

27 October 2008

Mr James Chisholm
Department of the Treasury
CANBERRA ACT 2600

By email: unitpricing@treasury.gov.au

Dear Mr Chisholm

ASMI would like to submit the following comments on the unit pricing issues paper.

ASMI's role and function

ASMI represents the interests of Australian manufacturers of non-prescription medicines, whether "over the counter" (OTC) or complementary medicines. Turnover of sales in this sector are over \$2bn annually.

Some information about ASMI is at Attachment 1.

ASMI's policies support principles of responsible self-medication. We believe that the idea of self-care includes the need for people to access medicines in a responsible and informed way. We support the idea that regulation of the medicines industry should be based on careful risk/benefit assessments, so that the minimum regulation, consistent with maintaining public health, ought to be the objective of governments.

Unit pricing for therapeutic goods

ASMI has carefully considered the matters set out in the issues paper. As well, we have been in touch with our colleague organisations in the UK, Europe and New Zealand. As you know, there is a European Union Directive on the matter, and we were keen to know how our colleagues saw it in light of their practical, commercial experience.

We have come to the view that unit pricing for therapeutic goods is inappropriate and that this class of goods should be exempted from the scheme. Our reasons for this view are set out below. But first, it is perhaps useful to outline a range of regulatory measures which are in force in relation to this special class of consumer goods.

Regulation of therapeutic goods

The Therapeutic Goods Act, Regulations and a large number of subordinate instruments regulate many aspects of the production, distribution and sale of medicines. The Act requires products which are to be Listed to satisfy quality and safety standards; and those to be Registered also to satisfy the authorities as to their efficacy.

Relevant to the present matter are:

- Provisions about the “presentation” of therapeutic goods;
- Scheduling of medicines, governing in what retail outlets medicines may be sold; and
- Regulation of the advertising of therapeutic goods.

“Presentation” of goods

In s.3 of the Therapeutic Goods Act, the following definition of “presentation” is given:

*“**presentation**, in relation to therapeutic goods, means the way in which the goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods”.*

It would seem that any scheme for the display of unit prices for therapeutic goods in retail outlets would fall within this definition. Under ss. 25 and 26, the Secretary must be satisfied that the presentation of therapeutic goods seeking Registration or listing is acceptable (s. 25) or not acceptable (s. 26).

Industry does not see how a unit pricing scheme could come into effect without a clear signification from the TGA that sponsors’ compliance with the scheme will not conflict with the provisions of the Act referred to above.

Retail outlets for goods

The scheduling of therapeutic goods is done by State legislation and each State is supposed to adopt “by reference” the *Schedule for the Uniform Scheduling of Drugs and Poisons*, which is drawn up and amended from time to time by the National Drugs and Poisons Schedule Committee, established under part 6-3 of the Therapeutic Goods Act.

The Schedule ranks medicines in an ascending hierarchy, in accordance with the Committee’s hazard assessments. This determines in what retail outlets medicines can be sold:

- S4 – prescription medicines – pharmacy only
- S3 – non-prescription – sold by a pharmacist only
- S2 – non-prescription – sold by a pharmacy only
- Unscheduled – “GSL” – general sale – groceries, supermarkets, etc.

From our reading of the Issues paper (p. 5), it is not clear yet which retail outlets might be bound by the unit pricing scheme. On the face of it, if pharmacies are included, then S3, S2 and GSL items would be covered. But, if supermarkets, groceries etc are the only outlets to be covered, then GSL items only would be covered.

The European Directive exempts small retail outlets from the requirement to display unit prices. Our information is that, in the UK, pharmacies have been regarded as small outlets and thus exempted. ASMI believes the same approach should be adopted here.

Adoption of such an approach would create difficulties for the sellers of goods that can be sold in either groceries, etc, or pharmacies, that is, GSL products. If unit prices were required in groceries, but not in pharmacies, consumers might seek to notice disparities, and draw uninformed conclusions. The cost structures of supermarkets, on the one hand, and pharmacies, on the other, are quite different. As well, some suppliers choose to confine their outlets to pharmacy only, even when the supermarkets are also lawfully available.

In the area of complementary medicines, similar issues arise, although not on account of Schedule differences. Some products are labelled “Practitioner only” and are supplied to customers only by a healthcare professional, as defined in Schedule 1 to the Therapeutic Goods Regulations.

And the broad range of complementary medicines will often be supplied by health food stores, as well as offered for sale in groceries, etc. The same issues as to size and disparity that we have mentioned in relation to pharmacy also apply in these cases. (Of course, most pharmacies also offer a range of complementary medicines).

Given the complexities outlined above, and given that many of the outlets for therapeutic goods are likely to be small retailers or pharmacies, ASMI believes that therapeutic goods should be exempted from any unit pricing scheme.

Advertising of therapeutic goods

The advertising of therapeutic goods is strictly regulated. See Therapeutic Goods Act, Chapter 5, Therapeutic Goods Regulations, Part 2 and the Therapeutic Goods Advertising Code (“TGAC”). For convenience, a copy of the Code is attached as Attachment 2.

