Boehringer Ingelheim Pty Limited

Submission into the Review of the Medicines Australia Code of Conduct 17th Edition

Transparency Model Consultation and Discussion Paper

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Part 1 Transparency Model Consultation and Discussion Paper

This section provides our submission responding to the Transparency Model Consultation and Discussion Paper developed by the MA Transparency Working Group (TWG).

1. Executive Summary

Boehringer Ingelheim (BI) recognises the critical role that healthcare professionals (HCP) and healthcare organisations (HCO) play in regard to the provision of legitimate expertise and services to the pharmaceutical industry. The interaction between pharmaceutical companies and HCPs / HCOs is important in ensuring appropriate education on the use of prescription medications, quality use of medicines, and improved patient outcomes. The interaction is also integral to addressing future needs of patients through future research.

BI also recognises the increasing expectation for transparency demanded by consumers in regard to the relationship between the pharmaceutical industry and HCPs / HCOs, and the steps already taken overseas in an attempt to address these demands. While BI recognises that our industry through MA has already taken significant steps to increase transparency, BI supports the move to increased transparency, reflecting the industry's fair compensation for the time and expertise provided by HCPs and HCOs. BI however is concerned at the potential for significant complexity, cost and infrastructure required in the TWG's proposal. BI also hold concerns regarding the proposed timing of implementation which it believes is not achievable, as borne out by experience in the US and Europe.

BI believes that while self-regulation needs to respond to the changing demands of society, Medicines Australia's (MA) Code of Conduct has evolved to very effectively regulate the conduct of its member companies in recent years. It is recognised that MA's Code of Conduct is more rigorous in its demands than most other industry groups (particularly in the health sector) in Australia. Good examples of this are the current reporting requirements for sponsorship of HCPs to attend educational events, advisory boards and consultancy agreements. Although the TWG has said they believe the transparency principles are applicable to all therapeutic goods companies BI is concerned that it is unlikely they will adopt similar transparency in reporting unless forced to by legislation – this makes it a somewhat uneven playing field even within the healthcare arena.

The TWG model is based on the Sunshine Act in the US and it should be remembered that this has been under development for a number of years with the first collection and reporting of HCP spend only happening now. In parallel the European Federation of Pharmaceutical Industries and Associations (EFPIA) has also developed a code on disclosure of transfers of value to HCPs and HCOs which is required to be included in all member country codes by January 2014. There are significant differences between the US and European codes, particularly in regard to the complexity of data collection and disclosure. The EFPIA Code was approved at its General Assembly on 24 June 2013, and as such may not have been considered by the TWG. It is important that the recommendations of EFPIA are now considered.

EFPIA requires that data collection in Europe commences in January 2015, eighteen months after the approval of the Code, which provided clarity in regard to both reporting categories and format. This time frame appears far more realistic than that proposed by the TWG. BI contends that the issue of primary concern to consumers is the potential for HCPs to be influenced through the transfer of value from commercial entities. In this regard it is the higher value items which present the greatest concern and these should form the focus of reporting, consistent with the guidance from EFPIA. Focus on transfers of value above $25 will capture those items of greatest concern, as well as enabling the industry to implement the process in a timely fashion. Many of these costs are already captured by companies (e.g. consultancy, advisory boards, sponsorhips, speaker's fees and honorariums). To focus on items of lower value will greatly delay the implementation of reporting, add hugely to the complexity and cost not only of data capture but also reporting, and is unlikely to provide any additional benefit to consumers.

Many urgent issues still need to be addressed including privacy legislation, hosting of reports and identification of HCPs. This makes the current proposed timing of implementation unrealistic. BI proposes that implementation of reporting should be delayed to 2017 to accommodate the necessary steps to achieve data collection from the start of 2016.

