[redacted]

Submitted to Proposed refinements to the requirements for medical device patient information materials
Submitted on 2021-08-18 11:34:47

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?

Consumer

Refinement 1: Provision of patient information materials

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

Yes

Yes

No

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?:

Both options would be better, i.e. a hard copy at discharge and an electronic record via several formats. Since all electronic copies usualy take time to be uploaded, a hard copy gives short term coverage as well as providing a back up to verify what has been loaded electronically is accurate.

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?:

Multiple options are best to make sure patients with all levels of literacy and computer skills are covered.

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?:

None. These are already provided in hard copy by manufacturers. Adding an electronic version would impose minimal costs. It would also allow manufacturers to update these documents quickly for the electronic versions.

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?

No

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

All of these devices are provided sterile and will therefore have a chart sticker supplied with the device that shows product name, size, manufacturer and expiry date. This can be loaded to My Health as well as given to the patient on discharge along with a PIL which will provide information on how long it will take for the product to be fully absorbed as well as any adverse affects to be aware of.

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?:

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?:

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?:

A system PIL would be sufficient. Given that the surgeon will not know the exact length or number of screws ahead of time, it would seem impractical to provide an individual PIC for each component of the system. The patient could be given a record of of what the system was and which type and length of component was implanted on discharge as well as via electronic means, e.g. My Health.

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.:

Not that I am aware of.

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?:

Multiple options should be made available for this information. Electronic information should be made available in multiple languages as well.

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

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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