Australian Competition
&
Consumer Commission

PRE-DECISION CONFERENCE

Minutes

Applications for revocation and substitution A91436 - A91440
lodged by Medicines Australia Limited

28 November 2014

The information and submissions contained in this minute are not intended to be a verbatim record of the pre-determination conference but a summary of the matters raised. A copy of this document will be placed on the ACCC's public register.

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Applications for revocation and substitution A91436 - A91440
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Australian Competition and Consumer Commission Offices located in Canberra, Sydney and Melbourne by video conference facilities. Teleconference from various locations

Attendees:

Australian Competition and Consumer Commission
Jill Walker, Commissioner (in Canberra)
Rami Greiss, Executive General Manager, Merger and Authorisation Review Division (in Canberra)
Richard Chadwick, General Manager, Adjudication Branch (in Canberra)
Darrell Channing, Director, Adjudication Branch (in Canberra)
Tess Macrae, Project Officer, Adjudication Branch (in Melbourne)
Natalie Plumridge, Project Officer, Adjudication Branch (in Melbourne)
Brooke Watson, Lawyer (in Canberra)

Medicines Australia
Tim James, Chief Executive (in Canberra)
Deborah Monk, Director, Compliance (in Canberra)
Fiona Crosbie, Partner, Allens (in Sydney)

Royal Australian College of General Practitioners
Stephan Groombridge, Program Manager, Quality Care, Policy, Practice & Innovation (by teleconference)
Justin Coleman (by teleconference)

Australian Medical Association
Anne Trimmer, Secretary-General (in Canberra)
Robin Langham, Chair of the Federal AMA Medical Practice Committee (by teleconference)

Royal Australian and New Zealand College of Ophthalmologists
Gerhard Schlenther, General Manager, Policy & Development (in Sydney)

Consumers Health Forum of Australia
Adam Stankevicius, Chief Executive Officer (in Canberra)

Public Health Association of Australia
Melanie Walker, Deputy Chief Executive Officer (in Canberra)
David Legge (in Melbourne)
Mary Osborn (in Sydney)

Novartis Group
Jodie Stocks, Director Integrity and Compliance (in Sydney)

Novo Nordisk
Shaun O'Mara, Director Biopharmaceuticals and Business Ethics Compliance Officer (in Sydney)

Professor Philip Morris (by teleconference)

Conference commenced: 1.15pm AEDT

Submissions received from interested parties are available at:
http://registers.accc.gov.au/content/index.phtml/itemId/278039

Commissioner Walker welcomed attendees, made some introductory remarks outlining the purpose of the conference, declared the pre-decision conference open and invited Dr Coleman on behalf of the Royal Australian College of General Practitioners (RACGP), who called the conference, to address the conference. Commissioner Walker proposed that the discussion be broken down into: the ACCC's proposed condition of authorisation; a possible condition requiring ongoing hospitality reporting; the implementation of a centralised database for individual reporting; and any other issues.

Dr Coleman (RACGP) submitted that the RACGP's main point is that if there is the option to opt-out of individual transparency reporting it will fundamentally undermine transparency and result in a situation where it is unclear which information has not been made transparent. Dr Coleman submitted the RACGP supports the ACCC's condition of authorisation.

Dr Coleman submitted the timeline for implementing transparency reporting is already generous and should not be extended by 12 months as requested by Medicines Australia. Dr Coleman stated the first publication of reports would be in August 2016 and this should not be delayed.

Dr Coleman noted Medicines Australia has stated it is happy to work towards establishing a centralised database. Dr Coleman submitted that without a centralised database it would be difficult for the average person to discover whether a conflict of interest exists because of the need to search the website of every member pharmaceutical company. Dr Coleman also submitted that although there will be some public perception that transparency reporting under the Code of Conduct (the Code) will be similar to reporting under the Sunshine Act in the USA, the current situation as it stands only requires reporting of significant direct payments and will not include any payments in kind. Consequently transparency reporting is likely to capture specialists and key opinion leaders while transfers to GPs will rarely be reported. As hospitality will no longer be reported and a generous cap on hospitality applies, the RACGP is concerned that there is actually a reduction in transparency under Edition 18 compared to Edition 17 of the Code.

