Response ID ANON-JBP6-MV6H-K

Submitted to **Proposed Enhancements to Adverse Event Reporting for Medical Devices - Industry**
Submitted on **2020-12-01 10:41:59**

Privacy and Personal Information

Respondent Information

1 What is your name?

Name:
Rowan Cockerell

2 What is your work title?

Work Title:
CEO

3 What is your company/organisation?

Organisation:
Continence Foundation of Australia

4 What is your company address?

Address:
1/407 Canterbury Road Surrey Hills VIC 3127

5 What is your contact phone number ?

Phone number: e.g. 042xxxxxx (without space) :
0386928400

6 What is your email address?

Email:
r.cockerell@continence.org.au

7 Which industry component do you represent?You may tick as many boxes as apply to you.

Industry organisation or peak body

If you choose 'other' option, then please specify:

8 May we contact you for more information or to seek feedback about how the consultation was undertaken?

Yes

9 Are you responding:

On behalf of an organisation

Introduction and Background

Proposal 1 - Make changes to the current adverse event reporting exemptions

1 Do you suggest removing all the current exemptions?

Yes (please specify and skip to question 10)

Please specify:
All current exemptions should be removed. The Continence Foundation of Australia (The Foundation) recognises the existing reporting rate for adverse events is considered to be low.1 Having exemptions may add to or facilitate a lower level of reporting on adverse events which can lead to an inaccurate expectation of medical device risk and safety for consumers.

We have provided specific reasons for removing the exemptions below:
Exemption 1 should be removed because it can be considered similar to a ‘near adverse event’ which might have led to a death or serious injury.

Exemptions 2-6 should be removed as underreporting can lead to mismanagement or unsafe use of the medical device leading to adverse events and harm.

Exemption 7 should be removed because despite notice being provided about risks, this does not exonerate suppliers from taking any further action. Harm can still occur and the onus is on the sponsor to address this actively. We take the example of Takata seatbelts and airbags for Toyota cars for which the manufacturer took proactive steps to contact, recall and replace the products in question. This was positive safety recall procedure which benefits many consumers before further harm could occur.

Exemption 8 should be removed if such exemptions do exist, these should be provided as part of this consultation for review so that the industry and the public have a chance to address these to confirm whether or not they are suitable.

Reference:
1. Craig A, O'Meley P, Carter P. The need for greater reporting of medical device incidents. EMJ Innovations. 2019;3(1):56-63.

2 Exemption 1, do you suggest:

Not Answered

Please specify:

3 Exemption 2, do you suggest:

Not Answered

Please specify:

4 Exemption 3, do you suggest:

Not Answered

Please specify:

5 Exemption 4, do you suggest:

Not Answered

Please specify:

6 Exemption 5, do you suggest:

Not Answered

Please specify:

If exemption five is removed then how many more reports would you need to submit per calendar year?:

7 Exemption 6, do you suggest:

Not Answered

Please specify:

If exemption six is removed then how many more reports would you need to submit per calendar year?:

8 Exemption 7, do you suggest:

Not Answered

Please specify:

9 Exemption 8, do you suggest:

Not Answered

Please specify:

10 While choosing your answers what factors influenced your decision?

While choosing your answers what factors influenced your decision? - The regulatory burden due to proposed changes might:
Increase

While choosing your answers what factors influenced your decision? - The financial burden due to proposed changes might:
Increase

While choosing your answers what factors influenced your decision? - Patient safety due to proposed changes might:
Increase

Please specify:
The Foundation represents a health professional membership base but also seeks to ensure its consumer base is protected against adverse events, primarily though professional education and policy advocacy. In line with the Review of medicines, and medical devices regulation report in 2015, we agree timely and effective post-market monitoring of medical devices is an essential element to an effective regulatory system. In addition, we agree there is a greater diversity and complexity to medical devices in postmarket surveillance as compared to drugs. We acknowledge this creates a steeper learning curve for health professionals and consumers in adopting new technologies, a shorter lifecycle and iterative nature of product development1 all of which create greater risks for adverse harm. We acknowledge the higher expected costs for sponsors and industry but believe this should be proactively addressed allowing for greater protections for consumer and health professionals as well as greater certainty about medical device safety for all.

