

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

Appendix

[To be read with accompanying MAIN REPORT]

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MHRA

**PUBLIC CONSULTATION WITH
PATIENT REPRESENTATIVES:**

*MEDICINES INFORMATION
AND ADVERTISING*

Appendix

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

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RESPONDENT GROUPS THAT WANTED TO BE NAMED AS SURVEY PARTICIPANTS

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APPENDIX 1: GROUPS THAT WANTED TO BE NAMED

Appendix 1:

Respondent patient and disability groups that wanted their organisations to be named

80% of the respondents in this survey answered in a personal capacity, and 18% on behalf of their organisations.

PAL = Patient Advice and Liaison (Service); PPI = Patient and Public Involvement; PPIF = Patient and Public Involvement Forum.

ADDER (Action for Dystonia, Diagnosis, Education, and Research)

http://www.dystonia.co.uk/home_page.htm

Alpha-1 UK

<http://www.alpha-1.org.uk>

Alzheimer's Society [Selby and York Branch]

<http://www.alzheimers.org.uk/BranchWebsites/York>

Anaemic Society

<http://www.anaemic-society.com>

Arthritis Care

<http://www.arthritiscare.org.uk>

Arthritis Patient Forum (Torbay Hospital, South Devon)

Brain Tumour UK

<http://www.braintumouruk.org.uk>

Breathe On UK

<http://www.breatheon.org.uk>

British Heart Foundation (BHF)

<http://www.bhf.org.uk>

British Polio Fellowship [Edinburgh Branch]

Chronic Myeloid Leukemia European Support Group (CML Support)

<http://www.cmlsupport.org.uk>

CJD Support Network

<http://www.cjdsupport.net>

Congenital Adrenal Hyperplasia (CAH) Support Group UK

<http://www.cah.org.uk>

Continence Foundation (CF)

<http://www.continence-foundation.org.uk>

Degos Disease Patient Support Network

<http://www.degosdisease.com>

Diabetes UK

<http://www.diabetes.org.uk>

Do You Panic

<http://www.doyoupanic.co.uk>

Darlington PCT

<http://www.darlingtonpct.nhs.uk>

Dumfries and Galloway Association for the Blind

Ekbom Support Group (ESG)

<http://www.ekbom.org.uk>

Epilepsy Action

<http://www.epilepsy.org.uk>

EUROPA DONNA—the European Breast Cancer Coalition [UK Forum]

http://www.cancerworld.org/CancerWorld/moduleStaticPage.aspx?id=819&id_sito=5&id_stato=1

European Network of (ex-) Users and Survivors of Psychiatry (ENUSP)

<http://www.enusp.org>

Expert by Experience

Gaucher's Association (UK)

<http://www.gaucher.org.uk>

HCV-Alert

Heart to Herts Cardiac Support Group

<http://www.heart-to-herts.fsnet.co.uk>

Help and Care

<http://www.helpandcare.org.uk>

Herpes Viruses Association (HVA)

www.herples.org.uk

Highland Users Group (HUG)

<http://www.hccf.org.uk/projects/HUG>

Huntington's Disease Association [Colchester and District Branch]

IBS Network

<http://www.ibsnetwork.org.uk>

Insulin-Dependent Diabetes Trust (IDDT)

<http://www.iddtinternational.org>

James Lind Initiative (JLI)

<http://www.jameslindlibrary.org>

Lanarkshire Links

<http://www.lanarkshire-links.fsnet.co.uk>

Leukaemia CARE

<http://www.leukaemiacare.org.uk>

Mencap

<http://www.mencap.org.uk>

Mind [Basildon]

<http://www.basmind.org/home.html>

Mind [Cymru]

<http://www.mind.org.uk/About+Mind/Mind+Cymru>

Mind [Havering]

Mind [Oundle Rural]

<http://www.mind.org.uk/Mind+in+your+area/Regions/eastmidlands/Oundle+Rural+Mind.htm>

Mind [Pembrokeshire]

<http://www.pembrokeshiremind.org.uk>

National Ankylosing Spondylitis Society (NASS)

<http://www.nass.co.uk>

National Osteoporosis Society [Exeter and District Support Group]

Neurological Alliance [South West]

<http://www.neural.org.uk>

Obesity Awareness and Solutions Trust, The (TOAST)

<http://www.toast-uk.org/index.php>

Pancreatitis Supporters Network (PSN)

<http://www.pancreatitis.org.uk>

Parents of Autistic Spectrum Disorder Adults, Edinburgh

Parkinson's Disease Society (PDS) [Canterbury Branch]

<http://www.parkinsons.org.uk/Templates/BranchInternal.asp?NodeID=90294>

Patient Information Forum (PIF)

<http://www.pifonline.org.uk>

Patients' Association (PA)

<http://www.patients-association.com>

PPIF [Central Liverpool PCT]

<http://www.cppih.org/forum/centralliverpool0137.html>

PPIF [Chesterfield PCT]

PPIF [Crawley]

<http://www.cppih.org/forum/crawley0202.html>

PPIF [East Kent and Coastal]

PPIF [Swale, Kent]

http://147.29.80.160/portal/topics/?topic_id=5300025

PPIF [Windsor, Ascot, and Maidenhead]

http://147.29.80.160/portal/topics/3900018_Windsor_Ascot&MaidenheadPCTPPIForum?topic_id=5000074

PPI Hospital Forum

- Perth Bipolar Group (PBG)**
http://uk.geocities.com/perthbipolar/main_page.html
- Pituitary Foundation**
<http://www.pituitary.org.uk>
- Plymouth Mind Oasis**
- Polychondritis Educational Society**
<http://www.polychondritis.com/RP/Polychondritis.html>
- Portsmouth Association for the Blind**
- Preston Carers**
<http://www.prestoncarers.org.uk>
- Prostate Research Campaign UK**
<http://www.prostate-research.org.uk>
- PSC Support**
<http://www.psc-support.demon.co.uk/index.html>
- PXE Support Group (PiXiE)**
<http://www.pxe.org.uk>
- Pulmonary Hypertension Association (PHA) UK**
<http://www.pha-uk.com>
- Rethink Severe Mental Illness**
<http://www.rethink.org>
- St Albans and District Voluntary Diabetic Support Group**
<http://www.diabetessupportstalbans.org.uk>
- Salford Heart Care Re-Hab**
- Society for Mucopolysaccharide Disease (MPS Society)**
<http://www.mpssociety.co.uk>
- Sunderland Cardiac Support Group**
<http://www.sunderland.nhs.uk/cardiac>
- Tameside Blind Association**
- Tasha Foundation**
<http://www.tasha-foundation.org.uk>
- UK Coalition of People Living with HIV and AIDS (UKC)**
<http://www.ukcoalition.org>
- Which?**
<http://www.which.co.uk/index.jsp>
- York Coalition of Disabled People**

Appendix 2

SURVEY RESULTS— TABLES AND CHARTS

PAGES 10-26

APPENDIX 2: RESULTS

Appendix 2: Survey results

Respondents' area of expertise

Speciality	% of total participants (n = 268)
Allergy	0.4
Arthritis	2
Blood (for instance, anaemia)	0.7
Bone	1.5
Cancer	4.9
Cardiovascular disease	1.1
Carers	4.5
Children's health / diseases	2.2
Chronic disease	0.7
Consumer	0.7
Continence	0.7
Diabetes	2.2
Endocrine	3
Gastrointestinal	1.1
Genetic / rare	3.7
Healthcare (aspects of)	4.5
Heart (for instance, congenital)	1.1
Health promotion	1
HIV/AIDS	0.7
Infectious	2
Infectious (other)	2.2
Learning disabilities	3.7
Liver	1.1
Mental health	14.2
Muscular / tissue disorders	0.7
Neurological	9.3
Older people	3.7
Pain	0.7
PALS / PCT	2.2
Patients' support / information	4.9
PPIs / PPIFs	5.2
Reproductive	1.1
Respite / rehabilitation	0.7
Visual impairment	3.4
Other	3.0

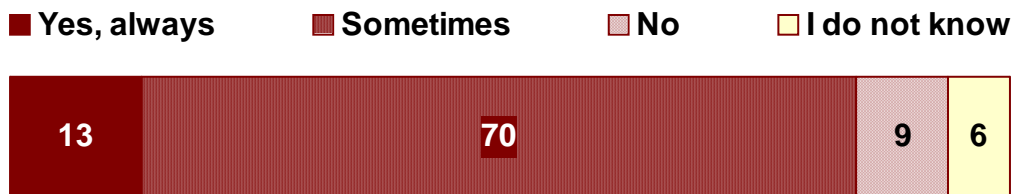
APPENDIX 2: RESULTS

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)?

[Please specify only one item]

% of respondents [number of whom = 268]



Note:

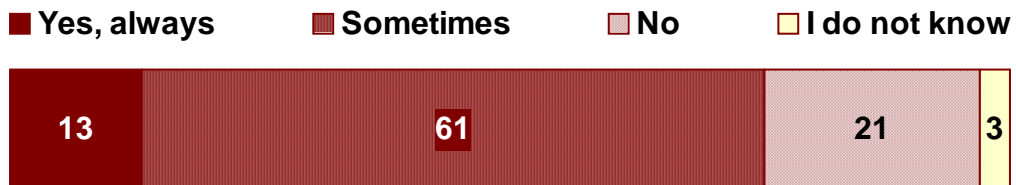
Percentages do not always add up to 100, as respondents did not always answer every question

The availability of high-quality patient information on medicines **(continued)**

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

[Please specify only one item]

% of respondents [number = 268]



Note:

Percentages do not always add up to 100, as respondents did not always answer every question

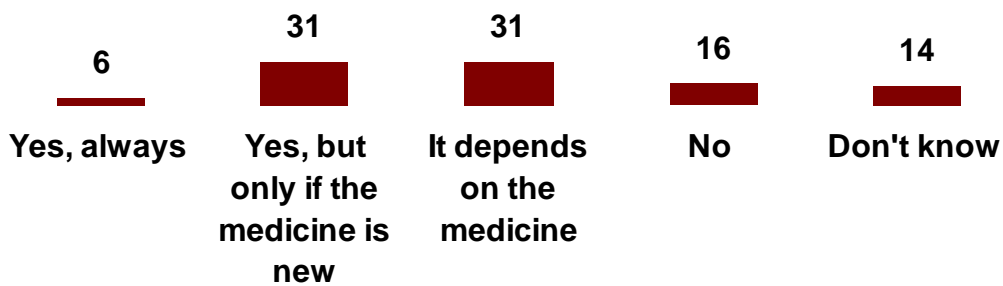
APPENDIX 2: RESULTS

Leaflets inside the packaging of medicines

Are the leaflets inside medicines packaging read by patients?

[Please specify only one item]

% of respondents [number = 268]



Note:

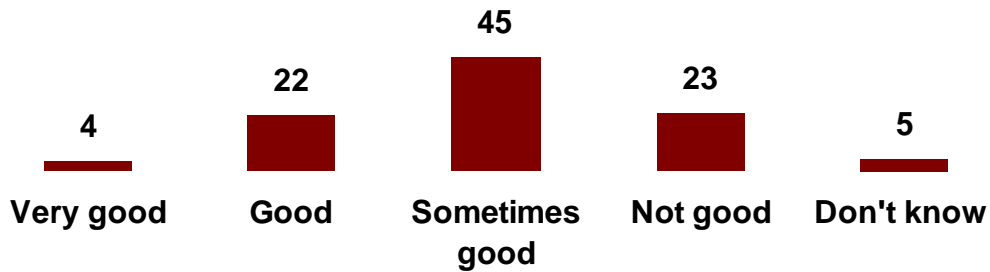
Percentages do not always add up to 100, as respondents did not always answer every question

Leaflets inside the packaging of medicines (continued)

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

[Please specify only one item]

% of respondents [number = 268]



Note:

Percentages do not always add up to 100, as respondents did not always answer every question

APPENDIX 2: RESULTS

Leaflets inside the packaging of medicines (continued)

Are medicines leaflets good at communicating information about safety considerations?

[Please specify only one item]

% of respondents [number = 268]



Note:

Percentages do not always add up to 100, as respondents did not always answer every question

APPENDIX 2: RESULTS

Leaflets inside the packaging of medicines (continued)

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

[Please specify only one item]

% of respondents [number = 268]



Note:

Percentages do not always add up to 100, as respondents did not always answer every question

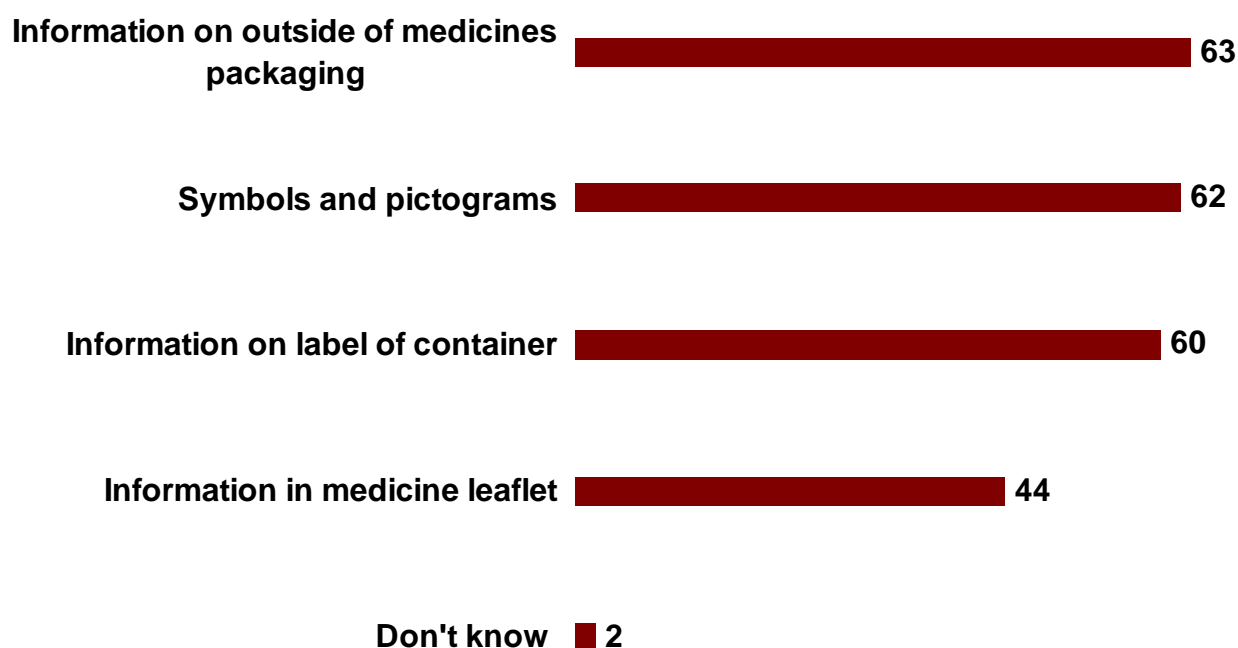
APPENDIX 2: RESULTS

Leaflets inside the packaging of medicines (continued)

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

[You can specify more than one item if you wish]

% of respondents [number = 268]



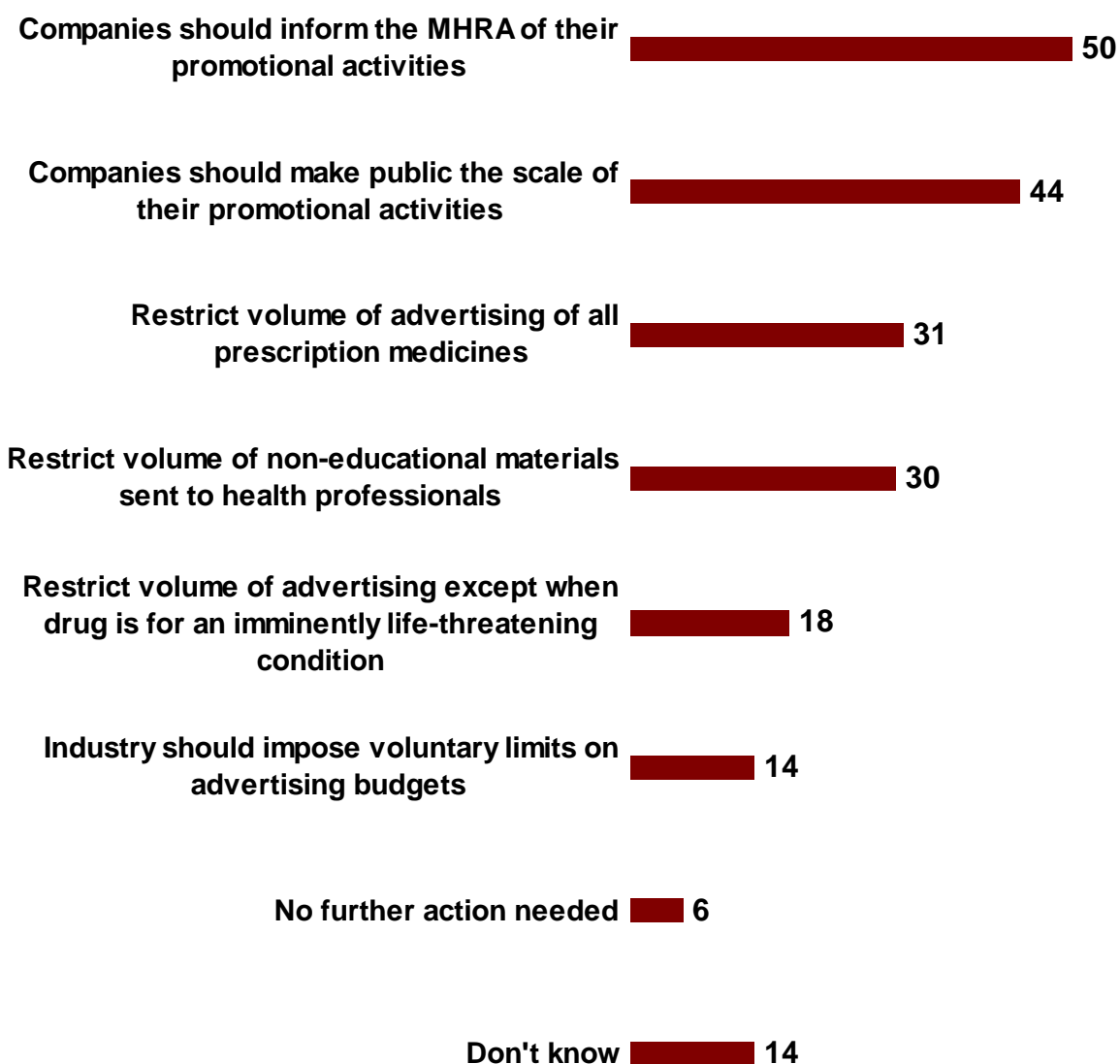
APPENDIX 2: RESULTS

Pharmaceutical companies' promotional activities to health professionals

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?

