Consumers Health Forum of Australia

27 September 2013

Sophie Hibburd
Code of Conduct Committee
Medicines Australia
16 Napier Close
DEAKIN ACT 2600

Dear Ms Hibburd

**Code of Conduct Review and Consultation on the Transparency Model**

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a submission to Medicines Australia (MA)'s *Code of Conduct* (the Code) *Review* and its consultation on the *Transparency Model Discussion Paper*.

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF and its members have a strong interest in the ethical promotion of therapeutic goods. As such, we welcome MA's work in this area, and recognise that MA has taken leadership on this issue, and extended beyond the usual remit of its work.

Our previous submissions to reviews of the Code have focussed on including individual level disclosure of payments and sponsorship by companies to healthcare professionals in the Code. CHF is therefore pleased to see the Transparency Working Group (TWG), under the auspices of MA, working towards incorporating a Transparency Model into the Code.

The first part of this submission focusses sections relating to the Code, namely patient support and product familiarisation programs. The second part highlights some barriers to transparency for MA and the TWG to consider, prior to finalising the Transparency Model.

In our comments, CHF recognises that some issues are beyond the direct control of MA and require the involvement of other stakeholders. However, CHF encourages MA to consider these issues and ways in which it can continue to play a leadership role.

The Transparency Model may result in a need to revise a number of sections within the Code. CHF would be happy to continue to work with MA on future revisions of the Code and in developing the Transparency Model.

CHF looks forward to providing input to subsequent consultations about the Code and Transparency Model. If you would like to discuss the issues raised in this submission in more detail, please contact CHF Policy Advisor, Mr Carlo Malaca, on 02 6273 5444 or at c.malaca@chf.org.au.

Yours sincerely

**Carol Bennett**
**CHIEF EXECUTIVE OFFICER**

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Consumers
Health Forum
*of Australia*

# Submission to the Medicines Australia Code of Conduct Review and Transparency Model Discussion Paper

**September 2013**

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## Introduction

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a submission to Medicines Australia (MA)'s *Code of Conduct* (the Code) *Review* and its consultation on the *Transparency Model Discussion Paper* (the Discussion Paper).

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

Codes of practice or conduct (Codes) for the medicines industry provide consumers with reassurance that there are standards that must be met, and penalties apply if these standards are breached. The Code is a valuable document that sets the benchmark for accountability within the Australian medicines industry.

CHF and its members have a strong interest in the ethical promotion of therapeutic goods. CHF was closely involved in the development and implementation of the Edition 16 of the Code, and provided submissions to MA (November 2011) and the Australian Competition and Consumer Commission (ACCC)'s consultations on Edition 17 of the Code in July and November 2012. In our submissions to the ACCC, CHF's primary concern was for the inclusion of individual level disclosure of payments and sponsorship by companies to healthcare professionals in the Code.

CHF welcomed the ACCC's decision to make individual level disclosure of payments and 'transfers of value'[1] from companies to healthcare professionals a condition of its authorisation of Edition 17 of the Code, for inclusion in Edition 18 of the Code. The Transparency Model being developed by MA will affect several areas of the Code and its incorporation may demand significant revisions of specific clauses in, and in some cases entire sections of, the Code.

This submission addresses broad issues and specific clauses relating to the Code, before providing comment on the Discussion Paper. CHF's comments on the Code relate to: Patient Support Programs; Product Familiarisation Programs; Abuse of the Code; and, a single code for the therapeutic goods industry. CHF then provides advice on how the Transparency Model could be enhanced to better serve consumers, while highlighting significant barriers to transparency that MA should consider before the Transparency Model is incorporated into the Code.

CHF understands that there will be future opportunities to comment on the Code and on the Transparency Model, including through the ACCC's authorisation process, and we look forward to providing further input to MA at these opportunities.

[1] 'Transfer of value' means a transfer of anything that would have a value to the recipient from the perspective of general community standards and value, as defined in MA's Transparency Model Discussion Paper.

