Consumers Health Forum of Australia

SUBMISSION

SENATE INQUIRY INTO THERAPEUTIC GOODS AMENDMENT (2016 MEASURES No. 1) BILL 2016

MARCH 2017

Consumers Health Forum of Australia (2017)
Submission to Senate Inquiry into Therapeutic Goods Amendment (2016 Measures No.1) Bill 2016. Canberra, Australia

P: 02 6273 5444
E: info@chf.org.au

twitter.com/CHFofAustralia
facebook.com/CHFofAustralia

Office Address
7B/17 Napier Close,
Deakin ACT 2600

Postal Address
PO Box 73
Deakin West ACT 2600

Consumers Health Forum of Australia is funded by the Australian Government as the peak healthcare consumer organisation under the

CONTENTS

Contents

Introduction

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. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems, CHF has a strong interest in the regulatory framework for medicines and medical devices as this is a key component in ensuring that Australian consumers can have confidence that the medicines and medical devices they use are safe and fit for purpose.

CHF welcomed the Expert Review of the regulatory framework chaired by Professor Lloyd Sansom (the Review) and has been an active participant through the review process. We contributed submissions to the Review and participated in consumer consultations with the Expert Panel to help shape their thinking. We participated in a number of the consultations undertaken by the Department of Health after the review released its reports and have been involved in some of the stakeholder conversations around the implementation issues.

We welcome this legislation coming forward as we believe many of the reforms covered by the review are overdue. This Bill set the groundwork for us to modernise the way we regulate medicines and medical devices and ensure that consumers can have the confidence to use them.

Whilst we do provide some comments on the key issues covered in the legislation we think it is important that they are looked at as a package. In particular we draw the Committee's attention to the reforms to strengthen post-marketing activity which were a key theme in our Submission to the initial review. The move to improve adverse event reporting and have more post market monitoring and surveillance is critical to ensuring the integrity of the system. The reforms to this component of the regulators work cannot be overemphasised from a consumer confidence perspective and without this many of the other proposed reforms would not be acceptable.

Issues

New pathways for approval of medicines and medical devices

We support the establishment of new pathways for the approval of new medicines and medical devices. We know that many patient groups have been frustrated by the length of time to get medicines approved and we support measures to speed the process up as they will improve access to innovate medicines. The measure suggested here balances speeding the process up with keeping high standards for safety/quality and efficacy

We support the move to introduce priority approvals for medicines and medical device because we believe that the standards of evidence for this assessment will be the same as for the normal pathway and so there will be sufficient checks on safety/quality and efficacy or performance to give consumers the confidence they need.

Variations to medicines through notification

This seems a common sense reform that if implemented would free TGA resources up to work on assessments of new and innovative medicines. We think the TGA should be given the authority to take a risk management approach. The strengthening of post marketing activities will be important here to help pick up any safety issues which might arise and deal with them.

Enabling Australian 'notified bodies' to undertake conformity assessment of medical devices

In our submission to the Review we did not support the move to using an overseas regulator and expressed some concerns with the idea of TGA outsourcing some of the assessments of medicines and medical devices. The Review recommended provision is made for conformity of medical devices by private bodies i.e. third party conformity assessment.

From a consumer perspective it is important that the designation of such third parties be a transparent process with a well- constructed set of criteria that they have to meet before being allowed to take on this role. For consumers to have confidence in such a process there would need to be a robust monitoring system that included spot checking so the TGA can see how the information used to inform the assessment and can query it or ask for more if they think it is deficient

We think such third party assessments are probably more useful for lower risk medical devices and probably not for the higher risk implantable devices and would like to see this reflected in the regulations for third party assessors.

Our support for a move to a limited third party conformity assessment regime is contingent on the improvements to the post marketing arrangements as covered later in the Bill.

Enabling health practitioners to supply certain therapeutic goods not on the Register to patients under a notification scheme

CHF supports this in principle as it is consistent with the idea of improving access to a broader range of therapeutic goods. However we have a number of concerns ns that will need to be addressed when the legislative instrument is developed.

It is important that this only be used for therapeutic goods that ware deemed low risk and sufficient safeguards put in place to ensure it does not become a back door to Australia n consumers. The notion of safe use in other countries needs to be tested and the countries identified as having robust regulatory framework with sufficient post market monitoring to have confidence that any problems would have become known and be documented.

It is also important that the legislative instrument includes a requirement that consumers be told that the good is not on the register. Compliance with the 28 day rule for notification will also need to be monitored.

Strengthening Post-Marketing Activity

CHF supports all the measures to strengthen post marketing activity as outlined in the Bill and sees them as probably the most important part of the reform package as presented.

In consultations with consumers this is the issue which comes up most often. People have expressed concerns that the focus has been too much on rushing medicines and medical devices to market and not enough consideration has been given to monitoring them for safety and quality when they move out of a trial environment into a population wide application. Whilst most people appreciate it is a balancing act between improving access and ensuring safety and quality there are many consumers who feel the pendulum has swung too far in favour of access

There needs to be an evaluation of the new post- market measures built into the process to assess impact, particularly as consumers want to see what impact if any they have.

Conclusion

Overall CHF supports the provisions of the Bill and recommends that the Committee support the legislation. It is clear that exactly how some of these measures are implemented will depend on the regulations and legislative instruments that will be developed. CHF is looking forward to working with TGA on the development of these measures to ensure consumers views are incorporated