[redacted]

Submitted to Proposed refinements to the requirements for medical device patient information materials
Submitted on 2021-08-17 20:18:23

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:
Dental Implant Registry

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?:

This should also be included not only for dental implants (General endosseous implant) and high risk implants subperiosteal and zygomatic implants but also the devices connected to them i.e. the Suprastructure which included dental abutments. These devices (unless temporary which are then replaced for a permanent component) are permanently installed by connecting them to the endosseous implant. Some of the devices that are being installed (currently) do not meet conformity (evidence can be provided). The following essential principles are not being meet by these devices -

Principle One: Use not to compromise health and safety; there is abundant clinical evidence that some of these devices definitely adversely affect patient health (bone loss requiring bone grafting and implant replacement).

Principle Two: Design and construction to conform with safety principles; The manufacturers of compatible devices can not comply with this essential principle if these do not undergo testing in vitro, animal or clinical trials, nor independent post market surveillance.

Principle Three: Must perform the way the manufacturer intended; see item b.

Principle Four: Must be designed and manufactured for long-term safety; Without post market surveillance no new product including compatible parts can comply with this EP.

Principle Six: Benefits must outweigh undesirable effects; The only way to comply with this item is to have long term independent data to compare new genuine devices or compatible devices (non-genuine) with the older components which have been in the market for a medium to long term time frame (5-10 years, which are common time periods used in the literature for assessment of device performance). Further information can be supplied to support above statement.

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?:

Currently the Dental Implant Registry provides digital PICs for patients for endosseous implant and abutments. This data is in the early stages of being included onto the My Health Record. This service is currently paid for by patients and subsidised one manufacturer at the moment. The Registry is working with insurers, manufacturers and dental associations to help subsidise this service and promote the importance of the new regulations in place and what it means to dental professionals (directly) and patients (via a patient advocacy group).

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?:

The cost to manufacturer/sponsor/consumers will occur with any new regulation. The cost of PICs and PILs can be distributed across the supply chain to ensure the regulatory burden and cost is not focused on one of the members of the supply chain, as this may:

1. Stifle R&D and supply to the market (manufacturers), or
2. Distribution to the dental professionals (manufacturers/sponsors) and
3. Ultimately consumers (dental professionals /patients) may forgo purchase and or treatment if significant additional costs are incurred or complex processes put into place to generate these documents.

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?:

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?:

From a dental the time frame does not seem to be clinically significant. Some studies show significant variation times in resorption (3-12 months, however some bone graft materials can still be present in situ for 5-11 yrs (https://bit.ly/3slrbrW).

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?:

NA

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?:

For the time being given limitations in technology this is a time consuming process. The PIL is not indicated if the devices are on the ARTG and in some cases these can be removed following additional surgeries.

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.:

NA

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?:

Patients are becoming more informed about the procedures and devices they receive especially permanent implantable devices. They are actively seeking more information about the procedures they are undergoing and devices they are receiving.

These new regulations on providing patients PIL/PICs align with the Australian Charter of Healthcare Rights indicates that patients (https://bit.ly/3ANewAX) should have access to their information:

Information
 Clear information about my condition, the possible benefits and risks of different tests and treatments, so I can give my informed consent

 Receive information about services, waiting times and costs
 Be given assistance, when I need it, to help me to understand and use health information
 Request access to my health information
 Be told if something has gone wrong during my health care, how it happened, how it may affect me and what is being done to make care safe

This is strongly supported by the DIR.

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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NA

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