Consumers Health Forum of Australia

SUBMISSION

TGA Consultation: Proposed enhancements to adverse event reporting for medical devices

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Consumers Health Forum of Australia (2020) *Submission to the TGA Consultation: Proposed enhancements to adverse event reporting for medical devices.* Canberra, Australia

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Overview

The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. The reforms will continue to improve the safety, performance, and quality of medical devices in Australia and improve health outcomes for patients who require medical devices. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates therapeutic goods, and is responsible for implementing the Government's reforms. The TGA conducted this consultation as part of the reform program. This consultation related to proposed enhancements to post-market adverse event reporting and improving communication with the consumers of medical devices.

The aim of a post-market monitoring and vigilance system for medical devices is to maintain the safety of patients and, through the collection, analysis, and action taken in response to adverse event reports, reduce the likelihood of adverse events recurring. Adverse event reporting allows the TGA to monitor medical device performance in the real world and identify emerging safety and performance issues. A number of reviews and inquiries have highlighted the safety of medical devices and the process for monitoring them once supplied on the market. While Australian regulatory practices are comparable to other regulators around the world, this consultation seeks feedback on proposals to strengthen them further. Improving Australia's adverse event reporting system will more promptly address threats to patient safety and to take quicker action.

The focus of this consultation was to seek feedback on five proposals. The proposals aim to improve access to information about medical device safety. In addition to making it easier to report problems with a medical device, information about known or suspected problems with devices must be accessible and be understood by consumers, their families and their health professionals.

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health consumer affairs, including health-based research. We have over 250 members reflecting a broad spectrum of organisations including state-based consumer peaks, condition-specific groups, volunteer patient groups, professional associations, Primary Health Networks (PHNs) and the research community.

We work in collaboration with our members, national partners and research collaborators to influence policy, programs and services to ensure they are in the consumer and community interest. CHF is pleased to make this submission in response to this TGA Consultation on enhancing medical device adverse event reporting.

Note that this consultation was administered as an online survey and this document has been adapted from the CHF submission to that survey.

CHF Submission

Proposal 1:

Consultation Paper Questions

Should the exemption rules for reporting medical device adverse events be changed? Which option/s are preferred and why? If not, then do you have alternative modifications to propose?

Yes we believe that the exemption requirements should definitely be changed. We strongly advocate for Option 1 be adopted and all exemptions be removed. We would strongly argue this position as seven of the eight criteria in our view do *not* justify exemption from reporting. The situations they relate to all indicate systemic failures and/or provide valuable aggregate data for regulator, industry and consumer action. Specifically looking at the eight exemptions:

1. *The deficiency of a new device was found by the user prior to its use.*

This qualifies as a "near-adverse event" which should be reported. The deficiency in the device potentially exists in other copies of the device and may not be found by all users before use without regulator action. As such exemption from reporting requirements is inappropriate.

2. *An adverse event was caused solely by patient conditions.*

This suggests that the conditions in which the device use is appropriate are narrower or more nuanced that previously thought or the device was somehow used in inappropriate conditions. In both scenarios this is information that is relevant for the regulator, healthcare professionals and consumers when considering if the device should be used or if it is being used appropriately. Even if the specific set of patient conditions that led to the adverse event was known or suspected to cause complications with the device, reporting such adverse events that confirm or reinforce this with more precise data is valuable information. As such they should not be exempted from reporting requirements.

3. *The device had exceeded its service life and the failure mode was not unusual.*

This suggests that devices are being used past their expected service life and the system for monitoring and replacing them has failed and needs review. Exemption from reporting requirements is inappropriate as it means this systemic failure may not be detected and corrected.

4. *A design feature protected against a fault becoming a hazardous situation.*

A fault still occurred and a "near-adverse event" happened. Exemption from reporting requirements is inappropriate as this is indicating a device flaw that could engager consumers if not corrected.

5. *The device was known to have a remote likelihood of occurrence of death or serious injury.*

Reporting such adverse or near adverse events will allow for regulators, healthcare professionals and consumers to have more precise knowledge about exactly how "remote" the likelihood is of death or serious injury is. Additionally it will allow for those same groups to determine whether the likelihood of such events is actually "remote" or if it is more likely than originally thought when the device was approved. Exemption from reporting requirements is inappropriate as this is critical data for reviewing the appropriateness for a device to remain available in Australia.

6. *The event was an unexpected and foreseeable side effect that is documented in the manufacturer's IFU or labelling.*

We're unsure how an unexpected side effect could be documented in the IFU or labelling, but in any event as with Exemption 5 having more concrete data as to the specific frequency and scale of these foreseeable side effects will allow for the regulator, healthcare professionals and consumers to make a more informed choice about the appropriateness of approving or using a specific device. As such exemption from reporting requirements is inappropriate.