[You can specify more than one item if you wish]

% of respondents [number = 268]



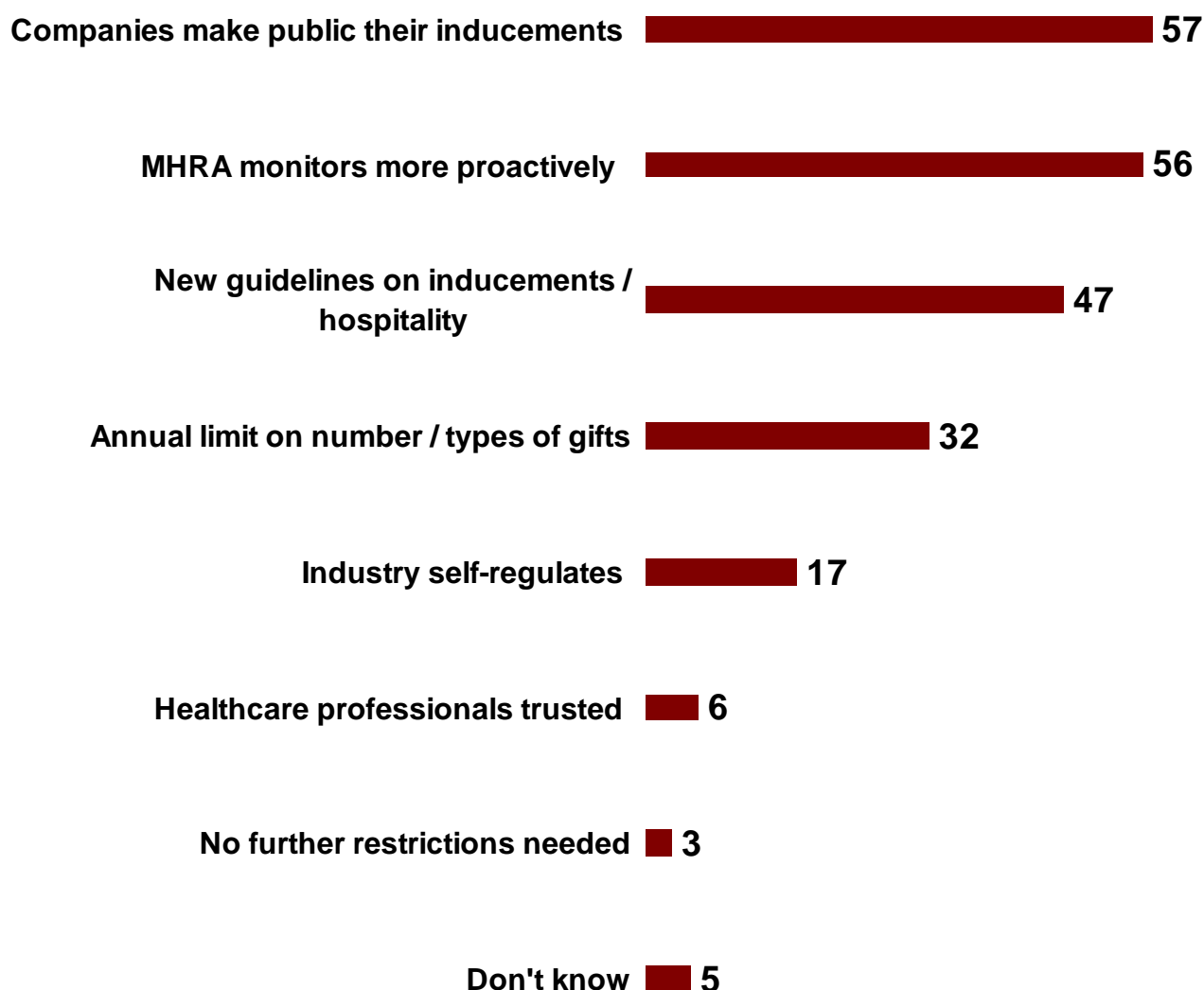
APPENDIX 2: RESULTS

Pharmaceutical companies' promotional activities to health professionals (continued)

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)?

[You can specify more than one item if you wish]

% of respondents [number = 268]



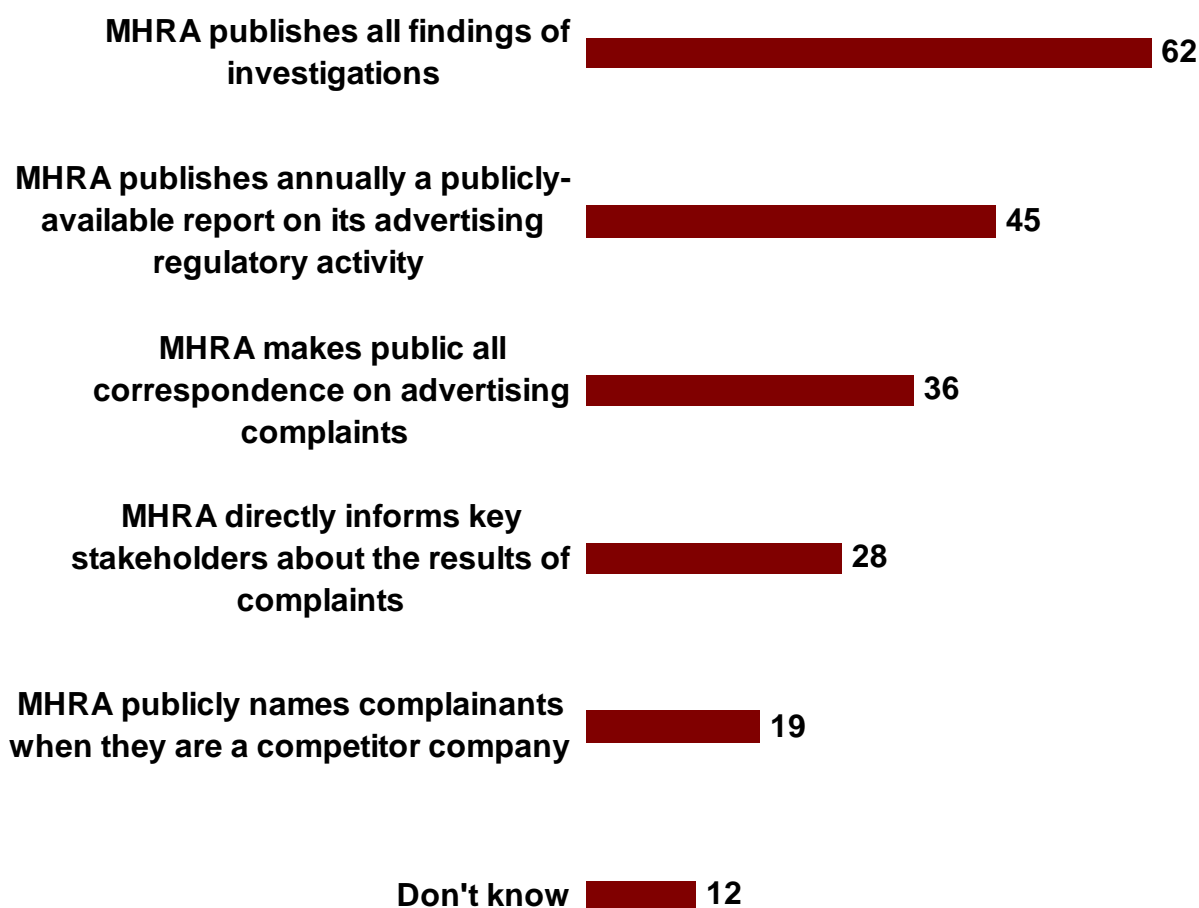
APPENDIX 2: RESULTS

**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?

[Please specify no more than three items]

% of respondents [number = 268]



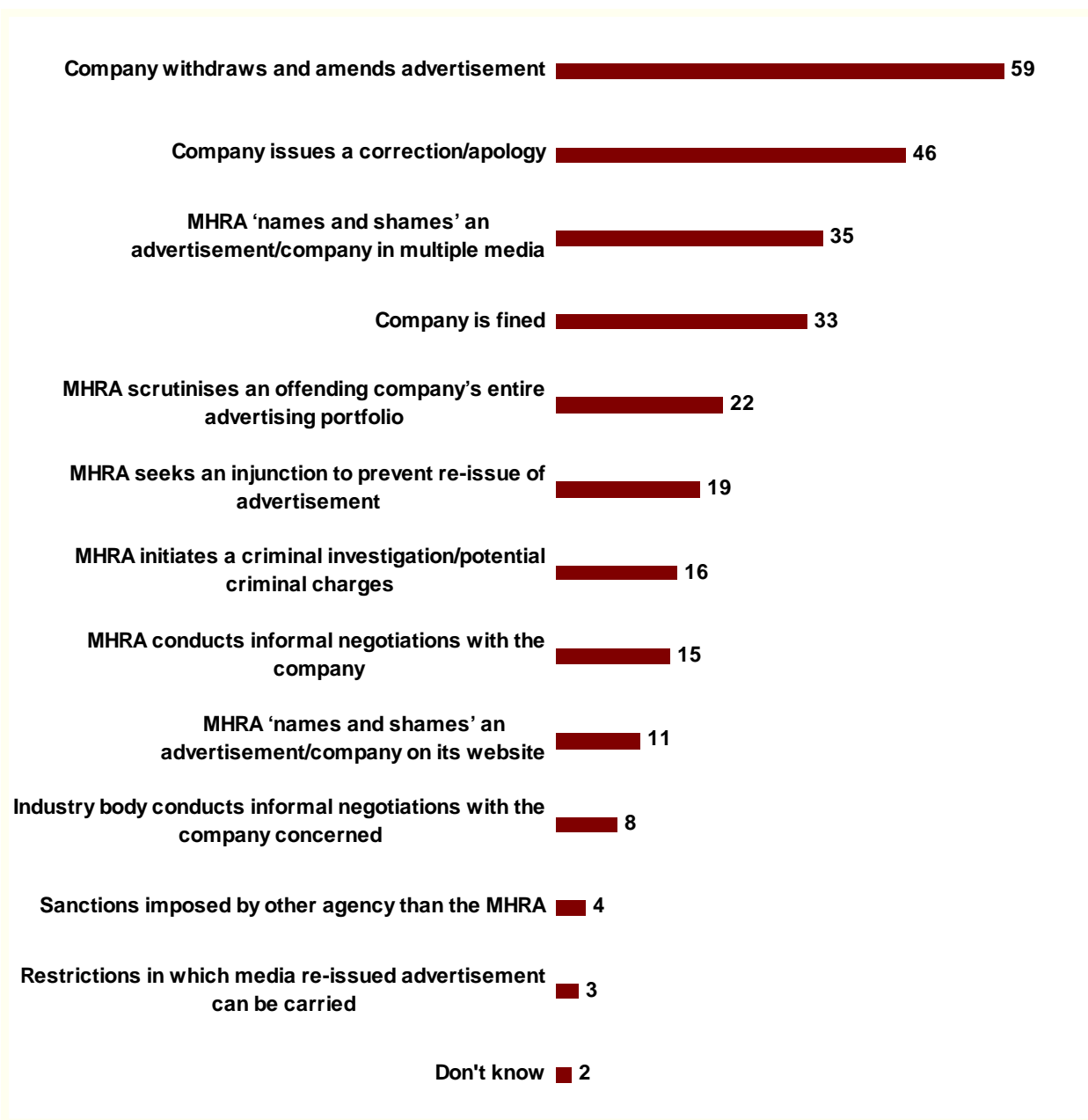
APPENDIX 2: RESULTS

Handling of complaints about medicines advertising (prescription and OTC) (continued)

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

[Please specify no more than three items]

% of respondents [number of whom = 268]



APPENDIX 2: RESULTS

Handling of complaints about medicines advertising (prescription and OTC) (continued)

When should actions be applied?

[Please specify only one item]

% of respondents [number = 268]



Note:

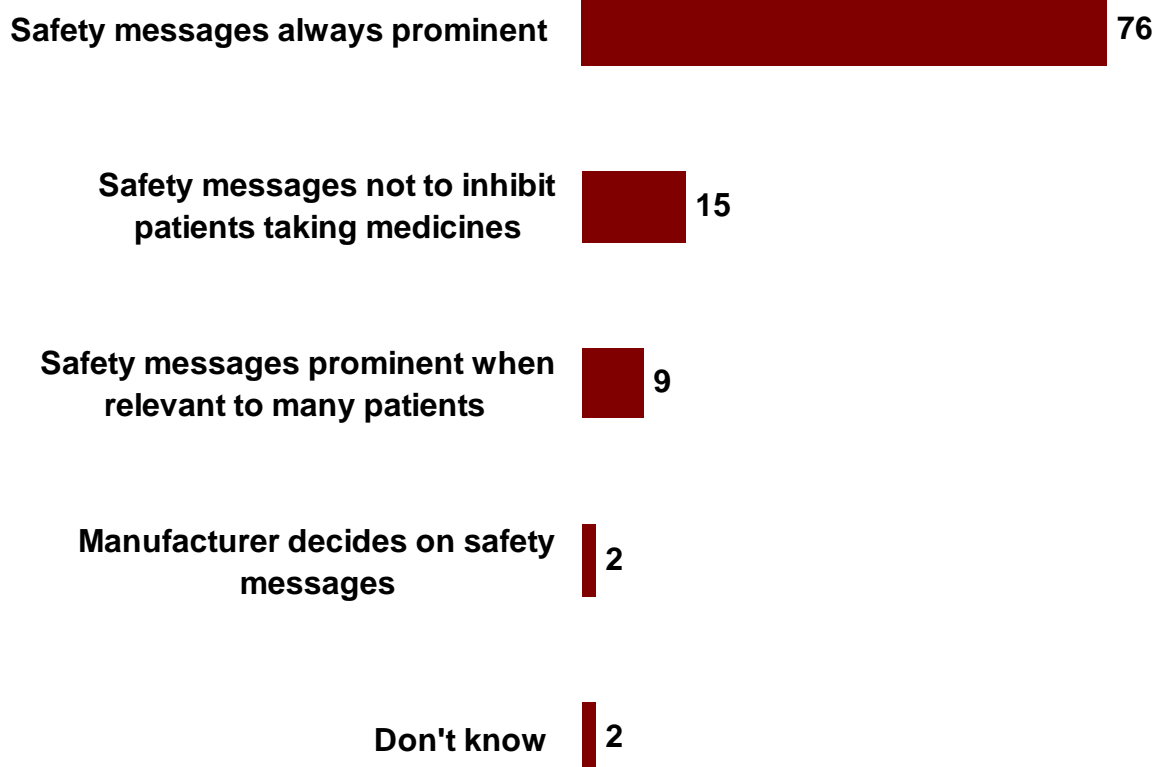
Percentages do not always add up to 100, as respondents did not always answer every question

Safety messages and claims in medicines advertising

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

[Please specify only one item]

% of respondents [number = 268]:



Note:

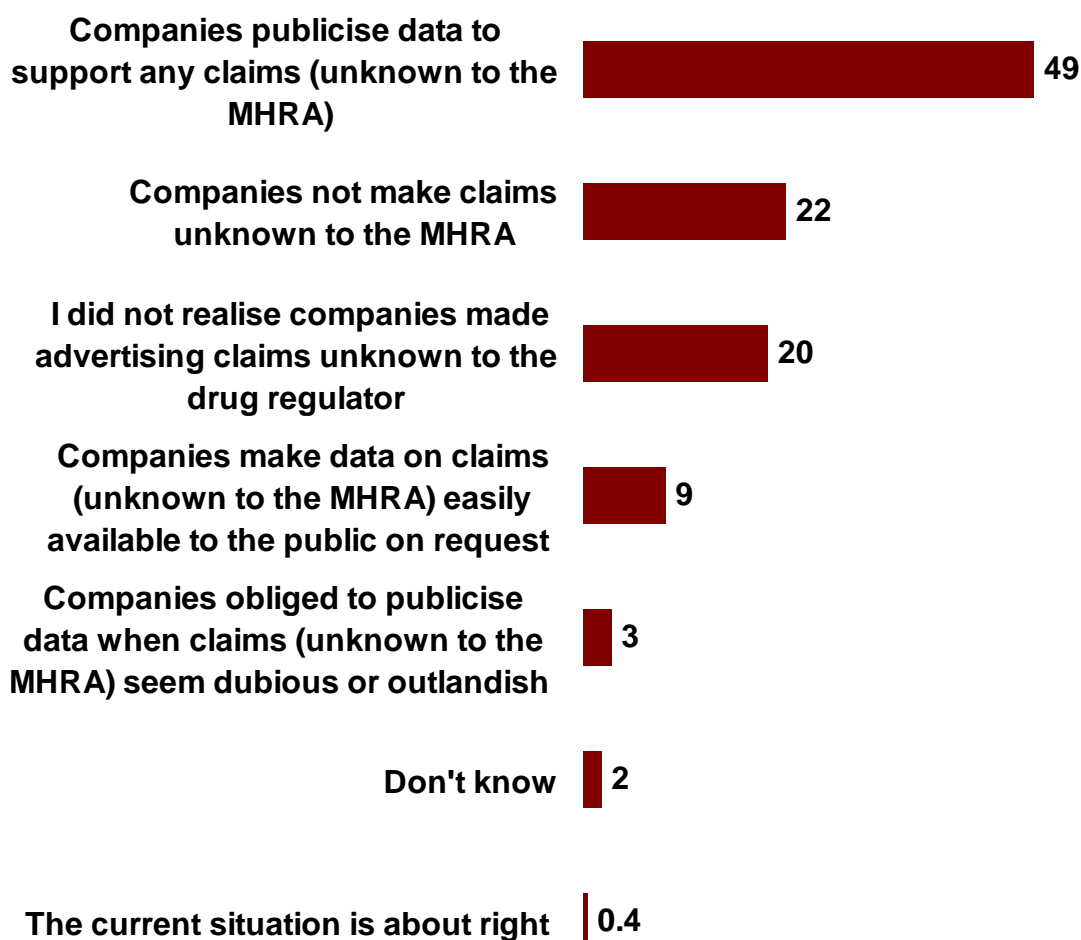
Percentages add up to more than 100, as some respondents ticked more than one item

Safety messages and claims in medicines advertising (continued)

Claims made in the advertising of medicines (both prescription and OTC) can sometimes go beyond what is agreed with the regulator. Such 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.] **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?**

Please specify only one item]

% of respondents [number = 268]



Note:

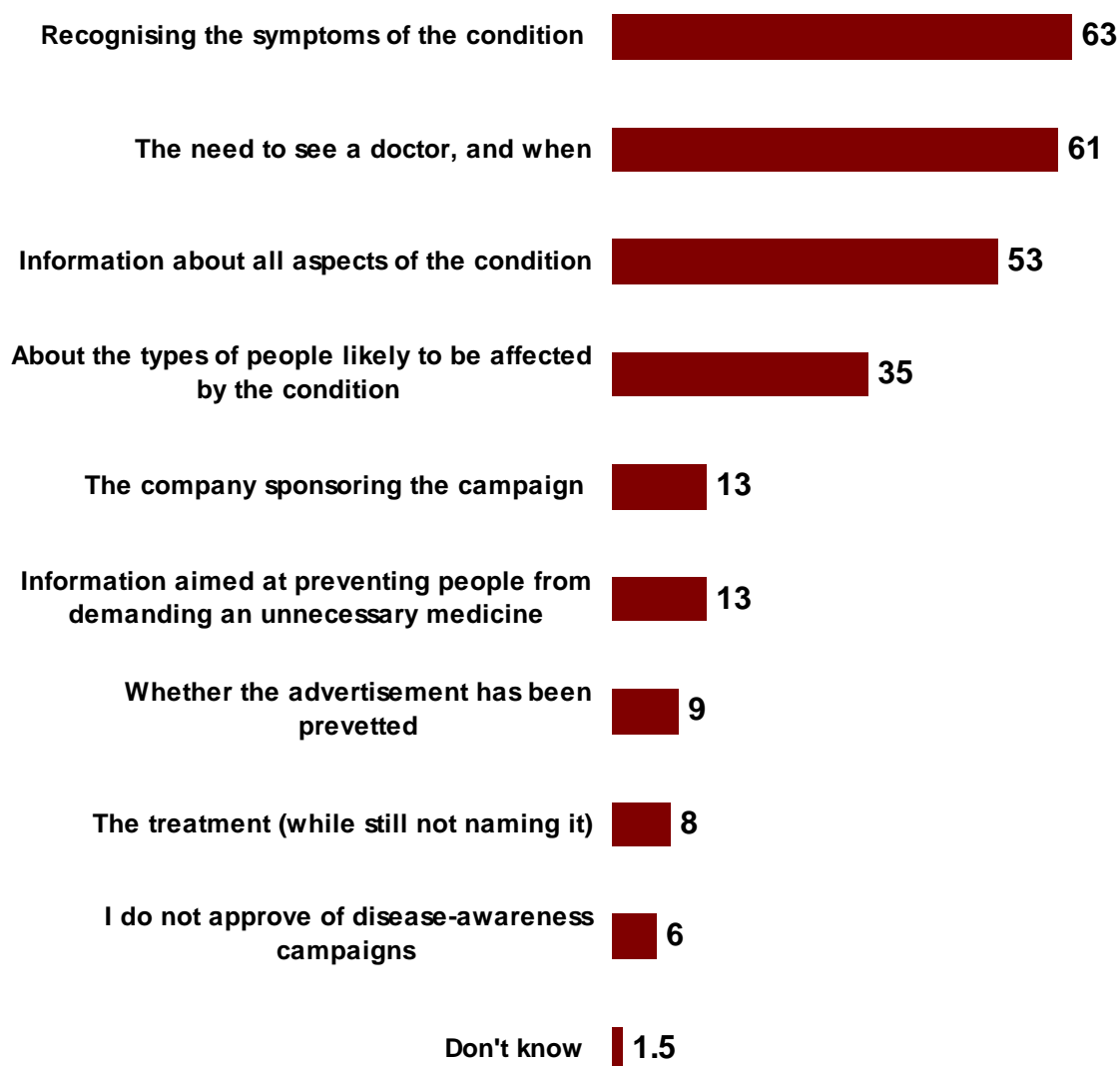
Percentages add up to more than 100, as some respondents ticked more than one item

Regulating disease-awareness campaigns

[Disease-awareness campaigns are advertisements designed to make the public aware of medical conditions that have prescription treatment/s] **Which types of information should be most prominent in disease-awareness campaigns?**

[Please specify no more than three items]

% of respondents [number = 268]



Appendix 3

COMMENTS FROM RESPONDENTS

PAGES 27-82

AS FAR AS POSSIBLE, PATIENTVIEW INCLUDED IN THIS DOCUMENT ALL RELEVANT COMMENTS RECEIVED FROM SURVEY PARTICIPANTS. ONE OR TWO COMMENTS THAT COULD BE CONSTRUED AS LIBELLOUS HAVE NOT BEEN REPRODUCED.

AVAILABILITY OF HIGH-QUALITY INFORMATION FOR OVER-THE-COUNTER MEDICINES

Group involved in health promotion. *The participant answered in a personal capacity.*

“Quality varies. Package inserts need to be more informative, spelling out real risks. And easier to read (they are way too small).”

PALS co-ordinator. *The participant answered in a personal capacity.* “Patients only have to ask a pharmacist (they are always pleased to help).”

Group specialising in consumer information. *The participant answered in a personal capacity.* “Should be always.”

Group specialising in pituitary disorders. *The participant answered in a personal capacity.* “Yes, mostly.”

Fenella Lemonsky of Expert By Experience. *The participant answered in a personal capacity.*

“Depends. Leaflets in medicines are simple. Internet information is good, but dependent on source. A nice website on painkillers is <http://www.coventrypainclinic.org.uk>, written by a pain specialist, with really useful detail. Wish more sites like this were available for other conditions. Not enough information exists on people on analgesia, and which type is appropriate for what, generally. 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! Flu-type medicines—why are patients not told that a hot lemon tea and paracetamol is ok, too? Imodium—how many patients get dietary

advice? That sort of thing is very poor. Also, pharmacists do not give enough general information on which painkillers can be safely combined—like ibuprofen and paracetamol and codeine, for maximum relief OTC, etc.”

York Coalition of Disabled People. “If information is not in accessible formats (such as large print, Braille, pictorial, or languages other than English), then it cannot be deemed ‘high quality’.”

Group specialising in visual impairment. “Patient inserts are not available in large print. The majority of patients are elderly, and more likely to require large print.”

Group specialising in various conditions particularly as they effect children. *The participant answered in a personal capacity.* “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.”

Group specialising in renal disease. *The participant answered in a personal capacity.* “The packaging and tablets should remain constant in appearance.”

Continence Foundation. *The participant answered in a personal capacity.* “Patients need to be pro-active in seeking information.”

Group specialising in older people. *The participant answered in a personal capacity.* “The information is available, but not always read, or listened to. Often, people are more likely to listen to information.”

Group specialising in physical and learning disabilities. *The participant answered in a personal capacity.* “Independent official information should be freely and easily available—a kind of BNF for dummies.”

Paschal McKeown of Mencap. *The participant answered in a personal capacity.* “The information provided needs to be made more accessible to people with a learning disability, with recognition given to the need for additional support and extra time. Also important 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.”

Arthritis Care. *The participant answered in a personal capacity.* “Not always available in certain formats, such as Braille, or for people with learning difficulties.”

Group specialising in osteoporosis. *The participant answered in a personal capacity.* “Pharmacies vary. Even in a regular one, advice depends on the pharmacist on duty at the time.”

Patient Information Forum. *The participant answered in a personal capacity.* “Provision is inconsistent. Information is not provided about all products. What is provided often differs according to sources sought.”

Parents of Autistic Spectrum Disorder Adults, Edinburgh. “Patient information leaflets are never useful, because the print is always extremely small and unclear.”

Group specialising in chronic back pain. *The participant answered in a personal capacity.* “Depends how busy the pharmacist is.”

Insulin-Dependent Diabetes Trust. “The question assumes that patients know what high-quality, useful information is. Not everyone does. 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.”

UK Coalition of People Living with HIV and AIDS. “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 use of even a simple anti-histamine if a patient is on certain anti-retroviral treatments).”

Group specialising in the after-effects of drugs. “It depends whether the source is physically accessible.”

Group specialising in cardiac arrhythmia. “If you have access (and the knowledge) to search the Internet.”

Regional PPI. *The participant answered in a personal capacity.* “But most are not aware of this.”

Professional nurse attached to a patient organisation. “Depends on access to a helpful pharmacist.”

Knowledge manager within the NHS. “If they know HOW to find it (that is, have information literacy skills).”

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* “Sometimes. But answers throughout will be based on our perception of patients’ knowledge of drugs (as determined by when they contact our information service).”

St Albans and District Voluntary Diabetic Support Group. “Depends on the pharmacist. Print on package inserts is often too small. Not all patients have access to, or can use, the Internet. So, a number never get good information.”

Group specialising in deafness and the hard of hearing. *The participant answered in a personal capacity.* “Not available in British Sign Language.”

Anonymous participant. “Family carers do not find the information useful.”

Group specialising in older people, dementia and mental health. The participant, *who answered in a personal capacity, was also a manager of a nursing home.* “Very dependent on the pharmacist.”

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* “Have found some labelling very good. Boots 'fish-oil' tablets have warnings on the label about taking warfarin, etc. But maybe could be bolder?”

British Heart Foundation. *The participant answered in a personal capacity.* “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.”

Highland Users Group. “Some people are confident in their pharmacist. Some people would not think to ask questions.”

Congenital Adrenal Hyperplasia Support Group. *The participant answered in a personal capacity.* “I think most patients have access to the Internet, or can get advice from their GP or pharmacist if they take the trouble to make their own enquiries!”

Group specialising in the promotion of health information. *The participant answered in a personal capacity.* “I would say ‘usually’.”

Local statutory group involved with carers of people with chronic illness. *The participant answered in a personal capacity.* “Patients who do not have a reasonable level of knowledge about pharmaceuticals, however, may not be aware of the information that they should be seeking.”

Group representing the interests of carers. *The participant answered in a personal capacity.* “Some chemists are very good.”

PPIF (Swale, Kent). *The participant answered in a personal capacity.* “Depends on the knowledge of the assistant.”

Mental health client. “Not sure about nebuliser for asthma, or Viagra.”

Anonymous respondent. “Small local pharmacists are very helpful. But not so those in larger establishments.”

Chair of local support group involved with women’s health; Vice-Chair of a PPI Forum; member of a parliamentary group and European alliance. *The participant answered in a personal capacity.* “Patients are generally not encouraged to find out.”

Group specialising in diabetes. *The participant answered on behalf of a small group of care advisers.* “Do not have data on this.”

Group specialising in congenital heart disease in adults. “The primary issue that occurs is when there is limited information on the possible interactions of OTCs and prescription drugs. The approach taken seems to be cover all basics, rather than providing specific guidance. When pharmacists are available, the advice they provide is normally excellent, but tends to be based on the norms, rather than on specific information of individual patients.”

Group specialising in learning disabilities. *The participant answered in a personal capacity.* “Information is not supplied in an accessible format for people with a learning disability / poor reading-and-understanding skills (or those who support them).”

Anaemic Society. “Some members have considered buying B12 injections on the Internet. Nothing is known about this medicine.”

Group specialising in asthma. “High-quality information is available, and patients do have major ongoing information needs. But it

seems that certain patients are not getting their information needs met.”

Patients' Association. “Some patients can, and will—if they know where to look.”

Salford Heart Care Re-Hab. “Poor information.”

Pharmacy manager at an independent healthcare provider. *The participant answered in a personal capacity*. “Advice is available through pharmacies—not from supermarkets.”

PPIF (East Kent and Coastal). *The participant answered in a personal capacity*. “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).”

Group specialising in older people. *The participant answered in a personal capacity*. “Only if you think to ask.”

PPIF. *The participant answered in a personal capacity*. “Not everyone is on the Internet.”

PPIF (Crawley). *The participant answered in a personal capacity*. “The best [information is] from a friendly pharmacist.”

Group specialising in the needs of carers. *The participant answered in a personal capacity*. “Depends on the quality and accessibility of a qualified pharmacist.”

Parkinson's Disease Society (Canterbury Branch). *The participant answered in a personal capacity*. “I feel there needs to be an in-between answer, such as “Generally” between “Always” and “Sometimes”.”

Heart to Herts Cardiac Support Group. “The information is only available after purchase.”

Arthritis Patient Forum (Torbay Hospital, South Devon). *The participant answered in a personal capacity*. “I don't know about medication bought on the Internet.”

Rethink Severe Mental Illness. “They may not always know what to ask for.”

Group specialising in mental health. “How do patients KNOW they are getting high-quality (or even accurate) information?”

PPI. *The participant answered in a personal capacity*. “Pharmacies vary.”

PPI Hospital Forum. *The participant answered in a personal capacity*. “Pharmacists are good at giving information.”

Group specialising in the needs of carers. *The participant answered in a personal capacity*. “A wealth of information is available, but people do not always know where to look.”

Group specialising in learning disability. “If bought in a supermarket—no.”

Perth Bipolar Group. *The participant answered in a personal capacity*. “On the Internet—with effort.”

Degos Disease Patient Support Network. *The participant answered in a personal capacity*. “Our disease is too rare to have any known treatments or cures.”

Group specialising in cancer of the blood. *The participant answered in a personal capacity*. “This is probably most significantly a problem with out-of-patent generic medicines, such as aspirin.”

Group specialising in HIV/AIDS. *The participant answered in a personal capacity*. “In the field of HIV/AIDS, a variety of good websites and support agencies are available.”

Lanarkshire Links. *The participant answered in a personal capacity.* "If you ask."

Group specialising in mental health. *The participant answered in a personal capacity.* "Not always in plain English."

Obesity Awareness and Solutions Trust, The (TOAST). *The participant answered in a personal capacity.* "Marketing and sales campaigns can mean that information is given the importance that the manufacturer gives it, rather than the priority that the patient needs."

Chairperson of a PCT. *The participant answered in a personal capacity.* "When the information recommends seeing a doctor, it should indicate whether it is urgent (in which case, use accident and emergency or out-of-hours service), or can wait until the GP practice is open again."

