CLINICAL REFLECTION

An ethical relationship with pharma

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SUMMARY

This brief article reflects on the relationship between psychiatrists and pharmaceutical companies (pharma), which continues to generate debate and concerns. We suggest that psychiatrists should consider both the biomedical ethical principles and how values guide actions and clinical decision-making in their dealings with pharma. In addition, the Royal College of Psychiatrists should err towards eschewing influences that might be regarded by others as distorting its position, and individual psychiatrists should declare interests that others might regard as competing/conflicting in order to maintain the trust of patients and the public.

DECLARATION OF INTEREST

S.M.B. practises as an independent systemic psychotherapist. Both authors have undertaken various roles within the Royal College of Psychiatrists and S.B. is involved in recruiting patients for clinical trials.

> 'Knowing is not enough; we must apply. Willing is not enough; we must do.'
> Johann Wolfgang von Goethe (1749–1832)

The relationship between pharmaceutical companies (pharma) and doctors generates debate and conflict. Concerns may be greater in psychiatry, owing to the subjective nature of diagnosis, effects of placebo and variable course of disorders. Psychiatrists, like all medical practitioners, have varied clinical, academic and research roles that may involve different levels of interaction with pharma: for example, they may have roles within pharmaceutical companies or accept research/conference support from pharma. Pharmaceutical companies play an important role in healthcare too, investing money in research, teaching, training, drug development and marketing. However, they may create bias by influencing the prescribing behaviour of psychiatrists.

Ethical and values-based perspectives

The four principles of medical ethics (Beauchamp 2001) (respect for autonomy; beneficence; non-maleficence; social justice) are widely used as a framework for ethical analysis. They guide medical practitioners in a wide range of ethical dilemmas involved in day-to-day practice and provide a philosophical/ethical basis for assessing areas related to psychiatrists' relationship with pharma. For example, pharmaceutical marketing might subtly or unconsciously influence a psychiatrist: indeed, the aim of marketing is to broaden the uptake of a particular product. Patients too are subjected to marketing information and have increasing access to wide-ranging sources of information and/or misinformation on the internet.

Choices are influenced by values and beliefs and it is important to acknowledge diverse values. 'Psychiatrists' relationships with pharma may be seen as lying on a spectrum. At one extreme, some will boycott educational meetings organised by drug companies and decline to use pens/stationery with drug company logos. Towards the other extreme are psychiatrists who work for pharmaceutical companies and those with close links with pharma: they might receive drug company research grants, employ sponsored staff or advise companies. Most psychiatrists fall in the grey area between. Complexities lie in the fact that psychiatrists may find it difficult to avoid their own or their employer's unconscious biases.

Another spectrum might describe the balance between pharmaceutical and psychological treatments: there are psychiatrists who practise at both extremes of this spectrum. How does an individual patient know where their particular psychiatrist stands in relation to these? How does the Royal College of Psychiatrists (RCPsych) accommodate psychiatrists at the extremes? It is important to acknowledge that research into psychological treatments may struggle for funding to investigate whether psychotherapies can be as effective as pharmaceutical approaches: is this an indication of psychiatry's unwholesome relationship with the drug industry?

Individual and organisational values guide actions and influence clinical decision-making. Awareness of values is important and involves making hidden values overt. Fulford (2017) argues that values-based practice is a skills-based approach to working with complex and conflicting values: this is precisely the situation with regard to the RCPsych's and individual psychiatrists' relationships with pharma. Table 1 sets out ways that these relationships might influence practice.

