Submission for the Review of the Medicines Australia Code of Conduct and Transparency Model

20 September 2013

sanofi-aventis australia pty ltd trading as Sanofi ABN 31 008 558 807
Talavera Corporate Centre, Building D, 12-24 Talavera Road, Macquarie Park, NSW 2113 -
Tel: +61 (0) 2 8666 2000 – Fax: +61 (0) 2 8666 3000 - www.sanofi.com.au

Preamble

At Sanofi, we believe in an industry that is transparent when interacting with healthcare professionals (HCPs) and the general public.

Our company is committed to promoting and maintaining high standards of Ethics and Governance that are aligned with Medicines Australia's Code of Conduct philosophy and general principles. We endeavour to always uphold and comply with both the spirit and letter of the Medicines Australia Code of Conduct and, in so doing, promote the Quality Use of Medicines and achieve better health outcomes for patients.

The implementation of new processes and systems across such a broad group of stakeholders offers some challenges. In our submission we outline some of these challenges and suggest how our industry can address them.

In conclusion, we believe there is a need to maintain a balance with strong ethical self-regulation that creates an environment in which companies can still succeed as viable business operations. This aligns with the National Medicines Policy (NMP).

Response to the Transparency Model Consultation and Discussion Paper

Outlined below are responses from Sanofi to the Transparency Model Consultation and Discussion Paper.

1. General Requirement: Implementation timelines

Sanofi feels the current timeline suggested for implementation of the transparency model is not sufficient, in particular the period from approval of the model by the ACCC and actual implementation by relevant parties.

For Sanofi's part, the administration of the model would require a custom built solution which isn't currently available either locally or globally. In addition, like many other member companies and healthcare stakeholders, this would require our company to scope out the actual project, allocate sufficient resources, and gain funding approvals. This is not possible until the actual model is approved; hence the need for a longer time for implementation.

We propose we would need a minimum of 18 months from the date the ACCC authorises the new Code and transparency model in order to implement the changes for recording of data and subsequently reporting.

2. Limitations

Sanofi does not wish to propose any changes for this section of the proposed model.

3. Information to be reported

Unique identifier for reporting purposes
In order to record and report on interactions with HCPs, a unique identifier needs to be attributed to each individual. This way a member of the public would be able to have a single reference point when accessing reporting for interactions their HCP has with healthcare companies.

Based on the stakeholder consultations conducted by Medicines Australia, and attended by HCP groups and industry representatives, it's apparent a consensus hasn't been reached on how to apply this identifier.

For example, one option proposed was to use the Australian Health Practitioner Regulation Agency (AHPRA) registration number. However, major concerns regarding the viability of this approach were voiced by HCP group representatives in attendance at stakeholder consultations.

Until such a consensus is reached, it isn't possible for companies such as ours to develop systems and processes that would be able to use this unique identifier. Therefore, in line with our previous comments on implementation timelines, this will influence the timelines on the implementation of the new Code and transparency model.

Privacy and taxation
In line with Privacy Legislation Amendment from March 2014, Sanofi is concerned there has not been sufficient legal consultation with relevant experts on the impact of the transparency model.

Similarly the implications of taxation are not fully understood at this stage. Sanofi recommends the Code Panel address the main issues on privacy, taxation and unique identifier prior to the commencement of any collection of individual data.

Provisions should be made on the development of a process on obtaining consent from individual HCPs for

the purposes of disclosure that is consistent across the industry. This removes ambiguity, as well as ensures any dispute on the data reported is minimised.

Section 3.5 Date of payment or transfer of value
We recommend this is changed to be the date of transfer of value rather than the date that payment is made, as this is generally after the actual engagement.

Section 3.7 Category of payment or transfer of value
We agree categories A-K sufficiently cover the types of payment that should be reported.

In addition, Sanofi seeks to understand what consideration Medicines Australia gave to attributing a transfer of value to HCP attendees at sponsored educational events during this consultation process.

This is currently reported as aggregated data under educational event reporting. Should a value for these events have to be attributed to individual HCPs in attendance, then this will add unnecessary complexities for little overall information. This is particularly the case for sponsored third party educational events where member companies have no immediate visibility and record of the HCPs in attendance.

4. Requirements for payments of other transfers of value related to CPD programs

Continuing professional development programs are vital for HCPs to keep up to date with their education and improving patient care. Sanofi believes it is important to exclude payments or transfers of value associated with formal independent CPD programs, as outlined in the transparency consultation paper. The provision of grants to third party professional development program organisers or medical education providers should not be reportable provided the company has no role in influencing the educational content, selecting the speakers or attendees.

5. Exclusions from reporting

Sanofi proposes the recording threshold of $25 and reporting annual cumulative threshold of $250.

We agree starter packs that are provided solely for patient use and not intended to be sold, should be excluded from any reporting requirement.

In addition, we agree clinical research and payment to expert witnesses in legal and administrative proceedings should be excluded as outlined in the consultation paper.

Finally, we do not agree that function costs (e.g. non-hospitality and non-travel costs) such as audio-visual and room hire costs should be recorded and reported for attending HCPs. We believe such costs do not represent a transfer of value to HCPs.

6. Procedures for electronic submission of reports

Sanofi requests clarity be given where meetings are sponsored by multiple companies (e.g. post conference educational meeting sponsored by four companies) and how the cost of related hospitality should be reported. In particular, would a report on the proportion of the cost be applied resulting in the need for the individual HCP to validate four separate reports for a single event?

Sanofi recommends the Code Panel to investigate the feasibility of an industry centralised cloud-based reporting system where all activities are recorded. This will allow for the HCP review and validation process for potential disputes and corrections.

Proposal for Amendments to the Medicines Australia Code of Conduct

The following points concern suggested updates to the current Edition 17 of the Code. We are proposing these to allow for better understanding for member companies and to reflect changes in the current Australian environment.

Relationship and Interactions with Patients

Section 17: Patient Aids

Patients, their families and carers increasingly refer to digital tools, such as the internet and social media as a source of information for support and management of various disease states. Sanofi requests this be recognised in the Code to improve the reliability of information for patients, particularly those with chronic conditions.

Sanofi proposes changes to Section 17 to include the following:

Patient aids that are product specific must be solely intended to provide information for the patient once a decision to prescribe that product has been made. Patient aids could include password protected websites providing product specific information or social media forums with restricted access.

New Section 19: Market Research with Patients

Sanofi proposes a new section outlining the requirements on market research undertaken with patients already prescribed a product to provide a distinction to Section 13 of the Code, which focuses generally on relationship with the general public. The suggested text is as follows:

The sole purpose of market research undertaken with patients must be to collect data and insights to enhance better health outcomes and quality use of medicines. As patients have been prescribed the medicine, specific questions related to the product may form part of the market research to better understand unmet needs of patients, provided they are not promotional.

Any market research undertaken by a company or contracted organisation with patients must comply with the Australian Market and Social Research Society Code of Professional Behaviour.

Any payment (whether cash or voucher in lieu of cash) must be kept to a minimum and should not exceed a level commensurate with the time involved.