



MEDICAL ONCOLOGY GROUP OF AUSTRALIA INCORPORATED

A.B.N 94 601 175 669

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Secretary Code of Conduct Committee
Medicines Australia
16 Napier Close
Deakin AT 2600

INTRODUCTION

The Medical Oncology Group of Australia incorporated (MOGA) as the peak, national professional body for Australian medical oncologists, welcomes the opportunity to review and respond to the ***Transparency Model Consultation and Discussion Paper*** developed by the Transparency Working Group established by Medicines Australia. It is noted that the review outcomes will be considered for potential inclusion into Edition 18 of the Code of Conduct.

MOGA, shares with Medicines Australia a professional commitment to transparency of payments and other 'transfers of value' provided by the Australian medicines industry to health consumer organisations and healthcare professionals. The Association also appreciates that the Code of Conduct includes requirements for reporting of payments and benefits to healthcare professionals and greater disclosure of the nature of industry relationships with health consumer organisations.

In reviewing the proposed model the Association would like to highlight a number of key issues that require attention in conjunction with the matters raised in the Discussion Paper:

- Taxation, privacy legislation and legal implications for Health Practitioners and Companies ;
- Cost, professional and management considerations for Health Practitioners and Companies;
- Implementation timelines and costs, including approvals, contractual and establishment considerations;
- Current and end data usage/needs; establishment and ongoing data management costs; and,
- Comparative costs/benefits analysis of US (Sunshine Act) and European models.

THE DISCUSSION PAPER

Management of Transparency Reports

MOGA notes that the transparency model has been developed with the intention that it will be included in the Medicines Australia Code of Conduct and is limited to payments or other transfers of value related to prescription medicines. MOGA is of the view that the transparency reports should be managed and published by an independent, non -partisan third party organisation preferably a new, purpose structured entity with no extant affiliations.

Organisations such the Australian Health Practitioner Regulation Agency or the Australian and State based Medical Boards are purpose structured entities. The Association agrees that some healthcare professionals may have concerns about a government regulatory body or professional medical registration agencies receiving data about payments from commercial entities regarding individual healthcare professionals.

MOGA would support considering extending the model to all therapeutics goods and provider companies in Australia, in order to provide a co-ordinated national approach.

Identifiers for healthcare professionals

Organisations such the Australian Health Practitioner Regulation Agency or the Australian and State based Medical Boards and the Learned Colleges are purpose structured entities that provide health

practitioners with specific purpose identification/ registration numbers. The Association is of the view that some healthcare professionals and authorities may have concerns about such identification/registration numbers being publically available and deployed for alternate non-regulated purposes by third parties without their consent and adequate legal and privacy considerations being in place. MOGA is of the view that the introduction of an additional suitable unique identifier for all Australian Health practitioners will require substantial administrative costs and legal requirements.

Category of payment or transfer of value

MOGA is of the view that the categories listed do not cover the full range of types of payment and transfers of value that may occur between industry and healthcare professionals. In practice the Company selecting as proposed “the best that applies” may result in lack of clarity and confusion as some of the categories are not exclusive viz., some professional payments/transfers could be allocated to more than one category. For instance, where an honorarium is also a payment/payment of value for services. It is recommended that the categories be refined and defined in more detail.

Payments to third parties, including registered charities

Section 3.8 sufficiently explains and achieves a good balance between the detailed options with regard to payment to third parties, appropriate transparency and avoiding inappropriate attribution of a payment. However, full transparency requires that in relation to clause 3.8.2 the name of the recipient of the payment should be recorded.

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

This section makes provision for payments or transfers of value for healthcare professionals attending or speaking at Continuing Professional Development (CPD) programs, to be exempt from reporting. This would include grants made to program organisers or medical education providers where the program is a formal CPD program, even if the grant is used to pay for travel and accommodation of invited attendees or speakers. Notably if a company has a role in selecting speakers or attendees or any other influence on the educational content then the transparency reporting requirements would apply to any healthcare professional receiving a transfer of value from the company's grant. The circumstances in which a payment or transfer of value to a healthcare professional in association with a CPD activity would or would not be required to be reported is well described and defined in this section. MOGA is of the view that it is reasonable to exclude payments or transfers of value associated with formal, independent CPD from the transparency reporting requirements as detailed in the provisions noted in this section and with reference to the standard of CPD required that meets the continuing professional development registration standard for the relevant health profession, published on the AHPRA website:
(<http://www.ahpra.gov.au/Education/Continuing-Professional-Development.aspx>)

Reporting threshold

The implementation and management issues on the need for, and, setting of a threshold for recording a payment or a transfer of value, are clear. MOGA is of the view that in the interest of transparency it is recommended setting a \$25 threshold for recording payments or transfers of value to healthcare professionals with reporting required for annual cumulative payments or transfers of \$100 or more to an individual healthcare professional.

