Draft Determination

Applications for revocation and substitution of authorisation

lodged by

Medicines Australia Limited

in respect of

the Medicines Australia Code of Conduct edition 18

Date: 17 October 2014

Authorisation numbers: A91436-A91440

Commissioners: Sims
Rickard
Schaper
Cifuentes
Court
Featherston
Walker

Summary

The ACCC considers that Medicines Australia's Code of Conduct results in public benefits and proposes to grant conditional authorisation to edition 18 of the Code for five years. In edition 18, Medicines Australia has introduced a regime which requires reporting of individual transfers of value made to healthcare professionals, except where the healthcare professional has not consented to the disclosure. The ACCC is proposing to impose a condition to ensure that all relevant transfers of value by pharmaceutical member companies to individual healthcare professionals are reported. The ACCC is also considering requiring ongoing hospitality reporting.

The ACCC will seek submissions in relation to this draft determination before making its final decision. The applicant and interested parties may also request the ACCC to hold a pre-decision conference to allow oral submissions on the draft determination.

Medicines Australia Limited (Medicines Australia) has applied for reauthorisation of edition 18 of its Code of Conduct (the Code) which sets the standards for the marketing and promotion of prescription pharmaceutical products in Australia. Amongst other things, the Code provides standards for appropriate advertising, the behaviour of medical representatives and relationships with healthcare professionals. All members of Medicines Australia must adhere to the Code, although membership of Medicines Australia is voluntary.

The ACCC has considered applications for authorisation of previous versions of Medicines Australia's Code on several occasions and the transparency regime provided in the Code has consistently been an important issue. Most recently, in authorising edition 17 of the Code in 2012, the ACCC stated that it expected Medicines Australia to complete its review of transparency under the Code and to incorporate new provisions into the next edition of the Code that would facilitate greater disclosure around sponsorship and fees paid by pharmaceutical companies to individual doctors. The ACCC noted that the Code should continue to reflect community expectations about the level of transparency around these relationships. Interested parties have been advocating for this change for a number of years.

Edition 18 of the Code introduces a new transparency regime which requires member companies to report on certain transfers of value made to individual healthcare professionals, and to identify those healthcare professionals by name, as long as the healthcare professional consents. 'Transfers of value' include: fees paid for speaking at an event, consultancy services, sitting on an advisory board, market research; sponsorship to attend conferences and other events. Currently, under edition 17 of the Code these transfers of value are reported at an aggregate level (e.g. by event) and do not identify the recipients.

Other key amendments in edition 18 of the Code include:

- setting a $120 limit on the value of each meal provided to healthcare professionals by member companies and the discontinuance of the reporting of such hospitality
- clarification of existing provisions in the Code regarding the nature and availability of information and claims about pharmaceutical products
- provisions regarding transparency of authorship of clinical papers
- clarification on the administration of the Code, the committees and the complaints process.

The ACCC accepts that the Code provides a framework for interactions between pharmaceutical companies and healthcare professionals and that the Code is likely to result in public benefits including protecting the public from inappropriate advertising, setting consistent standards for medical and promotional material and providing the potential for greater transparency around the relationships between pharmaceutical companies and healthcare professionals. The ACCC also notes that the Code results in minimal detriment.

However, the ACCC is concerned that, under edition 18 of the Code, member companies will not be required to publish information about a relevant transfer of value made to a healthcare professional where the healthcare professional does not subsequently consent to have information about that transfer of value reported. (In the event that consent is not granted, amounts will only be reported in aggregate, without the identification of the individual healthcare professionals to whom the transfers were made.)

The ACCC is concerned that the benefit from the reporting of individual disclosures of transfers of value will be threatened if there is incomplete information, and anything less than universal disclosure may significantly reduce the potential benefits of the regime. Without knowing what has and has not been reported (for example, in relation to a particular healthcare professional), it will be difficult to use or rely upon the information that has been reported. This fundamentally undermines the transparency objectives of the regime. While most interested parties support increasing transparency, many individuals and groups agree that not reporting all transfers of value will diminish the utility of individual reporting. Many of these interested parties, including the RACGP, CHOICE and the Consumers Health Forum, suggest that the ACCC should deny authorisation to a Code that makes it possible for healthcare professionals to receive benefits from member companies but then to choose not to permit such transactions to be reported.

The ACCC's decision to authorise conduct is discretionary and the ACCC is able to impose conditions upon authorisation.[1] In doing so it may have regard to considerations relevant to the objectives of the Act.[2] In appropriate circumstances, the ACCC may impose conditions with a view to yielding a more substantial benefit or to enhance the likelihood of realisation of the public benefit.[3]

In light of its concerns about serious flaws in the operation of the transparency regime proposed in edition 18 of the Code, and in order to ensure that the potential benefits from the regime are realised, the ACCC is proposing to impose a condition requiring Medicines Australia to amend its Code to, in effect, require members to ensure, before making any transfers of value to healthcare professionals, that they will be able to report those transfers, having regard to Australian privacy legislation. This will mean that all relevant transfers of value by member companies to healthcare professionals will be reported (and that reporting will no longer be contingent on healthcare professionals subsequently providing consent to the transfer being disclosed). Relevantly, Medicines Australia already requires that member companies advise health consumer organisations who receive a transfer of value from them that their information will be reported.

Medicines Australia submits that requiring disclosure of all relevant transfers of value will result in some healthcare professionals declining to participate in educational activities, with diminished health outcomes for patients and an uneven playing field for

[1] Section 91(4) of the *Competition and Consumer Act 2010* (Cth); see also Re *Medicines Australia Inc [2007] ACompT* 4 at paragraphs 106 and 126 to 134.
[2] Re *Medicines Australia Inc [2007] ACompT* 4, at paragraph 126.
[3] Re *Medicines Australia Inc [2007] ACompT* 4, at paragraph 128.

member companies when competing against non-member suppliers of prescription medicines.

The ACCC is not persuaded that such a requirement would result in healthcare professionals not being able to access critical medicines education or information. In particular, member companies can offer events that do not require reporting, and healthcare professionals can self-fund to attend third party conferences. Some healthcare professional industry associations (such as the RACGP, the SHPA and the RANZCP) support the need for full individual transparency as a means to provide meaningful information to patients about their health practitioner's relationships. The ACCC is also not convinced that this requirement will put member companies at a significant disadvantage relative to their competitors given that most of their competitors in the Australian originator medicines market are also members of Medicines Australia.

Concerns have also been raised about the discontinuance of the reporting on hospitality. Edition 18 of the Code imposes a hospitality cap of $120 per meal but the ACCC is considering imposing a condition requiring some form of continuing transparency around the provision of hospitality, given the potential conflict of interest that can arise. The ACCC has posed several possible options to address this issue.

Interested parties have suggested a number of other changes to the transparency reporting including reporting on research costs and Product Familiarisation Programs, applying the transparency regime across the industry more broadly, and providing the reports in the form of a searchable centralised database. With the exception of hospitality expenditure, the ACCC generally accepts that it is appropriate for the new transparency model to focus on the transfers of value identified by Medicines Australia as of most concern but considers Medicines Australia should expand the reporting requirements over time as appropriate.

Interested parties have also raised concerns about other requirements under the Code such as Product Familiarisation Programs, sanctions, the membership of the Monitoring Committee, coverage of healthcare organisations and restrictions on advertising. The ACCC is not proposing to require changes to address these other issues raised by interested parties but invites submissions on this approach.

While the ACCC is able to impose conditions on authorisation to enhance the likelihood that the public benefits will be realised (as it proposes to do here, as outlined above), it is not for the ACCC to construct and impose its ideal or preferred system of self-regulation.[4] Accordingly, the ACCC does not consider that it is appropriate for it to require all changes proposed by interested parties to be incorporated into the Code, even if such changes may result in some level of additional public benefit.

The ACCC is therefore proposing to exercise its discretion to grant conditional authorisation to edition 18 of the Code for five years.

Authorisation does not represent ACCC endorsement of a code. Rather, it provides statutory protection from court action for conduct that meets the net public benefit test and that might otherwise raise concerns under the competition provisions of the *Competition and Consumer Act 2010*.

[4] Re *Medicines Australia Inc [2007] ACompT* 4, at paragraph 134.

Contents

Abbreviations & definitions[5]

ACCC	Australian Competition and Consumer Commission
the Act	*Competition and Consumer Act 2010*
advisory board	a group of healthcare professionals with specific expertise contracted by a company to meet at regular intervals to provide advice on a Company's product or group of products
AMA	Australian Medical Association
APNA	Australian Primary Healthcare Nurses Association
ARTG	Australian Register of Therapeutic Goods
ASA	Australian Society of Anaesthetists
Cancer Voices	Cancer Voices Australia
change of clinical significance	any change in the Product Information that is likely to alter a decision to prescribe or not to prescribe the product and may include the following: a) approved indications for use b) precautions for use c) contra-indications d) warnings e) adverse effects and interactions f) available dosage forms g) dosage regimens and routes of administration h) dependence potential i) reference to special groups of patients (where necessary) j) boxed warnings
clinical research	planned research involving humans which is designed to investigate and report upon the effectiveness (including, but not limited to pharmacokinetics, dosage regimens, routes of administration, efficacy) and/or safety (including tolerability, immunogenicity, side effect profile, drug interactions) of a medicine
CHF	Consumers Health Forum of Australia
CMS	Centers for Medicare & Medicaid Services
the Code	Edition 18 of Medicines Australia Code of Conduct
Code Committee	Code of Conduct Committee
Commission	Trade Practices Commission
consultant	an Australian healthcare professional or group of Australian healthcare professionals providing consulting services to a company in relation to specific products. For the purpose of reporting consultant services, these are regarded as different from providing advice as a member of an advisory board

[5] Definitions are taken from Edition 18 of Medicines Australia's Code of Conduct.

Consumer Medicine Information	information about products written by the pharmaceutical company that makes the product. It is easy to understand and written for consumers. Companies writing Consumer Medicine Information leaflets follow guidelines to ensure the information is accurate, unbiased, and easy to understand. A separate Consumer Medicine Information leaflet is available for each prescription and many non-prescription products
EFPIA	European Federation of Pharmaceutical Industries and Associations
GMiA	Generic Medicines Industry Association of Australia
GSK	GlaxoSmithKline Australia Pty Ltd
the Guild	Pharmacy Guild of Australia
HCO	Health consumer organisation
health consumer organisations	not-for-profit organisations that represent the interests and views of consumers of healthcare. They may range from small volunteer groups to large organisations, and generally promote views that are independent of government, the pharmaceutical industry and professional health service providers.
healthcare professional	a healthcare professional registered to practice in Australia who in the course of their professional activities may prescribe, dispense, recommend, supply or administer a prescription medicine in Australia
hospitality	the provision of food and/or beverages
medical representative	a person expressly employed by a company whose main purpose is the promoting of the company's products to healthcare professionals
MSD	Merck Sharp Dohme
National Statement	*National Statement on Ethical Conduct in Human Research 2007* [updated March 2014]
Patient Support Program	a program run by a company with or without involvement from a health consumer organisation, with the aim of increasing patient compliance and positive patient health outcomes
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
Pfizer	Pfizer Australia
PFP	Product Familiarisation Program
Product Familiarisation Program	a program run by the company with the aim of allowing the medical profession to evaluate and become familiar with the product following TGA registration and/or approval of new indications
post-marketing surveillance studies	research intended to generate data on safety parameters of a product that has been approved for registration when used in accordance with the approved Product Information
Product Information	either the current Australian Approved Product Information or in the case of a product whose registration pre-dates the current regulatory review ('Grandfathered Product') the document registered is known as the 'Full Product Information'. This Product Information must comply with the format specified in the TGA *Australian Regulatory Guidelines for Prescription Medicines*

PSA	Pharmaceutical Society of Australia
Quality Use of Medicines	means: selecting management options wisely; choosing suitable medicines if a medicine is considered necessary; using medicines safely and effectively
RANZCP	Royal Australian and New Zealand College of Psychiatrists
RACGP	Royal Australian College of General Practitioners
registration	the issue by the TGA of an AUST.R number for a product approved for marketing in Australia in accordance with the Therapeutic Goods Act and Regulations
research and development	any early-stage research, such as target discovery, drug discovery, mechanism of action or proof of concept studies; pre-clinical research, such as toxicological studies; and human clinical trials
SAMAC	South Australian Medicines Advisory Committee
satellite meetings	meetings held in conjunction with international or Australasian congresses and are under the auspices of the Society, College or other non-company entity in question
SHPA	Society of Hospital Pharmacists of Australia
starter pack	a small pack size of a product supplied at no cost to medical practitioners, dentists and hospital pharmacists. Starter packs are also referred to as 'samples' by healthcare professionals
Sunshine Act	Section 6002 of the *Patient Protection and Affordable Care Act* (Public Law No. 111-148)
TGA	Therapeutic Goods Administration
Therapeutic Goods Administration	The Division of the Commonwealth Department of Health that is responsible for the regulation of therapeutic goods in Australia
TG Act	*Therapeutic Goods Act 1989*
therapeutic classes	the classification system used for defining and grouping products in an approved reference manual
transfers of value	a direct or indirect transfer of value, whether in cash, in kind or otherwise. A direct transfer of value is one made by a company for the benefit of the recipient. An indirect transfer of value is one made by a third party on behalf of a company for the benefit of a recipient where the identity of the company is known to, or can be identified by, the recipient
trade pack	a package of a product which is sold by a company supplying prescription products in Australia
trade display	a display or exhibit of promotional or educational material about a product or products
the Tribunal	Australian Competition Tribunal
TWG	Transparency Working Group

The applications for authorisation

1. On 2 July 2014, Medicines Australia Limited (Medicines Australia) lodged applications for the revocation of authorisations A91316-A91320 and the substitution of authorisations A91436-A91440 for the ones revoked (reauthorisation). Medicines Australia seeks reauthorisation in relation to edition 18 of its Code of Conduct (the Code) for five years.

2. The ACCC granted authorisation to Medicines Australia for edition 17 of the Code in 2012 for two years. In this time, the ACCC expected Medicines Australia to complete the work it had already commenced on increasing the level of transparency provided by the Code (such as the Transparency Working Group (TWG)) and incorporate new provisions into the next edition of the Code that would facilitate greater disclosure around sponsorship and fees paid to individual doctors.

3. Authorisation is a transparent process where the ACCC may grant protection from legal action for conduct that might otherwise breach the *Competition and Consumer Act 2010* (the Act). The ACCC may 'authorise' businesses to engage in anti-competitive conduct where it is satisfied that the public benefit from the conduct outweighs any public detriment. The ACCC conducts a public consultation process when it receives an application for authorisation, inviting interested parties to lodge submissions outlining whether they support the application or not. Before making its final decision on an application for authorisation the ACCC must first issue a draft determination.[6]

The conduct

4. The Code is a voluntary industry code of conduct which sets standards for the marketing and promotion of prescription pharmaceutical products in Australia. All member companies of Medicines Australia must adhere to the Code, although membership of Medicines Australia is voluntary.

5. Medicines Australia has sought reauthorisation on the basis that the Code may involve:

    - a provision of a contract, arrangement or understanding which:
        - may be a cartel provision
        - may be an exclusionary provision
        - has the purpose or effect of substantially lessening competition
    - conduct that may constitute exclusive dealing.

The applicant

6. Medicines Australia represents the interests of the innovative medicines industry in Australia. Its member companies supply 86% of the medicines

[6] Detailed information about the authorisation process is contained in the ACCC's Guide to Authorisation available on the ACCC's website **www.accc.gov.au**.

that are available to Australian patients through the Pharmaceutical Benefits Scheme (PBS) (by value) (65% by volume)[7] as well as providing a range of other medicines and vaccines to the Australian community.[8] Medicines Australia states that it represents the innovative medicines industry by:

- engaging with government and other parties to develop health and industry policy;
- building and maintaining relationships with government for fair reimbursement of medicines (through the PBS);
- administering the Code;
- working with other health professional and consumer organisations on issues of mutual concern;
- providing specialist advice to member companies; and
- educating the community about industry activities.[9]

7. Medicines Australia's membership is divided into four principal classes of membership:

   - Class One – for research based prescription pharmaceutical companies (innovators)
   - Class Two – for non-research based prescription pharmaceutical companies (generics)
   - Class Three – for companies significantly engaged in research into potential pharmaceutical products but which have not yet commenced commercial production
   - Class Four – being firms or companies ineligible for other classes of membership which are significantly engaged in the development, testing or registration of prescription pharmaceutical products or which are engaged with the research-based pharmaceutical industry for a significant part of their business.

8. Medicines Australia has 31 Class One members, six Class Two members, four Class Three members and 11 Class Four members.[10] It is a condition of membership to any class to adhere to the Code in its entirety.

[7] Medicines Australia submission dated 16 September 2014. Excludes medical devices (such as prostheses), over the counter medicines, complimentary medicines, and in-vitro diagnostic products.
[8] Medicines Australia website, **http://medicinesaustralia.com.au/about-us**. Accessed 16 October 2014.
[9] Ibid.
[10] Medicines Australia supporting submission, 2 July 2014.

Other parties

9. Medicines Australia seeks authorisation on behalf of current and future member companies of Medicines Australia. Under subsections 88(6) and 88(10) of the Act, any authorisation granted by the ACCC is automatically extended to cover any person named in the authorisation as being a party or proposed party to the conduct, including future parties.

Background

Prescription medicines

10. Prescription medicines are those medicines which require a doctor's prescription in order to access them. The supply and marketing of prescription medicines in Australia is subject to regulation designed to maintain public health and safety, and affordable access to medicines for consumers.

11. Any prescription medicine intended to be supplied in Australia must be approved and registered by the Therapeutic Goods Administration (TGA) in accordance with the *Therapeutic Goods Act 1989* (TG Act). The TG Act provides a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines and medical devices. It also sets out the legal requirements for the import, export, manufacture and supply of medicines in Australia, and includes details regarding product advertising, labelling and product appearance.[11]

12. The TGA evaluates the quality, safety and efficacy of medicines and approves them before they can be supplied in Australia.[12] The TGA carries out a range of assessment and monitoring activities to ensure that all therapeutic goods available in Australia are of an acceptable standard.[13] All prescription medicines must be registered or listed in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia.