Policy and guidance

Some guidance documents and standards of practice are not debatable and have to be respected,

TABLE 1 **Examples of how the relationship between psychiatrists and pharma might be deconstructed using ethical principles and of how competing interests might influence stakeholders**

Ethical principle	Brief summary – what the principle means in this context	Implications for psychiatrists	Implications for the RCPsych	Implications for pharma	Implications for provider organisations
Respect for autonomy	Respecting the decision-making capacities of autonomous persons, and enabling individuals to make reasoned informed choices	How to respect the patient's views, beliefs and preferences and work collaboratively with them, while being aware of the literature and evidence-based guidelines, their own clinical experience *and* being open about the influence pharma (and others) might have on them	How does the RCPsych's policy with regard to sponsorship by pharma potentially influence members (e.g. speakers at pharma-sponsored meetings using their College positions, speakers at College meetings disclosing connections with drug companies)?	Does this principle argue against the use of 'incentives', which potentially influence free choice of both psychiatrists and patients?	Do psychiatrists employed by a trust have access to a full range of treatments (pharmaceutical and psychological)? Do patients (in the context of clinical advice) have access to preferred treatments? How are purchasing and formulary decisions ethically overseen?
Beneficence	Balancing benefits of treatment against risks and costs, in order that psychiatrists act in a way that benefits the patient	How to work out with patients the 'best practicable healthcare' for them while respecting their priorities and wishes, alongside organisational and health service constraints and recognising possible competing influences	How does the RCPsych balance the benefits of involvement of pharma in meetings against the risks (e.g. that the College may be seen to be influenced and not impartial)?	Would this principle require drugs to be trialled on patient populations that reflect the complex mix of clinical practice rather than on carefully selected groups?	
Non-maleficence	Avoiding the causation of harm	Weighing up equitably the advantages and disadvantages of treatment options and the consequences of choices/ no treatment	If the RCPsych is viewed as partial then what are the risks to its reputation, the reputations of members, and its expressed guidance on behalf of the profession?	Might this principle be interpreted to require drug treatments to be tested against psychological treatments which might carry fewer/ different harms?	
Social justice	Fair distribution of benefits, risks and costs, so that patients in similar positions have equitable access to treatments	Not limited solely to fairness with regard to mental health but also physical health and the psychological and social aspects of care and treatment. Putting drug treatment in the context of other treatments. Psychiatrists who work for drug companies may have difficulty reconciling social justice with pressure to make financial profit	The potential influence of pharma might push the RCPsych towards favouring drug treatments over psychological and social treatments	How to balance the company's requirement to make a profit with making treatments as widely available as possible to those who might benefit from them?	Ensuring that patients have equitable access to treatments regardless of where they live, their social circumstances and other characteristics

for example guidance from the General Medical Council (GMC) and employing organisations. Government policies, guidance from agencies such as the Medicines and Healthcare products Regulatory Agency (MHRA) and the Association of the British Pharmaceutical Industry (ABPI), and from professional organisations, including the RCPsych (Royal College of Psychiatrists 2014, 2017) are also relevant. Similar guidelines apply to pharma. However, practice is rarely straightforward: sometimes the relationship between psychiatrist and pharma will work to everyone's benefit (including the patient), sometimes there may be clear personal benefit to the psychiatrist and to no one else. In the grey areas how is the relationship ethically assessed?

The influence of competing interests – bias

The RCPsych states that:

> 'A "competing interest" arises when a psychiatrist's professional judgement concerning a primary interest (such as a patient's welfare or the validity of research) could be influenced by another interest they hold (such as financial gain)' (Royal College of Psychiatrists 2017: p. 2),

and it requires a declaration to be made if an interest exists that could influence the psychiatrist's

professional judgement or could be construed or perceived by others as doing so.

Competing interests may be actual or potential, conscious or unconscious, implicit or explicit. Monetary reward is a powerful potential competing interest. Some declarations of interest focus purely on financial interests. For example, psychiatrists might recommend a particular treatment because of a financial incentive such as payment of fees to attend a conference; or an organisation might not provide psychological therapies as they are expensive in terms of staffing: drug prescriptions might be regarded as cheaper and are actively marketed by companies. In addition, organisations need to ensure ethical oversight of formulary decisions and allow clinical challenge of funding decisions. However, financial reward is not the only area of competing interests.