Despite the complexities and difficulties in calculating and allocating individual non-hospitality and non-travel function costs (such as AV costs and room hire costs), MOGA believes these costs should be treated as a transfer of value to the healthcare professionals who have attended an educational meeting to achieve full transparency. In order to achieve this and obtain consistency of end data an effective set of reporting parameters and guidelines is required.

The practical implications of the threshold for recording and reporting of payments including updating the threshold each year in line with the CPI (a reasonable proposition) for both companies and healthcare professionals will be considerable as will be the implementation and maintenance of

the system. A major consideration will be the lead and implementation periods needed by companies to implement mechanisms to record and report information.

Clinical research

Section 5.3 adequately describes and defines clinical research activities. MOGA is of the view that payments made under a product research or development agreement where there is a written agreement, a research protocol, or both between the company making the payment and the healthcare professional should be required to be reported, in the interests of transparency, unless legal requirements preclude this.

Starter packs

MOGA is of the view that starter packs provided to health practitioners by companies for patient use and passed on to the patient at no cost by the practitioner, should be excluded from any reporting requirement. The Association believes that starter packs should not be captured as a transfer of value to an individual healthcare professional because the practitioner provides them at no cost to patients and receives no value from the transfer.

Educational materials

MOGA is of the view that Educational materials and items that directly benefit patients or are intended to be used by or with patients, including the value of a company's services to educate patients regarding a prescription medicine should be excluded from any reporting requirement.

Transfers

MOGA is of the view that a transfer of anything of value to a healthcare professional when the healthcare professional is a patient, research subject or participant in data collection for research, or has requested access to a pharmaceutical product for their own treatment and on that occasion is not acting in the professional capacity of a healthcare professional should be excluded from any reporting requirement.

Trading Arrangements, Legal Payments and Personal

MOGA is of the view that the following items should be excluded from any reporting requirement:

- business to business trading arrangements relating to the purchase of therapeutic goods should be excluded from any reporting requirement.
- A dividend or other profit distribution arising from personal ownership or investment interest in a pharmaceutical company security or mutual fund instrument.
- A transfer of value to a healthcare professional if the transfer is payment solely for the services of the healthcare professional in acting as an expert witness to provide an expert's report for use as evidence in legal or administrative proceedings or proposed proceedings; and/ or to give opinion evidence in legal or administrative proceedings or proposed proceedings.
- A payment or transfer of value to a healthcare professional if the payment or transfer of value is made solely in the context of a personal, non-business-related relationship by an individual employee of a company at the employee's own expense.

Charity Care

MOGA is of the view that the following items should be excluded from any reporting requirement:

- in-kind items used for the provision of charity care, including the donation of medicines should be excluded from any reporting requirement.
- payments or other transfers of value made to a registered charity in lieu of payment to a healthcare professional where the healthcare professional performed a service, but neither

accepted the offered payment or other transfer of value nor requested that it be made to a third party should be excluded from any reporting requirement.

Electronic submission and publication of reports

MOGA is of the view that it is acceptable for reports to be electronically submitted to the agreed final management entity by May 31, 2016, and by 31 May of each subsequent calendar year and published by 30 June each year for the preceding calendar year (1 January to 31 December).

Period for review and error correction

MOGA regards as appropriate the proposed 45 day timeframe (from 1 March to 15 April) for healthcare professionals to review and correct (where required) the information recorded by the Company.

Process and Data Disputes

MOGA questions the proposal that data changes resulting from disputes initiated outside the review period may not be made until the next time the data is refreshed on the public website. Accurate and timely information provision of data on the website is required to comply with transparency requirements and avoid potential adverse privacy, legal and professional implications for health practitioners. It is therefore recommended that all data changes and amendments be implemented as they arise and as a priority with in a time frame of no less than 24 hours. The transparency model proposes that data for publication must be submitted by 31 May each year, irrespective of whether there is an unresolved dispute about the data and, on resolution, the corrected data may be submitted and the published data will be revised. MOGA is of the view that this is inappropriate and an alternative procedure that would ensure that accurate data is published without the publication of information being unreasonably delayed whilst a dispute is resolved is required.

Errors or omissions and updating the information

MOGA questions the transparency model's proposal that corrected and updated information will be published on the website at least once a year. Accurate and timely information provision on the website is required to comply with transparency requirements and avoid potential legal implications. It is therefore recommended that all data changes and amendments be implemented as they arise and as a priority with in a time frame of no less than 24 hours. MOGA also recommends that the website data should remain publically available via an archive mechanism with the data arrayed by year and that transparency considerations would preclude removal of historical information from the website.