13. All prescription medicines registered or listed on the ARTG must be accompanied with a Product Information sheet which provides a description of the characteristics of the active ingredient of the medicine, relevant clinical trials, as well as information about side effects, dosage and storage of the medicine.[14]

14. The TGA issues a marketing approval letter to a pharmaceutical company when the company's application for a particular prescription medicine to be listed or registered on the ARTG has been approved.

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[11] TGA website, *About the Australian therapeutic goods legislation*, **http://www.tga.gov.au/industry/legislation-about.htm**. Accessed 16 October 2014.
[12] TGA website, *What the TGA regulates,* **http://www.tga.gov.au/about/tga-regulates-what.htm**. Accessed 16 October 2014.
[13] See the *Therapeutic Goods Act 1989***.**
[14] TGA website, *Australian Regulatory Guidelines for Prescription Medicines*, July 2013, **http://www.tga.gov.au/industry/pm-argpm.htm**. Accessed 16 October 2014.

15. The advertising of prescription medicines is subject to a number of requirements in the TG Act, as well as the Act and other relevant laws. The TG Act prohibits the promotion of prescription medicines to the general public. Promotion to healthcare professionals is allowed under the TG Act and is regulated by the self-regulatory scheme operated by Medicine Australia through its Code.

16. One of the conditions of registration of a prescription medicine requires the *promotion* of all prescription medicines (whether a member or non-member of Medicines Australia) to comply with the requirements in the relevant sections of Medicines Australia's Code.[15]

17. Complaints about advertisements of prescription medicines directed to healthcare professionals are handled by Medicines Australia. If a complaint is made about the advertising activities of a non-member, the complaint is forwarded to the non-member with an invitation to have the complaint adjudicated by the Code of Conduct Committee (Code Committee). If the non-member declines, Medicines Australia may forward the complaint to the TGA or the ACCC where relevant. [16]

Branded vs generic medicines

18. Originator pharmaceutical companies compete in the development of new drugs. Pharmaceutical companies obtain patents for the development of new medicines which restrict other companies from manufacturing a copy of the medicine for the time period of the patent. Only when the patent on a medicine expires can generic versions be produced and compete with the originator brand. Even once a patent has expired branded drugs tend to sell at a premium to generics, as consumers perceive the product as in some way superior.

19. A generic medicine is a copy of a branded medicine whose patent has expired. It is chemically equivalent (bioequivalent) to its branded counterpart and must meet the same standards of quality and safety as branded drugs.

20. In 2007-08 approximately 37% of prescriptions dispensed on the PBS were generic drugs.[17] Where there are two or more brands of the same drug listed on the PBS, each brand receives the same subsidy – up to the cost of the lowest priced brand which in many cases is a generic brand. A brand price premium paid by the consumer applies to the more expensive brand.[18]

[15] DHA TGA website, *Regulation of therapeutic goods advertising in Australia*, **http://www.tga.gov.au/industry/advertising-regulation.htm**. Accessed 16 October 2014.
[16] DHA TGA website, *Regulation of therapeutic goods advertising in Australia*, **http://www.tga.gov.au/industry/advertising-regulation.htm**. Accessed 16 October 2014.
[17] Victoria University Centre for Strategic Economic Studies, *The Impact of PBS reforms on PBS expenditure and savings,* Table 6.5, **http://medicinesaustralia.com.au/files/2010/02/The-impact-of-PBS-reforms-on-PBS-expenditure-and-savings.pdf**. Accessed 16 October 2014.
[18] CHOICE website, *Buy generic drugs and save*, 25 November 2008, **http://www.choice.com.au/reviews-and-tests/food-and-health/general-health/medicines/generic-drugs/page/more%20about%20generic%20drugs.aspx**. Accessed 16 October 2014.

21. While the promotion of branded drugs is generally directed at prescribers, generic manufacturers predominantly compete in respect of the supply of products to pharmacists. This is because consumers are offered generic drugs as a substitute to the originator brand by the pharmacist when their prescription is being filled, rather than by the prescriber. Pharmacists tend to stock the originator brand and one bioequivalent generic brand for most products. Generic manufacturers compete for wholesale supply through volume discounts and non-price benefits to have pharmacists supply their products.

22. Although membership of Medicines Australia is open to generic drug manufacturers, the majority are represented by the Generic Medicines Industry Association of Australia (GMiA). GMiA members supply over 30% of all prescriptions dispensed under the PBS and manufacture 80% of all generic medicines dispensed in Australia.[19]

23. On 3 November 2010, the ACCC granted conditional authorisation for three years to the GMiA for its Code of Practice which included provisions for taking disciplinary action against GMiA members who breached that code. The conditions extended the reporting requirements under the GMiA Code of Practice.

24. The GMiA's code of conduct includes similar elements to Medicines Australia's Code, such as processes for reporting, complaints, imposing sanctions and Code administration, but is not as detailed as Medicines Australia's Code.

25. The GMiA decided not to seek reauthorisation on expiry of its authorisation in 2013. However the GMiA submitted that it was proposing to maintain its code in an amended form. To this end, the GMiA made a range of amendments to its code to ensure that its provisions do not raise any concerns under the Act. Changes included:

    - replacing the industry representatives on its Code Complaints Committee with independent persons
    - making event reporting principals an optional commitment for signatories, rather than a mandatory obligation.

The Code

26. The Code sets standards of conduct for companies for the marketing and promotion of prescription pharmaceutical products in Australia. The Code adds to the legislative requirements of the Therapeutic Goods Regulations and the TG Act.

27. In particular, the Code specifies standards for:

    - educational and promotional material directed at healthcare professionals
    - company representatives

[19] GMiA website, *Generic Medicines Facts*, **http://www.gmia.com.au/information-and-resources/**. Accessed 16 October 2014.

- provision of starter packs
- Product Familiarisation Programs
- relationship with: healthcare professionals; the general public; health consumer organisations and patients
- research.

28. Relevantly, the Code addresses potential conflicts of interest from unrestricted relationships between pharmaceutical companies and healthcare professionals, which may harm consumers, for example, through the risk of inappropriate prescribing by healthcare professionals. A key feature of the revised Code is the reporting of individual transfers of value provided to healthcare professionals.

29. Edition 18 of the Code introduces a new transparency regime which requires member companies to report on certain transfers of value made to individual healthcare professionals, and to identify those healthcare professionals by name, where the individual has given consent to this disclosure. The regime is outlined in more detail below.

30. Other amendments include:

- setting of specific limits on the value of hospitality provided to healthcare professionals by member companies
- clarification of existing provisions in the Code regarding the nature and availability of information and claims
- provisions regarding transparency of authorship of clinical papers
- clarification on the administration of the Code (in particular the roles of the Monitoring Committee) and the complaints process.

Existing transparency reporting to continue until 30 September 2015

31. Under edition 18 of the Code, in the period up until 30 September 2015, member companies will continue to comply with existing reporting requirements.[20]

32. These requirements include reporting on:

- payments made to healthcare professional consultants and advisory board members in respect of: consultancy fees, sitting fees, honoraria, chair person's fee or similar; hospitality; accommodation; and travel
- educational meetings and symposia held or sponsored by that company for each month of the financial year at six month intervals. The reporting table must include:
    - details of sponsorship (registration fees, costs of accommodation and travel) of healthcare professionals or non-healthcare professionals to attend any educational event.

[20] See section 41.2 of the Code. See in particular: section 41.2.1; section 41.2.2.

- details of any payments (fees, registration costs, costs of accommodation and travel) to speakers to attend and give a presentation at an educational meeting..

33. This information is currently provided in the following reports:

- Summary of Events Sponsored by Member Companies – including:
  - total sponsorship paid for each educational event or meeting and the total number of recipients; and
  - total amount paid in fees to speakers for each educational event or meeting and the total number of speakers receiving payment.
- Summary of Advisory Boards Convened by Member Companies – for each advisory board, reporting of the details, the number of members, honoraria/sitting fees, costs of any hospitality/accommodation/travel, venue details and any third party costs
- Summary of Health Professionals Consultancies Engaged by Member Companies – including total consultancies for the year, the cost of fees, the number of consultants and the cost of any hospitality/accommodation/travel
- Summary of Health Consumer Organisation Support by Member Companies (this report is retained under the new transparency regime) – including the name of the HCO and the support provided.

New transparency reporting from 1 October 2015

34. The new transparency regime imposes a general obligation upon member companies to report the transfers of value identified in section 41.3.1 of the Code, namely:[21]

- fees paid to healthcare professionals for speaking at an educational meeting or event
- sponsorship of a healthcare professional to attend an educational event (e.g. airfares, accommodation or registration fees associated with the meeting (whether held within or outside Australia))
- fees paid to healthcare professional consultants in Australia for consultancy services provided in relation to, for example, educational meetings, preparation of promotional materials or product position papers, assistance with training or any other advice to the company but excluding research and development work and clinical trials (e.g. payments in respect of consulting fees, accommodation and airfares (both within and outside Australia)
- fees paid to healthcare professionals for the purposes of market research where the identity of the healthcare professional is known to the member company.

35. Companies are only required to report the transfers of value that are related to prescription medicines.

[21] See section 41 of the Code which also cross references other sections of the Code, in particular section 9. The Introduction also outlines the importance of transparency.

36. Section 41.3.1 of the Code requires the following information to be reported for each relevant transfer of value:

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

37. The Code includes a template to be used by companies when making such reports.

38. As noted, transfers of value in respect of the provision of food and beverages will no longer be reported in most cases. However the Code:[22]

    - continues to require that any meals or beverages offered by companies to healthcare professionals are secondary to the educational content and not excessive
    - introduces a new requirement that the maximum cost of a meal and beverages provided by a member company to a healthcare professional within Australia must not exceed $120 (excluding GST and gratuities). Under the Code, this maximum would only be appropriate in exceptional circumstances and in the majority of circumstances, the cost of a meal and beverages should be well below this figure.

39. From 1 October 2015, member companies will separately report on sponsorship of educational meeting and symposia organised by third party organisations.[23] For example:

    - financial sponsorship of a third party educational event
    - monetary contribution to support the conduct of institutional grand rounds, clinic meetings or journal club meetings
    - purchasing space to provide a trade display at an educational event (including if this is the only sponsorship of an event).

40. If a company provides nothing directly to healthcare professionals other than food and beverages for an educational meeting (whether run by a member company or a third party organisation) then this information is not directly reportable (although the $120 limit per meal applies).

[22] See section 9.4.3 of the Code.
[23] See section 41.3.5 of the Code.

41. From 1 October 2015, transparency data will be produced by each member company in the following reports:

    - HCP Aggregate Transfer of Value Report – a new report, containing details of individual transfers of value to healthcare professionals. A template will be provided in the Code Guidelines.
    - Sponsorship of Third Party Educational Meetings and Symposia – based on the existing 'Summary of Events Sponsored by Member Companies' report
    - Summary of Health Consumer Organisation Support by Member Companies –report retained from the existing reporting regime.

42. The Code requires each member company to publish the HCP Aggregate Transfer of Value Reports on its own website (with hyperlinks available on the Medicines Australia website) for two years from the date of first publication.[24] The most senior executive officer of the member company must verify the report. The initial HCP Aggregate Transfer of Value Reports covering the period 1 October 2015 to 30 April 2016 must be published no later than 31 August 2016 and every six months thereafter.

43. The Third Party Educational Meetings and Symposia report (using the template in the Code Guidelines) and the Summary of Health Consumer Organisation Support by Member Companies report will be published on the Medicines Australia website. The Sponsorship of Third Party Educational Meetings and Symposia reports must be provided to Medicines Australia within four months for each six month period ending on 30 April and 31 October (the first report will be for 1 October 2015 to 30 April 2016). The Summary of Health Consumer Organisation Support by Member Companies reports must be provided to Medicines Australia on an annual basis by 30 April each year. Medicines Australia will publish these reports within two months of the date on which reports must be submitted.

44. Medicines Australia advises that it and its member companies are actively investigating the establishment of a central platform for future disclosure of individual transfers of value. Medicines Australia notes that there are outstanding issues to consider (outlined at paragraph 171).

Informed consent

45. As noted above, edition 18 obliges member companies to report all relevant transfers of value to healthcare professionals; however section 41.3.2 of the Code requires that member companies establish a means to ensure informed consent and maintenance of records which comply with Australian privacy legislation.

46. Medicines Australia explains that this means that member companies cannot report individual transfers of value made to healthcare professionals, where the healthcare professional has not consented to disclosure of the transfer. In these circumstances, these transfers will be reported in aggregate by each member company, along with the number of recipients, but without details of the healthcare professionals to whom they were made.

[24] See section 41.3 of the Code.

47. Medicines Australia submits that these provisions of the Code reflect the need for its members to comply with Australian privacy legislation in relation to the reporting of individual healthcare professional personal information.

Consultation on transparency

48. In August 2012, Medicines Australia established the TWG (following submissions concerning edition 17 of the Code). The TWG's aim was to identify measures and policies to further enhance transparency surrounding transfers of value between healthcare professionals and the pharmaceutical industry.

49. The TWG participants were drawn from a cross-section of the Australian health sector, which included member companies and a diverse range of health professional and consumer groups.

50. In June 2013, the TWG released a model for introducing greater transparency, which is outlined in its Transparency Model Consultation and Discussion Paper to aid discussion and facilitate submissions on the transparency provisions to be included in edition 18 of the Code (it should be noted that there was not consensus on all of the recommendations in the TWG's model).

51. Medicines Australia submits that it undertook substantial engagement with member companies, the health sector and the broader community in developing the proposed transparency model in the Code (including inviting submissions to the Code Review from 250 stakeholders, issuing a media release concerning the review, consumer workshops, stakeholder forums and meetings). In addition, for the first time representatives from the consumer and healthcare professional sectors were members of Medicines Australia's Code Review Panel. Medicines Australia submits that it received over 80 submissions and met with a number of relevant parties, and 39 people attended the consumer workshops.

52. Medicines Australia in consultation with its Code Review Committee revised the transparency reporting (as summarised above). These changes (along with other changes from edition 17 to edition 18 of the Code) were adopted by Medicines Australia's members on 17 June 2014.

53. The transparency regime proposed by Medicines Australia is broadly consistent with the proposal of the TWG in its Consultation and Discussion Paper insofar as it provides for the individual disclosure of benefits provided by member companies to healthcare professionals. However, some proposals of the TWG have not been directly adopted in the transparency model proposed by Medicines Australia. For example the TWG proposed:

    - the new regime commence on 1 January 2015
    - reporting of all transfers of value above a certain threshold (e.g. $25, or $10 if the total transfers to the healthcare professional in that calendar year exceeds $100)
    - continued reporting of food and beverage costs
    - inclusion of all travel costs in travel and accommodation reporting (such as taxis, parking and ground transfer costs, in addition to flights).

54. The TWG did not comment on whether healthcare professionals should have the option to receive a transfer of value without it being individually reported. This may be because it assumed that any reporting regime would be universal.

55. The TWG did not agree on whether other educational function costs (such as audio-visual and room hire costs) should be allocated as a transfer of value to healthcare professionals.

Transparency reporting in other jurisdictions

European Federation of Pharmaceutical Industries and Associations model

56. Medicines Australia submits that its transparency model adopts a similar approach to that of the European Federation of Pharmaceutical Industries and Associations (EFPIA)[25] Disclosure Code.[26]

57. The EFPIA Disclosure Code is an activity based model where transfers of value provided by its member companies to healthcare organisations and professionals are recorded and categorised by activity. The EFPIA reporting focuses on significant transactions such as donations and grants (healthcare organisations only), payments for consultancies, and contributions to costs related to events (excluding meals and drinks[27]).

58. All EFPIA member companies are required to incorporate the EFPIA Disclosure Code into their national codes in full. Where a provision of the EFPIA Disclosure Code conflicts with applicable national laws or regulations, deviations are allowed, but only to the extent necessary to comply with the national law or regulation.

59. The databases for reporting transfers of value will operate at a national level with each EFPIA member company able to decide how to present its transfer of value data. The first reporting period under the EFPIA Disclosure Code will be the 2015 calendar year, with the first reports released in 2016.

60. The EFPIA Disclosure Code stipulates that the disclosure of transfers of value by each member company shall be on an individual basis, subject to 'legal reasons', in which case amounts shall be disclosed on an aggregate basis.[28] In particular, Member Companies must comply with applicable data protection and other laws, which must be checked at a national level by

[25] EFPIA brings together 33 European national pharmaceutical industry associations, as well as 40 leading companies undertaking research, development and the manufacture in Europe of medicinal products for human use, **http://www.efpia.eu/about-us/who-we-are**. Accessed 16 October 2014.
[26] EFPIA HCP Code 2014 on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations, available at: **http://transparency.efpia.eu/uploads/Modules/Documents/efpia-disclosure-code-2014.pdf**.
[27] The provision of meals and drinks to healthcare professionals is governed by section 10.5 of the EFPIA HCP Code 2014, which states the value of food and beverages provided to healthcare professionals at events must not exceed the monetary threshold set by the relevant Member Association in its national code. See the EFPIA HCP Code, available at: **http://transparency.efpia.eu/uploads/Modules/Documents/efpia-hcp-code-2014.pdf**.
[28] See sections 3.01 and 3.02 of the EFPIA HCP Code 2014.

EFPIA members prior to any disclosure. Companies are encouraged to obtain consent from healthcare professionals.[29]

USA Sunshine Act

61. Some members of the TWG considered that the Sunshine Act (Section 6002 of the *Patient Protection and Affordable Care Act* (Public Law No. 111-148))[30] provides a better model of transparency. The Sunshine Act requires pharmaceutical and medical device manufacturers to report payments and transfers of value given to physicians and teaching hospitals.[31] Certain payments and transfers of value are exempt from reporting, such as: payments for speakers and faculty at certain accredited continuing medical education events; food and beverage provided to attendees of a large scale conference or meeting if the cost of each individual covered recipient's meal is not separately identifiable; product samples not intended to be sold and intended for use by patients; educational materials for use by or with patients; payments or transfers of less than $10 in value, unless they exceed $100 per year for an individual professional.[32]

62. Manufacturers of pharmaceutical and medical devices are required to report to the Centers for Medicare & Medicaid Services (CMS) (the agency responsible for implementing the Sunshine Act) identifying information about the physician to whom the payment was made, including their name, business address, specialty, National Provider Identifier number and license number, the nature and amount of the payment or transfer, and any explanatory details. Where applicable, the name of the manufacturer's product related to the payment or transfer will also be reported. The Sunshine Act requires data collection by manufacturers as of August 2013, with the first public report to be released on 30 September 2014.

