



Celgene Pty Ltd
Level 7, 607 St Kilda Road
Melbourne VIC 3004
T +61 3 9539 5500
F +61 3 9539 5566
ABN 42 118 998 771

2nd October 2013

Ms Sophie Hibburd
Code of Conduct Review Panel
Medicines Australia
Level 1, 16 Napier Close
DEAKIN ACT 2600

Re: Celgene Pty Ltd – Submission to Medicines Australia Code of Conduct Review Panel

Dear Ms Hibburd

Thank you for the opportunity to provide comment to the Code of Conduct Review Panel to assist the development of Edition 18 of the Medicines Australia Code of Conduct.

The focus of this submission is on the consideration, development, implementation, monitoring and evaluation of measures intended to provide greater transparency to consumers regarding the interactions between healthcare professionals and the prescription medicines industry.

Celgene maintains the highest standards of ethical conduct in its interactions with healthcare professionals and therefore supports in principle such transparency measures.

Celgene believes that any transparency model should:

- Explicitly recognise the obligation that the pharmaceutical industry has to provide information to, and share knowledge with, healthcare professionals regarding the safe, effective and compliant use of prescription medicines
- Set clear standards and guidelines for interactions between the pharmaceutical industry and healthcare professionals and clearly define exceptions in any transparency model
- Not compromise or limit forums for the sharing of medical and scientific information intended to support better patient treatment and health outcomes
- Demonstrate how the aim of consumers (increased transparency to foster trust and respect between patient and healthcare professional) will be met
- Be compliant with other applicable legislation and regulations including those relating to privacy and taxation
- Utilise an appropriate unique identifier
- Give careful consideration to the potential for unintended consequences, and put in place measures to limit such consequences
- Not be unfeasibly burdensome on industry or healthcare professionals
- Include provision for monitoring, evaluation and amendment
- Include manufacturers of generics and devices
- Allow adequate time for healthcare professionals to review and clarify any information held on them prior to any published reporting
- Not expose individual healthcare professionals or pharmaceutical companies to the risk of litigation

With regard to the process of developing and implementing a transparency model, Celgene suggests the following:

- Medicines Australia should provide opportunities for further consultation with external stakeholders (including representation from organisations that represent health professionals and consumers)
- Medicines Australia should provide opportunities for further consultation within the prescription medicines industry; such forums should be independently facilitated
- Alternative transparency models should be put forward for consideration
- The time frame for development and consideration of transparency models should be increased
- Once a transparency model has been agreed, the time frame for implementation should be increased; consideration could be given to a staged implementation
- Elimination of the current reporting requirements (to be incorporated into the new reporting framework)
- Incorporation of planned monitoring and review of any transparency model following initial implementation

Celgene also wishes consideration to be given to the following:

- Whilst Medicines Australia has the authority to set standards, monitor compliance and impose sanctions for its membership, it does not have the same authority for healthcare professionals and therefore would need to ensure and demonstrate that any commitment provided by representatives of stakeholder organisations to a transparency model has the support of their membership
- Organisations and/or individuals may withdraw from the process if it is too complex, unduly burdensome or has adverse consequences
- Determination of an appropriate body to administer the system and set up appropriate databases and other required infrastructure to administer the system; consideration of how the cost of such administration would be met
- Transparency models adopted internationally should be reviewed to inform the development of local models and to learn what has and has not been successful
- Community standards for other relevant interactions where “transfers of value” may occur should be considered; e.g. interactions with public officials/politicians
- Criteria for measuring the success of transparency measures in achieving their primary purpose should be determined prospectively and used to evaluate the model
- In order to verify the information pertaining to them which is reported by industry, healthcare professionals will need to set up their own systems for tracking their interactions with industry; it is unclear that healthcare professionals will have systems in place to do this in the timeframe proposed

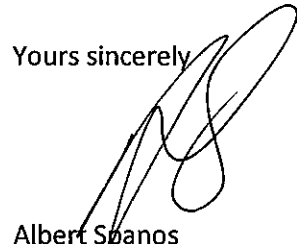
Celgene believes that the transparency model put forward by Medicines Australia/the Transparency Working Group for consideration does not meet the criteria nor address the concerns listed above. Only one model, which is almost a 1:1 adaptation of the American ‘Sunshine Act,’ has been put forward for consideration, and ignores substantial differences from a legislative perspective. Therefore a significant number of problems have already been identified with that model in stakeholder forums and submissions to Medicines Australia. Additionally, whichever model is adopted is likely to impose a substantial administrative burden on industry and healthcare professionals and so a longer timeframe for implementation is suggested.

The fundamental issue remains that the proposed model does not demonstrate that it will clearly and measurably meet the primary aim of providing greater trust and respect between patients and

their healthcare professionals, nor can it guarantee that such benefits will not be diminished by unforeseen negative consequences.

We therefore urge Medicines Australia to give careful consideration to the points Celgene has raised.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Albert Spanos', written over the text 'Yours sincerely'.

Albert Spanos
General Manager, Celgene Pty Ltd