## Recommendations

### Code of Conduct

1. Payments to healthcare professionals for enrolling consumers in PSPs is a 'transfer of value' and should be included in the relationships covered under the Transparency Model being developed by MA.
2. CHF recommends that a threshold dollar amount for individual payments be determined, and for an aggregate to be nominated for payments made to healthcare professionals as part of PSPs
3. A clause prohibiting package inserts to promote PSPs should be included in the Code. Package inserts promoting PSPs are arguably advertising material and not essential to the safe use of medicine.
4. The Code should include a clause that requires mandatory periodic reporting by all parties (the company, the prescriber and the consumer) either through the prescriber or directly to the TGA. The reporting should be in place for the entire life of the PFP.
5. The Code should include clear requirements for companies conducting PFPs to train healthcare professionals and to provide adequate and accurate information about the medicine. An information and advice line should also be set up by the company to operate for the life of the PFP.
6. The Code should require companies to proactively engage with clinicians and the regulator regarding safety concerns during Patient Familiarisation Programs, rather than relying on spontaneous reporting of adverse events.
7. Informed consent protocols around PFPs should be included in the Code. This should include information regarding the risks, any potential costs to the consumer and adverse event reporting options.
8. CHF calls for greater clarity within the Code around what constitutes a 'vexatious' or 'frivolous' complaint. This could provide clarity for those seeking to adhere to the Code, reduce abuse by companies, and improve the effectiveness of the Code and corresponding complaint channels by ensuring all parties are able to sufficiently understand their rights and obligations from the outset.
9. CHF strongly supports establishing a single, rigorous code of conduct for all pharmaceutical and therapeutic goods industries, for members and non-members of industry associations alike, with appropriate sanctions for non-compliance with the code.

### Transparency Model

10. To ensure companies are not utilising other channels to circumvent transparency, payments and transfers of value relating to OTC and complementary medicines in the years following the implementation of the Transparency Model should be monitored.
11. The Code should include a clause which requires MA member companies to adhere to the Code for all aspects of their business. Once the Transparency Model is incorporated into the Code, this

would result in the Transparency Model being applicable to MA members' conduct extending beyond prescription medicines

**12.** CHF recommends a separate Foundation be established to have oversight for the activities outlined in the Transparency Model.

**13.** The Transparency Model should not permit the identifier details of healthcare professionals to be left blank on the reporting form. To ensure compliance, a penalty for not providing this information should be applicable to companies.

**14.** All details relating to third party arrangements should be disclosed.

**15.** All payments or transfers of value should be recorded and assigned to individual healthcare professionals. Indirect and direct payments both have the potential to influence prescribing behaviour.

**16.** Of the options proposed, CHF supports alternative 2 which provides a threshold of $10, and for that amount to be reviewed annually in line with the Consumer Price Index.

**17.** Non-hospitality and non-travel costs should be part of the Transparency Model reporting.

**18.** Starter packs should be part of the Transparency Model reporting.

**19.** Acting as an expert witness in legal or administrative proceedings should be part of the Transparency Model Reporting.

**20.** Companies should be required to file a report which states that they made no reportable payments or transfers of value in the preceding year.

**21.** A review of the effectiveness of the electronic submission system should be conducted within six months after the first cycle

**22.** Regular correspondence should be sent to healthcare professionals to remind them about their Transparency Model reporting requirements.

**23.** The TWG should explore allowing more than one reporting period during a year for healthcare professionals to input their own records of payments or transfers of value

**24.** The Transparency Model should require a company to obtain some form of written declaration from the healthcare professional of having received the payment or transfer of value.

## Comments on the Code

### Patient Support Programs

Section 18 provides guidance for companies in establishing Patient Support Programs (PSPs). CHF welcomes the Code's acknowledgment that the purpose of PSPs is '*to assist patients in gaining benefit from their medical treatment and to improve health outcomes and promote the quality use of medicines*'. However, the current provision in the Code does not appear to support this aim.

In submissions to MA relating to Edition 17 of the Code, CHF noted its concern about the potential for PSPs to be utilised as a direct consumer-marketing tool, facilitated through healthcare professionals. These concerns remain issues in the current edition of the Code.

Subsection (a) and (b) states that:

a) The payment between the company and health professional to enrol consumers on PSPs must be disclosed in writing to a patient prior to their enrolment in the program, and
b) Such a payment should not be capable of influencing or intended to influence the prescribing or dispensing of a specific prescription product, respectively.

