

## Post-Print

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# Eliciting views of Australian pharmaceutical industry employees on collaboration and the concept of Quality Use of Medicines

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## ABSTRACT

**Background:** Pharmaceutical industry involvement in biomedicine has produced major benefits but has also caused concern. At present, there is no consensus as to how medical and government organizations should relate to the pharmaceutical industry and this is partly due to the absence of systematic study of the various alternatives. In Australia industry cooperation has been elicited via the “Quality Use of Medicines” framework within the “National Medicines Policy”. Little is known about the way employees of pharmaceutical companies respond to the QUM policy and strategies.

**Aims:** We aimed to examine the engagement of the Australian pharmaceutical industry with QUM with a view to assisting medical, government and consumer organisations who may wish to collaborate with industry.

**Methods:** We carried out a qualitative study using in-depth, semi-structured interviews with industry employees, primarily from medical and regulatory affairs departments.

**Results:** Employees of pharmaceutical companies claim that collaboration is important, and that they are altruistic and committed to QUM. At the same time, there is little evidence from this study to support the notion that QUM has brought about structural changes to industry or is positioned as the central goal or framework in designing a company’s operational strategies. Moreover, there is a significant degree of ambivalence towards governments and medical organisations.

**Conclusions:** Employees within the pharmaceutical industry claim a commitment to collaboration and QUM. While these claims cannot be taken entirely at face value, there is potential for meaningful collaboration with industry.

## Keywords

Pharmaceutical industry

Pharmaceutical ethics

Quality of healthcare

Health policy

Pharmacology

## INTRODUCTION

### Background

Medicines have made, and continue to make, major contributions to improving individual and public health. But medicines can also cause significant harm, and it is crucial that any new or established therapy is truly an advance over existing therapy; is safe and effective; is marketed, priced, prescribed and used appropriately; and is monitored to establish long-term benefits and harms, cost-effectiveness and impact upon quality of life. This way of thinking about medicines has recently been elucidated in the “Quality Use of Medicines” framework within the Australian government’s National Medicines Policy (NMP), which emphasises the degree to which all of the above activities are both necessary and interdependent<sup>1,2</sup>.

The pharmaceutical industry is responsible for many of the above activities, and the perceived importance of the pharmaceutical industry is evident in the increasing number and variety of alliances between researchers, clinicians, government bodies and the pharmaceutical industry. The National Medicines Policy, for example, has among its central objectives the need to maintain a responsible and viable medicines industry<sup>1</sup>. Medical organizations such as the Royal Australasian College of Physicians (RACP) also acknowledge that health professionals work with industry in a variety of situations and that industry has a valuable and legitimate role in the health care sector<sup>3</sup>.

While effective collaboration with the pharmaceutical industry is highly desirable, the interests of pharmaceutical companies are fundamentally different from those of clinicians, academic researchers, patients and policymakers. In recent years, a number of concerns have been raised about activities of pharmaceutical industry including: the tendency to fund studies that are likely to enhance profits rather than be innovative, and which tend to be relevant and accessible to only the wealthiest people in the wealthiest countries (the “90-10 divide”)<sup>4</sup>; the exploitation of vulnerable research populations, particularly in the developing world<sup>5</sup>; the influence that industry has over academic researchers and clinicians and government organizations<sup>6</sup>; and the techniques used to market medicines to consumers<sup>7,8</sup>.

In response to such concerns, organisations such as the RACP and the World Health Organization have developed guidelines for interactions with the pharmaceutical industry<sup>3,9</sup>. Medicines Australia (the peak body representing the interests of prescription pharmaceutical manufacturers in Australia) has also developed a Code of Conduct in response to professional and community consultation which has undergone many revisions and continues to be developed (Edition 16 has recently been approved by the ACCC)<sup>10</sup>.

### Rationale for this study

In order for such policies to be effective, and in order to maximise the potential benefits of engagement with the pharmaceutical industry, it is vitally important that we have a sophisticated understanding of the issues at stake. At present, however, debates about pharmaceutical involvement in biomedicine have a polarizing quality, with people tending to take strong pro- or anti-industry positions. Because debates about the influence of the pharmaceutical industry tend to be characterised more by passion and polemic than by

reasoned study, there has been limited consideration given to the range of policy, regulatory and clinical responses to issues raised by the participation of the pharmaceutical industry in medicine.

