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21 November 2014

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

This letter responds to the questions raised in the ACCC's draft Determination of 17 October 2014 in respect of Medicines Australia's application for authorisation of Edition 18 of the Medicines Australia Code of Conduct (the ***Code***).

1 Summary

Medicines Australia submits that the transparency regime currently contained in Edition 18 of the Code should be allowed to be implemented for a 12 month period from 1 October 2015 to 1 October 2016. From 1 October 2016 onwards Medicines Australia's member companies are prepared to accept the introduction of the ACCC's proposed condition. Other stakeholders, such as the Australian Medical Association also support a 12 month deferral.

Deferring the operation of the condition for 12 months will allow member companies and the industry, including healthcare professionals, time to adapt to the new reporting requirements. This is particularly important given that, as the ACCC has recognised in the draft Determination, the introduction of the transparency regime proposed in Edition 18 of the Code is a significant and important change to the Code.[1] Medicines Australia submits that significant changes to the Code must not be rushed, and the changes must be weighed against the risk of disruption to the current provision of important education provided by member companies to healthcare professionals.

Medicines Australia also strongly submits that it is unnecessary to impose a condition that would require some form of continued reporting of the hospitality provided by member companies to healthcare professionals, or which would reduce the mandatory $120 cap on hospitality expenditure contained in Edition 18 of the Code. Medicines Australia considers that the explicit prohibition in Edition 18 of the Code on the provision of hospitality to healthcare professionals exceeding $120 is appropriate, will be effective and must be considered with other provisions in the Code which ensure

[1] ACCC: Draft Determination, 17 October 2014, at [132].

that any hospitality provided in association with education is always secondary to that education, and is not excessive.

Medicines Australia does not consider it appropriate to name specific medicines in the transparency reports. It will be difficult, and in some cases impossible, for member companies to identify particular medicines referable to each transfer of value. Further, naming medicines in this manner may have unintended consequences with regard to the prohibition on promoting medicines to the general public and is also likely to increase the complexity and cost of reporting.

Medicines Australia also considers that it is neither necessary or appropriate to require a press release in respect of decisions by the Code or Appeals Committees to impose a fine on member companies who contravene the Code. Medicines Australia's current quarterly reports, which provide detailed information about complaints (whether a company is found to have contravened the Code or not) are appropriate and sufficient.

2 Condition requiring amendment of s 41.2.3 of the Code

In the draft Determination the ACCC recognised that significant public benefits arise from the Code and that these benefits outweigh the minimal anti-competitive detriment.[2] Regardless, the ACCC proposes to impose a condition on authorisation of Edition 18 by which Medicines Australia must require members to report transfers of value to healthcare professionals before making relevant transfers, by either:

- obtaining healthcare professional consent to disclose their data; or
- taking appropriate steps to give notice of the disclosure obligation so that healthcare professionals would reasonably expect the disclosure.

Should the ACCC impose the proposed condition requiring amendment of section 41.2.3 of the Code, Medicines Australia agrees with the AMA's submission that the application of the condition be deferred for 12 months following the implementation of the new transparency regime in Edition 18 of the Code. That is, Medicines Australia submits that:

- member companies will comply with the new transparency reporting regime currently contained in Edition 18 of the Code from 1 October 2015 to 1 October 2016; and
- from 1 October 2016 member companies will comply with the transparency reporting regime as amended by the operation of the ACCC's proposed condition.

Deferring the implementation of the ACCC's condition will:

- allow member companies and the industry, including healthcare professionals, time to adapt to the new reporting requirements;
- allow the effectiveness of the new regime to be considered in practice, rather than in the abstract;
- provide the industry with necessary information in order for it to plan for the ongoing interactions between member companies and healthcare professionals; and
- minimise any disruption to the current provision of important education provided by member companies to healthcare professionals.

