Submission to the Medicines Australia (MA) Code of Conduct (18th Edition) Review

Medicines Australia
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26 September 2013

Roche Products Pty Limited

Background

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics.

Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammatory and autoimmune diseases, metabolism and central nervous system.

Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management.

Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients.

In 2012, Roche invested over 8 billion Swiss francs in research and development worldwide, including approximately $36 million (AUD) in pharmaceuticals in Australia.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

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Overview

Roche is happy to provide this submission with respect to the development of the 18th Edition of the Medicines Australia (MA) Code of Conduct (the **Code**). Our submission is focussed on the issues related to the transparency model as provided by the Transparency Working Group (**TWG**).

Roche is supportive of the principles of providing transparency and would be supportive of meaningful changes to the Code if it will improve the levels of transparency associated with industry dealings with healthcare professionals (**HCPs**) and the general Australian community. However, we believe the proposed model does not meet this objective.

Roche has significant concerns about particular elements of the transparency model, in particular, that the current privacy legislation restrictions (e.g. right to not provide consent or have personal information deleted) have an overwhelming impact on the ability to deliver on the expected reporting process in the desired timeframes. To achieve the desired level of disclosure Roche assumes it would require changes to legislation, which, historically has seen to take some time to execute. It would therefore be Roche's view that the proposed timeline to deliver the disclosure by 2015 is unachievable based on this issue alone.

The model proposed is imbalanced in terms of costs and benefits. It is costly and complex for companies to establish and operate systems and train and educate staff. The dollar threshold proposed is so low that it is arguably of little benefit to the community of being publicly reported.

There are substantial unanswered issues associated with the taxation impact on HCPs who are engaged with industry either as consultants or as participants in medical education. Often they receive no direct financial benefit but the proposed model would attribute a financial value based on the cost of executing an event or engagement.

Roche doubts the viability of the proposed reporting process and the ability of HCPs to accurately verify the financial transactions between potentially many pharmaceutical companies and HCPs within the given timeframes.

Transparency should not be limited to the prescription sector of the health industry. We do not believe the public's interest is served with a model that lacks reliability and transparency across the health sector as a whole.

Roche strongly believes that MA must obtain independent legal advice on the privacy and taxation concerns as a matter of urgency before this review of the Code progresses any further.

General concerns

Roche has significant concerns that the delivery of the TWG proposed model in Australia appears to be a near 100% extraction from the Sunshine Act in the US. There needs to be greater review and due diligence paid to ensuring that the local conditions are appropriately considered rather than wholesale adoption of the elements of a transparency model designed for the US market.

The adoption of a legislated model from the US is significantly different to an application of a transparency model within a self-regulatory process in Australia. We believe a significant proportion of stakeholders may reject the validity and practicality of implementing the proposed model, with the unfortunate result that HCPs may refuse to participate and member companies unable to report the information the model calls for. Roche would strongly recommend that review of other similar models from Europe be evaluated as a matter of urgency.

Also a concern is the perceived imbalance of "ownership" of the disclosure requirements set out by the TWG. Roche believes that industry, HCPs and government must equally input into the process, as well as take accountability for the implementation of potential solutions.

To achieve the community's desire for uniform transparency, Roche believes that the model must extend to all providers of prescription medicines or commercial medical services, not just innovative pharmaceutical companies which are members of MA.

Custody and publication of data

There are significant issues as to how unique identifiers can be generated and attributed to all HCPs in Australia. HCPs have expressed concerns about the utilisation of the Australian Health Practitioner Regulation Agency (AHPRA) number being made available and associated with items not specifically related to HCP registrations.

Roche suggests that the already established reporting processes (for medical education, etc.) could continue to be managed by MA for the HCP transparency component. However, it will require a considerable financial investment for infrastructure and human resources to manage a high data load. Roche believes this financial impact should not be borne entirely by the membership.

Roche also believes that transparency must extend to all providers of prescription medicines or commercial medical services. Therefore, a centralised collection and reporting facility would be a logical option to reduce administrative burden on both companies and HCPs.

Roche does not support a model where industry will be expected to provide significant funds to external program administrators due to high overhead expense to operate the model.

Roche would propose that an independent site could be overseen by the Australian Competition and Consumer Commission (ACCC) or a similar Government agency. In these circumstances there should be a low or nil cost to the industry as this requirement would need to be underwritten by the Commonwealth.

Roche does not support the establishment of a Foundation without clarification of how it would be structured and funded.

Roche would seek a fully independent board for all decision processes. Any penalties processes must be 100% impartial in its deliberations.

Legal issues as to the ability to collect and report under current legislation

Roche believes there are significant unanswered questions with respect to the legality of collecting and reporting the required information where the individual HCP's details are to be fully exposed under the provisions of the current Privacy Act.

Without changes to current legislation, HCPs may exercise their right to refuse to have this information collected or published, which would be a failure for the model. If member companies proceed with disclosing such information after HCPs have "opted out", it may amount to a breach of the Privacy Act (assuming a relevant exemption does not apply). However, if member companies do not disclose the information, they may be found in breach of the Code. To achieve the desired level of disclosure Roche assumes it would require changes to legislation, which, historically has seen to take some time to execute. It would therefore be Roche's view that the proposed timeline to deliver the disclosure by 2015 is unachievable based on this issue alone.

Roche strongly believes that MA must obtain independent legal advice on the privacy concerns as a matter of urgency.

Data collection – payments and transfers of value

Roche believes that prior to progressing to a reporting model, clarity is required as to the processes that will need to be developed to be able to deliver realistic reporting associated with financial or value transfers. For example:

- When financial or value transfers are provided as a grant to a faculty or institution (third party), how are they then attributed to individuals?
- What criteria should be used to determine value of a company employee who supports projects with personal time?

