

27 September 2013

Via Email: secretarycodecommittee@medicinesaustralia.com.au
Secretary Code of Conduct Committee
Medicines Australia
16 Napier Close
DEAKIN ACT 2600

Dear Secretary of the Code of Conduct Committee,

Submissions to the Review of the Medicines Australia Code of Conduct 2013

GSK Australia has long been a vocal advocate for greater transparency in the pharmaceutical industry. Since 2010, GSK has voluntarily disclosed publicly, aggregate payments made to Healthcare Professionals annually, consumer organisations and not for profit organisations.

As publically stated, we support the introduction of individual payment disclosure as long as appropriate consultation has taken place. Robust discussion has and is occurring regarding the model, and stakeholders are voicing their opinions. This is a positive sign and demonstrates the willingness of industry and stakeholders to work towards greater transparency.

During this debate and while assessing the model we must not forget the reason we are doing this – trust.

Industry's purpose in adopting a transparency framework is to instil trust. Research indicates that trust for the Pharmaceutical industry increases with greater transparency around the relationships with stakeholders. Unfortunately, there are still many myths that need breaking to ensure our industry can continue to work with medical experts to deliver medicines that treat and prevent disease to better the lives of Australians.

Whatever transparency model that is chosen we must never lose sight of this. Let us not get lost in administrative detail, too cumbersome to agree on and to difficult and expensive to implement.

As presented there are some areas of ambiguity surrounding the proposals that require further consideration and development to better align with the objective of the transparency framework.

GSK believes that a pragmatic approach is required for transparency to achieve its desired result. The proposed model is a step in the right direction, but it appears from a broad range of stakeholder feedback, including industry and medical practitioners that the suggested monetary limits and reporting thresholds are going to be unworkable. Should this current model receive ACCC authorisation and be too difficult to implement there could be far reaching implications on our industry. GSK encourages further dialogue to ensure a positive working model of individual payment disclosure is implemented delivers transparency that consumers are looking for.

Reporting Thresholds

On the issue of reporting thresholds, there appears to be much debate. Again we need to be pragmatic on our approach. Very low thresholds will require burdensome manual oversight of individual Healthcare Professional (HCP) spending to ensure accurate recording and reporting. This process is likely to be arduous on medical practitioners and for what purpose? We need to question whether a social courtesy, such as purchasing a coffee, has the capacity to influence a HCPs prescribing practice. Do we really believe this of our doctors, nurses, pharmacists etc in Australia? GSK doesn't.

From a HCP administrative perspective, will sales representatives present a document outlining that this interaction involving low level hospitality will be recorded for Medicines Australia reporting purposes? Is this a good use of a HCPs time? Does this add any value to HCP reporting given it is such a negligible amount? This has the potential to become a burden for Healthcare Professionals and may prove a deterrent for HCP interactions with industry - interactions which contribute to patient care and the quality use of medicines.

Reportable Monetary Limits

The options for reportable monetary limits in the current model should be questioned. Section 5.2 proposes that transfers of value or payments exceeding \$25 must be recorded and reported. The threshold of \$25 is possible; however a higher threshold should be considered as part of a phased approach to individual disclosure as a more feasible option. A phased approach starting with the higher threshold amount will give industry and HCPs the opportunity to introduce and test the new systems and processes before broadening the reporting requirements.

It would also allow time to assess whether this level of reporting meets the objective of increasing transparency in our industry – would this meet community expectations and increase trust? If it didn't, then lower thresholds could be considered. Furthermore this approach would assuage concerns by HCPs and industry over diligently capturing and reporting expenses without being detrimental to our valued partnership with Healthcare Professionals. This limit captures the appropriate level of interactions with Healthcare Professionals and exemplifies the existing reporting requirements as per Edition 17 of the Code of Conduct.

Allocation of Non Hospitality

While it is imperative that all costs associated with educational meetings are reported, GSK firmly believes that associating and reporting non hospitality costs to individual HCPs is inappropriate. Costs such as venue and audio visual hire are essential measures to ensure meetings physically can occur in the first instance. These ancillary meeting expenses do not constitute a direct transfer of value to a HCP.

