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Bristol-Myers Squibb

20 September 2013

Sophie Hibburd
Manager, Code of Conduct
Medicines Australia
16 Napier Close
DEAKIN ACT 2600

Dear Ms Hibburd,

Re: BMS Submission to Code review Panel 2013

Thank you for the opportunity to input into the new edition of the Code of Conduct.

It is important to state from the outset, that BMS supports greater transparency of the pharmaceutical industry. However, BMS does not support either of the two models presented in the Transparency Model – Consultation and Discussion Paper. These two models are imbalanced in terms of costs and benefits. They also fail to recognise the need for incremental and stepped change. BMS does not wish to risk missing this opportunity for embedding greater transparency and asks the Panel to consider an alternative model that is activity based or focuses on higher cost transactions. This will allow all parties to become accustomed to new reporting requirements.

The Sunshine Act has only recently been implemented in the United States and is flawed in many ways. Furthermore, the lead-up to the roll-out of the Sunshine Act was lengthy. Firstly, a system such as the one implemented in the US is one of several models to consider and probably isn't the best option to meet the transparency needs in Australia. Secondly, before implementing a new system, it is important to understand the issues comprehensively and ensure a system and implementation timeline addresses them completely and appropriately.

In our view, transparency should not be limited to the Prescription Sector of the Pharmaceutical industry. For transparency to work, such initiatives must be implemented across all sectors of the Health Industry including the Device, Generic and Complementary sectors and across all HCPs (Doctors, Pharmacists, Nurses, Dieticians etc). Therefore, we would ask that Medicines Australia inputs into the authorisation of other Codes such as GMIA when called upon by the ACCC.

The following pages will outline the BMS position on several elements of the Code of Conduct. Should you have any questions, please do not hesitate to contact Aaron Guttmann, BMS Australia's Country Compliance Manager. We have no objection to having our submission posted on the Medicines Australia website.

Yours sincerely,

Anthony Mancini
Managing Director Australia/New Zealand
Bristol-Myers Squibb Australia Pty Ltd

PART 1 - BMS Comments on the Transparency Model Consultation & Discussion Paper

A. Page 2 - Glossary

BMS has no additional comments around this section

B. Page 3 - General Requirement & Limitations: Scope of the Transparency Model

BMS believes that the transparency initiatives must not be limited to the Pharmaceutical Industry (specifically the prescription medicine sector). To ensure the spirit by which the principles of transparency were drafted, all sectors must provide the same information consistently. For such an initiative to be credible, it must be implemented across all sectors of the Health Industry including the Device, Generic and Complementary sectors and across all HCPs (Doctors, Pharmacists, Nurses, Dieticians etc).

In-line with the 7th principle of transparency, BMS does support the use of AHPRA (or an equivalent organisation) to publish the reports. However, there must be a change to the AHPRA charter as currently AHPRA is not designed nor established for this activity. Otherwise, we believe there is a risk that HCPs will disengage from the process.

If Medicines Australia (MA) manages the transparency reports it will create the wrong impression that this is specifically for MA member companies and more importantly may face difficulty down the track should other industries follow suit. For example, the devices industry may not wish to have their reports managed through MA. Similarly MA should not be funding the management of transparency for the whole Health sector.

Before engaging in this activity; particularly if utilising AHPRA information, all privacy and taxation limitations must be explored and legal advice sought. There are numerous implications that must be explored prior to rolling out such a process/system. These issues alone may require more time to consider and make it very difficult to commit to a 1 January 2015 reporting period.

C. Page 4 - Identifiers for Healthcare Professionals (HCPs)

BMS supports the need to have unique identifiers in whatever form that may be. Without such an identifier, there is considerable scope for errors. The AHPRA registration number is generally appropriate but there are still factors that will need to be considered:

(1) How do we deal with HCPs with multiple numbers (eg. multiple qualifications)?
(2) How do we deal with HCPs with different registered names (eg. maiden name vs married name; shortened names by which consumers know their HCPs)?
(3) Privacy implications whereby the AHPRA site was never intended for this level of scrutiny by the public
(4) Would be use of AHPRA site and any modifications enable or disable any primary or secondary purpose for the site and thus lead to unintended consequences for participants?

D. Page 6 – Category of payment or transfer of value

BMS understands that some consumers and media would appreciate receiving a simple report such that they do not have to review a long list of transactions and data. However, it is important to note that the more general the report, the greater the chance of misinterpretation. Lumping all hospitality costs may result in a consumer misinterpreting the level of hospitality provided (eg. 10 occurrences of $10 meals will indicate $100 of hospitality being provided but the consumer will not understand that it involved 10 transactions).

Conversely, HCPs will want to see the report at a granular level to determine if the report is accurate. BMS believes that a detailed report be provided so it is clear what each activity is and what value is associated with the activity.