Mr James (Chief Executive, Medicines Australia) submitted Medicines Australia is working on increasing transparency proactively and is voluntarily seeking authorisation. Further, membership of Medicines Australia is voluntary and they need to bring their membership along with the changes to the Code. Mr James noted some other industry participants are not seeking authorisation, and some have walked away from authorisation. Mr James submitted Medicines Australia is lifting the bar in relation to transparency but others, in the interests of public policy, should also do so.

Mr James submitted Medicines Australia is willing to accept the ACCC's condition of authorisation from October 2016. The form of transparency reporting as currently drafted in edition 18 of the Code will enable Medicines Australia to inform and educate the industry and professionals about the changes and experience the reporting system (including publishing the first round of reports) prior to implementing the condition.

Mr James submitted that Medicines Australia is also concerned that the condition as drafted could place its members in a position where they cannot comply with both the

Privacy Act and the condition if a healthcare professional withdraws consent after a transfer has taken place. Medicines Australia has proposed an amendment to the condition that would allow aggregate reporting if consent is withdrawn prior to reporting.

Mr James submitted that Medicines Australia does not support a condition requiring some form of ongoing hospitality reporting, given that edition 18 of the Code introduces a $120 limit on meals (and noting that $120 would only be appropriate in certain circumstances).

CONDITION OF AUTHORISATION

Dr Osborn (Public Health Association of Australia (PHAA)) submitted the PHAA supports the condition of authorisation, and in particular supports Professor Morris' stand on the condition.

Dr O'Mara (Director and Business Ethics Compliance Officer, Novo Nordisk) submitted Novo Nordisk supports Medicines Australia's position outlined above.

Ms Stocks (Director Integrity and Compliance, Novartis Group) submitted Novartis also supports Medicines Australia's position.

Professor Morris submitted there were two issues in relation to the condition of authorisation: the ability to opt-out, and the timing for implementation (both discussed below).

Associate Professor Langham (Chair of the Federal AMA Medical Practice Committee, Australian Medical Association (AMA)) submitted that while the AMA supports transparency and the condition of authorisation, quite a large number of clinicians will be affected by transparency reporting, which gives rise to concerns about implementation. A delay would assist with smooth implementation.

CONDITION OF AUTHORISATION – WITHDRAWING CONSENT

Commissioner Walker clarified that the condition of authorisation as drafted would either require explicit consent or require steps to give appropriate notice of disclosure of information (that is, create a reasonable expectation).

Associate Professor Langham submitted a one year delay would allow all parties concerned to consider the issue of parties withdrawing consent. Associate Professor Langham submitted the Code Review Panel originally included the opt-out clause to address privacy legislation, and it was not intended to reduce transparency.

Ms Trimmer (Secretary-General, AMA) stated that the AMA's understanding was that a healthcare professional cannot opt-out of disclosure after they have received a benefit because receipt of the transfer of value is conditional upon disclosure. Ms Trimmer submitted there is confusion here about deciding in the future to cease receiving transfers and subsequently withdrawing consent.

Ms Trimmer submitted that reasonable expectation is quite a difficult test to meet because there has to be evidence of that level of expectation before releasing a person's personal information.

Professor Morris strongly opposes the possibility that healthcare professionals can opt-out of disclosure of transfers of value. Professor Morris stated the Privacy Commissioner's advice notes that if doctors go into an agreement knowing that there

will be a transparent reporting of the transfer of value then there is no issue with disclosing, and consent is not necessary (i.e. by relying on the second limb of the proposed condition). Professor Morris submitted that in the future, once the transparency arrangements are accepted in the industry, anyone who enters an arrangement with a member company for a transfer of value will understand that this transfer will be accounted for and made public.