In Australia, the Commonwealth Government takes the view that pharmaceutical industry activities are best mediated through both voluntary collaboration and regulation. In particular, the pharmaceutical industry is seen to have a key role to play in achieving Quality Use of Medicines and is expected to participate in implementing the “National Strategy for Quality Use of Medicines”<sup>2</sup>.

QUM comprises three principles which address the effective, safe and cost-efficient use of medicines: 1) selecting management options wisely; 2) choosing suitable medicines if a medicine is considered necessary and 3) using medicines safely and effectively. This means that the pharmaceutical industry is expected to contribute not only to the development and testing of medicines, but also to their safe and effective use. A recent development in this regard is that demonstration of compliance with QUM is now a prerequisite for listing medicines on the national Pharmaceutical Benefits Scheme, reflecting the government’s growing emphasis on “purchasing” QUM outcomes<sup>11</sup>.

These efforts to engage the pharmaceutical industry in QUM are based on the assumption that individual companies are committed to QUM, even when it threatens their commercial “bottom line”. While this is an appealing notion, the question of whether or not industry is willing and able to engage in truly collaborate activity is ultimately an empirical one. While studies have been conducted into the effects of QUM on prescribing<sup>12-14</sup> we do not know how industry has responded to QUM. We set out, therefore, to examine the engagement of the Australian pharmaceutical industry with the QUM policy and strategy.

## **METHODS**

We carried out a qualitative study using in-depth, semi-structured interviews with a range of pharmaceutical industry employees. The goal of sampling was to obtain a wide range of responses and opinions, so we used “snowball sampling” to recruit professional staff from various departments and across different seniority levels in different types of pharmaceutical companies. While we interviewed people from all departments (sales, marketing, medical, regulatory affairs and executive), the majority of volunteers came from medical and regulatory/public affairs and we chose to focus on these departments because they have primary responsibility for ensuring adherence to promotional standards as well as to aspects of QUM. Eleven companies were represented: six were innovative multinational companies, four were generic producers (both Australian and multinational) and one company produced non-prescription (complementary) medicines.

Participants were asked about their understanding of, and attitudes towards QUM, with questions being open-ended in order to elicit a depth of response that might reveal detailed and possibly unanticipated viewpoints. Emergent themes were grouped together into analytic categories and developed into more abstract “concepts.” Although thematic saturation was

reached after approximately fifteen interviews (that is, no novel issues emerged), a total of twenty four interviews were completed to cover the range of respondents from whom we wanted to hear. Interviews were analysed independently by two researchers.

Ethics approval was obtained from the research ethics committee at St Vincent's Hospital, Sydney and UNSW Human Subjects Protection Committee.

## **RESULTS**

Twenty four interviews were carried out with Australian employees of 11 largely multinational pharmaceutical companies. Demographic characteristics of the participants are shown (Table 1). Our results suggest that pharmaceutical company employees show signs of both acceptance of, and resistance to, QUM.

### **Signs of acceptance of QUM**

#### *Awareness, understanding and integration of QUM*

Without exception, study participants described themselves as being personally aware and having a good understanding of QUM. When asked to elaborate on their understanding, participants demonstrated both a general understanding of the goal of QUM ("the right drug, for the right patient, at the right time") and a sense of how QUM is expressed and enacted in their particular department. All participants agreed that QUM is important. QUM was described as a "framework" or "context" within which all company decisions are made and as a set of principles that are "embedded" and "integrated" into everyday pharmaceutical practice. [see Box 1.1]. Interestingly, these principles were seen by some to be learned implicitly, understood tacitly and applied unconsciously, such that integration did not require knowledge of the particular "QUM" phrase or policy (and may even have preceded the formal implementation of the policy) [1.2].