Reference:
1. US Food and Drug Administration (FDA). Strengthening our national system for medical device postmarket surveillance: update and next steps. 2013. Available from: https://www.fda.gov/files/about%20fda/published/Strengthening-Our-National-System-for-Medical-Device-Postmarket-Surveillance.pdf. [Accessed 2020 November 6]

11 Do you recommend adding more exemptions?

No

Please specify what would you like to add to the existing exemptions?:

Proposal 2 - Strengthen reporting requirements for medical device adverse events

1 Should the medical device adverse event reporting process be enhanced?

Yes

Please specify why? :
The medical device adverse event reporting process should be enhanced in order to have adequate and appropriate information provided by sponsors/suppliers on the nature of the incident. While open answer reporting should be kept and encouraged to ensure qualitative details relating to the incident and device are not lost, more specific closed-answer questions should be asked around issues such as the ‘Description of event or problem’. Having a specific list of options for users of the TGA Business Services (TBS) website (https://www.tga.gov.au/publication/mdir-guide) to outline the nature of the incident, e.g. device malfunction or cybersecurity breach will allow for a more efficient and targeted approach by the TGA, to determine if there is shared causality if and when multiple instances of adverse events occur and what follow up actions need to be taken. Considering the adverse event may represent a serious threat to public health allowing for only 48 hours for an initial report to be created, it is closed-answer options like these that can then help ease the burden and directly guide the reporter on what details are essential and adequate.

2 Should there be a specified time-frame for submitting a final medical device adverse event report?

Yes

3 What time-frame do you propose for submitting a final adverse event report?

Other (please specify)

If you choose 'other' option, please specify the time-frame that you propose for submitting a final adverse event report:
A specified time-frame for submitting a final medical device adverse event report should be put in place depending on the complexity of the device (device class) as well as the history of adverse events related to the device and its various iterations. This means a class I device such as a tongue depressor which has a lower complexity level should, barring other factors, have a lower specified time-frame for final report submission (30 days for example) than a class III device such as a heart valve which is likely to take more time to review and assess the reasons for the incident. 120 days should be considered the upper limit for reporting adverse events in this class unless the manufacturer applies to the TGA for an extension of time to complete the investigation.

4 Do you recommend an interim report to be submitted after the initial adverse event report?

Yes

Please specify why? :
The Foundation recognises the existing reporting rate for adverse events is considered to be low. This may due to a number of factors including fear of blame, lack of time, perceived ineffectiveness of reporting, complexity of reporting and lack of knowledge of the reporting system.1 In line with this and our answer to the previous question, we believe the interim report will likely not be required for lower class devices should they be given a lower reporting time-frame for submission of their final medical device adverse event report.

For higher class devices, interim reports should be encouraged but not considered to be necessary if final report deadlines are set. The encouragement of a greater level of reporting should be positive and not add unnecessary strain to the sponsor, health professional or consumer.

Reference:
1. Craig A, O’Meley P, Carter P. The need for greater reporting of medical device incidents. EMJ Innovations. 2019;3(1):56-63.

5 Adverse event reports should be submitted to the TGA:

Either through emails or the TGA Business Services (TBS) client's portal (please skip to question 7)

If you choose 'other' option, then please specify:

6 Please state the reason that is preventing you from reporting an adverse event through the TGA Business Services (TBS) client's portal.

Reason:

7 Are there any factors that would prevent you from providing the instruction for use (IFU), supply data and similar adverse event data to the TGA for a better understanding of the adverse event at the time of reporting?

Not Answered

Please specify the reason(s):

Proposal 3 - Implement a program of TGA inspections and audits of sponsor activities and premises

1 Should the TGA implement an inspection program for sponsors' premises and activities?

Yes (please specify)

Please specify why? :
The Foundation supports an inspection program for sponsors' premises and activities. We also agree this should be done on case-by-case basis based on a risk-based approach as indicated in the recent TGA webinars on this consultation. While the Foundation will respond to certain aspects of this proposal, we believe other individuals and organisations are better placed to answer the questions more thoroughly.

2 Please select one option per statement

Please select one option per statement - There should be a systems inspection (procedures, records etc as opposed to product inspection):
Agree

Please select one option per statement - A Guidance document should be published for the sponsors to understand the inspection process and outcomes:
Agree

Please select one option per statement - There should be a risk-based approach to prioritising and scheduling the sponsor inspections (based on risk factors, the medical device, history of adverse event reporting and compliance history):
Agree

Please select one option per statement - An inspection report should be provided by the TGA listing the key information (such as outcomes and findings of the inspection):
Agree

Please select one option per statement - A pilot program inviting sponsors to volunteer for testing the program design prior to implementation:
Agree

3 If the proposed sponsors' premises and activity inspection comes into force, do you foresee any impact on the regulatory burden?

Increase regulatory burden

Please specify:
We expect there to be a small increase in the regulatory burden on sponsors in having to adjust to the inspection process and in ensuring they are compliant with the requirements.

4 Please suggest alternative measures that the TGA can undertake to assist sponsors in identifying the gaps related to regulatory compliance?