63. Before the data is released publicly the Sunshine Act allows a 45 day period to review and dispute the data. Following technical issues with the online transparency reporting database in August 2014, CMS extended the dates for physicians and teaching hospitals to review the data for accuracy to 8 September 2014.[33] Because of the issues, the American Medical Association and other physician organisations called for the public release of data to be delayed by six months until 31 March 2015 in order to allow more time for doctor to register and review data.[34]

64. On 30 September 2014, CMS released the data from the last five months of 2013 on its Open Payments database. The data contains 4.4 million

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[29] EFPIA website, *10 facts for healthcare practitioners*, **http://transparency.efpia.eu/uploads/Modules/Documents/efpia_code_flyer_facts_v2.pdf**. Accessed 16 October 2014.
[30] The Sunshine Act was passed as part of the Patient Protection and Affordable Care Act (health care reform) in 2010.
[31] The categories of transfer of value are: consulting fees; compensation for services other than consulting; honoraria; entertainment; meals; travel expenses; education; research; charitable contributions; royalty or licence; current or prospective ownership or investment interest; direct compensation for serving as faculty; as a speaker for a medical education program; grants.
[32] These amounts are increased annually by CPI from 2012.
[33] CMS, *Open Payments System Reopens, Extends Physician Registration and Review Period*, media release, 15 August 2014.
[34] See: **http://freepdfhosting.com/aad0b68522.pdf**.

payments valued at nearly US$3.5 billion attributable to 546,000 individual physicians and almost 1,360 teaching hospitals. Future reports will be published annually and will include a full 12 months of payment data, beginning in June 2015.[35]

65. In the recently released data about 40 percent of the records published are de-identified. In cases where CMS was unable to match the physician information or the record was not available for review and dispute but the company had attested that the payment had been made, the personally-identifiable information has been suppressed temporarily in the record. CMS states this data will be fully identifiable in 2015 after the corrected data has been resubmitted and reviewed. Data that was disputed and not resolved by the end of the review period have not yet been published.[36]

Submissions received by the ACCC

66. The ACCC tests the claims made by the applicant in support of an application for authorisation through an open and transparent public consultation process. To this end the ACCC aims to consult extensively with interested parties that may be affected by the proposed conduct to provide them with the opportunity to comment on the application.

67. The views of Medicines Australia and interested parties are summarised below**.**

Medicines Australia

68. Broadly, Medicines Australia submits that edition 18 of the Code will, like edition 17, provide the benefits of a strong, voluntary industry code. The significant amendments made in edition 18 of the Code will make it an even stronger vehicle for providing greater transparency regarding the industry and greater stakeholder confidence in the industry. Medicines Australia also notes that the number of complaints received by its Code Committee has been progressively decreasing. Medicines Australia submits that the effect of edition 18 is to enhance greatly the existing public benefits that flow from the Code and result in minimal public detriment.

69. Medicines Australia submits that edition 18 of the Code incorporates new amendments to transparency reporting that focus on key interactions between member companies and individual healthcare professionals and facilitate greater disclosure. The amendments aim to maintain community confidence in the value of interactions between member companies and healthcare professionals.

70. Medicines Australia submits that the other amendments to the Code also strengthen the public benefits of the Code. For example, amendments to sections of the Code relating to advertising to the general public, standards for medical and promotional claims, relationships between pharmaceutical

[35] CMS, *CMS makes first wave of drug & device company payments to teaching hospitals and physicians public, media release*, 30 September 2014.
[36] CMS, *CMS makes first wave of drug & device company payments to teaching hospitals and physicians public, media release*, 30 September 2014.

companies and third parties and healthcare professionals, and monitoring and complaints.

Interested parties

71. The ACCC invited submissions from over 200 interested parties potentially affected by the applications for re-authorisation. The ACCC has received submissions from 50 interested parties, including pharmaceutical companies,[37] industry associations,[38] Government departments,[39] and other groups.[40] The ACCC also received a number of submissions from individuals,[41] including separate submissions from 25 individuals[42] (referred to throughout this submission as 25 Individuals) which were based on a common petition.

72. One of the key issues raised in submissions is the new transparency regime introduced in edition 18 of the Code. In principle, most interested parties are supportive of individual disclosure of transfers of value to healthcare professionals.

73. MSD, GSK, Pfizer, Therapeutic Guidelines Limited and the AMA support the revisions to the Code and reauthorisation, particularly the changes to transparency reporting.

74. A number of submissions consider that Medicines Australia's proposed model will not provide the level of transparency anticipated (and is not consistent with the TWG's recommendations) and thus will not increase the public benefits of the Code. Of particular concern is that healthcare professionals can withhold their consent to publish their information.

75. CHOICE, the CHF, Cancer Voices, the RACGP, Dr Harvey, Mr Kirwood, Professor Morris, Professor Haines and 25 Individuals do not support authorisation on the basis that the changes to the transparency reporting are flawed.

76. A number of interested parties suggest further changes to enhance the transparency regime.[43] For example, expanding the transparency reporting to include various other transfers of value (for example research and development, Patient Support Programs, hospitality, venue costs, transfers not related to prescription pharmaceuticals, and transfers to medical

[37] Merck Sharp & Dohme (Australia) Pty Limited; GlaxoSmithKline Australia Pty Ltd; Pfizer.
[38] Royal Australian and New Zealand College of Psychiatrists; Pharmacy Guild of Australia; Australian Primary Health Care Nurses Association; Society of Hospital Pharmacists of Australia; Australian Society of Anaesthetists; Royal Australian College of General Practitioners; Pharmaceutical Society of Australia Ltd; Australian Medical Association.
[39] Department of Health; South Australian Medicines Advisory Committee.
[40] CHOICE; Consumer Health Forum; Cancer Voices Australia; Therapeutic Guidelines Limited.
[41] Dr Ken Harvey; Geoff Kirwood; Professor Philip Morris; Professor Ian Haines; Shane Carney ; Alison Marcus; Dr Geoff Smith; Dr Rob McEvoy.
[42] Dr Stuart Anderson; Professor Jon Jureidini; Ms Kerry Holmes; Mr Robin M G Brown; Mr Peter J Bayly; Professor Joel Lexchin; Mr John T D Wood; Ms Margot Murphy; Mr Dan Kent; Dr Mary Osborn; Mr John Braithwaite; Mr Ross Gubbels; Mr Peter Sainsbury; Mr Sean Israel; Ms Roseanne Peel; Professor Alistair MacLennan; Professor Marcello Costa; Mr Jarrod McMaugh; Dr Tim Woodruff; Dr Elissa Campbell; Professor Peter Schönhöfer; Associate Professor Barbara Mintzes; Dr Robert Purssey; Dr Agnes Vitry; Ms Nikita Kotlarov.
[43] RANZCP; the Guild; SAMAC; APNA; SHPA; ASA; Department of Health; and PSA.

practices) and that the drug name should be reported. A number of parties also consider there should be an accessible centralised database for reporting.

77. Other key issues raised by interested parties were in relation to Patient Support Programs, PFPs/starter packs, membership of the Monitoring Committee, promotional materials, market research, ghost writing, clinical trials/scientific research, sanctions under the Code and coverage of healthcare organisations/employer organisations under the Code.

78. Interested parties also note that there are a number of pharmaceutical companies (as well as Australian health professional organisations) that are not subject to the Code and associated transparency reporting.

79. The views of Medicines Australia and interested parties are considered in detail in the evaluation chapter of this draft determination. Copies of public submissions may be obtained from the ACCC's website **www.accc.gov.au/authorisationsregister.**

ACCC evaluation

80. The ACCC's evaluation of edition 18 of the Code is in accordance with the relevant net public benefit tests[44] contained in the Act. While there is some variation in the language of the tests, in broad terms, the ACCC is required to identify and assess the likely public benefits and detriments, including those constituted by any lessening of competition and weigh the two.

81. In broad terms, the ACCC may grant authorisation if it is satisfied that the benefit to the public would outweigh the public detriments.

The future with and without

82. To assist in its assessment of the conduct against the authorisation tests the ACCC compares the likely future with the conduct that is the subject of the authorisation to the likely future without the conduct that is the subject of the authorisation. The ACCC will compare the public benefits and detriments likely to arise in the future where the conduct occurs against the future in which the conduct does not occur.

83. Neither Medicines Australia nor any interested party commented on what the most appropriate likely future without would be.

84. The current authorisation of edition 17 of the Code expires on 11 January 2015. Upon expiry of the current authorisation, and in the absence of reauthorisation (or interim authorisation), neither edition 17 nor edition 18 of the Code will have statutory protection.

85. The ACCC considers that in the absence of statutory protection under the Act it is unlikely that Medicines Australia and its member companies would

[44] Subsections 90(6), 90(7), 90(5A) and 90(5B), 90(8) of the Act. The relevant tests are set out in Attachment A.

choose to enforce either edition 17 or edition 18 of the Code in their current form.

86. As such, the ACCC considers that the most likely future without the conduct that is the subject of the authorisation is that a modified version of the Code would operate. In circumstances in which it would not have statutory protection from legal action under the Act, Medicines Australia may decide not to include detailed provisions in that code dealing with such matters as:

    - regulating member relationships with healthcare professionals which impose limits and restrictions on the provision of information and promotional materials, educational meetings, research activities and the provision of benefits such as sponsorship and hospitality;

    - providing for disciplinary measures.

87. Relevant legislation would continue to apply. The Act and relevant state and territory fair trading legislation contain general consumer protection provisions (but these are not pharmaceutical specific) and the TG Act regulates the advertising and promotion of pharmaceutical products to the public.

88. As found by the Tribunal, absent the conduct that is the subject of the authorisation, the provision of benefits to healthcare professionals by pharmaceutical companies are likely to be less regulated. While a culture of restraint and sensitivity to public criticism may moderate the development of the practice of conferring benefits to healthcare professionals, there is a real chance that, absent any mechanism for their limitation (and scrutiny), some companies (and doctors) would break out of that culture, and the conferring of benefits may take new and more subtle forms.[45]

The relevant area of competition

89. Medicines Australia submits that the relevant market is that for the supply of prescription medicines in Australia. No other party made submissions on the relevant area of competition likely to be affected by the Code.

90. The ACCC notes that the Code regulates the activities surrounding the promotion of prescription products on an industry-wide basis across all classes of prescription medicines. The ACCC recognises that not all prescription medicines are substitutable for one another and considers that there are likely to be individual product markets for different types and/or classes of drugs. However, the ACCC does not consider that a precise definition of the market is necessary for the assessment of the Code.

[45] Re *Medicines Australia Inc [2007] ACompT* 4, at paragraph 314.

Supply of prescription medicines – market failures

91. The ACCC recognises that the supply of prescription medicines is subject to 'market failures' which are common to many parts of the health sector:

    - The principal agent problem – the patient (principal) engages a healthcare professional (agent) because the patient does not have the expert knowledge required to diagnose and treat their condition. To the extent that the objectives of the patient and the healthcare professional differ (including as a result of a conflict of interest), market failure may occur because the patient is unable to properly observe the healthcare professional's objectives or evaluate their actions owing to the information asymmetry between them.

    - Information asymmetry – exists in markets where one party in a transaction knows a material fact that the other does not. Given the complexity of the products, Medicines Australia's members may have the ability and incentive to take advantage of their greater information advantage over patients and healthcare professionals.

    - Behavioural bias and conflict of interest – healthcare professionals like other consumers, are prone to biases that may be exploited by sellers of goods and services. These include excessive risk aversion and placing greater weight (consciously or subconsciously) on options that are easy to understand or presented in a manner that is 'educational' rather than promotional. Medicines Australia members may have the ability and incentive to exploit the behavioural biases of healthcare professionals and in turn influence their decisions in terms of the treatment recommended and the particular drugs prescribed. In particular, there are concerns that where healthcare professionals are receiving transfers of value from pharmaceutical companies, their professional judgement or actions may be affected or compromised in choosing a treatment for a patient.

    - Bounded rationality – some healthcare professionals and patients may lack the training and capacity to understand all the relevant information held by pharmaceutical companies. Even those healthcare professionals with relevant training may be time poor and unable to process the relevant information comprehensively and may rely on information provided by pharmaceutical companies. Given the complex nature of the relevant products, Medicines Australia's members may have the incentive and ability to engage in various practices that exploit the bounded rationality of patients, healthcare professionals and other third parties.

92. The ACCC notes that the following matters are also relevant to the supply of prescription medicines:

    - the PBS regulates the price paid by the public for most prescription medicines

    - advertising of prescription medicines to members of the public is prohibited by law

- the sale of prescription medicines is dependent upon the decisions of medical practitioners about which medicines they prescribe. Members of the public cannot purchase prescription medicines unless they have been prescribed by a healthcare professional and are reliant upon the healthcare professional's expertise and judgement to prescribe the medicine most appropriate to them

- aside from the TG Act (which primarily regulates advertising of prescription medicines to the public),there is no specific regulation under Commonwealth, state or territory law of the ways in which prescription medicines can be advertised and promoted to healthcare professionals.

Public benefit

93. Public benefit is not defined in the Act. However, the Tribunal has stated that the term should be given its widest possible meaning. In particular, it includes:

> …anything of value to the community generally, any contribution to the aims pursued by society including as one of its principle elements … the achievement of the economic goals of efficiency and progress.[46]

94. Medicines Australia submits that the Code provides significant benefits to the public. Medicines Australia notes the provisions of the Code:

    - effectively regulate interactions between member companies and healthcare professionals (noting the significant changes to the transparency reporting)
    - ensure high, consistent and industry-specific standards for medical and promotional claims
    - effectively protect the public from being exposed to inappropriate advertising
    - deal with interactions between member companies, patients and other third parties
    - require internal company training and compliance
    - cover the effective administration of the Code and the complaints process, and the proactive reviews of the Monitoring Committee.

95. Medicines Australia submits that it and its member companies are proud of their role in setting the standards for ethical conduct and transparency in Australia. Medicines Australia further submits that edition 18 of the Code achieves an appropriate balance between increased transparency regarding the industry and greater stakeholder confidence in the industry and a regime that is workable and effective because it has broad based support.

[46] *Re 7-Eleven Stores* (1994) ATPR 41-357 at 42,677. See also *Queensland Co-operative Milling Association Ltd* (1976) ATPR 40-012 at 17,242.

96. The ACCC's assessment of the likely public benefits from the provisions of the Code along with the key submissions of interested parties follows under the following headings:

    1) Standards for and disclosure of the relationships between pharmaceutical companies and healthcare professionals, including reporting transfers of value and standards for other interactions
    2) Relationships between pharmaceutical companies and health consumer organisations and patients
    3) Protection of the public from inappropriate advertising
    4) Standards for medical and promotional claims
    5) The requirement that pharmaceutical companies have an internal compliance procedure promoting compliance by all company employees
    6) Administration, monitoring and enforcement.

97. Consistent with the view of the Tribunal, the ACCC notes that it is not for the ACCC to construct and impose its ideal or preferred system of self-regulation.[47] However it may impose a condition to yield a more substantial public benefit or to enhance the likelihood that the public benefit will be realised. The ACCC's evaluation below is consistent with this approach.

1. Standards for and disclosure of the relationships between pharmaceutical companies and healthcare professionals

98. Medicines Australia submits that the Code continues to strictly limit the circumstances in which benefits may be provided to healthcare professionals in order to ensure there is no inappropriate influencing of healthcare professionals by member companies. Amendments in edition 18 include:

    - companies must have policies and procedures in place that will ensure that member companies adhere to existing and new Code requirements including the maximum cost of a meal;
    - a meal in Australia must not exceed $120 (plus GST and gratuities) per healthcare professional;
    - travel may only be provided if it is provided in direct association with the educational event and must be by the most practical direct route;
    - clarification that financial sponsorship of an independent educational event must be paid to the organisation arranging the event (not an individual healthcare professional);
    - the amount paid to an educational meeting organiser for a trade display must be reported in accordance with the new sponsorship of independent educational meetings report. [48]

99. The ACCC accepts that the relationship between healthcare professionals and pharmaceutical companies is an important one and that transfers of

[47] Re *Medicines Australia Inc [2007] ACompT* 4, at paragraph 134.
[48] Section 9 of the Code. In particular: section 9.3; sections 9.4.3, 9.7.7; sections 9.4.4, 9.7.5; section 9.5.1; section 9.6.5.

value made by companies to healthcare professionals in appropriate circumstances is legitimate.

100. However the ACCC considers that unrestricted relationships between pharmaceutical companies and healthcare professionals, particularly where there is some form of benefit provided to healthcare professionals, result in potential conflicts of interest and inappropriately influences prescribing practices. As noted by the Tribunal:

> …detriment lies in the effect that such conduct may have upon the prescribing practices of healthcare professionals directly influenced by it or by the views of professional opinion leaders who have links to particular companies. If the prescribing practices of healthcare professionals are influenced directly or indirectly by sympathies for particular products because of benefits derived from or links to the manufacturer or distributor of those products, patient care may be compromised. Patients in need of treatment will not necessarily be provided with that which is best for them. In an indirect sense there is also an anti-competitive detriment to the extent that key decisions in the relevant market may be affected by factors extraneous to the quality of the product and its cost.[49]

101. Accordingly, the ACCC sees public benefit in the continued regulation by the Code of the benefits which can be provided by member companies to healthcare professionals, and the circumstances in which they can be provided.

102. The ACCC also considers that there is a benefit in providing an appropriate dollar cap on hospitality provided by member companies (the ACCC has not reached a view on whether $120 per meal is an appropriate cap).

103. The reporting of transfers of value is considered below as well as setting the standard for other interactions with healthcare professionals such as promotional material, market research, Product Familiarisation Programs/starter packs, ghost writing, clinical trials and scientific research, and relationships with organisations.

Reporting requirements of pharmaceutical companies regarding their interactions with healthcare professionals

104. Medicines Australia has made significant changes to the transparency reporting under the Code which are due to commence on 1 October 2015 (a detailed summary is provided in the *Background* section above). Notably, under the new reporting regime in edition 18 of the Code:

- member companies must report transfers of value made to individual healthcare professionals (subject to the healthcare professional's consent), split up into 'registration', 'travel/accommodation' and 'fees';
- hospitality will no longer be reported (other than for third party run events) but, as noted above, is capped at $120 per meal, providing clarity and certainty regarding the scope of hospitality;
- event costs [such as event venue hire, transportation costs, materials provided to attendees, third party costs (such as event organiser) and audio visual costs] at company run events will no longer be reported;

[49] Re *Medicines Australia Inc [2007] ACompT* 4, at paragraph 315.