Non hospitality costs should be reported and attributed to an educational event in a format similar to the current reporting system. This will also address the issue of how to report third party sponsorship costs, which cannot be addressed within individual disclosure provisions.

Clinical Research

GSK believes the proposed definition of clinical research activities is sufficient. The definition makes no delineation between marketed and non marketed products and confirms that all product research and development activities are excluded from disclosure irrespective of the commercial status of the product under clinical investigation.

Starter Packs

The matter of disclosing provision of starter packs to HCPs is one which GSK firmly believes warrants further discussion and consultation with stakeholders. There is no current limit on the number of product starter packs which can be provided to HCPs, and limitation and transparency of the maximum number to be distributed is important to ensure the appropriate use product starter packs and to minimise the perception that such items are an inducement to prescribe. This more substantial option would make the reporting of the allocation of starter packs to HCPs redundant thereby reducing one of the administrative burdens of the new transparency model.

Further to these recommendations on the Transparency Model, GSK has made recommendations on several provisions contained within the current edition of the Code of Conduct to assist with the development of Edition 18.

Section 2: Promotional Material Directed at Healthcare Professionals

GSK believes the scope of promotional material directed at healthcare professionals (Section 2.1) should be broadened to encompass electronic advertising. Currently the provisions provide guidance on printed advertisements and audiovisual materials. GSK would recommend inclusion of a section which addresses electronic advertising to provide clarity on electronic primary, secondary and short advertisements.

Section 9: Relationship with Healthcare Professionals

The Guidelines under Section 9, Relationship with Healthcare Professionals, provides recommendations on the wording which can be used for CPD accredited education. GSK recommends that the Guidelines outline companies can only make reference to CPD points on their invites if the event is officially accredited by a professional body (or pending accreditation). Invitations to HCPs suggesting that they may have the opportunity to apply for CPD points and self-record may be misleading and are therefore inappropriate.

The Guidelines in Section 9.4.1 pertaining to Educational Content outline the responsibilities of companies with respect to company initiated events, specifically that a company 'must not be perceived to be encouraging use of unapproved products or unapproved uses of approved products.' This provision should include additional language to clarify that a company organised symposia aligned to scientific conferences / congresses are included in the definition of 'company initiated events' and that these events must not be an opportunity for companies to operate outside the responsibilities outlined in this Section.

We propose that the definition outlined in Table 4 of the Guidelines 'Company Organised Activities' (Edition 17, page 122) under 'Company initiated educational meeting of short duration (less than 6 hours total education provided)', the Guidelines should include the following additional bullet point example: 'Symposium organised by company as part of scientific conference/congress'. Furthermore, we propose that the definition for 'symposium' in the Glossary be amended to the following: 'Symposium means a scientific meeting sponsored/organised by a Company as an independent event or as a satellite to a congress.'

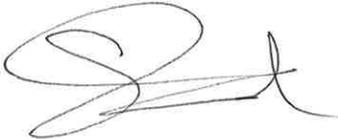
Section 13: Relationship with the General Public

GSK recommends that market research provisions, currently addressed in Section 13.10, should be expanded to include other types of information gathering, such as opinion polls and surveys. These are currently outside the scope of Medicines Australia.

Closing remarks

In closing, GSK continues to strongly support individual payment disclosure; however, the current draft model requires further discussion and development in order to address practical challenges which will hinder its success in achieving greater transparency. GSK urges industry and stakeholders to remember the reason we strive for greater transparency around interactions between industry and Healthcare Professionals. There is no doubt that consumers in Australia want this. However, we must be pragmatic and practical in our approach or risk the whole concept derailing or worse becoming so burdensome that it impacts the quality of medical care for Australian patients.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Geoff McDonald', with a stylized, cursive script.

Geoff McDonald
VP & General Manager, Pharmaceutical
GlaxoSmithKline Australia