Measures:
The proposals outlined in question 2 do appear to be satisfactory in providing adequate notice and assistance to sponsors participating in and responding to regulatory change.

5 Do you believe there is a need to educate and promote best practice regulatory compliance among sponsors?

Yes (please answer question 6)

Please specify why? :
The introduction of a new inspections process should ideally have an education aspect to inform sponsors on variations in inspection types on a case by case basis. It would be preferable to have a compliant and understanding sponsor group that can help keep the Australian public safe from adverse events than a non-compliant group who are unsure of what expectations have been set.

6 Please suggest the best ways to educate and promote best practice regulatory compliance among sponsors.

Suggestions:
A pilot program inviting sponsors to take part as brought up in question 2 would be ideal. Furthermore, the learnings from this process as well as any new changes to be made should be communicated to sponsors after this pilot program has ended. An inspection report should be provided following the pilot program which lists key information, issues of concerns and compliance levels.

Proposal 4: Review post-market definitions in the Medical Device Regulations

1 Should all or some of the words specified in the proposal be included in the Therapeutic Goods (Medical Devices) Regulation 2002 definitions?

Unsure

Please specify why? :
The Foundation will not be responding to this section as we believe that other individuals and organisations are better placed to comment.

2 What alternative ways do you suggest the definitions of the words specified in the proposal could be provided, without changes to the legislation?

Please specify:

Proposal 5: Find ways to enhance communication between the TGA and the consumers of medical devices

1 Do you feel adequately informed about the issues related to medical devices, such as alerts, adverse events, and recall actions?

Yes

Please specify why? :
As a health peak body, the Continence Foundation of Australia connects with various manufacturers and suppliers of continence products from around Australia. Along with the information from TGA, we believe we are adequately informed about medical device issues including alerts, adverse events and recall actions. However, from our work with the Consumers Health Forum, we believe that consumers in general are not adequately informed about the TGA, its role and the process for finding and reporting adverse events.

2 How can the TGA's communication process be improved to ensure that all impacted end users are adequately informed?

Please specify:
While the TGA has information on its website and on its social media platforms through which it makes connections with patient groups and medical practitioners, the Foundation points to the Community Affairs References Committee1 findings on transvaginal mesh implants that it is not funded to undertake large-scale consumer information programs.2 This latter aspect does need to be addressed so that the risk of future adverse events is mitigated. Furthermore, it was indicated in the Community Affairs References Committee report that the TGA received a low level of reports related to mesh implants as compared to other groups. 1 In recognising this, the TGA should develop existing relationships with state and territory government health safety and quality authorities, health consumer bodies and other organisations receiving reports of adverse events with medical devices to ensure timely and effective interventions and follow ups can be made with consumers, health professionals and sponsors as required.

References:
1. Community Affairs References Committee. Number of women in Australia who have had transvaginal mesh implants and related matters. The Senate. 2018. Available from: https://www.aph.gov.au/parliamentary_business/committees/senate/community_affairs/meshimplants/report. [Accessed 2020 6 November]
2. Community Affairs References Committee. Transvaginal mesh implants and related matters Transcript of proceedings (3 August 2017). The Senate. 2017. Available from: https://parlinfo.aph.gov.au/parlInfo/download/committees/commsen/05fd65f2-1b5d-4db5-9b27-657110f12f48/toc_pdf/Community%20Affairs%20References%20Committee [Accessed 2020 November 11]

3 Are you interested in information on issues related to:

Specific medical devices (e.g. implantable products)

Please specify why? :
As a health peak body with a specific focus on continence and incontinence-related issues, we are interested in products relating to continence matters.

4 At what stage of a medical device adverse event investigation do you consider the TGA should start communicating information to the consumers?

After identifying and verifying the cause of issue

Please specify why? :
The Foundation believes, alongside health professionals, that we should follow a strict guideline to do no harm to the patient (consumers). In line with this, it is of the utmost importance to begin communicating with consumers at an early stage which will not risk undue fear or panic which in this case is after identifying and verifying the cause of the issue. This may help many avoid the potential adverse effects of a specific product and better inform them about the risks involved.

5 What type of information regarding an adverse event investigation would you ideally want the TGA to communicate with the consumers?

Type of information :
The TGA should communicate the safety information relating to a device, comprising of a short summary of adverse events that have occurred in relation to this device. This will include the different categories assigned by sponsors or members of the public when providing the initial adverse event, e.g. device malfunction (see Proposal 2, Q1). Ideally, the actual incidence rate (number of similar events/product supplied x 100) should be included and other relevant information as outlined by the TGA Business Services Client Portal guide.