- reporting of third party run events is unchanged from edition 17 of the Code (other than that reporting is no longer required if the only cost is hospitality).

105. Medicines Australia submits that the interaction between pharmaceutical companies and healthcare professionals is important to the integrity of patient healthcare in Australia and it is essential that the community knows about it and appreciates its contribution.

106. Medicines Australia also emphasises the importance of transparency, noting in edition 18 that:

> Transparency reporting is a public benefit to provide visibility for consumers of payments and transfers of value to healthcare professionals who are engaged in patient care.

107. Medicines Australia submits that the amendments to transparency reporting in the Code:

- significantly strengthen and expand on the existing public benefits associated with the Code while ensuring that the public benefits associated with the interactions between member companies and healthcare professionals are not affected;
- in no way prohibit more stringent and comprehensive requirements being applied by individual companies;
- represent the growing community expectation identified by the ACCC in its authorisation of edition 17 of the Code that transfers of value to healthcare professionals be disclosed.

Interested parties

108. MSD, GSK, Pfizer, the AMA and Therapeutic Guidelines support the changes to the Code and/or reauthorisation, particularly the changes relating to transparency reporting:

- MSD and GSK consider that the changes to the Code are a significant shift towards greater transparency by the innovator pharmaceutical industry and are manageable and practical. GSK notes issues such as the the autonomy of healthcare professionals, privacy legislation, the importance of offering all healthcare professionals education and resource considerations.
- The AMA submits that the changes to the Code go further than those required by the ACCC in 2012 and represent a realistic and common-sense approach, noting that there is no evidence yet of the positive or negative impact of individual reporting on healthcare systems, healthcare professionals' decisions or patients.
- GSK submits that transparency will build on public understanding of the importance of educational events. GSK notes that it has been reporting since 2010 and is phasing out payments for speakers/conference attendees and incentives for direct sales representatives.
- Pfizer submits that educational events sponsored by the industry are valuable and that a healthy working relationship between the industry and healthcare professionals is in the best interests of patients.

109. The RANZCP, the Guild, the APNA, the SHPA, the ASA and the SAMAC support the transparency amendments in the Code in principle but suggest some changes. Further:

- The ASA notes the issues around transparency reporting and privacy, optional disclosure and the lack of a centralised database; however it notes that non-member companies have no reporting obligations.
- The APNA submits that the manner in which disclosure is managed should not infer bias or unfairly diminish the standing of healthcare professionals.

110. The PSA submits that the success of the Code should be closely monitored and refined as necessary.

111. A number of interested parties consider that the ACCC should not authorise edition 18 of the Code as it does not adequately achieve transparency:[50]

- The RACGP, Dr Harvey and CHOICE submit that the transparency in edition 18 of the Code is not an incremental improvement and its authorisation would result in public detriment.
- A number of parties suggest that the transparency regime fails to deliver on the key outcomes raised with Medicines Australia by interested parties and the TWG (including the TWG's principles, such as to give consumers well informed decisions, cover all transfers of value, report individually and utilise a central database) and that to claim broad support is flawed.[51]
- Professor Haines and the CHF submit that transparency of transfers of value to healthcare professionals is critical. Professor Haines submits that relevantly: there is a culture of entitlement amongst doctors; transfers of value affect how studies are designed and reported; key opinion leaders are influential; healthcare professionals are spending vast public money; and consumer safety must be considered.
- Ms Marcus considers that it is critical that regulators support transparency.

ACCC view

112. The ACCC accepts that there are benefits in appropriate reporting under the Code (noting that such reporting may not exist absent the Code) however the nature of that reporting should be guided by community expectations. The ACCC specifically emphasised this issue when it authorised edition 17 of the Code in 2012:[52]

> The ACCC remains of the view that there is merit in providing greater transparency around the sponsorship provided to healthcare professionals by pharmaceutical companies to attend educational events. The ACCC considers that there is growing community expectation that such payments will be disclosed, which is reflected in submissions received by the ACCC

[50] RACGP, CHOICE, CHF, Cancer Voices, Dr Harvey, Mr Kirwood, Professor Morris, Professor Haines, 25 Individuals.
[51] PSA, RACGP, SAMAC, CHOICE, Dr Harvey, Professor Morris, 25 Individuals.
[52] ACCC, *Determination on applications for authorisation lodged by Medicines Australia Limited in respect of Medicines Australia Code of Conduct edition 17*, 20 December 2012, p. 30.

and in developments such as the introduction of the US Physician Payment Sunshine Act.

…the ACCC considers that [the] benefits [resulting from reporting measures] may be undermined if the Code departs too widely from community expectations. The ACCC considers that the effectiveness of voluntary codes is enhanced when the standards incorporated are meeting identified objectives and current community expectations. The ACCC notes that the Code explicitly states that "therapeutic industry codes have as their primary objective the maintenance of the trust and confidence of, and accountability to, all communities with which they engage, the effectiveness of which is assessed through the eyes of the relevant community". [53]

…if the Code is not amended in a timely manner to reflect current community expectations, the public benefits from the Code could be undermined. Accordingly, the ACCC expects Medicines Australia to incorporate new provisions into the Code that will facilitate greater disclosure around sponsorship and fees paid to individual doctors prior to lodging any application for reauthorisation. In assessing any future application for authorisation of the Code, the ACCC will consider the extent to which the Code provides for disclosure of sponsorship and fees paid to individual doctors as part of its assessment of public benefits and detriments resulting from the Code. The ACCC also notes that the Tribunal has stated that where the relevant public benefits test under s90 is satisfied, the decision whether to authorise remains discretionary. [54]

113. The ACCC acknowledges that Medicines Australia has included new individual transparency reporting requirements in edition 18 of the Code. In principle, and insofar as they represent a move to individual reporting of benefits provided by member companies to healthcare professionals, these changes would seem to be significant and represent an improvement over edition 17.

114. However, the ACCC notes concerns raised by interested parties in relation to the following aspects of the new transparency regime:

a. that transfers of value can be made to healthcare professionals, but not reported, where the healthcare professional does not consent to reporting;

b. coverage of the regime and in particular, the reporting of hospitality; and

c. the reporting of the data, including the availability of a centralised database.

115. Each of these issues is addressed in more detail below.

a. Healthcare professionals' consent

Medicines Australia

116. Under the new reporting regime, individual transfers of value will only be reported if the healthcare professional consents to the disclosure. Medicines Australia is confident that a majority of healthcare professionals will consent voluntarily. Medicines Australia considers that it is inappropriate to make consent to disclosure a condition of receiving the transfer of value as, it says this will negatively impact patients and member companies.

[53] Medicines Australia Code edition 17, introduction, page 6.
[54] *Re Medicines Australia Inc [2007] ACompT 4* at paragraph 122.

117. Medicines Australia submits that its member companies must comply with Australian privacy legislation in relation to the reporting of individual healthcare professional personal information. In this regard, the Code requires member companies to establish a means to ensure informed consent and maintenance of records which comply with Australian privacy legislation. Where recipients of transfers of value cannot be identified for legal reasons (for example if a healthcare professional does not consent to have the relevant information published), these amounts must be reported in aggregate by each member company, along with the number of recipients. Member companies must also provide healthcare professionals at least six weeks to review and submit corrections to the information prior to publication.[55]

118. In deciding on this approach, Medicines Australia submits that it had regard to matters including the following:

- the application of Australian privacy legislation with respect to reporting a healthcare professional's personal information
- the purpose for which the information is collected in relation to Australian privacy law
- healthcare professionals retrospectively withdrawing consent to have their personal information published.

119. Medicines Australia sought the advice of the Australian Privacy Commissioner on the above issues on 8 April 2014. The Privacy Commissioner responded on 15 May 2014. With respect to the reporting of personal information relating to transfers of value made to individual healthcare professionals, the Privacy Commissioner advised that such reporting would be a secondary disclosure of the information and therefore that the information could only be disclosed if one of the following exceptions set out in Australian Privacy Principal 6 applied:

- the individual consents to disclosure; or
- 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 (for non-sensitive information).

120. The Privacy Commissioner also agreed with the view expressed by Medicines Australia that seeking consent would be 'best practice'.

121. Medicines Australia has considered the potential effect on the new transparency regime of healthcare professionals refusing consent for their personal information to be disclosed, acknowledging that 'it would undermine the underlying public interest that the transparency measure aims to address'. However Medicines Australia has reiterated its view that obtaining healthcare professional consent to this disclosure is best practice and submits that obtaining consent prior to disclosure is also important for the partnership between companies and healthcare professionals in improving transparency. Medicines Australia submits that if a transformation of this magnitude is to be achieved, the model adopted needs to be effective and have the support of stakeholders.

[55] See sections 41.3.1-41.3.3 of the Code.

122. Medicines Australia submits that it will, however, promote strongly to healthcare professional associations the benefits of the new transparency model and the Code more generally, and will continue to encourage healthcare professionals to consent to their information being disclosed.

123. In a recent survey, [56] Medicines Australia submits the majority of the 400 healthcare professionals surveyed (approximately 56%) stated it was likely they would consent to have information about them published in relation to transfers of value.[57] Medicines Australia is of the view that once the Code is authorised and is given time to become embedded in the industry, this number will increase exponentially as: healthcare professionals become familiar with the new regime; there is further education about the benefits of transparency; and the response of stakeholders to the publication is able to be assessed.

124. Medicines Australia submits that it is inappropriate for its members to 'boycott' those healthcare professionals who choose not to consent to disclosure. Medicines Australia submits that this would be contrary to the interests of public health because member companies would be prevented from facilitating medical education, which improves patient care and results in recognised public benefits, for particular healthcare professionals.

125. Furthermore, Medicines Australia submits that this would exacerbate the uneven playing field that exists between members of Medicines Australia and members of the GMiA. Medicines Australia considers that member companies could be further adversely affected by not being able to deal with individuals who do not give consent, particularly where this may include opinion leaders. This is unlike non-member companies who do not have to comply with such requirements.

Interested parties

126. Pfizer submits that increased transparency delivered by an industry code requires the support of healthcare professionals and peak bodies. Pfizer submits that transparency must be increased by reasonable and workable measures in order to maintain relationships, and there are a number of outstanding issues to be resolved through ongoing discussions.

127. The Department of Health supports requiring companies to report on transfers of value to individual healthcare professionals, pending the consent of the healthcare professional.

128. The AMA considers that it is unlikely that healthcare professionals who object to their information being disclosed will continue in such relationships with pharmaceutical companies.

129. A number of interested parties consider that healthcare professionals should not be able to accept transfers of value but choose not to consent to

[56] Medicines Australia commissioned a report from Cegedim Strategic Data, August 2014. Surveyed 400 healthcare professionals nationally regarding their attitudes to transparency reporting

[57] Although, the ACCC notes that some 30% of the healthcare professionals who participated in this survey (including 49% of the 200 participating General Practitioners) stated that they have never participated in collaboration with pharmaceutical companies.

their information being reported, since opting out of disclosure will mean that patients cannot access this information.[58] For example:

- the CHF submits that the transparency regime is undermined where practitioners have no commitment to ensure transparency and disclosure of these arrangements. Some of Medicines Australia's member companies already apply individual disclosure in countries such as the USA. Further, if a healthcare professional later withdraws consent, the individual should be required to repay the transfer of value;
- the RACGP, CHOICE and a number of individuals submit that the ability for healthcare professionals to opt out of disclosure defeats the purpose of the TWG proposal and is at odds with the submissions of interested parties more broadly;
- the PSA submits the fact that an individual may not consent to publication of their information is a barrier to the implementation of a comprehensive and detailed transparency model;
- the RACGP, Cancer Voices and Dr Harvey submit that the new model will not enhance transparency if consent is optional. CHOICE submits that as a result, edition 18 of the Code does not offer a tangible increase in public benefit compared to edition 17;
- The SHPA submits that the total cost for an attendee for an educational event or professional development activity should be advertised to invitees as part of the consent/acceptance process.

130. Professor Morris and Dr Harvey note concerns of Medicines Australia with compulsory disclosure, but submit the following:

- Professor Morris considers that Medicines Australia has not substantiated its concerns about the potential impact on public health and the uneven playing field in the industry. Further, these claims do not take into consideration the public benefits of disclosure that have been recognised by the ACCC in asking for these changes and by the Sunshine Act in the USA.
- Dr Harvey submits that there are sufficient non-industry controlled, independent, medical education opportunities to assist healthcare professionals (such as events run by the government funded National Prescribing Service).
- Professor Morris and Dr Harvey submit that there are opportunities for Medicines Australia companies to contribute grants to independent non-industry controlled medical education events to assist healthcare professionals with their continuing professional development. In this regard, Medicines Australia notes that its member companies regularly support educational events run by third party providers such as professional colleges.
- Dr Harvey submits that it is unlikely that imposing the transparency regime on member companies would provide any great advantage to generic companies. Generic manufacturers promote direct to pharmacists to encourage a consumer to accept the substitution of their specific generic brand. In contrast, Medicines Australia members

[58] RANZCP, SHPA, RACGP, CHOICE, CHF, Cancer Voices, Dr McEvoy, Dr Harvey, Professor Haines, Professor Morris, 25 Individuals.

promote to doctors in order to influence the drug prescribed. If an innovator brand is patent protected (and is the drug of choice) there is no competition from a generic manufacturer.

131. In response, Medicines Australia reiterated its previous submissions and, with respect to competition between its members and generic manufacturers, noted that the transparency regime also applies to interactions between member companies and pharmacists (not just doctors). Further, Medicines Australia submitted that at least 35% of medicines supplied under the PBS by volume are supplied by non-member companies, such as generic manufacturers, who compete with member companies.

ACCC view

132. The ACCC recognises that the introduction of a transparency regime requiring Medicines Australia's member companies to report on transfers of value provided to healthcare professionals on an individual basis is a significant and important change to the Code. The kinds of transfers subject to such reporting include those that have been identified by interested parties as being of greatest concern or value.

133. The ACCC notes that individual reporting has the potential to, at least partly, address the principal agent problem (and conflict of interest) by giving patients some transparency over a matter which may influence the objectives of, and treatment provided by, their prescribing healthcare professionals - being the extent to which those professionals have received transfers of value from pharmaceutical companies. Currently, patients have no way of acquiring such information. The ACCC considers that this reporting could also assist to maintain community confidence in the transactions between healthcare professionals and member companies.

134. 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 enables the patient to explore this further, should they so wish to do so. For example, a patient could search for the transfers of value received by their doctor and decide whether to raise this with their doctor, research the matter further or seek a second opinion. Such information could also be highly relevant to a patient's choice of healthcare professional in the first place.

135. This information could also be used by 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. Secondly and relatedly, it would deter member companies from making, and healthcare professionals from accepting, transfers of value which are inappropriate or which may raise conflicts of interest, if these transfers are subject to public scrutiny.

136. However the ACCC considers that in order for the individual transparency regime to be effective, <u>all</u> transfers of value must be reported.

137. The approach adopted by Medicines Australia in edition 18 means that individual reporting will only occur if a healthcare professional who has received a transfer of value explicitly consents ('opts in') to their information being reported individually. Therefore member companies will be able to

continue making transfers of value to healthcare professionals, without the transfers being individually reported.

138. It is difficult to envisage that all healthcare professionals will consent to disclosure. According to Medicines Australia's recent survey results, over 40% of healthcare professionals were unlikely to provide consent.[59]

139. Healthcare professionals' attitudes may also change once faced with the option to withhold consent, particularly if they are aware that their peers will not be 'opting in'. If a significant proportion of healthcare professionals do not consent to disclosure then it is hard to see that the new transparency regime offers any improvement over the existing transparency reporting.

140. Even if most (but not all) transfers of value are individually reported, without knowing what has not been reported, it will be difficult to use or rely upon the information that has been reported. For example, it will be difficult (if not impossible) for a patient to understand the significance or relevance of transfers made to a healthcare professional where it is not possible for the patient to ascertain:

- whether that is the full extent of transfers made to that practitioner (given that it is open to a healthcare practitioner to consent to the disclosure of some transfers of value but not others);
- the nature or extent of transfers made to other practitioners.

141. This results in a disclosure regime that cannot be relied upon as a means to disclose all potential conflicts of interest, which fundamentally undermines the transparency objectives of the regime and significantly compromises the potential benefits of an otherwise appropriate regime.

142. The ACCC agrees that any transparency regime should have regard to the requirements of Australian privacy legislation. However, the ACCC does not agree that this necessarily compromises the universality of the reporting regime. The ACCC considers that, rather than allowing companies to make transfers of value but not report them, where consent to disclosure is not given (as proposed by Medicines Australia), the only transfers of value which should be made are those which will be able to be reported. In effect, this means that member companies should only make transfers of value to healthcare professionals where, prior to accepting the transfer, the healthcare professional is made aware that their information will be disclosed for transparency purposes and/or consents to the disclosure.

143. The ACCC notes that Medicines Australia considers it is best practice to obtain consent to disclosure in this situation, and has no objection to Medicines Australia recommending that companies do so prior to making a transfer of value. (The ACCC expects that in any event once a universal transparency regime is introduced, an industry-wide expectation of individual reporting of transfers of value will quickly be established).

144. The ACCC acknowledges Medicines Australia's concerns that withholding transfers of value to some healthcare professionals may negatively affect

[59] And, the ACCC notes that this figure is likely to be generous, given that, the survey was not limited to doctors who have ever 'collaborated' with pharmaceutical companies. As noted above, some 30% of respondents to the survey stated that they have never participated in collaboration with pharmaceutical companies.

patient care and the competitiveness of its members. However the ACCC does not think these concerns justify compromising the transparency regime. If member companies are concerned that healthcare professionals may choose not to attend educational events because of the associated transparency reporting, companies can offer events that do not require reporting (for example, where no transfers of value are provided). Further, healthcare professionals who have concerns with individual reporting could rely on their employer to fund or self-fund to attend third party education events, rather than relying on sponsorship by a member company.

145. Relevantly, some healthcare professional industry associations (such as the RACGP, the SHPA and the RANZCP) support the need for individual transparency, which suggests that their members do not share a concern about missing out on educational content.