Professor Morris noted Dr Harvey's submission that the Transparency Working Group never talked about the ability of healthcare professionals to opt out of transparency reporting.

Professor Morris agreed that a healthcare professional should be able to decline receiving future transfers but should not be able to withdraw consent for reporting transfers already received.

Professor Morris noted that some existing contracts may run into the new reporting regime, but submitted that, in practice, people are given transfers of value for a specific purpose, on a case by case basis, rather than a long-term arrangement.

Mr James submitted that Medicines Australia is not looking to provide an opt-out to reporting. Instead, Medicines Australia is seeking an amendment to the condition in order to deal with reporting of transfers if consent is withdrawn.

Mr James submitted the Privacy Commissioner's advice does not provide absolute comfort with relying on reasonable expectation and his advice is not legal advice. Mr James submitted that if reasonable expectation was clearly the preferable option, the Privacy Commissioner would have referred to this rather than offering a choice.

Mr Stankevicius (CEO, Consumers Health Forum of Australia (CHF)) submitted that receipt of a transfer of value involves a contractual arrangement which should require the transfer of value to be repaid if the healthcare professional withdraws consent for reporting. Mr Stankevicius submitted that if a healthcare professional is provided with a contract when they receive a transfer of value which states that the individual's information will be reported then the healthcare professional is made reasonably aware.

Dr Coleman submitted that all medical bodies seem happy with not having an opt-out clause. Dr Coleman submitted that paying back transfers of value if consent is withdrawn is a fair solution. In addition, if member companies have got legal advice which says it is not possible to rely on reasonable expectation, this advice should be released. **Professor Morris** does not support the option for healthcare professionals to pay transfers of value back and queried how this would be policed.

Dr Osborn submitted healthcare professionals will be very aware of the implications of receiving a transfer of value and there should be no opt-out at all. Dr Osborn considered that healthcare professionals have to take some responsibility for themselves. If they accept a transfer of value then they need to be aware that it will be disclosed.

Dr Legge (PHAA) submitted that if a healthcare professional enters into a contract and acknowledges this then the issue of consent does not come into it. Dr Legge submitted that if disclosure forms part of the contract then a party cannot retrospectively withdraw from the contract. Dr Legge emphasised this is not a trivial issue and that this is a minor step in reining in the promotion of medications in terms of public policy, noting that, for example, the overuse of antibiotics has resulted in a health crisis.

CONDITION OF AUTHORISATION – DELAYED IMPLEMENTATION

Commissioner Walker asked Medicines Australia about its request for an extra year's delay before implementing the ACCC's condition.

Mr James submitted that this issue goes towards having a longer period before implementation of the condition. Medicines Australia wants to ensure the transparency reporting is done thoroughly and completely. Mr James noted that Medicines Australia was not seeking complete deferral of the transparency regime but rather an additional 12 months to comply with the requirements of the condition.

Mr James submitted that it if the ACCC is going to rely on the reasonable expectation test, it is all the more important to ensure the regime is understood and communicated to healthcare professionals and that there are effective arrangements in place.
Mr James suggested that this would take considerably longer than six or seven months.

Ms Monk (Director, Compliance, Medicines Australia) noted that even with the delay in implementing the condition of authorisation, pharmaceutical companies would still collect data from 1 October 2015 and report the next year. Ms Monk also noted that reporting will be based on the date the transfer took place; for example the date of the event rather than the date the transfer was offered or the agreement entered into.

Associate Professor Langham submitted that the AMA supports a delay to allow for a better and smoother implementation, as it represents a large change in the way Medicines Australia members interact with professionals and change of this nature can be difficult.

Professor Morris submitted that Medicines Australia does not need another year beyond October 2015 for the industry to be advised of the transparency reporting arrangements, noting that if the ACCC made a decision in February/March 2015 this would provide six to nine months' notice. Professor Morris noted the pharmaceutical industry chooses opinion leaders and high prescribers to receive transfers of value and these parties will be aware of the transparency reporting within a month or two of the ACCC's final decision.

