[redacted]

Submitted to Proposed refinements to the requirements for medical device patient information materials
Submitted on 2021-09-01 11:46:11

Privacy and your personal information

Introduction

1 What is your name?

Name:
[redacted]

2 What is your email address?

Email:
[redacted]

3 What is your organisation?

Organisation:
[redacted]

4 Are you a manufacturer/sponsor/consumer/health care professional?

Other

Refinement 1: Provision of patient information materials

5 Should patient information materials be provided in range of formats including:

Yes

Yes

Yes

Do you agree that the proposed wording of 'made available with' provides clarity for the format of and timing of when PICs and PILs are to be supplied?:

6 Do you have any other comments/suggestions that we should consider in relation to how PILs and PICs are made available?

Do you have any other comments/suggestions in relation to how Patient Information Leaflets and Patient Implant Cards are to be supplied?:

MTAA would like to emphasize the following:
1. There needs to be flexibility on how the PIC and PIL is provided. The patient materials should be able to be provided either in hard copy or electronically. While MTAA supports PILs being made available electronically, this should not be mandated, and sponsors/manufacturers should have the option to provide them in hard copy only.

2. PILs may be available electronically once the device is entered on the ARTG and while it may be best practice that these are available to doctors and potential patients prior to surgery, this may not always be the case. In some instances, the PIL may be provided post operatively to the patient to inform them of what the device does, information about what may happen after the surgery; and information about possible adverse events and circumstances when the patient should contact a health practitioner. This has the added benefit that the patient gets the information relevant to the exact device that has been implanted, as the device implanted may be different to that originally planned due to intraoperative surgeon decisions.

3. If patients choose not to have the hard copy of the card, it should not be the responsibility of the sponsor/manufacturer to ensure the information is uploaded into the systems mentioned in the survey.

4. It is important to note in part 2 of question 5 above, the patient does not choose a customised card as it is not universally offered. As noted by TGA in the introduction section of this survey, some device manufacturers do offer to "customise" the card to the patient, whereby the surgeon (with patient consent) provides the patient's name to the manufacturer, who then creates and sends (via mail) to the patient, a card with their specific information.

5. Specifically in relation to PILs, a separate PIL for each item of a construct is unnecessary and likely confusing as it is the full construct that is the treatment. PILs should therefore represent the overall construct, thus providing the most effective information to the patient

7 As a manufacturer/sponsor/consumer do you foresee any regulatory or cost implications or burden if the PICs and PILs are provided in more than one format?

Do you foresee any cost implications as a manufacturer/sponsor/consumer should the proposed change occur?:

Regulatory cost and burden for sponsors and manufacturers has already increased with TGA's timeline being ahead of EU MDR.
To ensure, no further regulatory, manufacturing, IT, or supply chain burden is encountered, it is essential that flexibility is provided in the way PICs and PILs are provided i.e. in hard copy or electronically. It should be the manufacturer/sponsor's decision to be able to meet the regulation in the way that best suits their internal processes and does not result in additional burden.

Refinement 2: Devices exempt from the requirements of patient information materials

8 Do you agree that it is unnecessary to provide Implant Cards if the device is going to be absorbed by the body within a certain timeframe? Should a PIL still be available?

Yes

7) Do you agree that devices absorbed within a certain timeframe should be exempt from providing PICs?:

It is unnecessary to provide Implant Cards if the device is going to be absorbed by the body within a certain timeframe – yes
Should a PIL still be available – this should be on a case-by-case basis and the responsibility of the manufacturer to decide based on the outcome of the risk assessment.

9 If you answered yes to the above question, tell us what would be a reasonable timeframe (e.g. devices absorbed within 3months/6 months), and why?

8) If yes, what is a reasonable timeframe (e.g. 6 months), and why?:

Regarding the reasonable timeframe where an Implant Card would not be required, MTAA would like this to be aligned with EU MDR timeframe which is 4 months.

10 If you are a manufacturer, describe the evidence that you could provide to demonstrate that the device will be absorbed within the stated timeframe.

9) If you are a manufacturer, what evidence could you provide to demonstrate that a device is absorbed within a certain timeframe?:

From a sponsor perspective, this data is in the approved supporting documentation held by the manufacturer.

11 Do you agree that it is unnecessary to provide Implant Cards for each pedicle screw, given that many screws could be used in one surgery. Should a PIL still be available? Please explain why?

Yes

Do you agree that an extra 18 month transition period is sufficient to allow the correct provision of PICs for non-exempt, non-sterile implants such as pedicle screws?:

PIC or PIL should not be required for pedicle screws for the following reasons:
- These screws are non-sterile so do not come individually packaged where it is easy to provide a card and patient label. Due to the nature of this product and its use in theatre (provided in bulk in a caddy) it is incredibly difficult to track. As the caddy is replenished after each operation, there is no way to know which individual items were supplied each time therefore providing a card to the patient trying to delineate specific screws is impossible and hence the requirement for individual PICs is useless.
- In relation to PILs for ancillary items, a separate PIL for each item of a construct is unnecessary and likely confusing for the patient as it is the full construct that is the treatment to be understood.

