Submission into the Medicines Australia Code of Conduct Review

AstraZeneca Australia Pty Ltd

September 2013

A. Background

AstraZeneca is committed to the highest standards of conduct in all of our operations, including the ways in which we partner with healthcare professionals. We believe that patients ultimately benefit when healthcare professionals are well informed about our medicines and we are proud of the advances in scientific practice that have resulted from our collaborations with clinicians.

AstraZeneca activities and interactions with healthcare professionals are conducted in compliance with the Medicines Australia Code of Conduct and are further bound by our own internal standards and policies. We acknowledge the value to consumers – in particular patients who are prescribed our medicines – of increased transparency around these interactions and we therefore support the principles of transparency advocated by the Transparency Working Group (TWG) in May 2013.

B. General Considerations around Transparency Working Group Model

Notwithstanding our strong endorsement of the principles of transparency, AstraZeneca has a number of concerns about the model proposed by the TWG. We are of the view that without significant revision the proposed model creates financial and bureaucratic burdens that significantly outweigh the benefits to patients of the transparency that it introduces.

i) Implementation Timeframes

The TWG model proposes that data collection around payments and transfers of value begins in January 2015. For AstraZeneca to do this, all necessary reporting systems and supporting processes would need to be in place by December 2014. Although the model, as presented, may appear relatively straightforward, it is technically very complicated to report transfers of value such as attendance at educational meetings for our current systems. Further adding to the complexity is the significant volume of data likely to be reported given the relatively low proposed thresholds of >$10 or >$25.

To extract all necessary inputs and to report them in the format proposed by the TWG will require significant investment in information technology solutions as well as changes to existing business processes across a range of core activities. Experience from the US suggests that implementation would take **at least** 12 months (and this timeframe would only be achievable where significant resources were invested). Accordingly AstraZeneca would need to commence implementation during the next two months if we were to meet the timeframes suggested. This is entirely impractical given that we will have no certainty about what we need to disclose until after the ACCC has authorised the Code in late 2014.

ii) Complexity

As well as being complex from a reporting perspective, the TWG's model may also appear complex to patients. AstraZeneca is concerned that the industry has adopted a model based on the US Physicians Payments Sunshine Provision of the Affordable Care Act rather than a model based on the needs of Australian patients. Such a model would be premised on detailed research that highlighted those areas in which patients had particular concerns about interactions between companies and their treating healthcare professionals.

AstraZeneca urges the Code of Conduct Committee to focus on utilising their consumer consultation activities to establish a clearer understanding of what information Australian patients would find valuable and the best format in which to present this. One way of doing

this would be to share with consumers samples of disclosure reports in different formats to seek comments on the usefulness of information being provided.

Many calls for improved transparency focus on payments to healthcare professionals and high cost transfers of value like international travel. However the TWG's model will require companies to direct the majority of their resource and effort to the disclosure of low value transfers and AstraZeneca remains unconvinced that the broad patient base will find this useful.

We do accept that some individuals see merit in having visibility of all transfers of value, however, for many others the volume of data that would be provided under such conditions would be overwhelming and merely serve to detract attention from those activities that are of interest.

AstraZeneca is also of the view that the level of complexity associated with this model is far higher for member companies with broader customer bases and higher volumes of activity. Acceptance of the model and associated timeframes by some member companies should not be seen as confirmation that all member companies will be able to do the same.

iii) Reaching Consensus

We are concerned about the industry's ability to reach consensus on the transparency model within the next nine months. That the TWG was unable to reach agreement on all aspects of the model after almost twelve months of deliberations suggests that that it will be extremely challenging for the broader membership of Medicines Australia and all the associated stakeholders to do so in time for ACCC authorisation.

