Submission to the

Review of Medicines and Medical Devices Regulation

January 2015

Introduction

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

CHF welcomes the opportunity to provide a submission to the Review of Medicines and Medical Devices Regulation. CHF considers this review to be of critical importance to every Australian health consumer. Consumers consistently raise with us their concerns about the safety and quality of medicines, giving details of personal experiences of when the safety regime has failed them. With this in mind, CHF strongly believes that the safety and quality of therapeutic goods in Australia should be the ultimate goal of this regulatory framework.

CHF has expressed disappointment that there was no consumer representative on the Expert Panel conducting that review. CHF is also disappointed that the Minister did not appoint a consumer advisory group to work with the Panel.

CHF welcomes the Review Panel's focus on identifying opportunities to improve the regulatory framework. CHF stresses that such enhancements must include initiatives which increase consumer confidence in the regulatory system, as well as positioning Australia to take advantages of global developments. We understand the Federal Government is looking to the review to identify unnecessary, duplicative or ineffective regulation as part of a broader government agenda to reduce red tape and ensure regulations do not constrain industry. We also acknowledge that medicine and medical device regulations play an important first step for many products, which proceed from regulatory approval to public subsidy, and as such, this regulatory regime cannot be considered in complete isolation from the broader objectives of the National Medicines Policy.

A major concern is that the reporting requirements for the Review do not include a requirement to report on the impact of any proposed changes on consumer and public safety. CHF is also concerned that the Review Discussion Paper's chapter on *Environmental Factors* focusses almost exclusively on industry and international competitiveness, with almost no mention of safety and quality issues. In particular, there is no inclusion of data on adverse events and consumer reporting to enable a holistic understanding of problems with the current system. This is a serious deficiency of the paper. CHF strongly recommends that the Expert Panel ensure consumer safety is given a much higher prominence in its final report and recommendations.

This Submission considers the principles that underpin the Review and outlines why CHF believes there needs to be a robust Australian regulator, identifies current weaknesses and how the functioning of the Therapeutic Goods Administration (TGA) could be improved to give consumers more confidence in therapeutic products available in Australia. The Review Discussion Paper discusses in detail how the approvals process could be streamlined, in particular considering how the use of a trusted overseas regulator could achieve this. CHF makes suggestions about this proposal, noting that there will always need to be an Australian regulator to safeguard consumer safety and the quality of medicines and medical devices. Given its current self-funded nature, the Review must also give consideration to how an Australian regulator will be funded, in an environment of significantly reduced application fees under the proposed trusted regulator regime.

Finally, this submission considers each of the groups of therapeutic goods, responding to questions raised in the Discussion Paper. We have confined our comments to the areas addressing consumer concerns and have not addressed issues we consider procedural or technical.

Issues

Principles Underpinning the Review

The Discussion Paper identified five key principles to underpin the Review:

- The role of regulation is to manage risk in order to protect public health and safety;
- The level of regulation should be commensurate with the risk posed by the regulated products;
- A risk-benefits approach to the regulation of therapeutic goods is appropriate;
- The regulation of therapeutic goods should take a whole of lifecycle approach; and
- The ultimate responsibility for medicines and medical devices regulation should remain with the Commonwealth.

CHF and its members agree that these are core areas for consideration, although we disagree with some of the conclusions the Discussion Paper has drawn from them. Our submission is informed by our approach to these core principles as well as additional areas of concern which we believe should inform this Review.

First we will look at the principles which we believe ought to be reconsidered by the Review.

The role of regulation is to manage risk in order to protect public health and safety

While we agree that managing risk is a part of regulation, the ultimate purpose of any regulatory scheme should be two-fold: To protect public health and safety *and* to provide consumers with confidence in the products they use to manage their health. It would not be appropriate to view regulations through the lens of whether they properly balance the risks they are attempting to mitigate, but rather whether there is a risk that needs to be mitigated in the first place that warrants regulating.

A risk-benefits approach to the regulation of therapeutic goods is appropriate

A risk-benefits approach *can* be appropriate in certain cases, but even this requires evaluation of the appropriateness of the product in treating the desired condition. The risk-benefits model should not be used as a way to evaluate the efficacy of a product "on the cheap" in order to rush it to market.

The regulation of therapeutic goods should take a whole of lifecycle approach

CHF agrees with this principle, which is why we are disappointed that the Review's Terms of Reference restricts a complete and thorough discussion of the impacts of regulatory change. CHF has abided by the Terms of Reference, and makes no comment about the impact of the Discussion Paper's proposals on the Pharmaceutical Benefits Scheme or reimbursement systems. However, CHF stresses that it will be imperative for the Review, in its final recommendations, to explain how

any changes it proposes might affect the processes by which medicines and medical devices are approved for public subsidy by the Pharmaceutical Benefits Advisory Committee (PBAC), Medical Services Advisory Committee (MSAC), Prostheses List Advisory Committee (PLAC) and other stakeholders.