- How would value be applied to interns/residents/registrars who attend Journal Clubs or Grand Rounds due to the company being unable to identify attendees' names?
- What processes will be put in place to ensure that the HCP is able to verify the value of every transaction between a pharmaceutical provider and the individual or practice?

Nominated categories for reporting

The categorisation provided by the TWG is identical to that provided within the Sunshine Act in the US. Roche does not believe that there has been adequate examination by the TWG with respect to the Australian market conditions. Roche calls for and supports a simplification of the reporting processes to be in line with similar and effective models that are being rolled out in other countries.

As examples:

Annualised reporting base on an aggregate report for each HCP.

A limited category list for each report to include:

- Medical education (including hospitality)
- Sponsorships and registration fees
- Fees for service (consultancies, advisory boards, speaker services etc.)
- Grants/donations

Roche believes that these conditions will fully meet the expectations for transparency of the financial and value transfers to an individual HCP. Roche believes it is impracticable to dissect expenses to the proposed fine degree, and that this does not add value to the objective.

Payments to third parties including registered charities

Roche does not support the allocation of value to a specific HCP for funds that are donated to charities. Such declaration goes against the intent of providing transparency about the value/financial benefit that an HCP has received. A donation to a charity does not provide a "financial" benefit to the HCP.

Roche sees a significant difficulty in accurately allocating a particular sum to a particular HCP when a grant is provided to a third party (e.g., medical institution). Most often, the institution controls the proportional allocation of the funds which is not visible to the company.

Roche supports the exemption of payments or other transfers of value related to continuing professional development programs. Roche believes that a similar level of value of education is also achieved when attending national and international, college- or academically-run congresses Roche finds it hard to distinguish the differences in these two areas of medical education.

Threshold for reporting of financial/value transfers

Roche does not support either threshold proposed by the model in terms of individual event reporting, as they are imbalanced in terms of costs and benefits. As an alternative, Roche would support aggregated expenditure and value transfer reporting, provided it was on an annual basis.

If it were to come to a position where alternatives are not considered, Roche would opt for the $25 threshold proposed by the TWG. This is on the basis of the cost impact of reporting at the $10 level would be disproportionately higher to the $25 threshold. The lower level could include trivial expenditure which would be a costly time investment to capture and report.

Medical education event logistics allocation

The TWG has proposed that the costs associated with hire of a venue or equipment to conduct medical education events be assigned as a percentage to each of the attending HCPs. Roche opposes this on the basis that these costs do not provide any direct financial or value transfer to the HCP, but rather are a general cost of conducting business by the pharmaceutical provider.

Alteration of the threshold on an annual basis in line with the changes to the Consumer Price Index (CPI)

Roche supports the use of CPI as a benchmark of changing thresholds for reporting; however, its application annually is impracticable. Roche suggests that any changes to match CPI be brought into line with timing to changes to the Code, approximately every three years.

Starter pack reporting

Roche does not support the notion that starter packs provide value transfer to HCPs, but rather that starter packs are a value transfer to the patient.

Legal testimony – expert testimony

Roche supports the proposal to exclude payments for expert witnesses as it considers expert testimony as an independent and impartial act conducted by the HCP for the benefit of the greater legal system.

Reporting logistics

As proposed, there are issues with the ability of companies to effectively gather correct information, for HCPs to be able to accurately verify each transaction easily and quickly, and for reporting to be clear for the end users. Roche believes that accountability for financial costs and administrative tasks related to reporting should be kept to a minimum, and that they should be spread equally amongst relevant stakeholders.

The proposed 45-day window for HCPs to verify reports from various companies is not workable; especially if HCPs are expected to review transactions from several companies at the same time, or via several different systems. Currently, there are no standard mechanisms for HCPs to accurately and quickly verify transactions in a standard format. This may negatively affect the delivery of care to patients due to administrative demands on the HCP. Additionally, the process and timelines for dispute resolution need to be taken into account so that reporting delays aren't drawn out.

Penalties

With the participation of other industry regulators, there must be equity in consideration, value and delivery of any penalties.

Roche agrees that the penalty determination would be most appropriately delivered by the MA Code of Conduct Committee. This would be delivered with a clear guide as to the penalty value for each breach level.

Under current privacy legislation, there is the risk of double penalties being issued should the Privacy Commissioner decide to take action as well as the MA Code Committee when companies report/not report information about individual HCPs.

Publication of reports even where there are disputed claims

Roche does not support the publication of any circumstances where there is a dispute as to the value or funds that were involved in a transaction with an HCP.

Roche believes that there is significant risk to the reputation of the HCP and/or the pharmaceutical company if unresolved/ongoing issues are published.

Other requests for consideration by the Code Review Committee

There are significant areas of uncertainty with respect to the applicability of certain articles of the Code when being applied to members of medical teams who are associated with clinical trials and other non-commercial elements of the business.

It would be useful if the Committee could make note of where there may be changes to the Code requirements in these kinds of circumstance.

Conclusion

Roche is supportive of the principles of providing transparency and would be supportive of meaningful changes to the Code if it will improve the levels of transparency associated with industry dealings with HCPs and the general Australian community. However, Roche strongly argues that the model for transparency proposed by the TWG is unworkable in its current format.

There are large and difficult issues associated with privacy, data collection, reporting and legal liabilities within the model as presented. It will also require a substantial investment by each company and the reporting body to provide the needed infrastructure to deliver on the model, in the timeframe required. Roche notes that these issues have been similarly expressed by other MA members, and the company is concerned that they may negatively impact membership if left unresolved.

While Roche does not support this particular model proposed by the TWG, the company would be open to consultation around other alternatives when developed.