



Submission into the Review of the Medicines  
Australia Code of Conduct 17<sup>th</sup> Edition

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This submission is not confidential.

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## Preamble

Janssen Australia thanks Medicines Australia (MA) for the opportunity to comment on Edition 17 of the Code of Conduct and the proposed transparency model. We also acknowledge and appreciate the efforts of the Transparency Working Group (TWG) in preparing the discussion paper.

Janssen supports the introduction of a model that brings greater transparency to the interactions between the medicines industry and healthcare professionals. We recognise there is a level of community unease regarding these interactions and believe increased transparency will improve public confidence in the medicines industry.

However, Janssen is concerned that the transparency model only applies to the innovator pharmaceutical sector. MA's transparency model will be the first of its kind in Australia and member companies will bear the entire cost and manage any and all issues associated with its introduction. Furthermore, other therapeutic goods companies are unlikely to voluntarily adopt transparency measures and this creates an uneven playing field within the healthcare sector.

The pharmaceutical industry has a valuable and legitimate role in the healthcare sector<sup>1</sup>. Healthcare professionals and Industry work together when conducting research, within organisations, when providing healthcare to the community and in education and training<sup>2</sup>. Janssen believes transparency requirements must be carefully constructed to ensure they do not become onerous and thereby diminish the quality and scope of these interactions.

Given the above, Janssen believes transparency requirements must enable the release of meaningful information whilst minimizing the administration burden on member companies. Janssen prefers a model that focuses on higher cost transactions and we propose that value transfers to individual HCPs be presented in the context of an educational meeting or event to ensure the information is not misinterpreted by the public.

Janssen is largely supportive of the principles of the transparency model. However, we recommend that Medicines Australia reconsiders the model in light of the issues raised in submissions to the review panel. In doing so, Medicines Australia may decide that a phased approach to transparency is more appropriate.

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<sup>1</sup> The Royal Australian College of Physicians (2006), *Guidelines for ethical relationships between physicians and industry*, Third Edition, p.4

<sup>2</sup> Royal Australian College of Physicians (2006), *Guidelines for ethical relationships between physicians and industry*, Third Edition, p.4

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## Part 1: Transparency Model Consultation and Discussion Paper

### General Requirement & Limitations: Scope of the transparency model

There are advantages and disadvantages of the different options for who should receive and publish the transparency reports. If a relevant third party publishes the reports, the data may appear more credible and objective. In addition, this model is more adaptive if other therapeutic goods companies implement transparency measures in the future. Under these circumstances, it is sensible to support this approach.

However, the transparency model will not apply to all therapeutic goods companies and MA members will bear the full costs and responsibilities associated with these measures. Given there is no identifiable commitment or timeframe from other members of the healthcare sector with regards to transparency, we can only assume this is some way off. With this in mind, Janssen sees merit in Medicines Australia receiving and publishing the reports. This will allow MA members to provide the data through established channels and for efficient handling of HCP disputes. Additionally if consumers, HCPs, journalists, or any member of the Australian community raise concerns about the reports, MA is well-positioned to triage queries and respond in a timely manner.

Janssen would prefer Medicines Australia to oversee and manage transparency reporting. Under this proposal, the MA website will need new functionality and there will be staff requirements to support the collection and publishing of data. In this case, Janssen supports engaging a third-party to develop and manage new reporting functionality and ongoing system requirements. Janssen recommends that the data collection and reporting functionality be designed in a way that is adaptable to other systems should the reports be published by a relevant third party, such as AHPRA, in the future.

#### Identifiers for healthcare professionals

A unique identifier is necessary to enable companies to track and monitor value transfers to individual HCPs. Since the Australian Health Practitioner Agency (AHPRA) number is a publically available identifier, Janssen believes it would be an ideal unique and standard HCP identifier. However, Janssen also believes there should be no inferred association between value transfer disclosure and a HCP's professional registration.

To disconnect disclosure requirements from professional registration, Janssen proposes that the identifier be used in a company's Customer Relationship Management (CRM) or other financial systems, but not displayed or linked to any published transparency reports. This will also remove duplication in search functions, as there will be no need for consumers to search

for and enter an AHPRA number into a transparency database. However, consumers will need to search for an HCP using one or more of the following identifiers:

- Full name (as listed on AHPRA Registry)
- Principal title
- Name of principal place of practice
- Address of principal place of practice

Any alternates to the AHPRA number would only lead to increased complexity and a loss of data quality.

### Category of payment or transfer of value

Janssen makes the following suggestions regarding the categories of payments and transfers of value:

1. Categories 'a', 'b', and 'c' be consolidated into two items:
  - Consulting Fee (referring to a part payment for an ongoing service); and,
  - Fee for Service (referring to a one-off transaction).
2. Category 'f) Education' needs further clarification as it is understood that companies need to capture events that are both company sponsored (internal) and non-company sponsored (external).
3. Categories 'd) Travel & Accommodation' and 'e) Food & Beverage' should be removed as individual categories. Instead they should be presented in conjunction with the educational event or meeting they relate to. As single categories, these items do not provide the context necessary for consumers to understand why they were provided nor fairly assess if the amounts were appropriate. If this information is not presented in context, there is a risk these items will be perceived and/or interpreted incorrectly by the media and the public.
4. The model does not stipulate what the online reports will look like. Member companies need clarification on whether or not the reports will show line items (payments line by line) or an aggregate amount for each meeting or education event.

