circumstances should any fees be charged for a variation, that would definitely be revenue raising.
5. Considering the amount of information required a 12 month transition is far too short.
6. Proposal 3(ii)
    a. This is going to be enormously expensive for the sponsor with very little or no gain in safety or quality.
    b. We asked a local distributor of a US made product what it was likely to cost to place the ARTG number of each box.
    c. The costs would be;
        1. Based on a medium size company ($50 million to $80 million) which only distributes for one manufacturer.
        2. Moving 60,000 cartons per month
        3. A cost of 5 to 8 cents if it can be automated or 25 to 30 cents if it is done manually,
        4. The cost would be between $36,000 and $57,600 if it can be automated or $180,000 and $216,000 if it was done manually.
        5. These costing do not take into account the purchase of any equipment to automate the process nor consumables.
        6. These costs do not take into account any additional labour costs to un wrap and re package packages.
        7. It also does not take into account the cost associated with the controls that would need to be in place to ensure that the correct label was placed onto the carton.
    d. The majority of sponsors in Australia distribute for more than one manufacturer so the issue of placing the ARTG on the carton becomes more complicated and automation near impossible.
    e. A very large number of sponsors distribute high volume devices so again the problem is compounded.
    f. Using the argument that you need only do this to satisfy regulation 10.2 will not work. There would be no excuse that would be acceptable to the TGA for not doing it.This would always leave the sponsor in a position of not knowing if they complied or not.
    g. What does the TGA suggest we do about reusable product as they will loose there identity after the first use.
    h. To comply with this requirement does it mean that all reusable instruments, for example, would need to be packaged individually so that they could be labelled?
    i. Reusable devices and instruments should be excluded from the requirements as no purpose would be served in having the ARTG on the device only at the time of delivery. Also, the costs simply would not be

justified by the outcome.

7. A transition period of 12 months is totally insufficient.
8. The TGA needs to clearly articulate the reason why they believe that this is such an important issue, other than it sounds like a good idea.
9. At all times it must be remembered that devices are not medicines so the argument that medicines have the AUSTR or AUSTL is not the same.
10. A regulator impact statement needs to be done on this issue alone so that it is not diluted by other considerations.
11. The regulatory impact statement needs to be done by an experienced person, or group, who understand the costs associated with manufacturing and logistics. It should not be done by someone in the TGA who only understands the process involved in preparing the document to satisfy the Finance Department rules.
12. Both the industry and individual sponsors need the right to submit costing data direct to the Department of Finance rather than via the TGA.
13. It is unlikely that large overseas manufacturers will be able to do this on-line successfully as it would make the products exclusively for Australia and prevent them from using a common worldwide English label product or a worldwide multi lingual product.
14. Many of the large and medium size sponsors sell their products via a range of distributors. This means that if you use the provisions of regulation 10.2 and for example ,place the information on the invoice or shipping documentation, the ARTG number will be lost at the distributor when they break down the shipment.
15. ARTG number are already available within the public and private hospital systems because when you submit a costing for a device(s) you are required to give the facility the ARTG number of the device. In the public health system you are required to send a copy of the ARTG certificate.
16. The TGA has not developed a rationale as to why this is needed and what, if any, safety or quality benefits would flow from placing the ARTG number on the device.

17 Many sponsors arrange to have overseas shipments delivered direct to their customers, there-by bypassing the sponsors warehouse. This would mean that the ARTG number would need to be over labelled at either the manufacturing site or a distribution centre. This would then place the control of this process outside of the control of the sponsor. It should also be noted that these shipments could vary from one homogenous product, with one ARTG number, to a mixed shipment with multiple ARTG numbers.

Proposal 4.

If the TGA wishes to make this information available to move towards greater transparency it can do so but it should not be done at the cost of the device industry. This is a Government/TGA initiative which they should pay for.

Proposals.

In addition to the comments above the TGA must;

1. Develop a coherent justification for changing the regulations to have the definition of

a “Kind of medical device “ changed to include individual device covered by a specific ARTG. This should be based around why safety and efficacy is impacted by not having this information.

2. Develop a coherent justification as to why there is a need to have the ARTG number as part of the labelling requirements. This should be based around why safety and efficacy is impacted by not having this information.
3. If the decision is made to require the ARTG number to be part of the labelling requirements, than reusable devices and equipment should be exempted.
4. Commit to ensuring that in both the short term and long term that evaluation times do not increase when implants are reclassified to class III devices.

Yours faithfully

Barry Evers-Buckland

Director
EBR Consultants