Eli Lilly Australia Pty Limited
112 Wharf Road
West Ryde NSW 2114
ABN 39 000 233 992

Phone (02) 9325 4444 Facsimile (02) 9325 4400

20 September 2013

Ms Sophie Hibburd
Secretary, Code of Conduct Committee
Medicines Australia
Level 1, 16 Napier St
DEAKIN ACT 2600

Dear Sophie,

Re: Comment on Transparency Working Group's "Transparency Model Consultation and Discussion Paper "

Thank you for the opportunity to provide comment on the Transparency Working Group's (TWG) Model. Eli Lilly Australia ("Lilly") supports the efforts of Medicines Australia (MA) to increase transparency around the prescription medicine industry's payments and transfers of value to healthcare professionals (HCPs). Lilly is supportive of a model that achieves this without incurring excess cost, which may result in the higher cost of medicines for the payer/consumer.

Lilly wishes to make comments on a number of the points raised in the TWG's paper. Of these comments, Lilly would like to direct the TWG's attention to its comments on the following sections within the model;

2. Limitations,
3.3 Identifiers for healthcare professionals,
3.8 Payments to third parties, including registered charities,
5.2 Reporting threshold and non-hospitality/travel costs,
5.4 Starter packs,
7.2 Notification, and
7.4 Data disputes.

Lilly will address comments on these sections and provide additional comments, which the TWG may wish to take into consideration.

Section 2: Limitations

Lilly supports the move towards increased transparency but is conscious that such a move by MA would only provide a mandate for prescription medicines companies, and those with a MA membership. This may put those companies

at a competitive disadvantage to other industry sectors. Lilly would like the Australian Competition and Consumer Commission (ACCC) to invoke the same transparency model upon all industry Codes. Alternatively, government legislation could make this mandatory.

Lilly would also like to highlight that by this model not being adopted industry wide, we will continue to draw criticism from the general public which does not distinguish one sector of the industry from another. This is of particular note for those companies within membership that have wider portfolios that include generic medicines, devices, and over-the-counter (OTC) medicines, particularly as the model specifically excludes activities in these spaces. Furthermore, there is the danger that companies with wider portfolios may 'cost shift' to other non reportable areas of their business to avoid reporting requirements.

Given the criticism that self-regulation attracts, Lilly is of the opinion that publication of an industry-wide transparency report should be operated under a third party organisation such as APHRA or the ACCC. The alternative of an independent foundation, which may have merits, would have additional costs to the industry.

Section 3.3: Identifiers

Lilly would like to draw the attention of the TWG to the National Privacy Principle number 7 (to become the Australian Privacy Principle (APP) number 9, on 12th March 2014) that specifically prohibits utilising government produced identifiers (APP 9.1). Lilly is of the opinion that the use of these identifiers as proposed by the TWG model does not meet the requirements of sections 9.2 or 9.3 of the APP which would overcome that obstacle.

Further, Lilly does not believe that it is feasible to obtain consents from all affected healthcare professionals for the purpose of reporting that would be required to overcome this obstacle. For these reasons, Lilly is of the opinion that the industry seeks exemption under the provisions APP 9.2 or 9.3 to be able to use Australian Health Practitioner Regulation Agency (APHRA) identifiers.

As an alternative, Medicines Australia purchase HCP lists e.g. via Cegedim and set up their own set of HCP identifiers.

A unique identifier must be provided to all member companies by MA or a 3rd party to ensure consistency of reporting across companies.

Section 3.7: Category of payment or transfer of value

In general, Lilly agrees with the proposed categories of payment/transfers of value. However, given that categories A-C are essentially payments for provision of service, Lilly questions the need for separate categorisation. Lilly

also questions whether charitable contributions as described in section 3.8 should be included.

Additionally, Lilly would like to raise the issue of whether the reported payments should be 'realised' payments and transfers of value versus 'non-realised' (e.g. honoraria paid into bank account versus service provided but not yet invoiced). It is Lilly's preference that 'realised' payments be the required data provided by companies.

Section 3.8: Payments to third parties, including registered charities

Lilly supports transparent reporting of all transfers of value, including payments made to third parties in lieu of payment to the HCP. Also, Lilly notes that payments to charities are already disclosed via current reporting mechanisms, whether at the behest of an HCP or separately by the company.

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

In essence, Lilly agrees with the proposed model in this area as it pertains to relevant colleges e.g. the Royal Australian College of GPs (RACGP).

However, Lilly is concerned that there are a number of CPD programs developed by external third parties which meet the criteria published on the APHRA website, but are nonetheless developed at the behest of companies. Consequently, full disclosure should include payments made to these entities. Lilly currently includes these programs in our educational event reporting to MA.

Section 5: Exclusions from reporting

Lilly is supportive of alternative number 1 proposed by the TWG, set at AUD25.00. Further, by basing the levels of reporting at AUD25.00, immaterial transactions are excluded that do not represent any value to HCPs. For clarity, Lilly believes FBT should be in addition to the AUD 25.00 limit.

Alternative number 2 would require significant systems development, additional resource, and investment to analyse the cumulative data sets which would be prohibitive even for larger companies and may result in the higher cost of medicines to the payer/consumer. Alternative 2 essentially transfers the US Sunshine Act to Australia, which does not align with the Australian financial systems currently employed at Lilly and other companies. Alternative 2 adds IT and operational complexity from a reporting perspective but does not help exclude immaterial transactions from disclosure. Alternative 2 also additionally opens up avenues of dispute from HCPs relating to minor hospitality costs.

