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30 March 2015

Dr Richard Chadwick
General Manager, Adjudication
Australian Competition and Consumer Commission
23 Marcus Clarke Street
Canberra ACT 2601

Dear Dr Chadwick

**Medicines Australia: Application for Revocation and Substitution
A91436-A91440**

The purpose of this letter is to provide further information in support of the following views of Medicines Australia:

- a hospitality condition is not necessary or appropriate; and
- member companies will publish transfers of value made to all healthcare professionals in a searchable format, but should not be required to provide transparency reports in Excel format.

1 Summary

1.1 A food and beverage reporting condition is not necessary or appropriate

Medicines Australia considers a food and beverage reporting condition is not necessary or appropriate as:

- (a) Edition 18 of the Medicines Australia Code of Conduct (**Code**) imposes a \$120 cap on food and beverage expenditure, and members now have comprehensive and rigorously enforced compliance policies and systems;
- (b) maintaining food and beverage reporting, given the considerable additional work required for individual healthcare professional reporting, is an undue and wasteful regulatory burden;
- (c) the two most significant transfers of value made to healthcare professionals, namely air travel and accommodation, will still be reported under the Code in addition to monetary payments such as honoraria, speaking or consulting fees; and
- (d) reporting an aggregate figure for member companies' food and beverage expenditure during a specified period would not provide any meaningful or interpretable information that would indicate whether the provision of food and beverages has increased inappropriately.

1.2 Reports should be made available in a searchable format but not in Excel format

Medicines Australia accepts that all member companies will publish payments and transfers of value made to all healthcare professionals for a given six month period in a searchable format and not only make available results relating to one healthcare professional based on searches conducted by

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consumers. Thus a viewer will be able to view payment and transfer of value data relating to all healthcare professionals if they choose. However, Medicines Australia does not support a requirement that the transparency reports be provided in Excel format for the following reasons:

- a requirement to publish data in Excel format could prohibit Medicines Australia, and member companies, from complying with the Australian Privacy Principles;
- specifying a particular format for reporting may serve to dissuade members from using or developing other disclosure platforms which could provide a greater ability for individual patients to search for information on their healthcare professional (whilst making all healthcare professionals information available for review); and
- member companies are concerned about the imposition of a requirement to use a particular proprietary software program.

Given the substantial improvements in transparency and the significant public benefits already arising from the Code, the imposition of unduly burdensome conditions do not sit well with principles of good regulation nor the Federal Government's 'cutting red tape' policy.

2 Food and beverage reporting not required

2.1 Robust compliance environment means reporting is unnecessary

The effectiveness of the \$120 cap on food and beverage expenditure, coupled with continued reporting of air travel and accommodation expenses, must be considered in the light of the increasingly robust compliance environment demonstrated by member companies.

Over the past five years, Medicines Australia's member companies have significantly enhanced their compliance functions into critical business units responsible for oversight and monitoring of compliance. The evolution of the compliance officer, a dedicated compliance professional, has developed in response to:

- ongoing strengthening of the Medicines Australia Code; and
- prosecutions by the U.S. Department of Justice (**DOJ**) in respect of the *Foreign Corrupt Practices Act of 1977* and the introduction of the *Bribery Act 2010* (UK).

The Criminal Division of the DOJ and the Enforcement Division of the U.S. Securities Exchange Commission have released guidance in respect of compliance programs, which have transformed compliance functions within member companies. For example, the publication titled *A Resource Guide to the U.S. Foreign Corrupt Practices Act*¹ sets out the following seven hallmarks of an effective compliance program:

- commitment from senior management and a clearly articulated policy against corruption;
- code of conduct and compliance policies and procedures;
- oversight, autonomy and resources;
- risk assessment;
- training and continuing advice;
- incentives and disciplinary measures; and
- third party due diligence and payments.

¹Available from <http://www.justice.gov/criminal/fraud/fcpa/guidance/>.

The *Bribery Act* (UK) establishes a statutory defence for commercial organisations who have in place adequate procedures designed to prevent persons associated with the commercial organisation from undertaking bribery: s7. The UK Ministry of Justice has released a guidance document², pursuant to s9 of the *Bribery Act*, which identifies six principles to inform the development of adequate company procedures to prevent bribery and corruption. The six principles are:

- proportionate procedures;
- top level commitment;
- risk assessment;
- due diligence;
- communication (including training); and
- monitoring and review.

