[redacted]

Submitted to Proposed refinements to the requirements for medical device patient information materials
Submitted on 2021-08-18 09:00:45

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?

Health Care professional

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?:

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?:

Hard copies will cost more and add additional time burden on admin staff who will need to upload onto patient record

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?

Not Answered

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

N/A

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?:

N/A

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?:

N/A

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?:

Unnecessary - an overall information sheet would cover each component of the restoration

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.:

Dental devices are low risk and removable either by patient or practitioner. Dental practitioners are already strongly regulated with respect to the safety of treatment provided to patients.

It is unnecessary to further regulate the manufacture of dental devices (except, CAD CAM on-site manufacturing if outside manufacturers specifications).

Sponsoring medical devices SHOULD however be regulated by the TGA.

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?:

Should be at the discretion of the treating clinician. Some materials will need to be translated in different languages, most will need to be in plain language so as to be understood and useful to patients. Too many requirements will make the documents so long they will not read nor understand them.

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 or my organisation's name (anonymously)

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

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

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

No

18 By making a submission, I acknowledge that:

I acknowledge the above:
Yes