By way of example, a deferral of 12 months would allow the industry, in particular healthcare professionals, to experience how the new reporting requirements operate in practice and to obtain comfort that the regime will operate effectively when reporting becomes 'mandatory' in accordance

[2] ACCC: Draft Determination, 17 October 2014, at [302], [305].

with the proposed condition. A deferral would also assist to ensure that any teething problems associated with the new regime (such as any issues associated with healthcare professional verification of data) can be addressed before the operation of the regime is expanded.

Although member companies will accept the ACCC's condition if implemented from 1 October 2016, member companies have some concerns with the terms of the condition proposed by the ACCC and how it will operate in practice. One potential problem with the condition is where a member company relies on item (1) in the ACCC's condition, namely, where the member obtains 'the consent of the healthcare professional to disclosure of individual healthcare professional data' before making a transfer of value. If the member company obtains this consent but the healthcare professional **subsequently withdraws his or her consent** after the transfer of value has been provided, the member company would no longer be able to rely on that consent to publish the information. Further, in such a case the operation of the Privacy legislation may preclude a member company from then relying instead on the 'reasonably expects' exception (item (2) in the ACCC's condition). In these circumstances member companies would be unable to comply with both the Code and with Privacy legislation and the operation of the condition therefore creates considerable uncertainty for members.

While Medicines Australia does not expect that there would be large number of healthcare professionals (if any) who would behave in this way, member companies cannot control this, and the possibility of a healthcare professional withdrawing consent after receiving a transfer of value cannot be discounted. This is one example of the potential consequences of the complex intersection between Privacy legislation and the ACCC's proposed condition. Member companies are concerned to ensure that they can comply with all legal requirements.

Medicines Australia therefore proposes that the condition include an amendment to deal with the potential situation where a member company chooses to rely on item (1) included in the ACCC's condition, namely, where the member has 'obtained the consent of the healthcare professional to disclosure of individual healthcare professional data' before making a transfer of value but where the healthcare professional subsequently withdraws his or her consent after the transfer of value has been provided. Medicines Australia recommends that the condition therefore include the text in bold below:

> Companies must not make a transfer of value of a kind referred to in section 41.3.1 unless they have either:
>
> 1. obtained the consent of the healthcare professional to disclosure of individual healthcare professional data; or
> 2. taken appropriate steps to give notice of this disclosure obligation, so that the healthcare professional would reasonably expect the disclosure.
>
> **If a company obtains the consent of the healthcare professional pursuant to (1) and that consent is subsequently withdrawn by the healthcare professional, such that the recipient cannot be identified for legal reasons, the member company must report the amount attributable to such transfers on an aggregate basis. The number of recipients involved must be stated and the aggregate amount attributable to transfers of value to such recipients.**

3 No condition should be imposed in respect of hospitality reporting

The ACCC seeks submissions on whether it should impose a condition on authorisation which requires some form of continuing reporting on the hospitality provided by member companies to healthcare professionals.[3]

[3] ACCC: Draft Determination, 17 October 2014, at [162].

Medicines Australia strongly submits that such a condition is not necessary. Edition 18 imposes a new requirement that the maximum cost of a meal (including beverages) provided by a member company to a healthcare professional must not exceed $120: section 9.4.3. This mandatory rule:

- ensures that the provision of expensive meals is **explicitly prohibited** under the Code while ensuring that low-level hospitality (such as coffee and a muffin) is not caught by the detailed expanded reporting requirements in the Code; and
- provides clarity and certainty to member companies and healthcare professionals on what can and can't be provided by a member company in terms of hospitality.

Medicines Australia also submits that a threshold of $120 for hospitality is appropriate and should not be reduced. In circumstances where member companies often need to utilise CBD venues such as hotels and conference centres for educational events, such venues routinely charge up to this amount per person for a set menu meal. Reducing the hospitality cap below $120 would make it very difficult for member companies to identify suitable venues in the CBDs of capital cities that can accommodate an educational meeting where up to several hundred healthcare professionals may be in attendance.

In any event, Medicines Australia considers that the significant majority of interactions with healthcare professionals involving hospitality will fall well below the $120 threshold. As outlined in section 9.4.3 of the Code, the maximum of $120 would:

> …only be appropriate in exceptional circumstances, such as a dinner at a learned society conference with substantial educational content. In the majority of circumstances, the cost of a meal (including beverages) should be well below this figure.