Other questions

12 Are there any other devices that could have implementation issues which are outside the control of the medical device sponsor and manufacturer? Please give examples.

Are there any other devices that could have implementation issues which are outside the control of the medical device sponsor and manufacturer? Please give examples.:

So far EU has not expanded their exemption list beyond that of TGA's list in that is currently in the regulations. For TGA to further specify non-exemptions within those ancillary items, some of these provided as examples below are not in alignment with what manufacturers will be required to supply.
- Rods (spine)
- Suture Anchors
- Wedges (augments)
- Laminar hooks
- Non-expandable cages
- Interspinous spacers
- Pedicle screws

This non-alignment not only goes against the MMDR recommendations but adding such extra items as non-exempt prior to any decisions by EU MDCG will cause extra burden on Australian sponsors, and further confusion and burden for hospitals.
MTAA also proposes a similar approach to the one Team NB has recently published

(https://www.team-nb.org/wp-content/uploads/2021/07/Team-NB-PositionPaper-ImplantCard-202107020.pdf) to allow manufacturers to make the decision on which items within the broad exempt list require a PIC/PIL.

Other devices that are anticipated to have implementation issues are
- Pledgets that are used with sutures. These devices only are ancillary in nature and provide support to the main device which is the suture. A pledget is like a washer in that it is designed to distribute the tension over a larger surface area and also in this case prevent the suture from cutting through the valve and soft tissue when they are tightened. This is always used with a suture, to help ascertain the intended purpose of the suture. Hence requiring a PIC for pledgets / sutures with pledgets would be burdensome to HCPs and increase operative time by needing to keep track of which sutures require PICs vs which ones don't.
- Bone screws which are similar to pedicle screws should be exempt as well.

MTAA would also like to highlight that a number of the items in the list above, non-expandable cages, augments, interspinous spacers, locking rings were moved from the exempt list in version 1.3 to non-exempt in version 1.4 on 13th August 2021. Given that these items were added to the list 3.5 months prior to the implementation, despite best efforts, there is no time to practically implement this requirement. The discussion that sponsors have been having with their manufacturers to get ready for the 1st Dec 2021 implementation date did not include these items and it is unreasonable to expect manufacturers to now be able to comply with the requirement for these extra devices.

13 Do you have any other comments in relation to patient information materials?

Do you have any other comments in relation to the above issues around patient information materials?:

MTAA and TGA meeting
Various issues and proposals raised by industry were considered by TGA for the provision of PICs and PILs that allow for flexibility for sponsors ahead of the EU MDR implementation in a meeting between TGA and MTAA held on June 3rd 2021:
- Ability to handwrite information on PICs
- Due to each manufacturer/sponsor utilising one or more formats, and especially if a sponsor represents more than one manufacturer, the ability to provide the sponsor's name in lieu of the manufacturer name and details. This provides a possibly more available contact and alleviates the burden and confusion for the hospital and the patient as to which generic card to provide.
- Provision of bulk cards to the hospital and replenished as necessary
- Sponsors being able to provide links to IFUs

Hospital engagement and education
The ultimate aim of the patient information materials is to benefit the patient. These include but are not limited to being able to identify the implanted device, get access to safety information, and identify themselves as persons requiring special care in certain circumstances. MTAA is supportive of any initiative that benefits patients.
The key to the successful implementation of this new requirement however involves not only sponsors and manufacturers but support from hospitals to act as the conduit in ultimately providing the cards to patients. After providing the patient information materials, sponsors/manufacturers are unable to control and have no visibility as to how the materials are used by hospitals and healthcare providers.
MTAA strongly recommends and requests that TGA has more engagement with hospitals to not only inform them of the new regulations but to educate them on the role that they will need to play to ensure that the information gets to patients.

MTAA would sincerely like to thank TGA for their continued collaboration and support in this matter. We would like to highlight that we are still providing feedback and there still no firm guidance from TGA regarding patient information materials as of the beginning of September 2021 with the deadline for this requirement commencing in 3 months. As such, we respectfully request that the above comments are considered and accepted by TGA and flexibility is provided in the way sponsors choose to meet the regulations for patient information materials.

Required - Final step - Publishing my response

14 Do you consent to the Department collecting the information requested in Citizen Space about you, including any sensitive information, for the purposes of this consultation?

I consent:
Yes

15 I consent to the submission made by me being published on the Department's website, and accessible to the public, including persons overseas, in accordance with the following preference:

Publish response, without my name but including my organisation's name

16 If there are questions that you don't want published, please indicate those below

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17 May we contact you for further information or to seek feedback about how the consultation was undertaken?

Yes

18 By making a submission, I acknowledge that:

I acknowledge the above:
Yes