Group specialising in mental health. *The participant answered in a personal capacity.* "Yes, I think so."

Mind (Pembrokeshire). "The patient has to be able to ask!"

Dr Karel van der Waarde of Graphic Design-Research. *The participant answered in a personal capacity.* "The decision which OTC medicine to buy is made by consumers inside a pharmacy or a shop. Verbal advice is usually available there, but not information from the Internet (pharmacies/shops contain no publicly-accessible computers) or patient-package inserts (consumers cannot open OTC packaging before purchase). The main visual source is the outer packaging. This packaging has several functions. One of them is to attract the attention of potential consumers. Another function is to inform about the product. Unfortunately, the information function is frequently underdeveloped."

Group specialising in diabetes. *The participant answered in a personal capacity.* "If the patient speaks English."

PPIF (Chesterfield PCT). "Impossible to generalise about the whole range of commercial OTC products."

Which? "In the absence of a central and impartial source of medicines and treatment information, we can only say that it is sometimes the case that high-quality information is available. The only consistent source of information about over-the-counter medicines is the patient information leaflet (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."

There are other areas of concern about information on over-the-counter medicines. Recently-reclassified medicines (those switched from POM to P) can be delivered to a range of different and potentially confusing protocols. The MHRA states that the drug manufacturer's protocol should be agreed with stakeholders—such as the Royal Pharmaceutical Society of Great Britain (RPSGB), the National Pharmaceutical Association (NPA), and the Centre for Postgraduate Pharmacy Education (CPPE). But these stakeholders do not need to have approved the protocol for the switch to receive its authorisation for sale as OTC from the MHRA. Moreover, anecdotal evidence suggests that, as a result of receiving various guidelines, pharmacists collate the information and draw up personalised/local versions of protocols.

Pharmaceutical companies use sophisticated techniques to advertise over-the-counter medicines to the public.

Advertisements, therefore, are a major source of information for consumers. Current arrangements for the monitoring of advertising material used to promote medicines are not sufficiently robust (or are applied with insufficient rigour) to ensure the accuracy and integrity of information provided. And the MHRA has been slow to take remedial action when malpractice in this regard has been brought to its attention. It is Which?'s view that the vetting and monitoring of all advertising and promotional activity should be carried out by a body that is wholly independent of industry, and which has a clear and unequivocal remit to promote public health."

Group specialising in older people. The participant answered in a personal capacity. "Patient package inserts are often ignored!"

Group specialising in depression. The participant answered in a personal capacity. "St John's Wort is sold in general shops with no information—which is a problem regarding interactions."

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum). "This largely depends on the pharmacy, and the willingness and ability of the pharmacist to advise. 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."

AVAILABILITY OF HIGH-QUALITY INFORMATION FOR PRESCRIPTION MEDICINES

Group involved in health promotion. *The participant answered in a personal capacity.* “Again, varies (depending on source).”

PALS co-ordinator. *The participant answered in a personal capacity.* “Patients only have to ask a pharmacist (who are always pleased to help).”

National Ankylosing Spondylitis Society. *The participant answered in a personal capacity.* “If patients ask their rheumatologists about their NSAIDs, they will be told.”

Group specialising in pituitary disorders. *The participant answered in a personal capacity.* “Yes, mostly.”

Group providing consumer information. *The participant answered in a personal capacity.* “Not always in accessible language.”

Fenella Lemonsky of Expert By Experience. *The participant answered in a personal capacity.* “Depends who gives out the information. Good websites that are credible are a hotch potch. NHS Direct is useless. Some pharmacists still don’t give out leaflet inserts in medicines. Do patients know that they can sue the PCT or acute trusts over this?”

Group specialising in endometriosis. *The participant answered in a personal capacity.* “The Internet can sometimes be a danger, due to misinformation. Sometimes, the best information is via charities working in the area relating to the drug.”

York Coalition of Disabled People. “Information is not in accessible formats (such as large print, Braille, pictorial, or languages other than English). Then, it cannot be deemed ‘high quality’.”

Group specialising in visual impairment. “Patient inserts are not available in large print. The majority of patients are elderly, and more likely to require large print.”

Group specialising in renal disease. *The participant answered in a personal capacity.* “The packaging and tablets should remain constant in appearance.”

Group specialising in brain cancer. *The participant answered in a personal capacity.* “I’d rather say ‘Usually’ and not ‘Always’ (although ‘Sometimes’ is too severe in my opinion). The information on prescription medicines is usually good. But there is limited warning about the possible side-effects. Just look at the current Vioxx saga.”

HCV-Alert. *The participant answered in a personal capacity.* “Doctors don’t have the time or the inclination to discuss. The Internet can give false and misleading information, and—in my experience—horror stories of adverse effects.”

Continence Foundation. *The participant answered in a personal capacity.* “Patients need to be pro-active in seeking information.”

Group specialising in genetic diseases. *The participant answered in a personal capacity.* “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. It would also depend on what the medicine was for (whether a minor or a major condition). Patients would generally ask more if the treatment was for something more severe.”

Group specialising in pregnancy loss. *The participant answered in a personal capacity.* “Usually [high-quality information] from package inserts. More varied from other sources (especially the Internet).”

Group specialising in physical and learning disabilities. *The participant answered in a personal capacity.* “Independent official information should be freely and easily available—a kind of BNF for dummies.”

Paschal McKeown of Mencap. *The participant answered in a personal capacity.* “The information provided needs to be made more accessible to people with a learning disability (with recognition given to the need for additional support and extra time). Also important 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.”

Arthritis Care. *The participant answered in a personal capacity.* “Not always available in certain formats, such as Braille, or for people with learning difficulties. But also depends on: a) the GP or consultant; b) the assertiveness of the patient; c) access to the Internet.”

Group specialising in primary immunodeficiency. *The participant answered in a personal capacity.* “Depends very much on the doctor.”

Group specialising in osteoporosis. *The participant answered in a personal capacity.* “In my case, almost always: ‘YES’. But I do hear some friends express concerns that they do not know what they have been prescribed, why [they have been prescribed it], or what effect to expect.”

Patient Information Forum. *The participant answered in a personal capacity.* “Provision is inconsistent. Information is not provided about all products. What is provided often differs according to sources sought. However, 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.”

Parents of Autistic Spectrum Disorder Adults, Edinburgh. “Not unless you ask, and then the side effects are not always discussed. Leaflets are always useless, as few people can see the print.”

Group involved with chronic back pain. *The participant answered in a personal capacity.* “My doctor is good. But most treat patient like they are idiots—although many [patients] don’t listen to what they are told.”

Do You Panic. *The participant answered in a personal capacity.* “Adverts can’t be trusted if commercial.”

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).”

UK Coalition of People Living with HIV and AIDS. “Patient groups are often a good source of information. But patients should be very wary of drug company-produced literature, which can be misleading or over-/under-play things like side effects (look at Vioxx, for example). The pharmaceutical industry’s imperative is to sell more drugs, while some effort is taken on getting patient safety data to pass safety protocols in connection with drug licensing. Where 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 down side, and trumpets over-effectiveness. This negates the information in patient information leaflets in packages of drugs. Doctors have limited time to explain

the ins and outs of prescription medicines, but informed patients probably have more luck in persuading them to spend time on attempting it. 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. And the quality of information depends on the doctor. If from a specialist in that field, the information is likely to be better than, say, from a GP with little knowledge of the specialisation. The Internet is a useful resource. But patients have to be careful about the veracity of the drug information on it. Critical appraisals of drug effectiveness and side-effects can be found. But pharmaceutical-industry sites should be avoided in favour of those where patients and doctors can discuss these issues unfettered by industry. And—alongside good information—there is plenty of disinformation on the Internet. Patients have to make a judgment on the quality of the particular sites they visit. Specialist pharmacist advice is useful, but provision can be patchy. In some places, pharmacists run clinic sessions with patients on a one-to-one basis. Whereas, other (ordinary) pharmacists dispense specialist medications, and merely go through the motions of asking stock questions like "Have you had these before?", or "Are you allergic to anything?". Absence of appropriate IT support to pharmacists doesn't do much to support patients on long-term medication."

Group specialising in health services provision. *The participant answered in a personal capacity.* "Only if you know the question to ask."

Regional PPI. *The participant answered in a personal capacity.* "But only some have the skills, confidence, ability, and capacity to search it."

Professional nurse attached to a patient organisation. "The public often finds difficulty in evaluating risk and worry, re interaction with other medications."

Senior psychiatric pharmacist working within the NHS. "I STRONGLY DO NOT BELIEVE that good-quality information, direct to patients, comes from the industry."

St Albans and District Voluntary Diabetic Support Group. "Usually only available if the patient asks. Many are hesitant to do so."

Anonymous participant. "Family carers do not find the information useful."

Group specialising in deafness and the hard of hearing. *The participant answered in a personal capacity.* "From doctors (if a BSL interpreter is provided for the appointment)."

PPIF member of ambulance service. *The participant answered in a personal capacity.* "It helps if the patient deliberately asks about side-effects."

European Network of (ex-) Users and Survivors of Psychiatry. *The participant answered in a personal capacity.* "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?"

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* "Personally, I have always managed to find plenty of information about the medications I have been prescribed: from BNF Online, the Internet, or from my consultant."

British Heart Foundation. *The participant answered in a personal capacity.* "The information is usually in plain English, clearly lays out risks and

benefits, and the information lies within the packaging. However, sometimes, people want to know to what extent they have choice, and which product could benefit them over another.”

Highland Users Group. “As a group, we do get good information. But we are assertive in asking for it.”

Group specialising in the promotion of health information. *The participant answered in a personal capacity.* “I would say ‘Usually’ ”

Local statutory group involved with carers of people with chronic illness. *The participant answered in a personal capacity.* “Patients who do not have a reasonable level of knowledge about pharmaceuticals, however, may not be aware of the information that they should be seeking.”

PPIF (Swale, Kent). *The participant answered in a personal capacity.* “Professionals do not always take enough time to speak to patients.”

Anonymous participant. “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.”

Local group specialising in autism. *The participant answered in a personal capacity.* “If not in the packet, you do not get any leaflets or information (apart from dosage).”

Group specialising in diabetes. *The participant answered on behalf of a small group of care advisers.* “Do not have any data on this.”

Group specialising in congenital heart disease in adults. “This should be offered by

the doctor. But many patients will need to be encouraged to ask questions. Offering the information upfront could address later concerns.”

Group specialising in learning disabilities. *The participant answered in a personal capacity.* “Information is not supplied in an accessible format for people with a learning disability / poor reading-and-understanding skills, or those who support them.”

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.”

Group specialising in asthma. “Sometimes the information about prescription medicines is available. But it does not mean that people who need it most are accessing this information.”

Patients’ Association. “Not if they restrict themselves to UK web sites.”

Salford Heart Care Re-Hab. “If you enquire.”

Group specialising in respite care. *The participant answered in a personal capacity.* “Not sure if all side effects are noted.”

Pharmacy manager at an independent healthcare provider. *The participant answered in a personal capacity.* “Only available with patient packs (PILS). The patient usually has to ask the pharmacist for further information.”

PPIF (East Kent and Coastal). *The participant answered in a personal capacity.* “GPs only advise on dosage, and will only give

information on other aspects (such as side-effects) if specifically asked. Package inserts can be misleading, as every possible side-effect or CI is listed to cover the manufacturer."

Group specialising in older people. *The participant answered in a personal capacity.* "Only if you ask."

PPIF. *The participant answered in a personal capacity.* "Only brief details from pharmacists."

PPIF (Crawley). *The participant answered in a personal capacity.* "Best from a friendly pharmacist."

Heart to Herts Cardiac Support Group. "Usually from the GP."

Group specialising in neurological conditions. *The participant answered in a personal capacity.* "It is sometimes difficult for people to get information on medication which has no product licence (for instance, antidepressants for neuropathic pain)."

Diabetes UK. "The information is available. It is just not presented in a useful form, or in a manner appropriate for the needs of different individuals. It does not, for instance, use a font appropriate for people with visual impairment."

Mind (Cymru). *The participant answered in a personal capacity.* "Especially with regard to new medications, or with mental health prescriptions."

Arthritis Patient Forum (Torbay Hospital, South Devon). *The participant answered in a personal capacity.* "I've always found my medication information ok."

Rethink Severe Mental Illness. "In some psychiatric hospitals, notes are removed."

Group specialising in visual impairment. "GPs do not explain side-effects clearly."

PPI Hospital Forum. *The participant answered in a personal capacity.* "Doctors give a range of drugs, and inform patients of the need to take them."

Group specialising in the needs of carers. *The participant answered in a personal capacity.* "Many people need medical matters explained to them in layman's language, and should be allowed time to ask questions, and to confirm their thinking—particularly our clients, who are often making decisions for a disabled or infirm loved one."

Group specialising in all types of sight loss. *The participant answered in a personal capacity.* "Our users are visually impaired, and largely elderly, and cannot read instruction leaflets. Most 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)."

Huntington's Disease Association (Colchester and District Branch). *The participant answered in a personal capacity.* "The media have just informed us [Monday, September 5th 2005] that our local PCTs in north-east Essex have directed their GPs NOT to prescribe high-quality prescription drugs, and to save money by only prescribing the cheapest/inferior/older medication. Prescriptions for new medications that result from up-to-date, quality research will not be prescribed—due to cost. Quite interesting, because many patients follow the research on medications that help their chronic medical conditions, and now will not be able to have access to these treatments through the GP system."

Plymouth Mind Oasis. *The participant answered in a personal capacity.* "I work with mentally-ill people, who are often not able to understand information unless it is clearly explained."

Group specialising in learning disability. “Only from pharmacists.”

Brain Tumour UK. *The participant answered in a personal capacity.* “Doctors do not always inform patients of side-effects, or explain why they have prescribed specific medicines.”

Group specialising in HIV/AIDS. *The participant answered in a personal capacity.* “Not always, as more options than BHIVA guidelines to take in patient lifestyles, etc.”

Lanarkshire Links. *The participant answered in a personal capacity.* “Yes—if you ask.”

Group specialising in mental health. *The participant answered in a personal capacity.* “Inserts often missing.”

Group involved in all disease areas (except cardiac surgery). “Original pack dispensing not 10%.”

Obesity Awareness and Solutions Trust, The (TOAST). *The participant answered in a personal capacity.* “Not informed of support packages and side-effects.”

Neurological Alliance (South West). *The participant answered in a personal capacity.* “Lots of drug reactions (some are nasty).”

Group specialising in mental health. *The participant answered in a personal capacity.* “Yes, from what I have seen for myself.”

Mind (Pembrokeshire). “[Sometimes.] If the patient is able to ask or seek support with this (and be able to comprehend pharmacology).

Dr Karel van der Waarde of Graphic Design-Research. *The participant answered in a personal capacity.* “Information is available, but frequently fairly hard to find (EMA website?), or difficult to understand.”

Group specialising in diabetes. *The participant answered in a personal capacity.* “Very dependent on the quality of the GP/ pharmacist, and the patient's ability to speak English.”

Which? “It is possible for consumers to get high-quality information from the sources identified [in the questionnaire]. However, our research has found that not all information about medicines is of high quality, and that it can be difficult to identify what high-quality information looks like. The comments we produced in our answer to question 1 (the quality of OTC patient information leaflets) apply equally to prescription medicines. In short, there is a great deal of information that is misleading, inaccurate, or simply does not meet individual needs. There should be 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.”

Group specialising in depression. *The participant answered in a personal capacity.* “The best information comes from pharmacists, and patient package inserts, but not always from doctors. Little comes from the Internet.”

Anonymous respondent. “The inserts should have large print.”

Anonymous respondent. “Not usually from GPs. Insufficient information from pharmacists. But [patients are able to [get information] from package inserts.”

Group specialising in Asperger syndrome.

The participant answered in a personal capacity.

“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.”

Group specialising in severe mental illness (especially schizophrenia).

The participant answered in a personal capacity. “Often, patients only get information from a doctor—which, in the case of psychiatry, is usually parlously inadequate to this day.”

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum).

“It can be enormously variable. Sometimes, package inserts are too small to be read easily. And Internet information cannot be guaranteed to be reliable.”

Group specialising in prostate cancer.

The participant answered in a personal capacity. “Side effects come as a complete surprise too often. We are not convinced (by a very long way!) that informed choices on treatment are the norm.”

Mind (Havering).

The participant answered in a personal capacity. “The inserts are good, but many people do not read them. Some people are prescribed medication, yet doctors do not talk about side-effects. Even when patients raise the subject, doctors minimise the significance of the side-effects.”

PPIF (Central Liverpool PCT). “Patients do not know what to believe regarding Internet information.”

Group based in an NHS hospital trust and advising on patient information.

The participant answered in a personal capacity. “Professionals do not always know the answers to patients’ questions.”

ARE THE LEAFLETS INSIDE MEDICINES PACKAGING READ BY PATIENTS?

National Ankylosing Spondylitis Society. *The participant answered in a personal capacity*. “I do not know. However, I think that very few read them.”

Group specialising in mental health. “Too much small writing.”

Group specialising in pituitary disorders. *The participant answered in a personal capacity*. “Yes, mostly.”