Furthermore, action taken to address and remediate the issues including suggested actions that consumers can take themselves will be important so that they are reassured of their safety and more understanding of the outcome. Finally, an avenue for consumers who have been affected to lodge an adverse event report, and subsequent information on when and how to do so, should be a key part of the communications. The latter can be provided as a link to existing information on the TGA website.

6 Have you searched for adverse event information on the TGA DAEN database?

Yes

7 Did your search recover the information that you were looking for?

Yes

8 How easy was it?

How easy was it? - To search for the information that you were looking for?:
Somewhat easy

How easy was it? - To understand the information that you found?:
Somewhat difficult

9 Please suggest how can we simplify the process of searching, navigating and understand the information on the DAEN database?

Please specify:
While the search process is fairly standard when compared to other databases and somewhat easy to use for those familiar with using databases, navigating to the report was not altogether straightforward or user friendly. When clicking on the ‘List of reports’ tab for a particular device, the first text we see is a link to ‘Further information about the list of reports’ which is misleading as we have to scroll further down to read the actual reports themselves.

There is also some difficulty in understanding the report information on the DAEN database. The use of complex terminology and jargon is not well suited to consumers nor other members of the public.

10 Is there any further information related to adverse events that you would like the TGA to include on the DAEN database?

Yes

Please specify:
It would be beneficial if there was further information here about other incidents that have been reported from other countries although a full summary would not be required. The incidence rate would also act as a tool to provide some perspective to consumers on associated safety of the medical device in question.

11 Where else do you search for ADVERSE EVENT information related to medical devices?

Please specify:
Google/Online search engines

12 Have you searched for recall information on the TGA SARA database?

Yes

13 Did your search recover the information that you were looking for?

Yes

14 How easy was it?

How easy was it? - To search for the information that you were looking for?:
Somewhat easy

How easy was it? - To understand the information that you found?:
Somewhat difficult

15 Please suggest how can we simplify the process of searching, navigating and understand the information on the SARA database?

Please specify:
Navigating to the information on recall for specific products, similar to the DAEN database, was not very clear. Given the fact that both the DAEN and SARA databases are run by the TGA, one could be forgiven for expecting the same format where reports are listed on a separate tab.

The information that was found related to the recall was again explained through jargon and much of the text was not aimed at consumers which could be off-putting and not likely to result in effective communication.

16 Is there any further information related to recalls that you would like the TGA to include on the SARA database?

Yes

Please specify:
Specific information on what actions the consumer has to take, in plain and simple language, is important to include.

17 Where else do you search for RECALL information related to medical devices?

Please specify:
Google/Online search engines

18 Have you ever searched the TGA website for safety information on a medical device? (other than the DAEN and SARA database)?

No (please skip to question 23)

19 Did your search recover the information that you were looking for?

Not Answered

20 How easy was it?

How easy was it? - To search for the information that you were looking for?:

How easy was it? - To understand the information that you found?:

21 Please suggest how can we simplify the process of searching, navigating and understand the information on the TGA website?

Please specify:

22 Is there any further information related to adverse events or recalls that you would like the TGA to include on the TGA website?

Not Answered

Please specify:

23 Where else do you search for SAFETY information related to medical devices?

TGA’s Facebook page, TGA’s Twitter handle

If you choose 'other' option, then please specify:

24 Please state the reason for choosing your preferred platform for safety information related to medical device(s).

Reason:
Both of TGA’s Facebook and Twitter pages provide easy to access information that summarises issues succinctly and relevant recent information is easy to browse through.

Summary

1 Can you or your organisation provide suggestions for mitigating any unintended consequences that may arise out of the proposed changes?

Please specify:
The removal of all exemptions as suggested in proposal 1 will likely lead to a higher regulatory burden for the TGA as well as sponsors. One way to address this is to ensure an effective and efficient Unique Device Identification system is implemented making it easier for all sponsors to register, monitor and report adverse events relating to medical devices. This system could be set up with alerts to remind sponsors to complete necessary reports on adverse events on time as well as provide a communication channel with the TGA for guidance and/or negotiate to extend deadlines for reports as required.

Publishing Your Response

1 Do you consent to the Department collecting the information requested in Citizen Space about you, including any sensitive information, for thepurposes of this consultation?

I consent

2 I consent to the submission made by me being published on the Department’s website, and accessible to the public, including personsoverseas, in accordance with the following preference:

Publish response, without my name but including my organisation's name

3 If there are questions that you don't want published, please indicate those below

Please enter your answer in the box below:

4 May we contact you for further information or to seek feedback about how the consultation was undertaken?

Yes

5 By making a submission, I acknowledge that:

I acknowledge the below