

HealthWatch Position Paper on Direct to Consumer Advertising of Prescription Medicines:

A BAD IDEA, BUT IF IT COMES IT NEEDS RIGOROUS CONTROL

HealthWatch

HealthWatch is a registered charity that promotes evidence-based assessment of all forms of treatment. Our objective is to provide the public with reliable information about healthcare. HealthWatch has no vested interest for or against direct to consumer advertising of prescription medicines (DtCA); our sole concern is in the honesty, reliability and transparency of claims made to people who are ill or who may be persuaded they are ill.

Our members include scientists, clinicians, lawyers and journalists; recipients of the annual HealthWatch Award have included leading health journalists as well as academics and clinicians.

DtCA is an EU matter but some of the issues are especially acute in the UK because of chronic problems in the NHS. This position paper is written largely from a British perspective.

Reason for this Position Paper

The European Commission¹ has proposed a large number of changes to the conditions under which medicines are sold in the EU. These include a provision that DtCA be permitted for some prescription medicines, specifically those intended for treatment of:

- acquired immune deficiency syndrome;
- asthma and chronic bronchopulmonary disorders;
- diabetes.

Advertising is to be controlled by self-regulatory procedures set up by the pharmaceutical industry at member state level.

Unlike consumer organisations, the medical profession or the pharmaceutical industry we have no particular commercial or other interests; nonetheless we share some of the reservations expressed by, among others, the UK Consumers' Association² and the European BEUC³. This is obviously of great significance in Europe, where state health schemes bear most of this burden. HealthWatch starts from the premise that freedom of expression is generally desirable, but nonetheless believes some of these concerns are valid.

The current position

DtCA has never been permitted for prescription medicines within the EU. The role of the physician has been that of *learned intermediary* – only he or she was thought to be qualified to make judgements about medicines that could be dangerous if misapplied. Over the last few decades, however, the relationship between doctor and patient has changed greatly. Decisions once accepted without question are now subject to consumer discussion; patients increasingly expect to be told about uncertainties and alternatives. Indeed some procedures (such as the MMR vaccine) are met with scepticism and even hostility.

The need for review

This democratisation has already been reflected in several important liberalisations about information on pharmaceutical products. In particular, prescribed medicines are no longer labelled *the tablets* and *take as directed*; the product is named and specific dosage instructions are given. In addition, a patient information leaflet (PIL) now accompanies products dispensed by a pharmacist on prescription. It explains the purpose of the drug, describes its constituents, warns about contra-indications and expected side effects and lists information that helps track down the cause of an allergic reaction.

Knowledgeable consumers can also ask their doctors for an SPC, or Summary of Product Characteristics. This provides detailed information on the product and is intended to assure EU-wide consistency in indications, dosage and use of medicines. In the UK, it is not legal for a pharmaceutical company representative to promote a product without first giving a copy of the SPC to the doctor, so that factual information can put the promotion into perspective.

Consumers can now access information about medicines in several other ways, including:

- newspapers and magazines (most of which now carry extensive copy about health issues);
- broadcasting;
- popular books;
- telephone advice lines;
- the Internet; and
- voluntary organisations and support groups.

Unlike PILs or SPCs, which are closely regulated by the regulatory authority (in UK, the MCA, in the EU, the EMEA), these other sources of information vary greatly in quality.

Newspapers and general magazines often carry a doctor's advice column as well as news and features on medicines. While these often contain good advice and balanced coverage, they sometimes show scant scientific literacy. Few journalists are specialists on medicines. Newspapers in particular, because of a journalistic imperative to create strong headlines, are prone to promoting health scares. Moreover, for commercial reasons they are loathe to confront misapprehensions among their readers and tend to massage preconceptions, sometimes devoting much uncritical space to complementary medicine.

Broadcasters tend to paint health issues in broad brush strokes because of the need to maximise audience interest and, with notable exceptions, rarely tackle complexities about medicines. News stories and documentaries they tend to have a driving narrative, which means that they may promote a particular perspective; but they have been generally more cautious than the print media, and probably of relatively little influence on medicine use. In the future, however, with the advent of multi-channel broadcasting, which can cater to niche audiences and is regulated with a light touch, broadcasting may follow the path of newspapers and magazines.

