Swisse

Submission- Enhancing sanctions and penalties in the Therapeutic Goods Act (1989)

Swisse Wellness

May 2017

EXECUTIVE SUMMARY

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Swisse Wellness welcomes the opportunity to be involved in the Therapeutic Goods Administration's (TGA) Consultation on the development of enhanced sanctions and penalties. As we have submitted in previous consultations, Swisse appreciate the extensive and collaborative nature of the entire process, noting that the recommendations currently being consulted on carry the in-principle support of industry. This submission will primarily address recommendation fifty-seven, given the advertisement of complementary medicines is directly impacted by the proposed reform agenda.

It is worth noting the involvement Swisse Wellness has had with the TGA on previous consultations relating to the reform of Medicines and Medical Devices regulatory framework. As an industry leader, we reiterate our support for the TGA remaining as the primary regulator of complementary medicines and therapeutic goods. Whilst we appreciate the importance of responsible advertising of therapeutic goods, the reality is that the TGA applies oversight relevant to the risk profile of complementary medicines, which sufficiently deters unsafe products from entering the market. Any reform to the legislative or regulatory framework should reflect this. Furthermore, we strongly support reforms aimed to improve consumer protection and effectively address non-compliant behaviour.

Swisse Wellness **opposes** the proposal to adopt the Regulatory Powers (Standard Provisions) Act 2014 to provide an ACCC-style schedule of sanctions and penalties available to the TGA or other regulatory authorities in other industries. It should be recognised that the TGA's regulatory remit to assess quality and safety is deliberately specific and unique. Therefore, it does not seem logical to duplicate compliance mechanisms already available to the Australian Consumer and Competition Commission (ACCC) and under the Australian Consumer Law (ACL) who could apply an appropriate schedule of sanctions, penalties and options commensurate with industry specifications.

Furthermore, the precedent established by following through with the proposal to adopt the RPSPA into the Therapeutic Goods Act (1989) is a dangerous one. It is ostensibly illogical that ACCC-style powers would be extended to the TGA, APVMA, FSANZ, NICNAS or any other regulator; effectively cloning the ACCC and challenging its mandate to protect the best interests of consumers.

Industry supports the TGA's ability to appropriately monitor the quality, safety and effectiveness of complementary medicines, with an overall view that the reputation of the TGA as a best-in-class therapeutic goods regulator is deserved. That there are arrangements (outlined in the Australian Consumer Law) operating in other highly regulated, consumer-facing sectors is worth considering; Reckitt Benckiser's recent $6Million penalty for falsely advertising claims is testament to the effectiveness of these arrangements.

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About Swisse Wellness

Swisse is a Melbourne based global leader in the natural vitamin, herbal and mineral supplement market. Recent expansion into sports nutrition, skincare and functional foods has been met with promising demand. With a significant and growing market penetration across Australia, the Asia Pacific, China and Europe, we are strong believers in selling locally-manufactured products of the highest quality, safety and efficacy.

GENERAL COMMENTS ON CONSULTATION

Swisse Wellness has been a contributor throughout the entire MMDR process. We have consistently stated that if Australia's Therapeutic Goods regulatory framework is to remain the gold-standard of comparable regulatory arrangements, reforms that improve consumer protection and develop a regulatory framework that is commensurate with consumer expectations and the risk profile of complementary medicines should be implemented as soon as it is practical.

There is broad agreement that existing arrangements concerning the advertising of therapeutic goods and the handling of breaches is inadequate and compromised. In light of the Complaint Resolution Panel's lack of accountability, transparency and objectivity, Swisse has been clear about its support for the abolishment of the CRP in favour of a model that puts an increased onus of being compliant on the sponsor, but introduces a more robust post-market consideration framework. Consequently, we have strongly supported the Advertising Standards Bureau proposed assumption of oversight of complaints handling and post-market monitoring given they have the processes, expertise, capacity and resources to act as an independent and accountable arbiter.

For this reformed framework to successfully deter negligent advertising and non-compliant marketing activity, the Claims Board of the ASB must be able to access provisions included in the ACL. This will allow the ASB to refer breaches to the ACCC, providing them with the power to leverage the extensive penalties and sanctions available. The powers, provisions and sanctions available to the ACCC are detailed within the Australian Consumer Law, which can be easily accessed online.