#### *Willingness to collaborate with government in implementing QUM*

Participants had a number of ideas as to how pharmaceutical compliance with QUM might be improved. They argued both for more industry self-regulation (with a view to harnessing the power of commercial competition as a regulatory mechanism) as well as more collaboration and coordination among stakeholders. Governments were seen to have an important role in educating both the pharmaceutical industry and prescribers and in coordinating shared industry-government post-marketing surveillance.

### **Reasons for acceptance of QUM**

The acceptance of QUM appeared, in turn, to be underpinned by personal and corporate identification with QUM, and by association of QUM with both altruism and commercial self-interest.

### *Identification with QUM*

At the corporate level, QUM was described as “what we do;” as “the reason we are here;” and as what a company “represents” in terms of its “mission”, “principles”, “values” and “philosophy.” Indeed, for some companies, commitment to QUM was seen as a kind of rite of passage and a measure of whether somebody is an appropriate company employee. Identification with QUM was described also at the personal level, with participants seeing QUM as intrinsic not only to their current roles and responsibilities, but also to their “pre-corporate” identities as doctors, pharmacists and researchers [1.3].

### *Altruism*

The desire to be altruistic appeared to be another key driver of acceptance of QUM, and it was argued repeatedly that people who work for pharmaceutical companies, and even the companies themselves, are concerned not only about money, but also about contributing to individual and population health [1.4]. Many participants noted that QUM activities, and the need to focus on “total health care” take time, require commercial sacrifice, and demand effort, moderation, leadership and a willingness to tolerate criticism.

### *Commercial self-interest*

At the same time, uptake of QUM was explained on the basis of company self-interest, with almost all participants observing that the application of QUM can lead to *both* improved clinical and economic outcomes *and* increased industry credibility, which ultimately impacts positively on the commercial “bottom line” [1.5].

## **Box 1. Illustrations of acceptance**

**1.1** I think we are getting to a stage that, QUM is not this ‘add on’ bit you might think it is. It is actually a way of working so that the QUM is embedded in the operational strategies of the company that everything I do, or in medical and marketing, that we do understanding QUM principles. It’s just the way of how we work and it is not something separated. [#22 External relations]

**1.2** I can’t think of anyone in the company that you would be able to go to them and say, ‘what you advocating is not QUM.’ So I think it’s very broadly and implicitly there but possibly not explicitly. [#23 Public affairs and policy]

**1.3** Interviewer: How important is [QUM] overall to you?

Participant: To me personally, it is very important. I think to be that’s because I have never put my physician hat off. Having worked for 10 years as clinician, I haven’t forgotten what that means to patients so that every decision that I make, every interactions that I have whether I consciously think about QUM or not, it’s always there. [#15 Medical advisor]

**1.4** I keep coming back to the theme that the reason we are here is to improve the health

outcome and that's for everybody, the doctors, the pharmacists, nurses and everybody here. That's the bottom line. [#21 Cooperative affairs]

**1.5** I think it is important if you want to get long term appropriate use. Say, we have sales spike for 3 months followed by a big dip. It's not our interest. We want long-term sales. To do that you have to be credible you have to be appropriate, which means QUM.[#9 Medical director]

### **Signs of resistance to QUM**

At the same time, there was evidence of resistance to QUM, in the form of both divisions within companies, and deeper ambivalence pervading the whole company.

#### *Divisions within the company*

While most participants described *themselves* as being deeply committed to QUM, most acknowledged that the same could not be said of their colleagues in sales and marketing. This led many participants to admit that they lacked power within their companies and that they could not assume collaboration among all of their colleagues. They also reflected on the need for significant cultural change and/or strict internal regulatory controls as well as incentives and "checks and balances" to ensure that sales priorities did not entirely override QUM concerns.

#### *Pervasive ambivalence*

There is nothing surprising about the finding that people in sales and marketing departments may lack commitment to QUM, but close questioning and analysis revealed a significant degree of ambivalence even among our participants. In contrast to claims of identification and altruism, participants also described QUM as something "forced" upon them through external regulation or by competition from other companies. Ambivalence was evident also in some participants' focus on the need to be rewarded for compliance and punished for non-compliance. While not incompatible with altruism and a genuine acceptance of QUM, this focus on compliance and incentives does suggest that some individuals and companies may be motivated more by external rewards and/or punishments than by intrinsic commitment to QUM.

