Pharmaceutical Marketing – Time for Change

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Abstract

This paper reviews current marketing practices in the pharmaceutical sector, and their impact on consumer and doctor behaviour. It identifies negative impacts which include misleading advertising, disease mongering and escalating costs. It argues the need to move from industry self-regulation to an independently monitored code of practice for pharmaceutical marketing.

Keywords

Pharmaceutical marketing methods, Direct to Consumer Advertising

Introduction

This paper reviews current marketing practices in the pharmaceutical sector, examining both consumer and doctor-oriented promotion. It presents examples of marketing practices and their impact on consumer and doctor behaviour. It identifies negative impacts of these practices which include misleading advertising, disease mongering and escalating costs. It goes on to argue the need for an independently-monitored code of practice for marketers in the pharmaceutical sector and a greater degree of consumer education for both end-users and those prescribing drugs.

The context

In May 2003 the British Medical Journal devoted a special edition to the relationship between doctors and pharmaceutical companies entitled"time to untangle doctors from drug companies"(Moynihan 2003). The theme was relationship between the medical profession and the pharmaceutical industry (Big Pharma). The medical profession in Europe, in conjunction with many social movements, has begun to consider seriously the appropriateness of current relationships between Big Pharma and the health sector. This is occurring in the context of legal actions around corrupt sales practices in Europe such as those against GlaxoSmithKline (GSK) in Germany (Gopal 2002) and Italy (Turone 2003), and the major action against TAP Pharmaceutical Products, Inc in the United States which resulted in a $875 million dollar settlement in 2001 (Riccardi 2002).

This debate is already very strong in the United States where it has further extended to encompass the relationships between Big Pharma and consumers. This is in part because of US practice of allowing direct- to-consumer advertising (DTCA) of prescription drugs. Industry organs such as PhRMA the umbrella organization of the American pharmaceutical industry argue that such advertising (properly regulated) allows consumers to inform and educate themselves about therapeutic options and achieve a more equal relationship with their physicians. On the other hand action groups such as the U.S. Public Citizen's Health Research Group oppose this practice as they contend that there is no evidence that such advertising improves health care.

For marketers it is perhaps a difficult area to engage with, given that Big Pharma is in many ways the ultimate marketing example. They engage in multi-million dollar marketing campaigns, use all methods of promotion from mass media advertising, to below the line spend on measures such as the engagement of key opinion leaders. Many billions of dollars have been spent on developing and protecting not alone their branded products but also their component drugs internationally.

How are drugs promoted?

The average cost to bring to market a so-called block-buster drug is currently estimated at $895 million (EFPIA, 2002). Obviously firms who spend that kind of money need to recoup their costs. Furthermore industry analysts point out that Big Pharma under pressure. It needs to expand sales of blockbuster drugs since there are fewer drugs in pipeline. In order to sustain current levels of growth, firms would need to introduce one new product each year that would sell $4.9 million for each 1 to 1.5 per cent it has of the world pharmaceutical market. "A company the size of the newly merged Glaxo Wellcome/Smith KlineBeecham needs three to seven products each year, while one the size of Astra Zeneca needs two to four products each year. The problem is that research productivity is failing. None of the major companies is close to the target." (Horrobin 2000)

Depending on the category of drug the nature of the marketing mission is different. There are essentially two categories of drugs: self-medication or over the counter (OTC) drugs, and prescription drugs - sometimes referred to as ethical drugs (de Mortanges and Rietbrock 1997). OTC drugs are promoted directly to consumers as well as physicians and other healthcare professionals and range

from analgesics such as paracetamol to anti-histamines. What is categorized as OTC varies from country to country and is dependent on the local legislative framework – usually a national medicines authority, so for example in the United States some anti-histamines are prescription-only.

Corstjens (1991) identifies four main buying parties for prescription drugs:

1. Prescriber – prescribing rights vary internationally and this category may include doctors, dentists, pharmacists, nurses and optometrists
2. Influencer – hospitals, nurses, professors, reimbursement agencies
3. Consumer – patient
4. Financier – partly patient, partly government or third party (varies by country), managed health care organization (hospitals, Health Maintenance Organisations etc.)