Australia's strong regulatory framework is the primary driver of the high-quality and safe profile of domestically produced Complementary Medicines. Industry does not seek to dispute the role the TGA has fulfilled in developing this reputation, however, we stress that the remit of the TGA is to evaluate the quality and safety of any given product or ingredient, and assess scientific evidence for indications as per standard practice.

To introduce measures that provide the TGA with the power to review, consider and adjudicate advertisements is a breach of the Therapeutic Goods Administration's duty to protect consumers from unsafe or scientifically invalid complementary medicines. Given the TGA and Department of Health have previously delegated oversight of pre and post-market advertising compliance to various bodies and panels, it can be said that neither the Department nor the TGA have held the appropriate technical or industry expertise to address these issues.

Finally, the TGA, Department of Health and relevant Ministerial offices must be acutely conscious of the precedent that would be established from issuing ACCC-style powers to the TGA. This sort of system would be exposed to complaints from industry antagonists that ostensibly concern the integrity of an advertised claim, but in reality are a premeditated philosophical attack on the scientific validity of the product in question. Inevitably, the potential reduction in capacity to monitor advertising compliance would decrease the deterrent against negligent advertisement, and ultimately promote consumer risk.

INTEGRATION OF REGULATORY POWERS (STANDARD PROVISIONS) ACT 2014

The risk of integrating new legislative powers within the existing legislative framework is that a re-drafted act, with new powers embedded within it, will foster further legislative and regulatory complexity and overwhelm efforts to boost the potency of deterrents and punitive actions. Swisse notes that this was the original intent of the Expert Review.

The entire MMDR review process was conducted on the fundamental premise that the Therapeutic Goods Administration is a specialist regulator tasked with the unique responsibility of overseeing a complex and ever-changing network of therapeutic goods that carry an element of risk. Whilst the TGA carries adequate technical expertise to validate the quality and safety of complementary medicines, it can be argued that it currently does not have the capacity to assume the responsibility to monitor, regulate and adjudicate on marketing compliance and complaints.

Swisse Wellness acknowledges that the schedule of penalties and sanctions included within the consultation document are less stringent than those currently available to the ACCC. Given these same penalty units would apply under our proposed model, we contend that the preservation of existing discretionary penalties and sanctions (within the ACL) would act as a more successful deterrent to non-compliant advertising.

With respect to the Regulatory Powers (Standards Provisions) Act of 2014, it is important note that whilst this legislation was designed to standardise enforceable regulatory powers across various Commonwealth authorities, the RPSPA lacks a consumer protection focus and does not account for the relevant risk-based approach to monitoring compliance that the advertising of low-risk and listed Therapeutic Goods requires.

SUBSTANTIATION NOTICES

Swisse recognises the recommendation that Therapeutic Goods Act (1989) be amended to allow the Therapeutic Goods Administration to issue substantiation notices where necessary. Consistent with our opposition to issuing ACCC-style provisions to the TGA, Swisse Wellness is **opposed** to this proposal. Swisse is of the view that the ACCC carries such capacity as appropriate.

The consultation document fails to detail the processes which would prompt the TGA to issue a substantiation notice. Considering the commitment to abolish the Complaints Resolution Panel, the

obscurity concerning who would be responsible for reaching the conclusion to issue a substantiation notice goes against the intent of the MMDR; that being to clarify a complex set of therapeutic goods regulations and ensure that consumers are as protected-as-possible from unsafe products.

Swisse seeks further clarification on how the issuing of substantiation notices will impact Complementary Medicines that have been registered (through the existing pathway), or evaluated (through the intermediate pathway that was recently consulted on). Given registered and evaluated products will have claims pre-approved for use by the TGA, our preliminary observation is that the regulator responsible for overseeing compliance would be limited in issuing substantiation notices to listed complementary medicines.

It is important to note that as part of standard pharmacovigilance practice for listed medicines, the TGA is able to issue a request to review the evidence supporting any claim made in the free-text field. Swisse assumes this provision will still be available to the TGA when the free-text field is replaced with a standardised list of available claims. Furthermore, in instances where the ASB has deemed an advertisement to be non-compliant and has chosen to refer the given case to the ACCC, the ACCC is at liberty to issue a substantiation notice and seek technical expertise to come to a final decision. The value of employing the Claims Board of the ASB, and the ACCC more generally, is their ability to independently oversee, monitor and arbitrate situations of potential or confirmed non-compliance, ensuring that credible issues are dealt with and – if necessary – legally enforce an undertaking to change, cease or desist non-compliant advertising.