2. Urgent issues to be addressed

2.1 Recognition that the proposed timing is not achievable

MA has proposed that a revised draft Code be approved by the MA board at the end of Q2 2014 for submission to the ACCC, with their recommendation anticipated 6 months later – potentially 31/12/2014. It is possible that any changes to the draft Code required by ACCC will not be known prior to this date. The TWG's proposal that data collection starts on 1/1/2015 means that there will be no opportunity to amend any processes prior to data collection. More importantly until we know the final outcome it makes no sense to start building any systems or processes that may or may not be required. This is likely to be a timely, costly process which will require budgets to be approved by parent companies. In the absence of any certainty on the criteria for data collection and reporting such budgets are unlikely to be approved. Once we have a clear understanding of what will need to be reported we can start to develop the means to do it. As systems development would most likely take 12 – 18 months, depending on the requirements, clearly an extension to the 1/1/2015 data collection commencement date is required. EFPIA, in their Code on Disclosure provided 18 months from finalisation to implementation, and this is considered an achievable and realistic timeframe. This would mean starting data collection from mid 2016, with publication in late 2017.

2.2 Privacy

The TWG have not addressed the privacy issues around the reporting of transfers of value (TOVs) to HCPs. Unlike the Sunshine Act, the transparency model is part of an industry self-regulated code and not legislation and there may be no requirement for HCPs to accept that TOV data identifiable to them be published. If HCPs can opt out of having their personal information reported then the entire concept fails. In addition there are issues around the collection, security, hosting, reprocessing and storage that need to be considered both by individual companies and MA.

It is therefore essential that MA obtain legal advice on the relevant privacy issues to determine if the publication of HCP payments is possible and, if so, under what conditions. This is an absolute priority as it will greatly influence any model for the future.

2.3 Unique Identifier

It has been noted that for any form of aggregation by consumers, the HCP payment data needs to be published with a unique identifier that is consitent across all companies. The TWG proposed that this should be the AHPRA Registration Number however it has not been established if this is allowable or how it can be accessed by MA member companies. As a unique identifier underpins one of the primary purposes of the model it is essential that a practical solution for this be identified as soon as possible.

The Code Review Panel should further explore the use of APHRA registration numbers or alternatives to determine if they can be used, how they can be distributed to the companies to tie in with their own databases (e.g. able to be provided by 3rd parties such as Cegedim) and how they will be updated.

BI's preference would be to utilise the AHPRA numbers as the unique identifier should this be allowable. If this is not possible it should be investigated whether the APHRA database of HCPs may be utilised either by MA or an independent third party who could then tag each HCP with a unique identifier and provide this list to MA member companies.

2.4 Consolidated Hosting & Reporting

The TWG has proposed that the published data be centrally hosted and published. This could be done by MA, a 3rd Party or a regulatory agency (e.g. APHRA). This has been done in the US and in the Netherlands however they have been working towards this for a long time and there are many issues to be covered off before this can be done. This will include:

- Who will pay for the system development and ongoing maintenance (this will be a sizable cost)?
- Who will develop the system specifications?
- How will the system receive data from companies?
- Will HCPs have separate access to the system and who will maintain this?
- Who would have responsibility for the integrity and accuracy of data stored in a central location?

In its Code EFPIA mandates that so long as disclosures are unrestricted and publicly available they may be made either on the relevant Member Company's website or on a central platform, such as one provided by the relevant government, regulatory or professional authority or body or a Member Association, but that these disclosures must be consistent with the structure mandated by EFPIA.

Responsibility for the data generated by a company remains with that company and the aggregation of such data by a third party brings into question who is then responsible for the integrity of this aggregated data. In light of these concerns BI supports a model where each member company of MA provides data in a pre-agreed template to be displayed on an MA website unchanged. In this manner

the integrity of the data is maintained, there is clear transparency in regard to any transfer of value between a company and HCPs, and the costs associated with aggregation of data are limited. Data regarding the sponsorship of HCPs attending educational meetings is already presented in this manner on the MA website.

BI fully supports the principles of transparency in regard to any transfer of value to HCPs, but believes that an appropriate balance between the significant costs and complexity of reporting needs to be struck with the level of reporting which would be demanded by the average consumer. BI believes that he proposal above would meet this balance and allow for transparency reports to be made available sooner.

