



Legal proposal on information to patients

Response from Mind

April 2008

Mind, our mission and values

Mind works across England and Wales for better mental health.

Mind's vision is of a society that promotes and protects good mental health for all, and that treats people with experience of mental distress fairly, positively, and with respect.

The needs and experiences of people with mental distress drive our work and we make sure their voice is heard by those who influence change

Our independence gives us the freedom to stand up and speak out on the real issues that affect daily lives.

We provide information and support, campaign to improve policy and attitudes and, in partnership with independent local Mind associations, develop local services.

We do all this to make it possible for people who experience mental distress to live full lives, and play their full part in society.

Being informed, diversity, partnership, integrity and determination are the values underpinning Mind's work.

Summary

Mind would welcome an EU strategy on medicines information for citizens, to assist people to make choices and use medicines safely and to best effect. We strongly disagree with the specific proposal under consultation as we think this effectively allows promotion of medicines to citizens and fails to address the real need people have for independently evaluated information that compares different treatments (both medicinal and other treatments).

1 Introduction

Mind welcomes the opportunity to comment on this proposal. Reliable information is essential for people with mental distress (and all other people with health issues or conditions) to make choices and use medicines and other treatments safely and to best effect. Providing information and campaigning for better information provision by others form a core part of Mind's work and policy agenda.

2 Information needs

Mind's campaigning and research about people's experience of adverse drug reactions and other aspects of treatment indicate the demand for information and the kind of information people want. People have told us about wanting

information before treatment is prescribed, wanting greater openness and honesty from health care professionals, wanting information about how best to stop treatment, wanting information that is independent, and particularly information based on the views and experiences of others who have had the same treatment. In a recent consultation we received the comment, "Have the people who have used it (i.e. not researchers or drug company reps) said it helps?"¹ People do not ask us to lobby for more information from the pharmaceutical industry. More detail on our findings is given as an annex to this response.

3 The legal proposal

Mind would welcome an information strategy for the EU that, as stated in the consultation document, ensured the provision of good quality, objective, reliable and non-promotional information to citizens across the EU. However we do not think that the proposal that has been drafted meets this objective and we have major concerns about it.

The source of the information – by handing responsibility for information provision to the marketing authorisation holder the proposal misses the point of citizens' demand for independent information they can trust. While the company that developed the drug must in many ways be the primary source of information, if the criteria quoted in 3.1 above are to be met, company data should be evaluated independently and be qualified or enhanced by information drawn from non-company research, pharmacovigilance activity and consumer reports. There should be no significant information that companies could convey to the public that is not already known by the regulatory agencies and that is not also being conveyed to the health care community.

The company's stake in making sales means that the public are unlikely to see the information as objective. Though addressing a different question, a public opinion poll carried out for Mind in 2004 gives an indication of levels of trust in the industry. The poll was concerned with company research and how and to whom it is reported. Only one third of the public trusted pharmaceutical companies to pass on their research findings voluntarily and 17 per cent did not trust them to pass it on even if legally required to do so.

Evidence to support the public's scepticism includes the difficulties experienced by researchers at the National Institute for Health and Clinical Excellence (NICE) in obtaining unpublished trial results about children and antidepressants², and more recently the outcome of the UK regulator's investigation into Glaxosmithkline. The investigation concerned whether GSK had reported information about the safety of Seroxat for under 18s in a timely manner. The regulator concluded that a criminal prosecution would not realistically succeed and that GSK's failure to disclose this information earlier

¹ Response to 'What do you think are the most important things to look at when deciding whether a particular treatment is beneficial?' in Mind's Big Ask survey carried out at the organisation's annual conference March 2007.

² Whittington, C et al (2004) Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data, *The Lancet*, 363, pages 1341 – 1345.

indicated the need to strengthen the law.

In any case, simply as the producer of the medicine and with no hint of misdoing a company cannot be objective about its own product. Outside the tightly prescribed arena of patient information leaflets and summaries of product characteristics virtually all producer-generated information is promotional to some extent. Simply by raising the profile of a product and getting exposure for its name a company may generate demand.

It is particularly hard to see how product-specific material broadcast on TV could be non-promotional with its potential for convincing acting and subliminal messages.

It is not a case of equalising access to information with that of health professionals. There is an extensive literature on the influence of the pharmaceutical industry on health care providers through a range of advertising and other promotional activity.³ Public concern about this is leading to greater circumspection among professionals (eg codes of conduct, greater transparency about conflicting interests). It is of particular concern when drugs are heavily promoted at the point of launch when their full side effect profile is not known. It is of no benefit if this kind of promotion is simply extended to the public.