7. *The events occurred after the manufacturer had issued an advisory notice.*

This suggests that the advisory notice was ineffective in preventing further adverse events and as such further preventative and protective actions may need to be taken. Exemption from reporting requirements is inappropriate.

8. *Reporting exemptions have been granted by the TGA for this particular kind of event.*

Given the nature of this exemption, there are not specific device or system issues that are potentially occurring that would be missed as with the prior 7. While we cannot envision specific circumstances where exemptions from adverse event reporting would be appropriate and outweigh the value of the report data, we acknowledge such circumstances could theoretically exist and see value in the Regulator maintaining the ability to give case or event specific exemptions to adverse event reporting in those circumstances.

However we would recommend an addendum to this exemption mechanism where the approval of and reasoning for exemptions to adverse event reporting are made publicly available and are brought to the attention of healthcare providers and consumers considering the use of a specific device; in the same way that the known/potential risks of the device are brought to their attention. This was the lack of any adverse event data reporting for such devices is not falsely taken by healthcare professionals and consumers as unambiguous evidence that there have been no adverse events or problems with the device.

Online Form Additional Questions

1. **Do you suggest removing all the exemptions?**

(•) Yes (please specify and skip to question 4) ( ) No (please specify)

Please specify why?

Please refer to responses to "Proposal 1: Consultation Paper Questions"

2. **Do you suggest removing some of the exemptions?**

(•) Yes ( ) No (please skip to question 4)

3. **Please suggest which exemption(s) should be removed?**

[x] Exemption 1 [x] Exemption 2 [x] Exemption 3 [x] Exemption 4

[x] Exemption 5 [x] Exemption 6 [x] Exemption 7 [ ] Exemption 8

Please specify why:

As noted previously we would suggest all seven specific exemptions should be removed but see the value in retaining Exemption 8 to give the Regulator flexibility to allow exemptions if a set of circumstances made it worthwhile, providing that it is modified so that the giving of such exemptions is made public knowledge.

4. **Do you suggest retaining but modifying the exemptions?**

(•) Yes (please specify) ( ) No

As noted previously we would suggest all seven specific exemptions should be removed but see the value in retaining Exemption 8 to give the Regulator flexibility to allow exemptions if a set of circumstances made it worthwhile, providing that it is modified so that the giving of such exemptions is made public knowledge.

5. **Did you experience an adverse event due to a medical device in the past two years?**

( ) Yes (please specify) (•) No

6. **What were your actions after being subjected to the adverse event mentioned above?**

☐ I reported the adverse event to the TGA

☐ I reported the adverse event to the distributor/ sponsor/ manufacturer

☐ I reported the adverse event to the health care facility/health care professional

☐ I did not report as I assumed my healthcare provider would have

☐ I did nothing about it

☐ Other (please specify)

☑ Not applicable

7. If you reported the adverse event to the TGA, were you satisfied with the way the TGA responded to your adverse event report?

○ Yes ○ No ◉ Not applicable

Proposal 2:

Consultation Paper Questions

Should the medical device adverse event reporting requirements be enhanced by the implementation of some, or all, of the options provided? If not, then do you have an alternative course of action to propose?

Yes, we would strongly encourage the adoptions of all three proposed options to enhance adverse event reporting. Looking at the three options suggested in turn:

1. *A final report could be required to be submitted within a specific time period; for example, within 90 days of the initial adverse event report.*

A specified timeframe for the final report to be provided with all the required information, as with the initial report following the adverse event, is such a self-evidently important requirement it is quite surprising that is not already in the legislation.

We would suggest that the default timeframe for the follow up report be identical to the timeframe of the initial report. For example a '"serious threat to public health" final report should be submitted within 48 hours of the initial report while a "might have lead to death or serious deterioration" final report must be submitted within 30 days of the initial report. As a side note, we presume those are 'calendar days' and not 'business days' but clarification on that should be made.

We would emphasise that those timeframes should be the *default* ones and that Sponsors should be given the ability to request additional time from the TGA should the specifics of the adverse event require more time to finalise the Final Report. With the TGA then able to make decisions on a case-by-case basis of providing additional time.

2. *Requiring the final adverse event report to include the IFU, supply data and similar adverse event data for the particular device.*

As with the prior proposed option, we strongly support the requirement for sponsors to include all device information in the final adverse event report in order for the TGA to effectively understand and respond to adverse event reports.

