

Communicating with patients

How should the pharmaceutical industry provide good-quality, objective, reliable and non-promotional information about prescription-only medicines to the public and patients?

The European Commission wants greater harmonisation of medicines information to ensure that all European citizens access the same information, and it has produced proposals to this end. The Association of British Pharmaceutical Industry supports the proposals, while Des Spence argues they are folly.

Information will improve patient care

The industry is committed to robust self regulation, maintains **Martina Bohn**

The Association of British Pharmaceutical Industry (ABPI) strongly supports the availability of good quality information to patients from a variety of sources – including health professionals, patient groups and the industry itself. The proposals are an opportunity for ensuring that all European citizens can obtain information about medicines.

Just to be clear, we are talking about information and not advertising. The pharmaceutical industry across the EU fully endorses the ban on advertising of prescription-only medicines to the public. The issue at stake is about providing reliable information about prescription-only medicines so that patients and their carers can access information about the treatment they have been prescribed.

In the UK, patients and carers already benefit from information about prescription-only medicines. Medicine Guides, for example, is an online resource,¹ providing information for most prescription-only medicines and offering links to other useful health information provided by the NHS. A consortium of stakeholders including the pharmaceutical industry provides Medicine Guides.

Quality standards

In addition to regulation governed in the UK by the Medicines and Healthcare products Regulatory Agency, pharmaceutical companies in the UK have to comply with quality standards set out in the ABPI Code of Practice for the pharmaceutical industry. The Code reflects and extends beyond

UK law. The transparency required by the Code, including the publication of full details of cases considered, shows that the industry is fully committed to effective, robust self regulation. Some EU member states do not have such detailed requirements and thus the EU proposed legislation will help clarify the provision of information to patients.

The EU proposal sets out very clearly that information provided must be objective and unbiased. If the information refers to the benefits of a medicinal product, its risks shall also be stated. It must be based on evidence, be verifiable and include a statement on the level of evidence. It must be up-to-date and include the date of publication or last revision of the information. The information has to be reliable, factually correct and not misleading, and accessible for the general public. It must clearly state the source of the information, the author, and provide references to any documentation that the information is based on. The proposal indicates that it must include a statement that the medicine is prescription-only, and that the information is to support and not replace the relationship between patient and health professional. A health professional should be contacted for clarification on the information provided.

Information will be monitored by member states after it has been disseminated. Internet sites containing information on prescription-only medicinal products will be registered and also monitored by the member states.

Distribution

Information can only be distributed in three ways. First, via health-related publications as defined by the member state of publication, to the exclusion of unsolicited material actively distributed to the public. Second, via websites on medicinal products, to the exclusion of unsolicited material actively distributed to the public; and third, in written answers to a request for information from a member of the public.

Information cannot be made available on TV or radio. However, we believe that certain information does benefit from being shown on film – for example, footage of the correct way to use an asthma inhaler should be allowed on relevant websites. Patients sometimes struggle to understand how to take their medicine and the benefits and risks associated with not doing so correctly. Information can empower patients to understand their treatments better and support any choices they may have to make. Ultimately, information about medicines should add value to the patient experience and improve patient care.

1. They can be accessed at www.medguides.medicines.org.uk or via the NHS Choices website: <http://www.nhs.uk/Pages/HomePage.aspx>



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More medication is not better medicine

We need more regulation, not less, says **Des Spence**

The European Commission is attempting to standardise access to medical and medication information. It suggests that pharmaceutical regulations be relaxed to allow companies to communicate directly with the public. The hope is that this process will inform and empower individuals, and might even actually improve care. But reading beneath the management speak, what will these changes actually deliver and what is the motivation of the pharmaceutical industry?

Powerful industry

The pharmaceutical industry already exercises hugely disproportionate influence over the health agenda, through lobbying at international and national levels, and extensive links through the medical media. Although the current proposals do not allow direct-to-consumer-advertising, they are in my view on the slippery slope towards the situation in the USA, where this is allowed. There, health costs are nearly twice those of other industrialised countries, yet the USA is consistently bottom of international health league tables. Is there much difference between disease promotion and promoting the 'treatment' for a disease? Medicines marketing disfigures health care when the real challenge is obesity, inactivity and drug dependence.

Even in the UK, with some of the tightest regulation, the industry is allowed to sponsor disease awareness campaigns directly to the public. A campaign jointly funded by antidepressant

manufacturers in the mid nineties, called Defeat Depression, sought superficially to de-stigmatise depression. The constant message was that depression was under-recognised and under-treated. The effect was to rebrand and medicalise unhappiness as 'clinical depression'. Antidepressants were very limited in use in the 1970s and 80s. In 2006, there were 31 million prescriptions for antidepressants in the UK, and now new guidelines are seeking to limit their use. Is humanity's happiness really in the gift of medication? Has our dependence on antidepressants in fact undermined society's wellbeing?

Adverse reactions

In 1999 Vioxx, an anti-inflammatory pain killer, was launched. It was marketed as being safer than older brands. It quickly gained huge market share even in the 'regulated' UK, and this type of medication became over 50 per cent of all prescribed anti-inflammatories. But in 2004, new research revealed that Vioxx increased heart attacks and stroke, and it was withdrawn. The company is now accused of concealing and even fabricating research data. An estimated 88,000 to 139,000 Americans suffered heart attacks directly related to Vioxx. But Vioxx is only one in a long list of dangerous medications. Indeed, estimates suggest that twice as many people per year die of adverse drug reactions as die on our roads. The rapid uptake of new medicines is bad medicine, and these proposals will put the public at risk.

The central assertion, that it is 'disease prevention, better awareness of symptoms which leads to earlier treatment' is pure fiction

Allowing more marketing opportunities will not serve the industry, either. Currently its research is focussed on profitable 'me-too medications' that are merely like different brands of the same cereal. Yet this type of research consumes some 80 per cent of the research budget, and is stifling true innovation. And it is this lack of real innovation that is corroding the profits of the industry.

Empowering anxiety

These proposals are folly and will serve only to ensnare the public in yet more pharmaceutical marketing. Governments are naive if they believe that self regulation will work, for the financial temptation to bend the rules is irresistible.

The central assertion, that it is 'disease prevention, better awareness of symptoms which leads to earlier treatment' is pure fiction. The reverse will follow, with those in lowest risk groups responding to any campaign. This will result in over-diagnosis and over-treatment, and empower only health anxiety. Information could at little cost be easily improved through existing independent agencies. More medication is not better medicine. We need more regulation of the pharmaceutical industry, not less.



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