Swisse believes arrangements surrounding the provision of a substantiation notice by the ACCC are sufficient. Should a person, sponsor or manufacturer be served with a notice, the requirement to comply within 21 days will remain unchanged. In the case that they respond, it is important the ACCC uses the evidence provided to diagnose whether a case for a further investigation remains; potentially drawing on the scientific and technical expertise within the TGA to assist in making this determination, or prompting the TGA to conduct a “targeted review” and evaluation of evidence in accordance with existing provisions.

Whether the ACCC choose to commence litigation or criminal proceedings, seek an injunction or issue infringement notices thereafter is a matter for the ACCC; however, should they choose to do so, industry can be certain of the independence of the decision and consumers can be assured that compliance breaches will not pose any more of an elevated risk than in current circumstances.

PUBLIC WARNING NOTICES

Consistent with our opposition to issuing ACCC-style provisions to the TGA, Swisse Wellness is **opposed** the proposal to amend the act to allow the TGA to issue public warning notices.

The ACCC is already permitted to issue a widely disseminated notice that contains a warning under Section 86DA of the Australian Consumer Law. To issue the TGA with this sort of provision

would be redundant given the ACCC would still be able issue a public warning notice, or choose to investigate suspected compliance breaches if the circumstances warrant this option.

Furthermore, given the highly regarded consumer-oriented nature of the ACCC, it would be more effective in informing the community of potential breaches which could expose them to risk or detriment. In the interest of securing the potency of the ACCC's entire set of powers, provisions and sanctions, only the ACCC should have the power to issue a Public Warning Notice should a person refuse or fail to respond to a substantiation notice.

INTRODUCTION OF INJUNCTIONS

Swisse **conditionally supports** the introduction of injunctions for advertising provided the ACCC is the sole authority with the capacity to seek them. Given the severity of an injunction, Swisse believe that the ACCC is the correct regulator to appropriately determine whether an injunction should be sought.

Swisse believes it is in the best interests of industry and consumers to support the ACCC's existing ability to apply to court for an interim or permanent injunction to immediately restrain a person from advertising when the given advertisement poses a serious risk to public health and safety. Given it is unclear whether a TGA-issued injunction can be appeal through standard mechanism, this proposal will secure appeal pathways through the court system.

The TGA is well intentioned in its desire to see a more robust regulatory framework that includes stronger penalties and sanctions, however, as with the introduction of injunctions, much of the solution lies in promoting the already functioning and fit-for-purpose consumer protection, complaints handling and compliance monitoring framework administered by the ACCC and ASB.

Provided the TGA, consumers or any other stakeholder is informed of the ability to seek an injunction, the application of this power to the TGA through the RPSPA is unnecessary and duplicative. In instances where the TGA holds the view that there is a threat to public health and safety, it should be encouraged to immediately inform the ACCC so that it can apply for the injunction within existing protocol and legislation. In instances where the Advertising Standards Bureau reviews a complaint and is also of view that there is an element of risk to public health, then they too would be able to advise the ACCC to seek a court-warranted injunction. Businesses and consumers are also able to exercise these options through existing notification pathways.

STRICT LIABILITY OFFENCES IN THE THERAPEUTIC GOODS ACT (1989)

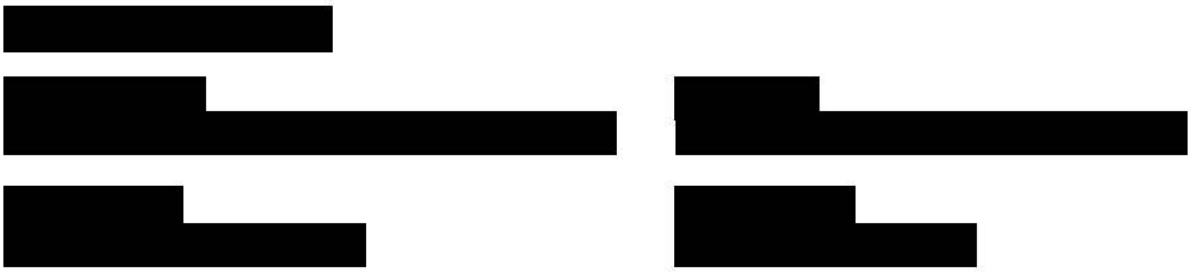
Swisse **supports the intent** of reforms to allow for graduate penalties in varying instances judged on seriousness, provided the penalties specifically relate to strict-liability offences concerning the quality and safety of the product, and not advertising compliance breaches. The flexibility provided to the regulator to respond accordingly to the severity of the breach is welcome, given the potential

to place targeted focus and penalties on addressing breaches that pose a serious risk to consumers.