The majority of Big Pharma's marketing budget is targeted at doctors and others with prescribing power, who are effectively the gatekeepers to drug sales. In 2002 the Canadian Medical Association Journal estimated some US$19 billion is spent by Big Pharma annually in promoting drugs to doctors in the United States alone. The methods used will be discussed later in this paper.

In the European Union only OTC drugs are promoted directly to consumers. Examples include analgesic preparations and some ailment-specific drugs such as the Schering Plough blockbuster Clarityn - a hayfever remedy. In 1998 Schering Plough spent $186 million promoting Clarityn, and as a result saw a half a billion dollar increase in sales year on year to achieve annual sales of $1.9 billion, (Maguire 1999).

In the United States all drugs may be promoted to consumers, but in practice direct to consumer advertising focuses on OTC and common-ailment targeted prescription drugs. There are other more limited application drugs for less common diseases that are only promoted to health care professionals, and hospital and organizational formulary committees (such as HMO formulary committees). The drug marketing process can be described by the model below in Figure 1, which shows the information flow from drug companies, both to consumers and doctors. It also shows the power that consumers, informed by DTCA and the Internet, have in "pulling" prescription drugs from doctors.

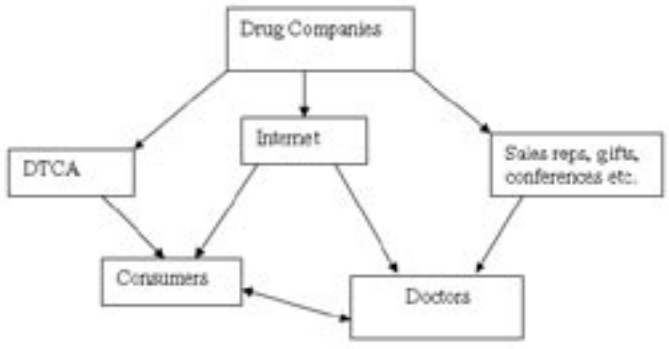

Figure 1. Pharmaceutical marketing process.

Creating the Pull – Directly and Indirectly:

Historically promotion for prescription drugs occurred only from manufacturer to prescriber so that physicians and others with prescribing powers were the gatekeepers to eventual drug sales. The promotion strategies therefore were all essentially "push" focused. However the decision in 1997 by the US Food and Drugs Administration (FDA) to relax restrictions on broadcast DTCA of these drugs has resulted in increased "pull" from consumers. In both the United States and New Zealand DTCA of prescription drugs occurs with considerable effect, as will be discussed below. A further source of 'indirect' pull has been the impact of the Internet on pharmaceutical promotion, which will also be discussed below.

Direct to consumer promotion – creating direct pull

In August 1997 the US FDA made significant changes in the regulations for broadcast DTCA of prescription drugs. Prior to 1997 DTCA had to include the entire brief prescribing information which meant that about 30 seconds out of a 60 second advertisement would consist of fine print scrolling across the screen. In 1997 the FDA dropped this requirement and said that DTCA had to mention the major side-effects, and also provide other ways that consumers could get more information about the drug (e.g. give a web site, a 1-800 number or refer to a print ad for the same product which contained the same information) and tell consumers to consult their doctors/pharmacists. In the four-year period from 1996 to 2000 promotional spend direct to consumer within the United States tripled (from $791 million dollars to $2.5 billion dollars, New England Medical Journal 14/2/02). New Zealand is the only other developed country that allows DTCA of prescription drugs. Burton (2003) details a report by academics from all of New Zealand's medical schools which recommended that the practice be discontinued. This report, based on a survey of all general practitioner doctors in New Zealand, found that seventy five per cent of respondents believed DTCA to be negative with patients frequently requesting drugs that were inappropriate to them. On the other hand in New Zealand drug advertising is not monitored by a state agency (whereas it is in the United States). The pharmaceutical and advertising industries are self-regulating. This leads to a less than ideal situation where only a small percentage of the televised pharmaceutical advertisements are compliant with the New Zealand Medicines Act regulations, which ostensibly control for information on contra-indications, and safety and quality of medicines (pharmacovigilance).

