Response ID BHLF-TKS9-WDQU-C

Submitted to Consultation: Improved sharing of information about medical devices | Proposed amendments relating to transparency of disruptions to supply of a medical device
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Introduction

About you

What is your name?:
Carlo Krikowa

What is your email address?:
[redacted]

Are you responding as an individual or on behalf of an organisation?

I am responding on behalf of an organisation. This means I am authorised by the organisation to convey its views, and I am only providing those views in the response.

If you are responding on behalf of an organisation, what is the name of the organisation that you represent?

Please enter your organisation name:

Select one (or more if applicable) of the stakeholder groups that best describes you or your organisation:

Consumer peak body or consumer or patient

Specify 'Other' in the box below:

Privacy and Personal Information

I CONSENT: I am okay for my response, name and organisation's name to be published.

Have you provided consent but there are particular questions you don't want us to publish?:

The TGA is aware that Artificial Intelligence (AI) may be used to assist in preparing responses to this consultation. It is a respondent's responsibility to ensure the accuracy of their response.

I acknowledge that I am responsible for reviewing and confirming the accuracy and completeness of my submission, accepting full responsibility for its content. I may have used AI in preparing my response; where AI has been used, I confirm that the content has been reviewed and confirmed by me.

Questions 1 and 2

1 Do you agree that the TGA should release information about medical devices for the purpose of managing shortages or disruptions to supply?

Yes

a. Please explain your answer (optional):

Yes, the TGA should release information regarding the management of medical devices for the purpose of managing shortages or disruptions to supply.
The Collaborative strongly supports this release where transparency across all details regarding medical devices is integral to the consumer's timely access to relevant services to support them. This is particularly important for multicultural communities who already face difficulties accessing appropriate health services and are generally not engaged in traditional communication pathways. Release of this information will remove one hurdle these communities typically need to bypass to otherwise reach these updates. However, the release of this information does not guarantee it will be accurately interpreted by the public. For multicultural communities, the language barrier to understanding content that is not provided in-language is another barrier faced by this population. Engaging with multicultural community representatives to develop these resources in-language ensures messaging is culturally appropriate, and that the information conveyed will have the desired outcome and reach the target audience.
Recommendation 1: Release information and resources that have culturally appropriate messaging and have been translated to be made available in-language across different languages and dialects.

2 Should the information be released publicly or be limited to specific stakeholders only?

Yes

a. Please explain your answer (optional):

Information should be released both publicly and to relevant stakeholders. Transparency only supports the move towards improving health outcomes for all consumers. Notably, the release of information to the public alone does not guarantee they are aware of where to access this resource, or that it exists. Specific stakeholders will be able to support more awareness of this information and facilitate more streamlined communication to specific populations of interest.
Alongside the listed stakeholders the TGA may include, the Collaborative along with other multicultural peak organisations, should be on included. Many multicultural Australians rely on community organisations to access health-related news and updates. Where the status of a medical device shortage can also and often does change quickly or further unanticipated disruptions could occur, prompt communication of these updates is imperative. By sharing information directly with multicultural peak bodies, multicultural health services, non-governmental organisations serving CALD communities, and other primary care networks known to support these communities, communication of this information will be streamlined and effective.
The TGA's intentional inclusion of these organisations as part of the specific stakeholders they share this information will also help mitigate the adverse health outcomes often experienced by this population following delayed access to support.
Recommendation 2: Make the information both available to the public and share it to specific stakeholders that should include multicultural peak bodies, multicultural health services, non-governmental organisations serving CALD communities, and other relevant primary care networks.

Questions 3 and 4

3 If we do not make information about disruptions to supply of a medical device publicly available, do you agree that information about supply disruptions should be released to the stakeholders outlined above?

Yes

a. Please explain your answer (optional) :

Yes, information about supply disruptions should be released to the stakeholders noted above. Alongside those listed, the Collaborative also strongly recommends the inclusion of multicultural organisations as part of these stakeholders. Many multicultural Australians rely on community organisations to access health-related news and updates. Further, here the status of a medical device shortage can and often does change quickly or further unanticipated disruptions could occur, prompt communication of these updates is imperative. By having targeted sharing to multicultural peak bodies, multicultural health services, non-governmental organisations serving CALD communities, and other primary care networks known to support these communities, communication of this information will be streamlined.

