

**MHRA PUBLIC CONSULTATION
WITH PATIENT REPRESENTATIVES:
*MEDICINES INFORMATION AND ADVERTISING***

Main report

[To be read with accompanying APPENDIX]

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**PUBLIC CONSULTATION WITH
PATIENT REPRESENTATIVES:**

*MEDICINES INFORMATION
AND ADVERTISING*

Main Report

**SURVEY AND ANALYSIS CONDUCTED BY PATIENTVIEW
SEPTEMBER 2005**

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Results of survey: *setting the scene*

The survey

During a four-week period in August-September 2005, PatientView † conducted on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA) a UK-wide email survey of organisations that represent the interests of patients and the public. The body of organisations approached had an interest in a wide range of diseases and medical conditions, as well as in carers, consumers, and people with a disability. Two types of statutory groups were also canvassed: Patient Advice and Liaison Services (PALS), and Patient and Public Involvement Forums (PPIFs) [the administrators of PPIFs are called PPIs in this report]. PALS are staffed by NHS employees, and offer support to patients who are unhappy with the care they receive in the NHS. PPIFs are staffed by local volunteers. They provide input from patients on the running of local NHS services, and suggest improvements to services.

This survey of NGOs and related statutory organisations was part of a public-consultation exercise on the subject of 'medicines information and advertising', with the aim of allowing the MHRA to (hopefully):

- 1.) advance its activities in improving the quality of patient information, and
- 2.) set standards for the advertising of medicines in the UK.

† [PatientView, an independent research and publishing organisation which works with patient organisations, conducted the survey and produced this analysis of the survey findings.]

Methodology

The survey questionnaire emailed to campaigners was fronted by a personal invitation from Professor Kent Woods, Chief Executive Officer of the MHRA, explaining the importance of the survey. The questionnaire itself comprised 15 questions on a range of topics that fall within the remit of the MHRA, namely:

- ▶ The availability of high-quality patient information on medicines.
- ▶ Leaflets inside the packaging of medicine.
- ▶ Pharmaceutical companies' promotional activities to health professionals.
- ▶ The handling of complaints about the advertising of prescription and over-the-counter (OTC) medicines.
- ▶ Safety messages and claims in the advertising of prescription and OTC medicines.
- ▶ Regulating disease-awareness campaigns.

The respondents

The target number of responses for the survey was 200. By the survey's closing date of Thursday, September 15th 2005, 268 valid responses had been received. Responses arrived from across the UK (Northern Ireland generated the least number of responses). The highest representation came from organisations specialising in:

- 1.) mental health (including anxiety, bipolar disorder, depression, eating disorders, schizophrenia, and the mental health of children/older people); or
- 2.) neurological diseases (including Creutzfeld-Jacob disease, chronic fatigue syndrome, dementia, multiple sclerosis, and myalgic encephalomyelitis).

Some 49% of the 268 respondents worked for organisations with a local remit; another 43% for groups with a national remit; while 13% of the groups maintained responsibilities of international proportions. A number of the respondent groups had more than one geographic area of responsibility (for instance, local and national, or national and international). Significant representation came from the statutory sector: 7.9% of the survey participants were either PPI/Fs or PALS.

The vast majority of respondents (82%) preferred to provide the survey with their personal opinions. The remaining 18% (nearly one fifth) provided the viewpoint of their organisations.

Most respondents were either board members, senior executives, policy advisors, parliamentary lobbyists, healthcare professionals attached to the organisation, support workers, individuals responsible for communicating information to patients, project workers, or volunteers. A few of the respondents were patients/service users themselves.

Just under one third of the respondents wished their organisations and/or themselves to be attributed as survey participants [see Appendix 1].

**THE AVAILABILITY OF
HIGH-QUALITY
PATIENT INFORMATION ON
MEDICINES**

Are patients able to get high-quality, useful information about over-the-counter (OTC) medicines (whatever the source—pharmacists, the Internet, patient-package inserts)?

Some 70% of the survey's 268 respondents felt that patients could only "sometimes" access high-quality useful information about their over-the-counter medicines (OTCs). A further 9% believed that such information was never available. Only 13% specified that patients have no difficulty in getting hold of information about their OTCs.

These latter respondents placed trust in **pharmacists** as a source of good data on OTCs. A respondent from a PPI Hospital Forum wrote: "Pharmacists are good at giving information". A PALS co-ordinator added: "Patients only have to ask a pharmacist (they are always pleased to help)".

Other respondents, though, were not as confident in the abilities of pharmacists to deliver information. "Experience has shown that pharmacists are often a good source of information. However, I have examples of when pharmacists' advice has been, at best, dangerous", wrote one respondent from a group specialising in childhood conditions. Some respondents noted that retail pharmacists do not appear to know enough about certain aspects of medicines (particularly drug interactions). The **UK Coalition of People Living with HIV and AIDS** commented: "There are gaps in information, particularly on drug interactions with other specialist drugs (example, the advice of a specialist HIV pharmacist is needed before considering the use of even a simple anti-histamine if a patient is on certain anti-retroviral treatments)". A respondent from a group specialising in depression also noticed that "St John's Wort is sold in general shops with no information—which is a problem regarding interactions".

Other respondents indicated that pressures of work sometimes prevented pharmacists from finding time to help. "Depends how busy the pharmacist is", wrote the respondent from a group specialising in chronic back pain. The respondent from the **East Kent and Coastal PPIF** noted: "Many pharmacists don't have the time or the inclination to give patients information—unless asked specific questions (which most patients are not knowledgeable enough to ask)". "Small local pharmacists are very helpful. But not so those in larger establishments", specified an anonymous respondent. The **Insulin-Dependent Diabetes Trust** thought that pharmacists could be uninformative: "Patients have to know where to find high-quality, useful information about OTC medicines—especially difficult if their pharmacy is not forthcoming with the information they need or want".

Respondents also observed that the advice provided by pharmacists appears to be determined by data gained from populations of patients. One group specialising in congenital heart disease in adults insisted: "When pharmacists are available, the advice they provide is normally excellent, but tends to be based on the norms, rather than on the specific information of individual patients".

ACCESS TO HIGH-QUALITY PATIENT INFORMATION ON OTCs (CONTINUED)

Fenella Lemonsky of the group known as **Expert by Experience** (which tackles issues faced by mental health service users) argued that pharmacists may also put their own vested interests above those of patients, rarely recommending OTC generics in preference to more expensive, branded OTC products—despite the fact that the active ingredients of both types of medicine are the same. “People will go to a chemist and buy, say, Nurofen if they don't have asthma, say. But they could have bought a generic cheaply. And, also, maybe paracetamol may have been more appropriate, or aspirin. But they don't know, and the chemist will always sell the most expensive branded product. I have witnessed this unless someone specifically asks for a generic!”, wrote Ms Lemonsky.

Ms Lemonsky also reported that pharmacists fail to make clear the fact that simple home remedies might occasionally resolve a patients' medical predicament as well as any OTC.

That said, a number of survey respondents did lament the lack of professional advice available when OTCs are purchased via the Internet or in supermarkets. “If bought in a supermarket—no”, pointed out a group specialising in learning disability. “As far as the Internet is concerned, not all patients have access, or want access, and not all patients are able to understand or interpret the information available”, stated the **UK Forum of EUROPA DONNA—the European Breast Cancer Coalition**.

Another important source of information on OTCs is the **patient information leaflet (PIL)**—a subject that engendered much (often critical) comment from respondents. Disadvantages with PILs seem to include:

- ▶ The size of font used in PILs is not large enough to be read easily (or at all) by many categories of patient. “Print on package inserts is often too small”, commented the **St Albans and District Voluntary Diabetic Support Group**. “Patient inserts are not available in large print. The majority of patients are elderly, and more likely to require large print”, noted a group specialising in visual impairment.
- ▶ The quality of the paper is poor, further reducing readability.
- ▶ Not all PILs are available in Braille. The respondent from **Arthritis Care** wrote: “Not always available in certain formats, such as Braille, or for people with learning difficulties”.
- ▶ The prose in PILs is far too complex and technical. “Not always in plain English”, argued the respondent from a group specialising in mental health.

Heart to Herts Cardiac Support Group drew the survey's attention to a major disadvantage of the medium—PILs cannot usually be studied before the patient owns the medicine. “The information [provided by PILs] is only available after purchase”, commented the group.

The **outer packaging of OTCs** prompted comment. One respondent was less than happy that manufacturers used commercial design-and-layout techniques on the

ACCESS TO HIGH-QUALITY PATIENT INFORMATION ON OTCs (CONTINUED)

packaging of OTCs to catch the eye of prospective customers. Dr Karel van der Waarde (who advises UK patient organisations on the accessibility of information) reported that these advertising messages and images can overwhelm important product-safety information: “This packaging has several functions. One is to attract the attention of potential consumers. Another function is to inform about the product. Unfortunately, the information function is frequently underdeveloped”.

A comment made by the campaigning consumer organisation **Which?** summarised the views elicited by the survey: “The only consistent source of information about OTC medicines is the PIL supplied with the packaged medicine. Which? believes that PILs are not working in the interests of patients at the moment. The information is often poorly organised, giving unclear details about side-effects, and the leaflets are often printed in a small font size, and on poor-quality paper”.

Which? mentioned that the advertising of OTC medicines is a major source of information for consumers—but added that it can lack integrity. A respondent from the **British Heart Foundation** thought that promotional activities even lead to sales of products that can claim little obvious merit: “This is usually influenced by the extent of commerciality—for example, vitamins which actually have very little existing evidence of benefit in terms of coronary heart disease prevention”. [The value of medicines advertising is covered in more detail later in this report.]