Books on health and medicine range from authoritative guides such as those published by the BMJ, through thoughtful, well-researched and critical appraisals, to wild and misleading nonsense.

Helplines include (in the UK) *NHS Direct* and advice lines from some pharmaceutical companies and insurance companies; but manufacturers of food supplements and other unregulated products are free to promote these by phone unfettered by constraints imposed on the pharmaceutical industry.

Another way in which patients can now access information about medicines is through various health charities and support organisations. Many of these are supported by pharmaceutical companies and 'health supplement' companies, sometimes with few strings attached but often as a cloak for public relations activities. There is little control over what can be said in the casual atmosphere of a meeting. Moreover some voluntary organisations may appear to be neutral while substantially relying upon financial support from these companies.

The Internet has seen a proliferation of sites advising on drugs, and there is a good deal of authoritative information available to diligent researchers. However, as with all publications on the Internet, quality varies considerably. There is often a direct or hidden bias. Many articles are written by well meaning but misguided people with information poorly supported by research findings, and countless sites contain claims that are frankly wacky.

The global nature of the Internet makes it hard to regulate; now that DtCA is permitted in the US, pharmaceutical companies are effectively free to promote prescription drugs worldwide. If the European Commission wanted to ban DtCA via the Internet it would be unable to invoke sanctions on pharmaceutical

companies which market in North America without a politically damaging battle with the US authorities and enthusiasts for the freedom of the world wide web; battles they would not be likely to win.

The present situation thus already allows largely uncontrolled collateral promotion of prescription products to the general public.

Now that in the US the rules on DtCA have been greatly liberalised, it is inevitable and right that rules should be reviewed in Europe.

The need for caution

As a general principle, HealthWatch takes it as self-evident that free expression is preferable to censorship and that reliable information is more likely to emanate from openness than from over-regulation. However strong the evidence appears to be in favour of a single view, however diligent and honourable the regulator, there must be room for challenge.

But medicines have several features that distinguish them from other goods and services. Their misuse can cause great harm, both to an individual and (as with abuse of antibiotics) to the wider community. Even proper use can sometimes be dangerous and medical supervision is often necessary or desirable - the same medicine can have subtle, and sometimes not so subtle, effects on different patients and at different times. Equally it can be dangerous if the proper medicine is not taken, or is not taken according to the proper recommendations.

Medicines are obviously intended for people who are ill and their illness may make them especially susceptible to misinformation. Half-truths may be damaging in any advertisement, but can be especially cruel when aimed at people desperate for a cure.

There are special economic issues with medicines. It is generally held in Europe that healthcare should be available to all on an equitable basis. Most medicines in the UK are provided through the state-funded NHS, with almost all the rest through private insurance companies. Few prescribed medicines are bought by individuals out of their own pockets. Moreover, healthcare is a scarce and expensive resource. The NHS is severely stretched so that treatments are rationed through queuing or non-availability; and prescribing is specifically restrained by budgets and guidelines from bodies such as NICE (the National Institute for Clinical Excellence). Insurance-based schemes are also highly sensitive to costs; premiums are already so high that most of the population is priced out of the market.

There is therefore a strong case for ensuring that medicines are not just effective and safe, but cost-effective too. Big companies promoting expensive products can substantially outspend small companies whose drugs may be just as good and perhaps a lot cheaper.

By definition, prescription medicines are controlled by doctors and pharmacists and it may be said that clinicians are quite capable of acting as proper guardians, regardless of consumer pressure. On this view, DtCA would make very little difference to the nature of prescribing since it is the doctors, not the patients, who make all the key decisions. HealthWatch regards this as naïve. Doctors are profoundly influenced by patients, and rightly so. Sometimes the views of patients are of paramount importance, but even when a clinician believes a patient is wrong, pressures of time and the desire to avoid a confrontation can lead to inappropriate prescribing. The hardheaded pharmaceutical industry does not spend hundreds of millions of dollars each year in the US for no return; they invest heavily in DtCA because they know consumers exert huge and effective pressure on prescribers. Indeed prescribers themselves are not immune to the persuasive influence of advertising. An obvious example of the power of DtCA is the explosive growth in prescriptions of the expensive COX-2 specific anti-inflammatory drugs Celebrex (celecoxib) and Vioxx (rofecoxib) despite complaints by American pharmacy managers and consumer groups⁴. In the UK, NICE has cautioned that for most patients cheaper compounds are just as safe and effective, but it is an open question how such recommendations would fare in the face of widespread demand for the more expensive drugs.