146. Further, healthcare professionals could take comfort knowing that all transfers of value from member companies to all healthcare professionals will be reported (i.e. a requirement that all transfers of value to healthcare professionals be reported will ensure a 'level playing field' between healthcare practitioners in their dealings with member companies).

147. The ACCC also notes that Medicines Australia members represent a significant proportion of the market share of originator pharmaceutical companies in Australia, and that the generic pharmaceutical companies generally have a different business model to originator companies (based on substitution of bioequivalent medicines at the point of the pharmacist dispensing the drug). The ACCC is therefore not convinced that Medicines Australia's members' competitiveness would be significantly affected as a result of the introduction of a compulsory disclosure regime given that most of their competitors in the Australian originator medicines market are also members of Medicines Australia.

148. As discussed in paragraphs 310 and 321 below, the ACCC proposes to grant authorisation subject to a condition to address these concerns about the operation of the transparency regime, by amending the Code to provide that member companies must not make a transfer of value to a healthcare professional, unless they have either obtained the healthcare professional's consent to disclosure or have taken steps to give notice of the disclosure obligation so that the healthcare professional would reasonably expect the disclosure. In this way, member companies will be able to report all transfers made.

b. Coverage of transparency regime

149. Medicines Australia notes that the new transparency model is similar to that introduced in Europe by the EFPIA in that recording is by activity rather than amount spent. Medicines Australia submits that like the EFPIA model, the Code:

- sets a maximum for the transfers of value associated with meals and beverages. This ensures that any hospitality is appropriate and reduces the reporting burden for member companies
- captures specific transfers of value
- requires reporting on a regular basis.

150. As noted above, the EFPIA model also requires individual disclosure (subject to 'legal reasons', such as data protection and other laws, in which case amounts shall be disclosed in aggregate).

151. Medicines Australia submits that benefits of this model include:

- capturing significant transfers of value while avoiding low level hospitality
- capturing a range of interactions between member companies and healthcare professionals
- avoiding the complexity and administrative burden of capturing low level hospitality at the individual healthcare professional level.

152. Medicines Australia submits that the model meets the needs of Australian consumers. Medicines Australia gauged from the consumer workshops and other feedback that there was general support for an activity based approach on the grounds that the type of activity leading to the transfer of value (rather than the dollar value) might be a more reliable predictor of influence, and would be the simplest, quickest and most cost effective way to get a model up and running.

Interested parties

153. The AMA and Pfizer support following the EFPIA model for the reasons noted by Medicines Australia.

154. Dr Smith agrees that reporting of small payments will only serve to obscure the large payments.

155. The Guild supports the changes to reporting of hospitality.

156. However, other interested parties suggested a number of areas where the transparency reporting should be expanded:

- The Department of Health submits that any payments relating to Patient Support Programs should be included.
- The SHPA, the RACGP and Dr McEvoy are concerned that hospitality costs and venue costs will no longer be reported. As such, healthcare professionals could attend a function that is no longer required to be reported.
- The RANZCP, the ASA and Dr Smith submit that the funding of health professionals for the purpose of pharmaceutical research and development should be reported.
- Cancer Voices submits that reporting should include the drug name.
- The RACGP considers company representative visits, for example for hospitality costing $25 or more, or $100 annually (i.e. accumulation of all hospitality above $10) should be reported.
- Ms Marcus considers that all acceptances of gifts, in kind or otherwise, should be recorded.
- Cancer Voices submits that sponsorship or gifts given to, for example, small practices should be reported.

- The SHPA and the SAMAC consider that PFPs and starter packs should be included in the new individual transparency reporting.
- Professor Lexchin submits that transparency reporting should extend to product samples, trial loans of medical devices, and educational materials that are intended to be used by or with patients.
- The SHPA submits that the Code should include a new section on the relationship between pharmaceutical companies and healthcare/employer organisations which mirrors the section relating to the relationship with individual healthcare professionals.

157. Some interested parties also suggest introducing reporting thresholds, for example:

- The RACGP suggests that there should be cumulative thresholds for reporting (e.g. in respect of hospitality). Further the RACGP considers that the $120 per meal limit for hospitality is too high.
- The APNA suggests aggregate reporting of transfers of value and individual reporting only in relation to healthcare professionals who depart from the mean or median for the profession.
- The Guild suggests encouraging healthcare professionals to report but requiring mandatory reporting for amounts above a threshold (and aggregate reporting for smaller amounts). If there is a high proportion of individuals not consenting then there may be a case to make disclosure mandatory in future editions of the Code.

158. In its response to third party submissions, Medicines Australia reiterated its previous submissions and also submits that:

- most costs attributable to an individual will continue to be reported, other than meals and beverages;
- the TWG did not reach consensus on a model. Following the release of the TWG's findings, the EFPIA published an activities based code. Medicines Australia submits that it raised the EFPIA code as an alternative with its Code Review Panel and in consumer workshops in October 2013 (and in further consultation and in seeking submissions in April/May 2014). Medicines Australia considers that it consulted widely on the activity based model and made the TWG paper readily available;
- visits from pharmaceutical sales representatives are not reportable under either edition 17 or edition 18 of the Code where those visits are not educational events;
- although costs of running educational events are not reportable, member companies cannot circumvent the transparency principles. In particular, there are provisions in the Code which ensure that educational events are appropriate having regard to content, venue, and food and beverages (entertainment continues to be banned). Also, the content of third party meetings is to be determined independently of sponsorship by a member company;
- clinical research should not be included in the transparency reporting as: this funding is generally provided to institutions such as hospitals rather than individual healthcare professionals (who are usually paid a salary, for example by the public hospital system); funding payments generally cover all of the costs relating to the conduct of the clinical trial (not just

the researchers' remuneration); and often multiple healthcare professionals will work on a clinical study over time;

- relationships with medical practices (or healthcare/employer organisations) are adequately addressed in the Code. For example: requirements for financial support for medical practice activities; reporting of transfers to an individual that are ultimately made to another entity; reporting of sponsorship of independent events; and a company may only temporarily loan a piece of equipment to a medical practice; and
- the value associated with starter packs/PFPs should not be reportable with respect to individual healthcare professionals under the transparency reporting as these items go directly to the patient.[60]

ACCC view

159. The ACCC notes the submissions of interested parties that transparency reporting should be expanded to include various other transfers of value (for example research and development, Patient Support Programs, hospitality, venue costs, transfers not related to prescription pharmaceuticals, and transfers to medical practices) and that the drug name should be reported. The ACCC notes that in respect of hospitality and venue costs in particular, these are currently reported in the educational event reports on a per-event basis.

160. The ACCC notes that sponsorship of third party-run events will continue to be reported in the current educational event reporting format (noting however that if a company provides nothing directly other than food and beverages for an educational meeting then this is no longer reportable). Medicines Australia submits that around 50% of events reported currently involve sponsorship for a third party institution. The ACCC has taken the submissions of interested parties to be mainly in relation to company-run events.

161. The ACCC notes that meals and beverages could be of significant value to healthcare professionals and could thus result in a potential conflict of interest. As such, the ACCC considers that there is merit in including some form of continuing reporting of hospitality provided by member companies. Possible forms of a condition are outlined under *Conditions of authorisation* below.

The ACCC seeks comments from interested parties on this issue.

162. The ACCC notes that there is likely to be utility from reporting the name of the relevant medicine in the individual reporting, if applicable. However, the ACCC acknowledges that reporting the particular drug name may increase the complexity and cost of reporting. The ACCC does not currently have sufficient information to decide whether such a requirement is appropriate.

The ACCC seeks comments from interested parties on this issue.

[60] See the following sections of the Code: 41.3.1; 9.5.1; 9.10; 9.12; 9.11.4.

163. The ACCC is not proposing to require Medicines Australia to report on the remaining transfers of value raised by interested parties, noting that:

- although venue costs could be significant, they should not be directly attributable to individual healthcare professionals and as such are not captured by the individual disclosure regime. The ACCC also accepts that these costs are less likely to influence an individual healthcare professional's decisions relative to more direct transfers. The ACCC acknowledges however that this represents an overall loss of reporting from edition 17;
- there are other mechanisms to report on sponsorship of research and development by pharmaceutical companies (such as clinical trials registries). In light of these other mechanisms, the ACCC does not consider that it is a priority to include research and development in Medicines Australia's reporting at this time;
- transfers of value not related to prescription pharmaceuticals are not covered by Medicines Australia's Code more generally and thus are not reportable;
- existing clauses of the Code are adequate with regards to interactions between member companies and practices/other organisations. Also such transfers are not received by an individual healthcare professional;
- payments with regard to Patient Support Programs are not currently reported in the transparency reporting.

164. While the ACCC accepts that it is appropriate for edition 18 to focus on the transfers of value of most concern, the ACCC expects that Medicines Australia will expand the reporting requirements over time as appropriate. This should include reviewing the inclusion of the abovementioned transfers of value identified by interested parties.

c. Accessibility of reporting data

165. In relation to reauthorisation of edition 17 of the Code, interested parties raised concerns that the format of reporting data was not accessible/searchable.

166. With respect to edition 18 of the Code, interested parties have again raised concerns about the accessibility of the reporting data, including the use of a centralised database for reporting the new individual data.

167. The RANZCP, the PSA, CHOICE and Cancer Voices submit that there should be a centralised and easily accessible database. Dr McEvoy agrees that the data should be presented in a searchable database (such as Microsoft Excel).

168. The RANZCP submits that reports should be submitted by member companies to an independent body, rather than to Medicines Australia.

169. The SAMAC submits that the new reporting should be implemented sooner than October 2015. Further, the reporting tables should specify whether amounts include GST.

170. Cancer Voices submits that the current proposal sees delays of up to 10 months between receipt of the transfer of value by the healthcare professional and notification.

171. As noted previously, Medicines Australia submits that it and its member companies are actively investigating the establishment of a central platform for future disclosure. Medicines Australia submits that there are several outstanding issues to address in order to establish a central platform:

- A unique identifier is necessary in a central database to ensure all member companies are able to report consistently and thus enable the data to be consolidated.
- If a unique identifier can be used, a process needs to be formulated in order to ensure the identifier and associated fields (name and primary practice address) can then be matched with company data.
- If a unique identifier cannot be used, other options include using a third party provider to record the data of all member companies, or using an agreed naming convention.
- Transparency reporting requirements would only be finalised once the Code receives ACCC authorisation.
- A centralised database will need to be scoped, designed and built. Some of the issues that need to be addressed include: who will own the database and the information within it; who will fund the database; who will build the database; who will maintain the database; who will fund the operation of the database; how will privacy requirements be met by the party that is responsible for the database.
- Given the likely cost of establishing and maintaining such as database, it is important to ensure the database is designed to reflect the expectations of potential users.
- Member companies will need to revise their internal systems, interfaces and processes in order to collect and maintain the data in the form required for that database.

172. Medicines Australia submits that other reporting regimes internationally, such as the EFPIA model, do not require reporting on a centralised database in all cases. Medicines Australia notes the difficulties experienced in the USA in implementing reporting under the Sunshine Act which it considers demonstrates logistical, legal and technological challenges.

173. Medicines Australia submits that publishing two years of reporting is appropriate so as not to require member companies to facilitate ongoing access to multiple years' worth of data (at least until a centralised database is introduced).

174. Medicines Australia submits that since November 2012, published transparency reports are character readable. In addition, the transparency reports that will be published under the new transparency regime proposed in edition 18 of the Code will also be published in character readable PDF format.

ACCC view

175. The ACCC notes that the Tribunal considered that the reporting requirement provides an incentive to comply with the provisions of the Code relating to hospitality provided at educational events. The Tribunal noted that this incentive is best secured by a combination of internal review and evaluation of such benefits and their accessibility to public scrutiny.[61]

176. The ACCC considers the reporting requirements in the Code (in particular, the HCP Aggregate Transfer of Value Report and the Sponsorship of Third Party Educational Meetings and Symposia report) provide transparency around the provision of hospitality to healthcare professionals (and other parties) and serves as a disincentive for inappropriate behaviour. The ACCC notes that this could be further strengthened through the provision of data in more accessible formats (and in a centralised database). The ACCC continues to consider that character readable PDF is the absolute minimum format acceptable for electronic disclosure.

177. The ACCC agrees that the utility of individual reporting will be greater if consumers can easily search for transfers of value provided to a particular healthcare professional in the one database. In particular, the benefits from a consumer perspective of a more transparent regime depend, to a large degree, on their ability to access the information made available in a practical way. Data posted on a single, central, searchable site will make it easier for individual consumers to access and rely upon coherent and complete information. In contrast, data included in separate reports across multiple websites would require consumers to either already know which company's records are likely to be relevant or review all sites in order to obtain information about a particular healthcare professional.

178. The ACCC notes the practical implementation issues identified by Medicines Australia and that Medicines Australia is actively investigating establishment of a central platform for reporting. The ACCC strongly encourages Medicines Australia to dedicate appropriate resources to developing a centralised database and implement it as soon as possible.

    The ACCC would also welcome submissions on the practical issues and timing for implementing such a database.

179. Having discussed the reporting of transfers of value to healthcare professionals, the following sections deal with the standard for other interactions with healthcare professionals such as promotional material, market research, PFPs/starter packs, ghost writing, clinical trials and scientific research, and relationships with organisations.

Promotional material directed at healthcare professionals

180. Section 2 of the Code regulates the provision of promotional material to healthcare professionals. Medicines Australia submits two amendments have been made to this section to increase existing public benefits:

    - text that is given prominence in printed forms of promotional materials, such as PBS information, qualifying statements and referring the prescriber to review the Product Information, should now be similarly

[61] *Re Medicines Australia Inc [2007] ACompT 4* at paragraph 360.

prominent by text size and location in electronic and audio-visual media, and new media;

- as above, for e-journals and e-newsletters. [62]

181. The Department of Health suggests that provisions be expanded to:

- reflect a commitment to increasing the information publicly available on new medicines considered by the PBAC including making public the evidence used by the PBAC in considering applications and the reasons for recommendations on use and access
- remind companies that it is an offence under subsection 22(5) of the TG Act to advertise a therapeutic good for indications other than those entered in the ARTG for that good and that practitioners are required to comply with codes of professional conduct as issued by their registration boards
- clearly define and delineate the difference between 'educational material' and 'promotional material'.

182. Medicines Australia notes that it will include references to the TG Act and the codes of conduct published by healthcare professional bodies (although Medicines Australia does not regulate the conduct of healthcare professionals) in the updated Code Guidelines. Medicines Australia is participating in discussions with the Department of Health on how to improve the transparency of the PBAC processes, and under the Code member companies must provide copies of substantiating evidence for a claim to another party on request.

ACCC view

183. The ACCC recognises that Medicines Australia has made incremental improvements in section 2 of the Code and that there is a general public benefit in those provisions of the Code which regulate promotional material. The ACCC notes the submissions of the Department of Health and Medicines Australia's response but is not proposing to address the Department of Health's issues in the current authorisation process.

Market research with healthcare professionals

184. Section 12 of the Code has been extended to ensure that market research is not used as a means to promote an unapproved product or indication. Fees paid in relation to market research continue to be reportable where the healthcare professional providing information is known to the member company and will be included in the new transparency reporting.

185. The Department of Health suggests that Medicines Australia could expand the post-market surveillance section of the Code to connect post-market surveillance activities undertaken by companies with the post-market programs conducted by both the TGA as regulators and the PBAC.

[62] Section 2 of the Code, in particular, section 2.2 and section 2.4.1.

186. The Department of Health also notes that there is no statement outlining any expectation of compliance with the *National Statement on Ethical Conduct in Human Research* (National Statement).

187. Medicines Australia does not consider that it is possible for the Code to refer to every statement or guideline which governs the prescription medicines industry (the Department of Health has made this suggestion in relation to a number of sections of the Code).

ACCC view

188. The ACCC notes the Department of Health's suggestion regarding post-market surveillance activities. The ACCC considers that these issues are best addressed between Medicines Australia and the Department of Health directly, and is not proposing to address these matters in the current authorisation process.

Product Familiarisation Programs and starter packs

189. Medicines Australia defines a PFP as a program run by a pharmaceutical company with the aim of allowing the medical profession to evaluate and become familiar with the product following TGA registration and/or approval of new indications. Healthcare professionals enrol patients in a PFP who are then supplied with the product for a fixed period.

190. Section 7 of the Code regulates how product starter packs can be distributed and has been amended such that:

- healthcare professionals, but not their receptionist, must sign a request for starter packs. Further, companies must keep all records of the request, supply, return and disposal of starter packs for at least two years;
- a member company must allow sufficient space on the primary label for a dispensing label and supply pre-printed adhesive labels that comply with the Standard for the Uniform Scheduling of Medicines and Poisons.[63]

191. Section 8 of the Code regulates the use of PFPs by member companies to ensure PFPs continue to be conducted in a rigorous manner and are appropriately regulated and are facilitated in a practical manner for patients, healthcare professionals and member companies. Section 8 has been amended to:

- introduce additional requirements in relation to patient information documents supplied in association with PFPs. In particular, a patient must sign their consent that the PFP will be provided for a fixed period after which it may only be available under a private script;
- include that only starter packs that comply with the requirements of section 7 of the Code may be supplied free of charge to prescribers for these programs for use by a patient (however trade packs may now be supplied free of charge for a PFP) ;
- allow for aggregated data on a healthcare professional's experience with the PFP product to be collected without a formal protocol. A PFP may

[63] See in particular section 7.7 and section 8.8 of the Code.

also enable the collection of individual patient data under a formal protocol;

- include a new section which provides that on request companies must promptly accept the return of and appropriately dispose of their products supplied under a PFP.[64]

Interested parties

192. The CHF supports informed consent protocols around PFPs such as a signed section for a patient to provide consent.

193. The Department of Health supports requiring companies to supply labels to healthcare professionals with a product starter pack. The Department of Health suggests a number of further changes, including:

- the Code should include a clearer differentiation between starter packs and product samples
- strengthening the requirement for companies to advise patients that the future availability of a PFP medicine at a concessional rate is not guaranteed, and to reiterate this advice at all stages of the distribution/supply chain
- companies should have a protocol for systematic collection and analysis of patient safety data and the findings and analysis of data arising from a PFP should be made available on the company's website and to the TGA/Drug Utilisation Sub-Committee/PBAC
- further clarification of when the rationale for a PFP will be made available
- a reference to the National Statement.

