Alignment with European medical device regulatory framework:
Up-classification of surgical mesh
Patient implant cards

Stakeholder background
Integra Neurosciences Pty Ltd welcomes the opportunity to comment on the TGA consultation on Alignment with European medical device regulatory framework: Up-classification of surgical mesh & Patient implant cards.

Integra Neurosciences Pty Ltd is an Australian sponsor of medical devices manufactured overseas, and is a wholly owned subsidiary of Integra Lifesciences Corp USA. Integra devices support the specialty areas of Neurosurgery, Tissue Technologies, Plastic Surgery and Extremity Reconstruction.

Terms of Reference for Feedback
Comments in this response relate solely to the "Patient Implant Card".

MISSING, AND POTENTIALLY MISLEADING, TGA INFORMATION REGARDING THE "TRANSITION" TIME FOR CONFORMITY ASSESSMENT APPLICATIONS.

Regarding the line under the title "Transition" on page 9, 2nd paragraph:
"From the time the regulatory amendments come into force, all relevant conformity assessment applications will be explicitly required to comply with this requirement"

The TGA has not provided this date at all. Many readers of this consultation document will think this date for conformity assessment applications is May 2020, or November 2020. It is not; **the TGA has verbally confirmed to this stakeholder the date is November 2017.**

The published consultation document has no date stated when the TGA estimates the regulatory amendments will come into force. Considering there are dates specified elsewhere within this document, it is concerning that the TGA have neglected to specify a date in this specific instance of new conformity assessment applications.

This date is barely 2-3 months from now, hardly a 'transition', and therefore should not even be under "Transition" but have it's own Section titled "Immediate enforcement for Conformity Assessment Applications November 2017". Considering this date has not been publicized at all by the TGA then the TGA are not being transparent by enforcing any such date. So that the TGA can quantify the regulatory impact, the TGA asks for costs involved in implementing the amendments described in the Consultation document. Almost all stakeholders will have assumed that the enforcement date for conformity assessments will align with the EU medical device framework. The missing fact that the TGA seeks to apply a specific and unique requirement almost 3 years earlier than the EU means that it

is unlikely stakeholders will factor this additional cost of doing this before the EU transition date. Since the manner in which this will be executed has not been fully fleshed out in the EU either, it is highly concerning that the TGA are choosing a specific requirement where there is no clear rationale in doing so. It is even more concerning that the TGA are doing this without any guidance of their own, and will thus be implementing some sort of as yet unknown unique Australian requirement ahead of the EU MDR requirement. This is contrary to Recommendation 20 of the Review of Medicines and Medical Devices Regulation that clearly states that 'Should the Australian NRA seek to apply specific requirements, there must be a clear rational to do so". No such clear rational has been provided.

Consultation Questions:

1. Do you have any suggestions about effective ways to ensure that the patient ID card reaches the patient?

- Firstly, the TGA must clarify whether the proposed Patient *Implant* Card is indeed a Patient *Implant* Card, or a "Patient *Identification* Card", as the TGA has stated in their question, ie 'patient ID card'. The latter implies some other form of Card that is clearly not aligned with the EU MDR. This may just be a typographical error, but a Patient *Identification* Card implies a card that is equivalent to something that an AIMD manufacturer, of say a pacemaker or implantable defibrillator produces and manages. In those cases, patients undergo continual monitoring by a manufacturer field representative after implant and it is imperative that the patient is identified to the manufacturer. This is an additional requirement to that in a Patient Implant Card.
- Our understanding is that the adoption of this Patient Implant Card is so that the TGA aligns with the EU medical device regulatory framework. Admittedly, there are differences in the way our hospitals may work with their interaction with patients. Currently no guidance has been provided in the EU how to implement the requirements with patients and hospitals and the practice is still being developed. It would be expedient for the TGA to wait to see how this will be dealt with in Europe, prior to requiring something that is very possibly additional to the EU MDR.
- The manufacturer, and sponsor, can only do so much in ensuring the patient receive the Patient Implant Card. Devices are quite often removed from their secondary packaging within a hospital theatre environment. The IFU is then often not available at the direct place of use. Ensuring a patient implant card is provided to the patient at the time of use, will mean that whatever method is used, the hospital will need to be educated in time, and implement their own internal processes in time for this to be effective. Without an adequate transition time for new conformity assessment applications to implement this, and with no guidance or education from the TGA whatsoever, then this will only create more confusion.