Indeed, we regard it as inevitable that DtCA will increase health costs. Pharmaceutical companies naturally tend to advertise costly blockbusters much more than marginally profitable generics, so that – assuming the advertising is successful – the pattern of spending will shift from cheaper generics to premium-priced proprietary medicines. HealthWatch strongly advises that any change in the rules on DtCA must be designed carefully so that they do not destabilise national health systems such as the NHS.

HealthWatch recommendations

For the reasons advanced above, HealthWatch strongly opposes DtCA of prescription medicines. However, if it is to be allowed in Europe, it should be started very cautiously. The proposals for DtCA for the limited number of conditions suggested by the Commission could be accepted if self-regulation can be made fully effective.

We are aware that once any DtCA is permitted pressure will grow for further liberalisation. Thus proper precautions should be built in from the start, mindful of the likelihood that advertising may become much more pervasive and emotive. We note the experience in the United States where drugs have been marketed with “splashy, expensive TV ad campaigns”⁴. We believe that in the European model some of the marketing money devoted to DtCA should be spent on providing balanced information which allows consumers to make reasoned judgements.

The Commission proposes that all advertisements should be submitted to the EMEA (the pan-EU regulatory agency) and can proceed if no objection is made within 30 days. HealthWatch believes this negative vetting process will not be effective and urges the Commission to incorporate an additional set of precautions, using systems similar to those already in place, which should therefore be easy for pharmaceutical companies to adopt. These would ensure:

- consistency between terms set by the regulatory agency and DtCA;
- quality of product description;
- honest disclosure of adverse events; and
- candid reporting of relative efficacy and price evaluations where they are available.

The methods proposed have the additional advantage of being largely self-policed, cutting the burden of regulation without reducing its potency.

HealthWatch proposes the following principles:

- ***At least 50% of DtCA spend must be on substantive advertising, defined as explanatory text, as opposed to marketing which relies mostly on slogans.***
- ***A summary of the PIL must accompany all substantive DtCA, as is now the case with the SPC for professional advertisements. The complete PIL must be linked prominently to Internet advertisements.***
- ***A summary of the other relevant information must be included in any substantive advertisement such that consumers can determine the class of drug, the context of rival products, and any authoritative judgement of cost-effectiveness. Because of differences in regulatory framework and language between EU Member States each Member State should determine the most appropriate frame of reference to ensure compliance with these rules. For example, in the UK reliance would most sensibly be placed on the BNF (the British National Formulary) and NICE (the National Institute for Clinical Excellence). Relevant texts from BNF and NICE would be reproduced in the same format and type size as the rest of the advertisement.***

The BNF is recognised as the main source of unbiased information on medicines in the UK and inclusion of BNF entries in advertisements has the merit of positioning each company’s product in relation to others available for the same condition. A synopsis of the relevant monograph should be carried prominently in any substantive advertisements, and all Internet

advertisements should also show links to the appropriate BNF web pages. Summaries in substantive advertisements may be brief but must be agreed in advance with the BNF. This is an important remedy for smaller pharmaceutical companies which lack the marketing muscle of larger rivals.

Similarly, and for similar reasons, all substantive advertisements must carry a summary agreed with NICE of any recommendations about the product and others for the same condition, with specific comparisons of cost-effectiveness where available, again with a link to the NICE site for Internet advertisements.