The only potential caveat is in how 'similar adverse event data for the particular device' is to be formatted and provided; as depending on the device and frequency of adverse event reports this may lead to a large amount of duplicate information being provided to the TGA. However we would hope that no device approved for supply in Australia would cause a sufficient number of adverse events for that to ever become a problem in a practical sense.

3. *The provision of data and documents to the TGA via an online form and in a specified format to facilitate effective data analyses.*

Again we have no issues with this proposal, strongly support its adoption and are mildly surprised this isn't already the case.

In the 21st century and an era of Big Data, providing information in the appropriate and usable format via an online tool such as a form is basic, fair and reasonable expectation. Other potential formats, e.g. verbally, via phone, via fax, via post etc are simply not appropriate and could potentially be viewed as uncooperative behaviour.

Online Form Additional Questions

1. **Have you submitted any adverse event reports to the TGA in the last two years?**

○ Yes ◉ No (please skip to question 5)

2. ~~**How many adverse event reports did you submit to the TGA in the last two years?**~~

~~○ 0-5 ○ 6-10 ○ 11-15 ○ 16-20 ○ More than 20~~

3. ~~**How did you submit the adverse event report(s) to the TGA?**~~

~~☐ Through emails ☐ Through the consumer web form~~

~~☐ Through the health professional web form ☐ Other (please specify)~~

4. ~~**How convenient was your chosen method of reporting the adverse event to the TGA?**~~

~~○ Very convenient ○ Somewhat convenient ○ Convenient~~

~~○ Somewhat inconvenient ○ Very inconvenient~~

5. **Should the medical device adverse event reporting be enhanced?**

◉ Yes ○ No ○ Unsure

6. **What measures do you recommend the TGA take to enhance adverse event reporting?**

Please refer to prior responses to “Proposal 2: Consultation Paper Questions”

7. **Do you feel it is reasonable for the TGA to publish adverse event reports on its web site?**

(•) Yes ( ) No ( ) Unsure

Please specify

We not only feel it is reasonable to publish this information publicly on the TGA website but feel such transparency is expected and it should be a *requirement* for adverse event reports to be published publicly in an accessible format. We would suggest a further step of not only should they be published on the TGA website but possibly also the Sponsors and Manufacturers as well to ensure that consumers or healthcare professionals considering a device will be more likely to be made aware of such adverse event considerations.

8. **Can the TGA do anything to encourage consumers to report adverse event(s)?**

Potentially (see Proposal 5 response). However we would hesitate relying on a consumer who has potentially just experienced a traumatic adverse event due to a medical device to have the resources and capacity to be relied upon to report the adverse event in a timely fashion. A more reliable process would be requiring both the sponsors/manufacturers and healthcare professionals to report adverse events (and unexpected side effects).

Proposal 3:

Consultation Paper Questions

Should the TGA implement both an on-site audit and education program relating to sponsors' premises and activities? Is an education and assistance program to promote best practice regulatory compliance the optimal approach or are there better approaches?

We would strongly support the implementation of an on-site audit program by the TGA for medical device manufacturing in line with how medicines are regulated. The action of such audits will ensure compliance with necessary standards and regulations. As with prior Proposals, this not already occurring is mildly surprising and should be rectified immediately.

We would also support the TGA implementing an education program in principle but note that Industry is best placed to know whether such a program would be beneficial or necessary.

Online Form Additional Questions

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

(•) Yes ( ) No

Please specify why?

Please refer to responses to "Proposal 3: Consultation Paper Questions", paragraph 1

2. **If the proposed sponsors' premises and activity inspection comes into force, do you foresee any benefit to yourself or your organisation?**

(•) Yes ( ) No ( ) Not sure

Please specify

We would have greater assurance that medical devices are being manufactured and produced at the high standards expected and required.

3. **How would you use the information that the proposed sponsors' premises and activity inspection might gather?**

We suspect we would not use the information gathered directly but rather use the TGAs (and Industry's) response to the inspections as part of the aggregate data available to make decisions about the use of medical devices. For example if an inspection found the manufacturing was compliant and appropriate, consumers would have assurance the devices from this sponsor would work as intended. Conversely if an inspection revealed non-compliance, that should lead to consumers and healthcare professionals who were potentially affected with substandard devices being notified and provided with resources to assist in reassessing their devices safety and efficacy.

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

Broadly speaking we think it is important for a 'carrot and stick' approach to be used. While we would defer to Sponsors to advise what the appropriate 'carrots' are, we would strongly suggest the 'stick' include both significant financial penalties and public reporting of gaps and breaches.