The *Foreign Corrupt Practices Act* (US) and the *Bribery Act* (UK) both have extraterritorial reach and affect almost all member companies. Practically, this means that the pharmaceutical company of today in Australia has a dedicated compliance function or representative proportionate to the size of the company to oversee, enhance and monitor compliance programs. Depending on the size of the member company, a compliance program will usually consist of the following:

- a dedicated compliance officer who reports to a regional/global compliance team;
- global and local policies and procedures which govern the way the business conducts itself;
- regular training programs on relevant policies and procedures;
- mechanisms for reporting non-compliance, including anonymous reporting hotlines;
- processes for approving the transfer of value to healthcare professionals, including for educational events;
- monitoring programs to identify instances of non-compliance;
- disciplinary procedures; and
- due diligence procedures for the selection of vendors.

Turning specifically to educational events, the typical processes undertaken by member companies to approve and monitor educational events include the following:

- an initiator identifies a need for education and develops a program;
- a member of the medical and/or compliance team reviews the program;
- if the program is approved, the initiator will then organise the educational event in line with company policies and procedures;
- the compliance officer may conduct live monitoring of the event. This means that a compliance officer attends the education event, including observing every meal provided during the educational event and the entire educational component, to ensure compliance with company policies and procedures;
- educational events are selected, either randomly or based on risk, for monitoring. Non-compliance is referred for disciplinary action, which ranges from verbal or written warnings to dismissal; and

² Available at <http://www.justice.gov.uk/downloads/legislation/bribery-act-2010-guidance.pdf>.

- company global internal auditors also conduct a review of the educational events during scheduled audits of the Australian affiliate's compliance program.

The robust compliance environment within member companies is demonstrated by the following two case studies.

Case Study 1: A medium-sized global pharmaceutical company

There are a number of approval processes and checks involved in approving and monitoring educational events. Annexure 1 is a flowchart outlining the approval processes of a medium-sized global pharmaceutical company. Annexure 2 is a copy of the form that staff at that company must complete for each educational event – both pre-event for approval by the compliance officer and post-event to demonstrate the event occurred as represented in the approval process.

Case Study 2: A large global pharmaceutical company

By way of example of the compliance processes in place in one of Medicines Australia's large member companies regarding developing and organising an educational event that involves a transfer of value to health care professionals:

- Annexures 3 to 5 illustrate compliance training; and
- Annexure 6 is a guide and checklist for staff to assist them in developing and organising educational events.

This evidence of robust compliance programs means the ACCC should be satisfied that members will strictly enforce the \$120 cap on expenditure.

In addition, Section 9.3 of the Code requires that member companies must have policies and procedures in place that will ensure that educational events for healthcare professionals comply with the Code, and in particular, the maximum cost of a meal stated in Section 9.4.3. The Monitoring Procedures defined in Section 31.2.1 of the Code specifically include, in part b), that the Monitoring Committee will review member companies' policies and procedures to ensure that educational events for healthcare professionals comply with the Code. The Monitoring Committee will require companies to produce their policies and procedures for its review to ensure that all member companies are complying with the \$120 meal and beverage cap. The Monitoring Committee may refer any instance where it considers that companies' policies or procedures are inadequate or where it receives information that a breach of the \$120 meal and beverage cap has occurred.

The Monitoring Committee's review of companies' policies and procedures will complement the Code of Conduct Committee's review of any complaints received by Medicines Australia that a company has exceeded the \$120 cap.

In addition, the Code of Conduct Guidelines Working Group has developed detailed guidance for companies regarding compliance with the \$120 meal and beverage cap. The following is an extract of the (near final) draft Edition 18 Code of Conduct Guidelines in relation to Section 9.4.3:

Company Educational Events

If a company is holding its own educational meeting it should ensure that any hospitality that is offered is consistent with the professional standing of the delegates but justifiable in the context of the quality and duration of the education provided. Companies should remember that hospitality must always be secondary to the educational purpose of the meeting. An appropriate level of hospitality would be what is expected at a normal business meeting.