There is a need to clarify what constitutes an amount (being able to influence) or intended to influence, prescribing or dispensing behaviour. The payment provided to each healthcare professional should also be included as part of the written disclosure provided to consumers being enrolled in PSPs.

**Recommendations**

1. Payments to healthcare professionals for enrolling consumers in PSPs is a 'transfer of value' and should be included in the relationships covered under the Transparency Model being developed by MA.
2. CHF recommends that a threshold dollar amount for individual payments be determined, and for an aggregate to be nominated for payments made to healthcare professionals as part of PSPs.

*Pack inserts*

Section 18 allows inserts about PSPs to be included in the product package. Pack inserts play a key role in providing consumers with information that supports them to use the medicine appropriately and safely. Pack inserts compensate for the limited space available on small containers and should only contain the most important information needed by consumers to support quality use of medicines. The safety of consumers may depend upon the information contained on pack inserts. Including non-essential information such as advertising and promotional material or information about PSPs, diminishes the importance of inserts and could result in consumers discarding essential information on inserts.

**Recommendation**

3. A clause prohibiting package inserts to promote PSPs should be included in the Code. Package inserts promoting PSPs are arguably advertising material and not essential to the safe use of medicine.

## Product Familiarisation Programs

Section 8 of the Code provides guidance for the conduct of companies in relation to Product Familiarisation Programs (PFPs). However, subsection (8.9) of the Code submits that 'No formal protocol is required for PFPs.' Consumers should have assurances that the same regulatory rigour and safety frameworks exist for the medicines as part of PFPs. There is the need to increase the quality and monitoring controls for companies conducting PFPs. Outlined below are issues that MA should consider in developing formal protocols and detailed guidance for member companies' PFPs.

*Risks not reflected in clinical trials*

The potential for rapid intake of a large number of participants for PFPs is of concern to CHF as the safety of new medicines on PFPs is still largely uncertain. Clinical trials alone are limited in predicting the experience that the general population will have with a medicine. Clinical trials do not account for all the potential medicine interactions that can occur from the range of medicines under the various conditions taken by consumers, or even the effect of switching from one medicine to the new one. A medicine that is new-to-market may carry greater risk than what was found in clinical trials. Therefore, they should be more vigilantly-monitored for a period after being granted market access.

Consumers being enrolled on PFPs should be made aware of the risks associated with medicines that are new-to-market. PFP protocols should also require closer monitoring of the consumer experience of the medicine by their prescriber, and then the company through the prescriber.

**Recommendation**

4. The Code should include a clause that requires mandatory periodic reporting by all parties (the company, the prescriber and the consumer) either through the prescriber or directly to the TGA. The reporting should be in place for the entire life of the PFP.

*Rapid uptake without adequate support to healthcare professionals*

A rapid intake of a large number of consumers through PFPs is an issue when those consumers present to emergency departments that are unaware or ill equipped to provide treatment for patients experiencing adverse events. In a recent PFP ran by Boehringer Ingelheim, there were reports, noted in ACCC's Determination to Edition 17 of the Code, that most prescribing and dispensing software carried inaccurate information about the medicine. Hospital staff simply did not know or have access to information that allowed them to provide the level of care consumers needed.

Regulatory frameworks contribute to ensuring the safety of consumers who use new medicines. These include pharmacovigilance requirements upon sponsors, information provision of Product Information (PI) and Consumer Medicine Information (CMI), healthcare professional knowledge of antidotes and adverse event management measures,

Companies should ensure that the rollout of a PFP is underpinned by up-to-date, unbiased information, including PI and CMI, available from a variety of electronic and hardcopy sources. The company should also ensure that healthcare professionals are adequately trained to discuss the risks associated with its use with the consumer before prescribing. PFPs should not be rolled out until healthcare professionals have received training about the new medicine, and only after adequate and up-to-date information is available for them to access online or through the company.

Consumers should be given information about the PFP that they can take home to review in their own time, and would benefit from being able to access dedicated information and telephone help-line for the life of the PFP.

**Recommendation**

5. The Code should include clear requirements for companies conducting PFPs to train healthcare professionals and to provide adequate and accurate information about the medicine. An information and advice line should also be set up by the company to operate for the life of the PFP.