3. Specific Comments on the Transparency Model

3.1 Initial Reporting

The aim of the model is to provide information to consumers on TOVs to HCPs. As we have noted due to the time constraints for understanding the reporting requirements and developing the approprate systems and processes, it would seem logical that we should focus on the categories of expenditure that have the most value, and are able to be provided with relatively little systems modification.

3.1.1 High value Items

This would apply to the following expenditure categories noted in 3.7 :

- Consulting
- Professional services (including chairperson or speaker at an educational event)
- Honorariums (including Advisory Board activities)
- Conference registrations
- Market research
- Royalties or licence fees
- Ownership or investment interest
- Grants

There would remain some issues that need to be addressed in this area which include:

- ensuring that all privacy aspects are covered off as this may involve amending contracts to cover HCP spend reporting;
- a clearer definition of when a payment is to an organisation (not reportable) and an individual within an organisation (reportable);

The areas that are more complex, but of lower value, are listed in 3.1.2-4 below.

3.1.2 Educational Events

These are currently reported on an aggregate basis with total hospital and total function costs separately disclosed, together with the number of HCPs who accepted invitations. If costs are to be allocated to individuals a number of issues require consideration, including how hospitality costs should be allocated, whether non-hospitality and non-travel costs (e.g. venue hire, AV) be allocated, and so on.

To establish a full allocation model would require the major development and master data alignment which would take from 1 year to 18 months develop (see 3.3 System development issues below) but would also require approval from our parent company prior to investment.

To facilitate the reporting of TOV at educational events BI proposes the use of a quoted reportable cost for each HCP attending an event. This reportable cost would be made available to the HCP prior to registration for a meeting, and part of the registration process would include acceptance of this cost as the appropriate TOV for attendance at the event. Internal processes to generate a reliable cost for a function and clear guidelines on what is included (food, drink, accommodation, travel, etc) and what number of attendees should be estimated.

Speaker costs would not be included as they would be already reported against that HCP.
Companies could undertake sample auditing of quoted reportable costs against actual costs to prove that the initial costings were accurate. This would be auditable by MA if required.

This proposal for quoted reportable costs has a number of benefits:

a) The HCPs know in advance what the reported cost will be, making later verification easier;
b) The privacy aspect is well covered;
c) Only those attending and receiving a transfer of value are reported;
d) There would not be the required allocation system development; and
e) This idea was proposed by one of the Consumer group delegates to the TWG.

The requirements for this to work include:

a) Acceptance by MA, ACCC & Stakeholders that the estimated cost is a reasonable approach and that there will not be a reconciliation process required to compare actual costs vs reported costs;
b) Agreement on what costs would be reportable (hospitality & function costs); and
c) Consideration of whether we should include the CPD hours and description of the educational content as a context to the hospitality costs as is currently provided by the aggregate reporting.

The substantial contribution of the industry to the education of HCPs and improved quality of care of patients should not be lost during this reporting process. Currently the education event reporting captures this substantial contribution. To this BI believes it important that the record of TOV not only includes details of monetary transactions, but also details of the nature of the event for which the TOV was made.

It is instructive that EFPIA, in their transparency reporting do not require companies to report costs of food and beverage. BI supports the reporting of costs for food and beverage in Australian reporting, subject to a threshold discussed later, but does not believe that the non-hospitality and non-function costs should be allocated to an individual, unless it is clearly specified that these costs are function administration costs. The cost would be split between hospitality and function costs for reporting – similar to what is done in the educational event reporting.

3.1.3 In-Surgery meetings

Lunches at in-surgery meetings are common place but are of low value. It is not unreasonable to expect that where educational meetings occur in HCP work premises over a lunch period, a modest lunch (e.g. sandwich) should be provided to the HCP. Such a low value item cannot be construed to influence HCP's prescribing behaviour, and perhaps for this reason EFPIA has not considered this a necessary item to report as part of its new disclosure code.

The system development to collect and allocate such low value expenditures would be extremely complex and totally out of proportion with the reported values. In addition to adding great complexity, cost and time for implementation there would be the added complication of needing to collect signatures from those attending the lunch to cover privacy requirements and the need to identify the TOVs for each HCP attending. This in itself poses significant practical issues, especially when such low value items are not likely to be the primary concern for consumers.