The ultimate responsibility for medicines and medical devices regulation should remain with the Commonwealth of Australia

CHF strongly agrees with this principle. It is essential that the Federal Government maintains a strong regulatory system to ensure the safety of medical devices, and to provide the capacity to address any issues quickly as they arise, given that Australian consumers stand to suffer the consequences of poor regulation. This is particularly the case for medical devices that are implanted into the body. In these circumstances, it is mostly not a straightforward matter to remove the device if something goes wrong. It requires traumatic, invasive revision surgery that puts the consumer's health, and sometimes their life, at risk.

It is unclear how the Federal Government will implement this principle when the Discussion Paper and the Review appear to pin much of the future of medicine and medical device regulation on the work of "trusted overseas regulators."

There is both a value and need to maintain substantive consumer and stakeholder consultation in reviewing the safety, quality and efficacy of medicines and medical devices

Whatever course the Review's recommendations take, it is imperative that they not diminish the role or capacity for consumers and other stakeholders to provide input to the process by which medicines and medical devices are approved for use in Australia. Reliance on trusted overseas regulators and accelerated approval processes should not outweigh the opinions and assessments of the Australian community – especially the consumers who would have to live with any adverse conditions which result from the use of medicines and medical devices. We also believe that such involvement should extend to the processes of 'trusted overseas regulators'.

CHF has consistently argued that consumers need to be involved in all of TGA's advisory mechanisms on entirely the same basis as other stakeholders. Furthermore, for this involvement to be more than tokenistic we have argued that there should always be two consumers on key committees so they can support each other and offer greater breadth and depth of experience.

Australia needs to maintain the capacity to conduct independent assessments should the reliance on trusted overseas regulators or other mechanisms fail

Australia must maintain a robust and responsive capacity to conduct independent assessments. The TGA currently recovers the full costs of its regulatory activities through fees and charges imposed on sponsors and manufacturers of therapeutic products. It should be assumed that in the move towards trusted overseas regulators that costs recovered from sponsors of medicines would decrease, as the role of the Australian regulator would be reduced. However, and in keeping with the principle that the Commonwealth of Australia should have the ultimate responsibility for the regulation of medicines and medical devices, there ought to be a mechanism – if not dedicated public funding – to ensure that the Australian regulator maintains the capacity and expertise needed to continue its function of ensuring the safety, quality and efficacy of medicines and

medical devices when necessary. The level of that funding would be determined by the extent and nature of the residual role.

Need for an Australian Regulator

Because it is imperative for the Federal Government to maintain ultimate responsibility for the safety and efficacy of medicines and medical devices, CHF's primary position in relation to the Review is that an Australian therapeutic goods regulator is retained, not necessarily in the current statutory form, and given the resources to effectively maintain its capacity and improve upon its existing work.

An Australian therapeutic goods regulator must have robust pre- and post- market assessment and surveillance strategies, as well as a transparent and accessible mechanism for consumers and medical professionals to report adverse events from medicines and medical devices. Furthermore, the Australian regulator must do more to educate consumers about the regulatory scheme and what it means for regular medicine and medical device consumers in terms of their safety and quality**.** CHF has consistently called for this level of transparency in many government reviews and parliamentary inquiries relating to therapeutic goods regulation.[1]

The value of maintaining an Australian regulator or requiring regulations additional to those required by overseas regulators in markets where a medicine or medical device is already approved, is that it gives Australian consumers the confidence that the Federal Government has, to the maximum extent practicable, taken steps to ensure their safety. It also means that an Australian regulator is able to actively respond to adverse events reporting, retain the competence and ability to undertake audits, post-market surveillance, and process applications for drugs where there has not been previous, agreed upon approval from one or several overseas regulators. This goes to the heart of ensuring the safe use of medicines and medical devices in Australia.

Consumer representatives consulted by CHF in connection with this and other reviews of the TGA have argued strongly that the TGA's response to receiving reports about devices indicating unusual performance is inadequate, and has been for years. The Australian regulator must be resourced and urged to take a more proactive and vigilant approach for post-market surveillance, particularly in light of the relatively low level of reporting of adverse events from clinicians and consumers.

