The influence of the pharmaceutical Industry: Health Policy, research, prescribing practice and patient use

Submission by Critical Psychiatry Network

Background

The Critical Psychiatry Network is a group of practising Consultant Psychiatrists based in the British Isles, who are critical of orthodox beliefs in psychiatry, especially the importance attached to biological interpretations of distress. The Network first met in Bradford in January 1999, and seeks to influence thinking and practice in the mental health field. We are sceptical about the validity of the medical model of mental illness. We disagree with the emphasis placed on biological research and treatments. We do not seek to justify psychiatric practice by postulating brain pathology as the basis for mental illness. We believe that the practice of psychiatry must recognise the primacy of social, cultural, economic and political contexts. We welcome the Health Committee's inquiry into the influence of the pharmaceutical industry in the NHS. It is timely given the widespread public and professional concerns.

Introduction

The factual basis upon which our evidence rests is that the great majority of common psychiatric conditions (such as depression or psychosis) are unlike other medical disorders *in that there is no evidence to support the view that these conditions are caused by underlying disturbances in brain function*. Psychiatric conditions are not medical condition like liver or kidney failure, both of which have identifiable pathological causes that predict treatment response and outcome. This has a number of consequences:

1. Explanations of mental health problems are strongly contested.[1] Many service users reject the idea that their problems arise from disordered brain chemistry to be rectified by psychiatric drugs.

2. The problems of definition and validation of illness in psychiatry means that the field is more open to manipulation by commercial interest than other areas of medicine.[2,3]

3. Psychiatry is unlike any other branch of medicine in that patients may be compelled to take medication for lengthy periods of time against their consent.[4] The government is about to introduce new legislation to replace the 1983 Mental Health Act, in which these powers of compulsion will be extend into the community. This change in the law has major ethical implications. It is absolutely essential that there should be no concerns about the integrity of the factual basis of the evidence for the efficacy or safety of drugs that are likely to be used in this way. All the evidence indicates that this is not the case.

We must emphasise that we are not against the use of medication in psychiatry. We use it daily in our work. Our view is that there has to be a more rational basis for the use of medication than is currently the case, one that is free of commercial pressure and interest, and more honest about the limitations and potential harm that medication can cause.

Specific Points

1. Drug Innovations

Our view is that commercial rather than clinical or scientific demands are becoming the dominant driving force for ‘innovation’, thus the popularity of cheaper "me too" options, and the promotion of new ‘disease concepts’ to allow the re-badging of old products to expand markets without major development costs [2]. An example of the latter is the granting of a product licence for the use of Fluoxetine for the treatment of ‘premenstrual dysphoric disorder’, a disorder constructed to create a new niche for the drug as its patent was about to expire. Other examples include social anxiety disorder and post-traumatic stress disorder.

2. The conduct of medical research

Perhaps more so than any branch of medicine, psychiatry is open to the influence of external interests, including the pharmaceutical industry. This can be seen in the influence that the industry has on the design, conduct and reporting of psychiatric research, which all serve to promote the sponsor’s drug in the most favourable light.[5,6] This has major implications for the design, conduct and interpretation of scientific studies of the efficacy of drugs in psychiatric conditions. There are high levels of media and public concern specifically about the influence of commercial interest on scientific knowledge, specifically in relation to side effects of the SSRI class of drugs.

3. Provision of drug information and promotion

We are deeply concerned about the influence of pharmaceutical company representatives in shaping the opinions of mental health professionals through promoting their companies’ products. We believe that they have an inordinately powerful influence in this respect. Their work represents the triumph of the science of marketing over the marketing of science. We believe that the health service and general public needs to be better informed about the *modus operandi* of pharmaceutical company representatives.

We believe that the interests of the public would be better served in this respect if Trusts had clear policies dealing with the relationships between clinical staff and representatives. For this reason we have recently undertaken an audit of all 83 mental health trusts in England by letter addressed to each Trust’s chief executive. At the time of writing the response rate is 73%. The figures for the 61 respondents are as follows:

Have a policy in place N (%)	*Draft policy* N (%)	*Considering a policy* N (%)	*No plans* N (%)
32 (52%)	9 (15%)	14 (23%)	6 (10%)

The Health Committee will no doubt be aware of growing trend to introduce nurse prescribing in the NHS. We broadly welcome this development, but we believe that it makes the introduction of clear policies regarding contact with pharmaceutical company representatives even more important. It is known that representatives ‘groom’ community psychiatric and ward nursing staff, especially when psychiatrists working closely with these nursing colleagues will not see representatives. Our view is that very close scrutiny must be made of the possible influence that representatives may have upon nursing colleagues in this respect. There must be very tight policies governing the type of preparations to be

prescribed by nursing staff, particularly with regard to new drugs. All Trusts must have agreed policies that specify what is and what is not acceptable in terms of the relationship between clinicians and representatives.