Swisse reaffirms its support for the Claims Board of the Advertising Standards Bureau to assume responsibility to oversee advertising compliance-breaches. Insofar as the role of the TGA in addressing strict liability offences, parameters set within the Therapeutic Goods Act (1989) and technical expertise would assist the Claims Board of the ASB in determining the difference between a strict-liability offence (where guilt does not have to be proven) and a minor compliance breach.

On advisement from the ASB, the ACCC and court system can access an appropriate schedule of penalties that was exercised in the recent Reckitt Benckiser/Nurofen case, negating the need to indicate penalties for certain levels of advertising non-compliance.

We are of the view that given the broad nature of the proposed reform in the consultation document, it is important that the legislation expressly removes any element of culpability (potential to cause harm or injury) in relation to strict liability offences concerning advertising. This will result in a substantial reduction of penalties, therefore making some progress in the panel's original desire to implement a graduated penalty framework. It is important, however, that Swisse and the Complementary Medicines Industry be further consulted on the operation of these provision when the draft legislation is available.



ADDENDUM 1:
ACCC and Federal Court successful application of penalty for misleading advertising by Nurofen

Full Federal Court orders $6 million penalty for Nurofen Specific Pain products

16 December 2016

The Full Federal Court has upheld an appeal by the Australian Competition and Consumer Commission against the penalty imposed on Reckitt Benckiser (Australia) Pty Ltd for contravening the Australian Consumer Law (ACL).

The Full Court ordered Reckitt Benckiser to pay a revised penalty of $6 million (up from $1.7 million) for making misleading representations about its Nurofen Specific Pain products.

“This is the highest corporate penalty awarded for misleading conduct under the Australian Consumer Law,” ACCC Chairman Rod Sims said.

The Full Court found that the initial penalty of $1.7 million was manifestly inadequate given the need for deterrence and the substantial consumer loss suffered.

“The ACCC welcomes this decision, having originally submitted that a penalty of $6 million or higher was appropriate given the longstanding and widespread nature of the conduct, and the substantial sales and profit that was made,” Mr Sims said.

In their joint decision, Justices Jagot, Yates and Bromwich stated: “The objective of any penalty in this case must be to ensure that Reckitt Benckiser and other ‘would-be wrongdoers’ think twice and decide not to act against the strong public interest”.

“The ACCC will continue to advocate for higher penalties for breaches of Australia’s consumer laws to ensure that they act as an effective deterrent and are not simply viewed as a cost of doing business,” Mr Sims said.

Background

In December 2015, following admissions by Reckitt Benckiser, the Court found that Reckitt Benckiser engaged in misleading or deceptive conduct between 2011 and 2015 by making representations on its website and product packaging that Nurofen Specific Pain products were each formulated to specifically treat a particular type of pain, when this was not the case.

In fact, each Nurofen Specific Pain product contains the same active ingredient, ibuprofen lysine 342mg, which treats a wide variety of pain conditions and is no more effective at treating the type of pain described on its packaging than any of the other Nurofen Specific Pain products.

On 29 April 2016, the trial judge Justice Edelman ordered Reckitt Benckiser to pay a penalty of $1.7 million for making misleading representations about its Nurofen Specific Pain products.

The ACCC appealed the Federal Court’s decision on 23 May 2016.

Update: 5 April 2017

Following the Full Court’s decision, Reckitt Benckiser applied for special leave to appeal to the High Court of Australia on a number of grounds, including that the Full Court had erred in its assessment of consumer loss and in finding that the original penalty was manifestly inadequate.

On 5 April 2017, the High Court dismissed Reckitt Benckiser’s special leave application with costs.

The ACCC has been advocating for increased penalties under the current review of the Australian Consumer Law. This review formally commenced on 31 March 2016 and a final report is expected by March 2017.

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