Meals (including beverages) offered by companies to healthcare professionals within Australia must not be in excess of \$120 (excluding GST and gratuities). This is a per person cost for a single meal. Companies are to ensure that provision of meals (including beverages) to healthcare professionals is not extravagant. Companies may have more stringent internal policies and limits. Hospitality must be secondary to the education provided. It is only appropriate in exceptional circumstances where there is substantial educational content provided that the maximum meal and beverage limit of \$120 is reached. It is an expectation that a breakfast or lunch would be well below this limit. The Code of Conduct provides the example of a dinner at a learned society conference. This example seeks to convey that there must be high quality, substantial education provided in order to justify reaching the \$120 limit. An educational meeting with one to two hours education provided would not justify providing hospitality (meal and beverages) at a cost of \$120.

It is important for companies to ensure compliance with the meals and beverage limit of \$120. Should the cost of a meal (including beverages) provided to a healthcare professional exceed \$120, this would constitute a breach of Edition 18 of the Code of Conduct. Companies are to ensure compliance with the \$120 maximum limit through internal policies and procedures to monitor hospitality expenditure and implement remedial actions in the event of a possible breach. The Medicines Australia Monitoring Committee will review company policies and procedures to ensure compliance with Section 9.4.3 of the Code.

Section 9.7.7 Meals and beverages provided to healthcare professionals attending international educational events

The Code of Conduct requires that the maximum cost of a meal (food and beverages) stated in Section 9.4.3 of the Code applies to hospitality provided to Australian healthcare professionals in association with an educational event held overseas.

Therefore, companies should plan that any meal (food and beverages) provided in another country either complies with the monetary limit set by the industry association in that country (where applicable) or costs no more than AUD \$120 (excluding taxes and gratuities). As the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations is now implemented across Europe, each country now has set a maximum limit on food and beverages. Companies should comply with the limit in each country. The Spanish Pharmaceutical Industry Association, Farmaindustria, provides an interactive map with each country's hospitality limit: <http://www.codigofarmaindustria.es/web.nsf/Banner.xsp>.

The guidance is that if a company is arranging a meal in a country that does not apply a local limit on hospitality (for example, the US or Canada), you should plan for the meal to be less than AUD \$120 at the exchange rate current at that time, with some flexibility 'built in'. For example, if at the current exchange rate the meal is AUD\$100 or \$110, but the Australian dollar weakens against the other country's currency between the date the event is arranged and the actual date, you would be able to demonstrate to the Monitoring Committee (if it asks for an explanation of the cost) that the meal was planned to be fully Code compliant and the exchange rate has resulted in a higher AUD cost. If the cost of a meal exceeds AUD\$120 a company would need to be able to justify that the meal was compliant with the Code to the Monitoring or Code Committee.

2.2 Significant administrative burden in requiring aggregate hospitality reporting

The process for recording aggregate hospitality expenditure is largely manual. Requiring member companies to continue to report on the hospitality provided to healthcare professionals, even in aggregate form, would impose a significant time and cost burden on member companies. This compliance burden, given the additional work that will be required for individual healthcare professionals reporting, cannot be justified as a matter of good regulation.

The current transparency reporting in place under Edition 17 of the Code requires member companies to report the total value attributed to a particular educational event. The reporting includes the following costs:

- consultancy fees paid;
- venue hire;
- audio visual hire;
- food and beverages costs;
- transportation expenses; and
- accommodation expenses.

Member companies are not able to extract food and beverage expenditure for current reporting purposes 'at the press of a button'. The information required is not readily ascertainable from member companies' existing financial data. This is because member companies do not have a separate budget for food and beverage expenses for healthcare professionals that could be utilised for reporting this expenditure. As noted in Medicines Australia's submission on 19 December 2015, expenditure on food and beverages represents only approximately 13 percent of total expenditure on educational meetings and symposia by member companies. In the context of overall company budgets for supporting marketed products, our member companies estimate that food and beverage expenditure in association with educational meetings would represent five percent or less of the overall company budget.

In practice, staff must physically review invoices to identify what is reportable and what is not and manually insert information into the relevant report templates. This is demonstrated in Case Study 3 below. Member companies therefore need to allocate funds and resources to the development of infrastructure within their financial systems to identify and extrapolate food and beverage costs attributed to a healthcare professional for a reportable purpose. It follows therefore that member companies cannot report food and beverage expenditure in the aggregate without engaging in the same burdensome manual process.