For these reasons, our view is that pharmacists working in the NHS, especially specialist pharmacists working in mental health, are a more appropriate source of impartial advice about pharmacotherapy for people with mental health problems. Mental health specialist pharmacists have a thorough understanding of the mode of action, effectiveness, risks and side effects of psychotropic medication. Although their sources of information are culled from the industry, they are (or should be) removed from the immediate commercial interests that drive the work of company representatives. They are thus better placed to appraise the claims made for the effectiveness of different drugs.

We are also deeply concerned about the growing trend for direct to consumer advertising, not out of the need to protect professional interest, but because it is in the interests of the pharmaceutical companies to shape the way the public understands emotional distress in order to market their products. We cannot overstate the power and influence of the pharmaceutical industry in alliance with influential elites (like psychiatrists) in this respect.

4. Professional and patient education

Biological explanations of mental disorder dominate contemporary psychiatry,[7] despite the absence of convincing evidence that conditions such as depression and schizophrenia have a biological basis. The education of psychiatrists continues to stress the importance of concepts such as schizophrenia, despite the overwhelming evidence that the concept is seriously flawed.[8] In our view one of the main reasons for this is that it serves the interests of the pharmaceutical industry.

We draw your attention to an important paradox here. Government policy in the health service has rightly attached particular importance to social and contextual factors,[9] and the democratic ideals of greater public involvement in the health service. This is of particular importance in psychiatry, where many service users feel alienated and excluded from society,[10] especially those from our Black and Minority Ethnic communities.[11] Despite this, the education and training of psychiatrists, arguably the single most powerful and influential group of professionals in mental health services, is dominated by biological accounts [6] that are incapable of responding to the social, cultural and political realities of many patients' lives.

5. Regulatory review of drug safety and efficacy

No comments.

6. Product evaluation, including assessments of value for money

Economic evaluations often use measures derived from value judgements, so it is very important that the researchers are impartial. Economic evaluations funded by drug companies show their own products favourably.[12] The National Institute for Clinical Excellence (NICE) does not appear to take into account the source of funding of research studies that it cites in evidence for the efficacy of drugs in producing its guidelines.

Recommendations for Action

We believe the following actions are necessary [2] :

1. The use of monies from the pharmaceutical industry to subsidise continuing medical education, both locally and nationally, must be examined. Policies and procedures must be introduced in discussion with the Department of Health, and bodies responsible for postgraduate medical education, to minimise or eliminate the use of such monies, at least for local teaching. This is a key route of influence upon trainees.

2. If sponsorship is deemed essential, the use of blind trusts should be investigated as an alternative to direct sponsorship.

3. Declarations of interest must be strongly enforced. The medical Royal Colleges should establish Registers of Members' Interests, which require all members to disclose annually the value of gifts and sponsorship received from drug companies. This information must be in the public domain, along the lines of the Register of Members' Interests in the House of Commons. If it is acceptable and right that members of the public can access their MP's business interests, we believe that the same standard should apply to other public servants, such as members of the medical and nursing profession.

4. Our view is that bodies like the Royal College of Psychiatrists have a duty to ensure not only that its members reach required educational standards, and that these standards are maintained (continuing professional development), but also that these standards are maintained alongside probity and transparency in terms of potential conflicts of interest.

5. All NHS Trusts should have comprehensive policies concerning sponsorship and the pharmaceutical industry. These policies should set out what is and what is not acceptable in the relationship between employees (i.e. all clinical workers, not just medical staff) and the industry.

6. We are extremely concerned about the possible influence of pharmaceutical company interests on government bodies, especially NICE and NIMHE. These bodies must be unimpeachable. They must be able to demonstrate that they are completely objective, and free of potential sources of bias and conflicts of interest, in the way they select and evaluate their sources of evidence. Links between officers of these organisations and the industry must be in the public domain. There must be no industry funding for any aspect of the activities of these organisations.

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For and on behalf of Critical Psychiatry Network
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