3.1.4 Grand Rounds

It is extremely difficult to identify who would be attending such events as the participants can come and go and overall these attract low cost hospitality (e.g. sandwiches). BI submits that these events be excluded from reporting as it is impractical to record attendees and allocate costs and that these activities would fall under the proposed exclusion from reporting point 5.1 in the TWG Consultation and Discussion Paper.

3.1.5 Reporting Hosting

BI submit that the HCP spend data be reported either on the company website in a standard format, or in an unchanged form on a MA website as proposed in the EFPIA model. The preferred option is to host on a company website as this avoids the need to establish a 3rd party hosting and file transfers from member companies. It also means that data is clearly seen as relevant to one company and not viewed in a mixed offering from a number of companies which can colour an observer's view and has the potential to generate errors in data transcription.

3.1.6 Reporting Threshold

BI would support the TWG proposal of a reasonable threshold of $25 per head for recording and reporting payments or TOVs to HCPs with an annual increase in line with the CPI. BI would establish internal processes to ensure that this threshold was not exceeded for lower value items such as working lunches.

Audits of randomly selected meetings would be performed to ensure compliance and these would be available for MA to review.

BI would not support the proposal for a $10 threshold for recording with reporting for annual cumulative payments or transfers over $100 for the reasons given previously in regard to limited benefit to consumers, added complexity, cost and time to implement.

3.2 Review Process

The review process for HCPs is likely to be labour intensive, though it is a necessary part of the process. The dispute resolution process would be onerous for the low value items (e.g. lunches) and the educational events if there need to be many allocated costs as this will require provision of an audit report detailing all calculations traced back to source documents. BI's proposal for a reasonable threshold and up-front quoted reportable costs will overcome most of these issues, since HCPs will have agreed to the payment or TOV prior to the event.

The model proposes that companies will publish the data even if it is still in dispute with the HCP. This is problematic as it may give rise to legal action against the company if the HCP believes their reputation has been damaged without fair hearing. BI proposes deferral of reporting if an amount is under dispute though this may encourage a rush of challenges just to delay reporting.

If there are numerous queries then the time frame proposed may not be adequate and could tie up significant resources.

3.3 System Development Issues

The in-house systems requirements to store the high volume, low value transactions such as educational events and in-surgery lunches are quite complex. This would involve the development of databases and specific interfaces between current sytems such as ERP, travel and expense systems, as well as creating of more detailed audit trails. This will be a costly and time consuming process for which a clear scope is required at the outset of the project.

This sort of system landscape is still in development by BI in the US even though they have been preparing for the Sunshine Act for a number of years and have significantly greater resources than BI Australia. Not all necessary sytems are available across the company globally with the parent company tightly controlling the rollout of systems such as the SAP ERP system. Any move to capture low value items will inevitably lead to delays in implementing reporting.

The development time, only once the reporting requirements have been finalised, would be around 12 months and this would also require implementation of new workflows and business practices.

4. Other issues raised in the TWG Model Proposal

The following points reference the relevant section of the discussion paper.

3.7 Category of payment or transfer of value.

The categories listed by the TWG appear sufficient to cover the types of payments and transfers of value which are likely.

BI believes it is important that the nature of the activity where a payment or TOV has taken place can be stated to enable consumers to understand the nature of the interaction between the company and the HCP.

It is worthy of note that the code mandated by EFPIA requires reporting only of an aggregated TOV, where all transfers of value for an individual HCP are summed up, with itemization available only for the individual recipient or public authorities' consultation. The Code Review Panel should give consideration to an aggregated figure per individual for ease of viewing by consumers.

3.8. Payments to third parties, including registered charities

BI supports the position taken by the TWG in regard to payments to third parties, including registered charities.

4. Requirements for payments or other transfers of value related to continuing professional development programs.

BI proposes that an additional condition be added to section 4.1 to read:

4.1 (d) The company does not have any influence or involvement in the preparation, creation or review of materials forming any part of the Continuing Professional Development activity.