Case Study 3: A large global pharmaceutical company's experience in the aftermath of an educational event

One of Medicines Australia's large members uses a number of systems to manage its expenditure on educational events: a colleague expense reimbursement system, a Purchasing system, a GL system and a CRM.

Following an educational event, the member company obtains the total expenditure on food and beverage at the event, together with a list of attendees. The company then reviews the list of attendees to separate employees, event planners and non-Australian healthcare professionals from Australian healthcare professionals. The Australian healthcare professionals are the subset for whom the member company has to allocate a portion of the total hospitality cost.

This manual review is undertaken in respect of each meal that takes place during the educational meeting. It is time consuming, given that each meal expense is recorded in a different source document. For example, expenditure on a breakfast is usually contained in the venue invoice; in respect of a lunch, the cost would be included in a conference day package on a separate venue invoice; dinner would usually be recorded on a separate invoice or require extraction from individual employees' expenses.

If the ACCC imposes a food and beverage reporting condition, the administrative burden and compliance costs for member companies will significantly increase under Edition 18. This is because member companies would need to, in most cases, maintain two separate systems – one dealing with aggregate food and beverage expenditure reporting and one dealing with individual healthcare professional reporting. This is an undue and wasteful regulatory burden.

2.3 Reporting food and beverage expenditure trends would not be meaningful

As stated in Medicines Australia's submission of 23 January 2015, Medicines Australia submits that requiring member companies to compile and report on their aggregate food and beverage expenditure would provide little, if any, meaningful information to consumers or the ACCC.

Such reporting would not:

- give any context on the types of educational events held by member companies or the background of the audience. It would therefore not be clear that the food and beverages were being provided in association with education;
- provide information on the duration of an educational event or its content;
- provide information on the number of attendees at an event; or
- provide information on the timing of the event and details of the venue.

Providing an aggregate food and beverage expenditure figure would also fail to enable the public or the ACCC to extrapolate the meaning of any trends relating to this expenditure, for example, whether it is increasing or decreasing year on year. This is because annual changes in an aggregate figure would not take into account any growth trends in the industry overall, the growth in size of an individual company or its product portfolio (a member company may have introduced multiple new medicines to the Australian market) or the decline in size of a company (following, for example, patent expiry). Aggregate reporting of food and beverages would therefore be of little or no practical benefit.

It is evident that food and beverage reporting in aggregate, could not and would not bring transparency to *relationships* because in the aggregated reporting model there would be no reporting of any particular relationships between an individual healthcare professional and a pharmaceutical company. It follows that the desire to address inappropriate prescribing by healthcare professionals ('which may harm consumers'³) could not be achieved by aggregated reporting of food and beverages. These concerns are now effectively addressed both by the new prohibition in Edition 18 and more particularly by reporting at the individual healthcare professional level, together with the existing controls.

Further, there is no evidence to suggest that companies' conduct with respect to food and beverage expenditure in association with educational events will fluctuate in any significant way under Edition 18. The aggregated data that Medicines Australia has provided to the ACCC to coincide with each publication of companies educational event reports do not suggest any significant increase in food and beverage expenditure (noting that these reports include travel, accommodation and food and beverages under the heading 'hospitality'). The controls that member companies exert over the conduct of educational events, as described in section 2.1 of this submission, will ensure that food and beverage expenditure is appropriate, secondary to the educational purpose of the event and that reportable payments and transfers of value to healthcare professionals will be correctly categorised and reported as required by the Code.

3 Form and content of transparency reporting

3.1 Content of report

Medicines Australia sets out below detail as to the nature and extent of healthcare professional personal information that will be included in transparency reports. This detail applies whether the healthcare professional personal information is collected with informed consent or under reasonable expectation of disclosure.

Edition 18 of the Code requires member companies to report the following payments and transfers of value to healthcare professional individually rather than in aggregate form from 1 October 2015:

- (a) fees paid to healthcare professionals (or to their employer or a third party organisation) for:
 - speaking at an educational meeting or event;
 - consulting services;
 - attendance at an advisory board meeting; and
 - participating in market research where the identity of the healthcare professional is known to the company;
- (b) airfares for travel both within and outside Australia;
- (c) accommodation provided whether in Australia or another country; and
- (d) registration fees to enable attendance at an educational meeting.