3. Are there any issues or unintended consequences that may arise out of this change?

- The TGA appear to be implementing ahead of the EU changes for conformity assessment applications– but have additionally not defined what they wish to see from manufacturers. Considering that the TGA enforcement date is Nov 2017 for new conformity assessment applications, exactly what will the TGA be asking for manufacturers to submit? Once this Change is up and running in the EU, and manufacturers start being certified to the new MDR, then these

manufacturers *must* produce a patient implant card. We cannot have something implemented in Australia, that may end up being different to the EU Patient Implant Card with no clear rationale for this difference.

- The TGA have proposed publication of 'patient information' on page 9, under the tile "Publication" It is assumed the TGA means 'consumer medical device information' or 'implant card information' and not 'patient information'. This is a TGA specific requirement, for which no clear rationale has been provided as per Recommendation 20 of the *Review of Medicines and Medical Devices Regulation*. The additional requirement for Australia suggests there is a deficiency with the EU MDR – and the TGA have not stated what this is. This will likely lead to confusion for the patient and their treating physician. If the depository of information is to be kept on the manufacturer's website – why should it be duplicated on the TGA website, creating more unnecessary work for all involved? Our experience with treating physicians is they go straight to our manufacturer's website as these currently contain relevant information about hazards, such as MR safety.
- It is unclear if the published 'patient information' will have identical information requirements to the patient implant card or if the TGA intends separate additional requirements for manufacturers/sponsors. It is not explained how or when the information should be submitted for publishing and who is responsible for maintaining this information. There is also no information given on how long the TGA plan to publish the information on the TGA website and what would happen in situations where the ARTG entry is cancelled when the implant continues to be implanted in the patient. Can the TGA make an overseas manufacturer maintain information on the TGA website for an ARTG entry that a sponsor has cancelled and product they no longer supply in Australia?
- At the time of implementation, there will be a number of implants in hospital inventory without Patient Implant Cards. Patients may query why they did not receive a Patient Implant Card for one implant, when they did for another.
- The TGA should also be aware that responses from manufacturers of certain devices where a sponsor field representative is almost always present is not indicative of all sponsors of implantable devices. Implanting AIMDs, and for many orthopaedic surgeries , the only two specialties highlighted in the Consultation Paper, involves the presence of a field representative during the case. It is more likely that the Patient Implant Card will reach the patient in these types of surgeries. There are far more devices that are implanted where a sponsor representative is not present during the case. In these cases, time for hospitals to firstly be educated, and to implement their own internal procedures is required. Asking for this to be done whereby a manufacturer must provide a Patient Implant Card after November 2017 for new conformity assessment applications does not in any way provide sufficient time for sponsors or hospitals to understand how to practically implement.

4. If there are issues; provide suggestions for mitigating them.

- Patient Implant Cards, unless necessary, must not be a Card, or process, where the sponsor or manufacturer maintains any information about the patient. The only time this is necessary is where ongoing monitoring by the manufacturer representative is needed for continuing function and safety of the implanted device, such as in an AIMD.

- The TGA have not allowed, nor even published, any transition time for new conformity assessment applications for the Patient Implant Card. The date should be as for any other device being Included on the ARTG. Generally there are 2 distinct types of devices that undergo conformity assessment by the TGA. Those that do not have EC certification, and there is no intention for the manufacturer to apply for certification under the EU Australia MRA, and those that already have EC certification. The latter case where EC certification already exists, only undergo TGA conformity assessment due to requirements under Part 4, Division 4.1 of the Therapeutic Goods (Medical Devices) Regulations 2002. The TGA already often use the already existing EC certification to abridge the TGA conformity assessment. For the former, I cannot state what is an appropriate or workable date. For the latter, where the devices already have EC certification, there is absolutely no reason the TGA cannot have a transition date of May or November 2020. The TGA then request that sponsors of these entries submit updated EU MDR certification that the manufacturer must have by May 2020. This effectively demonstrate that the manufacturer complies to the Patient Implant Card requirement.
- The TGA states that the Patient Implant Card requirements will not apply to "certain articles such as sutures, staples, dental fillings etc". This list is not as detailed as the list of exemptions in the new EU MDR and using the term "etc" is not clear at all for such a TGA document. Therefore, it is unclear from the consultation paper if TGA will apply the same or a different list of exemptions to the EU as part of alignment. The TGA must provide a clear list of exceptions.