

8 April 2014

Mr Timothy Pilgrim  
Privacy Commissioner  
Office of the Australian Information Commissioner  
GPO Box 5218  
Sydney NSW 2001

Dear Mr Pilgrim,

Medicines Australia is an industry association representing companies that are involved in researching, developing and marketing prescription medicines in Australia.

Medicines Australia is working to develop a measure that will provide transparency about pharmaceutical companies' payments and transfers of value to individual healthcare professionals in Australia. We are developing this transparency measure in response to the Australian Competition and Consumer Commission's expectation that "Medicines Australia (will) incorporate new provisions into the Code (of Conduct) that will facilitate greater disclosure around sponsorship and fees paid to individual doctors prior to lodging any application for reauthorisation of the Code".<sup>1</sup> The transparency measure also reflects a global move towards such transparency, which has been introduced in the US through the *Physicians Payments Sunshine Act 2010* and in Europe under the *EFPIA Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations*.

There are several matters on which we seek guidance from your Office in relation to compliance with the *Privacy Act 1988* to ensure the transparency measure reflects the ACCC's expectation while at the same time balancing the rights provided to individuals under the *Privacy Act 1988*. These issues are:

1. Identifying the reporting requirement as a primary purpose of collecting the personal information
2. Retrospectivity of a decision to withdraw consent for the disclosure of the personal information
3. Use of the Australian Healthcare Practitioner Regulation Agency (AHPRA) Practitioner number and/or the AHPRA Profession number with regard to Australian Privacy Principle (APP) 9.

### The proposed transparency measure

The Medicines Australia Code of Conduct is a self-regulatory standard established by Medicines Australia. Medicines Australia's Constitution requires all Member companies to be bound by the Code. Medicines Australia has submitted each edition of the Code of Conduct for authorisation by the ACCC from edition 14 in 2003 to edition 17 in 2012. In response to the ACCC's Determination concerning edition

<sup>1</sup> Australian Competition and Consumer Commission, *Determination – Applications for authorisation lodged by medicines Australia Limited in respect of Medicines Australia Code of Conduct edition 17*, 20 December 2012, (paragraph 158, p. 30)

17 of the Code, Medicines Australia's Code of Conduct Review Panel is proposing a transparency measure which would require each Member company to collect and publicly disclose on the company's website<sup>2</sup> the following information about the payments and transfers of value it makes to individual healthcare professionals:

- date of the educational event or provision of service;
- healthcare professional's name;
- type of healthcare professional (i.e. medical practitioner, pharmacist, nurse practitioner);
- healthcare professionals' principal practice address;
- description of the service (i.e. speaker, Advisory Board member, Chairperson at educational meeting etc);
- description of the event (i.e. Company sponsored meeting in Australia; independent meeting held in Australia; independent meeting held overseas; etc);
- whether the payment was made to the healthcare professional, the healthcare professionals' employer or another entity;
- the amount of the payment or transfer of value, subdivided into (where relevant) registration fees, travel and accommodation, and fees for service.

At the time of arranging an event or contracting the service for which a payment or transfer of value would be made, the healthcare professional would either be notified that in order to comply with the Medicines Australia Code of Conduct, their personal information will be disclosed or asked for their consent for the information to be disclosed. This notification or request for consent would:

- state the purpose for which the company is collecting and disclosing the personal information;
- describe the scope of the personal information that would be collected and disclosed;
- state where the information would be disclosed, and the duration that the information would be available from that location; and
- in the event that consent was required, advise the healthcare professional that they may decline to have the information disclosed.

Each Member company would progressively collect this information over sequential six month periods, from 1 October 2015. At the end of a six month period, each company would provide the payment information it has compiled for the preceding six months to each healthcare professional. Each healthcare professional would only receive their own information. The healthcare professional would be asked to review the information and advise the company whether the information is accurate, up to date and complete or to request an amendment if required. The healthcare professional would be advised that if they have not responded within six weeks, the company would proceed to publish the information.

Attachment 1 provides further details of the proposed transparency measure.

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<sup>2</sup> The initial transparency measure will involve each company publicly reporting the information on their websites. However, ultimately it is anticipated that each company will provide the reportable information to Medicines Australia and Medicines Australia will become the central repository for the published information.