Effects of DTCA on consumers

Flynn (1999) argues that DTCA makes consumers better informed and more sophisticated. In his view consumers are enabled, through DTCA, to better understand the market for drugs and the therapeutic options available to them. This view is also shared by Calfee (2002), who argues that consumers can engage in more equitable relationships with health care providers and become partners in their own health care as a result of DTCA. Mintzes et al (2002) found that consumers pulled prescription drugs through the system, going to physicians with requests for medications that they had learnt of through advertisements. Their research showed that patients normally got positive responses to requests for prescriptions. Their research also showed that physicians were influenced in their choice of drugs and might otherwise have prescribed different drugs.

Maguire (1999) likewise suggests that American physicians are being asked to 'rubber stamp' self-diagnoses and self-prescriptions by patients. Citing a study by Prevention magazine of the previous year she suggests that 15.1 million U.S. consumers asked their physician for a medication they saw advertised,

and that physicians honoured those requests eighty percent of the time, which translates into 12.1 million prescriptions generated by advertising. Further evidence of the effectiveness of DTCA is the fact that visits to doctors for conditions covered in advertising campaigns rose 263 per cent in the first nine months of 1998, in comparison to a general 2 per cent rise in visits to doctors. Lexchin and Mintzes (2002) examining the relationship between DTCA and prescribing practices find that DTCA does affect doctors' prescribing patterns, which they suggest is not always a positive development. They give as an example General Motors' 1999 internal study of the prescription of the gastrointestinal drug Prilosec (the second most heavily DTC promoted drug in 1999) to its employees. GM found that 92% of those who received a prescription for Prilosec had not received a previous prescription or even consulted a doctor previously for gastrointestinal problems. Most received Prilosec as a first line drug without first trying other cheaper and less intensive treatments. Lexchin and Mintzes argue that this is evidence that DTC has impacted on prescribing patterns, effectively creating consumer pull for in some cases inappropriate therapies.

Creating pull indirectly

Increasingly consumer pull for drugs is being created indirectly also by Internet promotion, and perhaps more questionably by partnerships with patient support groups.

The impact of the Internet

Consumers are able to purchase all kinds of prescription drugs online often without need for a prior prescription. Research conducted by Bloom (1999) showed that most Internet pharmacies provide poor quality information, fail to have adequate safeguards to ensure medicines are dispensed correctly, and also charge more for both products and services. Smith (2003), referring to an Australian study, found that online pharmacies often lacked important information about contra-indications for medications available on their sites. However even if one sets aside the impact of Internet pharmacies, on the basis that the additional costs may put them outside the reach of consumer, the Internet has also offered Big Pharma a largely unregulated way to reach the consumer directly – through company websites. For example, if one searches the Lilly blockbuster Prozac on the internet and goes to the manufacturer's website one can take self-diagnostic tests which allow the possibility for the internet user to self-diagnose depression, even if the site includes warnings and disclaimers.

Using patient support groups

Jeffries (2000) writing about the Association of the British Pharmaceutical industry's strategy for the future of its members "The ABPI battle plan is to employ ground troops in the form of patient support groups, sympathetic medical opinion and healthcare professionals – known as stakeholders" which will lead the debate on the informed patient issue". This tactic is well illustrated by the following quote from Boseley (1999) "A pharmaceutical company will tomorrow break new ground by encouraging the public to demand that the NHS pay to make available one of its drugs. The campaign, Action for Access, is funded by Biogen and organized by a PR company on its behalf. It will urge multiple sclerosis sufferers to demand their health authorities agree to prescribe beta-interferon on the NHS, a very expensive drug, which can help some sufferers, but not all". The United Kingdom Medicines Control Agency subsequently stopped this initiative citing it as unlawful promotion. However Herxheimer (2003) points out that in the absence of adequate independent funding patients organisations and lobbying groups are likely to continue to accept funding from pharmaceutical companies despite the clear ethical issues. He gives as examples the International Alliance of Patient Organisations and the Global Alliance of Mental Health Illness Advocacy which are both highly visible and linked financially to Big Pharma.

