Consumers Health Forum of Australia

SUBMISSION

# Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 and related bill

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# 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 have participated in many the consultations undertaken by the Department of Health after the review released its reports and in the discussions around implementation issues since the Government announced its response to the review recommendations. We also submitted to the Committee's inquiry into the first set of legislation in 2016.

This submission looks in detail at three areas covered by the legislation: the introduction of a provisional registration pathway for medicines; reforms to the regulation of complementary medicines; and changes to the regulation of advertising of medicines.

CHF supports all the other provisions in the Bill. CHF welcomes the move to strengthen the post market monitoring scheme and to changes in the enforcement and penalties as this areas become more important as regulation, particularly in the advertising sphere, is relaxed.

# Issues

## *Provisional registration of promising new prescription medicines*

CHF supports the introduction of a provisional registration pathway. We believe the safeguards outlined in the legislation particularly in Schedule 1 provide the right balance between allowing patients with serious conditions earlier access to promising medicines and ensuring use is regulated to protect patients' safety.

Many patient groups have been advocating for such a pathway and have welcomed the move to introduce this. The patient submissions to the 2015 Senate Inquiry into the availability of new, innovative and specialist cancer drugs in Australia highlighted the desire for patients to access drugs earlier and their frustration at not being able to do so. Whilst the approach taken here might not suit everyone as it is a long way from the 'right -to-try' approach which is available in the USA we believe limiting this pathway to medicines which have proven to be safe and have shown promising signs of efficacy is in most consumers' best interests.

CHF has had discussions with the TGA about this pathway and most of our issues around monitoring, ongoing data collection and adverse event monitoring have been addressed. We are particularly pleased to see the inclusion of rolling data collection and strong monitoring regimes that include collection of information on adverse events from people using the medicine. The inclusion of the black triangle on consumer information for provisionally registered medicines should also alert consumers to the need to report all adverse events.

One of the key issues is around patients understanding the status of the medicine and being given the right information so that they can give informed consent to using it. Whilst it is not part of the legislation we think it is imperative that there is a well- constructed patient information/education package that explains what a provisional registration means so that consumers understand that the medicines have not been through the full TGA assessment process and that there is a possibility that it may not get full registration. They need to understand what happens at that point.

Another key issue for consumers will be the cost of provisionally registered medicines and whether they are eligible to be subsidised through the Pharmaceutical Benefits Schedule. CHF's understanding is that they will be eligible to be assessed as they will be on the Australian Register of Therapeutic Goods.

## *Reforms to the regulatory framework for complementary medicines*

CHF welcomed the proposals to reform the regulatory framework for complementary medicines. It imperative that consumers are given more information about the medicines and that the information gives them a better understanding of what evidence there is around the potential efficacy of the complementary medicines so that they can make more informed decisions on whether to use it. This is not only important to informed decisions to use, but also informed decision to purchase. Australians spend considerably on complementary medicines on top of the growing out-of-pocket expenses they face for other healthcare. People have the right to be reassured they are purchasing products that are going to provide a level of benefit.

### *Establishing a list of permitted indications for listed complementary medicines*

CHF supports the development of a list of permitted indications as it put boundaries around what manufacturers could claim for their complementary products. The abolition of the free text approach to indications reduces the capacity of manufacturers to embellish their claims.

However, we share other groups' concerns about how this list will be? has been compiled. CHF participated in some of the discussions around the development of the list but feel that the manufacturers' position around what should be included held sway in the final decisions. We believe there are far too many permitted indications and this all-inclusive approach will diminish the benefits from having such a list.

Our concern is that the limitations of this list of permitted indications may not be understood by many consumers and it may give them some misplaced confidence in the evidence behind the list. If the proposal from the Review of Medicines and Medical Device Regulation that there

should be a disclaimer on all listed complementary medicines making it clear that the efficacy claims had not been independently verified, then this would not be such a problem.

We support the proposal in the submission to the Committee from Associate Professor Ken Harvey and Professor John Braithwaite that there should always be a disclaimer for claims based on 'traditional use' making it clear that it is based on alternative health practices and not based on modern scientific or medical practice.

### *Establishing a new assessment pathway for listed complementary medicines*

CHF welcomes the introduction of the assessment pathway that encourages manufacturers to seek and provide more evidence for the claims for their complementary medicines. This raising of the bar is in consumers' interests as they can have more confidence in using such preparations.

### *Allowing sponsors to claim evidence of efficacy*

We argue that there needs to be a prominent and well publicised claimer on the label of such products, showing consumers clearly that the claims have been independently assessed. This needs to be in words and have a logo or symbol. This would need to be backed up with consumer awareness campaign of what the symbol means so that consumers looking at complementary medicines on the shelves are easily able to identify those which have the higher level of claim. This would assist consumers and any retail staff, in pharmacies or elsewhere to distinguish between these products and those covered simply by the permitted indications list.

## *Advertising requirements*

CHF supports the decision to move the advertising complaints system into the TGA and emphasise the need for this function to be adequately resourced. It is important that complaints about advertising are handled in a timely manner, particularly if the decision to move away from pre-approval is implemented as we need to minimise the exposure to misleading and potentially harmful advertising. We have welcomed changes in TGA in the recent past which have made it more transparent and willing to disclose information about its performance and would encourage it to continue this path in developing its processes to handle advertising complaints.

We support the broader definition of 'advertisement' and the move away from specifying communication channels. This future-proofs the process as new technologies and channels emerge.

We support the proposal from Associate Professor Harvey and Professor Braithwaite that the current system of pre-approval should be maintained until the formal 3-year review of the reform package is completed. It is important that the package of reforms to improve post marketing surveillance and increase penalties and sanctions for regulatory violations have been implemented and we have had the chance to collect the data to see how these reforms are working before giving up this.

CHF has always had concerns about self-regulatory models and one of the strengths of the pre-vetting and approval process is that it was independent. The other strong point is that it

ensures that advertisements were assessed prior to publication so minimised the public exposure to them. Such an approach needs strong enforcement and penalties/sanctions to ensure that inappropriate and/or misleading advertisements and claims are identified and that the action taken against them is a strong enough deterrent to the manufacturer. Given these needed to be substantially strengthened we think it reasonable that they should be in place and tested before removing the final safeguard of the pre-vetting process.