Do you believe that patients get high-quality, useful information about prescription medicines (whatever the source—doctors, pharmacists, the Internet, patient-package inserts, etc)?

Taking all the respondents' comments into consideration, the types of queries that patients raise about their prescription medicines are as follows:

- ▶ Why have I been prescribed this medicine?
- ▶ Does the medicine work in someone like me?"
- ▶ What choices of treatment do I have?
- ▶ What beneficial effect can I expect?
- ▶ What are the side-effects?
- ▶ Do the benefits of medication outweigh the risks?
- ▶ How do I know whether the information I get on prescription medicines is high quality?

Only 13% of the survey participants stated that patients "always" get high-quality information about prescription medicines. Another 61% of respondents were certain that patients only "sometimes" get such information. Over one fifth (21%) considered that patients "never" accessed high-quality, useful information about prescription medicines.

Respondents' numerous comments to this question made clear that patients can tap into multiple sources of information on prescription medicines. The sources include: health professionals; patient information leaflets (PILs); the Internet; patient groups; and pharmaceutical companies.

Many respondents noted, however, that the information from all these supplies is not often readily at hand for patients. Only the PILs provide information passively. To draw information from any of the other potential sources requires patients to take the initiative, and to seek out (or ask for) the information themselves. "But only some [patients] have the skills, confidence, ability, and capacity to search [for] it", stated a respondent from a regional PPI. The **Highland Users Group** wrote: "As a group, we do get good information. But we are assertive in asking for it".

A respondent from a group specialising in Asperger syndrome explained why the situation was unacceptable: "The information is there if one asks, or researches it in books, or on the Internet. But, all too often, GPs do not volunteer it—especially with drugs used in psychiatry (such as anti-psychotics). These patients are often too vulnerable and in need to be able to research the often-horrendous side-effects".

The central message emerging from the responses to this question was the variable quality of information on prescription medicines (whatever the source). A respondent from the **Patient Information Forum** thought that the "provision [of information on prescription medicines] is inconsistent. Information is not provided about all products. What is provided often differs according to sources sought". **Which?**

ACCESS TO HIGH-QUALITY PATIENT INFORMATION ON PRESCRIPTION MEDICINES (CONTINUED)

added: “In short, there is a great deal of information that is misleading, inaccurate, or simply does not meet individual needs”.

Another factor which needs to be addressed, according to survey participants, is the timing for delivering information about prescription medicines to patients. “In life-threatening situations, or where patients are considerably distressed (for example, on diagnosis of a serious illness), the amount of information provided may be too much, too soon. For some, it will always be too much. But others may realise—some time after the consultation with a doctor—that they need to learn more”, remarked the **UK Coalition of People Living with HIV and AIDS**.

Thus, patients can face significant hurdles when attempting to get answers to their questions on prescription medicines. A respondent from the **European Network of (ex-) Users and Survivors of Psychiatry** mentioned yet another difficulty. Much of the patient information on prescription medicines (as with OTCs) is not meaningful to patients. “Where do you find unbiased information about how it will affect you (for your age, weight, height, gender, etc)? And, with side-effects: by percentage likelihood of being present. And how soon? Days, weeks, years?”, the respondent asked.

The consequences of a patient’s medical ignorance can be serious, stressed the **Insulin-Dependent Diabetes Trust**: “Patients do not get sufficient information to give them an informed choice of treatment (the risks and benefits of various medicines)”.

The survey found that all the usual sources of information on prescription medicines, even one of the oldest and most trusted—**doctors**, are burdened with inadequacies. Drawbacks with doctors as providers of information include:

- ▶ Doctors are too busy to act as conduits for information. “Doctors don’t have the time or the inclination to discuss”, argued a respondent from a group specialising in hepatitis C. “Professionals do not always take enough time to speak to patients”, wrote one of the volunteers from the **Swale (Kent) PPIF**. “Most [health] professionals give information far too quickly, and do not check that older patients have really absorbed the information (or give any prompting in an accessible format)”, declared a respondent from a group specialising in sight loss.
- ▶ Doctors vary in their willingness to convey information on prescription medicines to patients. “It would probably depend on the doctor or pharmacist, as to how much they explained to a patient prior to the patient taking the medicine”, pointed out a representative of a genetic disease group. A respondent from a group specialising in primary immunodeficiency was of the same view: “Depends very much on the doctor”.
- ▶ The paternalistic doctor still exists. The **St Albans and District Voluntary Diabetic Support Group** reported that information from the GP is “usually only available if the patient asks. Many are hesitant to do so”. “My doctor is good. But most treat patients like they are idiots”, was the message conveyed by a respondent from a group that specialised in chronic back pain (though the same respondent added that patients are partly to blame, as they “don’t listen to what they are told”).

ACCESS TO HIGH-QUALITY PATIENT INFORMATION ON PRESCRIPTION MEDICINES (CONTINUED)

- ▶ Doctors do not always understand the disease condition—leading to inappropriate prescribing. According to the **Anaemic Society**, “with pernicious anaemia (PA), it all depends on the attitude and knowledge of the GP/consultant. Some make an effort to explain what the medicine does. But far too many do not, or—surprisingly—do not really understand the condition. One member was diagnosed, and told to visit a vitamin shop and purchase B12 tablets, and return to the doctor in six months’ time”. Other respondents wondered how patients can know whether the information they have been given is wrong, one-sided, or sub-standard.
- ▶ “Doctors do not always inform patients of side-effects—or explain why they have prescribed specific medicines”, insisted a respondent from **Brain Tumour UK**. The **Parents of Autistic Spectrum Disorder Adults, Edinburgh** remarked: “Not unless you ask, and then the side-effects are not always discussed”. A group specialising in visual impairment agreed, stating: “GPs do not explain side-effects clearly”.

One of the most reliable sources of patient information should theoretically be the patient information leaflet (**PIL**). But, as mentioned in comments about PILs in the previous question on OTCs, the PIL is handicapped by numerous presentational deficiencies. Criticisms of PILs raised by respondents in this part of the questionnaire included:

- ▶ The PILs’ extensive list of side-effects devalues the format’s overall informational worth. One respondent who wished to remain anonymous wrote: “In most cases, I would not read the information (other than how to take the medication). Also, the information is too generic, in that you could suffer hundreds of side-effects—thereby negating the value of the information. This is the drug companies’ way of ensuring that they are covered”.
- ▶ The PILs’ informational content needs to be more accessible to people with a learning disability, said Paschal McKeown of **Mencap**. “Also important”, he insisted, “is the inaccessibility of some technology (such as telephone helplines, the Internet, etc) for individuals who may have communication difficulties, or who find it hard to understand information that is not tailored to meet their specific needs”. “PILs continue to be a regulatory / pharmaceutical vehicle and not one that is truly consumer-centric (despite welcome attempts—such as advertising—in this area). PILs need to be user defined, not merely user-tested”, expressed the respondent from the **Patient Information Forum**.
- ▶ PILs are sometimes not supplied to patients in hospital. **Rethink Severe Mental Illness** judged that this practice is particularly common in settings where psychiatric medicine is practised: “In some psychiatric hospitals, notes are removed”, wrote the group.
- ▶ PILs are of little use when drugs are prescribed off-label. “It is sometimes difficult for people to get information on medication which has no product licence (for instance, antidepressants for neuropathic pain)”, argued a patient advocate from a group specialising in neurological conditions.

As for the contribution of **pharma**, respondents were disappointed with the quality of the information that the industry placed in its prescription-medicine PILs. “Where

ACCESS TO HIGH-QUALITY PATIENT INFORMATION ON PRESCRIPTION MEDICINES (CONTINUED)

drugs are fast tracked (as has been the case with some HIV medicines), the danger lies in long-term use, and long-term side-effect profiles. The pharma industry always plays down the downside, and trumpets over-effectiveness. This negates the information in patient information leaflets in packages of drugs”, stated the **UK Coalition of People Living with HIV and AIDS**.

The consumer group **Which?** called for “an independent body to oversee the development of an effective patient-information strategy that would meet the needs of patients and carers for accessible and objective information. This body would assess patient information to ensure that it is accessible, accurate, appropriate, consistent, current, evidence-based, non-biased, timely, transparent and understandable”.

**LEAFLETS INSIDE
THE PACKAGING OF
MEDICINES**

Are the leaflets inside medicines packaging read by patients?

A meagre 6% of survey respondents assumed that patients always read the patient information leaflets (PILs). Just under one third believed that patients would read the leaflet if the medicine was new to them. A further 31% felt that it depended on the medicine. And 16% were certain that patients *never* read the PIL. “People often put them in the bin”, declared a volunteer and member of the **Windsor, Ascot and Maidenhead PPIF**.

Most patients do not bother to read the leaflet unless a doctor or pharmacist has warned otherwise, wrote a respondent from a group that represents the interests of older people. This participant specified that patients only feel impelled to study the PIL if the medication is novel, or when something has gone wrong. “Patients are more likely to read the packet” than the PIL, reported the respondent from the **Obesity Awareness and Solutions Trust**.