*Product Familiarisation Programs and Adverse Events*

CHF argues that it should be a requirement that any information regarding adverse events that occur during PFPs is made available to the regulator and to clinicians. Currently, the Code states that suspected adverse drug reactions that are 'spontaneously reported during the PFP' must be reported to the Therapeutic Goods Administration.

Given the value of adverse event data collected during PFPs to both the regulator and to clinicians, CHF argues that the Code should require that sponsors *proactively* engage with clinicians and the regulator regarding any safety concerns or other issues, rather than waiting for spontaneous reports.

**Recommendation**

6. The Code should require companies to proactively engage with clinicians and the regulator regarding safety concerns during Patient Familiarisation Programs, rather than relying on spontaneous reporting of adverse events.

*Informed Consent and Exit Strategy*

For consumers who have little option but to use medicines that are problematic or have severe side-effects, access to a new medicine that is promoted to be superior to the one they are currently using is an inviting prospect. Through PFPs, companies make this even more appealing by providing the new medicine free of charge for consumers who enrol. Given the lack of transparency and guidance surrounding PFPs in the Code, it is unclear what information is conveyed to consumers; whether the benefits of the medicine are exaggerated, or the risks downplayed; and, whether companies are exploiting consumer's hopes and desire for improvements to their health.

Companies must obtain informed consent from consumers before enrolling them in PFPs. Part of this process should outline the risks, any potential costs (for example, in relation to its Pharmaceutical Benefit Scheme (PBS) listing status), and avenues through which they can report adverse events. Providing the consumer with information about an exit strategy and changing back to their original medicine, if they chose to opt-out of the PFP, is also critical. Further, consumers on PFPs should not be used for commercial gain through attempts to influence any Government processes.

**Recommendation**

7. Informed consent protocols around PFPs should be included in the Code. This should include information regarding the risks, any potential costs to the consumer and adverse event reporting options.

**Abuse of the Code**

Section 25, Abuse of the Code, states that:

> *If the Code Committee forms the view that a complaint by a company might be considered frivolous or vexatious, before the Code Committee considers the matter, it will request the Complainant Company to provide its response to the concern, including any reasoning why the Committee should not impose a fine up to of a maximum of $200,000 for abuse of the Code of Conduct. The Complainant Company's response must be provided to Medicines Australia within ten (10) working days. The Complainant Company's response will be considered at the next Code Committee meeting.*

**Recommendation**

8. CHF calls for greater clarity within the Code around what constitutes a 'vexatious' or 'frivolous' complaint. This could provide clarity for those seeking to adhere to the Code, reduce abuse by companies, and improve the effectiveness of the Code and corresponding complaint channels by ensuring all parties are able to sufficiently understand their rights and obligations from the outset.

**A single code for the therapeutic goods industry**

Acknowledging that aspects of the Code can be improved, CHF considers it the benchmark for accountability within the Australian medicines industry. However, the Code operates in a system where there are several different self-regulated codes in place for different parts of the therapeutic goods industry. There is a wide variation in these codes including the expected standards for members; application and enforcement; levels of penalties and sanctions, and, complaints processes. Regardless of how robust the Code is, self-regulation means that companies who are not MA members can operate outside of the Code and can conduct their business without fear of sanctions or penalties.

Establishing a single code of conduct for the promotion of therapeutic goods would provide health consumers reassurance that the promotion of medicines and other therapeutic goods is ethical and ultimately done for their benefit. MA should engage with other therapeutic goods industry associations that have oversight for their respective industry and, using the Code as the foundation, work towards developing a single code for the therapeutic goods industry.

**Recommendation**

9. CHF strongly supports establishing a single, rigorous code of conduct for all pharmaceutical and therapeutic goods industries, for members and non-members of industry associations alike, with appropriate sanctions for non-compliance with the code.

## Comments on the Transparency Model Discussion Paper

CHF has long advocated for individual level disclosure of payments made by companies to healthcare professionals. CHF commends the work of the Transparency Working Group (TWG) and MA in developing the Discussion Paper. Overall, the Transparency Model provides a sufficient level of guidance for the range of activities relating to payments or transfers of value by companies to healthcare professionals. CHF acknowledges that the TWG did not reach consensus on every aspect of the Transparency Model, and one of the most debated points was on the threshold dollar amount for the recording and reporting of payments or transfers of value.

