

Guidelines for ASMI Members for procedures and interpretation of ASMI Code of Practice

These guidelines have emanated from decisions of the Marketing & Ethics Subcommittee in relation to learnings gleaned from recent formal and informal complaints which brought controversial issues to the fore. Marketing & Ethics Subcommittee agreed upon protocols for the ASMI Complaints Panel and clear interpretation of specific clauses of ASMI code which do not warrant any amendment of the code.

Intersection of CRP and ASMI Complaints processes

In the event of two concurrently pending complaints, one before Complaints Resolution Panel ("CRP") claiming breaches of the Therapeutic Goods Advertising Code ("TGAC") in relation to consumer advertising, and one before the ASMI Complaints Panel ("the Panel") in relation to the same campaign, claiming breaches of the ASMI Code of Practice- the CRP only has jurisdiction over consumer advertising and no jurisdiction over health care professional ("HCP") advertising whereas the ASMI Code applies to all advertising.

Therapeutic Goods Regulation 42ZCAF(2), paragraphs (b) and (c) allow the CRP to treat a complaint as withdrawn where it has already been dealt with by another authority or where the CRP considers another authority better able to deal with it. In a formal determination, the Panel decided that "the integrity of the system of therapeutic goods advertising co-regulation would be jeopardized if this Panel were to determine an issue that is already the subject of a complaint lodged with the CRP. Accordingly the Panel will consider only the advertisement directed to HCPs ... and only insofar as the issues are not replicated in the CRP Complaint." This approach is in accord with the rationale of the Regulation.

This clearly indicates that, if ever there were concurrent complaints about claims which are repeated in consumer and HCP advertisements, the Panel will only determine the HCP complaint if it considers that HCPs could have a different understanding from consumers. The Panel has decided that it will not determine a consumer complaint insofar as the CRP has been asked to decide the same issue, nor will it determine an HCP complaint if the same issue is pending in a consumer complaint before the CRP and the Panel considers the understanding of HCPs of the relevant claims would be no different from the understanding of consumers. A similar situation could arise, were court proceedings to raise issues duplicated in ASMI complaints. Indeed, it could be a contempt of the court for the Panel to determine a complaint which is pending before the court.

The following arrangements have been made for the administrative staff of ASMI and of the TGACC to avoid the possibility of duplication:

- (i) to identify to each other the advertisements or claims which are the subject of pending complaints so that both panels may be made aware of any concurrent complaints: and
- (ii) to ensure that where one panel decides to defer to the other, the other panel is so informed, thereby making it likely that the second panel will determine the complaint.

Where a complaint includes HCP advertising as well as consumer advertising, complainants usually find it more efficient to bring the whole complaint to ASMI. This might explain why it is rare for complaints to be duplicated.

It would be an abuse of the co-regulatory system and constitute undue harassment of the advertiser if a person were to complain about the same consumer advertising to both the CRP and ASMI.

Timing of Publicity

In future:

- The determination itself will clearly state that the unsuccessful party has a right of appeal, see below:

“Note: although this is called a Final Determination, each party has a right of appeal to the Arbiter. If no appeal is lodged, this determination will be published on the ASMI website once the time for lodging an appeal has expired. If there is an appeal, the Arbiter’s determination will be published on the ASMI website together with this determination. Until publication on the website, parties and their representatives should maintain the privacy of these proceedings”

- Before the case is heard, both parties will be advised that the determination will be published on the ASMI website when it is final (i.e. at the conclusion of any appeal or the expiration of time for appeal) and requested to respect the confidentiality of the proceedings until then.

Clarity of the determination (8.5.5)

In future:

- The Panel Chair will consult entire panel before ruling on claimed inconsistencies or ambiguities in a determination and will provide the Panel’s reasons.
- However, the panel will need to guard against the risk that this could turn into an unofficial appeal under the guise of alleged ambiguity or inconsistency.

Questions To The Parties (8.4.2.10)

- In future, the Chairman will make it very clear that the code states that they are only there to answer specific questions and must not engage in an exchange of words directly with the other party.

Sensory Testing- interpretation of clause 5.1.7 of ASMI Code of Practice

ASMI sought legal advice with regard interpretation of clause 5.1.7 of ASMI Code:

“Encouragement or support of unsolicited sampling of a placebo of therapeutic goods for internal use, by other than a healthcare professional, is prohibited.”

Clause 5.1.7 of the ASMI Code allows the use of samples (free of actives) for sensory testing in pharmacy so long as the aesthetic simulation is not unsolicited (i.e. if it is requested by the consumer). The use of word ‘placebo’ is to be avoided as it creates confusion. ‘Sensory Tester’ is a more appropriate term in respect of the current practice whereby the sample replicates within reasonable limits the taste/feel/appearance of the real product available on the market, devoid of any active ingredients. Both the ASMI Code and the TGAC require claims to be, accurate,

balanced and not misleading. The same applies to comparative claims. If the aesthetic simulation does not accurately replicate the therapeutic good (and any sensory advantages over other therapeutic goods), then the simulation and any claims made about it will potentially be in breach of these requirements

Sensory testers must not be presented directly to children. Children's products cannot be sampled in this way. The tester must be labeled in such a way that the consumer will understand that it is indeed a sample that is free of actives and does NOT send a confusing message to children and consumers at large about the differences between medicines and confectionary.

Sensory Testing is *permissible for all consumer healthcare products (i.e. OTCs and CMs) except Schedule 3 products NOT on Appendix H*. The aesthetic simulation and claims made about it will be considered to be advertisements. Advertising of Schedule 3 products which are not in Appendix H is prohibited. It is acceptable for sales teams to give testers to pharmacy assistants so long as it is not unsolicited, to let them experience the sensory qualities of a product.