Fenella Lemonsky of Expert By Experience. *The participant answered in a personal capacity*. “Often, patients fear the worst side effects mentioned (even if rare).”

York Coalition of Disabled People. “Information is not in accessible formats (such as large print, Braille, pictorial, or languages other than English). Then, it cannot be deemed ‘high quality’.”

Dumfries and Galloway Association for the Blind. *The participant answered in a personal capacity*. “They should be easier to read, and in larger print.”

Group specialising in brain cancer. *The participant answered in a personal capacity*. “This may be very different for different people. However, as a health professional, I have a certain cynicism about the description of side-effects—which is not in the [manufacturing] company's interest. But I read the leaflets if it is a new medicine, to check dosing instructions and warnings (such as for driving).”

Alzheimer's Society (Selby and York Branch). “This is, of course, assuming that the patient/carer is literate, and does not have impaired vision. Often, the type is so dense that it is difficult to read.”

Group specialising in genetic diseases. *The participant answered in a personal capacity*. “Rarely. Again, depends on the patient. They may read the information, but it is whether or not they understand it that is important.”

Group specialising in older people. *The participant answered in a personal capacity*. “Sometimes, the leaflet is only read if something appears to have gone wrong.”

Group specialising in physical and learning disabilities. *The participant answered in a personal capacity*. “I personally read, if new to me.”

Paschal McKeown of Mencap. *The participant answered in a personal capacity*. “The information provided needs to be made more accessible to people with a learning disability, with recognition given to the need for additional support and extra time. Also important 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.”

Pulmonary Hypertension Association UK. “The font size is often too small.”

Arthritis Care. *The participant answered in a personal capacity*. “Needs to be in a format that meets patients' needs.”

Group specialising in osteoporosis. *The participant answered in a personal capacity*. “I believe most patients do not bother. Layout is usually off-putting—typeface too small, etc, etc.”

Patient Information Forum. *The participant answered in a personal capacity*. “Anecdotal evidence exists. I don't read them, but family members do. Experts like Theo Raynor are conducting reviews in this area.”

Statutory body (Primary Care Trust) from East Anglia. *The participant answered in a personal capacity.* "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."

James Lind Initiative. *The participant answered in a personal capacity.* "When once I tried to assess from the leaflets which of six medicines being taken by an elderly relative might have been causing dizziness, I found the information unhelpful."

Parents of Autistic Spectrum Disorder Adults, Edinburgh. "Print size too small."

Group specialising in chronic back pain. *The participant answered in a personal capacity.* "I know many people who never read the leaflets."

Insulin-Dependent Diabetes Trust. "There is a problem with long-term medication, in that people do not read the patient information leaflets (PILs) 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."

UK Coalition of People Living with HIV and AIDS. "Perhaps the patient might read the patient information leaflet (PIL) once only on first prescription (assuming they actually understand the language used on the leaflet, and the importance of it). Again, if the information is produced by the manufacturer, they have a vested interest in playing down adverse side-effects, so the information may not be that trustworthy."

Darlington PCT. *The participant answered in a personal capacity.* "It also depends on the patient. Some will read the ones in new medicine packs."

Group specialising in health services provision. *The participant answered in a personal capacity.* "Regrettably, the assumption is that, once read, the advice remains the same. Special attention should be drawn if there are changes."

Regional PPI. *The participant answered in a personal capacity.* "Writing often very small."

Group specialising in information on assistive technology for older and/or disabled people. *The participant answered in a personal capacity.* "Depends on several factors: whether the way that the medicine is administered is complex or simple (complex—the patient feels there is a need to be told how to use it); whether the patient has used a similar medicine before; and how easy it is to find the information you need on a leaflet that is often small text and contains other information."

Professional nurse attached to patient organisation. "The writing is too small, and often uses medical jargon—not user friendly. I feel it is more relevant to litigation cover."

Polychondritis Educational Society. "Information on the package inserts tends to be beyond the level of understanding of many patients."

Participant (who answered in a personal capacity) works as a knowledge manager within the NHS. "But whether they do or don't, I would think it would only be if the medicine is new to the patient—unless a health professional highlights that there have been changes to guidance or information."

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* “We feel that people are more likely to read the leaflets if the medication is new. This, of course, will vary greatly with the individual.”

St Albans and District Voluntary Diabetic Support Group. “Another option (“It depends on the patient”) is needed!! If not read, can be because: a) it must be OK if the doctor prescribes it; b) the writing is too small; c) all the listed possible side-effects are frightening; etc.”

Anonymous participant. “Rarely, as people find it too generalised or irrelevant. Frightened of side-effects in the absence of someone to talk to.”

Group specialising in deafness and the hard of hearing. *The participant answered in a personal capacity.* “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.”

PPIF member of ambulance service. *The participant answered in a personal capacity.* “The GP should explain about side-effects when first prescribing the medicine.”

Group specialising in visual impairment. “The print is too small.”

Group specialising in older people, dementia and mental health. *The participant, who answered in a personal capacity, was also a manager of a nursing home.* “Very rarely, in my experience.”

Anonymous participant. “It is up to the individual to read.”

PPIF. *The participant answered in a personal capacity.* “I always read them, but most patients I know do not read them.”

PPIF (Windsor, Ascot and Maidenhead). *The participant answered in a personal capacity.* “Sometimes. People often put them in the bin.”

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* “Some people read the entire leaflet. Others don't seem to bother.”

British Heart Foundation. *The participant answered in a personal capacity.* “The information is often referred to if the person is suffering from symptoms that they can't explain.”

Highland Users Group. “Leaflets can be a bit alarming. Better than they used to be.”

Group specialising in prostate cancer. *The participant answered in a personal capacity.* “Some patients read them sometimes.”

Group specialising in dementia. *The participant answered in a personal capacity.* “The leaflets are often in small type, and cannot be read by those with poor sight.”

Group specialising in older people. *The participant answered in a personal capacity.* “Some patients always read them. Others, not at all.”

Congenital Adrenal Hyperplasia Support Group. *The participant answered in a personal capacity.* “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. Then they will read it, to see if their symptoms match the side-effects listed.”

Local statutory group involved with carers of people with chronic illness. *The participant answered in a personal capacity.* “Most people I know don't bother to read these leaflets. Many assume that they wouldn't understand,

even though the language used these days is actually very patient-friendly.”

PPIF (Swale, Kent). *The participant answered in a personal capacity.* “Do not assume all can read.”

Anonymous participant specialising in mental health. “The print is small.”

Anonymous participant specialising in mental health. “The print is too small.”

Anonymous participant. “They probably read it if they are suffering a possible side effect.”

Help and Care. *The participant answered in a personal capacity.* “Patient information is often inaccessible and confusing. Should be in Plain English.”

Group specialising in learning disabilities. *The participant answered in a personal capacity.* “Many people with a learning disability cannot read the leaflets. Those who support them often find leaflets difficult, too.”

Group specialising in learning disabilities. *The participant answered in a personal capacity.* “Too-small writing.”

Anaemic Society. “This usually happens when first diagnosed.”

Group specialising in asthma. “The difference is not about the medicines, but the individuals who are taking them. For example, those who tend to read the leaflets inside medicines packaging are from higher social classes, are literate, and well educated. It is therefore important to adapt leaflets to reflect the realities of people in our society.”

Epilepsy Action. “Our clients with epilepsy tend not to read the patient information leaflets (PILs) regularly. Many still say they

do not get the PIL—especially if it is in a 'broken' package, or if a generic. Sometimes, clients have taken the drug for so long, they completely ignore the PIL.”

Patients' Association. “Depends, too, on the patient.”

Pharmacy manager at an independent healthcare provider. *The participant answered in a personal capacity.* “It depends on the patient, not the medicine.”

PPIF (East Kent and Coastal). *The participant answered in a personal capacity.* “I think very few patients read medicine leaflets.”

Group specialising in older people. *The participant answered in a personal capacity.* “Leaflets are too long and complex. They [are there to cover] the manufacturer, not to help patient.”

Prostate Research Campaign UK. “But probably not.”

Group specialising in neurological conditions. *The participant answered in a personal capacity.* “Difficult for people with visual problems, cognitive problems, or difficulty in reading.”

Mind (Cymru). *The participant answered in a personal capacity.* “I work with mental healthcare users, and most say that they do not read them.”

Arthritis Patient Forum (Torbay Hospital, South Devon). *The participant answered in a personal capacity.* “Some people read them, some don't.”

Rethink Severe Mental Illness. “The language used in leaflets can be too technical, and, consequently, difficult to read.”

Group specialising in chronic diseases. *The participant answered in a personal capacity.* “Unlikely.”

Group specialising in mental health. “Not always—but increasingly so. Remember, though: some patients cannot read.”

Group specialising in visual impairment. “What if the patient is visually impaired, and cannot read print?”

Group specialising in the needs of carers. “It also depends on the patient.”

Group specialising in eczema. *The participant answered in a personal capacity.* “Depends on the PATIENT, not the medicine.”

Huntington's Disease Association (Colchester and District Branch). “Most leaflets are in a font type and size that renders them unreadable to anyone with a slight-to-severe sight impairment, or to people wearing spectacles.”

Group specialising in learning disability. “Many people do not read the leaflets unless the doctor or pharmacist points out that they should.”

Brain Tumour UK. *The participant answered in a personal capacity.* “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.”

Group specialising in cancer of the blood. *The participant answered in a personal capacity.* “I would have recommended another option here: “It depends on the patient”.”

Group specialising in HIV/AIDS. *The participant answered in a personal capacity.* “Maybe more in HIV/AIDS, as most patients [in this disease area] tend to know people with bad reactions to medications.”

Group specialising in osteoporosis. *The participant answered in a personal capacity.* “Some are. But some are so badly presented that people do not bother [to read them].”

Group involved in all disease areas (except cardiac surgery). “Some patients read them.”

Obesity Awareness and Solutions Trust. *The participant answered in a personal capacity.* “Leaflets are often not given the importance they need to have. Patients are more likely to read the packet.”

Chairperson of a PCT. *The participant answered in a personal capacity.* “The print is often small.”

Neurological Alliance (South West). *The participant answered in a personal capacity.* “I mostly read these leaflets, but my mother and others do not want to know.”

Group specialising in mental health. *The participant answered in a personal capacity.* “Yes, I am pretty sure they do.”

Mind (Pembrokeshire). “The print is too small, and patients lack understanding of the language used.”

Group specialising in brain-related conditions in children. *The participant answered in a personal capacity.* “Some people do, some don't.”

Dr Karel van der Waarde of Graphic Design-Research. *The participant answered in a personal capacity.* “Please check the recent Ph.D thesis by Robert van der Stichele for an answer to this question: <http://users.ugent.be/~rvdstich/thesis>.”

Group specialising in diabetes. *The participant answered in a personal capacity.* “Not easy to read. The print is too small. You need to be able to read (and read English), and not have poor eyesight or a learning difficulty.”

PPIF (Chesterfield PCT). “The North Derbyshire PCT PPI Forums are concerned to know more about this topic, and plan a sample survey to investigate it.”

Which? “It is impossible to make a general statement about how widely read patient information leaflets are. We know that there are serious issues with the current format of patient information leaflets, and that these can prevent people from using them. 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.”

Tameside Blind Association. *The participant answered in a personal capacity*. “The print is too small for us visually-impaired people. We depend on someone reading to them to us.”

Group specialising in older people. *The participant answered in a personal capacity*. “Many patients rely on verbal instructions.”

Anonymous respondent. “Not always. Depends entirely upon the patient. And the print on package inserts is tiny.”

Portsmouth Association for the Blind. “Usually need to read them if requested.”

Group specialising in Asperger syndrome. *The participant answered in a personal capacity*. “GPs should go through the leaflets if they feel that the patient might not read them.”

Group specialising in severe mental illness (especially schizophrenia). *The participant answered in a personal capacity*. “That is usual in psychiatry.”

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum). “It depends also on the patient (so the comments I made in response to questions 1 and 2 are also relevant to this).”

Mind (Havering). *The participant answered in a personal capacity*. “I always read mine if the medicine is a new one, or if I get a side-effect.”

British Polio Fellowship (Edinburgh Branch). “It depends on the patient. Not everyone is able, or bothers, to read the insert. Information given can be frighteningly detailed (for instance, about unpleasant side-effects).”

PPIF (Central Liverpool PCT). “Some patients do; some do not. It depends on factors such as sight. Leaflets are too long; a lot are complicated; and they are not written in a style accessible to everyone.”

ARE MEDICINES LEAFLETS GOOD AT EXPLAINING HOW TO GET THE MOST BENEFIT FROM THE MEDICINE?

Group involved in health promotion. *The participant answered in a personal capacity.* “Again, further explanations are needed in simple language.”

National Ankylosing Spondylitis Society. *The participant answered in a personal capacity.* “I believe that patients depend on their doctors for this information. Pharmacists, though, are quite good about OTCs.”

CJD Support Network. *The participant answered in a personal capacity.* “Many leaflets could be improved by being more ‘patient focused’, and written by lay people.”

Fenella Lemonsky of Expert By Experience. *The participant answered in a personal capacity.* “Best one I ever saw was for Zoton, which made a good effort at encouraging lifestyle change.”

York Coalition of Disabled People. “If information is not in accessible formats (such as large print, Braille, pictorial, or languages other than English), then it cannot be deemed ‘high quality’.”

Alzheimer’s Society (Selby and York Branch). “Rarely. I think it is usually expected that doctors will give this information.”

Group specialising in pregnancy loss. *The participant answered in a personal capacity.* “Usually.”

Paschal McKeown of Mencap. *The participant answered in a personal capacity.* “See the points I made before about the need for more-accessible information for people with a learning disability.”

Arthritis Care. *The participant answered in a personal capacity.* “The leaflets are often long, and in small print.”

Patient Information Forum. *The participant answered in a personal capacity.* “Again, there is so much variability across the range of medicines.”

Parents of Autistic Spectrum Disorder Adults, Edinburgh. “The print size is too small.”

Group specialising in chronic back pain. *The participant answered in a personal capacity.* “Many are far too technical for the average lay person.”

UK Coalition of People Living with HIV and AIDS. “Leaflets might explain how to take the drugs in line with pharmacokinetic research, but they use words that need further explanation. ‘Take with a snack or meal’ doesn’t indicate what constitutes either, and patients may underestimate the amount of food to be taken in order to get the best absorption of medicine, for example. Patients need to know if ‘twice a day’ is at precise twelve-hour intervals, or how much leeway there is in this—how forgiving a particular medicine is to being taken slightly or more late. Drug troughs can cause drug resistance, for example. Gastrointestinal side-effects can be managed, but this information is not usually present on information leaflets. Advice like ‘Discuss these with your doctor or pharmacist’ might be helpful.”

Group specialising in the after-effects of drugs. “This is a very arbitrary survey—it must depend on whether the ‘patient’ is on medication, and whether or not they believe what they read, or whom they ask for advice. Individuals will vary according to their past experience, and there will always be some

people who will thoroughly read the information, and others who will not bother.”

Group specialising in health services provision. *The participant answered in a personal capacity.* “This is not universally so.”

Group specialising in irritable bowel syndrome. *The participant answered in a personal capacity.* “More basic commonsense information is needed on the regularity of the time of administration, how to take the medication, and with what. Could be more legible, too.”

Professional nurse attached to a patient organisation. “No.”

Tony Gavin of Leukaemia CARE. *The participant answered in a personal capacity.* “The inserts frequently seem to be more concerned with the pharmacology of the product and potential S/E’s (which can be quite disconcerting), than actually being informative.”

Alpha-1 UK. *The participant answered in a personal capacity.* “Sometimes the writing is small, and the information can be over-technical.”

Polychondritis Educational Society. “When medications are used for off-label usage (as prescribed by their doctors), we see a lot of patients not understanding that the dosage for off-label usage is different—hence the symptoms and interactions may be different. The druggist or doctor may not understand this, and fail to explain it fully to their patients.”

Senior psychiatric pharmacist working within the NHS. “Regulations are coming out that insist that industry try to address this issue.”

St Albans and District Voluntary Diabetic Support Group. “Often, the print is too small. Sometimes, this information is lost in the welter of other information.”

Anonymous participant. “Carers would welcome this information.”

PPIF member of ambulance service. *The participant answered in a personal capacity.* “Sometimes overcomplicated by the need to cover product liability.”

Group specialising in older people, dementia and mental health. The participant, *who answered in a personal capacity*, was also a manager of a nursing home. “More information generally needed.”

Group specialising in visual impairment. *The participant answered in a personal capacity.* “Too-small print.”

PPIF (Windsor, Ascot and Maidenhead). *The participant answered in a personal capacity.* “Leaflets do not tell you the optimum time of day to take the medication.”

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* “My medications tell me about whether you need to take them with food / avoid alcohol, etc.”

Highland Users Group. “The group had a split opinion. We would rather ask a pharmacist.”

Group representing the interests of carers. *The participant answered in a personal capacity.* “Not always in easy-to-understand language.”

PPIF (Swale, Kent). *The participant answered in a personal capacity.* “More information could be made available if needed—ask patient groups or support groups.”