## **Additional Considerations**

The discussion paper states that the categories should be interpreted using the ordinary meaning attributed to each item. However, Janssen is particularly concerned about how the transparency reports will be interpreted by consumers and other stakeholders without provision of a baseline, comparator, and/or any context regarding the meeting or educational event. Janssen recommends that Medicines Australia consider ways to expand on these definitions in order to avoid confusion and misinterpretation of the facts.

Pharmaceutical companies' interactions with HCPs are integral to ensuring the quality use of prescription medicines and optimising patient outcomes. This model proposes that Industry measure the costs or financial transactions associated with the provision of education, yet none of these categories attempt to measure the value of the education provided. Janssen suggests that in future reviews, Medicines Australia consider how the value of the educational content might be measured, in order to ensure the reports reflect the true value of educational events.

## **Payments to third parties, including registered charities**

Janssen does not make any payments to third parties (including and especially charities) at an HCP's request.

## **Requirements for payments or other transfers of value related to continuing professional development programs.**

The MA Code of Conduct currently allows companies to pay for speakers selected by third parties for third-party organised educational events as part of an overall sponsorship. Oftentimes, a third party requests that the sponsoring company pay the HCP directly. In such cases, Janssen states the terms of the sponsorship, including the provision of speaker fees so it is clear that the third-party selected the speaker. Additionally, our internal compliance policies require the execution of a separate agreement with the speaker directly. As such, this will be considered a direct value transfer to a health care professional and according to the principles of this model should be declared.

If the Code is silent or ambiguous on this matter, it is possible that companies will stop such sponsorships or require third-party organizations to receive the overall sponsorship payment and directly pay the HCP. This should be clarified so companies and third-party organizations can manage such requests.

## Reporting Threshold

Janssen recognises this item primarily speaks to hospitality (i.e., meals and beverages) rather than fees for service. Janssen believes there is a need to consider the rationale behind both thresholds as reporting low values would create a significant administrative burden with minimal benefit. Janssen believes that the reporting of low value transfers goes beyond the expectations of the ACCC determination and would be a substantial undertaking that is not feasible in the time frame allowed.

The discussion paper asks companies to consider the practical implications of different reporting thresholds. However, we encourage Medicines Australia to consider the relational and political implications of these proposals. Janssen respects the intelligence and independence of Australia's HCPs, and rejects the premise that an inexpensive coffee or sandwich might cloud clinical judgment.

## Clinical Research

Janssen agrees that the proposed definition adequately defines clinical research activities and that payments associated with these activities be excluded from reporting requirements.

## Starter packs

Janssen rejects the notion that starter packs should be captured as an item of value for HCPs. All doctors are entitled to starter packs if requested for the specific purpose outlined in the MA Code of Conduct. Starter packs benefit individual patients who meet strict prescribing restrictions - not HCPs.

## Procedures for electronic submission of reports

### Preferred option for management of transparency reports

The proposed launch date of 1 January 2015 appears optimistic especially if reporting requirements are confirmed in late 2014. As stated in other submissions, companies might have multiple general ledger and enterprise resource planning systems, which will need to be modified in order to capture the required data. This will require substantial administrative and financial resources. In addition, MA or the third-party tasked with publishing transparency reports will require new website functionality and resources.

Janssen recommends member companies work together to ensure suitable transparency requirements are included in Edition 18 of the MA Code of Conduct. However, Janssen suggests that the actual launch date be extended to allow time for all parties to implement the system and staff requirements.

### **Data dispute timeframes**

Janssen believes the suggested timeframe of giving companies from 31 December to 1 March each year to compile the information is acceptable. In terms of the suggested timeframe of 45 days for HCPs to review the data, we encourage MA to defer to submissions from medical associations and individual healthcare professionals on this matter.

### **Streamlining electronic submission of reports**

To streamline this process, Janssen encourages MA to consider if there is benefit in increasing the frequency from annual to quarterly reporting (as per the current MA Code reporting requirements). Logistically, this allows member companies to aggregate smaller amounts of data more frequently, rather than shouldering the entire reporting burden at the beginning of a new calendar year. This proposal also goes some way in addressing concerns regarding Australian Privacy Principle 13, where individuals (HCPs in this case) have the right to ask what personal information a company holds on them and requires erroneous information be corrected at any time (and therefore, dispute resolution cannot be contained to a 45 day period from 1 March to 15 April).

Finally, there are a number of outstanding questions regarding the procedures for electronic submission of reports and data disputes. Such as, who will be responsible for managing communication with health care professionals? How will the data be organized to facilitate HCP review and access by the general public? How will MA inform consumers that the transparency database is available?

### **Updating the information**

Janssen believes there should be a defined period after which historical data is removed from the website. Janssen supports a period of five years as this is in-step with Australian tax record retention requirements.