Recently, CHF and TGA have been engaged in the CLEVER project with other stakeholders to explore the improvement of adverse event reporting. However waiting for the outcomes of this project should not preclude steps the TGA can take now to enhance post-market surveillance more broadly in Australia. Adverse event reporting is an important mechanism for signalling potential problems with a recently approved product. In similar countries such as the UK, the free post yellow card system allows doctors to easily report and consumers can report online to yellowcard.mhra.gov.uk. The introduction of such an approach would reassure consumers and clinicians that action is being taken, making them more likely to report adverse events in the future.

[1] These are available on the CHF website at www.chf.org.au

What are the features of an effective post-market surveillance system?

Even with a very good pre-market assessment system in place, therapeutic goods are not truly tested for safety, quality and efficacy until they are in use among the general population. This is because medicines and devices are generally tested in 'perfect' populations e.g. where people don't have co-morbidities or other complicating factors. Having a strong and effective post-market surveillance means that data can be obtained more quickly about the performance of medicines and medical devices and any problems can be addressed appropriately on a nationally consistent basis.

Some features of an effective post-market surveillance system could include:

- Mandatory reporting requirements for doctors/pharmacists to report adverse events. Consumers consulted by CHF argued that current regulations that compel sponsors/manufacturers to report adverse events should be extended to clinicians, particularly as consumers were more likely to report adverse events to their doctor/pharmacist, rather than to the sponsor/manufacturer of their device

- A transparent and accessible mechanism for consumers (such as the UK's Yellow Card system) to report adverse events from medicines and medical devices, as well as ongoing programs and support to increase public awareness of the need to report adverse events

- The ability to collect data about the performance of medicines and medical devices from the national patient data sets collected by Australian hospitals as a condition of public funding. There is the ability to add an Australian Register of Therapeutic Goods (ARTG) number to this data set to provide more information about the kinds of therapeutic goods that are being used and the problems that arise with their use, including revision surgery.

- The establishment of more registries to collect data, for example following the model of the National Joint Replacement Registry (NJRR), which collects data after each joint replacement procedure. Consumer representatives consulted by CHF were concerned that that there was little information or activity to suggest that the two high-risk medical device registers announced in the 2013–14 Budget were underway. CHF had previously welcomed the establishment of the clinical registers for pace makers and breast implants, so that potential faults with devices can be detected more quickly and followed up appropriately.

The role of e-health and the personally controlled electronic health record will also be vital in providing significant opportunities for enhanced adverse event reporting, as well as for consumers and health professionals to work together to routinely monitor the health of a patient who has been the recipient of a medical device or ongoing medicinal treatment.

Trusted Overseas Regulators

The Discussion Paper places considerable emphasis on the idea that TGA move to a position of accepting the outcomes of reviews undertaken by "trusted overseas regulators." This means going beyond adopting other nations' regulatory schemes and effectively permitting other nations' regulators to make decisions about the types of medicines and medical devices which should be made available to Australians.

CHF believes that allowing the Australian regulator to be effectively bypassed in favour of the opinions of overseas regulators contradicts the Discussion Paper's stated key principle that, "The ultimate responsibility for medicines and medical devices regulation should remain with the Commonwealth."

Having said that, CHF appreciates that there may be circumstances where a broad consensus of overseas regulators concerning a medicine or medical device exists or where there is an exigent need to make a medicine or medical device available to certain consumers, that it makes sense to give added weight to overseas regulators in the approval process. In particular, CHF recognises weaknesses with the current pre-market assessment system concerning medical devices (particularly for smaller impacted population groups), and so there may be some advantages in moving towards clearly articulated and well-structured, global harmonisation in some specific circumstances.

CHF proposes the following criteria as a baseline for any possible adoption of a trusted overseas regulator model:

- The overseas regulator is internationally recognised for having robust, independent, transparent and trusted processes in place for the evaluation of medicines and medical devices;
- The overseas regulator has proven and effective mechanisms to involve and consult with consumers, and for the reporting of adverse events;
- The overseas regulator undertakes a similar annual volume of work that is either comparable to or exceeds the volume of work performed by the TGA over a three-year period;
- The overseas regulator has a credible and consistent track record of approving safe and effective medicines and medical devices;
- The overseas regulator has a credible track record of reviewing and recalling unsafe or ineffective medicines and medical devices;
- The overseas regulator has jurisdiction over a population that is comparable to the Australian population in either size or composition; and
- The overseas regulator has similar or more restrictive burdens of proof for the marketing of medicines and medical devices than what presently exists in Australia.

Whatever criteria might be settled on, however, should be enshrined in legislation, and not overlayed on the existing regulatory scheme. The system and criteria should be the subject of robust public and parliamentary discussion.