Group specialising in diabetes. *The participant answered on behalf of a small group of care advisers.* “The amount of information in leaflets can sometimes be confusing, as there is a lot to read, and small print.”

Group specialising in learning disabilities. *The participant answered in a personal capacity.* “If they do this, it is often not clear enough.”

Anaemic Society. “For many members, the leaflet is the source of information about their condition and medicine. Members are prescribed two main medicines: hydroxocobalin and 5mg folic acid.”

Group specialising in asthma. “The leaflets do contain information about the benefits of medicines, but we need to make it easier and more accessible to the audience. One suggestion is to target messages about benefits to a lay audience: provide pictures; make it easy to read; and include things 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.”

PPIF. *The participant answered in a personal capacity.* “Also, the print is too small.”

PPIF (East Kent and Coastal). *The participant answered in a personal capacity.* “Depends on the illness being treated.”

Group specialising in the needs of carers. “Too much information on obscure possibilities.”

Group specialising in older people. *The participant answered in a personal capacity.* “All medicines are useless unless you can remove the top—which is hard (as is the case with so many ‘safety’-designed caps).”

Prostate Research Campaign UK. “They tell you about side-effects, not how to benefit.”

Chronic Myeloid Leukaemia Support Group. “Should give some information on how to deal with side-effects.”

Rethink Severe Mental Illness. “They are mainly about what the manufacturer thinks needs to be said, rather than what the patient needs to know.”

PPI Hospital Forum. *The participant answered in a personal capacity.* “Normally, the label placed on the outside of the medication container by the pharmacist states when to take [the medication].”

Group specialising in the needs of carers. *The participant answered in a personal capacity.* “More use of everyday language is needed in some medicine containers.”

Scottish group specialising in older people. *The participant answered in a personal capacity.* “Often in very small print—which is not of use to older people, or people with visual impairment.”

Group specialising in learning disability. “They mainly comment on possible side-effects.”

Brain Tumour UK. *The participant answered in a personal capacity.* “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).”

Group specialising in HIV/AIDS. *The participant answered in a personal capacity.* “We find patient information from specialist agencies. NAM and I-Base are the most appropriate.”

Group specialising in osteoporosis. *The participant answered in a personal capacity.* “Insufficient relevant information is HIGHLIGHTED (for instance, with ‘A glass of water’, what size should the glass be?).”

Mind (Pembrokeshire). “If the patient is able to access other ways to improve health.”

Group specialising in brain-related conditions in children. *The participant answered in a personal capacity*. “Often very reliant on going back to a doctor.”

Dr Karel van der Waarde of Graphic Design-Research. *The participant answered in a personal capacity*. “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.”

Group specialising in diabetes. *The participant answered in a personal capacity*. “Not very educational to the patient. Confusing, and not easy to understand.”

Tameside Blind Association. *The participant answered in a personal capacity*. “This is only relevant if read by the sighted.”

Group specialising in depression. *The participant answered in a personal capacity*. “Some people may find leaflets too complex. They need more summaries with clearer (but briefer) information.”

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum). “We are not really clear about the point here. The doctor should have explained the benefit of the medicine, and the reason for prescribing it.”

Mind (Havering). *The participant answered in a personal capacity*. “Not really—they only tell you the dose.”

PPIF (Central Liverpool PCT). “Leaflets do not fully explain side-effects.”

ARE MEDICINES LEAFLETS GOOD AT COMMUNICATING INFORMATION ABOUT SAFETY CONSIDERATIONS?

Group involved in health promotion. *The participant answered in a personal capacity.* “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.”

Group specialising in young families and expectant parents. *The participant answered in a personal capacity.* “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.”

Group specialising in pituitary disorders. *The participant answered in a personal capacity.* “Many patients become unnecessarily alarmed, and stop taking their medications.”

York Coalition of Disabled People. “If information is not in accessible formats (such as large print, Braille, pictorial, or languages other than English), then it cannot be deemed ‘high quality’.”

Group specialising in brain cancer. *The participant answered in a personal capacity.* “People may not read it. 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.”

HCV-Alert. *The participant answered in a personal capacity.* “Due to the fact that the information tries to include all known side-effects it can lead patients to become scared to take medicine.”

Continence Foundation. *The participant answered in a personal capacity.* “A lack of clarity about the degree of risk.”

Group specialising in physical and learning disabilities. *The participant answered in a personal capacity.* “Possibly some are, some are not. Perhaps statutory and standardised information (like on food packaging) may help.”

Arthritis Care. *The participant answered in a personal capacity.* “[This information] needs to be the first thing you see. Often, it is too far down the sheet.”

PIF Hospital Forum. *The participant answered in a personal capacity.* “As for question 4, I don’t know how to answer. Is a car safe?”

Group specialising in primary immunodeficiency. *The participant answered in a personal capacity.* “I have worked in patient organisations for 25-plus years, and have rarely found a patient who reads anything !!!”

Parents of Autistic Spectrum Disorder Adults, Edinburgh. “If the leaflets were printed in a reasonable size of print, it is unlikely that anyone would take anything.”

Insulin-Dependent Diabetes Trust. “[Sometimes good at communicating safety information.] For example, 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.”

Group specialising in the after-effects of drugs. “This must depend on the drug companies, and what exactly is being prescribed.”

Group specialising in health services provision. *The participant answered in a personal capacity.* “Most medicines appear to offer sound advice.”

Group specialising in irritable bowel syndrome. *The participant answered in a personal capacity.* “The leaflet is too general, and could perhaps be in a different print type.”

Regional PPI. *The participant answered in a personal capacity.* “Questions about contra-indications, alcohol, etc, are often not addressed.”

Group specialising in information on assistive technology for older and/or disabled people. *The participant answered in a personal capacity.* “There are usually warnings about storage, whether to take before or after meal times, to keep out of reach of children, do not take with alcohol, etc. But, again, the text is often small, and patients have to scan through lots of text to find the information.”

Professional nurse attached to a patient organisation. “No—[leaflets are] more concerned about the litigation element, and frightening patients.”

Polychondritis Educational Society. “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—as is the case with tylenol.”

Group specialising in undiagnosed conditions. *The participant answered in a personal capacity.* “The language used is not always appropriate to a patient’s level of understanding.”

St Albans and District Voluntary Diabetic Support Group. “Too many possible adverse side-effects are given equal weight.”

Group specialising in older people, dementia and mental health. *The participant, who answered in a personal capacity, was also a manager of a nursing home.* “Very variable—often dependent on the drug company.”

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* “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?”

British Heart Foundation. *The participant answered in a personal capacity.* “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. This can lead to the danger of stopping the drug. There are many people who refuse to take an important medication because they are concerned about the risk factors, and exaggerate their potential effect.”

Highland Users Group. “Quite vague.”

Group specialising in the promotion of health information. *The participant answered in a personal capacity.* “There seem to be a lot of side-effects listed—enough to put people off, or for them to just ignore the lot.”

PPIF (Swale, Kent). *The participant answered in a personal capacity.* “All safety considerations should be in red.”

Group specialising in Von Hippel Lindau syndrome. “Sometimes, the amount of information given in these leaflets is quite frightening for those concerned.”

Local group specialising in autism. *The participant answered in a personal capacity.* “But these are not always taken seriously by doctors when followed up.”

Group specialising in diabetes. *The participant answered on behalf of a small group of care advisers.* “Within the bounds of the medicine.”

Group specialising in congenital heart disease in adults. “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.”

Group specialising in asthma. “Medicine leaflets do give information about safety. But the language is too scientific and/or complex, and the typeface is too small. Some people do not have the ability to process this information, or to establish the degree of risk involved. The context in many occasions is missing, and people’s conception of risk differs from one person to another.”

PPIF. *The participant answered in a personal capacity.* “Also, the print is too small.”

Pharmacy manager at an independent healthcare provider. *The participant answered in a personal capacity.* “Always requires interpretation by the pharmacist.”

PPIF (East Kent and Coastal). *The participant answered in a personal capacity.* “Any serious safety considerations should be re-emphasised by the pharmacist and the GP.”

Group specialising in the needs of carers. “Need to prioritise information, not just bulk.”

Group specialising in older people. *The participant answered in a personal capacity.* “What ‘safety’ are you meaning? Mostly, leaflets say ‘Go and talk to your doctor’. The doctors are too busy.”

PPIF. *The participant answered in a personal capacity.* “The writing on the leaflets is much too small for older patients.”

PPIF (Crawley). *The participant answered in a personal capacity.* “Too much information covering the producer.”

Diabetes UK. “Contraindications are included often, but not presented in a clear and understandable format.”

Mind (Cymru). *The participant answered in a personal capacity.* “They are not accessible at all, because the writing is far too small. So, this disbars most people from receiving the information.”

Arthritis Patient Forum (Torbay Hospital, South Devon). *The participant answered in a personal capacity.* “Up to a point. But they can’t list all drug interactions.”

Group specialising in mental health. “An over-emphasis, if anything—probably for litigation reasons.”

Group specialising in visual impairment. “What if the patient is visually impaired, and cannot read print?”

Group specialising in all types of sight loss. *The participant answered in a personal capacity.* “But, again, they are no good if someone cannot read the print.”

Huntington's Disease Association (Colchester and District Branch). “Again, due to font size and leaflet size, the safety information does not always stand out. Historically, [patients think] ‘the GP knows best’, and if he prescribed it, ‘then it must be OK’.”

PALS. *The participant answered in a personal capacity.* “From a personal perspective—yes.”

Perth Bipolar Group. *The participant answered in a personal capacity.* “Damaging side-effects are given, without any indication of how likely they are to occur.”

Group specialising in cancer of the blood. *The participant answered in a personal capacity.* “A 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.”

Group specialising in HIV/AIDS. *The participant answered in a personal capacity.* “[The leaflets] do not take in the abilities of patient (for instance, their reading, and reservations about some medications and adverse effects).”

Neurological Alliance (South West). *The participant answered in a personal capacity.* “One lady given gabapentin had Stevens Johnson syndrome. All her skin peeled off. I had gabapentin, and my mouth and tongue became anaesthetised—I could not speak properly, and had R.T.A. as a result (being a zombie). Hideous pain on stopping immediately. I have taken Vioxx, and had two ECGs. I took Seroxat a long time back—so ill on it. I took serenid D, and my pupils dilated—I could not see where I was going.”

Mind (Pembrokeshire). “Information on side-effects is often insignificant.”

Group specialising in brain-related conditions in children. *The participant answered in a personal capacity.* “Safety: yes, I think so. Contraindications: not necessarily.”

Dr Karel van der Waarde of Graphic Design-Research. *The participant answered in a personal capacity.* “Some leaflets handle this well. But most classify the safety considerations under the heading ‘Take special care with XX’. This heading does not cover the warnings, and must be made more specific. I would not know how ‘to take special care’. I need to know what to do exactly. Furthermore, there are many ‘safety considerations’ for each medicine. Not only personal safety, but also environmental safety needs to be considered. ‘Safety’ is a very broad issue, and it is difficult to answer this question without specifying details.”

Group specialising in diabetes. *The participant answered in a personal capacity.* “Not very specific about why the patient cannot, say,

drink grapefruit or alcohol (and what the effects of doing so are). Does not give enough importance to taking too much medication, and what the side-effects of doing that are.”

Tameside Blind Association. *The participant answered in a personal capacity.* “Can be too informative at times.”

Mind (Basildon). *The participant answered in a personal capacity.* “The print is too small.”

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum). 1) The text is often too small to be read by elderly or poorly-sighted people. 2) The number of precautions and possible side-effects listed can be daunting, confusing, or even frightening.”

NHS pharmacist. “Quite often, the context isn’t explained, and patients just worry when they see all the ADRs. They don’t understand what is meant by common, rare etc (and that some of the ADRs also occurred in the placebo group).”

Group specialising in prostate cancer. *The participant answered in a personal capacity.* “The likelihood of a rare and disastrous side-effect doesn’t seem to be well differentiated from the common, and less problematic, side-effects.”

Mind (Havering). *The participant answered in a personal capacity.* “No they just say in the event of an overdose. They could say more about what might happen, and what damage you could do.”

PPIF (Central Liverpool PCT). “This information should be on the packet, as well as in the leaflet.”

ARE MEDICINES LEAFLETS GOOD AT INFORMING PATIENTS ABOUT THE EFFECTS (IF ANY) OF A MEDICINE ON DRIVING ABILITY?

Alzheimer's Society (Selby and York Branch). "I have never particularly noticed any information about possible effects on driving ability (except, perhaps, with tranquillisers)."

Group specialising in physical and learning disabilities. *The participant answered in a personal capacity.* "Needs to be made absolutely crystal clear—like health warnings on cigarettes."

Pascal McKeown of Mencap. *The participant answered in a personal capacity.* "Few people with a learning disability can drive."

Arthritis Care. *The participant answered in a personal capacity.* "I cannot immediately recall when I have read about driving on a medicine (including diabetes tablets)."

Group specialising in osteoporosis. *The participant answered in a personal capacity.* "Leaflets are usually good. But, since most patients don't read them, it is academic."

Parents of Autistic Spectrum Disorder Adults, Edinburgh. "If they can be read."

UK Coalition of People Living with HIV and AIDS. "You might find this 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."

Group specialising in health services provision. *The participant answered in a personal capacity.* "The quality of the advice is varied, which raises questions about the dependability of the advice."

Group specialising in irritable bowel syndrome. *The participant answered in a personal capacity.* "But do patients really take it on board, and read this, or think it relates to them?"

Regional PPI. *The participant answered in a personal capacity.* "Should state clearly 'Yes' or 'No'. If it does not state either, assume that it is alright to drive."

Group specialising in information on assistive technology for older and/or disabled people. *The participant answered in a personal capacity.* "Leaflets may instruct that you should not drive, but do not say much about how the medicine affects driving ability."

Professional nurse attached to a patient organisation. "Need to be more emphatic. No one wants to give up driving."

Tony Gavin of Leukaemia CARE. *The participant answered in a personal capacity.* "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."

Alpha-1 UK. *The participant answered in a personal capacity.* "Warnings are also usually on the label that the pharmacist attaches."

Senior psychiatric pharmacist working within the NHS. "[Very good.] ESPECIALLY on psychiatric medication."

St Albans and District Voluntary Diabetic Support Group. "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 1 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."

Group specialising in deafness and the hard of hearing. *The participant answered in a personal capacity.* "As long as you can read the information."

Group specialising in older people, dementia and mental health. *The participant, who answered in a personal capacity, was also a manager of a nursing home.* "Not clear enough."

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* "[Leaflets are good.] But, then, I always read the entire leaflet. Not everyone does."

Highland Users Group. "We have to make a decision on very little information."

Congenital Adrenal Hyperplasia Support Group. *The participant answered in a personal capacity.* "I have found that, as well as stating on the leaflet if a medication affects driving ability, it is usually stated on the label too—making the information stand out for those who do not bother to read leaflets!"

Group specialising in the promotion of health information. *The participant answered in a personal capacity.* "There is a stock line that ends: 'If affected, do not drive'. Again, may be ignored."

PPIF (Swale, Kent). *The participant answered in a personal capacity.* "Should always be in red."

Group specialising in learning disabilities. *The participant answered in a personal capacity.* "This is often not relevant within a learning-disability context."

Group specialising in asthma. "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."

Salford Heart Care Re-Hab. "Not highlighted."

PPIF (East Kent and Coastal). *The participant answered in a personal capacity.* "This information is usually very extreme (such as is the case with paracetamol), and is probably ignored by a lot of patients."

PPIF (Crawley). *The participant answered in a personal capacity.* "Most urge caution—but you can only find out when you get into trouble."

Prostate Research Campaign UK. "This information usually appears on the container."

Parkinson's Disease Society (Canterbury Branch). *The participant answered in a personal capacity.* "Sleep inducement is usually covered. But other disabling side-effects (such as dyskinesia) are ignored."

Group specialising in neurological conditions. *The participant answered in a personal capacity.* "I think it is hard to advise on this, due to individual differences."

Mind (Cymru). *The participant answered in a personal capacity.* "The GP is the one who should highlight this, as it is so important."

Rethink Severe Mental Illness. “This advice is generally expressed in stark, abbreviated terms.”

Group specialising in visual impairment. “What if the patient is visually impaired, and cannot read print?”

Group specialising in all types of sight loss. *The participant answered in a personal capacity*. “Again, print size!”

Huntington's Disease Association (Colchester and District Branch). “But, again, this precaution should be one of the first items on the leaflet.”

PALS. *The participant answered in a personal capacity*. “From a personal perspective—yes.”

Brain Tumour UK. *The participant answered in a personal capacity*. “If a medicine might have an effect on driving, the leaflet does say ‘If affected, do not drive or operate machinery’. But, again, it is usually in small print.”

Perth Bipolar Group. *The participant answered in a personal capacity*. “Often vague.”

Group specialising in HIV/AIDS. *The participant answered in a personal capacity*. “One-to-one communication is more effective.”

Group specialising in osteoporosis. *The participant answered in a personal capacity*. “In most cases that I have seen.”

Mind (Pembrokeshire). “They do not explain why.”