BMS believes that it is unlikely that grants are provided for individuals and greater clarity is needed as the current provisions may be confusing for the industry. BMS asks that it be made clear that a grant to an organisation requested by an individual is outside the scope of the transparency reporting and cannot be attributed to that individual.

BMS suggests combining honorarium and consulting fees as these terms are interchanged fairly often.

E. Page 7 – Payments to third parties, including registered charities

BMS understands that payments to third parties or charities on behalf of a HCP as part of (or in lieu of) an honorarium is proposed to be included in the transparency reporting. Using the definition of "transfers of value" it remains unclear where such payments fit in. BMS recognises there may be some reputational enhancement for the HCP in requesting payment be made to charities. Furthermore, while there may be some tax benefits for the individual, they may or may not be recognised or realised by the HCP.

BMS supports the inclusion of payments to 3rd parties/charities but questions whether this goes beyond the scope of this initiative. The reporting may not confer the transparency of the interaction fairly or accurately, leading to complications and complexities in reporting and understanding. For example, should the HCP nominate several charities from which the company chooses, does this exempt the reporting of the honorarium? BMS believes that this should be reported as the HCP has played a role in selecting the charity. Moreover, how would such reporting be checked for accuracy by the HCP, or even fairly attributed as transactional benefit? While BMS believes that this transaction should still be included in the reporting, attribution is problematic. BMS believes that this practice be banned as it is up to the HCP to decide to donate to their prospective charity.

F. Page 8 – Continuing Professional Development Programs

BMS supports the proposal to exclude payments or transfers of value to a healthcare professional in association with a CPD activity as the company does not choose the speaker(s). Furthermore, logistically it is difficult to apportion the cost of a speaker as normally a lump sum of money is provided to the independent organization. This can used for different elements of the activity and may also involve other companies.

G. Page 9 – Reporting Thresholds

The two models proposed are imbalanced in terms of costs and benefits. They also fail to recognise the need for incremental and stepped change. Instead, BMS asks the Panel to consider an alternative model that is activity based rather than focusing on a monetary value. Reporting on contracted activities can be implemented immediately, reduces the likelihood of disputes and more particularly, is most closely aligned to matters that could be perceived as influencing.

BMS proposes the following:

- Full disclosure of all activities contracted by a company. This would include:
    - any paid consultancy or speaking engagement
    - any sponsorship to attend a 3rd party educational meeting
    - any supported medical activity (eg. temporary provision of a nurse) – please note that this is unlikely to be reported as the transfer of value is unlikely to be allocated to an individual.
- Any transfer of value uncontracted exceeding $1000 which is in-line with the *Commonwealth Electoral Amendment (Political Donations and Other Measures) Bill 2010.*

BMS fundamentally disagrees with an aggregate level being implemented regardless of the total amount as it would mean companies would require implementing sensitive systems that go to the absolute granular level. Every coffee, muffin or sandwich would be required to be monitored in the case the total aggregate exceeds the limit. Such a system would require significant cost and time that would be unrealistic to implement by the 2015 data capturing period.

It is important to note that one cannot assume that systems potentially implemented in other markets such as the US could be automatically implemented in Australia as different systems and vendors may be used. It would also be helpful to better understand the approach taken on transparency in markets that are similar to Australia such as Canada.

BMS also believes the $10 or $25 limit is unrealistic and goes well beyond what the average person may consider as “influencing” and therefore creates an imbalance of the costs of implementation versus the very limited benefits. Most healthcare professionals would pay considerably more for a meal themselves. As described above, even at a political value, they would only need to disclose amounts greater than $1000. BMS understands that the proposed $10 limit is based on the US Sunshine Act. It is important to note that what is available for $10 USD is quite different to what would be available in Australia.

Moreover, the Sunshine Act is a legislatively based provision, which carries all the protections and obligations of same; including provision for appeals and redress. The responsibilities for implementation are also framed in legislative framework. While not advocating for a legislative framework for Australia's requirements, this major difference in approaches underpins why the Australia's transparency provisions will be different in scope, implementation, and outcomes.

In summary, BMS strongly believes that the two proposed models are unachievable in a short timeframe, with unacceptably high costs, with benefits highly questionable and uncertain. Rolling-out a transparency initiative around an amount rather than an activity will result in numerous logistical and system issues that can reduce the reporting quality or cost to MA or the industry making it untenable. BMS advocates for an activity based transparency model rather than a cost based model (eg. contracted services and sponsorships).

An acceptable alternative would be limiting the reporting to higher cost transactions such as transactions over $1000. BMS believes that no aggregation requirements be imposed as this adds to the complexity of the process. .

H. Page 10 – Non-Hospitality, non-Travel costs

BMS believes that it is inappropriate to apportion costs associated with AV hire, venue hire, etc to individual HCPs. The underlying reason for the reporting is to highlight benefits that may be perceived as "influencing". There is no direct benefit to the individual for these elements of a meeting. Furthermore and importantly, the transparency elements must not be considered in isolation from the rest of the Code. Venues and similar elements must not bring the industry into disrepute and there are separate and adequate provisions in the Code that specifically assess for venue-related elements.