An academic competing interest might involve recommending that a patient enter a drug trial in order for the psychiatrist to gain credit as a participating recruiter. A professional competing interest would arise for a psychiatrist who has a connection with a drug company and is involved in drawing up clinical practice guidelines that might be relevant to the use of the company's products. Other competing interests include relational, clinical and those deriving from beliefs (e.g. religious or political beliefs).

Psychiatrists may not themselves be aware of a potential conflict, but other people may take a different view. Each individual needs to exercise judgment: the very fact that we acknowledge the potential for interests to compete supports the need to err towards declaring and managing possible conflicts. Patient and public concerns will persist if effective management does not follow disclosure. In the absence of a culture of professionalism, competing interests might influence professionals' decision-making consciously and/or unconsciously: hence, there should be clear requirements for public disclosure of interests.

Evidence shows that, although doctors in general feel that marketing could influence their prescribing, they consider that they would not succumb to such pressures. Indeed, resistance to marketing might lead psychiatrists not to prescribe appropriate medication. There is evidence not only that marketing can contribute to unconscious bias in decision-making and advice-giving, but that physicians underestimate such biases (Morgan 2006). There are also broader economic aspects, such as economic evaluations of medicines, questions about what constitutes a reasonable profit and how pricing is decided. These too have the potential to distort practice and can influence the clinician–patient/clinician–organisation encounter.

RCPsych guidance states that 'the dominating or intrusive presence of commercial or other organisations at College meetings is not appropriate' and that if pharma 'organises its own educational meeting, no implicit or explicit endorsement from the College should be claimed' (Royal College of Psychiatrists 2017: p. 8). It is therefore essential that College office holders who are speakers, chairs or discussants at pharma-organised, College-organised and other meetings declare their College affiliation and any other interests: otherwise, the public might regard their participation as implicit endorsement. Declaration in advance allows delegates to decide whether or not to attend a particular talk, meeting or conference.

Perhaps there is no conflict if research or education sponsored by drug companies is ultimately for the benefit of patients (Bhattacharyya 2007). After all, an ideal relationship between pharma and medical professionals would be one where 'freebies' do not influence the care given to patients (Bhattacharyya 2007): but how can observers (patients, professionals, the public) be certain that this is the case?

The grey area…

Psychiatrists are aware of policies and guidance relating to dealings with pharma. Undoubtedly, in some situations (at both ends of the spectrum) the relationship works well and with transparency: for example, where patients and the public benefit through research and new drug development. There are other situations where potentially only the psychiatrist, provider organisation or pharma may benefit. Complexity and uncertainty lie in the grey areas, which are more difficult. For example, increasingly psychiatrists have to follow their organisation's guidance on first- and second-line prescribing of drugs, which may be cost-effective for the organisation but not always clinically efficacious for individual patients. Organisational guidance may be seen as a response to pharma's marketing and pricing strategies. Dilemmas lie in the conflict between policy, guidance and the complex relationship between patient, psychiatrist, organisation and pharma.

Conclusions

In theory, research or education sponsored by drug companies is for the benefit of patients, but it also involves potential major financial gains for companies and their shareholders. It is difficult for psychiatrists to remain completely detached from possible influences of pharma: who has never had a free lunch, never accepted a drug company pen or sticky pad, and never been paid to give a lecture at a meeting? Competing interests threaten not only the integrity of scientific research and objectivity of medical education, but also the quality of patient care and the public's trust in psychiatry. The core of psychiatric practice is that a

BJPsych Advances (2018), vol. 24, 398–401 doi: 10.1192/bja.2018.19

psychiatrist's primary obligation is to their patient. Psychiatrists need to keep the four ethical principles in mind in everyday practice and they must be honest and transparent in declaring possible competing/conflicting interests, recognising that others may weigh these influences differently. This means that individual psychiatrists should reflect on what interests might be influencing their decisions and err towards declaring all possible interests (even those that they do not regard as competing/conflicting) in order to maintain the trust of their patients and the public. Similarly, the RCPsych should err towards eschewing influences that might be regarded by others as distorting its position.

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