Member companies will be required to report transfers of value in accordance with a template in the Code of Conduct Guidelines, which prescribe requirements contained in section 41.3.1 of the Code. Annexure 7 to this letter is a copy of the template. The template is in a table form and requires reporting of all individual transfers of value for each healthcare professional by providing the following information:

³ ACCC Media Release, 3 December 2009, titled 'Transparency is the key for drug industry relationships' (see <http://www.accc.gov.au/media-release/transparency-is-key-for-drug-industry-relationships-0>).

- (a) **date of the event or provision of service** – date format to be 'Month (full word) - Year (4 digits)' for a single event date. If the activity extends over more than a month (eg, a consultancy) the format to be 'Month (full word) – Month (full word) Year (4 digits)';
- (b) **healthcare professional's full name** – format to be 'Surname, first name middle initial' (eg, Lloyd, David M) with no other punctuation;
- (c) **type of healthcare professional**, to be selected from the following options (noting that no specialty for healthcare professionals will be included):
- medical practitioner;
 - pharmacist;
 - dentist;
 - nurse;
 - nutritionist/dietician;
 - optometrist;
 - physiotherapist;
 - psychologist; or
 - podiatrist;
- (d) **healthcare professional's practice address**, with details of the street number, street name, suburb or town, and state;
- (e) **type of service** – a description of the service selected from the following:
- Advisory Board/Committee member;
 - educational meeting speaker or chair person;
 - consultant;
 - educational meeting attendee; or
 - market research participant;
- (f) **type of event or activity** – a description selected from the following:
- company meeting in Australia;
 - company meeting overseas;
 - independent meeting in Australia;
 - independent meeting overseas;
 - market research;
 - consulting service; or
 - Advisory Board or Committee Meeting;
- (g) **payment made to** – who the payment was made to, selected from the following:
- the healthcare professional;
 - healthcare professional's employer; or
 - third party; and
- (h) **the amount of the payment or transfer of value**, exclusive of GST, subdivided into:

- registration fees (where paid);
- travel and accommodation (a single amount relevant to the particular event or activity); and
- fees for service (a single amount relevant to the particular event or activity).

The transparency report will be sorted alphabetically by surname, then by first name, then by middle initial, then by event date. As a result, all payments and transfers of value to a particular healthcare professional will appear one after the other in chronological order for that individual.

3.2 Content of report where informed consent has not been provided or has been withdrawn

In the period until Section 41.3.2 is amended in accordance with the proposed condition, companies will be required to maintain records of when informed consent has been obtained from individual healthcare professionals.

If informed consent is not given or is withdrawn after having been given, all payments and transfers of value to that healthcare professional or professionals must be reported in aggregate as indicated in the reporting template at Annexure 7. The template requires reporting of the total number of healthcare professionals for whom personal data may not be published and the total monetary amount paid or transfers of value provided to, subdivided into:

- registration fees (where applicable);
- air travel and accommodation (where applicable); and
- fees (such as sitting fees, honoraria, consultancy fees, where applicable).

If a healthcare professional withdraws consent for publication of personal data after a report has been published, a member company will not be required to remove the data from the published report. However, for unpublished reports the healthcare professional's personal data will be excluded from the report and included in the aggregate data section of the report.

3.3 Validation and correction of data

Healthcare professionals will be given the opportunity to review and make corrections to the payment and transfer of value data collected by a member company: section 41.3.4 of the Code. Healthcare professionals must be given at least six weeks to review and verify or correct their data.

Further, healthcare professionals will continue have the right to correct information held by a member companies, even after a report has been published, in accordance with the Australia's privacy legislation.

3.4 Availability and scope of the transparency reports

Medicines Australia confirms that it has consulted with member companies and all member companies will publish payments and transfers of value made to all healthcare professionals for a given six month period in a searchable format and not only make available results relating to one healthcare professional based on searches conducted by consumers. A viewer will be able to view payment and transfer of value data relating to all healthcare professionals if they choose.

Reports will be published on member companies' websites and will be easily located by consumers. In addition, the Code states that Medicines Australia will provide hyperlinks to each company's report. Medicines Australia will have a dedicated page on its website for these hyperlinks.