There are many logistical issues that would make accurate reporting difficult. For example: if a limited number of keypads were used as part of an educational event it would be extremely difficult and impractical for a company to identify who used one.

Similarly, costs of webinars or other forms of educational delivery mechanisms do not themselves confer value and availability of the tool is unlikely to be "influencing". It would be unreasonable to expect that the costs of webinars be reported against an individual if the HCP reviews the webinar from home with no hospitality provided.

I. Page 10 – Clinical research

BMS supports the proposal to exclude clinical research from the transparency reporting. Clinical Research is outside the scope of the Medicines Australia Code of Conduct.

J. Page 11 – Starter Packs

BMS supports the proposal to exclude starter packs as the benefit ultimately is transferred to the patient. Whilst there may be some enhanced relationships generated from Starter Packs, this is more likely to be associated with the Medical Practice rather than the individual healthcare professional.

K. Page 12 – Expert Witnesses

BMS supports the proposal to exclude payments for expert witnesses as ultimately the benefit is to the Courts. However, BMS would support the reporting of such payments if part of a contracted service. The same will be true for expert submissions to the TGA as part of a regulatory submission.

L. Page 12 – Procedures for electronic submission of reports

BMS has no concerns about the reporting dates. We note that the proposed dates occur outside the busy holiday period. Submitting reports or dealing with disputes in late December or early January would be problematic as many HCPs and company employees are absent and not contactable.

As stated previously (Section B), BMS's preference is not to have Medicines Australia administer the transparency reporting as this initiative should be consistent across the entire Health Industry, including device companies, generic companies, and complementary medicine companies. It is unfair and unrealistic to expect MA member companies to fund the entire operation.

M. Page 13 – Notification

BMS has no additional comments around this section. We believe the timeframe for comment is reasonable.

N. Page 13 – Data Disputes

BMS accepts that this is an important component to any model around transparency but also envisages this will cause a significant amount of labour and time to deal with. BMS believes that the lower the threshold for reporting as discussed in Section G of this document, the more disputes will occur and potentially reduce the quality of the report. Similarly providing a total value associated with a category of "transfer of value" will also result in numerous disputes as HCPs question what the total value includes (section D)

BMS reaffirms our position that transparency reporting be limited to contracted activities whereby disputes are less likely and consumers will not need to review extensive data to understand the transfer of value to the HCP. Once this is in operation, the industry can consider other opportunities to improve transparency.

BMS questions whether the publication of data being disputed is fair. Whilst understanding delays in reporting is not ideal, errors in reporting even under the category of "disputed" can compromise the position of a HCP and may contravene the principles of natural justice. Rather than listing and associating a cost to a disputed activity, BMS believes a broad statement to say "Other activities involving this healthcare professional and Company X" are in dispute". If after a period of time (eg. 3 months) agreement cannot be reached, the activity can be arbitrated by Medicines Australia or listed on the internet site as disputed (ie. activity, cost under a heading of disputed).

O. Page 15 – Updating the information

BMS does not see the value of keeping the information on the website after the year of reporting is finished. BMS proposes that after 12 months, the new annual transparency data replaces the previous data.

P. Other considerations

BMS believes that there are other exclusions that should be considered. For example, it would be unfair and highly inappropriate that HCPs applying for positions at a pharmaceutical company be disclosed. The anonymous and confidential nature of job applications must remain in place and disclosure of travel/hospitality should not compromise these requirements.

BMS believes that the implications of the Sunshine Act has not been evaluated as yet and as an industry we should tread carefully before immediately implementing the same in Australia. Apart from issued raised previously, BMS believes that due consideration to unintended consequences be given. For example, it would be disappointing if the quality, engagement or scope of educational meetings is hampered by inordinate costs or misguided perceptions of influence. Accuracy of reporting and an ability to understand and correctly interpret the data is important. In an environment whereby government is potentially reducing its support for medical education (annual tax deduction for self-education reduced to $2,000), a lack of attendance to appropriate and well-designed education events due to fears or uncertainties for Australian HCPs will only reduce the quality of care of patients. BMS strongly believes a step by step approach should be implemented starting with the reporting of contracted activities which can be determined by Medicines Australia (eg. sponsorships to domestic and overseas independent educational events and consultancies including but not limited to speaking engagements, advisory board participation).

PART 2 – Comments on 17th Edition of the Medicines Australia Code of Conduct

A. Section 37– Reporting

BMS asks that when publishing the Code of Committee findings, that the Code of Conduct Committee put some key messages at the end of each case that companies should consider. This will assist in companies understanding the issues presented and what should be considered for the future. In many cases it is easy to determine but other times the case may be quite complicated and key messages or conclusions from the Committee findings may facilitate learning across the industry; particularly if companies are unable to see any materials that are the subject of the complaint.