



Consumers Health  
Forum OF Australia

SUBMISSION

ALIGNMENT WITH EUROPEAN  
MEDICAL DEVICE REGULATORY  
FRAMEWORK

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Consumers Health  
Forum of Australia  
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device regulatory  
framework*)

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# Introduction

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The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. It works in the public interest to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF welcomed the Review of Medicines and Medical Device Regulation. Consumers constantly raise with us their concerns about safety and quality of medicines and medical devices often giving us examples of when the system has either failed or its response has been less than optimal. We have heard some disturbing stories of misadventure involving implanted devices that have resulted in poor quality of life and other significant impacts for people and their families. For many people, this is what leads them to be active consumers as they see the need for systemic change and want to be part of that change.

We are also aware of many instances where the system's checks and balances have worked very well, and many consumers acknowledge that the existing regulatory framework, despite the room for improvement, has delivered peace of mind for many Australians when they take a medicine or use a medical device.

CHF accepts the need for there to be a balance between protecting the consumer and reducing the burden of regulation. However, throughout this process, CHF has maintained the key principle that any reforms to the regulations must:

- ensure Australians have access to medicines and medical devices that are of high quality and safe: and
- increase consumer confidence in the regulatory system.

We supported the first tranche of legislative changes as we believed they were consistent with those principles.

We supported Recommendation 20 to align our regulatory framework for medical devices and welcome the opportunity to comment on the areas covered by this consultation paper: *Alignment with European medical device regulatory framework: Up-classification of surgical mesh & Patient implant cards*. It is important that regulation is commensurate with risk.

Much of the evidence presented to the current Senate Inquiry into the number of women with transvaginal mesh implants has highlighted some issues around the existing regulation of surgical mesh. It also shows many consumers have lost confidence in the current regulatory approach. There is clearly a need for some immediate action to raise the standard of assessment for all surgical mesh to better recognise the level of risk associated with what is often a permanently implanted device. The evidence given by many women to that inquiry and to the survey conducted by the Health Issues Centre<sup>1</sup> also highlights the need for better patient information about the devices and some way of tracking when and where they are used.

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<sup>1</sup> Health Issues Centre (2017) IC Submission to Senate Inquiry into Number of women with transvaginal mesh implants and related matters (Submission 115)

## Issues

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### Up-classification of surgical meshes

CHF supports the move to make all synthetic surgical meshes Class **III** devices as we believe this better reflects the risks associated with using them. This has been recognised in the European Union (EU) which has moved to up-schedule surgical mesh. Bringing Australia into line with the EU should make it easier for manufacturers who supply cross the two markets. We are pleased that it will be all meshes and not restricted to those used for transvaginal implants as we know from the stories supplied to HIC and as highlighted in the combined health council's<sup>2</sup> submission to the Senate Inquiry they were approached by people reporting problems with mesh used for other purposes.

We believe the up-scheduling will help restore some confidence amongst consumers in the assessment process to ensure they are safe to use.

We support the move to transfer all mesh applications under way at the time of the rule change to Class III applications. This is important in terms of consumer confidence and is a clear signal that things have changed.

CHF has some concerns about the three year transition period as it allows manufacturers to continue to supply meshes which have been assessed as Class IIb which is now recognised as inadequate in terms of risk for these products. Ideally, in the interests of maximising consumer protection, all Class IIb meshes should be taken off the market until they have undergone reassessment to meet Class III standards. However, if this is not considered feasible as it does not match the European approach, there needs to be some clear warnings given to consumers now that the product is a Class IIb with an explanation that clearly shows this is lower level of assessment. There needs to be some standardised words developed by the TGA in collaboration with CHF to ensure they are consumer friendly and appropriately framed to take into account the varying levels of health literacy across the Australian population. This information must include the option for the consumer to wait until a Class III product is available.

We are concerned that marketing applications will continue under Class IIb throughout the transitional period. Given the problems with some of the meshes and the fact that this issue is urgent enough to come forward first in the response to recommendation 20 then this seems an inadequate approach as it effectively gives the manufacturer three years of supplying without the desired level of assessment. It would need to have the same caveat as above with manufacturers making it clear the product is assessed as Class IIb rather than Class III and what that means.