Dr Karel van der Waarde of Graphic Design-Research. *The participant answered in a personal capacity*. “It is obligatory to mention driving, but the position in the package leaflet is very strange: in between ‘Pregnancy and breast-feeding’ and ‘The

excipients warning’. All three appear under the heading ‘Before you take XX’. Although this warning is necessary to consider before a medicine is taken, it would be easier to remember if integrated into the instructions in section 3. It depends on the value of this warning for a specific medicine.”

Group specialising in diabetes. *The participant answered in a personal capacity*. “Rarely tells patients: ‘Do not drive’. Leaves it to the individual—which can be dangerous, as some people drive irrespective of the effects of medication.”

PPIF (Chesterfield PCT). “Have not investigated this topic.”

Which? “This is part of the general problem of the presentation of patient information.”

Group specialising in depression. *The participant answered in a personal capacity*. “This key information needs highlighting.”

Anonymous respondent. “They could perhaps emphasise the effects more strongly in print.”

Group specialising in severe mental illness (especially schizophrenia). *The participant answered in a personal capacity*. “They 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.”

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum). “Good—in the main.”

British Polio Fellowship (Edinburgh Branch). “Especially in the field of mental health (for instance, anti-depressants, tranquilisers, etc).”

Group based in an NHS hospital trust and advising on patient information. *The participant answered in a personal capacity.* “More specific information on what effect the medicine would have on driving ability would be useful and more of a deterrent.”

HOW SHOULD MEDICINES PACKAGING INFORM PATIENTS ABOUT THE CONSEQUENCES (IF ANY) OF DRIVING AFTER TAKING THE MEDICINE?

PALS co-ordinator. *The participant answered in a personal capacity.* "Repeating the message would be a safeguard to ensure that it (the message) gets home."



CJD Support Network. *The participant answered in a personal capacity.* "A universally-recognised symbol is needed, such as 'Be aware' or 'Driver-in-a-driving-seat symbol, with a line through it' [see diagram]."

York Coalition of Disabled People. "If information is not in accessible formats (such as large print, Braille, pictorial, or languages other than English), then it cannot be deemed 'high quality'."

Group specialising in older people. *The participant answered in a personal capacity.* "A range of symbols showing whether driving, consumption of alcohol or certain foods, etc, is allowed would make it clear to all."

Patient Information Forum. *The participant answered in a personal capacity.* "But this should not just be restricted to this particular warning. Other warnings are equally valid."

Group specialising in endocrinology. *The participant answered in a personal capacity.* "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."

Parents of Autistic Spectrum Disorder Adults, Edinburgh. "Only if they can be seen."

Group specialising in health services provision. *The participant answered in a personal capacity.* "There should be clear, unequivocal advice—in bold, on the bottle."

Group specialising in cardiac arrhythmia. "Symbols and pictograms would be a very good idea."

Regional PPI. *The participant answered in a personal capacity.* "All should be labelled."

Tony Gavin of Leukaemia CARE. *The participant answered in a personal capacity.* "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)!!"

Society for Mucopolysaccharide Disease. *The participant answered in a personal capacity.* "A 'no-driving' symbol could be developed."

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* "Critical information should be prominently displayed. Information leaflets seem led by the manufacturer, giving the patient information, but not necessarily telling them what they need to know in a direct and straightforward way."

Group specialising in undiagnosed conditions. *The participant answered in a personal capacity.* "Not everyone has a good command of English."

Senior psychiatric pharmacist working within the NHS. "This question baffles me. It is a legal requirement that medications

dispensed by a pharmacy as a TTA have a label on the outside of the packaging, and on the label, AND in the PIL. Symbols and pictograms are often like abbreviations, and, IN FACT, many studies show that they make things much more confusing—please contact NPSA!!”

Group specialising in deafness and the hard of hearing. *The participant answered in a personal capacity.* “The more places it is, the better. And a symbol would be clearer.”

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* “The ability to drive or not is very important, and every effort should be made to stress possible effects for safety.”

British Heart Foundation. *The participant answered in a personal capacity.* “As this is an important area for most people, there may need to be a separate title to attract people’s attention on the information sheet. If there is a real hazard, this should be on the cover of the box that contains the tablets.”

Highland Users Group. “Not all of us are so affected by our medication that we cannot drive.”

Congenital Adrenal Hyperplasia Support Group. *The participant answered in a personal capacity.* “I don’t think that you can overstate this.”

Group specialising in the promotion of health information. *The participant answered in a personal capacity.* “Bold print, if there are common side effects.”

Local statutory group involved with carers of people with chronic illness. *The participant answered in a personal capacity.* “Perhaps a version of the traffic-light system would be very noticeable (and easy to interpret) for drivers.”

Anonymous participant. “Should use BOLD CHARACTERS, as on cigarette packets.”

Group specialising in women’s health and neurology. *The participant answered in a personal capacity.* “More notice is generally taken of symbols.”

Group specialising in diabetes. *The participant answered on behalf of a small group of care advisers.* “If the medication could have an effect on driving, information about that should be very visible.”

Group specialising in learning disabilities. *The participant answered in a personal capacity.* “Larger print size.”

Anaemic Society. “It isn’t really the side-effects of the medicine that will impair driving ability. But if the patient is having a ‘fog day’, then he or she should refrain from driving. This could be printed on the leaflet, but unfortunately ‘fog days’ are not really recognised by the medical profession.”

PPI. *The participant answered in a personal capacity.* “A specific hazard notice—a pictogram and written text is needed.”

PPIF (East Kent and Coastal). *The participant answered in a personal capacity.* “Symbols and pictograms would have more impact, be easier to identify, and easier for patients whose first language may not be English.”

Mind (Cymru). *The participant answered in a personal capacity.* “The GP and the pharmacist have to say something, as well.”

Rethink Severe Mental Illness. “Briefly on the label, but in more detail in the leaflet.”

Group specialising in mental health. “Symbols are essential for visually-impaired patients and non-readers—if the sign is known, of course!”

Group specialising in the needs of carers. “The GP should inform the patient, and the pharmacist should remind the patient when dispensing the prescription.”

Scottish group specialising in older people. *The participant answered in a personal capacity.* “A combination of all of the [potential answers on the questionnaire].”

Group specialising in all types of sight loss. *The participant answered in a personal capacity.* “But symbols need to be large and clear.”

Brain Tumour UK. *The participant answered in a personal capacity.* “Symbols make this type of information much clearer. It would be good if the same symbols were used throughout the pharmaceutical industry.”

Group specialising in HIV/AIDS. *The participant answered in a personal capacity.* “Taking into account people’s reading skills.”

Neurological Alliance (South West). *The participant answered in a personal capacity.* “We are getting too much packaging to throw away. I much prefer the tablets to be all ready in a bottle—without the child-proof cap. As a disabled person with myalgic encephalomyelitis (ME), I cannot pop blister packs, or get the tops off the medicine bottles.”

Mind (Pembrokeshire). “The GP should also offer information.”

Group specialising in brain-related conditions in children. *The participant answered in a personal capacity.* “I haven’t come across medicines with pictograms in this way, but have done with the instructions to DIY products (and things like that). I find that, most of the time, pictograms obscure, rather than clarify—but then I’m not a ‘visual’ person.”

Dr Karel van der Waarde of Graphic Design-Research. *The participant answered in a personal capacity.* “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. The use of symbols and pictograms must not be considered: they cannot convey information about medicines safely.”

Group specialising in diabetes. *The participant answered in a personal capacity.* “Universal symbols and pictograms are useful to people who do not read English.”

PPIF (Chesterfield PCT). “Crucial that this topic be highlighted.”

Group specialising in children with autism-spectrum disorders. *The participant answered in a personal capacity.* “Symbols and pictograms may be useful for people who have difficulty reading.”

Group specialising in older people. *The participant answered in a personal capacity.* “A symbol/pictogram would have to be international.”

Group specialising in depression. *The participant answered in a personal capacity.* “Especially when people are unable to read/understand the language.”

Anonymous respondent. “These are perhaps being done already, but need to be more prominent.”

Group specialising in severe mental illness (especially schizophrenia). *The participant answered in a personal capacity.* “Again, a doctor’s advice may be necessary—attention should be drawn to this.”

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum). “This should appear bold, and a symbol would be useful for non-readers (if [its meaning is] properly pre-advertised).”

Group specialising in prostate cancer. The participant answered in a personal capacity. “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.”

Mind (Havering). *The participant answered in a personal capacity.* “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.”

British Polio Fellowship (Edinburgh Branch). “Allow for difficulties with literacy/language.”

Group based in an NHS hospital trust and advising on patient information. The participant answered in a personal capacity. “Pictures can be helpful, as they are a brief and concise way of conveying this information.”

PHARMACEUTICAL COMPANIES OFTEN SEND DOCTORS ADVERTISING AND PROMOTIONAL MATERIAL ON NEW PRESCRIPTION MEDICINES. SHOULD RESTRICTIONS BE IMPOSED ON THE VOLUME OF SUCH MATERIAL FOLLOWING THE LAUNCH OF A NEW MEDICINE?

Group involved in health promotion. *The participant answered in a personal capacity.* “You need to ask doctors if they actually read any of it.”

CJD Support Network. *The participant answered in a personal capacity.* “Doctors need to know—but do they have the time to read it?”

Group specialising in consumer information. *The participant answered in a personal capacity.* “Far too much non evidence-based information.”

Dumfries and Galloway Association for the Blind. *The participant answered in a personal capacity.* “Only doctors can answer this one.”

Group specialising in brain cancer. *The participant answered in a personal capacity.* “Regulatory body or watchdog.”

Group specialising in genetic diseases. *The participant answered in a personal capacity.* “I am not familiar with the current situation.”

Arthritis Care. *The participant answered in a personal capacity.* “GPs should declare any connection to a particular product or company.”

Group specialising in osteoporosis. *The participant answered in a personal capacity.* “The impression given by GPs is that there is an overload [of advertising and promotional material]. However, it is very important for them to be made aware of developments.”

James Lind Initiative. *The participant answered in a personal capacity.* “It is not just the scale that should be made public, but the evidence supporting the claims made.”

Group specialising in endocrinology. *The participant answered in a personal capacity.* “Unable to give a response (I am not a medical practitioner).”

Parents of Autistic Spectrum Disorder Adults, Edinburgh. “The volume is impossible for anyone to remember [anything].”

UK Coalition of People Living with HIV and AIDS. “Much of this activity 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 such as HIV, where drugs are used in combination.”

Group specialising in the after-effects of drugs. “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.”

Regional PPI. *The participant answered in a personal capacity.* “Far too much spent on promotion.”

Group specialising in information on assistive technology for older and/or disabled people. *The participant answered in a personal capacity.* “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.”

Professional nurse attached to a patient organisation. “Doctors receive too much information. It needs to be in a user-friendly format, and easy to file for future reference (for instance, same-size paper).”

Tony Gavin of Leukaemia CARE. *The participant answered in a personal capacity.* “This is an easier question to ask than to answer. We all know how difficult it is to educate (or, should I say, “keep informed”) many of our doctors once they have left full-time training! There seems to be an inbuilt inertia among some doctors, who appear to be reluctant to keep up to date with all the changes/ advances that occur within the various fields of medicine. If nothing else, promotional material mailed out by the pharmaceutical companies will make these doctors aware of (if not conversant with) the newly-launched medicines, and may, in some instances, catch their imagination sufficiently for them to research the drugs’ usefulness (or otherwise). Not all medical advances occur in the ‘life-threatening’ arena. Many of the newer agents will be classified as ‘quality-of-life enhancing’, and, as such, new prescription medicines (whether they are for imminently life-threatening conditions or not) should not have promotional restrictions placed upon them in a draconian manner. Major advances in medicines these days will be made in small increments, leading to the overall goal of treatment success or cure—if cure is possible. Classic examples of this include the improvements made in treating diabetes and the cardiovascular disorders. To cut out the intermediary steps may have quite easily prevented the major advances. Each step forward made by pharmaceutical research is extremely costly, and could be said to be spiralling out of control. In order not to discourage research by the major drug companies, or ‘blue-sky’ research by the universities, the results of that research must be allowed to earn its keep. Bearing in mind that we are talking about new prescription medicines, we can assume that they have already been cleared by the MCA, and given a product licence. 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 on what can and cannot be said about any POM 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 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.”

Alpha-1 UK. *The participant answered in a personal capacity.* “How much of this promotional material is actually read by GPs?”

Polychondritis Educational Society. “We are a rare disease organisation. We have seen an increase in patients demanding medications that they have seen advertised—without their knowing the long-term side effects. This should be the doctors’ position, and not the patients’. I believe that marketing directly to the patient is a breach in ethics by the pharmaceutical companies.”

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* “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.”

Senior psychiatric pharmacist working within the NHS. “Once again, the second statement [restrictions on the volume of advertising,

except when the drug is for an imminently life-threatening condition] is slightly baffling. I have been involved very closely with drug companies/industry. They don't 'advertise' (depending on the severity of a condition). They advertise to make money. All you need to do is compare the number of times you've seen an advertisement for zidovudine versus ibuprofen! (One is an antiretroviral, the other a NSAID.)"

PPIF (Windsor, Ascot and Maidenhead). *The participant answered in a personal capacity.* "High volumes of literature tends to be ignored by the surgeries. It has to get past the practice manager before the doctors read anything."

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* "Maybe more information on new, improved medications?"

British Heart Foundation. *The participant answered in a personal capacity.* "It would be ideal if all the relevant drug companies associated with a specific treatment or condition joined as a group, and provided patients and health professionals with a balanced view of treatments (in line with relevant guidelines). This would allow their credibility to be maintained. But will that happen?"

Highland Users Group. "The promotional activities of drug companies are viewed with suspicion by users."

Group specialising in prostate cancer. *The participant answered in a personal capacity.* "I'm not a GP."

Congenital Adrenal Hyperplasia Support Group. *The participant answered in a personal capacity.* "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."

Group specialising in the promotion of health information. *The participant answered in a personal capacity.* "It would be good to know that the leaflets' claims had been verified independently."

Anonymous participant. "Doctors can be swayed into using the latest drug they have read about, or which drug company gave them the biggest bottle of champagne, etc."

PPIF (Crawley). *The participant answered in a personal capacity.* "Doctors should inform patients of the newness of medicines."

PPIF (East Kent and Coastal). *The participant answered in a personal capacity.* "Doctors should be asked this question. It is irrelevant for lay people to judge how doctors need to acquire knowledge about medicines. Doctors must be kept up to date on ALL prescribed medicines."

Heart to Herts Cardiac Support Group. "Leave it to the professionals. The MHRA should already know."

Mind (Cymru). *The participant answered in a personal capacity.* "It is unethical to give rewards which will encourage a GP to prescribe something that might not be appropriate, and which could be dangerous."

Arthritis Patient Forum (Torbay Hospital, South Devon). *The participant answered in a personal capacity.* "Voluntary limits won't work. Drug companies are primarily after profits."

Rethink Severe Mental Illness. "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."

Huntington's Disease Association (Colchester and District Branch).

"I believe my earlier comment on the current directive to GPs to use the 'cheapest' will act as a filter, and companies will realise that advertising is non-productive."

Group specialising in cancer of the blood.

The participant answered in a personal capacity.

"The category of health professionals (who may be provided extended information) should be extended to include those who are registered with the Health Professionals' Council, and who can demonstrate a legitimate need for access. I, for example, am a state-registered biomedical scientist, and have a Master's degree in Clinical Oncology. Yet, for the purposes of the regulation, I am considered a layperson. This significantly impacts on my ability to best function as the Clinical Information Officer for the second-largest cancer research charity in the UK."

Group specialising in HIV/AIDS.

The participant answered in a personal capacity.

"The restrictions in place in the UK now are useless. You can as just use a US website to look at drug information."

Chairperson of a PCT.

The participant answered in a personal capacity.

"NICE or a similar organisation to advise doctors on new medicines."

Neurological Alliance (South West).

The participant answered in a personal capacity.

"Scandalous, some of the 'freebies' that go with it—forcing doctors to prescribe sometimes unsuitable medicines."

Mind (Pembrokeshire).

"Open and transparent."

Group specialising in diabetes.

The participant answered in a personal capacity.

"All incentives should be strictly monitored for all HCPs."

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'."

PPIF (Chesterfield PCT).

"We do not exclude further restrictions, but are not qualified to make specific recommendations."

Which?

"GPs are short of time, and may find it difficult to keep themselves updated. Even a small item (such as a post-it pad, or a pen from a company representative that offers a prescribing solution for a given diagnosis) may have a disproportionate influence on prescribing behaviour."

Group specialising in severe mental illness (especially schizophrenia).

The participant answered in a personal capacity.

"It does not take a lot of expensive hard-sell advertising to sell a medicine on its merits."

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum).

"Restricted and more-focused pharma educational material would be less likely to hit the waste bin, and be less costly to the advertising budget."

Group specialising in prostate cancer.

The participant answered in a personal capacity.

"Advertising should be heavily restricted. Doctors are not as dispassionate and scientific as they would have us believe. They are as easy to influence as the sheep-like masses!"

Mind (Havering).

The participant answered in a personal capacity.

"They should publicise—especially the amount that doctors are paid to do drug trials. And there should be statutory restrictions."