Medawar (2002) quotes the Chairman of the Danish Migraine Association who suggests that patient organizations are becoming more sophisticated in their interactions with Big Pharma and may become hardened to this form of below the line promotion. The chairman tells of the association's experiences when it refused to take industry assistance in its activities – magazines, lectures and administration. "the industry, generally assisted by the research doctors, literally created a new patient organization as a substitute for the Migraine Association in 1996. This was a bit too blatant to be generally accepted among informed patients and opinion makers, but only because we did not accept the situation gracefully and made the press aware of our situation. …. Luckily we have a growing awareness about the problem."

Medawar points out that Big Pharma have been successful in presenting their concerns to reach consumers directly as a consumer rights issue, and a potential positive contribution to national health profiles. He suggests that Big Pharma is "gradually shifting the core of its business away from the unpredictable and increasingly expensive task of creating drugs and toward the steadier business of marketing them."

The Push Strategy: Promotion to Physicians and health-care professionals

"Despite the boom in consumer ads, doctors are still king" Maguire (1999)

However enormous the implications of DTCA of drugs and the budgets devoted to this, the issue of physician targeted promotion is significantly greater on all fronts, both financially and in terms of eventual outcomes. Komesaroff and Kerridge (2002) state that promotion and marketing to doctors makes up a quarter to a third of their annual budgets "… totaling more than US$11 billion each year in the United States alone). There are no comprehensive figures available, but it is estimated that, of this, about US$3 billion is spent on advertising and US$5billion on sales representatives, while expenditure per physician is believed to be over US$8000." As mentioned earlier in this article the Canadian Medical Association Journal in 2002 estimated the US promotional spend to be even higher at approximately $19 billion dollars. This activity includes advertising, gift giving and support for medically related activities such as travel to meetings and support for conferences.

Why do firms spend so much on promotion to doctors? Essentially because they rightly see that doctors are the gatekeepers to the success of individual brands. To quote Barnes (2003) "Prescribing 'events' such as a physician swapping one brand for another …. Can make or break a brand's success."

Doctor-targeted promotion takes a variety of forms:

- Gifts, such as free samples, small stationery (Riccardi 2002), travel to conferences and educational events, and, some argue, cash (Medical Marketing & Media 2003, Prawirosujanto 2001, Strout, 2001)
- Sponsorship of conferences and educational events

(Moynihan 2003, Hayes et al 1990, Komesarroff and Kerridge 2002)

- The use of key opinion leaders – i.e. senior clinicians and medical educators as speakers at learned conferences Lerer (2002) Burton and Rowell (2003)
- Funding of medical journals through advertising. Pharmaceutical companies use medical journals to advertise their products, and frequently advertising revenue is the only source of funding of these journals, which are often sent free to doctors. Smith (2003), the editor of the British Medical Journal, writes thus of advertising by Big Pharma "To attract advertising these publications have to be read by the doctors whom the advertisers want to reach. So the free publications work hard at making themselves attractive, relevant, interesting, and easy to read – in contrast to journals, which are often delivering complex, difficult to read material of limited relevance." Davidoff et al 2001 write of a decision among the editors of some of the world's largest medical journals to adopt a common policy of disclosure of information about the source and validity of articles submitted for publication, and possible conflicts of interest. Hence, for example, contributors to the British Medical Journal must disclose any potential conflicts of interest that might arise. This policy does not however apply in the non-medical press and women's magazines, and many of the world's broadsheets carry thinly-veiled info-mercials for medical conditions, such as Revill's coverage of female testosterone deficiency in the United Kingdom national newspaper The Observer in Jan 2003.