Existing overseas regulators which might fall into the "trusted" category, depending on the final criteria, include:

- Food and Drug Administration (United States)
- European Medicines Agency (European Union)
- Medicines and Healthcare Products Regulatory Agency (UK)
- Canadian Agency for Drugs and Technologies in Health (Canada)

- Swissmedic (Switzerland)
- Pharmaceuticals and Medical Devices Agency (Japan)
- Medsafe (New Zealand)

The Australian regulator should only undertake an accelerated review of new chemical entities (NCEs) and medical devices if two or more trusted overseas regulators have approved the identical NCE or medical device for the same purpose. CHF strongly advises against adopting an approach in which only one trusted overseas regulator is relied upon to fast-track the review and approval process for a NCE or medical device in Australia. In no circumstances should provisional or conditional approval by an overseas regulator, trusted or otherwise, be acceptable for the fast-tracking of a medicine or medical device for use in Australia.

To the maximum extent practicable, a product under consideration for the Australian market that has been approved by an overseas trusted regulator should be identical to the form that was approved. It should be incumbent on the sponsor of the medicine or medical device under evaluation to explain to the Australian regulator how any variances between applications are minimal, and the Australian regulator should undertake an assessment to verify the sponsor's claims. Should there be disagreement between trusted overseas regulators concerning the approval or use of a medicine or medical device under application for use in Australia, the Australian regulator should retain the ability and responsibility to undertake its own review of the medicine or medical device to ensure its appropriateness, safety, and efficacy in the Australian context.

As with the process for approvals, should either or any of the trusted overseas regulators, apply conditions, or withdraw approval, for a medicine or device, then the Australian regulator should be immediately prompted to consider necessary and appropriate action in Australia.

CHF would be willing for this option to be explored further, but only on the condition that the existing post-market surveillance mechanism is significantly enhanced and strengthened to ensure consumer safety, and that the system is completely transparent. Reliance on trusted overseas regulators should not usurp the Australian regulator's ability and responsibility to conduct robust post-market surveillance of medicines and medical devices.

The Australian regulator should develop and maintain a robust and transparent adverse event reporting system that is accessible by consumers, medical professionals, and other stakeholders. Presently, and according to consumer representatives consulted by CHF, there is no evidence that the TGA has enhanced its post-market activities, nor its processes despite numerous government reviews and parliamentary inquiries recommending that it do so.

Regulation of prescription medicines

The Australian regulator's ability to conduct assessments, audits, and pre- and post-market assessments of prescription medicines should be maintained and enhanced. The Australian regulator should be compelled to improve the transparency of its communications with consumers so that they understand its regulatory role, the purpose and effect of regulations, and are able to make timely reports of adverse events relating to prescription medicines.

We believe that there should be reliance on at least two overseas regulators in determining whether to fast track the approval of a prescription medicine and CHF would oppose regulations

that allow the Australian regulator to use conditional or provisional approvals by overseas regulators as a way to initiate a fast track of the prescription medicines approval process.

Is there good reason why Australia should 'impose additional requirements' or conditions in respect of the approval of medicines?

The Australian regulator should have the responsibility for conducting its own assessment in cases where there is disagreement among overseas regulators about the use, safety, quality or efficacy of a prescription medicine. This check is vital to ensuring the safety of the Australian population, and that they are exposed to the least necessary risk. While the Australian regulator's review should, at minimum, cover those aspects of the application or medicine which are in dispute, the Australian regulator should have the discretion to expand its review if it feels there is good reason to do so (e.g., reported adverse events or expansive use of the medicine "off label"). Furthermore, the Australian regulator should, when supported by evidence, have the flexibility to impose additional conditions on the use of medicines that have been approved by trusted overseas regulators in order to ensure the safety of Australian consumers.

Does the product have to be identical in all regards or can there be variations that do not necessitate a full or partial re-assessment?

A product under consideration for the Australian market that has been approved by at least two overseas trusted regulators must be identical to the form that was approved in those other markets. It should be incumbent on the sponsor of the medicine to explain to the Australian regulator how any variances are minimal, and the Australian regulator should undertake an assessment to verify the sponsor's claims. Additionally, changes to medicines that have been approved by trusted overseas regulators that may affect the medicine's safety, quality or efficacy ought to immediately trigger an assessment by the Australian regulator. The regulator would retain the power and discretion to expand its review to other aspects of the medicine if it feels there is evidence to do so.

Where there are changes to medicines on the market that are determined to be of low risk or variance, which CHF would want expressly defined in legislation and limited to "cosmetic changes," then the Australian regulator could rely more heavily on the decisions of trusted overseas regulators. CHF agrees with the suggestion in the Discussion Paper that these kinds of low risk variations could conform to the Type IA classification used by the European Union.

