[redacted]

Submitted to Proposed refinements to the requirements for medical device patient information materials
Submitted on 2021-09-01 10:02:51

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?:

I think it is best practice for the patient to have the card on them- in wallet/ purse/ health documentation.
It is good to have it also on the my Health record but all options should e covered and available to be complementary and not exclusive.

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?:

The preparation and reading of patient information leaflets prior to a medical consult with ongoing options through website or on line for FAQs and a response.

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?:

If there is a perceived burden it will be offset by an improvement in comprehension and therefore patient safety with an expected reduction in complications/ representations/ patient concerns.

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?:

No card is required but providing information prior to the procedure of the absorption is helpful/important.

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?:

I think absorption within 6 months would be reasonable.
It is expected that there will be patient follow-up during this time.
If a concern occurred within that timeframe then it will be detected/ reviewed by the clinical or treating team.

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?:

A patient information leaflet to inform that screws will be left in place is sensible so that there is an awareness.
Individual cards are not required.
A single card that confirms the presence of screws- of different sizes- would be reasonable.

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.

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N/A

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?:

It is helpful to have access to an ongoing communication for patients/ carers if they have a concern in regard to an implantable device.

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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N/A

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