Given the ACCC's stated expectation was that Medicines Australia members disclose "…sponsorship and fees paid to individual doctors"[1], AstraZeneca believes that the industry must consider an interim and simplified approach to transparency reporting that meets the ACCC's requests but could also be implemented in the short time frame available. We believe it would be easier for companies to reach agreement on a "phased in" approach.

iv) Consolidated Reporting & Unique Identifiers

One of the cornerstones of the TWG model was to "provide access to the information in a single, public repository, that is readily searchable"[2]. While AstraZeneca supports an easy to use system, we are concerned that the costs of developing and maintaining this repository could outweigh the incremental benefits provided to patients. In order to offer the necessary security and functionality, the portal would need to be professionally developed and the costs of doing so could be significant. As such, we encourage the Code of Conduct Committee to urgently establish likely costs so members understand the required investment. If the costs are prohibitive, and are to be worn by members, the Code of Conduct Committee should allow companies to publish on their own websites in an agreed format.

Consolidation relies entirely on the use of a unique identifier. It is clear that using an existing government identifier (e.g. AHPRA number), is preferable to the industry. However, it is not without complication. Initial advice sought by AstraZeneca suggests Medicines Australia or individual member companies may need to seek special permission under the Privacy Amendment (Enhancing Privacy Protection) Act 2012 (Cth). Accordingly we urge the Code

[1] ACCC Determination December 2012
[2] TWG Principles of Transparency Paper 2013

of Conduct Committee to immediately seek clarification from the Office of the Australian Information Commissioner. In particular it should seek clarity on the timeframes required to secure the necessary permissions to use an existing government identifier. Given reluctance by healthcare professionals to use the AHPRA number in this manner, any timeframes must build in the potential that granting special permission could be subject to significant challenge.

v) Privacy and other legal considerations

AstraZeneca urges the Code of Conduct Committee to immediately seek legal advice as to the implications of the *Privacy Amendment (Enhancing Privacy Protection) Act 2012 (Cth)* on plans to disclose identifying information about healthcare professionals with whom we interact. Additionally, the Code of Conduct Committee should consult directly with the Office of the Australian Information Commissioner to identify any additional privacy considerations that the model may give rise to.

vi) Application to other manufacturers of therapeutic goods and devices

There is general acceptance that the implications of the TWG's proposed model will be significant both for HCPs and for member companies of Medicines Australia. However, the lack of level playing field across the broader therapeutic goods and devices sector is concerning and could have a range of unintended consequences.

AstraZeneca strongly encourages all efforts to introduce consistent transparency measures across the broader sector. We call on the Code of Conduct Committee to engage directly with other industry associations to determine what elements of the model are likely to be broadly adopted and hope that this information would inform decisions made about our preferred transparency reporting model.

C. Detailed Response to the Transparency Model Consultation & Discussion Paper

i) Glossary

Underpinning the introduction of transparency reporting in the US has been a significant undertaking to provide detailed definitions of all aspects of the model and clear guidance on what needs to be included. The initial explanatory document supporting the *Patient Protection and Affordable Care Act (2009),* was over two hundred pages long. Furthermore, the Centers for Medicare and Medicaid have provided ongoing clarification of different aspect of the model through hundreds of FAQs to impacted companies.

This suggests that the proposed glossary is likely to be insufficient. Accordingly the Code of Conduct Committee should consider the establishment of a mechanism (possibly an FAQ approach) where points of clarification, including definitional and scoping issues, can be collated and shared to ensure consistent adoption of the agreed model.

Furthermore, the Code of Conduct Committee should carefully consider the resources required by whoever is tasked with providing guidance to member companies. It is likely that as companies commence the development of systems and the collection of data, they will identify significant areas that require clarification.

ii) General Requirements and Limitations: Scope of the transparency model

AstraZeneca believes that the simplest and most cost effective option of receiving and publishing the reports should be adopted. As such we believe that the reports should either be:

a) Received and published by Medicines Australia on their existing website; or
b) Published directly by member companies on their own websites (companies would be required to publish at the agreed time and confirm with Medicines Australia that publication had taken place).

While option b does not provide a single point of access for patients, this approach has the benefit of being the most cost effective. More importantly it ensures that transparency reporting could commence in a timely manner rather than be delayed as infrastructure (reporting portals, unique identifiers etc) was developed. If this approach were to be adopted, AstraZeneca would advocate some central guidance (e.g. product details, links to company reporting) being placed on the Medicines Australia website to enable patients to easily locate data they were interested in seeing.