Should Australia introduce an accelerated approval program(s)? What are the potential risks and benefits of such programs and how might the risks be managed and the benefits maximised?

CHF would be supportive of such a program that is in line with the FDA's multiple pathway approach. The conditions under which a medicine could be considered for and approved under the program ought to be clearly defined in legislation, to include the criteria for defining an "unmet medical need" that would warrant the use of the accelerated program, and it should be the role of the Australian regulator to conduct the accelerated assessment. In its assessment, the Australian regulator should not be permitted to rely solely on overseas regulators' assessments and decisions, although CHF would not be opposed to using approval by trusted overseas regulators as one of the legislated criteria for permitting a medicine to undergo accelerated approval.

If, under the accelerated approval program, a medicine (or medical device) were to be provisionally approved based on more limited clinical data than is traditionally required for a full approval, CHF would expect that the provisional approval would be time-limited until more carefully and comprehensively reviewed. Furthermore, consumers, GPs, and pharmacists should be given very clear information about the medicine's provisional approval, and what it means for the consumer. This information could include clear indications on the medicine's packaging and labelling, information distributed to pharmacists and GPs, and clear, accessible warnings on the Australian regulator's website, among other possible avenues.

In the case of medical devices approved under the fast track program, medical professionals should very clearly articulate to consumers that the device has only been provisionally approved, what the rationale for the accelerated process are, what the conditions of the approval are, and how all of these might impact on the consumer. Additional information that should be provided by health professionals includes the inherent risks associated with the use of medical devices more broadly.

Finally, for both medicines and medical devices approved through the accelerated process, information about the medicine or medical device, the accelerated approval process, and any provisions or conditions of approval should be made available by the Australian regulator in an easily accessible and comprehensible manner for consumers on its website, or other relevant publications.

Regulation of over-the-counter medicines

The Discussion Paper asserts that "some regulatory requirements are not considered to be commensurate with the risk posed by the regulated products." We do not believe that it is the purpose of regulation to strike a balance with the potential risk, but to assess whether there is a risk in the first place, and how serious that risk might be.

CHF believes that the current scheduling classifications are mostly appropriate. However, we believe that the classifications, and the drugs listed under them, ought to be reviewed regularly and transparently following a formal methodology that is developed in consultation with all stakeholders. Likewise, any decisions to change the classification of medicines ought to be the result of robust consultation with stakeholders.

Communication surrounding scheduling decisions must be transparent and clear to consumers, and CHF would welcome efforts by the Australian regulator to enhance consumer understanding of the methodology and implications for such decisions. The information currently on the TGA's website relating to the scheduling of medicines is comprehensive, however, it is neither concise nor written in a manner that facilitates consumer understanding. The information on the website also does not clearly illustrate the link between the scheduling decisions by TGA and its implications for medicine advertising, promotion, and packaging and labelling, which will subsequently affect consumers.

We have raised these and similar concerns with the TGA in several forums, but notably our March 2011 submission to the *Review to Improve Transparency of the Therapeutic Goods Administration* and November 2012 submission to the TGA and Medsafe Consultation Paper *Over-the-counter medicines business process reform*, as part of the *OTC Business Review Project*.

Regulation of generic medicines and biosimilars

Should the TGA approve the registration of a generic medicine on the ARTG on the basis that a trusted overseas regulator has assessed it as being bioequivalent to a reference product available in the overseas market and the sponsor provides evidence that the overseas reference product and the Australian reference product are identical or interchangeable?

Any evaluation of the appropriateness, efficacy, safety and quality of a medicine for use in Australia that relies on trusted overseas regulators ought to be on the basis of decisions by more than one such regulator which meets the criteria we have outlined. In the case of generic medicines and biosimilars, it should be incumbent on the sponsor to demonstrate to the Australian regulator's satisfaction that the reference products are identical and interchangeable. It is vital that the Australian regulator undertake the assessment for bioequivalence in order to ensure the accuracy of the sponsor's claims to minimise the risk to consumers.

To accomplish this, the Australian regulator's processes and definitions for evaluating biosimilars must more closely conform to international standards and rigour.

While the TGA has already adopted the European Medicines Agency (EMA) *Evaluation of Medicines for Human Use Guideline on Similar Biological Medicinal Products,* which acknowledges the issues associated with applying the same pharmacovigilance processes for chemically-derived medicinal products on biological medicinal products, this does not translate into Australia's regulatory approach to biosimilars. The TGA uses a different framework to regulate 'biologicals.' However, the term 'biological' is defined as 'an item made from, or containing, human cells or human tissues,' which does not adequately capture biosimilars.