In addition to the $120 cap, the Code contains a number of detailed requirements on the circumstances in which hospitality may be appropriate including:

- section 9.3 which provides that: 'Company involvement in [educational] events must have the objective of providing current, accurate and balanced medical education in an ethical and professional manner. When organising or sponsoring educational events, it is also important to ensure an appropriate balance between the duration of educational content and any hospitality provided to delegates';
- section 9.4.3 (and 9.7.7) which provides that: 'Any meals or beverages offered by companies to healthcare professionals must be secondary to the educational content. Meals and beverages must be appropriate for the educational content and duration of the meeting and should not be excessive';
- section 9.5.5 which provides that, in the context of sponsored educational events: 'Companies must critically examine whether any hospitality provided at the sponsored educational event is appropriate for the educational content and duration of the meeting and is secondary to the educational content'; and
- section 9.13 which provides that: 'Interactions with healthcare professionals must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry. A breach of this requirement is a ‘severe breach’ of the Code of Conduct'.

Medicines Australia therefore submits that the provision of hospitality is adequately dealt with in Edition 18 of the Code and that a further condition on authorisation should not be imposed.

In addition, with respect to the other options put forward in the draft Determination:

- the ACCC has proposed a condition on authorisation that will effectively require member companies to report on every relevant transfer of value made to an individual healthcare professional (or else preclude member companies from providing transfers of value to

healthcare professionals who do not want their details published). The additional burden associated with adding hospitality to the transfers of value reported under such a regime would be significant for member companies, both in terms of administration and cost;

- significant administrative burdens would also arise if member companies are required to prepare an additional, separate, educational event report which covers hospitality only; and
- additional complexity in the reporting regime should be avoided, at least until the industry has had the time to embed and consider the operation of the new reporting requirements.

4 Transparency reporting should not refer to the name of individual medicines

The ACCC seeks submissions on whether the name of a relevant medicine should be included in the transparency reports. Medicines Australia submits that there are several reasons why it would not be appropriate to require the name of a particular medicine to be included in those reports:

- it will often be difficult, or impossible, for member companies to identify a particular medicine in respect of which a transfer of value is made. This is especially the case for activities such as (a) conferences or lectures where multiple medicines are discussed or (b) Advisory Boards, where there may not be a medicine developed yet which can be identified by name or where a number of different products are assessed and discussed;
- the transparency reports will be available for review by the general public. Although not strictly 'promotional' activity, identifying particular medicines by name and associating those medicines with a particular event (such as a reference to a conference on 'new indications for medicines used in treating cancer') may be problematic. Naming medicines may also raise concerns for patients that a particular drug prescribed for them by a healthcare professional may have adverse indications when it does not, depending on the title of the paper or issue discussed at the event. Further, a particular issue could arise in respect of medicines that are not approved for specific indications, references to which could be problematic if seen to be promoting the use of that medicine for a non-approved indication; and
- as the ACCC acknowledges, reporting on a particular drug name may increase the complexity and cost of reporting.[4] In circumstances where the new transparency reporting regime is a significant change to the Code and will generate large associated administrative costs, additional complexity should be avoided – at least until the operation of the new regime has become embedded in the industry and its effectiveness assessed. Identifying which medicines should or should not be included in the reports will be time consuming and the potential for administrative errors requiring rectification may also increase.

5 Centralised database

Medicines Australia considers that there are a number of practical issues that must be addressed before a centralised database for transparency reporting can be implemented. These include determining:

- who will build/develop the database;
- who will manage and maintain the database on a day to day basis;
- how the database should best be designed to meet the needs of member companies and users;

[4] ACCC: Draft Determination, 17 October 2014, at [161].