CHF provides further comment on this issue below but would, however, like to reiterate that the purpose of the Transparency Model is to illuminate the nature of the relationship between healthcare professionals and pharmaceutical companies, not to set limits that could potentially conceal them.
CHF notes that a great deal of detail will need to be determined prior to the implementation of the Transparency Model. The practicalities of rolling out such as scheme will require wide consultation with all the relevant stakeholders, including consumers. CHF also appreciates the care shown by the TWG to draft a model that extends beyond the MA Code's mandate, and that has wider applicability beyond the prescription medicines industry.

The document provides a solid foundation to improve transparency surrounding the relationships between industry and healthcare professionals. CHF has no major concerns about the the document. However, CHF has provided comment on aspects of the Transparency Model with the aim of achieving the end goal of better informing healthcare consumers and the Australian public. Consumers should have access to all the information necessary to allow them to decide for themselves what the drivers of their healthcare professional's prescribing behaviour might be.

### Section 1, General Requirements; and Section 2, Limitations

*Limited Application of the Transparency Model*
CHF acknowledges that MA's remit extends only to prescription medicines, and that the Transparency Model, although drafted to be relevant and applicable to all therapeutic companies, only applies to payments or transfers of value from MA members and only for prescription medicines. This creates a situation where companies that are not MA members can continue to make payments or provide incentives to healthcare professionals in attempts to influence prescribing and dispensing behaviour.

This limitation also allows MA member companies that market over-the-counter (OTC) and complementary medicines to continue providing transfers of value to healthcare professionals, without the need to report them, if they relate to these medicine types.

**Recommendation**

10. To ensure companies are not utilising other channels to circumvent transparency, payments and transfers of value relating to OTC and complementary medicines in the years following the implementation of the Transparency Model should be monitored.
11. The Code should include a clause which requires MA member companies to adhere to the Code for all aspects of their business. Once the Transparency Model is incorporated into the Code, this would result in the Transparency Model being applicable to MA members' conduct extending beyond prescription medicines.

*Appropriate Oversight Body*
The Discussion Paper provides three options for who should receive and manage the reports arising from MA member companies' reporting of payments or transfers of value to healthcare professionals: MA; the Australian Health Practitioner Regulation Agency (AHPRA); or, the establishment of a separate Foundation, as has occurred in The Netherlands.

Irrespective of the option, the administrative and resource implications for managing the database and oversight of the Transparency Model will be significant. It will therefore need to be adequately funded. It will be important for such an oversight body to be independent of industry. Equally, this body should have the ability to place sanctions and apply penalties to those who submit inaccurate or misleading reporting, or whose conduct is not in the spirit of transparency.

**Recommendation**
12. CHF recommends a separate Foundation be established to have oversight for the activities outlined in the Transparency Model.

**Section 3, Information to be reported**
Section 3 outlines the information that is to be included in the reporting provided by companies. Comments in this section are based on AHPRA allowing its healthcare identifiers (registration numbers) to be used as part as part of the Transparency Model monitoring.

*Subsection 3.3, Identifiers for healthcare professional recipients*
It is important for *all* transfers of value to be recorded so that consumers can obtain a complete picture of the nature of the relationship that their healthcare professional has with companies. Clause 3.3 would permit the AHPRA registration number of the healthcare professional receiving the payment or transfer of value to be left blank, 'indicating the company could not determine one'. This will become problematic if ever there are two or more healthcare professionals who have identical or similar names who happen live in the same locality.

Every effort must be made to assign a payment or transfer of value to a single healthcare professional. Simply allowing a company to leave it blank runs counter to the aims of the Transparency Model. This clause should be amended to make it a requirement for every payment or transfer of value to be recorded against an individual healthcare professional's registration number or, noting that the AHPRA registration number may not be the unique identifier used, whichever other unique identifier is chosen.

**Recommendation**
13. The Transparency Model should not permit the identifier details of healthcare professionals to be left blank on the reporting form. To ensure compliance, a penalty for not providing this information should be applicable to companies.