Lilly is not supportive of increasing the value of the reporting threshold by the Consumer Price Index (CPI). Using such a benchmark would not necessarily be indicative of the increase in costs associated with pharmaceutical industry transactions nor is there relevance in reporting against a threshold that may involve a figure measured in cents. Lilly proposes that an appropriate method would be to review the threshold value once every three years.

Lilly does not agree with function costs being apportioned amongst attendees. Whilst Lilly acknowledges the concern of the TWG that cost shifting may occur, the transparency report would be easily compared against the other reports now required and for any company that would take this risk; the current monitoring system would identify this and serve as a deterrent. It is Lilly's opinion that function costs do not provide or transfer a benefit to the attendees and therefore be reflected as a cost to the company.

Section 5.3: Clinical research

Lilly considers that section 5.3 adequately establishes that clinical research payments are excluded from reporting. However, Lilly suggests that the scope of what is considered "clinical research "is specifically defined in the glossary.

Lilly recommends that transfers of value associated with consulting aspects of clinical research or site selections outside of a specific clinical protocol are included in the scope of the TWG model as these are direct transfers of value to individuals. This is not to be confused with payments made in relation to conducting the clinical trial itself, which oftentimes do not go to the investigator but rather to the institution or to service providers e.g. pathology.

Section 5.4: Starter Packs

Lilly agrees that there is merit in taking the view that starter packs are for patients and do not represent a financial gain to HCPs. Furthermore, Lilly would attest that the intrinsic value is not tangible given that the wholesale cost is not necessarily the transfer of benefit (i.e. the value of a starter pack of an antibiotic is essentially the same as a starter pack of a biological despite the large difference in wholesale cost). In addition, the PBS cost to the patient would not form part of this assessment.

In a similar way that Lilly does not identify that function costs primarily benefit the HCP, the provision of starter packs likewise are not a benefit or transfer of value to HCPs and should therefore not be a reporting requirement. Further, to include starter packs would again require the redesign of reporting systems.

However, Lilly does support the establishment of limits on the number of starter packs that may be made available to individual HCPs in a calendar year.

Section 5.11: Payments for expert witness in legal or administrative proceedings

Given there is legal precedence that such expert witnesses are a witness of the court rather than of a company, despite payment being made by the company, Lilly agrees that such payments should not form part of the model for reporting.

Section 6: Procedures for electronic submission of reports

Given Lilly's position stated in section 2 above, Lilly agrees that if reporting is limited to member companies of MA, that MA is the appropriate recipient and processor of reports. However, if transparency is adopted industry wide, it is Lilly's opinion that transparency reporting should reside with either a governmental or independent body.

Given the timing for other reports currently required, Lilly has no concerns with a May 31 timeframe. One comment is that the defined timeline for range is not described in the paper. Lilly's preference is that the submission date of May 31 covers the previous calendar year only.

Section 7: Period for review and error correction

Lilly has concerns regarding protracted disputes with HCPs particularly regarding some of the less obvious intangible transfers of value. Certainly there can be little dispute regarding honorariums that have been contracted. There would need to be consultation and guidelines developed with relevant medical bodies regarding disputes which set out what can be disputed. As companies are custodians of the data, apportioned data (e.g. food and beverage etc.) should not be open to dispute, as there is likely to be situations where an HCP will claim not to have partaken of food or will, if venue and audiovisual is apportioned, dispute the fairness of it.

In general, Lilly is not in favour of a pre-view period. If such period is required, the proposed deadline of March 1 is very unrealistic to provide a full year's worth of data within 60 days after year end close. Lilly would propose the preview period start on April 1. Lilly also questions whether the timeframe for notification to all HCPs is an additional administrative burden and indeed, whether it undermines the timeframe for publication as the data has effectively become public domain once the notification process has begun. Lilly does not support providing individualised statements to HCPs. Lilly proposes instead that there is an option for HCPs to log in to a database after submission but before publication. This database should be owned and maintained by MA or an independent 3rd party.

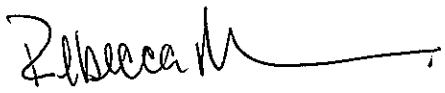
Section 7.5.2: Updating the information

Lilly does not see value in having reporting information available on the MA website for an extended period of time. All corrections should be feasible within the first year, and retaining this corrected information for a further 2 to 3 years will permit relevant comparisons with subsequent years for those that are interested.

Additional Comments

Lilly has significant concerns on capturing data under the new transparency guidelines starting January 1, 2015. It is Lilly's understanding that this transparency review will continue until middle of 2014 and then potentially approved by the ACCC towards the end of 2014. Due to the system complexities, Lilly cannot invest in re-configuring our IT systems to capture the data until the final transparency guidelines are agreed and approved by the ACCC. Lilly's recommendation is that at least a 12-18 month preparation period be allowed once approval is obtained from the ACCC. (i.e. if ACCC approval is Dec 2014, data capture at the very earliest could begin January 1, 2016 but more likely July 1, 2016).

Yours sincerely,



REBECCA MORISON
GENERAL MANAGER
AUSTRALIA & NEW ZEALAND