Respondents provided the following explanations for patients’ unwillingness to read PILs:

- ▶ The non patient-friendly format of medicines-packaging inserts prevents many patients from reading the information they contain. Patients with impaired vision and learning difficulties are particularly disadvantaged. A respondent from a group specialising in deafness and the hard of hearing noted: “The print is too small. The leaflets contain too much information. British Sign Language is the first language for many deaf people, so the information on the leaflet is too dense for them to understand”.
- ▶ Some patients do not think that reading the PIL is necessary, “because it must be OK if the doctor prescribes it”, advised the **St Albans and District Diabetic Support Group**. The respondent from the **Congenital Adrenal Hyperplasia Support Group** agreed: “I personally do read the leaflets inside medicine packaging, but I am probably in the minority! I feel most patients trust their GPs/consultants/pharmacists, and often don't read the literature unless they feel the medication makes them worse”. A group specialising in learning disability added: “Many people do not read the leaflets unless the doctor or pharmacist points out that they should”.
- ▶ An asthma patient organisation mentioned that whether patients consulted PILs or not was dependent on their socio-economic grouping. PIL readers are from “higher social classes, are literate and well educated”, wrote this respondent.
- ▶ The **Insulin-Dependent Diabetes Trust** also warned: “There is a problem with long-term medication, in that people do not read the patient information leaflets on the assumption that they have read them before, or it is not a new medicine for them. They do not realise that, although the medicines may not be new, there may be new information included in the PIL”. “Sometimes, clients have taken the drug for so long, they completely ignore the PIL”, insisted **Epilepsy Action**.

Many respondents believed that patients who do read their PILs seem to be no better off than the individuals who avoid reading the leaflets—because members of

READING MEDICINES LEAFLETS (CONTINUED)

the public cannot disentangle which part of the PILs' information is relevant to them. A respondent working at a Primary Care Trust in East Anglia suggested: "Leaflets sometimes put patients off taking their medicines, because, by law, they have to list all possible side-effects, and do not always make clear how often they occur. Patients are not good at assessing the risk-benefit". A respondent from a group specialising in genetic disease stated: "Rarely [do patients read the medicine leaflet]. Again, depends on the patient. They may read the information, but it is whether or not they understand it that is important". A respondent from **Brain Tumour UK** echoed the sentiments of peers: "The information is sometimes very long-winded, and contains medical jargon. And the explanations and the print are also very small, making the leaflets difficult to read and understand". **Rethink Severe Mental Illness** wrote: "The language used in leaflets can be too technical, and, consequently, difficult to read".

The consumer group **Which?** emphasised the need for PILs to be tested on users before public release: "Focus-group research carried out by the Consumers' Association, and published in 2000, found that PILs fail to give patients the information they need in a way that is easy to understand [*Patient Information Leaflets: Sick Notes?*, CA, 2000]. These issues have been outlined above, and they informed the work of the CSM Working Group on Patient Information and its report, *Always Read the Leaflet*. With the introduction of user testing of patient information leaflets, it is to be hoped that improvements will be seen, and information will be presented in a more user-friendly way".

Are medicines leaflets good at explaining how to get the most benefit from the medicine?

Roughly one quarter of the respondents judged PILs to be either “very good” or “good” at explaining how to get the most benefit from the medicine. But almost 68% of respondents pronounced PILs either “not good” or only “sometimes good” at this task. The executive responding on behalf of the **Prostate Research Campaign UK**, and Tony Gavin, CEO of **Leukaemia CARE**, both wrote that PILs inform about side-effects, not medicine benefits. Other groups commented that side-effects were not sufficiently covered in PILs. **Central Liverpool PCT PPIF** believed: “Leaflets do not fully explain side-effects”, while the **Chronic Myeloid Leukaemia Support Group** recommended that PILs “should give some information on how to deal with side-effects”.

The views expressed in the survey suggest that patients prefer to ask their doctors (and sometimes their pharmacists) for information about the benefits of medicines. As a respondent from the **National Ankylosing Spondylitis Society** conjectured: “I believe that patients depend on their doctors for this information”. The **Alzheimer’s Society (Selby and York branch)** was of the opinion that most patients look to doctors to tell them why a drug will do them good: “Rarely. I think it is usually expected that doctors will give this information”. “The doctor should have explained the benefit of the medicine, and the reason for prescribing it”, remarked the **UK Forum of EUROPA DONNA—the European Breast Cancer Coalition**. The **Highland Users Group** opted for pharmacists over doctors: “We would rather ask a pharmacist”.

Many respondents put forward arguments to explain why PILs fail to transmit the advantages a drug might bring to patients. A respondent from a group specialising in learning disabilities mentioned: “If they do this, it is often not clear enough”. The respondent from **Havering Mind** elaborated: “Not really—they only tell you the dose”. The respondent from the **Windsor, Ascot and Maidenhead PPIF** noticed: “Leaflets do not tell you the optimum time of day to take the medication”. The respondent from **Brain Tumour UK** concurred: “Leaflets do not usually tell you the best time to take medication. This is left to the GP (with food or not; time of day; number of times per day; etc)”.

Respondents were more divided on the topic of whether a greater amount of information on medicine benefits would be welcome in PILs. One carers’ group said that they would appreciate such information. The respondent from a group specialising in osteoporosis argued: “Insufficient relevant information is highlighted (for instance, with “A glass of water”—what size should the glass be?)”.

Other respondents considered that the PIL was not the best place to convey the advantages of treatment. An asthma patient group wrote that information in PILs about benefits is often difficult to comprehend, and should be reorganised: “The leaflets do contain information about the benefits of medicines, but we need to make it easier [to understand] and more accessible to the audience. A suggestion is to target messages about benefits to a lay audience, provide pictures, make it easy to

MEDICINES LEAFLETS AND EXPLAINING THE BENEFITS OF MEDICINES (CONTINUED)

read, and include devices such as ‘Step 1, 2, 3’ or ‘Stages 1, 2, 3’. This will allow more people to read the leaflets, and also to understand how to get the most benefit from their medicine”.

The subject of the relative unintelligibility of PILs was a recurring refrain among respondents. “Not very educational to the patient. Confusing, and not easy to understand”, specified a respondent from a diabetes group. A respondent from a group specialising in depression stressed: “Some people may find leaflets too complex. They need more summaries with clearer (but briefer) information”.

Rethink Severe Mental Illness offered an explanation for the apparent complexity of PILs: “They are mainly about what the manufacturer thinks needs to be said, rather than what the patient needs to know”. A respondent from a PPIF member of an ambulance service agreed, elaborating: “[PILs are] sometimes overcomplicated by the need to cover product liability”.

Dr Karel van der Waarde summed up the situation: “One of the problems with these leaflets is that the sequence of their contents is strictly regulated by EU and UK laws. The benefits must be mentioned at the beginning, while the risks are mentioned throughout. This, in practice, prevents patients from making a considered benefit-risk decision”.

Are medicines leaflets good at communicating information about safety considerations?

A small percentage (6%) of respondents thought that PILs were “very good” at communicating information about the safety considerations that must be borne in mind when taking a particular medicine. Just over one third believed that PILs were “good” at this task. But the majority of participants were less convinced that PILs were effective at informing patients about safety issues—one third of respondents indicated that PILs were only “sometimes good” in this regard, while just over one fifth (21%) pronounced them “not good”.

Some divisions appeared among respondents as to whether PILs contained too much or too little information. A respondent from a group specialising in irritable bowel syndrome thought that “the leaflet is too general”, and the **Highland Users Group** also wrote that PILs are “quite vague”. On the other hand, a group specialising in Von Hippel Lindau syndrome observed: “Sometimes, the amount of information given in these leaflets is quite frightening for those concerned”. And the respondent from the **Tameside Blind Association** was certain that PILs “can be too informative at times”.

Many respondents suspected that PILs could do better on the subject of side-effects. The **Polychondritis Education Society** explained: “I believe that leaflets should simplify their information. With their wordiness and confusion, it is often hard to determine if the medication is more harmful than the disease”. Another example of the bewilderment that patients can experience after reading a PIL was provided by an advocate from a group specialising in young families and expectant fathers: “Leaflets sometimes say ‘Do not drink, or operate machinery’, even when the product is deemed to be non-drowsy—which then becomes confusing to the patient”. A respondent from a group specialising in prostate cancer added: “The likelihood of a rare and disastrous side-effect doesn’t seem to be well differentiated from the common, and less problematic, side-effects”.

Several respondents considered that the contents of PILs reflected a desire among manufacturers to protect themselves from legal action. A professional nurse attached to a patient organisation wrote: “No—[PILs are] more concerned about the litigation element, and frightening patients”. A group specialising in mental health stated: “An over-emphasis, if anything—probably for litigation reasons”. The respondent from the **Crawley PPIF** was in agreement: “Too much information covering the producer”.

Many respondents expressed a belief that the warnings in PILs were frightening, and might have an unfavourable impact upon patients. “Many patients become unnecessarily alarmed, and stop taking their medications”, warned a representative from a group specialising in pituitary disorders. The **Parents of Autistic Spectrum Disorder Adults, Edinburgh** conjectured: “If the leaflets were printed in a reasonable size of print, it is unlikely that anyone would take anything”. A respondent from a group specialising in cancer of the blood shared the opinion: “A

MEDICINES LEAFLETS AND EXPLAINING SAFETY CONSIDERATIONS (CONTINUED)

long list of all potential side-effects—which inadequately differentiates common from very rare—can be intimidating to patients. Frankly, I doubt if one would even take aspirin if one saw a complete list of potential adverse effects”. A group specialising in congenital heart disease in adults wrote: “The advice and contraindications given seem to be all those possible—rather than being focused. This can lead to people not taking their medications due to fear—rather than there being a real concern”. According to the respondent representing the **British Heart Foundation**: “There are many people who refuse to take an important medication because they are concerned about the risk factors, and [mentally] exaggerate their potential effect”.