In 2012, the TGA released *Minor Variations to Registered Prescription Medicines: Biological Medicines*, which outlines the process for varying biological medicines Registered on the ARTG. This further conflates biosimilars and generic, chemically-derived medicines. The same year, the TGA released Version 1 of the *Australian Requirements and Recommendations for Pharmacovigilance Responsibilities for Sponsors of Medicines.* The document does not mention biosimilars, nor does it reflect the advice in the EMA Guideline for more stringent pharmacovigilance processes for biosimilars, given that biosimilars are not necessarily clinically interchangeable and may produce different therapeutic effects than the products they are intended to simulate.

Should an update to the indications for a generic medicine which is in line with the originator medicine, be treated as a variation, rather than as creating a separate and distinct good?

CHF believes that any updates other than minor or cosmetic variations to a medicine ought to trigger an assessment by the Australian regulator for that medicine's continued use and classification in the Australian market. We would not be opposed to a review mechanism that might *at first* treat changes as a variation. However, if the Australian regulator assesses the variation as inconsistent or of such a degree that a separate and distinct good has been created, then the medicine ought to be evaluated under the existing approval process.

Regulation of Medical Devices

Should the TGA undertake its own assessment of the competency of the EU notified bodies? How might this occur?

CHF has previously expressed concerns about the role of EU notified bodies in the conformity assessment process for medical devices supplied in Australia. Recent academic and media reports have raised concerns for consumers relating to the current reliance on EU notified bodies, and whether this provides sufficient protection to Australian consumers. We support the Discussion Paper's assessment that the European system has been shown to have systemic weaknesses.

For example, an investigation undertaken in conjunction with the *British Medical Journal* found that a notified body in Slovakia was willing to provide approval for a metal-on-metal hip implant similar to one which had been withdrawn in Australia, the UK, the United States and elsewhere.

Further, the experience with the PIP breast implants in France demonstrated that reliance on third party assessors means that a conflict of interest is created between the third party assessor (who is paid by the manufacturer) and the manufacturer who is being assessed. This has served to undermine the regulatory process and has had a severely negative impact on the many thousands of women with faulty breast implants.

Accordingly, CHF supports the Australian regulator undertaking its own assessment of the competency of the EU notified bodies to provide greater public confidence in the quality, safety and performance of medical devices.

CHF is supportive of the proposed changes to premarket assessment requirements outlined in the TGA's proposal paper published in 2013 on *Changes to premarket assessment requirements for medical devices.* In particular, we welcomed the expanded list of medical devices that are subject to a TGA mandatory audit to include all surgically invasive devices intended for long-term use and implantable medical devices, including all Class IIb and Class III medical devices.

We also welcomed the proposed introduction of a 'Level 3 audit', which would provide a new, higher level of scrutiny at the audit stage for active implantable medical devices and Class III medical devices that are implantable or surgically invasive for long-term use.

CHF notes that the subsequent Exposure Draft made a number of changes to the original proposal paper based on industry feedback, which significantly weakened consumer protections within the regulatory framework. We recommend the Panel consider the proposals as they originally appeared in the proposal paper, particularly around the expanded range of devices subject to a TGA mandatory audit.

Is the current regulatory framework and classification system flexible enough to accommodate new and emerging device technologies? If not, why not? How could it be improved?

We note the Discussion Paper states that medical devices are subject to many modifications as a result of continuous development following real world use. In this context, it is difficult to obtain long-term data on the use of each iteration of the device, and we would urge that the safety and wellbeing of consumers is prioritised over the flexibility of the pre-market assessment process.

Should low risk devices that are not subject to an independent conformity assessment be included on the ARTG?

A problem identified in the Discussion Paper is that the inclusion of low-risk devices on the ARTG may provide a false impression to consumers and health professionals that the goods have undergone an independent assessment of their safety, quality and performance when this may not be the case. CHF considers that this issue can be better addressed by educating the public on the role of the Australian regulator and the limitations of pre-market assessment rather than removing low-risk devices from the ARTG, particularly as a key role of the ARTG is to provide information on the goods that can be lawfully supplied in Australia, and the sponsor who has legal responsibility for the goods.

Should information about regulatory decisions in respect of medical devices be publicly available? (evaluation report or other relevant information) If yes, how would this benefit consumers, clinicians and industry? How could any risks be managed?