" We doctors are shamelessly manipulated by drug companies in all sorts of ways. ..the methods cover the whole spectrum from subliminal to brazen, from little pens that don't work to pushy reps" (Farrell 2000).

Doctors' responses to Big Pharma promotion

Doctors are obviously not undiscerning recipients of advertising and other forms of promotion. Smith (2003) says "Your opinion may not be bought, but it seems rude to say critical things about people who have hosted you so well." He goes on to say that the easy dichotomy of pharmaceutical giants as villains and doctors as innocent victims is over-simplifying the situation. Clearly doctors need to use drugs in order to deliver their services, and it is also reasonable that firms should be allowed to promote their products. "But surely doctors should be looking also to independent sources of information, and how did we reach a point where so many doctors won't attend an educational meeting unless it's accompanied by free food and a bag of 'goodies'?"

Separate studies by McInney, Scheidermeyer, Lurie et al (1990), Banks and Mainour (1992) and Chren, Landefeld and Murray (1989) all found that there was a strong correlation between doctors' tendencies to recommend drugs and their receipt of gifts/sponsorship/ non-related payment etc. Studies by Wazana (2000), Chren et al (1989) and Thomson, Craig and Barnham (1994) all show that gifts impact on doctors' prescribing practices. Wazana (2000) examined 29 empirical studies of the impact of interactions between the medical profession and Big Pharma. Synthesising these findings certain negative outcomes were found to be associated with interactions with the industry:

- Inability to identify inaccurate claims about medications
- Rapid adoption and prescription of new drugs
- Formulary requests for medications without important advantages over existing listed medicines
- Nonrational prescribing behaviours
- Increased prescribing rates, and
- Prescribing of fewer generics and more expensive new medications at no demonstrated advantage.

Komesaroff and Kerridge (2002) also point to the many studies that indicate the advertising rather than clinical evidence alone affects clinical decision-making. They cite Peay and Peay (1988) who found that physicians exposed to advertising are more likely to accept commercial evidence, rather than well-established scientific views.

As Lexchin and Mintzes (2002) argue, if advertising results in these negative outcomes with physicians who are more knowledgeable about drugs and can more easily access objective information, "how realistic is it to believe that consumers will be positively affected?"

Why should this we be concerned with this?

There are a number of key reasons for concern about the impact of pharmaceutical companies' marketing strategies. These include:

- The fact that drug promotion is often misleading
- The risk of disease mongering
- The increasing costs of drugs within national health systems
- New drugs are the ones most heavily promoted and these are the ones with the least well-understood safety profiles.

Drug promotion often misleading

Much drug advertising is misleading. A U.S. congressional inquiry reported that from August 1997 to August 2002 the FDA issued 88 letters accusing drug companies of advertising violations. In many cases companies overstated the effectiveness of the drug or minimised its risks (Gottlieb 2002). Aitken and Holt (2000) found that the FDA filed violation notices for one in four products supported by DTCA. As discussed earlier the instance of non-compliance with medicines board's requirements for accuracy is even higher in New Zealand. PHARMAC, the New Zealand government's drug purchasing agency, has raised considerable concerns about the impact of DTCA saying that consumers interpret the existence of DTCA as government approval of advertised brands, which leads them to discount potentially important risk information.

Misleading advertising can lead to unrealistic expectations

There are many instances of inappropriate drug advertising. Healthy Skepticism New Zealand (HSNZ), a publication of the Medical Lobby for Appropriate Marketing, focused on some of the issues relating to promotion of Viagra in June 2000. They found that the product claims made were in many cases inappropriate since they did not offer enough clarity. The Pfizer ad in New Zealand was as follows "About 52% of men aged 40 to 70 are affected by erectile dysfunction …..In clinical trials 78% of men reported improvements in their erections. So Viagra will work in about 4 out of 5 men." HSNZ took issue with the ad on the following grounds:

- The 52% figure was inaccurate and misleading and had no basis in fact. It was rather the extrapolation of a very limited but favourable related clinical trial.
- This claim could affect men with confidence rather than medical problems – they argue that "exaggerating the severity and/or frequency of conditions to expand markets has been described as disease mongering"
- That "will work" was misleading since it might give the impression that Viagra would "work well enough to enable successful sex" which was not always true. They point to clinical studies which suggest that the success rate of Viagra was in fact 44%.
- They also point out that efficacy in the real world may not equate to the efficacy reported in clinical trials because of halo effects created by enthusiastic specialists.
- They suggest that the ad is "a fallacy of over-simplification" which doesn't convey that improvement in dysfunction may not result in successful sex, and is a function of the degree of pre-existing dysfunction.

