Comment on the TGA Discussion paper
"Reforms in the medical devices regulatory framework".

Submitted by:
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Proposal 1

Smith & Nephew Pty. Ltd. supports the Proposal, provided that all aspects of the reclassification are fully harmonised with the EU regulatory system for medical devices, i.e. there are no circumstances where a device would be classified differently in Australia vs. EU.

The additional cost to industry in TGA fees associated with additional assessment is likely to be very high and will be a major issue for many sponsors. This requires further consultation with industry to develop an abbreviated, low-cost assessment regime for the up-classified products.

Proposal 2

Refer specific comments below.

Proposal 2A

Smith & Nephew Pty. Ltd. broadly supports Proposal 2A, but seeks further detail on the proposal for recognition of third party assessment bodies.

Proposal 2B

Refer specific comments for Proposals 2B (i) and 2B (ii).

Proposal 2B (i)

Smith & Nephew Pty. Ltd. does not support this proposal if the intention is to subject additional categories of CE marked Class III medical devices to the same level of assessment as those currently requiring TGA conformity assessment certification.

TGA should explore ways to streamline the assessment and approval of devices requiring TGA conformity assessment certification, in particular those devices which have already been CE marked. The current approval processes and timelines, even for abridged assessments, are far too onerous in that they replicate assessment already carried out by the EU Notified Body and result in significant delays in bringing CE marked device products to the Australian market.

For CE marked medical devices, Smith & Nephew strongly supports a TGA conformity assessment regime which fully recognises and augments the EU assessment without introducing additional time-consuming repetition. This could be assisted by re-focussing the TGA assessment role to verification of the EU assessment e.g. by way of Application Audit and review of the EU Design Examination Report.

Smith & Nephew Pty. Ltd. also recommends that the current review of the MRA with EU should extend the scope of the MRA to allow assessment of devices currently requiring a TGA conformity assessment certificate (e.g. devices containing medicinal and animal content), to be conducted simultaneously for both EU and Australia by a European Notified Body (refer Proposal 2C (i)).

Proposal 2B (ii)

Smith & Nephew Pty. Ltd. does not support the addition of further product categories to the list of products requiring mandatory Application Audit. In the spirit of harmonisation, TGA should accept evidence of CE marking as suitable evidence for entry to the Australian market.

Proposal 2C

Refer specific comments for Proposals 2C (i) and 2C (ii).

Proposal 2C (i)

The discussion paper does not adequately justify a case for further confidence building. TGA should elaborate on why it believes that confidence building is required.

In relation to the current review of the MRA, Smith & Nephew Pty. Ltd. strongly recommends extension of the MRA to allow assessment of those devices which require a TGA conformity assessment, e.g. medical devices containing medicinal and animal content. This would allow such devices to the assessed simultaneously for both EU and Australia by a European Notified Body, thereby achieving speedier entry to the Australian market.

Proposal 2C (ii)

Smith & Nephew Pty. Ltd. supports the proposal for recognition of Australian third party assessment bodies. The Proposal as framed invites further consultation in order to discuss options for such a system. Smith & Nephew Pty. Ltd. supports the need for broad stakeholder consultation on this Proposal.

Proposal 3

Refer specific comments for Proposals 3 (i) and 3 (ii).

Proposal 3 (i)

Smith & Nephew Pty. Ltd. supports the proposal to add details of product variants to the ARTG, provided only that this is implemented as a simple fee-free notification process. This fee-free notification system should continue for new products introduced following the transition period. It should be recognised that the information proposed to be added to ARTG is supplementary information which does not alter the fundamental structure of the ARTG entry i.e. it does not change the "kind of medical device" (i.e. sponsor, manufacturer, class and GMDN code). As such, there should be no requirement for this information to processed as a variation, which, under the current system, would require payment of fees and pre-market assessment and approval.

The discussion paper does not adequately specify the level at which individual products are to be entered onto the ARTG. This is a fundamental question which must be discussed further, and which needs to consider a variety of medical device products currently marketed in Australia. To ensure that the administrative burden on sponsors is kept to a minimum, the specificity of product detail to be entered on the ARTG should not exceed that which is reasonably required by a user to identify a product.

Proposal 3 (ii)

Smith & Nephew Pty. Ltd. rejects the proposal to amend Regulation 10.2 to require ARTG number on the labelling of medical devices. Smith & Nephew rejects the proposal for many reasons including:

- The cost of complying with this proposal would be unacceptably high.
- Why generate the enormous workload & cost across all impacted products for extremely minimal gain, vs implementing an electronic database solution, with adequate search facility (see SUGGESTION below)?
- Smith & Nephew as a multinational operates directly in approx 40 countries and sells products in > 80 countries. To our knowledge, this requirement is not identified anywhere in the world. What gain can be achieved, uniquely for a country as small as Australia vs the simple solution described above?
- Given Australia is generally just 1-2% of global volume in most multinational production demand, many multinationals will reject this requirement outright? This in turn will lead to either, product withdrawal, range reduction, increased pricing to consumers and the healthcare system, or all.

- This proposal if it proceeds should lead to Australia being singled out in the global 'harmonisation' movement as an 'outlier' clearly not committed to moving true harmonisation forward.

- This proposal needs the agreement of the peak bodies representing all impacted products / companies – vs. simply determining that it should be forced upon them (despite the many massive implications it will create).

- Other countries may not allow the sale of products labelled with another regulators codes (e.g. ARTG). This would impact 1000's of SKU's and lead to the requirement for a large volume of specialised Australia-only product. Sponsors will then face issues associated with minimum order quantity impacts, unique product codes, and complex production scheduling, resulting in massive cost impact and potential large scale product rationalisation – to the detriment of patient care. Such changes would make many areas of medical and dental care unviable for business to support.

- Per above points, this cost would be passed on by industry to the Australian health care community in the form of increased product pricing.

- Smith & Nephew Pty. Ltd. anticipates that its overseas suppliers will not agree to modify device labelling to comply with this proposal. This would place the onus on Smith & Nephew (as Australian sponsor) to implement a local over-labelling process, which would costly and prone to error. We believe that many other Australian sponsors will face the same difficulties. It should be noted that a large number of Australian sponsors do not have manufacturing capability or expertise, and should not be faced with the prospect of over-labelling products.

- ARTG numbers are not usually available when product labelling is being developed. This would mean that an artwork change process would be required to accommodate the Australian requirements i.e. changes down the track of product development / production will be extremely complex and costly.

- If in the event this proposal progressed (despite the myriad problems it would create), the proposed 12 month transition time for this proposal is inadequate, considering the numerous complexities associated with the proposed change.

- ARTG numbers are already made available to users of medical devices via various means e.g. NPC (National Product Catalogue).

- **SUGGESTION:** As a simple and practical alternative to inclusion on product labelling, the need for ARTG numbers to be accessible to users could be accommodated as part of the proposed solution to 3 (i), i.e. with the introduction of enhanced eBS search facilities described under that Proposal, a user could readily establish the ARTG number for a given product. <u>An electronic database solution will address all the issues and solve the TGA concerns.</u>

Proposal 4

Further discussion with stakeholders is required to identify the fundamental need for this information (can TGA provide evidence that it is required?), the extent of information to be provided, the responsibility for producing the information, and the resources required to produce it.

The discussion needs to focus on the fundamental differences between medicines and medical devices, and to recognise the fact that a great many medical devices at the lower end of the risk scale have very little product information associated with them.

The Proposal as framed cannot be accepted without further stakeholder consultation.