5.3 Clinical research

BI supports the TWG proposal to exclude clinical research payments from reporting.

5.4 Starter packs

BI supports the TWG proposal to exclude starter packs from reporting as these do not represent a TOV to HCPs, but rather to consumers. Reporting of starter packs as a TOV to HCPs may result in reduced access of starter packs for patients. These packs are considered to be of benefit by patients and the removal of them is unlikely to benefit consumers.

5.11 Payments for expert witness in legal or administrative proceedings

BI proposes that if the HCP is selected as an expert witness by a third party then this payment should not be recorded, but where a HCP is selected as an expert witness by a pharmaceutical company then this payment should be reported. In this instance the HCP is performing a professional service requested by the company for which he/she is receiving a fee.

7.5 Updating the information

BI proposes that historical information is removed from the public website after a period of 3 years as mandated in the EFPIA Code on Disclosure.

Part 2 Comments to Code of Conduct 17th Edition (apart from Transparency)

This section provides our submission responding to the remainder of the revisions to the Code.

1. Section 7. Product Starter Packs

   BI is mindful of prior discussion regarding the provision of product starter packs to HCPs and wishes to express its support for the current guidance provided in Code edition 17 for the provision of starter packs.

   These are of value to patients being prescribed a medication for the first time, helping to ensuring tolerability to the product before larger quantities are dispensed.

   BI believes that the current provisions under the Code are sufficient to ensure appropriate distribution, use and recording of product starter packs.

2. Section 8. Product Familiarisation Programs (PFP)

   There has been much public comment on the role and appropriateness of PFPs in recent years. Unfortunately it has not been uncommon for much of this discussion to be ill informed, without due regard to the extensive measures put in place to educate HCPs in the appropriate use of medications, educate HCPs and patients on the conditions of the PFP and the measures instituted to ensure reporting of any adverse events.

   PFPs provide an opportunity for the managed entry of new medications. Programs such as this allow HCPs limited access to new medications in a controlled manner, as opposed to the open access available immediately upon PBS listing. The potential for much more rapid uptake of new medications immediately following PBS listing, particularly in primary care, without the opportunity for managed entry poses considerable challenges.

   BI's experience with PFPs has been to launch such programs only where the product has received a positive PBAC recommendation (and in some cases, such as Pradaxa, where pricing has also been agreed with the Health Department). A positive PBAC recommendation provides an indication for the patient criteria that should be employed in the PFP. BI remains concerned that PFPs should only be initiated following a positive PBAC recommendation as launch of a program without this (or even following PBAC rejection) means that the enrolment criteria for patients may not meet future PBS listings, creating a population of patients on medication who will only be able to maintain treatment via private scripts upon PBS listing.

Currently the Code prohibits the collection of individual patient data in PFPs. Whilst simplifying the process of the PFP with the prohibition of formal data collection, there is a lost opportunity to collate what could be useful information. BI proposes that such programs would have greater utility and external validity if they could be used to gather "real world data". Collection of such data would be required to be by a third party.

The requirement to use product starter packs only for these programs appears to be an unnecessary complexity, and unless required under legislation BI suggests that trade packs may be supplied as part of PFPs. The use of trade packs may more easily enable a role for pharmacy in the dispensing of product as part of a PFP. The involvement of pharmacy in such programs is to be encouraged in the interests of quality use of medicines however this must be considered carefully verses the benefits from having patients regularly present to their doctor to collect medication and have their progress carefully reviewed.

3. Section 13.8 Use of the internet

Section 13.8.1 of the code states that "In relation to company disease state websites there should not be a focus on the company's product(s)".
BI proposes that the following wording be placed in the preamble for section 13.8:

"Website addresses must not contain any product brand name".

Use of a brand name on a website address (url) contravenes the prohibitions on marketing prescription pharmaceuticals direct to the general public under the Therapeutic Goods Act. In particular Section 42DL of the TG Act prohibits advertisements to the general public which refer to substances containing materials listed in Schedule 4 of the Poisons Standard 2012.