**Section 3.8, Payments to third parties, including registered charities**
CHF supports subsection 3.8.1, but not 3.8.2 or 3.8.3. Payments to a third party, whether they are charities or other individuals, at the request, designated on behalf of a healthcare professional or without their knowledge, must not be used to avoid transparency requirements. Subsections 3.8.2 and 3.8.3 provide an opportunity for payments or transfers of value to be concealed through third party arrangements.

**Recommendation**
14. All details relating to third party arrangements should be disclosed.

**Section 4, Requirements for payment or other transfers of value related to continuing professional development**

Section 4 provides a narrow list of conditions to be met before payments or transfers of value to healthcare professionals for attending or speaking at a continuing professional development (CPD) program would not be required to be reported. The basic argument underpinning this is that companies would not be able to directly influence or nominate who would receive the payment or transfer of value, so should therefore not have to be recorded against the individual who received it.

However, even though companies would not directly select the healthcare professional, the indirect payment or transfer of value still has the potential to influence healthcare professionals. Section 2.6 of the MA Code prohibits brand name reminders, which are of little monetary value, precisely because of their potential to influence prescribing behaviour. Unless a CPD event in no way advertises who is supporting the attendance of healthcare professionals, then the association between receiving a benefit from a company could still be drawn.

**Recommendation**
15. All payments or transfers of value should be recorded and assigned to individual healthcare professionals. Indirect and direct payments both have the potential to influence prescribing behaviour.

**Comment**
Consumers should be able to determine the level of influence a payment or transfer of value may have on the healthcare professional they visit.

**Section 5, Exclusions from reporting**

Section 5 lists the type of activities that are excluded from reporting requirements. CHF's position is that there are limited circumstances which would warrant exclusion from reporting requirements. 'Onerous administrative requirements' or a purported lack of direct benefit received by a healthcare professional is not an acceptable justification to exclude an activity.

The aim of the model is to increase transparency, and to ensure that consumers have all the information to decide for themselves what may, or may not, be influencing the behaviour of their healthcare professional. Excluding activities from reporting reduces transparency and may allow companies to avoid it. Therefore, it should be permitted only for activities where there is no possible chance that it is information that a consumer would want to know. Further comment is provided below.

*Subsection 5.2*

Subsection 5.2 deals with a threshold amount for reporting and provides two alternatives for comment. While CHF advocates for full disclosure of *all* payments, from the options provided in the Discussion Paper, CHF supports alternative 2 which requires payments or transfers of value less than A$10 not to be recorded and reported, as opposed to alternative 1 which provides a threshold of less than A$25.

A $10 threshold would capture items of low monetary value, such as lunches at a healthcare professional's office, which, of it itself is may not be a significant amount, but when aggregated over

a period of a year could total a substantial figure. The U.S. *Physician Payments Sunshine Act* sets a threshold of $10 and, acknowledging the arguments made by MA member-Company Chief Financial Officers of the incompatibility of implementing overseas systems in Australia, CHF sees no reason why companies in Australia cannot implement this standard. CHF would also support the proposal to review this threshold annually, in line with the Consumer Price Index.

**Recommendation**
16. Of the options proposed, CHF supports alternative 2 which provides a threshold of $10, and for that amount to be reviewed annually in line with the Consumer Price Index.

*Non-hospitality and non-travel costs*
The Discussion Paper discusses whether non-hospitality and non-travel function costs should be allocated as a transfer of value to healthcare professionals who have attended an educational meeting. CHF's concern, which is represented in the Discussion Paper, is that there is a risk that companies might instead shift costs into other costs categories to avoid transparency and disclosing payments made at the individual level.

**Recommendation**
17. Non-hospitality and non-travel costs should be part of the Transparency Model reporting.

*Starter Packs and other items intended to directly benefit consumers*
CHF argues that starter packs and other items which are intended to directly benefit consumers should **not** be excluded from the transparency reporting requirements. While the healthcare professional may not directly receive a benefit from receiving the starter packs or other products, they are arguably still a form of marketing by the company that consumers should be aware of.

Subsection (7.7) of Section 7 of the MA Code states that company representatives must keep records of any request, supply, return and disposal of starter packs for at least three years, and in a way that they are available for inspection by appropriate authorities. Given that companies are already required to keep these records, providing them as part of the Transparency Model reporting should not produce significant additional resource demands for companies.