AstraZeneca does not support the formation of a separate Foundation to manage reports given the significant additional cost burden to member companies that would likely result. When considered in conjunction with the investment that will be required to create transparency reports this option becomes infeasible.

AstraZeneca does not believe that there is currently a government department or regulatory agency that has the legislative mandate to manage the collection and reporting of this data. Accordingly attempting to find such a body would likely delay the introduction of transparency. We are also concerned that providing this data to Government for consolidation and reporting is “out of step” with Medicines Australia’s position on self regulation.

iii) Information to be Reported and Identifiers for HCPs

Feedback from the US business suggests that one of the most difficult aspects of introducing transparency reporting has been the creation of accurate customer data against which to report. If the Code of Conduct Committee is unable secure agreement on the use of an existing identifier (e.g. the AHPRA number) it cannot be assumed that the industry will be able to easily create its own unique identifiers. The cost of doing so will be significant and the Code of Conduct Committee should urgently seek quotes so that members companies can form a view of the required investment prior to Code finalisation.

If companies were able to publish on their own websites, the need for unique identifiers would be removed. This would represent a significant reduction in cost and administrative burden while still ensuring that data was available in a timely manner.

AstraZeneca would encourage the Code of Conduct Committee to further clarify the categories provided in the TWG model. Currently the explanations are high level and when applied against actual activities conducted by companies there is likely to be a lack of consistent application. For example:

- The distinction between category “a – Consulting Fee” and category “c – Honoraria” are not clearly differentiated.
- Category “f – Education” contains sufficient explanatory detail to ensure full coverage of payments or transfers of value.

Furthermore, it is essential that for each category included in reporting, a clear standard of conduct has been established within the Code of Conduct.

iv) Requirement for Payments or Other Transfers of Value Related to Continuing Professional Development Programs (CPD)

In principle, AstraZeneca supports the position that entirely independent CPD programs should be excluded from reporting. However, we are concerned that programs developed by private, for profit, professional development vendors who have been engaged directly by a company do not meet the test of independence. AstraZeneca would suggest that programs developed by not for profit medical groups (e.g. Colleges, Medicare Locals) be excluded as long as the company has played no role in the development of content and the selection and invitation of attendees however all other CPD programs would be subject to disclosure.

v) Reporting Threshold

We have already outlined our need for a “grace period” in which to prepare our systems for transparency reporting. However, we believe that existing systems and processes would allow us to capture the following transactions with only minor changes (and therefore minor delays):

- Direct payments (financial transactions) to HCPs; and
- Travel support provided to HCPs (for both domestic and international events).

We would encourage the Code of Conduct Committee to consider this type of simplified reporting for a period of 12 – 24 months in order to assess how useful this information is for patients. Any decision to expand reporting into lower level transfers of value should be

guided by feedback from patients about the usefulness of doing so. If a decision was made to expand reporting, AstraZeneca would advocate a threshold of >$25.We do not support proposals to report all transfers >$10 due to the cost and complexity of doing so.

Should the Code of Conduct Committee agree a model in which transfers of value >$25 are to be collected from 1 January 2015, AstraZeneca would be at risk of accuracy issues as we would be relying on an entirely manual process. AstraZeneca would like to make clear that we would be unable to introduce reporting at the >$10 limit within the timeframes proposed by the TWG.

Beyond the reporting challenges we have already highlighted our concerns that setting the threshold for reporting too low creates a scenario in which less frequently high value payments are deemphasised amongst the vast amounts of extremely low value transfers. We also acknowledge that difficulties with accuracy at a lower level are likely to create more opportunities for disputes with customers and hence further increase the administrative burden on members companies.

AstraZeneca does not view total function costs (e.g. room hire, AV) as a transfer of value to HCPs and therefore we do not believe these should be allocated within the transfers of value. As well as artificially inflating the amounts disclosed against a customer's name this would also serve to create a further administrative challenge for companies.