194. The PSA and the SAMAC submit that the use of starter packs should be discouraged. Mr Carney, Ms Marcus and the SAMAC also have concerns with the use of PFPs, submitting that PFPs:

- should only be used when a drug has been considered by the PBAC and added to the PBS
- should guarantee continuity of supply until the patient is able to access the product through an alternative funding mechanism.

195. Medicines Australia submits that the Code already appropriately regulates the use of starter packs/PFPs (noting that without the Code there would be no regulation of PFPs/starter packs). However, Medicines Australia submits it will provide clearer differentiation between product starter packs and product samples in the Code Guidelines for edition 18.

196. Medicines Australia notes edition 18 incorporates several amendments which go toward addressing the Department of Health's concerns, for example with respect to the information provided to a patient about a PFP, requests for the rationale of a PFP and reporting adverse drug reactions under the TG Act.

[64] See in particular the following sections of the Code: section 8.11; section 8.7; section 8.9; section 8.4.

ACCC view

197. The ACCC notes the concerns of interested parties about the impacts of PFPs and starter packs. However, the ACCC accepts that PFPs and starter packs can benefit healthcare providers and patients if used appropriately. The ACCC accepts that there are some public benefits arising from the regulation of PFPs/starter packs under the Code.

198. Interested parties raised similar concerns with respect to edition 17 of the Code. At that time, the ACCC encouraged Medicines Australia to assess the use of PFPs during the next review of the provisions of the Code. The ACCC notes that Medicines Australia has made several improvements to the relevant section of the Code, and encourages Medicines Australia to continue to include PFPs (and starter packs) in future reviews of the Code.

Ghost writing

199. Section 11 of the Code has been amended to define a ghost writer as a writer who is not acknowledged in a publication, as distinct from professional medical writers who are acknowledged (ghost writing is not acceptable under the Code).

200. The Department of Health submits that to ensure transparency of authorship or contribution to a publication, companies should follow the principles described in, or the Code should make reference to, various position papers, statement and codes.[65]

201. Dr Mintzes submits that the Code has a 'weak standard' to prevent ghost writing and that the Code only addresses clinical trial publications.

202. In response, Medicines Australia reiterates that ghost writing (as defined above) is unacceptable under the Code and is not limited to clinical trial publications.

ACCC view

203. The ACCC considers that Medicines Australia's amendments to section 11 of the Code represent an improvement on edition 17 and a public benefit.

Clinical trials and scientific research

204. The Department of Health submits that with respect to research:

- the introduction and the Research section of the Code should include references to relevant codes and position papers;[66]

[65] These include:

- the IFPMA *Joint Position on the Publication of Clinical Trial Results in the Scientific Literature* (2010)
- the obligations on researchers and institutions relating to authorship that are set out in the *Australian Code for the Responsible Conduct of Research* (2007) and to the recommendations of the International Committee of Medical Journal Editors in *Defining the Role of Authors and Contributors*
- the National Statement on Ethical Conduct in Human Research.

[66] In particular: *National Statement on Ethical Conduct in Human Research*, 2007; IFPMA/EFPIA/ Pharmaceutical Research and Manufacturers of America/Japan Pharmaceutical

- the Code could encourage all researchers to ensure that an open access version of their publication is made available.

205. Medicines Australia submits that as the Code does not apply to researchers or research institutions the Code is not the appropriate vehicle to encourage researchers to publish results of their research. Medicines Australia submits that as the Code does not regulate clinical trials (the conduct of clinical trials is regulated by legislation) the Code is not the appropriate vehicle to deal with the conduct of clinical trials.

ACCC view

206. The ACCC notes Medicines Australia's response to the Department of Health's concerns and considers that these issues are best dealt with between the parties, and is not proposing to address these matters in the current authorisation process.

2. Relationships between pharmaceutical companies and health consumer organisations and patients

207. The Code regulates member companies' relationship with Health Consumer Organisations (HCOs) and patients, including sections in the Code regarding: relationships with HCOs; sponsorship of patients or representatives of HCOs to attend events; trade displays at conferences; Patient Support Programs; and member company access to dispensary data.

208. In this and/or previous authorisation processes interested parties have raised particular concerns regarding relationships with HCOs and the use of Patient Support Programs, which are discussed further below.

Health consumer organisations

209. Edition 18 of the Code continues to require member companies to provide Medicines Australia with information on the support provided to HCOs. The report must list the HCOs that receive support from the member and must also include: a description of the nature of the support; and the monetary value of financial support and of invoiced costs, or a description of non-monetary costs.

210. Medicines Australia does, and will continue to, make the reports publicly available on its website within two months of receiving the reports. Member companies must inform the HCOs that sponsorship will be publicly disclosed.

ACCC view

211. The ACCC considers that maintaining the existing reporting requirements ensures ongoing transparency. The ACCC considers this constitutes a public benefit.

Manufacturers Association *Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases* (2009); and *Joint Position on the Publication of Clinical Trial Results in the Scientific Literature* (2010) in relation to disclosure and publication.

Patient Support Programs

212. Medicines Australia submits that section 17 of the Code regulates Patient Support Programs and already ensures that patients receive direct disclosure about any payments made to healthcare professionals in association with such programs. Edition 18 of the Code has been amended to include an explicit requirement that suspected Adverse Drug Reactions noted during monitoring of a Patient Support Program must be reported to the TGA.

213. The Department of Health suggests further amendments to section 17 of the Code, namely to:

- clarify that 'the healthcare and wellbeing of patients must be the *only* objective of a Patient Support Program'
- better clarify what is encompassed by Patient Support Programs
- require that 'all information provided to patients must comply with Sections 13 and 17 of this code'
- specify that the Consumer Medicine Information provided to the patient must be the same version as published on the TGA website to ensure it is not promotional
- include a statement outlining an expectation of compliance with the National Statement.

214. The CHF suggests that the Code should include a clause prohibiting package inserts to promote Patient Support Programs, as package inserts should only contain the most important information needed by consumers to support quality use of medicines.

215. Medicines Australia notes that the introduction to the Code has been drafted to adopt the 'Guiding Principles' from the International Federation of Pharmaceutical Manufacturers & Associations' (IFPMAs) Code of Practice (2012). Medicines Australia submits the IFPMA Code sets out principles for the ethical standards expected of the medicines industry globally.

216. Further, Medicines Australia submits it has adopted several of the Department of Health's suggested amendments. For example, section 17 of edition 18 of the Code now provides that the 'health and wellbeing of patients must be **the** objective of a Patient Support Program', rather than the 'primary objective' as previously drafted. However, Medicines Australia submits it will consider including further detail on clarifying what is encompassed by Patient Support Programs in the Code Guidelines.

217. Medicines Australia also notes that Patient Support Programs must not be promotional and have been accepted by the TGA as a legitimate activity. Medicines Australia submits other sections of the Code are also relevant and ensure that promotion to the general public does not occur.[67] Medicines Australia considers these sections of the Code appropriately regulate the provision of such programs and that further amendment to the Code is not required.

[67] For example section 13 of the Code.

ACCC view

218. The ACCC previously noted that the Code recognises that Patient Support Programs may assist patients to understand their condition and better manage their health, or encourage adherence to the medicines they have been prescribed.

219. The ACCC accepts that the Code regulates the way in which Medicines Australia members operate Patient Support Programs, and encourages compliance with the legislative prohibitions on advertising to the public. The ACCC accepts that these constitute public benefits.

220. However, the ACCC considers that it is important that Medicines Australia members ensure that the boundaries between activities that aim to inform consumers and direct-to-consumer advertising do not become blurred. The ACCC acknowledges that Medicines Australia has made changes to section 17 of the Code and encourages Medicines Australia to continue to review this section of the Code as appropriate, perhaps in any future review of the Code.

3. Protection of public from inappropriate advertising

221. Medicines Australia submits that the Code contains an overarching general principle that pharmaceutical companies cannot promote prescription medicines to the general public.

222. Medicines Australia considers that section 13 of the Code as amended in edition 18 encourages compliance with the existing legislative provisions prohibiting the advertising of prescription medicines to the public, and ensures that the prohibitions and guidelines about inappropriate advertising in the section are clear and definitive. Medicines Australia submits that this strengthens the public benefits associated with these provisions of the Code.

223. Amendments to section 13 of the Code include:[68]

- requiring that all information provided by member companies to members of the general public must be current, accurate, balanced and not mislead, and statistics must be referenced
- requiring that educational material that can be accessed by the general public *must not* (rather than should not) focus on a particular product. Also, the linking of a disease education activity/website to a specific prescription product would breach the Code and therapeutic goods legislation
- introducing a new definition of patient aids
- clarifying what constitutes market research. Patients who have been prescribed a particular prescription medicine can now be asked market research questions as long this is not promotional.

[68] See in particular: section 13.1; sections 13.6, 13.8, 13.9; section 13.7; section 13.11.

224. The ACCC notes that the Department of Health has suggested a number of further amendments, in particular the Code should:

- remind companies that it is an offence under the TG Act to advertise to the public a therapeutic good that contains a substance included in the relevant schedules of the Poisons Standard
- include provisions that demonstrate Medicines Australia's commitment to open and unambiguous data and analysis, particularly relating to PBS expenditure, by crediting all sources
- specifying that branding of that patient aids should not be product branded, as this may breach the TG Act
- market research may constitute an activity for which the requirements of the National Statement apply
- incorporate the 'reasonable person' test in its *'Advertisement'* definition to be fully consistent with the TG Act.

225. In response, Medicines Australia reiterates that edition 18 of the Code requires that all public statements must be referenced to their source. In relation to patient aids, the Code provides that any item (including patient aids) that is used outside the home (i.e. where a member of the public could see the item) may not be product branded.

ACCC view

226. The ACCC has previously accepted that the Code encourages compliance with existing legislative prohibitions on advertising to the public and results in a public benefit. As noted by the Tribunal there are limits to legislation and the Code has a potentially wider coverage.[69] Further there are costs associated with the investigations and judicial processes involved in the enforcement of statutory regulation.

227. The ACCC considers that the provisions in edition 18 of the Code that protect the public from inappropriate advertising continue to give rise to a public benefit.

228. The ACCC notes that Medicines Australia has already addressed some of the suggestions from the Department of Health and the ACCC considers that any further discussions should be conducted between Medicines Australia and the Department of Health directly.

4. Standards for medical and promotional claims

229. Medicines Australia notes that the Code contains provisions that:

- require all promotional claims to be consistent with Product Information approved by the TGA;
- specify the content and layout of minimum Product Information and the circumstances in which each must be used; and

[69] *Re Medicines Australia Inc [2007] ACompT 4 at paragraph 342.*

- prohibit the use of abstracts and poster presentations as primary evidence to support a promotional claim and specifies the circumstances in which such information may be used as secondary evidence.

230. Three amendments have been made to section 1 of the Code relating to the nature and availability of information and claims made regarding member companies' products:[70]

- with regard to ensuring medical claims are balanced, 'companies must ensure that adequate safety information is included in relation to efficacy or other promotional claims.';
- with respect to false or misleading claims, data previously valid but made obsolete or false *must* (rather than should) not be cited;
- there is now a mechanism to make information available about unapproved products and/or indications via a medical information website, subject to certain guidelines;
- clarification that companies must not promote that a product will be listed on, for example, the PBS prior to receiving written advice from the Department of Health stating the listing date.

231. Section 3 of the Code addresses the Product Information which is included with promotional material for healthcare professionals. Amendments include:[71]

- an explicit requirement that the Minimum Product Information must be reviewed and updated in a timely manner following a change to the Product Information
- removing the specifications of the manner in which a change of clinical significance is communicated to healthcare professionals, and providing that companies must communicate a change to the Product Information in accordance with any direction from the TGA.

232. Medicines Australia submits that amendments included in edition 18 of the Code ensure that member companies can determine with ease, clarity and specificity how they may present their promotional claims. Medicines Australia submits that the Code ensures that healthcare professionals have up to date and accurate information in relation to medicines prescribed by them and that healthcare professionals always have access to detailed prescribing information about products, in a targeted way not done easily in legislation.

233. Medicines Australia submits that these amendments continue to ensure that a high, consistent and industry-specific standard for medical and promotional claims is sustained and results in further public benefits relative to edition 17.

Interested parties

234. The Department of Health supports permitting companies to make information (which is not promotional) about unapproved products and indications available through a public website, and requirements regarding

[70] See in particular: section 1.7; section 1.3; section 1.4; section 1.1.
[71] See in particular sections 3.2 and 3.3 of the Code.

currency of information to reflect a change in the TGA approved Product Information.

235. The Department of Health also submits that while the current Code refers to a general commitment to Quality Use of Medicines and rational prescribing, it is now timely to consider the inclusion of stand-alone provisions within the Code to address antimicrobials, and in particular, antibiotics. The Department of Health suggests that the Code ensure that companies provide accurate information to providers, dispensers, and the general public that stresses the importance of the judicious use of antimicrobials. Further, advertising and promotional material and Product Information relating to antimicrobial products should acknowledge that inappropriate prescribing and use may contribute to the emergence of antimicrobial resistance.

236. The CHF supports the strengthening of sections related to the promotion of unapproved products or indications. The CHF supports the additional requirements to ensure that adequate safety information is included in relation to efficacy or other promotional claims. The CHF also supports additional media requirements to cover electronic media such as smartphone applications, electronic tablets and other mobile devices and software.

237. The SHPA submits that if Product Information was available for all registered and listed medicines this would dramatically improve and support the appropriate advertising of therapeutic goods. The SHPA also has concerns regarding advertising via the internet, email, SMS and MMS.

238. In response, Medicines Australia notes that Product Information and Consumer Medicine Information are governed by the TG Act and the Code goes further than the legislation. Medicines Australia submits that the Code already covers electronic advertising. The Code and the TG Act prevent promotion to the general public, including via the internet, email, SMS and MMS.

ACCC view

239. As noted by Medicines Australia, the Tribunal previously found there was substantial public benefit in the provisions which set standards for medical and promotional claims.[72] The ACCC has previously agreed that medical practitioners might not always possess perfect information on the range of remedies available and may not have sufficient time to absorb the volume of scientific studies and research available on pharmaceutical products. As a result medical practitioners might rely heavily on information provided by pharmaceutical manufacturers and it is important this information is balanced and accurate.

240. While there are general legislative prohibitions on misleading and deceptive conduct, the ACCC notes that the standards in the Code are specific to pharmaceuticals and that their breach will trigger possible disciplinary action and sanctions under the Code. For these reasons, the ACCC considers that such provisions, as amended in edition 18, will continue to give rise to public benefits.

[72] *Re Medicines Australia Inc [2007] ACompT 4 at paragraph 342.*

241. The ACCC considers that the suggestion raised by the Department of Health that a section regarding antibiotics be included in the Code is best addressed between the Department of Health and Medicines Australia directly, and is not proposing to address these matters in the current authorisation process.

5. The requirement that pharmaceutical companies have an internal compliance procedure promoting compliance by all company employees

242. Medicines Australia submits that the Code provides stringent requirements in relation to member companies implementing internal training and compliance procedures to ensure staff are appropriately trained in relation to, and comply with, the Code.[73]

243. Medicines Australia notes that the Code imposes training and knowledge requirements on various industry participants. Company representatives are required to (a) possess sufficient medical and technical knowledge to present information on the company's products in a current, accurate and balanced manner and (b) to be cognisant of all provisions of the Code. Medical representatives are also required to undertake the endorsed Medicines Australia education program.

244. Anyone directly involved in the development, review and approval of promotional and educational materials for the general public or who has direct interaction with healthcare professionals regarding prescription products is required to complete the Code component of the education program and regular training on privacy and competition and consumer legislation.

245. These sections are not amended in edition 18 of the Code.

ACCC view

246. The ACCC agrees that imposing training and knowledge requirements on various industry participants is likely to assist in ensuring their interactions with the public, healthcare professionals and other parties are appropriate. The ACCC considers that an internal compliance program to ensure that company representatives are not only aware of the Code, but comply with the Code and maintain a level of professionalism in their dealings with healthcare professionals, will also result in a public benefit.

6. Administration, monitoring and enforcement

247. In its review of previous editions of the Code, the ACCC has noted that any public benefits associated with the substantive provisions of the Code will only arise to the extent that the Code is effective in its operation. In relation to edition 18 of the Code, interested parties have raised particular concerns about:

- the effectiveness and consistency of sanctions under the Code;

[73] See in particular sections 5, 6 and 39 of the Code.

- the absence of a full pharmacist member on the Monitoring Committee.

248. Medicines Australia submits that relevant revisions in edition 18 of the Code include:

- a new preamble in relation to Code administration
- clarifying the relationship between the Code and the Medicines Australia Constitution, and between the Medicines Australia Board and the Monitoring, Code of Conduct and Code of Conduct Appeals Committees
- providing a discretion for the acceptance of complaints where the issue is also the subject of legal proceedings between the relevant parties
- clarifying the membership of the committees
- amending the types of review undertaken by the Monitoring Committee in order to continue to ensure that that committee operates effectively.

249. The effectiveness of the Code is dealt with under the following headings:

- The effectiveness of the Committee and the code administration
- Complaints process
- Effectiveness of sanctions under the Code.

The effectiveness of the Committees and the code administration

250. Medicines Australia submits that it actively promotes understanding of the Code and seeks to reduce non-compliance. Relevantly, Medicines Australia submits that the Code provides for three committees and a Secretariat. In addition, Medicines Australia publishes written Code Guidelines, conducts other formal training and education sessions, and provides informal guidance on the operation of the Code.

251. The roles of the committees are:

- The Monitoring Committee – proactively monitors the promotional material and conduct of member companies, in order to promote compliance with the Code and therefore support the quality use of medicines (the Monitoring Committee is discussed further below).
- The Code Committee – supervises the administration of the Code and is accountable to the Medicines Australia Board; hears and determines complaints against member companies and non-members who agree to have a complaint adjudicated by the Code Committee; and is empowered to impose sanctions for breaching the Code.
- The Appeals Committee – hears appeals against findings and/or sanctions imposed by the Code Committee and is responsible to the Medicines Australia Board.

252. Edition 18 of the Code clarifies certain processes for these committees, such as the requirements for a properly constituted meeting, appointments, membership and attendance by observers and Secretariat.