Respondents recommended a number of ways to improve the safety information in PILs:

- ▶ Safety information should be upfront and prioritised. “This [information] needs to be the first thing you see [in a PIL]. Often, it is too far down the sheet”, wrote the respondent from **Arthritis Care**. A group specialising in the needs of carers offered: “Need to prioritise information, not just bulk”. A respondent from a group specialising in multiple sclerosis stressed: “I think that very important information could be highlighted more—perhaps in red? Maybe develop a set of symbols to indicate to patients that they MUST read this part?”. The respondent from the **Swale (Kent) PPIF** argued along similar lines: “All safety considerations should be in red”.
- ▶ More emphasis should be placed on the dangers of over-medication. A respondent from a group specialising in diabetes commented: “[PILs] do not give enough importance to taking too much medication, and what the side-effects of doing that are”. The respondent from **Haverling Mind** commented: “No. [Medicines leaflets are not good at communicating information about safety considerations.] They just say in the event of an overdose. They could say more about what might happen, and what damage you could do”.
- ▶ Larger font size needed. The recurring comment about the excessively small size of font used in the typeface in PILs was again mentioned by a number of respondents. A respondent from an anonymous PPIF noted: “The writing on the leaflets is much too small for older patients”. The respondent from **Mind (Cymru)** judged: “They are not accessible at all, because the writing is far too small. So, this disbars most people from receiving the information”. The **Huntington's Disease Association (Colchester and District Branch)** wrote: “Again, due to font size and leaflet size, the safety information does not always stand out”.
- ▶ Safety information should be on the container. “People may not read it [the PIL]. Elderly people may have poor sight, and/or limited capacity for intake of a large amount of detailed information. I would like to see strong warnings on the container (and the item), accompanied by detailed information in the leaflet”, insisted a respondent from a brain cancer organisation. “This information should be on the packet, as well as in the leaflet”, agreed the **Central Liverpool PCT PPIF**.
- ▶ Contra-indications should be better explained. “Questions about contra-indications, alcohol, etc, are often not addressed”, commented a respondent from a regional PPI. “Contraindications are included often, but not presented in a clear and understandable format”, was the opinion of **Diabetes UK**. The

MEDICINES LEAFLETS AND EXPLAINING SAFETY CONSIDERATIONS (CONTINUED)

Insulin-Dependent Diabetes Trust made a comparable point: “The section on drug interactions lists the names of drugs—these are meaningless to many people. They may be aware of brand names, but not drug names.”

- ▶ Examples should be given. A respondent from a group involved in health promotion advised: “If there are too many 'way-out' risks (such as stroke, etc), it can make the risks seem too abstract. It would be great to get examples”.

But, even if PILs were subject to improvements, the respondent from the ***East Kent and Coastal PPIF*** felt that it was important for “any serious safety considerations to be re-emphasised by the pharmacist and the GP”. The respondent from the ***British Heart Foundation*** considered the same: “There can be a problem if the person is not guided adequately by the health professional to weigh up the benefit of the drug in treating the illness against its inevitable (maybe small), side-effects”. A respondent from a group specialising in older people, however, was less impressed with the idea of asking a doctor to explain safety matters: “What ‘safety’ are you meaning? Mostly, leaflets say: ‘Go and talk to your doctor’. The doctors are too busy”.

Are medicines leaflets good at informing patients about the effects (if any) of a medicine on driving ability?

Respondents were split on the question about the ability of PILs to deliver information on medicines and driving. Some 44% of respondents believed that PILs were either “very good” or “good” at providing information about the effects of a medicine on driving ability. A similar figure—46%—thought that PILs were only “sometimes good”, or “not good” at the task. (A further 8% of respondents did not know how to answer the question.)

However, as a respondent from a group specialising in osteoporosis remarked: “The leaflets are usually good [at this]. But, since most patients don’t read them, it is academic!”. Paschal McKeown of **Mencap** reminded the survey: “Few people with a learning disability can drive”, while a respondent from a group specialising in learning disabilities pointed out that information on medicines and driving “is often not relevant within a learning-disability context”.

Respondents produced a number of recommendations as to how warnings on medicines and driving could be improved in PILs:

- ▶ Greater emphasis on these warnings in PILs. Some respondents were unhappy with the current shape of the information about the effects of medicine upon driving. **Salford Heart Care Re-Hab** wrote: “Not highlighted”, and a respondent from a group specialising in older people, dementia and mental health stated: “Not clear enough”. A respondent from a group specialising in irritable bowel syndrome wondered: “But do patients really take it on board, and read this, or think it relates to them?” A number of respondents called for more weight to be given within PILs to any information about driving. A professional nurse attached to a patient organisation stressed: “Need to be more emphatic. No one wants to give up driving”. A respondent from a group specialising in depression wrote: “This key information needs highlighting”. The respondent from the **Swale (Kent) PPIF** insisted: “Should always be in red.”
- ▶ Greater consistency in safety messages. “Usually no differentiation between levels of risk. So, the information is either ignored, or taken too seriously. A current good example—though NOT linked to driving—is provided by the switching of many patients from atorvastatin to simvastatin, which advises avoidance of grapefruit (or grapefruit juice) during treatment. However, patients seeking clarification of this are being told, for example, that there is no harm in continuing with half a grapefruit a day if that is what they usually do. And an Internet site advises not to exceed one litre of grapefruit juice a day(!) This sort of thing erodes patients’ trust and compliance, and the same is true of the impact of poor information on driving ability”, noted the **St Albans and District Voluntary Diabetic Support Group**.
- ▶ Greater clarity of information on driving matters. “Needs to be made absolutely crystal clear—like health warnings on cigarettes”, advised a respondent from a group specialising in physical and learning disabilities. A respondent from a group specialising in diabetes offered similar advice: “Rarely tells patients: ‘Do

MEDICINES LEAFLETS AND EXPLAINING EFFECTS ON DRIVING (CONTINUED)

not drive'. Leaves it to the individual—which can be dangerous, as some people drive irrespective of the effects of medication". A respondent from an asthma patient organisation noted: "Medicines leaflets do usually inform patients about the effects of medicine on driving. But this information could be better, and could indicate other things (such as the dangers or implications of driving while taking such medicines). The information would also need to differentiate between the degrees of dangers of driving while taking such medicines". And the **UK Coalition of People Living with HIV and AIDS** added: "You might find this [information] in the small print. But what you might also find are phrases such as: 'This medicine has not been tested on whether it impairs your ability to drive or operate machinery'—which is not much help".

- ▶ More on the how and the why. "Leaflets may instruct that you should not drive, but do not say much about how the medicine affects driving ability", argued a respondent from a group specialising in information on assistive technology for older and/or disabled people. "Most leaflets will comment on the fact that driving skills will be impaired, but lack detail as to how and why. Drug interactions liable to cause a reduction in concentration are often left out", wrote Tony Gavin of **Leukaemia CARE**.

Some respondents wished PILs to include a recommendation that patients go to a doctor to seek advice on medicines and driving. The respondent from **Mind (Cymru)** was clear: "The GP is the one who should highlight this, as it is so important". A respondent from a group specialising in severe mental illness favoured a similar approach: "They [the PILs] might draw attention to the fact that when polypharmacy is involved, the doctor should be consulted, because there would not be the space in the leaflet to cover all combinations that might have an effect". And a respondent from a group specialising in HIV/AIDS stipulated that "one-to-one communication is more effective."

How should medicines packaging inform patients about the consequences (if any) of driving after taking the medicine?

Respondents seemed to agree that the subject of information on medicines and driving was important. **Chesterfield PCT PPIF** felt that it was “crucial that this topic be highlighted”. The respondent from the **Congenital Adrenal Hyperplasia Support Group** stipulated: “I don’t think that you can overstate this.” As a result, respondents were enthusiastic about providing advice on how the information should be conveyed. Suggested techniques for improving the communicational ability of the information included:

- ▶ Repetition. A PALS co-ordinator commented that “repeating the message would be a safeguard to ensure that it (the message) gets home”.
- ▶ Bold, prominently displayed. The **UK Forum of EUROPA DONNA—the European Breast Cancer Coalition** wrote: “This should appear bold”. A respondent from a group specialising in the promotion of health information agreed with the principle of bold font: “Bold print, if there are common side effects”. A respondent from a group specialising in endocrinology summed up the approach (although this respondent preferred to refer only to the PIL): “Warnings on the leaflet should be in large, bold (and even red) type, so that they stand out from the rest of the leaflet. People rarely read the whole leaflet”.
- ▶ Universally-recognised symbols and pictograms that show in a graphic fashion whether driving is allowed/advised or not. The respondent from the **CJD Support Network** considered that “a universally-recognised symbol is needed, such as ‘Be aware’ or ‘Driver-in-a-driving-seat symbol, with a line through it’ [see diagram in *Appendix*, page 59]”. Mr Gavin of **Leukaemia CARE** made the case: “A pictogram (backed up by a wide-ranging publicity campaign on its meaning) would be an ideal method of informing patients. We have to acknowledge: 1) There is a high degree of illiteracy in the UK (and many people who can read may not have the skill base to understand the messages given by the inserts!); and 2) We have a large, multi-racial population, many of whom do not read English (either at all, or as their first language)!” A group specialising in cardiac arrhythmia believed that “symbols and pictograms would be a very good idea”.

While agreeing with the concept of symbols, several respondents suggested that certain actions would first have to be performed before symbols could be recognised universally. The respondent from **Havering Mind** cautioned that the use of pictograms would need to be preceded by a public familiarisation campaign: “Information should be highly visible. So, maybe a pictogram that was easily recognisable by the public would be a good idea. But it would have to be publicised widely, so that people knew what it meant”. A respondent from a group specialising in older people noted: “A symbol/pictogram would have to be international”. And the respondent from **Brain Tumour UK** specified: “It would be good if the same symbols were used throughout the pharmaceutical industry”.