AstraZeneca does support indexation, however we would suggest that this be done on a three year basis as annual changes would create confusion and increase the training and communication requirements.

vi) Clinical research

AstraZeneca believes that clinical research and associated activities should be excluded from reporting. Reporting of clinical research payments would be extremely complex and since these activities receive oversight by established ethics committees, the benefits of transparency in this area do not outweigh the cost and burden. This is particularly true if the complexities associated with reporting Clinical research related payments and transfers resulted in delays to the introduction of reporting.

vii) Starter Packs

Starter packs are provided for the benefit of patients rather than HCPs and as such should be excluded from transparency reporting.

viii) Payment for Expert Witnesses in legal or administrative proceedings

AstraZeneca agrees with the TWG that payments for expert witnesses in legal or administrative proceedings should be excluded from transparency reporting.

ix) Procedures for Electronic Submission of Reports

AstraZeneca sees clear benefit for patients of more regular reporting of data than the annual cycle proposed by the TWG. As companies will be managing smaller volumes of data each quarter this is also logistically preferable than a single annual report.

We request that the Code of Conduct Committee considers reporting on a quarterly basis in line with the following schedule:

Date	Data Reporting for Q1
1 Jan - 31 March	Collect data
1 April – 30 June	Review and confirm data with HCPs
31 July	Publish data

x) Data Disputes, Errors or Omissions

AstraZeneca is extremely concerned about the resource requirements associated with the data validation and dispute resolution processes. Furthermore we do not believe that it is sufficient for companies to be expected to resolve all disputes directly with customers. At some point the customer will need to be able to escalate a dispute through an agreed conflict resolution process.

We are also of the view that errors and omission must be updated more regularly than has been proposed by the TWG. If companies were reporting this data on their own websites, AstraZeneca would commit to updating errors and omissions within one week of confirmation. We believe that this is better aligned with Privacy requirements and demonstrates greater cognition of the potential damage that incorrect data could have on a healthcare professional's reputation.

D. Suggestions for Review of other areas of the Medicines Australia Code

i) Digital

There has been a significant increase in the use of digital technology by member companies since Edition 17 was introduced. Particular issues include:

- The development of apps to support disease state awareness, product usage, prescribing etc
- Google and other forms of online advertising that are less controlled than direct advertising in online journals
- Requirements around URLs (in particular issues with product names)

AstraZeneca calls for more detailed guidance within the Code to address these issues and to place some parameters around emerging digital issues that have yet to be considered.

The industry must also acknowledge that the internet is becoming an increasingly important source of health information for patients. Patients can now access company developed promotional websites from the US and New Zealand (both markets where direct to consumer advertising is allowed). Perhaps more concerning, consumers can access information about products via less controlled areas of internet including forums, blogs and similar sites. As such, further consideration needs to be given to whether current rules are in the best interests of patients.

ii) Company Interactions with Medical Students (Undergraduate)

It is AstraZeneca's interpretation of the Code that undergraduate medical students do not meet the definition of a healthcare practitioner and therefore should not attend company organised educational events. However, feedback from healthcare professionals suggests that this is not an approach applied consistently by all member companies. Accordingly, AstraZeneca seeks clarification within the Code on this matter.

In developing a clear position on this, AstraZeneca calls on the Code of Conduct Committee to consider that there may be particular community concern in relation to the skills and experience of undergraduate medical students to assess information provided, particular in the context of promotional activities. Feedback from the Australian Medical Students Association (AMSA) may be sought to further clarify this position.

iii) Product Starter Packs

AstraZeneca proposes no change to the Code provisions around the distribution of product starter packs to healthcare professionals. Feedback from healthcare professionals identifies enormous patient benefit associated with access to samples.

iv) Reporting of Educational Events, Payments to Healthcare Professional Consultants and Advisory Board Members

If transparency measures are introduced around HCP payments and transfers of value AstraZeneca proposes concurrent discontinuation of requirements for companies to submit Educational Events and Payments to HCP reports for consultancies and Advisory Boards. This will avoid duplication of effort in reporting what is essentially the same information in a different format.