The transparency reports will remain available on member companies' websites (and the hyperlinks on Medicines Australia's website) for three years from the date of first publication. That is, once six, six-monthly reports have accumulated, when the seventh report is added, the first report would be removed from the website, and so on.

3.5 Proposed Excel format is not appropriate

As set out in our letter of 20 February 2015, Medicines Australia does not support a requirement that the transparency reports be provided in Excel format for a number of reasons:

(a) Compliance with the Australian Privacy Principles

Medicines Australia is concerned that a requirement to publish data in Excel format could prohibit it, and member companies, from complying with the Australian Privacy Principles (**APP**). This is because publishing a healthcare professional's personal information in Excel format will affect the security of the data and allow third parties to access, disclose (that is, re-publish), extract, modify the information or misattribute transfers of value to healthcare professionals, and to do so for purposes unrelated to those for which the data was collected.

Pursuant to APP 11, if Medicines Australia (or its member companies) holds personal information, it must take 'such steps as are reasonable' to protect the information from:

- misuse, interference and loss; and
- unauthorised access, modification or disclosure.⁴

'Misuse' is defined as use for a purpose which is not permitted by the *Privacy Act 1998* (Cth).⁵ The permitted uses are defined in APP 6. In this case, the use is restricted to the purposes for which the information is provided, unless an exception applies.

Medicines Australia notes that the purposes for which member companies collect information for individual disclosure, as identified in the ACCC's Draft Determination, are:

- having the potential to address the principal-agent problem by giving patients some transparency over a matter which may influence the objectives of their prescribing healthcare professional: at [133];
- being aware of transfers of value received by a particular healthcare professional may alert a patient to a possible influence on their healthcare professional's prescribing decisions, and enable the patient to explore this further: at [134];
- enabling fellow healthcare professionals to inform themselves about matters which may be relevant to their understanding of, for example, a key opinion leader in their field: at [135]; and
- deterring member companies from making, and healthcare professionals from accepting, transfers of value which are inappropriate or which may raise conflicts of interest, if the transfers are subject to public scrutiny: at [135].

Given that healthcare professionals provide their information for these purposes and no other exceptions under the APP apply, member companies are accordingly under an obligation to take reasonable steps to protect the personal information from use for some other purpose. Just as it would be a breach of the *Privacy Act* for a member company to use this information for other purposes, so too it is a breach for the member company not to take reasonable steps to prevent the information being used for another purpose.

Although circumstances will differ as to what is required to satisfy the 'reasonable steps' obligation, if a member company makes data available on the internet without taking any steps to prevent misuse then it will clearly not have taken reasonable steps. As a result, if

⁴ Australian Privacy Principles: *Privacy Act 1988* (Cth) Schedule 1.

⁵ Australian Privacy Principles Guidelines, para 11.11.

member companies publish personal information in Excel format, which can easily be extracted, modified or disclosed by third parties, they will be at risk of breaching APP 11.1.⁶

For this reason, member companies intend to publish the relevant information in a format that does not allow the data to be extracted and modified (such as a readable and searchable PDF). Medicines Australia considers this will strike the right balance between ensuring that individual patients (and healthcare professionals) will have access to sufficient data to meet the purposes articulated above, while ensuring that the integrity of the personal information is protected from inappropriate use.

(b) Stifling future development

Medicines Australia is also concerned that specifying a particular format for reporting may serve to dissuade members from using or developing other disclosure platforms which could provide a greater ability for individual patients to search for information on their healthcare professional (whilst making all healthcare professionals information available for review). This issue is of particular concern in circumstances where the ACCC proposes to authorise Edition 18 of the Code for a period of five years and where there may be technological advances during this period that will enable data to be published and disclosed using different software programs or in different formats to those currently available. Many member companies have invested considerable resources in reporting systems and platforms which go well beyond Excel in nature and scope.

(c) Requirement to use a specified program

Medicines Australia notes that its member companies have expressed surprise and concern that the ACCC proposes to require them to use a particular proprietary software program.