Three respondents, however, were unhappy with symbols as a means of communicating detail about medicines and driving. Dr Karel van der Waarde wrote: “The use of symbols and pictograms must not be considered. They cannot convey information about medicines safely”. A senior psychiatric pharmacist working within

IMPROVING WARNINGS ABOUT DRIVING AND TAKING MEDICINE (CONTINUED)

the NHS (who had been passed the questionnaire by a patient representative) also disputed the ability of images to express important information: “Symbols and pictograms are often like abbreviations, and, IN FACT, many studies show that they make things much more confusing—please contact the NPSA!!” [Editor: NPSA is the National Patient Safety Agency, created by the Department of Health.] And a respondent from a group specialising in brain-related conditions in children professed unease at any attempt to communicate information via symbols or pictograms: “I find that, most of the time, pictograms obscure, rather than clarify—but then I’m not a ‘visual’ person”.

Respondents were divided on the best location for information about medicines and driving. 44% of the respondents thought that such information should go in the PIL. Approximately 60% of the survey participants argued that the information should be positioned elsewhere:

- ▶ The outside of the medicines packaging. A respondent from a group specialising in deafness and the hard of hearing summed up the thinking here: “The more places it is, the better”. **Rethink Severe Mental Illness** affirmed: “Briefly on the label, but in more detail in the leaflet”.
- ▶ On the container that holds the capsules, pills, tablets, or liquid. A respondent from a group specialising in health services provision insisted: “There should be clear, unequivocal advice—in bold, on the bottle”.

A number of respondents argued that information on medicines and driving should be positioned in a combination of all possible places (including the PIL, the medicines packaging, and the medicine container), and that symbols should be employed, too. “These [four measures] are perhaps being done already, but need to be more prominent”, wrote a respondent who wished to remain anonymous. A respondent from a Scottish group specialising in older people agreed: “A combination of all of the [potential answers on the questionnaire]”. The respondent from the **Patient Information Forum** went further, believing that all of the four suggested measures should be employed to inform patients of the consequences of taking medicine and driving: “But this should not just be restricted to this particular warning. Other warnings are equally valid”.

Dr Karel van der Waarde was not so sure. He counselled that too much information was already lodged on the outside packaging of medicines and in the PIL: “I would be very hesitant to add more information to the outer packaging, label, or leaflet. Only in those circumstances where it is really important—and then I would mention it everywhere. Where it is not relevant, please leave it out”.

Some groups reiterated the belief that doctors must play a role in transmitting information about medicines and driving. “Again, a doctor’s advice may be necessary—attention should be drawn to this”, emphasised a respondent from a group specialising in severe mental illness. This perspective was endorsed by a respondent from a group specialising in prostate cancer: “It should be explained by the doctor when prescribing. If a patient’s livelihood depends on driving, there is going to be a huge ‘compliance’—to use the old phrase—either with the drug regime, or with the driving instruction”. The respondent from **Mind (Cymru)** concurred: “The GP and the pharmacist have to say something, as well”.

**PHARMACEUTICAL
COMPANIES' PROMOTIONAL
ACTIVITIES TO DOCTORS**

Pharmaceutical companies often send doctors advertising and promotional material on new prescription medicines. Should any of the following restrictions be imposed on the volume of such material following the launch of a new medicine?

This survey showed that healthcare-oriented organisations representing the interests of patients and the public hold strong feelings about pharmaceutical company advertising and promotion to doctors—even when the advertising only concerns newly-issued prescription medicines. Some 80% of the respondents supported the idea of further interventions to curb the practice.

Divisions of opinion appeared, however, when respondents indicated what such intervention/s might be:

- ▶ Half of the respondents believed that companies should inform the MHRA of their promotional activities.
- ▶ 44% of respondents considered that companies should make public the scale of their promotional activities.
- ▶ 31% thought that the volume of all prescription medicines' advertising should be restricted.
- ▶ 30% stipulated that the volume of non-educational material sent to health professionals should be restricted.

Few respondents opposed instituting the above actions. Only 18% declared that pharmaceutical companies should be able to advertise and promote new prescription medicines if the product was designed to treat a life-threatening condition. And only 14% felt that the industry was capable of self-regulating company advertising budgets.

The many respondents who approved of some sort of further restriction/s provided the following explanations for their viewpoints:

- ▶ Too much pharmaceutical company marketing material sent to doctors lacks evidence-based information, maintained a pharmacist adviser from a group specialising in consumer information. The **UK Coalition of People Living with HIV and AIDS** supported a similar position: "Much of this activity [pharmaceutical company advertising and promotion] is funded as 'marketing', and should be acknowledged as such in that it potentially negates the scientific evidence (also funded by the companies) or cross-company comparison with similar drugs—particularly in areas like HIV/AIDS, where drugs are used in combination".
- ▶ The amount of money that pharmaceutical companies spend on promotion is too high, concluded one regional PPI. "Scandalous, some of the 'freebies' that go with it—forcing doctors to prescribe sometimes-unsuitable medicines", wrote the respondent from the **Neurological Alliance (South West)**.

PHARMA PROMOTION AND ADVERTISING PRACTICES (CONTINUED)

- ▶ Patients are concerned about the influence of pharmaceutical companies upon doctors. “A sentiment often expressed to different degrees is that doctors are, to some extent, directed by pharmaceutical industry concerns. However inaccurate this feeling, it is reinforced by a doctor’s office full of items bearing logos or endorsements”, was the opinion of a respondent from a group specialising in multiple sclerosis. And, according to **Rethink Severe Mental Illness**: “Mental health patients are suspicious of the influence that drugs companies have on prescribers. It is important that the methods of publicity are well known”.
- ▶ Medicines should be prescribed according to their merit, not because incentives were received. “Medication should be issued on the basis of what is best for the patient, and not according to incentives. Incentives to sponsor events/ individuals' education, etc, should all be monitored, to ensure that treatment of patients is based on 'medical need and best practice”, determined the branch secretary of a local diabetes organisation.

Some respondents expressed alternative opinions. Although in favour of several more restrictions being imposed on the promotion of new medicines, the **Parents of Autistic Spectrum Disorder Adults, Edinburgh** pointed out that the very quantity of advertising and promotional material currently sent to doctors is vast enough to make the practice self-defeating for the pharmaceutical companies: “The volume is impossible for anyone [any doctor] to remember [anything]”. A respondent from a group specialising in information on assistive technology for older and/or disabled people was of the same opinion: “Publicity is important, to raise awareness of new drugs. But too much unsolicited mail means more goes unread, and is put straight in the bin”. One group specialising in the after-effects of drugs also suspected that promotional material may have less influence upon doctors than might otherwise be expected. This group trusted doctors to know and do what is best: “Surely one has to have faith in the doctor’s experience, to either accept or reject claims for specific drugs. Most doctors will check in their medical 'bible' for both the affects and effects of particular drugs”. The respondent from the **Congenital Adrenal Hyperplasia Support Group** took a pragmatic line: “I think it is important that doctors are aware of new medications. I don’t feel that they are swayed by advertisements, but—in most cases—bear in mind medication that may be useful for their patients”.

In defence of the current situation

Tony Gavin of **Leukaemia Care** was one the few respondents to vote for the status quo: “Bearing in mind that we are talking about new prescription medicines, we can assume that they have already been cleared by the MCA [Editor: Medicines Control Agency, now replaced by the Medicines section of the MHRA], and given a product license. And, to get to this stage, they will have already gone through many rigorous checks and balances, to prove safety and efficacy. And, bearing in mind the very strict code of practice set up by the ABPI [the Association of the British Pharmaceutical Industry] on what can and cannot be said about any POM [prescription-only medicine] through adverts or directly via representation (and guidelines on the volume of promotional mailing), then I feel that there is sufficient restriction present already. We are already ‘over-enforced’ in many areas of medicine now. We do not need any more rules and restrictions. What we can do is to police the rules and restrictions that are already in place to protect us from the

PHARMA PROMOTION AND ADVERTISING PRACTICES (CONTINUED)

excessive enthusiasm of the industry to promote their products. And, we can ensure that they also apply and police their own Code of Practice with vigour, and give them the ‘teeth’ to fully enforce this Code of Practice, should the need arise”.

Other suggestions

Further additional methods of policing pharmaceutical company promotional campaigns were proposed by respondents. Suggestions included:

- ▶ “GPs should declare any connection to a particular product or company”, was the feeling of the respondent from **Arthritis Care**.
- ▶ “It is not just the scale that should be made public, but the evidence supporting the claims made”, commented the respondent from the **James Lind Initiative**.
- ▶ “It would be good to know that the leaflets’ claims had been verified independently”, reflected a respondent from a group that provides healthcare information to patients.
- ▶ A respondent from the **Crawley PPIF** and from **Age Concern** advised: “Doctors should inform patients of the newness of medicines”.
- ▶ **Rethink Mental Illness** advocated: “Mental health patients are suspicious of the influence that drug companies have on prescribers. It is important that the methods of publicity are well known”.
- ▶ A chairperson of a PCT recommended: “NICE or a similar organisation to advise doctors on new medicines”.
- ▶ The respondent from **Havering Mind** supported legal intervention: “They should publicise—especially the amount that doctors are paid to do drug trials. And there should be statutory restrictions”.

Should any of the following limitations be placed on inducements and hospitality offered at conferences and meetings to healthcare professionals (doctors, nurses, therapists, managers, etc)?

Survey participants were asked whether they wanted any reforms to the practice whereby pharmaceutical companies offer hospitality to health professionals at conferences and meetings. A range of potential changes was provided for consideration by any respondent who might prefer the idea of reform.