5. **Do you have suggestions for the best ways to educate and promote best practice regulatory compliance among sponsors to ensure consumer safety?**

Please refer to responses to "Proposal 3: Consultation Paper Questions", paragraph 2

Proposal 4:

Consultation Paper Questions

Should the new EU adverse event definitions (as above) be included in the Australian Regulations and/or Guidance documentation? Are there substantial benefits of including definition of these words or are they self-explanatory?

On balance we would recommend adopting the definitions that do not already exist in the Australian Regulations and Guidance Documentation. While we agree that many of these terms are likely quite self-explanatory, we suspect it is a case of "better safe than sorry" to make sure that all parties are using the same definitions and ideas. Otherwise there is chance that differences may emerge that compound and to negative outcomes due to miscommunications.

We note that adopting a definition of 'incident' may lead to a requirement to further refine the regulations and processes as per the difference between an 'incident' and an 'adverse event' and what the different required responses are. Similarly adopting definitions around 'serious adverse event' and 'serious incident' may then require further refinements as to what actions do and don't need to be taken for the different scenarios.

Perhaps related to this, we note significant concern about the surprisingly narrow definition of 'Adverse Event' presented on Page 9 of the Consultation Paper. While we agree all the circumstances listed count as adverse events, we would contend that adverse events are not limited to death and *serious* injury but *any* negative effect caused by a medical device. A device having large amounts of 'minor' negative effects is cumulatively just as problematic as a device having a small number of 'major' negative effects.

We have previously expressed concern about the term 'adverse event' as too narrow and limiting, potentially discouraging consumers from reporting some complications so broadening the terminology and definitions used could have other positive effects in this area.

In a similar vein we would advocate for defining, regulating and requiring reporting of any unintended or unexpected side effects, whether negative or not, as distinct from adverse events. It is as important for consumers and healthcare professionals to be aware of all effects of medical devices, not just intended effects and adverse effects, when deciding if a device is appropriate for a particular situation. So we believe that reporting requirements should be expanded beyond just adverse effects to include unintended side effects.

Online Form Additional Questions

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

(•) Yes ( ) No ( ) Unsure

Please specify why?

Please refer to responses to “Proposal 4: Consultation Paper Questions”.

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

N/A

Proposal 5:

Consultation Paper Questions

Please provide feedback on whether or not the TGA is effectively communicating the issues related to medical devices based on:

- *Availability*
- *Applicability*
- *Accessibility*
- *Useability*

Please provide your suggestions on how the TGA can improve communication about the medical device incident related information to the end users?

There are two key consumer groups who need to know about medical device information including adverse events and adverse event reporting: consumers considering using a medical device and consumers who are already using a medical device. While we support the TGA communication tools currently in use, none of them are really designed to effectively target either of these two groups.

To reach the former group of consumers, the TGA should require the generation and provision of information sheets analogous to the CMI leaflets required for medicines. However these should be provided to consumers *before* they agree to purchase the device unlike current documentation (e.g. PI leaflets and implant cards) so the consumer is able to specifically review the known risks, side effects, adverse events, reporting options etc before committing to a specific device, perhaps in consultation with their health provider.

In addition these information sheets need to be *device-specific*. Sponsors cannot mass produce a general sheet to provide information for multiple devices. Each specific device must have a device-specific information sheet that discusses it specifically.

Lastly these information sheets must go through consumer testing to ensure the information is presented, ordered and highlighted in a way that is consumer friendly and not simply a mechanism for the sponsor or manufacturer to attempt to indemnify themselves from legal repercussions should issues arise.

However we recognise this it not be financially feasible for consumer testing device-specific sheets and would suggest as an acceptable alternative that the TGA mandate a specific template to be followed, along with some exemplars, which are consumer tested for usability and appropriateness. With the additional requirement for device-specific information sheet consumer testing based on to-be-developed criteria e.g. high risk devices, long term implantable devices, devices/sponsors that have multiple adverse events reported leading to regulatory action, proposed information sheets that deviate from the TGA template etc.

To reach the latter group of consumers, the TGA should mandate that the sponsor obtain and maintain a secure directory of contact information for all healthcare professionals who

provide/use and consumer who use/receive their medical devices and be required to directly inform both groups about both adverse event reporting and relevant adverse event reports. This could be linked in with the current TGA project on a medical device unique device identifier (UDI) scheme.

For example Healthcare Providers should be regularly asked/reminded e.g. annually, every six months; to report adverse events or unexpected side effects in the event they had forgotten to in the moment when they occurred. While consumers who receive/use medical devices should be reminded at set intervals after receiving/using a medical device about reporting any adverse events or unexpected side effects e.g. after 30 days, after 6 months, after 12 months, after 5 years etc.