The greater the access of the industry to the public, the greater will be the industry's influence over attitudes towards both treatment and conditions for which they are promoted and prescribed.⁴

The scope and purpose of the information – clearly people need to know about specific products they are taking (or considering taking). The Patient Information Leaflet is the main means for conveying this information and the quality and accessibility of PILs has been improving, not least through the user testing required by the EU.

In our view, the information gap is not for more product-specific information but information addressing particular conditions and the range of treatments and other interventions that can help. (This is not the same as disease awareness campaigns driven by a pharmaceutical industry agenda.) This would quite specifically compare different treatment approaches and show the relative risks and benefits of each. It would also address the question of how best to stop as well as start treatment.

Such information needs to make clear that a pharmaceutical product may not be the best treatment for an individual or in certain circumstances, or for some conditions ever. This is unlikely to be a message that is well-profiled in company information.

As shown in the information cited in the annex, drawn from Mind's surveys and other research, much of what people want by way of improvements is improved communication with their health care providers and information from their peers – other people with experience of the same health issues. This

³ For example this is examined in the House of Commons Health Committee (2005) *The influence of the pharmaceutical industry*. London: The Stationery Office.

⁴ A critique of psychiatric drug treatment which includes the role of the industry is Moncrieff, J (2008) *The myth of the chemical cure*. Palgrave.

will not be addressed by the proposal.

We think it would be well worth the EC working on an information strategy to meet these needs across the EU and Mind would be happy to contribute to thinking on this.

Monitoring – Monitoring of existing industry information activity would be helpful but we are concerned that the proposal may not be sufficiently robust and particularly that the proposed co-regulatory body has industry representation. It is also after the event.

4 Conclusion

Our concerns are that this proposal does not address the real needs of citizens for objective, reliable information about the range of treatments that might help (or harm) them.

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Annex

A.1 Mind's campaigning and research about people's experience of adverse drug reactions and other aspects of treatment indicate the kind of information people want. In responses to a side effect survey run by Mind in 2001 (502 responses)⁵:

- 61 per cent of respondents said they had not received enough information
- 33 per cent said it was not relevant
- 34 per cent said it was not understandable
- 38 per cent said it was not given at the right time.

A. 2 Several people commented on their good experience of information but the vast majority suggested ways in which information could be improved. The strongest themes to emerge were the need for more information and honesty about side effects and better explanations particularly before treatment is prescribed. We drew from the themes the following recommendations.

Content of information

A.3 People wanted to know:

- what the drugs are and what they are for
- possible side effects including long term risks
- other alternatives
- what other people taking the drug thought about it
- how they work and what they do to the brain
- length of treatment
- withdrawal symptoms
- new ways of using drugs.

How information is communicated

A.4 People wanted:

- written information to keep and refer back to
- clearer, more understandable language and larger print
- more detail
- discussion of treatment, not written information only (with enough time for it, eg a longer appointment when treatment first prescribed)
- automatic provision of information especially in hospital where it is particularly lacking
- information by right (for example statutory wording about risk, or a right to a clearly defined amount and quality of information).

Sources of information

A.5 People wanted:

- doctors and community psychiatric nurses to provide more information
- independent advice from pharmacists
- access to the British National Formulary
- independently produced factsheets
- information from others taking the drug, eg off the internet
- information from voluntary organisations.

Timing

A.6 People wanted information before prescribing or at the time of treatment so that they could make choices, be prepared for more common side effects and recognise more serious ones and know what to do about them.

⁵ Mind's Yellow Card for reporting drug side effects: a report of users' experiences. 2001.

Doctor – patient relationship

A.7 People wanted their doctors to be more honest and open with them and to treat them with respect, taking seriously their accounts of side effects.

Information about stopping medicines

A.8 Following the yellow card project Mind commissioned service user researchers to do further work looking at people's experiences of stopping or trying to stop taking psychiatric medicines.⁶ This drew out many themes about why people stop, what happens, and what helps make it successful. Among other things it identified the need for information for everyone involved (ie the person taking/stopping drugs and those providing care and support) about possible adverse effects when coming off, best ways to come off, and good ways to support someone who is coming off.

⁶ Jim Read (2005) Coping with coming off, Mind.