# Response ID ANON-GFK1-Z4CS-D

Submitted to Proposed refinements to the requirements for medical device patient information materials
Submitted on 2021-08-24 18:29:16

## Privacy and your personal information

## Introduction

1 What is your name?

Name:
Scott Fletcher

2 What is your email address?

Email:
[redacted]

3 What is your organisation?

Organisation:
Nil

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?:

yes

## 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?:

12m
to allow use of approved resorbables without additional regulation

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?:

Evidence required for TGA approval

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?:

## 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.:

Anything absorbable that has regulatory approval (TGA) should be exempt from un-necessary (additional) regulation.

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?:

Patients are overwhelmed by information, yet they need information to satisfy informed consent
Leaflets and cards should be used during the peri-operative period. This can be uploaded to the my health care web site if desired.

In orthopaedics, all the information that is required by the patient is held by government funded NJRR
Rather than create another monster with un-intended consequences, (it would be) smarter to use existing databases. ( e.g. allow users access to prostheses information through the joint registry patient portal or through TGA patient portal).

## 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, including both my name and organisation's name

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