While patients might be very disappointed because of unrealistic expectations based on advertisements, these are not as serious as what HSNZ see as the irresponsible downplaying of risks. In a much smaller font on the ad the following three sentences are printed in bold: "You must not take Viagra if you are using any nitrate medication including amyl nitrate (poppers). It may lead to a severe drop in your blood pressure, that may be difficult to treat. As sexual activity may be a strain on your heart your doctor will need to check whether you are fit enough to use Viagra." HSNZ take issue with this warning because they feel it is inadequate, because the use of technical terms such as nitrate medication, rather than brand names may mean that those potentially at risk do not recognize the risks; "readers may not realize that the 'severe drop in blood pressure' may be a euphemism for death"; and it does not refer to existing evidence of the considerable risks that may exist for some potential users and the number of deaths that have been associated with the inappropriate use of Viagra. In 1998 Brooks showed evidence that 69 deaths associated with the inappropriate use of Viagra with legitimately prescribed but contra-indicated drugs. HSNZ make reference to a number of studies that show that there are many contra-indications for Viagra, and they feel that these contra-indications should be more openly and clearly flagged. For similar issues see also Blondeel (1997), www.bbc.co.uk/panorama - Seroxat (2002), and Oldham (2003).

Disease Mongering

Thomas (1980) wrote of his concerns about the potentially negative impacts of increased drug and disease promotion. He felt that the constant emphasis on health risk and the promulgation of the view that people are "fundamentally fragile, always on the verge of mortal disease" was simply untrue. He suggested that "The new danger to our well-being, if we continue to listen to all the talk, is in becoming a nation of healthy hypochondriacs, living gingerly, worrying ourselves half to death." This view is also held by Mintzes (2002) who gives examples of the direct relationship between exposure to advertising and enrolment in drug regimens that are not always necessary or appropriate. Shapiro and Shultz (2001) argue that the increased public exposure to media advertising and discussion of antidepressants such as Paxil (Seroxat) and Prozac have directly led to the inappropriate prescribing of these drugs to patients whose symptoms do not merit such extreme therapies, a view shared by Medawar (2001).

These views are directly at odds with the reality of pharmaceutical industry practices such as that of increasing brand penetration through identifying new ailments that may be treated by existing drugs (thus extending the brand's target markets and potentially its sales). This is well illustrated by U.S. advertisements promoting the Pfizer anti-depressant Zoloft as a potential solution to PMDD – pre-menstrual dysphoric disorder, which has symptoms not that dissimilar to pre-menstrual syndrome (PMS). Similarly the BBC reported a story in Sep 2000 of the propensity of U.K. doctors to prescribe Proxac for PMS (BBC website Sep 2000).

Ever-increasing costs

Ess, Schneeweiss and Szucs (2003) show that expenditures on drugs have grown faster than the gross national product in all European countries, as in the United States. They identify the various methods by which member states attempt to control. Increased controls on costs – by price fixing, or drug budgetting . This parallels the United States where Health Maintenance Organisations and company health schemes already limit their formularies and will not pay for certain drugs (this is not to suggest formulary limitation is in itself wholly negative, it depends on the selection criteria used to make decisions on whether to include or exlude drugs).