Following are the issues on which Medicines Australia requests guidance from the Privacy Commissioner:

1. Identifying the reporting requirement as a primary purpose of collecting the personal information

Medicines Australia notes the APP Guidelines describe what is considered to be a 'primary purpose' or a 'secondary purpose' for collecting information. We also recognise that personal information may not be used or disclosed for a purpose other than the primary purpose of collection without the individual's consent as per APP 6.1.

If a healthcare professional was notified at the time of collection that their personal information was being collected for the primary purpose of making and reporting on the payment or transfer of value to them as required by the Medicines Australia Code of Conduct, in the Office's view, would the disclosure of their personal information require consent? Alternatively, could the disclosure be considered to fall within the ambit of APP 6.2(a)(ii) provided the healthcare professional was notified of this reporting requirement as per APP 5.1?

While Medicines Australia recognises that obtaining consent would be considered 'best practice', we are also cognisant that if healthcare professionals are required to provide their consent to the disclosure and choose to withhold that consent, this would undermine the underlying public interest that the transparency measure aims to address.

If the disclosure of the healthcare professional's personal information could not be considered to be a primary, or sufficiently related, purpose of collection, then Medicines Australia is aware that each company would be required to obtain the consent of the healthcare professional to meet its reporting obligations. In these circumstances, as outlined above, the company would seek express consent to facilitate the disclosure.

2. Retrospectivity of a decision to withdraw consent for the disclosure of the personal information

Medicines Australia understands that if a healthcare professional initially consents to their personal information being disclosed as described, but at a later date withdraws consent because they decide that they do not want the information published, the company must not continue to publish the information. We seek your guidance about whether a company also would be expected to remove from public view any personal information that previously had been published. For example, companies will be publishing a report every six months covering payments and transfers of value to individual healthcare professionals. Up to four six-monthly reports would be available on a website. If a healthcare professional withdraws their consent for publishing the information, would a company be obliged to revise any previously published reports, which are still viewable on a website, to remove the personal information relating to the healthcare professional?

**3. Use of the Australian Healthcare Practitioner Regulation Agency (AHPRA) Practitioner number and/or the AHPRA Profession number with regard to Australian Privacy Principle (APP) 9**

Consumers have expressed their preference that the information about payments and transfers of value to healthcare professionals would be available in a collated form through a single, publicly accessible website on which a person could search and view information about their healthcare professional.

In order to accurately collate data from forty to fifty companies relating to a large number of healthcare practitioners, a unique identifier for each healthcare practitioner would be required. A unique identifier is available from the Australian Healthcare Practitioner Regulation Agency (AHPRA), which regulates the professional practice of 14 health professions in Australia. AHPRA assigns a Profession number to each healthcare practitioner, which is associated with their professional registration, and a Practitioner number. Whereas an individual might have two or more Profession numbers (for example, if they are both a registered medical practitioner and a registered pharmacist), the Practitioner number is unique to each person.

Medicines Australia proposes to use the AHPRA number as a mechanism to combine healthcare professionals' personal information relating to payments from multiple companies. Each company would use the AHPRA number as a unique identifier for each healthcare professional within the company's internal records. The central data repository of all companies' records of payments to healthcare professionals would combine these records using the AHPRA unique identifier. The AHPRA number would not be public; it would only be used as a function within companies' internal records and within the central database.

Medicines Australia requests guidance from the Privacy Commissioner about whether the use of the AHPRA Practitioner number and/or the AHPRA Profession number would be regarded as "using" or "adopting" a "government related identifier of an individual" as described by Australian Privacy Principle 9.

As you will appreciate, the introduction of the transparency measure in Australia is a significant change to the management of healthcare professionals' personal information. Medicines Australia would welcome the opportunity to meet with you in order to discuss this important issue.

Yours sincerely,



**Brendan Shaw**  
**Chief Executive**

## **Medicines Australia Proposed Transparency Model For inclusion in the Code of Conduct, Edition 18**

The following activities would be reported for individual healthcare professionals, with the amount of the payment or transfer of value:

- Fees and/or speaking fees
- Sponsorship of a healthcare professional to attend an educational event. This includes airfares, accommodation or registration fees directly associated with the meeting (whether held within or outside Australia).
- Fees paid to healthcare professional consultants in Australia, or to their employers on their behalf, for specific services rendered by them. This includes all payments in respect to consulting fees, accommodation and airfares (both within and outside Australia) associated with the provision of the consulting services
- Fees paid to healthcare professionals in their role as Advisory Board members. This includes all payments in respect of Advisory Board sitting fees, accommodation and airfares (both within and outside Australia) associated with the activities of the Advisory Board.
- Fees paid to healthcare professionals for the purpose of market research, ONLY where the identity of the healthcare professional is known to the company.
- Payment of a grant or sponsorship to a specific healthcare professional

Where a healthcare professional requests a payment for any of the above to be made to a third party or financial entity (e.g. an institution, hospital, charity or healthcare professional controlled company), these payments must still be disclosed for the individual healthcare professional, however the report would identify that payment was made to a third party or financial entity (but not naming the third party).

The report of individual all payments and transfers of value for each healthcare professional would indicate the nature/purpose of each engagement with the healthcare professional as well as the date, value of payment/transfer of value and healthcare professional personal information, including the healthcare professional's name and principal practice address.

If a healthcare professional does not agree to this information being disclosed, the payments and transfers of value would be reported as an aggregate, with the total monetary amount or value and the total number of healthcare professionals to which it relates.



Our reference: 13/001256

RECEIVED  
16 MAY 2014

BY: .....

Dr Brendan Shaw  
Chief Executive  
Medicines Australia  
16 Napier Close  
DEAKIN ACT 2600

Dear Dr Shaw

### **Privacy implications of pharmaceutical company transparency measures**

I am writing in response to your letter dated 8 April 2014 in which you sought advice about the privacy implications of a new measure to increase transparency about pharmaceutical companies' payments and transfers of value to individual healthcare professionals in Australia. This measure would involve the publication of healthcare professionals' personal information with details of the payments and transfers of value received from pharmaceutical companies. I have provided guidance below on each of the issues outlined in your letter.

#### ***1. Identifying the reporting requirement as a primary purpose of collecting the personal information***

In your letter, you ask whether consent would be required for the disclosure of healthcare professionals' information if they were notified at the time of collection that their information was being collected for the primary purpose of making and reporting on the payment or transfer of value to them.

Based on the information that you have provided in your letter, it appears that reporting health professionals' personal information for transparency purposes would not be the primary purpose of collection. You have set out the kinds of personal information that would be included in transparency reporting, including the healthcare professional's name, profession and principal practice address. I assume that this kind of information would need to be collected for the purpose of arranging events and contracting services for which a payment or transfer of value is made. It appears that the collection of personal information is for the primary purpose of arranging events or contracting services and making associated payments and transfers of value, rather than for the purpose of reporting this information, even if there is an intention that this information would later be reported.

The reporting of the personal information would therefore be a secondary disclosure of the information. Organisations may only disclose personal information for a secondary purpose if one of the exceptions set out in Australian Privacy Principle (APP) 6 applies. These exceptions include:

- if the individual has consented to the disclosure of the information (APP 6.1(a))
- if the individual would reasonably expect the organisation to disclose the information for the secondary purpose and the secondary purpose is related to the primary purpose. This exception applies for personal information other than sensitive information (APP 6.2(a)(ii)).

As you note in your letter, seeking consent would be best practice. Further details on requirements for valid consent are set out in the *Australian Privacy Principles guidelines* (APP guidelines).

The proposed disclosure of the personal information could also fall within APP 6.2(a)(ii). As set out in the APP guidelines, there is a two part test for this exception:

- whether a reasonable person, who is properly informed, would expect their information to be disclosed for the secondary purpose, and
- whether the secondary purpose is related to the primary purpose of collection.

As set out in the APP guidelines, the 'reasonably expects' test is an objective one that has regard to what a reasonable person, who is properly informed, would expect in the circumstances. The APP guidelines include examples of where an individual may reasonably expect their personal information to be used or disclosed for a secondary purpose, including where organisations have notified the individual of the particular secondary purpose in the collection notice that they are required to provide under APP 5.1.

If pharmaceutical companies are seeking to rely on this exception, they will need to ensure that any usual disclosures are clearly outlined in their collection notice. I note that these disclosures may include publication of the information on company websites, as well as possible future disclosures to Medicines Australia for the purpose of including the information in a central repository and publishing the information.