“Advertising” is part of the “presentation” of goods (see s. 3, above) and is defined in the TGAC this way:

“**Advertisement** in relation to therapeutic goods as defined in the Therapeutic Goods Act 1989 includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods”.

The TGAC controls advertisements in “mainstream media” and also in “specified media”. The latter is defined this way:

“**Specified media** in relation to an advertisement or generic information, means:

- (a) mainstream media, within the meaning of s. 42B of the Act; or
- (b) broadcast media, within the meaning of s. 42B of the Act; or
- (c) cinematograph films; or
- (d) displays about goods, including posters:
 - (i) in shopping malls (except inside individual shops);
 - (ii) in or on public transport; and
 - (iii) on billboards.”

It would seem that any unit price display on retail shelves would be caught by para (d). Therefore unit price displays would have to conform with the TGAC as a whole. On the other hand, according to para 3 (1) (c) of the TGAC, it does not apply to “information material which complies with the *Price Information Code of Practice*” (“PICP”). In relation to this latter Code, see further below. But staying with the TGAC for the moment, we draw attention to para 4 (5), about “Comparative advertising”. The para says:

“Comparative advertisements must be balanced and must not be misleading or likely to be misleading, either about the therapeutic goods advertised or the therapeutic goods, or classes of therapeutic goods, with which it is compared. Points of comparison should be factual and reflect the body of scientific evidence. Comparisons should not imply that the therapeutic goods, or classes of therapeutic goods, with which comparison is made, are harmful or ineffectual.”

Price Information Code of Practice

A copy of this Code is at Attachment 3.

The PICP was drawn up in order to “complement[s] Recommendation 11 (c) of the COAG’s *Review of Drugs, Poisons and Controlled Substances Legislation* (the Galbally Review). The recommendation relates to informing consumers of the prices of medicines in S3, 4 and 8 ...”. However, by virtue of para 11, medicines scheduled as GSL, S2 or S3 are covered by the Code. By para 4 (1), however, the price information “may only be provided by retail pharmacists ... or dispensing doctors”. It follows that the PICP would only be of relevance to the unit pricing scheme if it were extended to pharmacies. For the reasons set out above, we consider this to be inappropriate.

The PICP remains a work in progress. In its present form, it was intended for adoption by the Trans-Tasman Agency, but that lapsed when New Zealand withdrew from the arrangement. We understand that the Government has future arrangements under consideration.

What goods may be advertised?

Only GSL, S2 and some S3 products may be advertised to the public. Advertisements have to be pre-cleared and are subject to a complaints system once published.

It would seem, therefore, that, should it be decided to apply the scheme to pharmacies, those S3 goods which may not be advertised would (or should) be exempt from it.

ASMI submits that the arrangements set out in the TGAC, complemented by the PICP, together amount to a scheme which protects the interests of consumers and informs them of relevant price information in ways that are preferable to a unit pricing arrangement.

What is the “unit” to be priced?

Beyond all the issues so far identified there is a practical question about what “unit” is to be compared to as between different brands?

Therapeutic goods are commonly made up of one or more active ingredients and delivered in dose form as a combination of the a.i. with a range of excipients. In theory, it might be possible to identify the weight or volume of a.i. per capsule, dose or powder, then divide that by the retail price. But it gets more complex when a product contains more than one a.i. – take, for example, the range of multi-vitamins products now offered for sale, containing scores of actives.

In the case of mouth washes, disinfectants and the like, which are offered for sale in liquid form, one might imagine that a “per ml” unit could be adopted. Even here, however, the products may be offered at different concentrations, or with a different range of additives.

It seems to us that another possible “unit” would be “per recommended dose” or “per recommended daily dose”. Even then, however, the outcome is unlikely to result in comparing like with like. Many medicines sponsors develop formulations which they present to the market as unique – “not just another headache pill”. Pack product differentiation is an essential element in our competitive economy. Over-prescriptive regulation on unit pricing could dull that edge significantly.

A further consideration – and one that goes to public health and safety – is that a “dose” of several OTC medicines will vary with the age of the patient. Children’s and infants’ doses are commonly smaller than those for adults. Affixing unit prices “per dose” in such circumstances could cause confusion at best and inappropriate consumption at worst.


Conclusions

It will be seen from the above that any unit pricing scheme, if applied to the sale and advertising of medicines, would need careful design to ensure consistency with existing regulatory arrangements.

ASMI considers, however, that the complexities identified above, and the already regulated nature of medicines sales, do not justify the imposition of a further layer of regulation.

As we have shown, there remain many unanswered questions as to the nature and scope of the scheme. **ASMI considers, however, that enough is known to justify our request for medicines to be exempt from the proposed scheme.**

Yours sincerely

A handwritten signature in black ink that reads "Juliet Seifert". The signature is written in a cursive, flowing style with a large initial 'J' and 'S'.

Juliet Seifert
Executive Director