4 Do you have any concerns regarding the proposal for releasing information about disruptions to supply for a medical device?

Yes

a. Please explain your answer (optional):

Yes. The Collaborative acknowledges the importance of having publicly available and non-public information to systematically manage the impact of the device disruption, and in some cases to limit public panic in response to a disruption. However, we believe the current items listed as information that may not be publicly available should be. There already exists distrust between multicultural communities and the healthcare system, directly contributing to poorer health outcomes. Transparency across all known details surrounding the shortage will build this trust, critical for the uptake of health services and other health-related information.
In particular, information around the nature of the shortage, anticipated dates for the disruption, and information about the availability of alternatives are details that should not be withheld from the public. Where multicultural communities already experience delayed access to care and services through access barriers within the health system, providing insight that can prepare these populations ahead of time will support their timely response to the shortage when it occurs.
Alongside the information proposed to be released, the Collaborative also recommends the inclusion of an impact assessment as part of information made available to both the public and the stakeholder. Whilst there is no legislated requirement for sponsors to report potential medical device supply disruptions, sponsors should be compelled by the TGA to conduct an impact survey, like the one currently mandated for medicine shortages, where the results should then also be shared as part of the information release. The impact survey should consider the nature and size of the population affected by the shortage.
When disruptions occur in localised areas, the TGA should release their own assessment of whether certain multicultural communities that most commonly reside in these areas may also be disproportionately affected by this disruption (See Example 1.). From here, specific implications for access for these communities should be included, addressing the cost, availability, and accessibility of alternatives and clear next steps for consumers to reach these alternatives or express enquiries. Targeted advice for community health providers should also be highlighted, with suggestions for culturally appropriate care pathways and any further resources they are able to disseminate to their communities directly.
Example 1. There is a higher prevalence of South Asian immigrants in Australia who have been diagnosed with Type 2 diabetes, suggesting this population likely requires more blood glucose monitoring devices, such as CGMS, and insulin injection devices (Tan et al., 2023). In the scenario of a shortage of such medical devices localised to places near or in areas that have a higher South Asian population, the TGA should closely consider this impact as part of what is to be released. To strengthen the usability of all content being released across diverse populations, engaging multicultural representatives during the drafting process of this information and co-designing any adjacent resources from this release will ensure it has the cultural sensitivity required to be useful for communities.
Recommendation 3: Information being released should include all available insight from sponsors (cause, solution, and timelines), equity impact considerations, implications for access for affected populations, and targeted advice for community health

providers. This information should be made available to both the stakeholder and the public.

Questions 5, 6 and 7

5 Do you agree it is appropriate for the TGA to release the information identified above in the event of a disruption to supply of a medical device?

Yes

a. Please explain your answer (optional):

Yes, it is appropriate for the TGA to release the information identified above in the event of a disruption to supply of a medical device. However, as previously mentioned, this should not be limited to what has been listed but also include the items that are currently listed, as well as those recommended by the Collaborative

6 Should sponsors of medical devices impacted by disruption to supply be provided with a notice of intent and offered an opportunity to comment on the release of the information?

Yes

a. Please explain your answer (optional):

Sponsors should be notified of the information before it is released and given the opportunity to also comment on it only where their comments continue to maintain transparency surrounding the medical device shortage/disruption. Here, sponsors should be upfront with all known details of the shortage/disruption, minimising the need for constant changes of this information and risk of inconsistencies. However, given the importance of having the most up-to-date information available, ad hoc comments provided by sponsors to stay current should be allowed and encouraged. Whether a sponsor's comments are included and thought to be in the interest of the public's health should be up to the TGA's discretion, prioritising timely communication with the public.

Recommendation 4: Sponsors should be given the opportunity to comment where their input maintains transparency, is in the interest of public health, and provides additional up-to-date insight on the status of the disruption. The decision to includes these comments should remain the discretion of the TGA.