253. The Department of Health considers that there could be further clarity around determining conflict of interest of members of the Committees.

254. Medicines Australia submits that it regularly engages in communication activities to raise awareness, promote understanding of the Code and encourage compliance; for example, by meeting with pharmaceutical companies, healthcare professional organisations, consumers, health consumer organisations and agencies, and businesses working with the industry. During the last financial year Medicines Australia staff participated in 34 communication activities with a total audience of 906 people.

255. Further, Medicines Australia submits that the Secretariat now provides regular monthly training webinars for any member company, non-member company or agency personnel, in addition to webinars on specific topics when required.

256. The Code Guidelines are also prepared to provide assistance to companies in complying with the Code. The Guidelines are regularly updated as issues arise or when requested and will be updated to reflect the new transparency requirements during the second half of 2014.

257. Medicines Australia submits that it responds to many requests for informal guidance and advice on the Code from member and non-member companies, healthcare professionals, consumer organisations, members of the public, the media and agencies working in the healthcare sector.

ACCC view

258. The ACCC has previously accepted that promotion of the Code by Medicines Australia through both formal and informal measures increases the effectiveness of the Code. The ACCC has not received any submissions which indicate that this has changed since the ACCC authorised edition 17 (or previous editions) of the Code.

259. The ACCC acknowledges that Medicines Australia has included a consumer representative and a healthcare professional representative, nominated by the CHF and the AMA respectively, on the Code Review Panel, consistent with its undertaking in 2012.

The Monitoring Committee

260. Edition 18 specifies that each financial year the Monitoring Committee conduct:

- a minimum of three reviews of promotional materials within one or more therapeutic classes;
- a minimum of three reviews of different activities across all therapeutic classes; and
- reviews of the educational meetings and symposia data provided by member companies.

261. Under edition 18, a member company will only be required to provide promotional materials or information on no more than three occasions during a calendar year.

262. Medicines Australia considers that these amendments ensure that the Monitoring Committee continues to undertake a detailed and effective

review of the activities of member companies while ensuring the scope of that review is not unduly burdensome.

263. Medicines Australia submits that in recent years the Monitoring Committee has seen an increased level of compliance with the Code by member companies. The activities of the Monitoring Committee in 2012/13 are shown below.

Figure 1: Summary of materials and activities reviewed by the Monitoring Committee in 2012/13 (source: Medicines Australia supporting submission)

Therapeutic Class	Types of material subject to review	Number of companies	Number of items	**Number of meetings to undertake review**
All therapeutic classes	Product specific media releases issued to healthcare professionals	10	15	1
Central Nervous System	Product Familiarisation Programs	1	8	1
All therapeutic classes	Continuing Education Program Audit	39	39	2
Infections and Infestations	Printed promotional material	8	45	1
All therapeutic classes	Starter packs	29	29	1
All therapeutic classes	Company Corporate Websites	40	42	1
All therapeutic classes	Market Research with healthcare professionals*			1
TOTAL		n/a	178	8

264. The Department of Health expects that, with respect to recent amendments to the Code, Medicines Australia's Monitoring Committee and Complaints Committee will take an active role in monitoring and responding to compliance issues and reporting unintended consequences.[74] In particular, the Department of Health refers to the changes regarding: websites for unapproved products/indications; requirements for minimum Product Information; product labels for starter packs; and the new transfer of value reporting.

265. The PSA submits that there should be the inclusion of a full pharmacist member on the Monitoring Committee.

266. In response, Medicines Australia submits that although the Monitoring Committee does not currently include a pharmacist as a full member, its membership is broad. Also, a representative of the Guild, the PSA or the SHP is eligible to be a full member of the Code Committee and Appeals Committee where a complaint relates to activities directed at a pharmacy.

[74] See in particular: section 41; sections 3.2 and 3.3; section 7.8; section 1.4.

ACCC view

267. The ACCC considers that the effectiveness of the Code relies on Medicines Australia becoming aware of any breaches. In particular, the activities of the Monitoring Committee should be sufficient to identify breaches. No submissions have been received to indicate that this is not the case.

268. The ACCC also notes the submission of the Department of Health that Medicines Australia's Monitoring Committee and Complaints Committee should monitor compliance with new requirements of the Code. The ACCC agrees with this sentiment. Any other measures that Medicines Australia takes to ensure that the Monitoring Committee effectively identifies breaches of the Code will further increase the chance of the benefits arising.

269. The ACCC notes the PSA's request for the inclusion of a full pharmacist member of the Monitoring Committee. The ACCC accepts Medicines Australia's submission that membership of this committee is broad and also notes that it may not always be possible to represent all interests on such committees.

Complaints process

270. Medicines Australia submits that its complaints process provides an appropriate forum for the adjudication of complaints, noting that the membership of the Appeals Committee is diverse and flexible and conflicts of interest are identified.

271. Amendments in edition 18 of the Code include:[75]

- where a complaint is also the subject of legal proceedings in an Australian court or Administrative Tribunal, Medicines Australia has the discretion to either not accept a complaint or delay referring it to the Code Committee;
- Medicines Australia has the discretion to not accept a complaint that has already been substantially dealt with by the Code Committee;
- guidelines for complainants including non-industry generated complaints. Also, the Secretariat will always offer the services of an independent facilitator to assist a non-industry complainant to identify relevant sections of the Code. This will reduce the potential burden on non-industry complainants by ensuring that they have access to assistance in formulating their complaints;
- additional clarity on the process for industry generated complaints by requiring a record of meeting to be submitted to Medicines Australia and the senior executive officer of the companies involved;

272. Medicines Australia submits that these provisions in the Code help ensure that the complaints process is effective for industry and non-industry complaints alike and that the public benefits associated with the process remain substantial.

273. Medicines Australia considers that its complaints process is accessible to complainants, as demonstrated by the variety of stakeholders who have

[75] See in particular section 20.1 and Appendix 1 to the Code.

lodged complaints. Between 2008/2009 and 2010/2013, 23% of complaints were from healthcare professionals, 5% from organisations, 33% from the Monitoring Committee, 32% from pharmaceutical companies and 7% from other stakeholders. Further, the complaint form is readily available from the Medicines Australia website and is easy to understand.

274. Medicines Australia notes that in 2012/2013, the average time to resolve a complaint was 34 working days (or 27 working days where the complaint was not subject to an appeal), down from 41 working days in 2009/2010.

275. Medicines Australia notes that any potential contraventions of the Code identified by the Monitoring Committee are referred to the Code Committee as a complaint. The table below lists the complaints received by the Code Committee from 2008/2009 to 2012/2013.

Figure 2: Complaints received by the Code Committee from 2008/09 to 2012/13 (source: Medicines Australia supporting submission)

Source/ Year	2008/09	2009/10	2010/11	2011/12	2012/13
Healthcare professionals	11	8	4	6	3
Organisations (e.g. TGA, College/Society, Consumer Organisations)	6	1	0	0	0
Other (general public and academics)	2	6	2	0	0
Monitoring Committee	26	14	2	2	3
Pharmaceutical Companies (member and non-member companies)	14	10	6	4	12
Total	59	39	14	12	18

276. Medicines Australia submits that the number of complaints received by the Code Committee has progressively decreased from 59 in 2008/09 to 18 in 2012/13. The number of complaints referred to the Code Committee by the Monitoring Committee has also decreased since 2008/09, despite the fact the Monitoring Committee continues to review a large number of promotional materials each year. Further, there have been no complaints in the last two financial years from organisations such as the TGA or healthcare professional societies and no complaints from members of the general public or academics. The largest number of complaints continues to come from pharmaceutical companies.

ACCC view

277. The ACCC accepts that, based on the data above, the number of complaints has generally been decreasing in the past five years.

278. The ACCC has previously expressed concerns, in authorising previous editions of the Code, that an onerous complaints process may decrease the effectiveness of the Code. Relevantly, the fact that there have been no complaints from members of the general public or academics in the past two financial years could either suggest that these individuals do not have

concerns, or it could indicate a reluctance to use the complaints process. However the ACCC has not received submissions from interested parties on this issue in the current reauthorisation process.

279. If in the future the complaint procedures were shown to be ineffective this would be of significant concern to the ACCC. In authorising edition 17 of the Code, the ACCC recommended that Medicines Australia should review its complaints procedures in future reviews of the provisions of the Code to ensure that they do not become overly onerous on complainants, and that procedural fairness is afforded to all complainants. The ACCC noted that the ability for the public to make complaints is an important feature of increasing the transparency around the relationship of the pharmaceutical industry with healthcare professionals.

280. The ACCC considers that clarification in edition 18 of the Code that a facilitator will always be offered to a non-industry complainant is a step in the right direction, as is ensuring that the complaints form is easy to understand and readily available on Medicines Australia's website. Medicines Australia should continue to consider further incremental improvements in future editions of the Code, as appropriate.

Effectiveness of sanctions under the Code

281. Medicines Australia submits that the power of the Code Committee to impose sanctions is a public benefit. The sanctions available are: modification or discontinuance of a practice; publishing corrective statements; and paying fines.

282. Medicines Australia notes that, as a general rule, moderate to severe breaches will require corrective action. Medicines Australia can also forward a complaint/appeal to the TGA or the ACCC if a subject company does not pay a fine within 30 days, and publicise the failure to comply.[76]

283. The maximum fine under the Code for severe or repeated breaches is up to $250,000, with a cumulative maximum of $300,000 per complaint. The maximum fines have not been amended in edition 18 of the Code.

284. Medicines Australia submits that the imposition of fines for breaches of the Code is the norm. Sanctions imposed in 2012/13 are summarised in the below graphs.[77]

[76] See sections 28.2 and 28.3

[77] More recently, from July 2013 to March 2014, the Code Committee found that six companies had contravened the Code and in each case a fine was imposed. The two largest fines were $250,000. This will be reported in the 2013-2014 Medicines Australia Code of Conduct Annual Report.

Figure 3: Sanctions imposed by the Code and Appeals Committees on companies with complaints found in breach and finalised in 2012-13 (source: Medicines Australia Code of Conduct Annual Report 2012-2013)

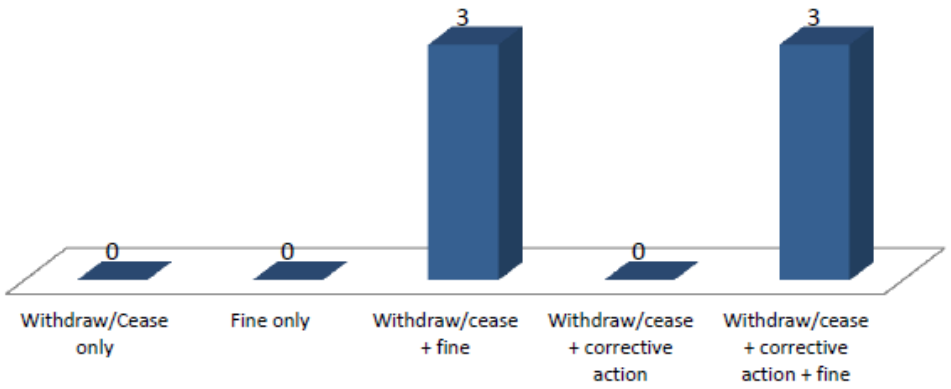

Figure 4: Fines imposed by the Code and Appeals Committees on companies with complaints found in breach and finalised in 2012-13 (source: Medicines Australia Code of Conduct Annual Report 2012-2013)

285. The CHF queries whether the level of financial penalties is sufficient, noting that penalties in other countries are substantially higher and that some companies continue to breach the Code (based on the Code of Conduct Annual Report 2013).

286. Medicines Australia does not consider that the quantum of fines/sanctions should be amended. Previously, Medicines Australia has pointed to the high level of fines under the Code compared to other codes (e.g. the GMiA Code of Practice) and noted that the Code allows for non-monetary penalties. Medicines Australia suggested these sanctions are taken seriously by member companies. Medicines Australia submits that the Monitoring Committee has seen an increased level of compliance with the Code by member companies in recent years, which demonstrates the effectiveness of existing sanctions.

287. Medicines Australia submits that it provides transparency in relation to outcomes of the complaints process by preparing quarterly reports, a Code of Conduct Annual Report, and in the case of complaints relating to an activity directed at the general public, publishes details on its website.

ACCC view

288. As in 2012, the ACCC notes that it is difficult to determine whether the existing level of fines is appropriate. It is clear that the low level of fines available under the Code would not be substantial enough by themselves to deter a profitable breach, given the low probability of a breach being detected and a fine being imposed. The ACCC would be concerned if it was provided with specific evidence of systemic breaches of the Code as this would undermine the effectiveness of the Code. To date the ACCC has not received any submissions which detail specific evidence of systemic breaches of the Code.

289. The ACCC notes that financial sanctions are part of a package of disciplinary measures. Further, under the Code, member companies are required to cease any activities that are deemed to breach the Code.

290. It is not clear whether the reduced number of complaints is directly related to the effectiveness of the monetary fines. However given the apparent level of compliance with the Code reported by Medicines Australia, the ACCC accepts that the monetary and non-monetary sanctions currently available under the Code (together) likely provide an effective deterrence against breaches of the Code by member companies. The potential for a legislative response by government if breaches were to become systemic is likely to deter companies from breaching the voluntary code. The potential for public criticism surrounding the imposition of a fine may also increase the effectiveness of the fine itself.

291. In order for public criticism to be an effective deterrent, decisions to impose a fine should be adequately publicised. For example, the ACCC queries whether important decisions should be circulated in the form of a media release, in addition to the existing reporting and web updates.

The ACCC seeks comments from interested parties on this issue.

292. The ACCC accepts that the fines must be kept at an effective level and encourages Medicines Australia to maintain fines at a level such that the fines and their enforcement deter any breaches of the Code.

ACCC conclusion on public benefits

293. The ACCC accepts that the following public benefits are likely to result from edition 18 of the Code, when effectively monitored and enforced:

- addressing the principal agent problem and the scope for the prescribing practices of healthcare professionals to be inappropriately influenced (subject to the proposed condition of authorisation – see below). The Code does this by outlining the boundaries for appropriate relationships between pharmaceutical companies and healthcare professionals to limit the potential for conflicts of interest and opening these relationships to public scrutiny by requiring the reporting of transfers of value;

- reducing the potential for conflicts of interest that may arise between pharmaceutical companies and health consumer organisations and patients by providing for greater transparency around these relationships and regulating, for example, Patient Support Programs ;

- encouraging compliance with legislation and protecting the general public from inappropriate advertising;

- ensuring medical practitioners (who may be subject to bounded rationality or information asymmetry) can rely on information provided by pharmaceutical manufacturers by setting consistent standards for medical and promotional material thereby reducing misleading claims about medicines; and

- ensuring industry participants interact appropriately with other parties by imposing training and knowledge requirements and requiring pharmaceutical companies to have an internal compliance procedure promoting compliance by all company employees.

294. The ACCC accepts that there are significant public benefits arising from various sections of the Code and is satisfied that, overall, the conduct the subject of the authorisation results in significant public benefits. However the ACCC considers there to be serious flaws in the operation of the transparency regime, which the ACCC considers are likely to significantly undermine the transparency benefits of the Code.

Public detriment

295. Public detriment is also not defined in the Act but the Tribunal has given the concept a wide ambit, including:

> …any impairment to the community generally, any harm or damage to the aims pursued by the society including as one of its principal elements the achievement of the goal of economic efficiency.[78]

296. Medicines Australia submits there is minimal potential anti-competitive or other public detriment identifiable in edition 18 of the Code, and that minimal detriment is substantially outweighed by the already existing public benefits associated with the Code, which will be significantly strengthened following the amendments in edition 18.

297. The RACGP, Dr Harvey and CHOICE submit that the transparency in edition 18 of the Code is not an incremental improvement and its authorisation would result in public detriment.

298. The ACCC notes that anti-competitive detriments may arise insofar as the Code limits the ability of companies to freely compete with each other through the advertising and promotion of their products, particularly to healthcare professionals. In particular, the ACCC notes the detailed provisions regulating member conduct in relation to promotional activities and material directed at healthcare professionals (including brand name reminders) and relationships with healthcare professionals. The ACCC also notes that the administration and enforcement of the Code, as well as the requirement for certain persons to participate in an education program endorsed by Medicines Australia, may give rise to anti-competitive detriment.

[78] *Re 7-Eleven Stores* (1994) ATPR 41-357 at 42,683.

299. However, the ACCC considers that the Code includes such restrictions as a means for addressing market failures which may arise in the health sector.

300. The Tribunal was satisfied in its consideration of edition 15 of the Code that 'there is little in the way of significant anti-competitive detriment' resulting from the Code and that the:

> ...restrictions imposed by the Code do not strike at the heart of competitive conduct as to price and quality and lawful communications of the benefits and characteristics of pharmaceutical products to appropriately qualified healthcare professionals.[79]

301. The ACCC considers that this remains the case for edition 18 of the Code.

ACCC conclusion on public detriments

302. The ACCC considers that any anti-competitive detriment resulting from the Code is likely to be minimal. While the Code restricts to some degree the promotional activities of Medicines Australia members and non-members, the ACCC accepts that the Code does this to address potential market failures which may arise.

Balance of public benefit and detriment

303. The ACCC may grant authorisation if it is satisfied that, in all the circumstances, the proposed conduct is likely to result in a public benefit, and that public benefit will outweigh any likely public detriment, including any lessening of competition.

304. In the context of applying the net public benefit test in subsection 90(8)[80] of the Act, the Tribunal has commented that:

> … something more than a negligible benefit is required before the power to grant authorisation can be exercised.[81]

305. For the reasons outlined in this draft determination, the ACCC is satisfied that the likely benefit to the public would outweigh the detriment to the public including the detriment constituted by any lessening of competition that would be likely to result. However, the ACCC retains concerns about the operation of the transparency regime proposed in the Code, which it believes is likely to significantly undermine the transparency benefits of the Code.

306. Accordingly, while the ACCC is satisfied that the relevant net public benefit tests are met, the ACCC proposes to impose the condition of authorisation set out below.

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79 *Re Medicines Australia Inc [2007] ACompT 4 at paragraph 333.*

80 The test at subsection 90(8) of the Act is in essence that conduct is likely to result in such a benefit to the public that it should be allowed to take place.

81 *Re Application by Michael Jools, President of the NSW Taxi Drivers Association* [2006] ACompT 5 at paragraph 22.