Dr Osborn submitted that most healthcare professionals have ethical guidelines or codes of conduct and are aware of requirements around receiving transfers of value. Therefore it will not take long for parties to learn about the transparency reporting.

Professor Morris noted an issue for consideration would be if a healthcare professional is subject to an existing agreement that will be ongoing at the time the new transparency regime comes into effect. This would need to be taken into account in terms of advising the healthcare professional that their information will be reported.
Dr Coleman submitted that if any doctor wants to continue on an existing contract for a transfer of value then the only change will be that the transfer of value will now be reported.

Mr Stankevicius submitted if there was a 12 month delay in implementing the transparency regime the CHF would want to see evidence of genuine progress along the way to continue to build community confidence regarding transparency.
Mr Stankevicius submitted that Medicines Australia could meet certain milestones to demonstrate progress. The CHF considers that a seven month delay would be more reasonable.

HOSPITALITY

Mr James submitted that Medicines Australia's focus is about getting the principle right; that is, ensuring hospitality spending is not inappropriate. Mr James submitted that if the purpose of transparency is to deter inappropriate conduct then Medicines Australia is going well beyond that by moving to a self-regulatory situation which prohibits meals above $120. If member companies are in breach of the relevant sections of the Code, this can be enforced by Medicines Australia.

Dr Legge submitted that in public policy terms the provision of hospitality to thousands of doctors is of comparable risk to healthcare as other larger transfers of value. It represents a very powerful marketing force and the pharmaceutical industry should be held accountable for this. Dr Legge submitted that $120 is very generous as a cap. Dr Legge stated that aggregate reporting of hospitality should be kept, and it should be below an appropriate per meal cap.

Dr Legge submitted that the cost of medicines for the PBS due to overprescribing is a far bigger issue than the cost of reporting transfers. For example, the PBS cannot fund hepatitis drugs because the cost to the PBS from overprescribing is such a big issue.

Dr Coleman submitted that the value of the cap amount does not matter because there are ways around it (for example, a company can redistribute costs from food/beverages to venue costs). Therefore, a cap will change little and will not increase transparency. Dr Coleman queried why as part of an increase in transparency Medicines Australia chose to exclude hospitality reporting in aggregate.

Ms Monk noted there is significant effort required by pharmaceutical companies to report on individual transfers of value. Medicines Australia considers that it is too much of an impost on pharmaceutical companies to also have to report aggregate hospitality costs. Ms Monk submitted that Medicines Australia had looked to the European model where there is a hard limit on hospitality spending. Ms Monk stated that $120 was chosen to recognise that for a small number of meetings, it is difficult to get a meal for less than $100 (and the Code makes clear that this maximum is only appropriate in specific circumstances).

Ms Trimmer submitted that, in deciding whether the cost is appropriate, it is relevant to realise that imposing a significant cost on member companies by requiring this reporting will ultimately be a cost to the healthcare system. Ms Trimmer noted that Medicines Australia has chosen to focus on the far more relevant transfers.
Ms Trimmer submitted that the AMA is not expressing a view either way but there is a need to focus on the big picture.

Mr James submitted that the RACGP could make hospitality reporting a requirement of healthcare professional members under its code(s) of conduct. **Mr Groombridge** (Program Manager, RACGP) noted that this is not the role of the RACGP.
Dr Coleman submitted that it makes more sense for member companies to report as they would only need to report once for each event.

Mr James submitted that Medicines Australia rejects the suggestion that the actions of the drug companies are a threat to the industry. Mr James suggested that Medicines Australia's members have a lot to contribute to the industry. Mr James submitted that it seems some interested parties would like pharmaceutical companies to have no interaction with healthcare professionals which would be a terrible outcome.