7 Please provide any further feedback or comments you have regarding proposals to collect and share information about disruption to supply of a medical device.

Please provide any further feedback in this field.:

Strategy 1: Improve how new devices get on the market
The Collaborative supports the TGA strengthening its assessment process on how medical devices are approved for use in Australia through public consultation. To add rigour to this assessment, we recommend direct consultations with multicultural communities and peak bodies representing these populations to understand how user experiences across these devices differ between populations. Including these representatives on the specialist unit and as part of the TGA's medical device review team whilst also building the cultural competency of those currently a part of the review team will equip the experts with the ability to engage in more meaningful decision-making.
Ensuring medical devices are accessible to multicultural communities is integral to improve patient safety widely, which calls for devices that are designed with and for communities. When medical devices lack multicultural representation in the process of clinical testing, participants across a range of physical characteristics are not accounted for which risks the use of these devices furthering health disparities (see Example 2.). The Collaborative recommends consideration of localised design and testing of new devices alongside diverse participant recruitment to mitigate this risk. Where it is not always feasible to recruit diverse participants due to budget and time constraints, partnerships with community groups will assist with these logistical barriers.
Example 2. Pulse oximeters, a medical device measuring oxygen saturation, have been found to report higher values of oxygen saturation in individuals with pigmented skin compared to those with less pigmented skin, such inaccurate readings having severe implications for those with darker skin where low blood oxygen levels are likelier to be missed (Crooks et al., 2022).
Strategy 2: Strengthen the monitoring and follow-up of devices already in use
The Action Plan rightly acknowledges the importance of developing accessible formats for consumers to report adverse experiences with their medical devices. Where the TGA is working closely with health consumer organisations and healthcare facilities, the Collaborative recommends also working directly with relevant multicultural health organisations to develop these new methods. This requires ensuring there are community representatives on these working groups and consumer groups. The inclusion of perspectives and expertise from those connected to our Australian multicultural communities will guide resources informed by lived experiences and ensure a user experience that is appropriate for all consumers.
For the development of the education programs on rapid information sharing, consulting with community representatives and bicultural navigators to ensure these programs also build the cultural competency of the healthcare professionals and hospital workforce to be able to take a culturally informed approach to reporting that is in public interest.
As part of the move towards greater data analysis and information sharing, the Collaborative also calls for the collection of ethnicity and language fields within these reports filed from healthcare professionals and hospitals. This will begin to build critical insight into the types of medical devices being used by which ethnic groups and support the monitoring of access to healthcare services from these populations.
Strategy 3: Provide more information to patients about the devices they use
The TGA's proposal to co-design strategies raising awareness about the safety of medical devices is closely aligned with the

Collaborative's commitment to equity in healthcare. However, the Collaborative recommends including multicultural community representatives and bicultural navigators as part of the consumer and advocacy groups working on the development of these strategies (see Example 3.). Direct consultations with these representatives from inception and at every stage that follows up until its delivery will centre the voices of those who are already experiencing difficulties accessing health-related information. By co□designing with these communities, co-designed resources informed directly by their input will also support its uptake.

Example 3. As part of a Bicultural Navigator Pilot in Sydney, general practices that employed bicultural navigators to support their patients demonstrated improved communication, trust, and system navigation. These demonstrate the successful outcomes regarding consumer engagement with the health system that bicultural navigators can achieve, relevant for the sustained uptake of the new resources regarding medical devices.

The Collaborative supports the TGA's commitment to creating consumer friendly documents that are accessible to non-expert audiences but notes the need for translation beyond only plain English. Translations of these documents to multiple different languages and formats that have been culturally adapted and co-designed with communities to ensure the accurate delivery of content.

Notably, the Collaborative supports the TGA's proposal to establish expert working groups with consumer representation. Here, we strongly recommend the establishment of an expert working group specifically for multicultural consumer representation. This working group will facilitate more timely communications with multicultural communities that are already often difficult to reach and directly access their input. Where it is known certain ethnic populations have higher prevalence rates of particular health issues, lending itself to the increased use of particular medical devices, having these expert groups to provide focused feedback on these devices will contribute significantly to improved health outcomes for this population (See Example 1.)