- *Companies would be liable to the regulatory authorities (the EMEA or, for example, the MCA in the UK) for all statements made in DtCA and for compliance with the above terms. In addition to corporate accountability, each company placing DtCA must appoint a suitably qualified pharmaceutical physician to take personal responsibility that all advertisements are consistent with the marketing authorisation and to agree texts with the appropriate agencies. The qualified person would accept liability similar to, and parallel with, responsibilities already demanded for quality and pharmacovigilance functions, and could be disciplined or even disbarred if the regulatory authority found incorrect information had gone into advertisements.*
- *Where a company gives financial support to a patient group or other organisation working in a field in which its products may be used, it must ensure that the link is transparent. This is analogous to the present situation when companies support professional meetings, where they must make their vested interest overt. Where more than 20% of the finance or other resource for such an organisation, or for one of its projects, comes from a pharmaceutical company, newsletters and other documentation from the organisation must acknowledge prominently the obligation to the company and its relevant product(s). The company will be obliged to set out details of its links with such organisations in its annual report.*

We believe these proposals strike a fair and proper balance between the needs of pharmaceutical companies, clinicians and consumers. They ensure that a reasonable proportion of the marketing power is committed to balanced information as opposed to simplistic or largely emotional appeals. By placing the emphasis on self-policing they minimise the administrative and financial burdens on companies and on the regulatory authorities.

We believe the mix of substantive advertising with the freedom to place strap-line commercials will allow companies to stress the scientific merits of their products and also to deliver more traditional persuasive messages. It may be necessary to monitor that the substantive and emotive advertisements are not aimed at different audiences, but we believe the 50% spend rule could help to ensure that substantive advertisements are aimed at the popular media in reasonable proportion. Additional measures will be needed if the rule does not achieve this.

We believe this mix will produce a flow of information which will inform the intelligent consumer without misleading the stressed or gullible and, through its attractiveness and authority, will rival less reliable information available elsewhere.

Postscript

HealthWatch is concerned about honest dealing in all healthcare: orthodox and complementary. The European Commission proposals on DtCA rightly enshrine careful controls of direct advertising for prescription medicines, to which we have added our own suggestions; but we point out that other medicines will be subject to much less stringent constraints. In some respects this is justified. If consumers are persuaded to buy for themselves expensive OTC brands, as opposed to generics, there are no repercussions on the NHS and no added health risks to patients. However, it is a different matter with complementary medicines. A few are harmful, most make vague but enticing claims which may mislead sometimes vulnerable consumers, and in general their marketing creates pressure to provide such alternative treatments on the NHS and through insurance schemes. HealthWatch believes complementary medicines should be

treated in the same way as orthodox pharmaceutical products; not simply to create a level playing field, though that is an important part of competition policy, but to safeguard public health.

Acronyms used:

- BEUC:** *Bureau Européen des Unions de Consommateurs* – the European Consumers’ Organisation, which represents 32 independent national organisations from 20 European countries
- BNF:** *British National Formulary* – a publication of the BMA and Royal Pharmaceutical Society, a primary source of unbiased information on medicines in the UK
- CA:** *Consumers’ Association* of the UK
- DtCA:** *Direct to Consumer Advertising* (of prescription medicines, in this context)
- EMA:** *European Medicines Evaluation Agency* – the EU RA, which acts on the advice of the EU Committee for Proprietary Medicinal Products
- EU:** *European Union*
- MA:** *Marketing Authorisation* – RA approval for the marketing of a medicine
- MCA:** *Medicines Control Agency* – the UK RA, which acts on the advice of the Committee on Safety of Medicines
- NICE:** *National Institute for Clinical Excellence* – an NHS Health Authority charged with evaluating the cost-effectiveness and fair availability of medicines and medical procedures
- PIL:** *Patient Information Leaflet* – information on a prescription medicine addressed to the patient. All products receiving an MA must have a PIL approved by the RA.
- RA:** *Regulatory Authority:* in UK the MCA, for the EU the EMA.
- SPC:** *Summary of Product Characteristics* - information on a prescription medicine addressed to the doctor. All products receiving an MA must have a SPC approved by the RA.

References

- (1) Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC. COM(2001) 404 final. 26/11/2001.
- (2) Consumers’ Association comments on the European Commission’s proposals to amend the EC medicines regulatory system (2001 review) – as requested by the Medicines Control Agency. 15th April 2002.
- (3) The revision of the pharmaceutical legislation. BEUC position paper. BEUC/052/2002. 7/02/2002.
- (4) Asia Intelligence Wire via NewsEdge Corporation, Suz Redfearn, 06/04/2002

References are available through the HealthWatch website: www.healthwatch-uk.org.

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