- who will own the database and the information contained within it;
- who will fund the database;
- how healthcare professionals will be identified;
- how inaccuracies and data integrity issues will be dealt with. Potential issues requiring consideration include how to ensure that information is attributed to the correct healthcare professional and how errors in data entry can be easily resolved. This is particularly important as it is likely there will be hundreds, if not thousands, of individual data line items that will need to be uploaded into the database each year;
- how to ensure that privacy requirements are met; and
- how and in what circumstances users of the database will be able to extract data from the database.

Also relevant to this consideration is the process involved in member companies revising their internal systems, interfaces and processes in order to collect and maintain the data in the form required for whatever database is ultimately designed.

The importance of ensuring that these issues are considered in advance of making available a database is demonstrated by the difficulties experienced in the US pursuant to the Physician Payments (Sunshine) Act. The significant problems and delays associated with the introduction of the US database (discussed in Medicines Australia's previous submissions)[5] demonstrate the importance of ensuring that the logistical, legal and technological challenges associated with implementation are addressed effectively before a database is established.

In terms of timing, other jurisdictions that have similar reporting requirements (such as the US and the UK) have taken or are taking several years to build and implement a centralised reporting database. Medicines Australia considers that a period of at least two to three years will be required in order to investigate, develop and build an effective database that avoids the implementation issues associated with, for example, the US Physician Payments (Sunshine) Act.

The ACCC is aware of the practical implementation issues identified by Medicines Australia in relation to the establishment of a central platform for reporting. In the draft Determination the ACCC has encouraged Medicines Australia to dedicate appropriate resources to developing a centralised database and to implement it as soon as possible, while noting that the reporting requirements in the Code provide transparency around the provision of hospitality to healthcare professionals and serve as a disincentive for inappropriate behaviour.[6]

Within six months of authorisation (should it be granted) Medicines Australia will liaise with its member companies to discuss the development of a centralised database with the aim to set up a process to be followed for its establishment (such as, for instance, taking steps to form a working group that will be tasked with investigating practical options for the database).

6 Decisions on complaints are adequately publicised

The ACCC has asked whether decisions to impose a fine should be circulated in the form of a media release, in addition to the existing reporting and web updates.[7] In Medicines Australia's view it is not appropriate or necessary to require a press release in respect of a decision to impose a fine in circumstances where:

[5] See for example Medicines Australia's submissions of 28 August 2014, 16 September 2014 and 2 October 2014.

[6] ACCC: Draft Determination, 17 October 2014, at [176], [178].

[7] ACCC: Draft Determination, 17 October 2014, at [291].

- Medicines Australia already publishes detailed quarterly reports which provide a significant amount of information about complaints heard and any fines imposed. A quarterly report is the best way to capture this information in circumstances where there may be a period of up to six weeks after a complaint is heard, but before a decision on appeal is finalised. It would not be appropriate to publish a press release before any appeal was finalised; and
- a press release could be seen as an additional form of penalty imposed on the member company in question. This is not necessary in circumstances where the Code already imposes adequate sanctions on companies that contravene its terms. These include:
  - financial penalties of up to $250,000;
  - an ability for the Code Committee to forward a complaint/appeal to the TGA or the ACCC if a subject company does not pay a fine within 30 days and to **publicise** the failure to comply: section 28.3; and
  - the requirement for corrective action to be taken where moderate or severe breaches are found. The Australian Competition Tribunal accepted that a requirement for corrective advertising or corrective letters would be a significant sanction that may cause reputational consequences.[8]

7 Other matters raised in the draft Determination

Medicines Australia agrees with the ACCC that the transparency reporting (and ACCC condition) should focus on key transfers of value and not on items such as venue costs.[9] In particular, Medicines Australia does not consider that sponsorship of research and development should be included for the reasons outlined in its submission of 28 August 2014.[10]

8 Pre-decision conference

Medicines Australia confirms that it will attend the pre-decision conference scheduled for 28 November 2014.

Yours sincerely

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[8] *Re Medicines Australia* [2007] AComp T 4 at [164].

[9] ACCC: Draft Determination, 17 October 2014, at [163].

[10] Medicines Australia, 28 August 2013, section 2.3.