CHF has had a longstanding concern about the inadequacy of information about medical devices, for which there is no Consumer Medicines Information (CMI), Product Information (PI) or Australian Public Assessment Report (AusPAR) equivalent. Moreover, there is arguably an increased need for information about medical devices as they cannot be ceased in the way that medications can be when problems occur. It is particularly important for consumers to have access to high quality, independent information *before* a device is implanted.

Accordingly, CHF would welcome the publication of information both about, and which supports, regulatory decisions. This could include information about the degree to which a medical device has been assessed prior to inclusion on the ARTG. It could also include decisions about medical devices for which applications were not approved.

Is the regulation of medical devices transparent enough in terms of informing health professionals and consumers about the level of scrutiny that a device has undergone? If not, how could it be improved?

There is currently a lack of understanding among health consumers and the general public of the role of the TGA, most notably the extent of the role that it plays in the regulation of some therapeutic goods. It is unlikely that consumers are aware of the level of scrutiny (or lack of scrutiny) that a device is subjected to prior to approval. For this reason, CHF has argued for consumer education to increase public understanding of the role of the TGA, including sponsor/manufacturer compliance requirements, complaints mechanisms, and where and how to report adverse events.

Fundamentally, it is important for the Australian public to have an honest and realistic understanding of the Australian regulator's role in the regulation of medical devices, including its limitations. For example, it is unlikely that the public is aware that the majority of medical devices used in Australia do not undergo assessment by the TGA, and that most of the assessment is paper-based, where the TGA reviews evidence about the device to show that it has been subject to a level of regulatory scrutiny equivalent to that which would be applied if the device was presented to the TGA for assessment; the TGA does not actually assess the product.

Should there be a system for medical devices similar to the AUST R and AUST L system for medicines? If not, why not?

It is important that consumers understand the benefits and risks of using (or not using) various devices. CHF can see the advantages of introducing a system for medical devices similar to the AUST R and AUST L system for medicines.

However, it is important to note that there is a lack of public understanding of AUST R and AUST L numbers, which has led CHF in the past to call for the TGA to develop initiatives to improve consumer understanding of how medicines are regulated in Australia, including the difference between AUST R and AUST L numbers.

Framework for advertising therapeutic goods

Should Australia allow advertising of prescription medicines to the general public?

CHF strongly opposes *any* relaxing of Australia's laws concerning direct-to-consumer (DTC) advertising.

Evidence from the United States, one of only two countries (the other being New Zealand) to allow DTC advertising of pharmaceutical products suggests that for every $1 spent on advertising, pharmaceutical companies realise $4.20 in increased sales[2]. At the same time, there is a dearth of conclusive evidence that DTC advertising either improves consumers' health or lowers the cost of medicines (as neither of these things appears to be happening in the US). Furthermore, while it is often claimed that the profits realised from DTC advertising are used to fund medical research, the evidence shows that the pharmaceutical industry in the US spends 19 times as much on advertising than on research[3] - or put another way, a mere 1.2 per cent of profits realised from DTC advertising are put towards medical research.

CHF disagrees with the underlying assumption of the Discussion Paper that all that is needed with DTC advertising is a mitigation of risk, or robust regulation to ensure truth in advertising.

Likewise, CHF summarily rejects the suggestions raised in the Discussion Paper that self-regulation in advertising would result in truthful advertising. Conversations which consumers need to have about medicines ought to remain between them, their doctors, and their pharmacists – not their local media. We note that of the complaints to the Advertising Standards Board over the past 15 years of its existence, three advertisements from a particular pharmaceutical provider of erectile dysfunction medication are included amongst the top 15 most complained about advertisements.[4]

DTC advertising of pharmaceuticals does little more than create a market for a particular drug where one does not currently or urgently need to exist. Moreover, it places demands on GPs from consumers to switch their existing drug regimens to those promoted through the media, instead of those informed by medical opinions or clinical advice.

[2] http://scholarworks.gvsu.edu/cgi/viewcontent.cgi?article=1013&context=spnhareview
[3] http://www.bmj.com/content/345/bmj.e4348
[4] http://www.joomag.com/magazine/advertising-standards-bureau-review-of-operations-2013/0500926001401061344?preview

The only conclusion which can be drawn from this information is that calls to relax regulations concerning DTC advertising of pharmaceuticals is purely profit-driven, and clearly not in the interest of public health and safety.

Is the current self-regulatory scheme for advertising of medical devices effective?

CHF notes that the Discussion Paper has referred to our submission on the *Regulation Impact Statement: Regulating the Advertising of Therapeutic Goods to the General Public* published in 2013. The Discussion Paper outlined our concerns with the lack of pre-publication approval for medical devices, which may result in consumers being exposed to advertisements that are false, misleading or deceptive.

