BORDER CROSSING Tessa Richards

Purely medicinal?

We must grasp the opportunity to respond to a controversial EU proposal to allow drug companies to provide information on prescription only drugs directly to the public

How easy is it to draw a clear line between providing information about a product and promoting it? Most of us would regard it as difficult, if not impossible. Not the European Commission, though—at least not when the product is a drug. This is evident in a new and already much criticised consultation paper on patient information (http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm). This paper sets out the commission's ambitious proposals to provide Europe's citizens with "uniform access to understandable, objective, high quality, and non-promotional information" on drugs. Central to these plans is a move to allow manufacturers to provide information on prescription drugs directly to the public, under the "clear safeguard" that advertisement is banned. Responses to the paper are invited to help inform a draft directive that will include proposals to reform the way drugs are assessed and priced. So why the criticism?

The answer lies in the history behind the document as well as its content.

Europe's drug industry has been struggling. Eight years ago the European Commission's enterprise and industry directorate tried to assist it by proposing that Europe should sanction direct to consumer advertising of prescription drugs. Health lobby groups went into overdrive. They cited evidence from the United States and New Zealand (which both allow direct to consumer advertising) that although such advertising is good for the industry it drives up the cost of drugs and fuels inappropriate use. The European parliament rejected the proposal.

Thwarted, the industry adopted other ways to raise demand for its products. These have included supporting patients' groups and "disease awareness" campaigns. Here the disease envelope has been rudely stretched to include a range of "pre-diseases" and such dubious entities as female sexual dysfunction and restless legs. Meanwhile the enterprise and

industry directorate pursued other tacks and in 2005 set up a pharmaceutical forum. Chaired jointly by the EU commissioners for industry and health, it is charged with improving industry's performance and its contribution to social and public health. Few doubt the balance of power lies with the industry.

Last year there was speculation, hotly denied, that the commission was nurturing plans to overturn the ban on direct advertising (*BMJ* 2007;334:664-6). Now it has put its cards on the table with the current proposal on patient information (and an equally controversial one on pharmacovigilance). Lobby groups, including Health Action International, the Medicines in Europe Forum, and the International Society of Drug Bulletins, are already up in arms (www.isdbweb.org). Picker Institute Europe, a UK based charity that works to promote the interests of patients, has expressed misgivings, and the BMA and the Standing Committee of European Doctors are poised to do likewise.

A glance at the commission's paper is enough to understand why. Firstly, it proposes to extend the legal rights of drug companies to provide information to the public. Critics argue that this is unnecessary and unwise. Their view is understandable. Currently a large media company in Canada is challenging the government's prohibition on direct to consumer advertising of prescription drugs on the grounds that it infringes its right to freedom of expression.

Secondly, the paper proposes allowing the industry to disseminate information "through TV and radio programmes [and] through information in printed media." This has to ring warning bells. Many argue that allowing the industry to use the media to propagate messages about products is tantamount to opening the promotional floodgates. Television advertisements, in particular, may be heavily nuanced. Barbara Mintzes, a researcher at the University of British Columbia, paints a vivid picture of the US genre. The

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small print and muted voiceovers may meet regulatory requirements, she says, but it's the "emotionally charged" images that convey the message. The ill, worried, and embarrassed are transported to a happier land; disease has been controlled or prevented, unwelcome symptoms banished.

This puts the spotlight on a third problem: the proposal that new national co-regulatory bodies (without legal powers) will maintain quality control of the information and ensure that the line between information and promotion is not crossed. Leaving aside the highly contentious view that this line can be drawn, the evidence that it will be possible to police it effectively is sparse. Experience from the US shows that post hoc vetting is not easy, and it takes time to act against companies that have strayed into the promotional ballpark.

Others see merit in the commission's proposals. Among them is Joanne Shaw, who heads the UK's Medicines Information Project (www.medicines.org.uk), a public-private partnership that produces drug guides for the public. Her view is that open collaboration with the industry is better for patients and the public than continuing confrontation. Last week Robert Madelin, head of the European Commission's health directorate, said it was inevitable that industry's role in information provision would increase. Robin Ferner, coauthor of an article in this week's *BMJ* on over the counter drugs (*BMJ* 2008;336:694-6), would agree. His dystopian vision, he told me, is of a world where drugs are like online music: information and procurement a mere mouse click away.

Time will tell. For now, the chance to respond to the commission's paper should be grasped before the consultation closes on 7 April. If the commission is to transmute it into a proposal that holds as much promise for Europe's citizens as it does for the industry, it needs constructive input.

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