### **Reasons for resistance to QUM**

Resistance to QUM among those in sales and marketing was not difficult to explain, and was attributed to a number of factors ranging from a simple lack of awareness or understanding

(perhaps because of non-medical backgrounds) [2.1] to deeply conflicting commercial priorities. The more pervasive ambivalence expressed by our participants appeared to have a more subtle basis, arising from both mistrust of other stakeholders and a sense of disempowerment.

#### *Mistrust of other stakeholders*

Mistrust of government was pervasive, and the government was seen to be, at best, well intended but under-resourced or faced with conflicting priorities and, at worst, closed-minded, biased and short sighted in its commitment to cost-cutting. This was frequently attributed to cost-shifting caused by the split in Australia between Federal and State health systems. There was a sense that the government is a competitor rather than a collaborator, and is not truly committed to QUM, and this was noted to be a powerful barrier to collaboration [2.2]. This mistrust of government was, in turn, embedded in a more general mistrust of other pharmaceutical companies (which were seen to be less committed to QUM) and of non-industry stakeholders. Even doctors and pharmacists were seen by participants to lack an understanding of, and genuine commitment to QUM. Taking a particularly pessimistic view, some participants argued that QUM is merely rhetoric and that *nobody* in the current health system can be trusted to advocate for patients [2.3].

#### *Disempowerment*

This mistrust of other stakeholders was accompanied by a pervasive sense of disempowerment, and it was frequently noted that the ultimate power to implement QUM lay with governments and clinicians rather than with industry. Several participants expressed frustration that their companies' efforts to implement QUM were frequently thwarted by poor clinical practice [2.4], while only one participant argued that the industry might have some responsibility for ensuring QUM [2.5]. Disempowerment also manifested itself also in frequent complaints about being misunderstood and mistreated, and medical organisations and governments were seen to be overtly "hostile" or "antagonistic" towards the pharmaceutical industry, failing to acknowledge that industry can contribute to health outcomes [2.6].

Taken together, this sense of mistrust and disempowerment provides an explanation for ambivalence towards QUM even among those who claimed to be convinced of its importance.

#### **Box 2: Illustrations of resistance**

**2.1** Interviewer: What are the major reasons that there's a spectrum of understanding?

Participant: Because I suppose it is not something that you necessarily learn when you learn about marketing and sales...In the older days, we used to call it 'rational use of medicines' and then it kind of made more sense for a lot of people, but, what does quality use of medicines mean? It's not intuitive for some people.[#8 Managing Director]

**2.2** In terms of PBS, there's certain amount of money in the pool, you'll have to spend it as effectively as possible. But you see in some of the medications, where patients are being deprived, medications can really improve their quality of life. [#3 Education]

- 2.3** You know, what do doctors get paid for? They get paid to see patients; what do pharmacists get paid? They get paid for providing prescriptions; what do we get paid? We get paid to supply drugs. There's nobody advocating for the patients to make sure they get those drugs at the right time at a right dose. [#10 Pricing and reimbursement]
- 2.4** [Doctors] would tend to rely on the information provided by the [government]. They argue that they are independent and of course doctors will believe what they read in newspapers, which is um, often not the whole truth. [#1 Medical Affairs]
- 2.5** I don't think it's up to the minister of health to solve the problem. I've been the company for many years and they are still making the same mistake. Like, they don't get their dosing range right. They put the drug onto the market for a couple of years, and you realise you should be using only half of the dose. To me that's poor science. And that happens again and again and again. [#14 Medical Affairs]
- 2.6** One of the issues that I find is the criticism that the industry [is] caught [in] all the time. There seems to be a lack of genuineness in wanting to work with us. We get criticised for how we promote our product. That's fair enough. But there are very few stakeholders seem to be willing to work with us...That's one of the biggest issues, we've always been criticised. [#22 External relations]

## DISCUSSION

### Summary of key findings

Our findings suggest that employees of pharmaceutical companies see collaboration with other stakeholders as important, and see themselves as being altruistic and deeply committed to QUM. At the same time, there is little evidence from this study to support the notion that QUM has brought about structural changes to industry or is positioned as the central goal or framework in designing a company's operational strategies. Moreover, there is a significant degree of ambivalence towards QUM. Taken together, these findings suggest that uptake of QUM is far from perfect and that the "collaboration" is infused with issues of power and vulnerability; trust and mistrust; altruism, self-interest and coercion.