Conditions of authorisation

307. Subsection 91(3) of the Act allows the ACCC to grant authorisation subject to conditions specified in the authorisation.

308. The power conferred upon the ACCC to authorise conduct is discretionary.[82] In exercising that discretion, it may have regard to considerations relevant to the objectives of the Act.[83]

309. The ACCC may impose a condition in circumstances where, although the relevant public benefit test is met without the condition, the ACCC would not be prepared to exercise its discretion in favour of authorisation.[84] Where there is limited public detriment (as in the case of the present application) the ACCC can impose a condition to yield a more substantial public benefit or to enhance the likelihood that the public benefit will be realised.[85]

310. Edition 18 of the Code imposes an obligation on all member companies to publish reports on the transfers of value to healthcare professionals specified in section 41.3.1 (Reporting of Transfers of Value to Healthcare Professionals). The information to be reported is also set out in section 41.3.1.[86] On its face, this obligation requires universal reporting.

311. However, Medicines Australia considers this obligation to be subject to section 41.3.2,[87] which provides as follows:

> ***41.3.2 Informed Consent***
>
> Companies must comply with Australian Privacy legislation (Privacy Act 1988 (C'th)) in regard to the reporting of individual healthcare professional data. Each company must establish a means to ensure informed consent and maintenance of records which comply with Australian Privacy legislation.
>
> Where recipients of transfers of value cannot be identified for legal reasons, the amount attributable to such transfers must be reported on an aggregate basis by each company. The number of recipients involved must be stated and the aggregate amount attributable to transfers of value to such recipients.

312. In other words, Medicines Australia considers that member companies would be required to report transfers of value to healthcare professionals only where the recipient healthcare professional has provided informed consent to the transfer being reported.

313. As set out in paragraphs 132 to 148 above, the ACCC is concerned that section 41.3.2 of the Code would operate to enable member companies to provide benefits to healthcare professionals without reporting the benefits (where healthcare professionals choose not to consent to the benefits being disclosed).

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[82] *Application by Medicines Australia Inc* (2007) ATPR 42-164 at paragraph 106,
[83] *Application by Medicines Australia Inc* (2007) ATPR 42-164 at paragraph 126.
[84] *Application by Medicines Australia Inc* (2007) ATPR 42-164 at paragraph 133.
[85] *Application by Medicines Australia Inc* (2007) ATPR 42-164 at paragraph 128.
[86] See paragraphs 33–39 above for more details.
[87] See, for example, 5.4(b) of at pages 18-19 of Medicines Australia's submission accompanying its applications for authorisation dated 2 July 2014.

314. The ACCC appreciates Medicines Australia's concern to ensure that its members comply with privacy legislation when reporting relevant transfers of value, and has no objection to the Code requiring such compliance.

315. However, the ACCC does not accept that the need to comply with privacy legislation is a reason for transfers of value made to individual healthcare professionals to go unreported. As noted above, universal disclosure is key to the utility of the broader transparency regime.

316. In order to secure universal reporting and to ensure that the associated public benefits are realised, while having regard to Medicines Australia's concern to ensure that its members comply with privacy legislation, the ACCC proposes to impose a condition that would amend section 41.3.2 to require members to take any steps necessary to be able to individually report (including complying with Australian privacy law) *before* making a transfer of value.

317. Accordingly, the ACCC is proposing to impose a condition which requires Medicines Australia to vary the Code, within six months of the authorisation coming into effect, by amending section 41.2.3 as follows:

a. deleting the title 'Informed Consent' and replacing it with the following:

> '*Requirements for Making and Reporting Transfers of Value to Healthcare Professionals*';

b. deleting the words '*informed consent and*' from the second sentence of the first paragraph; and

c. deleting the second paragraph and replacing it with the following:

> '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.'

318. As a result of the amendments required by this condition, section 41.2.3 would read as follows (with additions underlined):

> ***41.2.3 <u>Requirements for Making and Reporting Transfers of Value to Healthcare Professionals</u>***
>
> Companies must comply with Australian Privacy legislation (Privacy Act 1988 (Cth)) in regard to the reporting of individual healthcare professional data. Each company must establish a means to ensure maintenance of records which comply with Australian Privacy legislation.
>
> <u>'Companies must not make a transfer of value of a kind referred to in section 41.3.1 unless they have either:</u>
>
> 1. <u>obtained the consent of the healthcare professional to disclosure of individual healthcare professional data; or</u>

2. taken appropriate steps to give notice of this disclosure obligation, so that the healthcare professional would reasonably expect the disclosure.'

319. The condition is designed to increase public access to, and scrutiny of, meaningful information about benefits provided by medicines companies to healthcare professionals. In particular, it addresses the key deficiency of the proposed transparency regime and will therefore enhance the likelihood that potential public benefits resulting from the transparency reporting provisions of the Code will be realised. These benefits are described in section 41.3 of the Code as:

> *…to provide visibility for consumers of payments and transfers of value to healthcare professionals who are engaged in patient care.*

320. The ACCC has also had regard to the burden associated with the imposition of the condition, and considers it to be reasonable, having regard to the benefit likely to be derived from the condition.

321. The ACCC expects that Medicines Australia (as it proposed to do in respect of the current concept of 'informed consent' in section 41.3.2), will provide guidance to its members to assist them in complying with the new reporting requirements in section 41.3.1 and the steps that they will need to take to ensure, prior to making a transfer of value, that it meets the new requirements in section 41.3.2.

The ACCC invites submissions from interested parties and Medicines Australia on this proposed condition of authorisation.

322. The ACCC also considers that there is merit in including some form of continued reporting of hospitality provided by member companies (in addition to or instead of a monetary cap on hospitality). Relevantly, hospitality is a direct transfer of value to individual healthcare professionals and is reported by member companies (in an aggregate form) under the current transparency reporting.

323. The ACCC has not decided whether to require reporting or if so the form of reporting but options include (either with or without retaining a cap on per meal hospitality costs):

- adding hospitality (above a threshold amount) to the transfers of value reported under the new individual reporting regime
- requiring the existing educational event reporting to continue (i.e. on a per event basis), either in its current form or for the hospitality component only
- requiring member companies to provide aggregate reporting about hospitality expenditure in the reporting period
- rather than requiring hospitality reporting, reducing the cap on hospitality down from the $120 per meal proposed, to a level that may be of less concern to the community (for example $70).

The ACCC seeks comments from Medicines Australia and interested parties about whether such a condition is necessary and the form that it should take.

324. The ACCC will take into account submissions received from Medicines Australia and interested parties in response to this draft determination in deciding on any conditions of authorisation imposed in the final determination.

Length of authorisation

325. The Act allows the ACCC to grant authorisation for a limited period of time.88 This allows the ACCC to be in a position to be satisfied that the likely public benefits will outweigh the detriment for the period of authorisation. It also enables the ACCC to review the authorisation, and the public benefits and detriments that have resulted, after an appropriate period.

326. In this instance, Medicines Australia seeks authorisation for five years.

327. Medicines Australia submits that a shorter authorisation period will not allow sufficient time for the new transparency regime to be embedded in the industry and its effectiveness appropriately evaluated, noting the timing of the first publication of the new transparency reports. Medicines Australia submits that a five year authorisation is also appropriate considering the significant time and effort required in updating each edition of the Code, noting however that Medicines Australia will continue to review the provisions of the Code every three years.

328. Interested parties have provided limited feedback on the period of authorisation at this stage. As noted above, a number of parties oppose authorisation of edition 18 of the Code in its current form. The AMA considers that any public reporting approach implemented by Medicines Australia should be reviewed after a few years of operation and supports a five year authorisation.

329. The ACCC accepts that it will take some time for the new individual transparency regime to be fully operational and for any implementation issues to be smoothed out. In particular, the first transparency reports are not due to be released until 31 August 2016. The ACCC considers that, subject to the proposed condition of authorisation, the new transparency reporting is an important development that should be given sufficient time to become properly implemented before being reviewed.

330. As such, the ACCC proposes to grant authorisation for five years. In any event, the ACCC notes that Medicines Australia has undertaken to review its Code after three years. Therefore assuming that Medicines Australia seeks reauthorisation for the next versions of its Code it is likely to do so sooner than five years.

Scope of the authorisation more broadly

331. The SHPA, the SAMAC, the CHF, Dr Harvey and 25 Individuals submit that the Code should apply more broadly (for example, to all pharmaceutical companies or sponsors including those not in an industry association,

[88] Subsection 91(1) of the Act.

health professional organisations, therapeutic goods industry associations, and to transfers of value not related to prescription medicines).

332. The ASA, Dr Harvey and 25 Individuals submit that transparency should be legislated by the Regulatory Policy and Governance Division of the Department of Health, the TGA and the Federal Government.

333. The ASA notes that there are companies that are outside of the Code.

334. Medicines Australia submits that there are significant public benefits associated with developing and complying with voluntary industry codes, including where this reaches beyond statutory regulation. Medicines Australia cannot force companies to join Medicines Australia. However 86% of medicines supplied under the PBS are supplied by Medicines Australia members. Further all promotional material (not just that of member companies) must adhere to Medicines Australia's Code. Medicines Australia submits that this issue does not go to whether the ACCC should authorise the Code.

335. The ACCC acknowledges that non-member companies, including generic manufacturers are required to comply with those provisions of the Code relating to promotional material by virtue of the TGA's marketing approval letter. However, the ACCC understands that the requirement in the TGA marketing approval letter does not extend to the provision of hospitality at educational events and other aspects of the manufacturer/healthcare provider relationship. Further, potential breaches of the standards in the Code by non-members may not amount to a breach of the TG Act or the Act. The ACCC notes that few complaints against non-member companies are referred to the ACCC for investigation as a potential breach of the Act.

336. Breaches of the standards set by the Code, even by non-member companies, particularly around the provision of inappropriate hospitality to healthcare professionals, impact the reputation of the industry as a whole. Further, inconsistencies in the standards expected of different groups within an industry create an unequal playing field.

337. More concerning is that relationships between pharmaceutical companies not subject to the Code and healthcare professionals are largely unrestricted and not transparent. The ACCC notes the creation of an arms-length and transparent relationship between pharmaceutical companies and healthcare professionals addresses the concern about potential conflicts of interest, particularly that unrestricted relationships may influence the prescribing practices of healthcare providers, and may ultimately compromise patient care.

338. The ACCC considers there is significant benefit in regulating the provision of benefits by all manufacturers of therapeutic products including manufacturers of generic drugs, prosthetics and other medical devices. However, the ACCC is not able to impose conditions through this authorisation requiring non-members of Medicines Australia to comply with this Code, or a similar code. It is however open for other industry associations or groups to develop a code with similar standards of conduct and to seek authorisation from the ACCC, as the GMiA did to increase transparency in the generic pharmaceutical industry (although the GMiA has not sought reauthorisation of its code from the ACCC).

339. The ACCC notes that the authorisation process is not necessarily the appropriate mechanism to redress inconsistencies between various industry codes. The ACCC is required to assess any code for which authorisation is sought on a case by case basis according to the likely public benefits and detriments flowing from that particular code as required by the statutory tests for authorisation. Whether other industry sectors should be required to comply with similar standards as contained in Medicines Australia's Code is ultimately a decision for those industry sectors or government.

340. In this respect, the ACCC notes the Department of Health Working Group on the Promotion of Therapeutic Products made a number of recommendations for industry, government and healthcare professionals in 2011.89 The report includes a set of high level principles as the basis for strengthening and aligning industry codes of conduct. The Australian Government has stated that its preference is to maintain an emphasis on self-regulation and strongly supports industry's initiative to harmonise their codes of conduct.

Draft determination

The application

341. On 2 July 2014, Medicines Australia Limited (Medicines Australia) lodged applications for revocation and substitution of new authorisations A91436-A91440 with the ACCC. Applications A91436-A91440 were made using Form FC Schedule 1, of the Competition and Consumer Regulations 2010. The applications were made under subsection 91C(1) of the Act for edition 18 of its Code of Conduct (the Code) which sets the standards for the marketing and promotion of prescription pharmaceutical products in Australia.

342. Medicines Australia seeks authorisation of these arrangements as they may contain a cartel provision and may have the effect of substantially lessening competition within the meaning of section 45 of the Act. The arrangements may also contain an exclusionary provision (within the meaning of section 45 of the Act) that may also be a cartel provision. The conduct may also constitute exclusive dealing.

343. Subsection 90A(1) requires that before determining an application for authorisation the ACCC shall prepare a draft determination.

The net public benefit test

344. For the reasons outlined in this draft determination, the ACCC considers that in all the circumstances the proposed arrangements for which reauthorisation is sought is likely to result in a public benefit that would

[89] Working Group on Promotion of Therapeutic Products, *Report to Parliamentary Secretary Catherine King*, 18 March 2011, **http://www.health.gov.au/internet/main/publishing.nsf/Content/A34929E0507FB7E8CA257BF0001C1C28/$File/Report%20of%20the%20Working%20Group%20on%20Promotion%20of%20Therapeutic%20Products.pdf**. Accessed 16 October 2014.

outweigh the detriment to the public constituted by any lessening of competition arising from the conduct.

345. For the reasons outlined in this draft determination, the ACCC is also satisfied that the proposed arrangements for which reauthorisation is sought is likely to result in such a benefit to the public that the conduct should be allowed to take place.

346. However, notwithstanding the above, the ACCC has serious concerns about the transparency reporting regime set out in the Code.

347. As noted above, the power conferred upon the ACCC to authorise conduct is discretionary.90 The ACCC may impose a condition in circumstances where, although the relevant public benefit test is met, without the condition, the ACCC would not be prepared to exercise its discretion in favour of authorisation.91 Where there is limited public detriment (as in the case of the present application) the ACCC can impose a condition to yield a more substantial public benefit or to enhance the likelihood that the public benefit will be realised.92

348. The ACCC proposes to impose a condition upon the exercise of its discretion to authorise the Code in order to address its concerns about the transparency reporting regime.

349. The ACCC therefore proposes to revoke authorisations A91316-A91320 and grant authorisation to applications A91436-A91440 in substitution subject to a condition as outlined at paragraphs 317 to 318 above and set out in Attachment B.

Conduct for which the ACCC proposes to grant authorisation

350. The ACCC proposes to grant conditional authorisation to Medicines Australia for edition 18 of its Code which sets the standards for the marketing and promotion of prescription pharmaceutical products in Australia, subject to the condition set out in Attachment B.

351. Further, the proposed authorisation is in respect of edition 18 of the Code as it stands at the time authorisation is granted. Any changes to the Code during the term of the proposed authorisation would not be covered by the proposed reauthorisation.

352. Authorisation does not represent ACCC endorsement of a group or scheme. Rather, it provides statutory protection from legal action for conduct that meets the net public benefit test and that might otherwise raise concerns under the competition provisions of the Act.

353. This draft determination is made on 17 October 2014.

[90] *Application by Medicines Australia Inc* (2007) ATPR 42-164 at paragraph 106. As noted by the Tribunal at paragraph 126, in exercising that discretion, the ACCC may have regard to considerations relevant to the objectives of the Act

[91] *Application by Medicines Australia Inc* (2007) ATPR 42-164 at paragraph 133.

[92] *Application by Medicines Australia Inc* (2007) ATPR 42-164 at paragraph 128.

Further submissions

354. The ACCC will now seek further submissions from interested parties. In addition, the applicant or any interested party may request that the ACCC hold a conference to discuss the draft determination, pursuant to section 90A of the Act.

Attachment A - Summary of relevant statutory tests

Subsections 90(5A) and 90(5B) provide that the ACCC shall not authorise a provision of a proposed contract, arrangement or understanding that is or may be a cartel provision, unless it is satisfied in all the circumstances that:

- the provision, in the case of subsection 90(5A) would result, or be likely to result, or in the case of subsection 90(5B) has resulted or is likely to result, in a benefit to the public; and
- that benefit, in the case of subsection 90(5A) would outweigh the detriment to the public constituted by any lessening of competition that would result, or be likely to result, if the proposed contract or arrangement were made or given effect to, or in the case of subsection 90(5B) outweighs or would outweigh the detriment to the public constituted by any lessening of competition that has resulted or is likely to result from giving effect to the provision.

Subsections 90(6) and 90(7) state that the ACCC shall not authorise a provision of a proposed contract, arrangement or understanding, other than an exclusionary provision, unless it is satisfied in all the circumstances that:

- the provision of the proposed contract, arrangement or understanding in the case of subsection 90(6) would result, or be likely to result, or in the case of subsection 90(7) has resulted or is likely to result, in a benefit to the public; and
- that benefit, in the case of subsection 90(6) would outweigh the detriment to the public constituted by any lessening of competition that would result, or be likely to result, if the proposed contract or arrangement was made and the provision was given effect to, or in the case of subsection 90(7) has resulted or is likely to result from giving effect to the provision.

Subsection 90(8) states that the ACCC shall not:

- make a determination granting:

  i. an authorization under subsection 88(1) in respect of a provision of a proposed contract, arrangement or understanding that is or may be an exclusionary provision; or

  ii. an authorization under subsection 88(7) or (7A) in respect of proposed conduct; or

  iii. an authorization under subsection 88(8) in respect of proposed conduct to which subsection 47(6) or (7) applies; or

  iv. an authorisation under subsection 88(8A) for proposed conduct to which section 48 applies;

unless it is satisfied in all the circumstances that the proposed provision or the proposed conduct would result, or be likely to result, in such a benefit to the public that the proposed contract or arrangement should be allowed to be made, the proposed understanding should be allowed to be arrived at, or

the proposed conduct should be allowed to take place, as the case may be; or

- make a determination granting an authorization under subsection 88(1) in respect of a provision of a contract, arrangement or understanding that is or may be an exclusionary provision unless it is satisfied in all the circumstances that the provision has resulted, or is likely to result, in such a benefit to the public that the contract, arrangement or understanding should be allowed to be given effect to.

Attachment B – Proposed condition of authorisation

The ACCC is proposing to require, within six months of the authorisation coming into effect, Medicines Australia to vary the Code by amending section 41.2.3 as follows:

a. deleting the title 'Informed Consent' and replacing it with the following:

   '*Requirements for Making and Reporting Transfers of Value to Healthcare Professionals*';

b. deleting the words '*informed consent and*' from the second sentence of the first paragraph; and

c. deleting the second paragraph and replacing it with the following:

   '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.'