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## RE: Therapeutic Goods Advertising Code

SHPA is the national professional organisation for over 4,400 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals.

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As discussed in SHPA's submission to the Therapeutic Goods Administration (TGA) in May 2017 regarding the Scheduling Policy Framework, SHPA does not support the advertising of Schedule 3 (Pharmacist Only) medicines in any form of media. SHPA believes that consumers should make decisions regarding their medicines to treat a disease/condition/ailment in conjunction with their healthcare providers, and not have this important relationship, founded on trust, to be undermined by commercial interests. SHPA is not aware of any instances where the advertising of Schedule 3 medicines has improved the quality use of medicines among the general population, which is integral to the TGA's role as the regulator.

### The Advertising Code and Proposed Code Changes

However, SHPA notes the support from a significant majority of stakeholders for broadening the direct-to-consumer (DTC) advertising of medicines containing these substances. Whilst it is not a position that SHPA implicitly supports, we are intent on ensuring that the relaxation of important regulatory controls put considerations to patient's health and wellbeing first.

SHPA agrees with TGA's intent to minimise subjectivity in the interpretation of provisions in the Advertising Code, as well as the four core objectives for the new Advertising Code described in Section 4.2 of the consultation paper, however its consistent application to stakeholders, sponsors and pharmacies is critical to its success.

We note that analgesic medicines containing ibuprofen claiming to have 'targeted pain relief', unsubstantiated by evidence, were only affronted by the Australian Competition and Consumer Commission after over four years of commercial sales, resulting in a \$3.5 million fine to the medicine sponsor. This was despite that in the four years, the pharmacist community knew that these claims of 'targeted pain relief' were untrue. SHPA hopes that transitioning to a new Advertising Code will strengthen the TGA to undertake compliance and audit activities.

## Advertising Framework for Schedule 3 (Pharmacist Only) medicines

The consultation paper discusses a proposed approach where all Schedule 3 medicines are included in Appendix H and can be directly advertised to consumers **unless** the Delegate determines that advertising is not appropriate. It proposes that a working group of various stakeholders is engaged to undertake this review of all medicines in Schedule 3 to determine their appropriateness for direct to consumer advertising.

SHPA believes that ensuring representation of independent clinicians on this group is critical to ensure a robust and transparent process. Due to the private retail pharmacy model who employ the majority of Australia's registered pharmacists, there would be a litany of actual and perceived conflicts of interests if these stakeholders were represented on the working group. This contrasts with pharmacists who provide care for patients in the public health facilities who are free from commercial interests, and would be suitable candidates to provide advice to the TGA and the Delegate.

The list of factors that the Delegate considers when deciding whether a medicine should be included in Schedule 3 of the Poisons Standard is robust, however its application has been inconsistent and unaligned with what evidence suggests.

For example, while codeine-containing analgesics will be upscheduled to Schedule 4 Prescription Only from February 2018, these medicines have been on the market for over a decade when the evidence for low-dose codeine was questionable. Furthermore, the increasing prevalence of proton pump inhibitors (PPIs) in Schedule 2 Pharmacy Medicine which allow for self-selection, are at odds with advice from the Royal Australian College of General Practitioners' Choosing Wisely Australia recommendations. The evidence demonstrates that PPIs are associated with heightened risks of gastrointestinal infection (incl. clostridium difficile), community acquired pneumonia, osteoporotic fractures, interstitial nephritis, and nutritional deficiencies (B12, Fe, Mg), particularly in the elderly or immunocompromised.<sup>1</sup>

SHPA believes additional factors that the Delegate should consider when making decisions about Schedule 3 and Appendix H inclusions, is an assessment of whether the decision will improve the quality use of medicines in the community, noting that there are at least 230,000 medicine related hospitalisations annually at a cost of \$1.2 billion.<sup>2</sup>

If you have any queries or would like to discuss our submission further, please do not hesitate to contact [REDACTED].

Yours sincerely,



Kristin Michaels  
Chief Executive Officer

## References

1. Reimer C. (2013) Safety of long-term PPI therapy. Best practice & research Clinical gastroenterology. 27(3):443-54.
2. Australian Commission on Safety and Quality in Health Care. (2013) Literature Review: Medication Safety in Australia. ACSQHC, Sydney