The vast majority of respondents (92%) indicated a willingness to see some alterations made to the custom of pharmaceutical company hospitality at meetings. The **Huntington's Disease Association (Colchester and District Branch)** gave one explanation why: "This activity has led to patient suspicion of 'new' medication, as there is an awareness that 'freebie luncheons' are welcomed by medical professionals—and this can engender a patient 'mistrust' as to why the GP is promoting the 'new' medication". The respondent from the **British Heart Foundation** was also concerned about patients being kept in the dark: "When commerciality comes into the scene, there really does need to be some control (either internally, or externally), so that the patient is fully informed". A respondent from a group specialising in diabetes spelled out another reason for change: "I am very concerned that incentives lead to the incorrect use of medication, and to change for the sake of incentive, rather than because it would be more beneficial to the patient".

Respondents shared a certain unanimity as to how the pharmaceutical industry's efforts at offering hospitality could be curtailed:

- ▶ 57% of the respondents wished companies to make public all the inducements they provide to health professionals. A respondent working in the field of health services provision argued that such transparency was necessary because: "Inducements should be in the public domain, and should be subject to scrutiny—in the same way as is the case with other public servants. The whole system of inducements is highly suspect, and open to misuse". A respondent from a group based in an NHS hospital trust (and advising on patient information) preferred the responsibility for declaring perks to fall on the shoulders of doctors: "Healthcare professionals should declare incentives accepted". A senior psychiatric pharmacist working within the NHS [who had been passed the questionnaire by a patient organisation] wanted both ends of the inducements spectrum to be more transparent: "It is IMPERATIVE that, not only the companies make public their inducements, but healthcare professionals as well".
- ▶ 56% expected the MHRA to play a more active role in monitoring the hospitality activities of companies. The respondent from the **East Kent and Coastal PPIF** stated: "Doctors often change a prescription habit when favourable inducements are offered. Doctors like perks. This is the way that drug companies get their slaves. If the MHRA monitors this practice, it has a lot of work to do!" The respondent from **Lanarkshire Links** commented: "A watchdog body is needed".

PHARMA AND HOSPITALITY INDUCEMENTS (CONTINUED)

- ▶ 47% of the respondents called for new guidelines on pharmaceutical company hospitality practices. A few of the replies outlined areas in which such guidelines might be instituted. The respondent from the **Society for Mucopolysaccharide Disease** believed that patients with rare diseases suffered as a result of prescribing habits driven by pharmaceutical company hospitality: “This is a particular problem where rare diseases are concerned, and drugs are prescribed based on experience of one drug company”. A nursing-home manager who also worked for an organisation dealing with dementia and mental health in older people backed the banning of hospitality to doctors “unless in very controlled, specific areas for stated purposes—and this should be known”. A respondent from a prostate cancer organisation remarked: “Need to differentiate between a free biro and [the gift of] a golfing weekend”.
- ▶ Nearly one third of respondents (32%) held that the number and types of gifts supplied by pharmaceutical companies to health professionals should be limited per year. The **St Albans and District Voluntary Diabetic Support Group** told the survey why they supported limitations: “Decisions about prescribing should be based on unbiased medical evidence. Doctors are as human as the rest of us, and the constant repetition of a brand's name can consciously or subconsciously affect their decision about what to prescribe. With fewer ‘goodies’ around, perhaps the companies could reduce their prices to the NHS without affecting their profits!”
- ▶ Under one fifth of respondents (17%) voted for industry self-regulation. Only two of the 268 respondents, however, favoured this approach in preference to any other interventions. The other respondents who sponsored the notion of self-regulation also approved of other levers to control industry hospitality.
- ▶ Just 6% of respondents trusted health professionals to hold the interests of patients above personal vested interests. The **British Polio Fellowship (Edinburgh Branch)** was of the belief that “non-pharmaceutical treatments (such as psychotherapy and physical therapies) become neglected because they are displaced in medical awareness and medical budgets as a result of heavy promotion of pharmaceuticals”. The consumer group **Which?** referred to its May 2004 research with GPs, that revealed “many doctors enter into a symbiotic relationship with pharmaceutical companies. These relationships require little proactivity from GPs (who value the ‘educational’ aspect to them), but may then exert a steady influence on prescribing behaviour”. A respondent from a group specialising in brain cancer, on the other hand, was confident in the ability of medical professionals to remain impervious to inducements: “The profession always seems to like these ‘freebies’, and I don’t feel it has any effect on their professional behaviour”.

Respondents mentioned further possible controls on pharmaceutical company hospitality. “GPs should also declare these [inducements and hospitality]”, stressed the respondent from **Arthritis Care**. Some respondents asked that limitations on the pharmaceutical industry’s offerings apply to other healthcare stakeholders, as well as to health professionals. The **UK Coalition of People Living with HIV and AIDS** argued: “Patients can be targets of pharma inducements, too. There should be provision for pharma support of patient groups to be more rigorously controlled on an unrestricted educational basis. No patient group should be allowed to merely

PHARMA AND HOSPITALITY INDUCEMENTS (CONTINUED)

reproduce pharma-inspired information without some kind of critical analysis of what it says. Thankfully, in many cases, patient groups can be more sceptical, and refuse inducements that they see as unethical or biased towards a particular position”.

Six respondents were adamant that nothing less than an outright ban would do:

- ▶ “There should be no inducements or hospitality”, wrote an anonymous respondent.
- ▶ “Not allowed at all”, commented a pharmacy manager at an independent healthcare provider.
- ▶ “There should not be any gifts made to health professionals. Educational grants are fine, as long as all areas of medicine are included. There should be more support for furthering surgical training, and expertise in areas such as women’s health and neurology”, insisted the Chair of a local support group specialising in women’s health (who was also the Vice-Chair of a PPI Forum, and a member of a parliamentary group and European alliance).
- ▶ “Gifts, etc, should be banned”, emphasised the respondent from the **Crawley PPIF**.
- ▶ “I don’t think that drug companies should be allowed to give gifts at all”, indicated the respondent from the **Arthritis Patient Forum of Torbay Hospital**, South Devon.
- ▶ “Inducements should be banned entirely. I have seen these in action, and have been shocked to see doctors who have been uninterested in anything available at an event, except the inducements”, noted the respondent from a group specialising in brain-related conditions in children.

Several respondents opposed action on inducements and hospitality. Tony Gavin of **Leukaemia CARE** believed that the status quo was effective as is, and needed no further tinkering: “The ABPI does have a very strict code that places stringent controls on hospitality. The MHRA may wish to liaise with the ABPI on this subject, and offer to monitor the situation more proactively. Indeed, this may be the most sensible option. But, as to imposing more rules and restrictions—NO!”.

Two survey participants protested that a custom which allows medical professionals to benefit from hospitality also endows patient groups with vital income.

- ▶ A respondent from a group specialising in cystic fibrosis argued: “The current system may seem to be influencing health professionals in their decision to prescribe certain drugs. But the voluntary sector also benefits hugely from pharmaceutical companies. And where we would like health professionals to be more impartial, we would not like the support of the companies to lessen”.
- ▶ And a respondent from a group specialising in HIV/AIDS remarked: “As a patient advocate, it provides me with opportunity to attend international events which otherwise would be beyond the means of a voluntary-sector charity”.

**HANDLING OF COMPLAINTS
ABOUT
MEDICINES ADVERTISING
(PRESCRIPTION AND OTC)**

Which of the following activities is MOST effective at maximising transparency following complaints about medicines advertisements?

For this question, the MHRA suggested five possible ways in which it could ‘beef up’ the transparency of its complaints procedures on medicines advertising.

The need for improvement in the complaints procedure was thought to be paramount by the chairperson of a local group specialising in back pain: “The public are kept in the dark most of the time about complaints”.

Top of the wish list of respondents’ preferred modernisations was that the MHRA should publish all the findings of its complaints investigations. The next most-popular desire was that the MHRA should publish annually a report on its advertising regulatory activity. Over a third of respondents (36%) wished the MHRA to make public all correspondence on advertising complaints. Over one quarter of respondents (28%) wanted the MHRA to keep key stakeholders informed (the **Parents of Autism Spectrum Disorder Adults, Edinburgh** insisted that “key stakeholders should include patient representatives”). Just under one fifth of respondents recommended that the MHRA should name the complainant (when a competitor company).

A few health campaigners put forward their own ideas for opening up the MHRA’s advertising complaints procedure:

- ▶ A PALS representative called for total clarity in any documentation on complaints transactions published by the MHRA: “Transparent means transparent to everyone, not just to selected groups. The public should be aware, as should professionals. The effectiveness is in the way in which the information is given to the public—clear, explained, and in plain English”.
- ▶ A professional nurse attached to a patient organisation indicated that one move in the right direction would be “objective reporting via the media, and direct to stakeholders”. An anonymous respondent saw newspapers as the best medium of publicity: “Perhaps publishing a table, etc, in the national papers”.
- ▶ The respondent from the **Parkinson’s Disease Society (Canterbury Branch)** opted for the use of the Internet: “A monthly online report would be useful”.
- ▶ **Which?** considered that improvements to the MHRA’s transparency were only part of the story. The group declared an altogether different aim—seeing a new body administer complaints about medicines advertising: “Investigation of complaints about medicines advertising should be open, transparent and timely—and this should extend to the links between the MHRA and other bodies investigating advertising complaints (the Prescription Medicines Code of Practice Authority [PMCPA], the Proprietary Association of Great Britain [PAGB], the Advertising Standards Authority [ASA], and Office of Communications [OFCOM]). While any increase in transparency is welcomed, on its own it adds little value because the enforcement system, and penalties are weak, or expensive, and complicated to operate. Which? would like to see responsibility for monitoring all forms of pharmaceutical industry advertising and promotion transferred to a new, independent regulator”.

