Medicines Australia Submission

From: MA CFO Group

18th Code Edition: Transparency model issues

Preamble:

The MA CFO Group will present their views on the practicality of the Transparency Model options through their member companies.

However, such is the importance of these practicalities; the CFO's also wish to make a separate submission to ensure their voice is heard.

Members of the Transparency Working Group and other stakeholders often are not in a position to appreciate the complexity behind some of the recommendations and/ or the implementation timelines required across the member companies.

The Group has addressed six areas of concern and each are more fully described below:

1. Systems implications for each company
2. Consolidated Reporting / Unique Identifier
3. Thresholds
4. Privacy/ Tax/ HCP consent
5. Dispute process
6. Summary of timing issues and recommended next steps.

1. <u>System implications for each company</u>

   There is a misconception that if a member company's HQ organisation has developed systems to allow transparency of HCP interactions, then it is only a matter of 'lift and drop' of that system into Australia.

   The fact is that it is rare for any global organisation to have all markets operating on the same systems.

   - Pfizer US is on SAP, Pfizer Australia is on Oracle ERP, Veeva CRM and Concur Expenses
   - BI in the US & Europe is on SAP, ANZ are on Sun Systems.
   - Sanofi ANZ – Asian hosted SAP not in alignment with its parents European SAP platform, ANZ sales CRM is Stay-in-front Jigsaw whereas Europe is cegedim dendrite.
   - Novartis is using SAP for Finance, Concur for Expenses and Agora as its CRM. Some platforms are multi-country and some are local.

- Takeda is using SAP for Finance, Concur for Expenses and Cegedim for its CRM. Some of which are multi-country and some are Australia specific.

Therefore, the development time for proposed changes will be from a zero base, and that will be dependent on the availability of global resourcing & approval for the relevant systems.

In some cases, three or four systems will have to be changed, all resourced by different global teams. Eg ERP, Expenses, Purchasing and CRM systems.

Due to the investment involved, HQ organisations offshore will not approve development spend until the ACCC has approved the exact requirements which can be scoped. This makes implementation January 1 2015 impossible if the requirements are only finalised in late 2014.

We note that the European (EFPIA) code was approved in June 2013 for a first reporting period of 2015, allowing 18 months for companies to prepare. The EFPIA model also has less reporting requirements than the Sunshine model on which the TWG model is based.

2. <u>Consolidated Reporting/ Unique Identifier</u>

The CFO Working Group's understanding is that the intention of the TWG recommendation is to create a solution whereby:

i) the consumer can search by HCP, and see all transfers of benefit provided by members for the reporting period

ii) HCP's can securely review and dispute their allocated transactions with all member companies.

iii) Transparency reports can be published.

For that to be possible the following must occur:

a) The ACCC has to approve the Code Review Panels' recommendations. Nothing can start at any level until we know what is required.

b) Funding for the development and on-going maintenance of a consolidated platform needs to be agreed.

c) A consolidation platform or central repository has to be scoped, designed and built which provides uniform fields and firm direction on the unique identifier for each HCP. At this stage there is no insight on what that unique identifier will be & how it will be retrieved in a format that can be uploaded into a myriad of global & local systems. Further, a regular update method & timing has to also be found and agreed. This may involve a yet to be determined organisation having to negotiate with multiple companies.

This platform should be managed by a 3rd party (MA, AHPRA, Independent foundation, etc.)

d) Once the method & source of obtaining unique identifiers has been settled, and reporting fields identified, member companies will be in a position to take the user requirements specifications (URS) and commence work on their requirements. This would be in parallel to the building of the central consolidation platform.

e) Companies will need six months post receipt of the URS to do even very basic manual reporting.

3. Thresholds & reportable cost determination

The CFO group supports the higher threshold on the basis that low volume, high value recording and reporting will be a much simpler solution and remove significant administrative burden. If the final requirements are that a low threshold be implemented, a significant amount of time will need to be added to the start date in order to allow our companies to build the systems to capture this data.

4. HCP Consent / Privacy/ Taxation advice

There is a concern from the CFO Group that member companies will be caught up in an expensive and bureaucratic process obtaining, tracking and retaining HCP consents for various interactions.

If there is a general opt out provision for all interactions with a particular member company by a HCP due to privacy or other concerns, that HCP may miss important educational & product information. Ultimately patient care is at risk.

If a HCP chooses to opt in or out by event, there is a burden on the systems and administrative resources of the company to track & retain those directions.

Our recommendation is that the TWG / Code Panel address the privacy issues formerly in this project. It appears guidance has not yet been sought on this despite widespread concern.

The Group recommends Section 3.8 of the recommendations be reviewed from an ATO perspective. The current intent and wording is not optimal from a Tax perspective.

5. Dispute Resolution

The dispute resolution process will likely be onerous. The member companies believe there will be a need to employ additional resources to not only manage the dispute resolution process, but to manage all of the reporting.

This financial and resource burden appears inequitable when not all companies in the industry are bound by the proposed rules. MA should address this with the ACCC to ensure a similar transparency guidelines are put in place across the broader healthcare industry.

6. Summary of timing issues and recommended next steps

The TWG recommendations cannot be delivered within the timelines proposed. This is a commercial reality

Accordingly, the only practical solutions to achieve transparency require the following to be adopted:

a) Acknowledgement that the proposed reporting requirements will take between 18 months and two years for member companies to implement *from* the date of ACCC approval

b) A higher level threshold being adopted or limit the categories to be reported on.

MA to accelerate the draft Code submission timelines to maximise the period between approval and implementation.