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<sup>2</sup> Health Councils Across Australia (2017) Submission to Senate Inquiry into number of women with transvaginal mesh implants and related matters Submission 21

Without the caveats for both groups of products there will be confusion amongst consumers and they will not be giving informed consent to the use of the products as they will be missing a vital piece of information.

## Patient implant cards

CHF supports the proposal to make it mandatory to have patient cards and information leaflets for all implantable devices and to have clear process for this information to be made available to consumers. We are particularly pleased that this requirement is not just confined to meshes but would apply to all implantable and long-term surgically invasive devices.

The device card information needs to be given to both the consumer and held by the provider and manufacturer to assist with contact if problems arise with the device over time. The transvaginal mesh implant inquiry and follow up work has been hindered by no one having a good idea about the number of women involved; either the number who had had this time of implant or the number who might be suffering adverse consequences. CHF supported the call for a mesh registry and believes the introduction of device ID cards is a precondition for such a registry.

There needs to be a public awareness campaign of the change and consumer organisations could play a key role in raising awareness of the device ID card and encouraging them to ask for it. Its existence should be on the patient checklist that they receive before having the device implanted so both consumers and service providers are constantly prompted to provide it.

The information identified in the new European regulations would meet consumers needs and give them a much better understanding of the device which has been implanted. However, we know from the experience with Consumer Medicines Information that we need to look at both the content of the information and how consumers access it if it is indeed going to help them understand. Medicines Australia is facilitating a conversation about ways to redesign the CMI to improve its readability and how to improve consumer access to CMI. It would be useful for TGA to have some discussion with them about this as it could help inform this work.

The development of the information needs to be co-designed with consumers to ensure it is understandable and does indeed give them what they feel they need to make an informed decision about having the device implanted and the alternatives, if any exist. At the outset it would be useful to speak with some of the women who had had transvaginal mesh implants to gain a good understanding of what they see as the deficiencies in the information they were given. The information needs to be relevant, outlining what has been implanted and possible side effects. It is important that not too much information is given as people need to be able to find what they are looking for. It should not replace the conversation between the doctor and the consumer but rather be an aid to that conversation both pre and post implant.

Just having an information leaflet achieves little unless someone takes responsibility for making sure the patient is aware of it and has understood it sufficiently enough to act on the information. CHF would be pleased to be involved as advisers as the communications strategy is developed.

Most importantly the information needs to be given to people before having the device implanted. We support the information being web based as this allows for it to be updated as new evidence on side effects or changes to the possible use of the device become available. The health professional should either give them a printed copy or ensure they know exactly how to access it from the TGA website or the manufacturers website.

There needs to be an opportunity for them to discuss with the health professional recommending the use of the device any issues / questions they might have. This is part of informed consent and the leaflet needs to assist with the process. The TGA needs to work with the clinical colleges to ensure giving out the information leaflet is understood to be part of the consultation and an integral part of their practice.

In our submission to the Senate Inquiry into transvaginal mesh implants CHF flagged the possibility of devices having a scheme like the black triangle warning on medicines. Such a marker would alert doctors and patients that the device is higher risk, either because it is new or because there is a suspicion of problems. The introduction of device information leaflet would provide an excellent place for such a marker. This would bring additional post market surveillance into play and would improve the chances of picking up problems earlier.

As with the up-scheduling CHF has some concerns about the three year transition process as the problem is immediate and consumers need better information now. These devices are high risk and can impact, positively and negatively, on people's and well-being. We need to try to speed up the process for newly listed and newly manufactured devices.

## Conclusion

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Overall CHF welcomes the move to improve information for consumers about medical devices and believes the package outlined in the TGA's discussion paper concerning alignment with EU regulations along with our recommendations herein will achieve that. We would emphasise the need to involve consumers in the design of information and education packages as this would ensure they meet consumers needs and so have a greater chance of being read and understood. The package of measures should increase consumer confidence in the regulation and marketing of medical devices.