Which of the following actions would you MOST like to see taken when an advertisement for a medicine (OTC or prescription) is found misleading?

In this question, just four respondents did not know whether any of a number of actions proposed by the MHRA would prove valuable in regulating misleading medicines advertisements.

The other 264 respondents took a position. [The *Alzheimer's Society (Selby and York Branch)*, though, criticised the question for offering “no middle ground between informal negotiations, and formal (and quite draconian) actions”.] Two participants told the survey that the serious nature of misleading advertising justified full and proper action:

- ▶ The respondent from a group specialising in physical and learning disabilities advocated: “As we are considering the health and welfare of the general public, there should be much more stringent rules—and correspondingly serious implications for companies”.
- ▶ The *UK Coalition of People Living with HIV and AIDS* underscored the argument: “Penalties must be appropriately severe, to prevent recurrence of misleading or inappropriate advertising. The larger the company, the larger the penalty”.

Respondents favoured the following actions:

- ▶ Over half of the respondents (59%) thought that the first action to be taken in the case of a misleading advertisement was the withdrawal and amendment of the item by the company concerned. For instance, the *Heart to Herts Cardiac Support Group* stated: “Correction of the error should be acknowledged and confirmed”.
- ▶ 46% of respondents believed that the company ought to issue an apology and correction. For example, a respondent from a group specialising in diabetes reported: “Companies should issue corrections and apologies within the same media (with the same-size advertisement) as the original advert—or on TV in the same slots as those in which they misled the public. The apology should be scrutinised by the MHRA before it is issued, to ensure that the apology/correction is clean”.
- ▶ Just over one third supported the suggestion that the MHRA should ‘name and shame’ the company in multiple media.
- ▶ Exactly one third of respondents argued for the fining of the company.
- ▶ 22% concurred with the idea that the MHRA investigate an offending company’s entire advertising portfolio.
- ▶ 19% approved of the MHRA seeking an injunction against the company. A respondent from a group specialising in brain-related conditions in children advised that this form of punishment, though, ought to be limited to repeat offenders: “Injunction only if the offending information reappears after corrective action should have been taken”.

CORRECTIVE ACTIONS ON MISLEADING ADVERTISEMENTS (CONTINUED)

- ▶ 16% aligned with the notion that the MHRA might go so far as to press for criminal proceedings against the offending company. For instance, the respondent from **Alpha-1 UK** specified: "In some cases, criminal proceedings should be considered".

The respondent from the **Parkinson's Disease Society (Canterbury Branch)** suggested that, whatever action is taken, speed was of the essence: "A fast time limit should be enforced on the correction and amendment". The respondent from the **Perth Bipolar Group** recommended that all options remain open and be used in a graduated fashion: "A sequence of escalating actions should be employed".

A number of respondents, in fact, judged that the punishment should be appropriate to the crime. For instance, a respondent from a group specialising in older people stated: "It depends on the seriousness of the situation". A respondent from a group specialising in diabetes wrote: "Depends on the degree of attempt to mislead". And a respondent from a group specialising in mental health affirmed: "Depends entirely upon the nature of the misinformation as to how to deal with the individual company".

Fewer respondents professed themselves happy with the use of 'softly, softly' tactics against an offending company:

- ▶ 15% of respondents indicated that the MHRA would be right to conduct informal negotiations with the company which had committed the alleged misdemeanour.
- ▶ 11% asked for the MHRA to limit the 'naming and shaming' exercise to the MHRA's own website.
- ▶ 8% reckoned that the industry's own trade associations could act as effective 'policemen'.
- ▶ 4% were convinced that an agency other than the MHRA should handle matters. For instance, the **Insulin-Dependent Diabetes Trust** wished "these matters are entirely dealt with by the Department of Trade and Industry, under breach of the Trade Descriptions Act". The respondent from a PPI asked for "links to the Advertising Standards Agency (ASA), and notice to all Trading Standards officers".
- ▶ Only 3% of respondents wanted restrictions on which media re-issued advertisements could be carried.

Which? criticised the MHRA for not fully exploiting its powers of sanction against misleading advertisements. The group stressed that what it regarded as the MHRA's relative inactivity on this front implied a low priority by the agency towards the job of correcting such wrongdoing. (This, presumably, may be why one respondent specialising in visual impairment had "never heard of any action against a company" in the matter of misleading advertisements.)

Which? is an active proponent for improved transparency. Nonetheless, the organisation felt that any 'naming and shaming' routine that limits itself to publishing details only on websites could never be adequate. The public have seen such

CORRECTIVE ACTIONS ON MISLEADING ADVERTISEMENTS (CONTINUED)

exercises in apportioning blame before, said **Which?**, yet violation of the regulations continues unchecked.

Which? contended that “redress should involve contrite corrective advertising, payment of the regulator’s legal costs, and other relevant financial elements (such as a substantial fine, or bearing the cost of running an industry training seminar for the benefit of others in the industry)”. The consumer group asserted that “a combination of an effective penalties-and-enforcement system, and subsequent publication of case investigations and outcomes is needed urgently”.

The majority of respondents clearly favoured some action against those responsible for issuing a misleading medicine advertisement. Tony Gavin of **Leukaemia CARE**, though, pointed out the distinction between a company that knowingly produces a misleading advertisement, and a company that merely commits an oversight.

The respondent from the **British Heart Foundation** made the astute observation that misleading advertisements for OTC or prescription medicines “would be better discouraged in the first place!”.

When should action on misleading advertisements be applied?

Around 56% of the respondents wanted the MHRA to act whenever a company technically breached the law. The respondent from the **Windsor, Ascot and Maidenhead PPIF** asked: "Define 'technically' ". Other respondents, however, were more certain that this option was the choice for them. A respondent from a group specialising in brain-related conditions in children stipulated: "Should be applied to anything misleading at all". **Which?** Took a similar line: "Actions should be applied whenever advertising regulations are breached. Consistency of approach is important in maintaining the integrity of the system". And a respondent from a group specialising in physical and learning disabilities insisted: "Cut out the legal messing about. It should be as simple as when an advert for medicines could be misleading to the man on the Clapham omnibus".

Another 38% of respondents felt it more appropriate that the MHRA should only bring action when an advertisement was judged to be truly misleading. 4% of respondents did not know how to answer the question.

Though respondents supplied only a few comments to this part of the questionnaire, all were salient, and tried to tackle the problem of the most effective way of getting offending companies to toe the line [see Appendix 3; Comments from respondents; Question 12].

**SAFETY MESSAGES AND
CLAIMS
IN MEDICINES ADVERTISING
(PRESCRIPTION AND OTC)**

How should safety messages be incorporated into advertisements for medicines (both prescription and OTC)?

This question offered respondents a number of options as to how information about medicines safety ('safety messages') should be relayed in advertisements. The response from respondents was definitive: just over three quarters affirmed that safety messages should be prominently displayed in advertisements—whatever the circumstances. Only 15% of respondents thought that safety messages should be carefully positioned (in advertisements for OTC medicines), so as not to frighten patients away from taking medicines. Another 9% argued that safety messages should only be prominently displayed when relevant to a wide patient population. Another 2% of respondents believed that the manufacturer was best qualified to decide how to display these messages. And 2% did not know how to answer the question.

In the survey's earlier questions, respondents registered worries about the dangers of scaring patients by putting 'frightening' information about rare side-effects in PILs. A respondent from a group specialising in physical and learning disabilities expressed related concerns over safety messages and advertising: "Could be difficult to get the right balance. But some information referring the public to wider implications may be applicable in this case (for instance, 'May cause drowsiness—see product information', or 'Not suitable for pregnant women')".

Many respondents, however, considered the trade-offs were such that information about side-effects should be thoroughly visible in advertisements for OTC medicines—even if this meant that some patients might be prompted into worrying about safety. **Heart to Herts Cardiac Support Group** thought that safety messages were so important that they should be as prominent in OTC medicines advertisements as health warnings are on packets of cigarettes. A respondent from a group specialising in diabetes was equally unequivocal: "Minimum basic safety messages should be imposed on every advert. Prominent messages should be advertised when they are pertinent to wide patient populations. For instance, if the medication contains aspirin: 'Seek advice before taking if you take daily aspirin'. Or, if the medication contains paracetamol: 'Seek advice before taking if you use paracetamol for pain relief, or take other medications containing paracetamol'".

A respondent from a group specialising in child health explained one of the reasons why warnings were necessary: "Safety messages should be clearly labelled in adverts (and on outer packaging), so that choices can be made prior to the purchase or collection of prescriptions". A respondent from a group specialising in visual impairment made the same point: "It is about patient choice. If they do not have the information, then they cannot make an informed decision about their treatment". And the respondent from **East Kent and Coastal PPIF** reiterated: "Given information, patients can make informed choices. Without it, there is no choice".

A respondent from a group specialising in children's brain conditions asked that safety messages not be over-burdened with lists of side-effects: "Evidence-based

HOW SAFETY MESSAGE MIGHT APPEAR IN ADVERTISEMENTS (CONTINUED)

safety messages should be given at the bottom of anything published. However, this does not necessarily mean a detailed list of side-effects, etc”.

