[redacted]

Submitted to Proposed refinements to the requirements for medical device patient information materials
Submitted on 2021-08-26 10:17:48

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?:

As an interventional cardiologist, I was not aware of patient implant cards being required for coronary stents. I don't think patients are being provided with these cards routinely in public or private health system in my region.

I record the brand / model of the implanted device (stent) in my procedure report (but this does not include serial / batch number)

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?:

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?:

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?:

Not in my area of expertise.

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.:

Coronary stents - not possible to determine in advance which stent(s) will be used. Often coronary stenting is not planned in advance. This limits use / utility of patient information leaflet.

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?:

As an interventional cardiologist, I was not aware of patient implant cards being required for coronary stents. I don't think patients are being provided with these cards routinely in public or private health system in my region.

I record the brand / model of the implanted device (stent) in my procedure report (but this does not include serial / batch number)

In regards to coronary stents, I do not see the value of patient implant cards. I think batch / serial number should be recorded by the hospital in case of device recall / alert.

Similarly, patient information leaflets that have a long list of rare potential events are rarely helpful.

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