Concurrently when a sponsor becomes aware of an adverse event they should be required to contact the healthcare provider group who have used/provided the specific device when the initial report is lodged to the TGA and then notify both the healthcare provider group and consumer group when the final report is lodged. As well any further follow up required by the TGA.

Online Form Additional Questions

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

○ Yes ◉ No

Please specify why?

While CHF as an organisation is subscribed to the Recall Notification mailing list and is told about individual recalls, we don't feel that we have a good grasp of the overall picture of and general trends within medical device regulation. Such as how many adverse events are reported each year, what the nature/causes of these adverse events are or what the changes, consequences or penalties arising from these adverse events are.

Perhaps some sort of Annual Report detailing these things and other similar information would help paint that larger picture. Similar in concept to the Annual Advertising Compliance Report the TGA produces.

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

Please refer to responses to "Proposal 5: Consultation Paper Questions".

3. **Are you interested in information on issues related to:**

(•) All medical devices ( ) Specific medical devices (e.g. implantable products)

Please specify why?

Potentially both, depending on the context of the question. As an organisation CHF is interested in specific medical devices that result in a high frequency of adverse event reports and/or report of high severity adverse events. But we are also interested in the larger picture issues around medical device regulations in general.

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

( ) At the start of the investigation

( ) After identifying and verifying the cause of issue

( ) After the investigation is complete

( ) When there is a decision on the necessary action to be taken

(•) Other

Please specify why?

It depends on the seriousness of the reported adverse event. The more serious the reported adverse event then the earlier in the process consumers (and the healthcare professionals who provided them the device) should be notified.

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

What the adverse event was, what caused or is suspected of causing or contributing to it, what the consumer should do and why that is the recommended course of action. Potentially what changes the sponsor have implemented and penalties the TGA have applied where they exist.

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

( ) Yes (•) No (please skip to question 11)

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

~~Yes~~ ~~No~~

~~8. How easy was it?~~

	~~Easy~~	~~Somewhat easy~~	~~Neutral~~	~~Somewhat difficult~~	~~Difficult~~
~~To search for the information that you were looking for?~~					
~~To understand the information that you found?~~					

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

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

~~Yes~~ ~~No~~

~~Please specify~~

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

We would suggest the places consumers would search for such information include:

- Google (and to a lesser extent other internet search engines)
- The materials provided with the medical device.
- Healthcare professional who supplied the device and/or regular GP.
- Patient groups.
- Sponsor/Manufacturer website.

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

Yes No (please skip to question 17)

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

~~Yes~~ ~~No~~

~~14. How easy was it?~~

	~~Easy~~	~~Somewhat easy~~	~~Neutral~~	~~Somewhat difficult~~	~~Difficult~~
~~To search for the information that you were looking for?~~					
~~To understand the information that you found?~~					

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

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

~~Yes~~ ~~No~~

~~Please specify~~

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

Please specify

We would suggest the places consumers would search for such information include:

- Google (and to a lesser extent other internet search engines)
- The materials provided with the medical device.
- Healthcare professional who supplied the device and/or regular GP.
- Patient groups.
- Sponsor/Manufacturer website.

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

Yes (please skip to question 23)

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

~~Yes~~ ~~No~~

~~20. How easy was it?~~

	~~Easy~~	~~Somewhat easy~~	~~Neutral~~	~~Somewhat difficult~~	~~Difficult~~
~~To search for the information that you were looking for?~~					
~~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?

Improving the processes for using the TGA website to search, navigate and understand are part of a larger set of known and previously discussed issues about the TGA website. While important to solve they are perhaps beyond the scope of this specific consultation paper submission.

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

Yes No

Please specify

A clearer articulation around what consumers should do if an adverse event is reported for a device they are using or may use in the future and why they should do that specific action.

As well as articulation around what steps have been taken by the sponsor to correct the problem and what, if any, penalties resulted from investigation into the reported adverse event

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

☐ TGA's Facebook page ☐ TGA's LinkedIn page ☐ TGA's Twitter handle

☐ TGA's YouTube account ☐ TGA's Instagram account ☑ Other (please specify)

We would suggest the places consumers would search for such information include:

- Google (and to a lesser extent other internet search engines)
- The materials provided with the medical device.
- Healthcare professional who supplied the device and/or regular GP.
- Patient groups.
- Sponsor/Manufacturer website.

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

We would suggest that the reasons for the choice of preferred platforms relate to the following factors:

- Convenience of access.
- Trustworthiness of source.
- Awareness of the platforms existence.
- Prior recommendation to use that platform from other trusted sources of information.
- Clarity of the information provided for a non-expert audience

Online Form Summary Section

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

At this stage we are unaware of any potential unintended, negative consequences that may arise from these changes.