For example both the Californian Health Maintenance Organisation Kaiser Permanente, and the NHS in Britain refuse to reimburse patients for Viagra. Moynihan (2003) also points out that costs have spiraled for drugs, vastly exceeding national rates of inflation. Echoing Medawar's (2002) point, it would seem clear that Big Pharma has decided to harvest its investments in development. At least some of the considerable national expenditures on drugs each year is due to inappropriate prescribing for conditions that do not require drugs – the disease mongering spoken of earlier. Another considerable element of the expenditure is related to prescribing newer more expensive medications where older less expensive medications would be just as good. This would seem to be borne out by Stern and Ehrenberg's (2003) finding that 80% of pharmaceutical marketing managers believed that the easiest way to increase the sales of their drugs was to get existing users to prescribe them more. They argue however that pharmaceutical firms would be better advised to acquire more customers, i.e. generate more occasions for prescribing. Either way the implications for costs are enormous. It is important to note though that that increased prescribing is only cost inefficient if medications are prescribed inappropriately. If they are being used appropriately they may save money from other more expensive elements of the health care system, in particular hospital costs.

What needs to happen?

Current regulation of marketing practice by pharmaceutical manufacturing consortia such as the Association of the British Pharmaceutical Industry (ABPI), US PhRMA organisation and the Irish Pharmaceutical Healthcare Association (IPHA) is more than forgiving. For example in the case of sponsorship of sponsorship of overseas travel the IPHA has the following to say:

"Companies may be requested to sponsor the travel expenses of a member of the health professions attending and overseas

international scientific conference. The expenses incurred by the delegate in attending such a conference can reasonably be paid to the delegate by the company and this is acceptable. Hospitality extended by a company to a delegate attending an overseas meeting must be reasonable in level and secondary to the major purpose of the occasion at which it is provided. Hospitality must not be extended beyond health professionals." (IPHA 1999)

Similarly the ABPI has this to say about members' involvement in continuing medical education: "the pharmaceutical industry is also deeply involved in doctors' continuing education, and helps in training prescribers in the uses and techniques of new medicines. G.P.s and other health professionals would find it difficult to keep up to date with scientific and medical advances without these initiatives." (ABPI 2003)They go further in a position paper to say that the ABPI directly complies with UK statutory regulations on the marketing and promotion of medicines.

The US equivalent organization PhRMA adopted a voluntary code of practice for its member organizations in July 2002 that seems to propose the toning down of the extremes of gift-giving and inducements to doctors. However in reading the question and answer section ay the end of the code of practice it is clear this is not the case. Gift giving and generous hospitality, and in some cases, fees for endorsement of products, are still very much allowable. It is important to note that in the United States while PhRMA has its own voluntary code, the FDA still actively monitors promotion, though it lacks the resources to monitor more than a fraction of all promotion, and there are mixed views on its efficiency.

This begs the question is it appropriate to allow an industry such as Big Pharma to self-regulate in the area of marketing? Should this not be the role of government, or wider industry organs such as the International Chamber of Commerce (ICC). Taking the ICC role first it is clear that while individual pharmaceutical companies may well be members of the ICC, they do not often adhere to the again voluntary code of marketing practice which states the following about sales promotion for example "all sales promotions should be legal, decent and honest … all sales promotions should be so designed and conducted as to avoid causing justifiable disappointment or giving any other grounds for reasonable complaint" (ICC2002). Would pharmaceutical promotion meet these standards? The evidence of research into the promotion of products such as Viagra , Seroxat/Paxil and Baycol would suggest not. The fundamental issue in the case of industry organization codes (including ICC) is the real absence of sanction. PhRMA's code of practice is voluntary, as are IPHA's and ABPI's, and "each member company is strongly encouraged to adopt procedures to ensure adherence to this code"(PhRMA 2002). It could be argued that such voluntary self-regulatory codes are not designed to ensure accuracy and objectivity, but are instead set up to 'level the playing field' among member companies. An examination of the origin of complaints to such bodies indicates that most tend to come from other drug companies (Lexchin 2003).

Role of Government

While there are government agencies charged with monitoring the marketing of medicines, typically this is one of many briefs for these agencies and is often only in a reactive fashion. In other words such monitoring as does occur, occurs only in response to complaints, and even then is often very slow and cumbersome.