In the event that the ACCC has any residual concerns to ensure the reports are easily searchable, Medicines Australia again submits that the proposed condition should be phrased in a technology neutral way. For example, the proposed condition could be amended to only specify the criteria that the format must fulfil, for example, 'reporting must be in a form that is easily accessible and searchable by patients'. In this regard, Medicines Australia notes that other jurisdictions such as the UK do not require data to be published using a specific proprietary software, but simply provide that the method of publication have certain qualities with respect to searchability.

Please let us know if you would like to discuss any of the matters raised in this letter.

Yours sincerely

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⁶ Note that the obligation in APP 11.1 to 'take such steps as are reasonable in the circumstances' is not qualified by the words 'if any' which appear in several other APPs – see for example APP 5.1 and 10.1. Hence member companies cannot argue that in these circumstances APP 11.1 can be satisfied by doing nothing.

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Annexure 1:
**A medium-sized global pharmaceutical company's
approval processes for educational events**

[Redacted for confidentiality]

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Annexure 2:
**A medium-sized global pharmaceutical company's
educational event approval form**

[Redacted for confidentiality]

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Annexure 3:
**A large global pharmaceutical company's
compliance training**

[Redacted for confidentiality]

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Annexure 4:
**A large global pharmaceutical company's
compliance training**

[Redacted for confidentiality]

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Annexure 5:
**A large global pharmaceutical company's
compliance training**

[Redacted for confidentiality]

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Annexure 6:
**A large global pharmaceutical company's
guide and checklist to an educational event**

[Redacted for confidentiality]

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Annexure 7:
Template for reporting transfers of value
under Edition 18 of the Code

HCP Transfer of Value (ToV) Report for the period 1/1/yy to 30/6/yy
 Company Name: ABC Ltd

| Date of event or provision of service | Full name of HCP | Type of HCP | Practice Address | Type of Service | Type of Event or Activity | Payment made to: | Registration Fees | Travel & Accommodation costs | Fees for Service and Consultancy |
|---------------------------------------|------------------|------------------------|--------------------------------------|---|-------------------------------------|-------------------------------------|-------------------|------------------------------|----------------------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| April-2015 | Lloyd, David M | Medical Practitioner | No / Street / Suburb or Town / State | Advisory Board/ Committee member | Company meeting in Australia | Health Care Professional | \$ | \$ | \$ |
| April- November 2015 | | Pharmacist | | Educational meeting speaker or chair person | Company meeting overseas | Health Care Professional's Employer | | | |
| | | Nurse | | Consultant | Independent meeting in Australia | Third Party | | | |
| | | Psychologist | | Educational meeting attendee | Independent meeting overseas | | | | |
| | | Optometrist | | Market research participant | Market Research | | | | |
| | | Nutritionist/dietician | | | Consulting Service | | | | |
| | | Physiotherapist | | | Advisory Board or Committee Meeting | | | | |
| | | Dentist | | | | | | | |
| | | Podiatrist | | | | | | | |

Aggregate total of ToVs where HCPs have not consented to data being reported individually

| | | | |
|--------------------------|----|----|----|
| Aggregate ToVs | \$ | \$ | \$ |
| Aggregate number of HCPs | | | |

Format

- 1 Month- full word. Year 4 digits. For both the range and single date. Range is required if contracted service covers more than one month.
 - 2 Surname, first name middle initial. No other punctuation. If two middle names, only first initial. Report will be presented by Surname then by event date
 - 3 Drop down list to be provided by MA. Perhaps mirror the TGA list and include physios, optometrists etc
 - 4 The address we have in our systems regardless of being principal. Street number, suburb or town and state. City or unit number irrelevant
 - 5 Will be drop down box
 - 6 Will be drop down box
 - 7 Will be drop down box
 - 8 Paid, actual whole dollars excluding GST
 - 9 Paid, actual whole dollars excluding GST
 - 10 Paid, actual whole dollars excluding GST
-
- A If payments are made in advance of an event eg air tickets, they will be reported in the period in which the event occurred (after the event has actually occurred).
 - B Fundamental definition that TOV cannot occur until payment is made (with exception of A above)
 - C Earliest we will report anything is after the event occurs.
 - D Timing of payments will depend somewhat on Member payment terms; the time it takes HCP's to invoice members and the receipt and analysis of meeting organiser invoices.
 - E Only events occurring after 1/10/15 are to be reported - even if the payment is made after 1/10/15.