CENTRALISED DATABASE

Dr Osborn submitted that development of a centralised database for reporting individual transparency data is a key issue and congratulated Medicines Australia for recognising its importance. Dr Osborn submitted the benefit of a centralised database far outweighs the cost. Dr Osborn and **Ms Walker** (Deputy Chief Executive Officer, PHAA) asked Medicines Australia about the timeframe for a centralised database and requested that the ACCC ensure interested parties are kept up-to-date on its progress; for example, setting tangible milestones, or requiring progress reports. Dr Osborn noted that member companies already publish aggregate information on their website but it is the centralised format that is useful (because aggregating information from all member websites is time consuming).

Mr James submitted that Medicines Australia has committed to creating a working group in January 2015 to consider if and how to implement a centralised database. Mr James also noted that the Privacy Commissioner suggested Medicines Australia undertake a privacy risk assessment in relation to a centralised database. Further, the Privacy Commissioner has advised that Medicines Australia cannot use AHPRA numbers as an identifier. Mr James submitted that the challenges of dealing with personal information cannot be underestimated. Medicines Australia has made a commitment to move forward on this issue, however Mr James cautions against rushing.

Mr James submitted that before Medicines Australia can get into the when, Medicines Australia needs to address the questions of if, how and by whom. Mr James submitted it is not appropriate to have a strict timeframe for implementation of a centralised database. Mr James submitted there are a range of issues that need to be worked through, and it depends on getting the advice required. Mr James submitted there is also a significant cost.

Ms Trimmer submitted that it may not be achievable to have a centralised database if you cannot use the APHRA number as an identifier. As such, any ACCC condition may not be able to be met.

Associate Professor Langham submitted there is significant risk of misattribution of information that could arise with a centralised database.

Dr Legge noted Professor Morris' suggestion that individual companies initially implement their own databases for reporting so that they can contribute their experiences to assist in the development of a centralised database. **Mr James** submitted that having 55 separate databases will not necessarily help inform building a centralised database, noting that each individual company may have a different approach.

Dr Coleman noted that Medicines Australia's proposal as it stands requires each company to identify a recipient healthcare professional by name, town etc. and that this information is not currently reported. Dr Coleman agreed that the centralised database is important but the big change is that there will be individual doctors identified on member companies' website.

Commissioner Walker asked if Medicines Australia could provide an indication of the nature of the problems in relation to the database used for reporting the Sunshine Act data in the USA.

Ms Monk submitted that when healthcare professionals in the USA checked the reported data they found a lot of errors. Because of inaccuracies in the data, 25% to 30% of data was not able to be reported initially.

OTHER

Commissioner Walker invited comments from attendees on any other issues.

Dr Coleman noted there is a clause in edition 18 of the Code which states reported data is only required to be published for two years. Dr Coleman submitted that five years is a reasonable time to retain data. **Mr James** queried what utility or need for the information exists beyond two years. Mr James submitted Medicines Australia considers two years is reasonable and adequate, and five years would be an overreach, particularly considering the data relates to personal information. Mr James referred to Australian privacy principle 11.2 which requires that private information should be destroyed when no longer needed.

CLOSING STATEMENT

Mr James submitted that the Medicines Australia Board and membership are committed to providing transparency. Mr James noted Medicines Australia's Code had been in place for many years. In 2015 when edition 18 of the Code comes into effect, it will have been in operation for 65 years. Mr James stated he considers Medicines Australia's Code the most effective self-regulatory code in Australia. Mr James submitted the changes to the Code to increase transparency are a voluntary step by Medicines Australia and they are waiting on the rest of the industry to come along. Mr James requested the ACCC authorise edition 18 of the Code so Medicines Australia can continue to increase transparency.

Commissioner Walker confirmed that no party wished to make any further comments. The Chair closed the conference by noting that parties could provide further submissions to the ACCC by 12 December 2014 and that the ACCC would provide participants with a record of the conference, which would also be placed on the ACCC's public register.

Conference closed at 3.05pm AEDT