A way forward

Clearly there are many aspects to this issue, not least the argument frequently put forward by Big Pharma that they fund the majority of research into often life-saving therapies and are therefore net contributors to society. There are also obviously the wider philosophical debates about the degree to which societies should be regulated, and issues around defining reasonable profit and appropriate business behaviour which beleagur many sectors, not just Big Pharma. However not withstanding these elements, I argue that two things should happen –

- Independent monitoring bodies should be established to police marketing codes of practice with real penalties and,
- increased attention should be paid to the education of the consumers of pharmaceutical advertising, in particular those with prescribing powers.

Independent monitoring of marketing codes of practice with real penalties

The pharmaceutical industry should not be self-regulating in this vital area since misleading/inaccurate pharmaceutical promotion can have very serious impacts. Rather governments and national medicines agencies should take pro-active stances in monitoring drug advertising and promotion practices, with real penalties, in particular substantial fines. The current reactive and non-dedicated status of monitoring agencies is inadequate. This is in part due to the inadequate resourcing of such organisations. This might be countered by an arrangement such as that underpinning the Superfund of the US Environmental Protection Agency, where industry members pay a levy to fund the monitoring of environmental impact and the policing of polluting behaviour. Similarly, in 2002, the U.S. Government's Sarbanes-Oxley Act established the Public Company Accounting Oversight Board to be funded by industry contribution, which replaced industry self-regulation, which was seen to have failed following the major financial scandals associated with Enron and WorldCom.

In addition to adequately funded monitoring bodies to oversee marketing practice, the system of penalties for infringement need to be overhauled. While many countries have codes of practice, and agreed understandings as to appropriate practice, such as the U.S. FDA code of practice, often the penalty systems are inadequate to the point of being ineffectual.

For example under the United Kingdom's ABPI code of marketing practice complaints about infringement can be made by anyone including members of the public. The company has six weeks to respond in writing, with a defense of the issue at hand. This complaint is then considered by a panel of three people with legal backgrounds, on behalf of the ABPI. If the company is found to be in breach of the code of practice they will incur a fine in the order of £1000 (approx US$1670) and be required to give an undertaking to withdraw all offending materials within approximately two weeks. If the breach is judged to be serious, and to "bring the industry into disrepute" then the fine will be more severe, but still relatively small.

If one considers the profits to be made within the pharmaceutical sector, and the potential human risks associated with misleading or inaccurate promotion, it would seem clear that the penalties for breaches of marketing codes of practice should be commensurate. It could well be argued that the fines that apply in many countries are financially insignificant to Big Phar-

ma, and therefore considered effectively a cost of doing business rather than a risk.

Increased education of consumers and those with prescribing powers

In addition to increasing the monitoring and policing of Big Pharma promotion, it would seem prudent to increase the awareness and sophistication of the key promotion targets, through increased education about marketing. General consumer education is difficult to achieve, as is daily evidenced by the limited success of public health promotion campaigns such as those around the health risks of smoking. That is not to suggest that it should not be attempted, but it would be unwise to expect it to have immediate and universal impacts. While general consumer awareness may be difficult to achieve, considerable opportunity exists for increasing the knowledge base of those with prescribing powers. A review of the curricula of medical schools, for example, across Ireland and Britain shows that at present there is no education in the area of business and in particular marketing (English Maher 2003). This should surely be addressed, so that at least doctors, and others with prescribing powers, would understand the techniques and practices to which they will be subjected as practitioners.

Initiatives are being taken to increase awareness of the nature and impacts of pharmaceutical promotion in the United States. Significantly the American Medical Student Association has recently begun a campaign to regulate the relationship between Big Pharma and medical students (Moynihan 2003). The PharmFree pledge that the American Medical Student Association propose students sign includes the following "I will make medical decisions … free from the influence of advertising or promotion. I will not accept money, gifts or hospitality that will create a conflict of interest in my education, practice, teaching or research." The tenor of the PharmFree pledge should be the guiding point for setting standards of practice for pharmaceutical marketing.

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