The second part of the test is whether the secondary purpose is related to the primary purpose of collection. As noted in the APP guidelines, a related secondary purpose is one which is connected to or associated with the primary purpose. It appears the reporting of payments and transfers of value made to individual healthcare professionals, as required under a code of conduct, could be considered to be related to the original purpose of collection (that is, arranging events or contracting services and making associated payments and transfers of value).

## ***2. Retrospectivity of a decision to withdraw consent for the disclosure of the personal information***

You have also asked in your letter about whether a decision of a healthcare professional to withdraw consent will need to be applied retrospectively, requiring the removal of previously published information. This question will only be relevant if pharmaceutical companies are disclosing the personal information with consent. If they are relying on the exception permitting secondary disclosure of the personal information set out in APP 6.2(a)(ii), consent is not required.

The APP guidelines state clearly that once an individual has withdrawn consent, an organisation can no longer rely on that past consent for any *future* disclosure of the individual's personal information. The guidelines are silent on whether a decision of an individual to withdraw consent should be applied retrospectively. In my view, if the past disclosures were made with the consent of the individual (taking into account all the elements required for consent to be valid outlined in the APP guidelines), the organisation would not be required to remove information contained in past reports that were published when the consent was still current.

I note that these comments are based on the assumption that you would be seeking to rely on explicit consent from healthcare providers for the disclosure of their personal information. If you are seeking to rely on an opt out consent model, you will need to consider the factors which an organisation may need to meet to establish an individual's implied consent, set out in paragraph B.34 of the APP Guidelines. These include that an individual who opts out at a later time will, as far as practicable, be placed in the same position as if they had opted out earlier.

### ***3. Use of the Australian Healthcare Practitioner Regulation Agency (AHPRA) Practitioner number and/or the AHPRA Profession number with regard to APP 9***

Your letter sets out a proposal to use identifiers issued by AHPRA as a mechanism to combine healthcare professionals' personal information relating to payments from multiple companies, and asks whether this would constitute a 'use' or 'adoption' of a government related identifier as set out in APP 9.

It appears that the proposed use of these identifiers would constitute an 'adoption' of these identifiers. The APP guidelines state that:

*An organisation adopts a government related identifier if it collects a particular government related identifier of an individual and organises the personal information that it holds about that individual with reference to that identifier.*

You state in your letter that each company would use the AHPRA number as a unique identifier for each healthcare professional within the company's internal records, and that a central data repository of all companies' records of payments to healthcare professionals would combine these records using the AHPRA identifier. In this scenario, each company would be organising the personal information that it holds about individuals with reference to the AHPRA identifier. This would fall under the definition of 'adoption' set out in the APP guidelines.

As this proposed use would be an 'adoption', pharmaceutical companies and Medicines Australia would need to have regard to the requirements set out in APP 9.1. The proposed adoption of the identifiers does not appear to meet either of the exceptions permitting adoption set out in APP 9.1, so an alternative method of organising this information that does not rely on the adoption of government related identifiers will need to be identified.

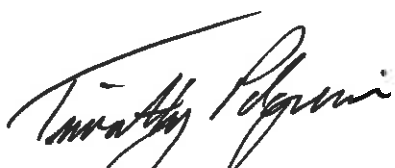
If pharmaceutical companies and Medicines Australia are considering using or disclosing (rather than adopting) the AHPRA number, they will need to assess whether this use or disclosure would meet any of the exceptions set out in APP 9.2. The exception that is most



likely to be relevant is APP 9.2(a). For this to apply, the use or disclosure of the identifier must be reasonably necessary for the organisation to verify the identity of the individual for the purposes of the organisation's activities or functions. As outlined in the APP guidelines, it would not be sufficient for the use or disclosure to be merely helpful, desirable or convenient. A use or disclosure will not usually be considered to be reasonably necessary if there are reasonable alternatives available; for example, if an organisation can verify an individual's identity by using or disclosing other types of personal information.

I hope this information is useful to you. I note that the comments above are intended as general guidance only, and would not bind my decisions in the event of a complaint or investigation. If you would like to discuss this letter in more detail, please contact Mr Jacob Suidgeest, Director, Health and Audit on (02) 9284 9809 or at [jacob.suidgeest@oaic.gov.au](mailto:jacob.suidgeest@oaic.gov.au).

Yours sincerely

A handwritten signature in black ink, appearing to read 'Timothy Pilgrim', written in a cursive style.

Timothy Pilgrim  
Australian Privacy Commissioner

15 May 2014