**Recommendation**
18. Starter packs should be part of the Transparency Model reporting.

*Subsection 5.10*
A dividend or other profit distribution arising from personal ownership or investment interest in a pharmaceutical company or mutual fund received by a healthcare professional should be declared to consumers; however, the transparency model may not be the most appropriate mechanism through which this is done.

**Comment**
Healthcare professionals should disclose personal ownership or investment in a pharmaceutical company to their patients as part of the informed consent process, but this does not necessarily need to occur as part of the Transparency Model reporting process.

*Subsection 5.11*
A transfer of value to a healthcare professional to act as an expert witness in legal or administrative proceedings should **not** be excluded from the transparency model. Payments to healthcare

professionals, for whatever purpose, should be made transparent, recorded and reported. Although the healthcare professional's appearance may come at the request of the court, CHF's concern is that companies could develop relationships with 'preferred' healthcare professionals, resulting in a regular revenue stream from one or more companies.

**Recommendation**

19. Acting as an expert witness in legal or administrative proceedings should be part of the Transparency Model Reporting.

**Section 6, Procedures for electronic submission of reports**

CHF's only comment for this section relates to subsection 6.3.1. Rather than a company not being required to file a report if they made no reportable payments or transfers of value in the previous calendar year, the company should instead file a statement that declares this fact. Apart from this, CHF suggests that the procedures for submission of reports be reviewed within a few months after the first cycle to monitor its effectiveness.

**Recommendations**

20. Companies should be required to file a report which states that they made no reportable payments or transfers of value in the preceding year.
21. A review of the effectiveness of the electronic submission system should be conducted within six months after the first cycle.

**Section 7, Period for review and error correction**

The Discussion Paper proposes a timeframe of 45 days, from 1 March to 15 April of every year, for healthcare professionals to review and correct information about payments or transfers of value made to them by companies. The timeframe for reviewing the information is appropriate. However, to ensure healthcare professionals remain cognisant of their reporting requirements, correspondence should be sent to them at regular periods throughout the year to remind them to keep track of the payments and transfers of value they receive.

Alternatively, rather than only having one reporting period, the Transparency Model could allow for opportunities every quarter-year to allow healthcare professionals to update the system themselves. This would assist healthcare professionals to keep track of the payments or transfers of value on an ongoing basis, rather than being required to recall all of them at once, some of which may have occurred up to a year prior.

**Recommendations**

22. Regular correspondence should be sent to healthcare professionals to remind them about their Transparency Model reporting requirements.
23. The TWG should explore allowing more than one reporting period during a year for healthcare professionals to input their own records of payments or transfers of value.

*Subsection 7.3.4*
To reduce the risk of healthcare professionals disputing the information recorded against their name, the Transparency Model should require any payments or transfers of value to be agreed to in writing, whether that be through a signature on a sign-on sheet or a more formalised document, appropriate to the nature of the payment or transfer of value.

**Recommendation**
24. The Transparency Model should require a company to obtain some form of written declaration from the healthcare professional of having received the payment or transfer of value.

## Conclusion

This submission addressed sections of the Code, focussing on strengthening the guidance, and protecting consumers and their interests, on issues surrounding patient support programs and product familiarisation programs. CHF then provides comments against questions and issues raised in the Discussion Paper, with the aim of further increasing transparency of the payments and transfers of value by pharmaceutical companies to healthcare professionals.

CHF's advice is underpinned by the principle that consumers should have access to all information about the relationship between healthcare professionals and the companies that may be influencing their behaviour, allowing consumers to make their own decision about what acceptable levels of influence are. This submission has highlighted significant barriers to transparency that MA should consider before incorporating the Transparency Model into the Code.

CHF appreciates the opportunity to provide a submission to the *Medicines Australia Code of Conduct Review and Transparency Model Discussion Paper*, and looks forward to providing further input at later stages of its development. If you would like to discuss the issues raised in this submission in more detail, please contact CHF Policy Advisor, Mr Carlo Malaca, on 02 6273 5444 or at c.malca@chf.org.au.

Consumers Health Forum of Australia

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

1. advocating for appropriate and equitable healthcare
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reaches Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.

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