

Submitted to Proposed refinements to the requirements for medical device patient information materials
Submitted on 2021-08-19 11:56:41

Privacy and your personal information

Introduction

1 What is your name?

Name:

2 What is your email address?

Email:

3 What is your organisation?

Organisation:

4 Are you a manufacturer/sponsor/consumer/health care professional?

Sponsor

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?:

need to reflect needs of varying population
younger people prefer everything electronically - stored for easy access
older people currently more used to hard copy information
logic indicates best in both forms

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?:

depends on the accepted time frame for the material to be absorbed.

As stated, once absorbed, it doesn't exist per se

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?

Not Answered

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?:

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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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?:

A conundrum exists for dental crowns and implants:

the list of exemptions includes dental crowns, with the definition in the document defining a crown as a device that covers an existing tooth

the list of exemptions includes general dental (endosseous) implants under the heading of "screws" and dental abutments under the heading of "connectors"

HOWEVER - what about dental crowns placed on implants? These are not definitively identified as an exemption

I recommend strongly that the definition of dental crowns should be changed to include crowns placed onto implants

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