There is an increased need for accurate information on medical devices, particularly in the context for which there is no CMI, PI or AusPAR equivalent. While health professional intervention may mitigate some of these issues for high-risk medical devices through the provision of clinical advice and by seeking informed consent from consumers, there is no safeguard for lower-risk medical devices directly-advertised to consumers.

In our view, no medical device is completely safe, or immune from failure – including so-called lower-risk devices. Accordingly, CHF believes that medical devices should have applied to them the same advertising regulatory requirements as medicines, based on the risk-based approach adopted by the TGA.

Is the TGA website easy to navigate? If not, how might it be improved?

Consumers consulted by CHF over many years have indicated that the TGA website is not consumer friendly and is not easy to navigate for the general public.

Conclusion

Safety and quality of medicines and medical devices is often the essential element of managing or recovering from health conditions, disease and incidents. Australians assume that the medicines they take or medical devices that have been used are rigorously assessed.

CHF believes that there is a need for reform of the regulatory system for medicines and medical devices. These reforms need be consumer-centred with the aim of improving quality and safety of, and consumer confidence in, therapeutic goods. We are concerned that the Discussion Paper has put an emphasis on the needs of industry and has not articulated clearly how the balance between consumer and industry interests will be achieved.

Whilst acknowledging that the TGA processes need some streamlining, CHF is concerned that the proposal to move to using a trusted overseas regulator's assessment and decisions will lead to the Australian regulator being left without adequate resources or capacity to be able to undertake assessments when necessary. This could then provide an incentive for all medicines and devices to be assessed offshore which could have a negative impact on safety, quality, research and development in Australia.

We are also concerned that the Discussion Paper does not pay more attention to the need for a stronger post market monitoring and surveillance regime, including the way adverse events are

reported and acted upon. We believe this will become more important if the trusted overseas regulator model is adopted and becomes the way the majority of medicines and devices are assessed for safety and quality.

CHF is urging the Expert Panel to ensure a thorough examination of the impact on safety and quality of any changes they recommend, including the provision of data which allows a thorough understanding of the current adverse events reporting environment. Without this information, the Review will be seen as myopic and simply focussed on industry interests, rather than the public interest.

We believe consumers should be more thoroughly consulted before the Panel's recommendations are finalised to ensure that the public interest has been taken into account.

Summary of CHF Position

- An independent Australian therapeutic goods regulator should be retained (not necessarily in the current statutory form) and effectively resourced to undertake its own review of medicines or medical devices to ensure their appropriateness, safety, quality and efficacy in the Australian context when required or necessary.

- The Australian therapeutic goods regulator must maintain strong consumer and stakeholder consultation mechanisms, as well as membership on expert advisory panels and that there should always be two consumers on key committees so they can support each other and offer greater breadth and depth of experience.

- The Australian therapeutic goods regulator must have robust pre- and post- market assessment strategies, and these should be enhanced from what is presently practiced by the TGA.

- Any changes to the regulation and approval of medicines and medical devices must be the subject of broader community and parliamentary debate by all stakeholders.

- Should the approval and regulation of medicines and medical devices move towards reliance on trusted overseas regulators, than this shift ought to be enshrined in legislation and with extensive community consultation, not overlayed onto the existing regulatory scheme.

- The Australian regulator should only undertake an accelerated review of NCEs and medical devices if two or more trusted overseas regulators have approved the *identical* form of the product for the *identical* purpose.

- Any medicine or medical device under consideration for the Australian market based on evidence or approval from a trusted overseas regulator ought to be the identical form of the product that was approved by the trusted overseas regulator.

- In no cases should an Australian regulator rely on conditional or provisional approval by a trusted overseas regulator as acceptable for the fast-tracking of a medicine or medical device's review.

- In any case where a trusted overseas regulator applies conditions or withdraws approval for a medicine or medical device that was approved for use in Australia based on the trusted overseas regulator, the Australian regulator must immediately undertake a review of that medicine or medical device's safety and efficacy.

- Any medicine or medical device that is provisionally approved based on a fast-track process ought to have its approval time-limited and very clearly indicated to consumers and medical professionals.

- Australian laws regarding direct-to-consumer advertising of medicines and medical devices must not in any way be relaxed, bypassed or compromised in any future regulatory arrangement.

Consumers Health Forum of Australia

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

CHF does this by:

- advocating for appropriate and equitable healthcare
- undertaking consumer-based research and developing a strong consumer knowledge base
- identifying key issues in safety and quality of health services for consumers
- raising the health literacy of consumers, health professionals and stakeholders
- providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.