### Strengths and weaknesses

This study is, to our knowledge, the first systematic empirical exploration of the attitudes of pharmaceutical company employees towards industry-government collaboration around a QUM strategy within a national medicines policy. This study has three limitations. First, this is a small qualitative study which aimed for depth and variety of responses rather than for generalisability. Our numbers were also not sufficiently large to draw conclusions about differences in uptake of QUM between innovative companies, companies producing generic medicines and companies producing non-prescription or complementary medicines (it could be



hypothesized that it would be easier for producers of generic medicines to comply with QUM because they do not face the same pressures as innovative companies do to recoup investment). Second, our participants were primarily from medical and regulatory affairs departments and, as our results suggest, cannot necessarily be generalised to other pharmaceutical company employees. Third, this is a study of attitudes rather than outcomes and therefore does not tell us how pharmaceutical company practice has been affected by the QUM strategy, and whether this has had real effects on resource allocation and health outcomes.

### **Practical implications**

While this study focused on a particular collaboration between industry and government, the results have implications for any organisation (medical, government, consumer) wishing to form partnerships with the pharmaceutical industry. On the one hand, these findings show that while employees of industry may profess altruism and allegiance to collaborative efforts, they are also subject to commercial pressures and other, more subtle forms of ambivalence, which cannot be ignored. This suggests that industry claims of commitment to a collaborative effort cannot be taken at face value—a conclusion that would come as no surprise to those with a skeptical view of the pharmaceutical industry and its motives. However, these findings also point to at least some potential for meaningful collaboration. In particular, this study shows that pharmaceutical company employees in medical and regulatory affairs departments continue to identify with their original professions (medicine, pharmacy, research, etc) and this suggests that their altruism is likely to be both genuine and a potential anchor for collaboration.

On a more practical note, these results suggest that collaboration with industry would be best achieved through a number of simultaneous approaches which tap into *all* industry motives for cooperation. Altruism could be harnessed by giving more respect and responsibility to those within industry who are likely to respond to such measures. At the same time, it seems important to acknowledge the reality of self-interest and the potential for abuse of power, by retaining at least some restrictive regulation and making use of financial incentives and disincentives to motivate cooperation. This is, of course, aspirational at this point in time. For such measures to be effective, pharmaceutical companies would need to be provided with clear guidance as to how to make a strong case for their compliance with QUM; clear measures of compliance would need to be developed (e.g. performance indicators, milestones) and sources of funding for financial incentives (perhaps by redistributing funds accrued from penalties) would need to be found.

Finally, these results point to several ways in which relationships between industry and other stakeholders might be improved, since the causes of the translation failures identified in this study are not necessarily irreparable. It seems reasonable to assume, for example, that collaborative efforts could be improved by greater clarity regarding roles and responsibilities; by all stakeholders—including governments and medical organisations—demonstrating their genuine commitment to the policy; and by all stakeholders showing more genuine inclusion of, and respect for, their industry partners.

## Future research

The results of this study provide a solid framework for larger scale investigations of collaborative relationships between the pharmaceutical industry and other organisations (government, professional or consumer). These findings suggest also novel ways of conceptualising and studying the collaborative relationship between industry and health care practitioners.

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Table 1. Demographic characteristics of participants

		n=
Gender (n = 24)	Male	10
	Female	14
Positions Departments (n = 24)	Executive	1
	Medical department	11
	Public and Regulatory Affairs	9
	Sales and marketing	3
Company type (n = 11)	Innovative (multinational)	6
	Generic (Australian and multinational)	4
	Non-prescription (complementary medicine)	1