Chesterfield PCT PPIF was one of a number of respondents that wished to see a firm, clear-cut approach taken to safety messages in advertisements: “Specific hazards should be highlighted verbally, visually, and consistently. This area should decidedly NOT be left to each manufacturer, but should be standardised as far as possible. Due attention should be paid to the needs of visually-impaired patients, and those with limited cognitive skills. These comments apply to packaging, as well as to advertisements”. The **UK Forum of EUROPA DONNA—the European Breast Cancer Coalition** also recommended that “safety messages must be boldly displayed in laypersons’ language (and may use symbols for endorsement)”. And a group specialising in mental health noted: “Too many ‘judgement calls’. Safety messages should ALWAYS be prominent”.

The respondent from the **Patient Information Forum** inserted a note of caution by reminding the survey of the purpose of any safety-message exercise—effective communication: “But they [safety messages] should be patient-friendly—unlike the babble that accompanies many FSA-regulated adverts”.

The **UK Coalition of People Living with HIV and AIDS** felt that pharmacists should absorb more of the task of delivering safety messages. Tony Gavin of **Leukaemia CARE** agreed, judging that, “for OTC medicines, the pharmacist must take his share of responsibility”.

The **British Polio Fellowship (Edinburgh Branch)** thought that advertisements for prescription medicines—which are directed at doctors, not patients—“may need to be more detailed than those to patients”.

Again, Mr Gavin considered that health professionals ought to convey the fact that risks are attached to the taking of drugs (and specify what those risks are): “For prescribed medicines, the prescribing doctor should inform the patient about both the safety data, and the treatment outcomes should the medicine not be taken, or not taken as prescribed”. The respondent from **Brain Tumour UK** approved of doctors delivering safety messages: “The prescribing doctor should know the safety of the medicines prescribed, and should inform the patient of possible side-effects, and the medicine’s compatibility with other prescribed medication”.

Should companies be obliged to publicise data that supports their claims in the advertising of medicines (both prescription and OTC) when these claims have not been officially reported to drug regulators?

This question opened with a brief explanation for respondents: *Claims made in the advertising of medicines (both prescription and OTC) can sometimes go beyond what is agreed with the regulator. Some of these claims may either be valid, or they may be exaggerated. The claims may not always be supported by high-quality data, or by public-domain data.*

One respondent from a group specialising in HIV/AIDS gave the survey an example of a valid situation in which a pharmaceutical company might make a claim in an advertisement, even when the claim had not been agreed with the MHRA: “There are sometimes other options, especially with new drugs—that is, once daily (which fits into people’s routine, but is not licensed yet in the UK)”.

But other respondents felt a need to be watchful about such pharmaceutical company activity. The main worry for these respondents seemed to be that an unfettered pharmaceutical industry would make lofty, unsubstantiated claims about its products, and put trusting patients in extreme danger. Above all, respondents believed that all claims should be backed up by unbiased, evidence-based research.

The senior executive who responded from the **British Heart Foundation** was adamant that “the data available to support the claim should, as far as is possible, come from an unbiased source—which may be, for example, that the researchers are not on the manufacturer’s payroll”. The respondent from the **East Kent and Coastal PPIF** concurred, writing: “All data published must be backed by research trials, giving names of investigators, and full details of the trial”. A respondent from a group specialising in brain-related conditions in children commented similarly: “I think it would be useful to state what kind of findings are the basis of the claims. Firstly, what type of research (clinical trials, statistical evidence, case studies etc). And, second, the status of independence from the promoting company (whether the promoting organisation funded all the work, or whether there is independent research as well)”.

This question in the survey generated the following breakdown of responses:

- 49% of respondents judged that pharmaceutical companies should publicise data supporting all claims.
- 22% of respondents determined that pharmaceutical companies should not make any claims that were not known to the MHRA. A respondent from a group specialising in brain cancer stated: “The MHRA should be notified in advance by the companies of the claims they want to make in advertisements, and the supporting data. I would also advocate companies publicising references to relevant research on their promotional material (ideally, research data not only derived from company research)”. **Diabetes UK** maintained: “All claims should

UNREPORTED ADVERTISING CLAIMS (CONTINUED)

be presented and known to the MHRA, and all negative findings also". "This should be strictly enforced", stated a respondent from a group specialising in diabetes.

- 9% of respondents indicated that pharmaceutical companies should make data on claims that are unknown to the MHRA easily available to the public on request.
- 3% of respondents felt that pharmaceutical companies should be obliged to publicise data when claims that are unknown to the MHRA seemed dubious or outlandish.
- Only one respondent thought that the current situation was about right.

A fifth of respondents did not realise that pharmaceutical companies could make advertising claims which were unknown to the drug regulator. The respondent from the **Herpes Viruses Association**, for example, wrote: "It is shocking to learn that adverts can go beyond what has been shown and peer-reviewed!" The respondent from the **Patient Information Forum** also admitted being unaware of this situation: "And I'm supposed to be in the know!". A respondent from an anonymous PPIF declared: "I think this is a frightening situation, and should not have been allowed—ever". Tony Gavin of **Leukaemia CARE** was equally aghast: "If claims are made in the advert that go beyond that which is agreed with the regulator (supported or not by high-quality data), then they should be reprimanded/or fined, if necessary. It is not beyond the wit of man to inform the regulatory bodies in advance of a promotional campaign if new claims based on new, sound, scientific research are to be made, and not beyond the skills of the regulatory bodies to respond within a reasonable time, to allow the campaign to progress—if the data is sound!!"

The respondent from the **Windsor, Ascot and Maidenhead PPIF** wondered, though: "What is the cost to the MHRA if they are to investigate all data on claims?"

**REGULATING
DISEASE-AWARENESS
CAMPAIGNS**

Which types of information should be most prominent in disease-awareness campaigns?

This question also began with a brief definition: *Disease-awareness campaigns (DACs) are advertisements designed to make the public aware of medical conditions that have prescription treatment/s.*

The consumer group **Which?** did not accept the survey's definition of the term 'disease-awareness campaign': "Which? has been concerned for some time that disease-awareness campaigns (DACs) are a covert marketing technique employed by the pharmaceutical industry—which is prohibited from advertising prescription-only medicines direct to the consumer. These campaigns are promotional, and exist to increase demand for a company's products among the public (while coinciding with marketing campaigns directed at healthcare professionals). The definition adopted in this consultation document confirms these fears. Here, the MHRA has chosen to define DACs as 'advertisements designed to make the public aware of medical conditions that have prescription treatment/s'—when the MHRA's own guidance on DACs states something quite different: 'DACs are concerned with providing information, promoting awareness, or educating the public about health, diseases, and their management. DACs must not promote medicinal products to the public.'" [Editor: the survey questions were framed in a technical but necessarily simplified manner, with the aim of being understandable to the maximum number of respondents. The survey definition of 'disease-awareness campaigns' was not intended to suggest that such campaigns promote prescription medicines to the public—a practice that would be against the law.]

Definitions aside, a number of respondents clearly approved of DACs. A respondent from a group specialising in multiple sclerosis observed: "Public-awareness campaigns for certain diseases which may be life-threatening (such as bowel cancer or diabetes) are very useful in educating the public, and explaining groups of symptoms together". The **Anaemic Society** expressed much the same opinion: "There is an urgent need for more education as to the nature of pernicious anaemia (PA). Too many [of our group's] members suffer from more than just PA, and not all patients are able to carry on a normal life after being diagnosed". The respondent from **East Kent and Coastal PPIF** wrote: "Disease-awareness campaigns are vital to patient responsibilities for their own health". The **Highland Users Group** held a less certain viewpoint: "The campaigns are needed, but we worry that the drug companies benefit from these".

Although some respondents endorsed the idea of DACs, others demanded improvements in the educational and informational content of the campaigns:

- 63% of respondents desired DACs to prominently display useful details on how to recognise the symptoms of a condition.
- 61% of respondents thought that information about the need to see a doctor—and when—should be more noticeable in DACs.

DISEASE-AWARENESS CAMPAIGNS (CONTINUED)

- Just over half of the respondents (53%) wanted information about all aspects of the condition to be highly obvious in DACs.
- Just over one third (35%) believed that facts about the type of people likely to be affected by the condition were important considerations for DACs.
- But only 8% of respondents preferred more information on the treatment itself to be given out in DACs (even if the treatment does not get to be named). One of these respondents, a patient advocate from the **Continence Foundation**, explained that facts about treatments allowed patients access to more potential choices: “The treatment should be referred to, but in the context of balanced information about any non-pharmaceutical treatments for the condition”.

On the issue of regulation, respondents’ comments discussed the possibility of making DACs and other public-awareness campaigns more accurate, and less confusing in content. A respondent from a group specialising in diabetes argued that “the miracle cure’—one-size-fits-all—should be removed from advertising”. The **Central Liverpool PCT PPIF** wrote that the Department of Health should assume responsibility for mounting DACs—as opposed to “companies with special interests”. And the respondent from **Arthritis Care** counselled: “Need to be aware of drug companies ‘constructing’ new diseases”. Few other respondents, though, called for significantly greater intervention in the regulation of disease-awareness campaigns than already exists today.

DACs have sustained criticism in the media and from various quarters about their apparent lack of transparency as to the origins of the sponsor. However, only 13% of respondents announced that they would like to see the name of the campaign’s sponsoring company presented more overtly. One respondent who did wish greater prominence to be attached to the sponsoring company’s name was Tony Gavin of **Leukaemia CARE**, who requested: “I would also like the campaign to have its sponsor named (even if just by carrying the company logo)”.

The vast majority of respondents—some 90%—were uninterested in whether the advertisement had been pre-vetted. One exception was the respondent from the **Herpes Viruses Association**, who stated: “I think that all such information should be pre-vetted. The public assumes that all statements about illnesses and treatments are factual. They are unaware that ‘public-awareness campaigns’ are advertising”.

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