Consultation submission cover sheet

This form accompanies a submission on:

Proposal paper 'Changes to premarket assessment requirements of medical devices'	
Name and designation	Sally Crossing AM
Company/organisation name and address	Cancer Voices Australia
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I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*	☐ Yes ☒ No
I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.	☐ Yes ☒ No

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: *(tick all that apply)*

Business in the therapeutics industry *(please tick sector):*

☐ Prescription medicines ☐ Complementary medicines ☐ OTC medicines

☐ Medical devices ☐ Blood, tissues, biological ☐ Other

☐ Sole trader ☐ Business with employees

☐ Importer ☐ Manufacturer ☐ Supplier ☐ Industry organisation

☐ Government ☐ Researcher ☐ Professional body

☒ Consumer organisation ☐ Institution (e.g. university, hospital)

☐ Regulatory affairs consultant ☐ Laboratory professional

☐ Health professional – *please indicate type of practice*:

☐ Other - *please specify*:

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Dear Sir / Madam

Changes to premarket assessment requirements for medical devices

Cancer Voices Australia wishes to provide consumer comment on aspects of the TGA's proposals for changes to premarket assessment requirements for medical devices.

Cancer Voices Australia is the independent, 100% volunteer voice of people affected by cancer, working to improve the cancer experience for Australians, their families and friends. We are active in the areas around diagnosis, information, treatment, research, support, care, survivorship and policy. To achieve this we work with decision-makers, ensuring the patient perspective is heard.

Cancer Voices has led the cancer consumer movement in Australia since 2000. Cancer Voices organisations across Australia share the same objectives and work together on national issues identified as important by their members, with consumers working to help others affected by cancer.

General

Cancer Voices is aware that the current arrangements around TGA approvals in the pre-market situation do not protect the consumer as well as the community expects. For example, currently there are no requirements that low risk devices show the potential purchaser any evidence that they are either safe or effective. We support any proposals to improve this situation.

Meaning of "low risk"

In relation to the aim to "refine a risk-based approach to regulation", while we support the general principle, we recommend that a fuller discussion is undertaken about the meaning of "low risk".
We also ask that the TGA notes our concern about the definition or understanding of the category "low risk'.

What may appear to have no immediate physical consequences for the consumer purchasing the product, may well have very serious consequences relating to their decision-making about major interventions and indeed their psychological quality of life. An obvious example is the use of so-called breast dancer diagnostic devices and the impact of a positive "result" – this could have a huge impact of that person who may now falsely believe she has breast cancer. We understand that devices lie this can be marketed without a review of either their performance or performance related safety. Diagnosing cancer is a complex technical undertaking – to allow it to be seen otherwise would be see by the community as misleading.

Other regulatory reforms

Cancer Voices supports proposals that allow:

- Australian companies which manufacture low risk devices to be certified by a recognised, probably international third party – eg European Conformity. We agree that this process must include certification of third party assessment bodies

- All models or variation of a device should be registered to ensure safety of use, and to remove confusion as to exactly what is registered and what is not.

- Agree that devices approved by the TGA must show their ARTG entry number on the information that accompanies the device.

- Medical device regulatory decisions should be published.

- We strongly support more product information being required to be published on the TGA website, as suggested in Proposal 4, in order that more informed decisions may be made by the purchaser of the device about its safety and efficacy.

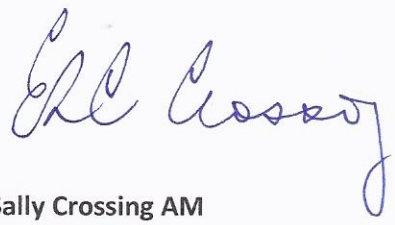
Pre marketing assessment in the public interest

Cancer Voices would like to see much greater rigour in the pre marketing assessment of medical devices, and indeed of complementary and OTC medicines. We believe this is a responsibility of Government, and while we appreciate that the TGA must currently work on a revenue neutral basis by ensuring manufacturers and marketers contribute to the cost of their products' assessment, that this principle should be re-examined in the public interest.

At a minimum, proponents of all products and devices seeking pre-market approval should be required to demonstrate that their products are both safe and effective. We would like to see a system which used recognised standards of evidence in its assessment of safety and efficacy. Using comparators like "low risk', without evidence does not cut it for protecting the public interest – a role we think is intrinsic for a government agency.

Thankyou for the opportunity to contribute to this consultation process. We very much appreciate that the TGA is interested in hearing the informed consumer view.

Yours sincerely



Sally Crossing AM
Executive Committee
12 February 2013