Group based in an NHS hospital trust and advising on patient information. *The participant answered in a personal capacity.* "Patients are not always aware of the incentives that health professionals receive."

SHOULD CERTAIN LIMITATIONS BE PLACED ON INDUCEMENTS AND HOSPITALITY OFFERED AT CONFERENCES AND MEETINGS TO HEALTHCARE PROFESSIONALS (DOCTORS, NURSES, THERAPISTS, MANAGERS, ETC)?

National Ankylosing Spondylitis Society. *The participant answered in a personal capacity.* “I get the impression that things have improved in the last few years. However, the drug companies make a valuable financial contribution to important annual scientific meetings. My experience is limited to my observations of the British Society of Rheumatology annual meeting.”

Group specialising in young families and expectant parents. *The participant answered in a personal capacity.* “Free gifts and inducements seem to lead medical professionals to prefer one product over another in order to receive these inducements. Professionals should be using products based on the benefits of the product to the patients’ condition, and not what they are likely to gain out of it!”

Group specialising in consumer information. *The participant answered in a personal capacity.* “No such thing as a free lunch!”

Group specialising in visual impairment. “Patients are generally unaware of inducements, etc. Inducements without explanation of the benefits of the product to the healthcare professional are morally indefensible.”

Group specialising in brain cancer. *The participant answered in a personal capacity.* “The profession always seems to like these ‘freebies’, and I don’t feel it has any effect on their professional behaviour.”

HCV-Alert. *The participant answered in a personal capacity.* “Doctors tend to change certain medications because of perks given, and I think this is wrong—especially with new drugs that have just come on market, with negligible patient trial history over time.”

Alzheimer’s Society (Selby and York Branch). “I certainly do not think we can trust drug companies to self-regulate. We patients need to know that doctors—as to what they will prescribe—are not being unduly swayed by advertising.”

Group specialising in older people. *The participant answered in a personal capacity.* “Difficult to say, as the health professionals often ask for the inducements (particularly hospitality) at conferences and at sponsorship of events. Without these perks, some professionals do not attend.”

Arthritis Care. *The participant answered in a personal capacity.* “GPs should declare these.”

Patient Information Forum. *The participant answered in a personal capacity.* “Similar to MPs’ expenses.”

Parents of Autistic Spectrum Disorder Adults, Edinburgh. “Any promotional activities should include patient representatives.”

UK Coalition of People Living with HIV and AIDS. “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 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.”

Group specialising in health services provision. *The participant answered in a personal capacity.* “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.”

Regional PPI. *The participant answered in a personal capacity.* “Needs proper external regulation.”

Tony Gavin of Leukaemia CARE. *The participant answered in a personal capacity.* “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!”

Society for Mucopolysaccharide Disease. *The participant answered in a personal capacity.* “This is a particular problem where rare diseases are concerned, and drugs are prescribed based on experience of one drug company.”

Polychondritis Educational Society. “It is unrealistic to believe that all persons and corporate identities—if they are self-monitoring—will do what is beneficial for the public at large. While there are ethical doctors, companies, and corporations, there are also those that only care about the bottom line. This may not be in the best interest of the patients they serve.”

Senior psychiatric pharmacist working within the NHS. “It is IMPERATIVE that, not only the companies make public their inducements, but healthcare professionals as well.”

St Albans and District Voluntary Diabetic Support Group. “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!”

Group specialising in older people, dementia and mental health. The participant, *who answered in a personal capacity, was also a manager of a nursing home.* “Inducements should not be financial—unless in very controlled, specific areas for stated purposes (and this should be known).”

British Heart Foundation. *The participant answered in a personal capacity.* “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.”

Highland Users Group. “Regulation should be imposed. Meetings sponsored by drug companies can be informative.”

Group specialising in older people. *The participant answered in a personal capacity.* “GPs receive too many inducements.”

Congenital Adrenal Hyperplasia Support Group. *The participant answered in a personal capacity.* “I would hope this is the case!”

Group specialising in the promotion of health information. *The participant answered in a personal capacity.* “Does this affect what doctors use? If not, then they can carry on as now.”

Anonymous participant. “There should be no inducements or hospitality.”

Chair of local support group involved with women's health; Vice-Chair of a PPI Forum; member of a parliamentary group and European alliance. *The participant answered in a personal capacity.* "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."

Salford Heart Care Re-Hab. "Gifts given should be relevant to work."

PPIF (Crawley). *The participant answered in a personal capacity.* "Consultants should always advise patients that the medicine is on trial, or new."

Pharmacy manager at an independent healthcare provider. *The participant answered in a personal capacity.* "Not allowed at all."

PPIF (East Kent and Coastal). *The participant answered in a personal capacity.* "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!"

PPIF (Crawley). *The participant answered in a personal capacity.* "Gifts, etc, should be banned."

Heart to Herts Cardiac Support Group. "I am not competent to judge."

Arthritis Patient Forum (Torbay Hospital, South Devon). *The participant answered in a personal capacity.* "I don't think that drug companies should be allowed to give gifts at all."

Group specialising in cystic fibrosis. *The participant answered in a personal capacity.* "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."

Huntington's Disease Association (Colchester and District Branch). "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."

Plymouth Mind Oasis. *The participant answered in a personal capacity.* "What is the difference between inducement and a bribe?"

Group specialising in HIV/AIDS. *The participant answered in a personal capacity.* "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."

Lanarkshire Links. *The participant answered in a personal capacity.* "A watchdog body is needed."

Mind (Pembrokeshire). "Increased m & e."

Group specialising in brain-related conditions in children. *The participant answered in a personal capacity.* "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."

Group specialising in diabetes. *The participant answered in a personal capacity.* "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."

Which? "Which? research with GPs [May 2004] revealed that 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."

Group specialising in severe mental illness (especially schizophrenia). *The participant answered in a personal capacity.* "I think the evidence is that doctors, too, are susceptible to advertising techniques of the psychological type."

Group specialising in prostate cancer. *The participant answered in a personal capacity.* "Need to differentiate between a free biro and [the gift of] a golfing weekend."

Mind (Havering). *The participant answered in a personal capacity.* "Make guidelines public."

British Polio Fellowship (Edinburgh Branch). "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."

Group based in an NHS hospital trust and advising on patient information. *The participant answered in a personal capacity.* "Healthcare professionals should declare incentives accepted."

WHICH ACTIVITIES ARE MOST EFFECTIVE AT MAXIMISING TRANSPARENCY FOLLOWING COMPLAINTS ABOUT MEDICINES ADVERTISEMENTS?

PALS. *The participant answered in a personal capacity.* “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.”

Parents of Autistic Spectrum Disorder Adults, Edinburgh. “Key stakeholders should include patient representatives.”

Group specialising in chronic back pain. *The participant answered in a personal capacity.* “The public are kept in the dark most of the time about complaints.”

UK Coalition of People Living with HIV and AIDS. “To what extent do the MHRA and the ASA regularly review their activities in this area?”

Professional nurse attached to a patient organisation. “Objective reporting via the media, and direct to stakeholders.”

PPIF (Windsor, Ascot and Maidenhead). *The participant answered in a personal capacity.* “The cost of administering these activities should be taken into account. Otherwise, less money gets to the front line of patient care.”

British Heart Foundation. *The participant answered in a personal capacity.* “It may be helpful that all health professionals are first made aware of any problems or complaints, so that they are informed and prepared before the public are aware. This can allow the public to understand the context, be informed, but not over-anxious.”

Highland Users Group. “We were not aware of any of these possibilities.”

Mental health client. “More public awareness.”

Anonymous participant. “Perhaps publishing a table, etc, in the national papers.”

PPIF (East Kent and Coastal). *The participant answered in a personal capacity.* “Of course the public should be made aware of these complaints. How else can patients make an informed choice?”

Parkinson’s Disease Society (Canterbury Branch). *The participant answered in a personal capacity.* “A monthly online report would be useful.”

Heart to Herts Cardiac Support Group. “I am not competent to judge.”

Mind (Cymru). *The participant answered in a personal capacity.* “Why no more than three [options in the answer to this question]?”

Group specialising in mental health. “Freedom of information.”

Which? “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 the 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 ACTIONS WOULD YOU MOST LIKE TO SEE TAKEN WHEN AN ADVERTISEMENT FOR A MEDICINE (OTC OR PRESCRIPTION) IS FOUND MISLEADING?

Group specialising in visual impairment. “I have never heard of any action against a company.”

Alzheimer’s Society (Selby and York Branch). “Why [does the questionnaire offer] no middle ground between informal negotiations, and formal (and quite draconian) actions?”

Group specialising in physical and learning disabilities. *The participant answered in a personal capacity.* “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.”

Patient Information Forum. *The participant answered in a personal capacity.* “What do other industries do, re advertising?”

Insulin-Dependent Diabetes Trust. “[Other]: that these matters are entirely dealt with by the Department of Trade and Industry, under breach of the Trade Descriptions Act. I would actually like to tick all [of the questionnaire’s choices], except for the first two [Question: ‘Industry body conducts informal negotiations with the company concerned’; ‘MHRA conducts informal negotiations with the company’] and the last option [‘Sanctions imposed by another agency than the MHRA’].”

UK Coalition of People Living with HIV and AIDS. “Penalties must be appropriately severe, to prevent recurrence of misleading or inappropriate advertising. The larger the company, the larger the penalty.”

Group specialising in health services provision. *The participant answered in a personal capacity.* “Court action and the application of sanctions are only for severe cases.”

Tony Gavin of Leukaemia CARE. *The participant answered in a personal capacity.* “There are, however, always degrees of guilt. If the advertisement was deliberately misleading, then the full rigour of the law should be applied to prosecute the offending company. But if the error was by oversight or unintentional (or otherwise), then the above three items [Question: ‘Company issues a correction/apology’; ‘MHRA ‘names and shames’ an advertisement/company in multiple media’; and ‘Company is fined’] would suffice for me.”

Alpha-1 UK. *The participant answered in a personal capacity.* “In some cases, criminal proceedings should be considered.”

Knowledge manager within the NHS. “If a company is fined, the fine should be high enough to prove a deterrent. And, thus, fines should be based on a percentage of the offending company’s income (before tax), rather than a standard amount within minimum and maximum boundaries.”

British Heart Foundation. *The participant answered in a personal capacity.* “Ideally, it would be better discouraged in the first place!”

Group specialising in older people. *The participant answered in a personal capacity.* “It depends on the seriousness of the situation.”

Anonymous participant. “The negotiations should be of a formal nature.”

Group specialising in diabetes. *The participant answered on behalf of a small group of care advisers.* “Depends on the degree of attempt to mislead.”

Anaemic Society. “This is a problem for the Society, too. Many ‘members’ join, and then

simply use their personal details to get other members to visit their websites advertising 'quack' or irrelevant 'cures'. I periodically have to remove such 'member.s'. The problem is defining advertising—especially with the rise of the Internet, spam, cookies etc.,.”

PPI. *The participant answered in a personal capacity.* “Links to the Advertising Standards Agency (ASA), and notice to all Trading Standards officers.”

Parkinson's Disease Society (Canterbury Branch). *The participant answered in a personal capacity.* “A fast time limit should be enforced on the correction and amendment.”

Heart to Herts Cardiac Support Group. “Correction of the error should be acknowledged and confirmed.”

Perth Bipolar Group. *The participant answered in a personal capacity.* “A sequence of escalating actions should be employed.”

Group specialising in disability. *The participant answered in a personal capacity.* “Further action may be needed, depending on the severity of the misleading information.”

Group specialising in mental health. *The participant answered in a personal capacity.* “Depends entirely upon the nature of the misinformation as to how to deal with the individual company.”

Group specialising in brain-related conditions in children. *The participant answered in a personal capacity.* “Injunction only if the offending information reappears after corrective action should have been taken.”

Group specialising in diabetes. *The participant answered in a personal capacity.* “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.”

PPIF (Chesterfield PCT). “While we are not qualified to be specific in this area, in general, we believe public interest to require that penalties be graded according to the gravity of the offence, increasing sharply in the event of flagrant and/or repeated breaches—in respect of which widespread publicity and severe commercial sanctions should be applied.”

Which? “Prescribers and patients using medicines need to know when they may have been misled by advertising materials. And so widespread publication of complaints is important for patient safety, and for building confidence in the regulatory system. The MHRA has strong powers to take sanctions against misleading advertising, but it appears to under-use these powers—thereby appearing to place low value and importance on problems in medical advertising. Publishing complaints on websites is not adequate. 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). Publicising breaches of advertising regulations and codes is not a new phenomenon. Complaints about advertising of medicines have been published by both the PMCPA and the ASA for some time—and yet illegal practice is still occurring. A combination of an effective penalties-and-enforcement system and subsequent publication of case investigations and outcomes is needed urgently.”

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum). “Clearly, there would need to be a more detailed procedure put in place, which may include some of the other items listed [in the question].”

WHEN SHOULD ACTIONS BE APPLIED?

Group specialising in physical and learning disabilities. *The participant answered in a personal capacity.* “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.”

Patient Information Forum. *The participant answered in a personal capacity.* “The law is not there to be broken.”

Tony Gavin of Leukaemia CARE. *The participant answered in a personal capacity.* “Repeat offenders, however, would be a different case entirely. They should be dealt with severely.”

PPIF (Windsor, Ascot and Maidenhead). *The participant answered in a personal capacity.* “Define 'technically' [Question: 'In all cases which technically breach the law?']”

Group specialising in brain-related conditions in children. *The participant answered in a personal capacity.* “Should be applied to anything misleading at all.”

Group specialising in diabetes. *The participant answered in a personal capacity.* “This may seem over the top, but pharmaceutical companies will change their way of working if they know that they cannot get away with anything. Otherwise, they will be trying to find ways of getting away around any MHRA restrictions.”

Which? “Actions should be applied whenever advertising regulations are breached. Consistency of approach is important in maintaining the integrity of the system.”

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum). “According to the MHRA *Blue Guide*, there is clear legislation. However, whichever option better protects the public should be put in place.”

HOW SHOULD SAFETY MESSAGES BE INCORPORATED INTO ADVERTISEMENTS FOR MEDICINES (BOTH PRESCRIPTION AND OTC)?

National Ankylosing Spondylitis Society (NASS). *The participant answered in a personal capacity*. “The trouble about information is that few patients read them. Prescription medicine should not be aimed at patients.”

York Coalition of Disabled People. “If information is not in accessible formats (such as large print, Braille, pictorial, or languages other than English) then it cannot be deemed ‘high quality’.”

Group specialising in visual impairment. “It is about patient choice. If they do not have the information, then they cannot make an informed decision about their treatment.”

Group specialising in child health. *The participant answered in a personal capacity*. “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.”

Group specialising in physical and learning disabilities. *The participant answered in a personal capacity*. “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’).”

Patient Information Forum. *The participant answered in a personal capacity*. “But they should be patient-friendly—unlike the babble that accompanies many FSA-regulated adverts.”

James Lind Initiative. *The participant answered in a personal capacity*. “Estimates of the frequency/likelihood of unwanted effects of drugs should be made public.”

UK Coalition of People Living with HIV and AIDS. “‘Always read the label’ is not really sufficient. Pharmacists need to play a bigger role, and warnings on packages to patients taking other medications should be more prominent.”

Tony Gavin of Leukaemia CARE. *The participant answered in a personal capacity*. “Safety messages should always be prominent. But, by the same token, they should not inhibit the patient from taking the medicine. 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. Provision must always be made for those people who cannot read, or who do not have English as their first language. With prescription medicine, this role should be fulfilled by the prescribing doctor. For OTC medicines, the pharmacist must take his share of responsibility. The ABPI could also become involved, by running a series of generic adverts looking specifically at safety messages for both prescribed and OTC medicines.”

Group specialising in visual impairment. “In 16+ point.”

Group specialising in older people, dementia and mental health. *The participant, who answered in a personal capacity, was also a manager of a nursing home*. “The emphasis should be on prominent—often very difficult to read small print.”

PPIF (East Kent and Coastal). *The participant answered in a personal capacity*. “Given information, patients can make informed choices. Without it, there is no choice.”

Heart to Herts Cardiac Support Group. “The same as cigarettes.”

Group specialising in mental health. “Too many ‘judgement calls’. Safety messages should ALWAYS be prominent.”

Brain Tumour UK. *The participant answered in a personal capacity.* “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.”

Mind (Pembrokeshire). “Safety messages standards.”

Group specialising in brain-related conditions in children. *The participant answered in a personal capacity.* “Evidence-based safety messages should be given at the bottom of anything published. However, this does not necessarily mean a detailed list of side-effects, etc.”

Group specialising in diabetes. *The participant answered in a personal capacity.* “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’.”

PPIF (Chesterfield PCT). “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.”

Which? “Presume that, by safety messages, you are referring to risks of side-effects, contraindications and when not to take a medicine, and what to do in an emergency.”

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum). “We consider both to be important. Safety messages must be boldly displayed in laypersons’ language, and may use symbols for endorsement.”

British Polio Fellowship (Edinburgh Branch). “Safety messages to the prescriber may need to be more detailed than those to patients.”

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?

York Coalition of Disabled People. “If information is not in accessible formats (such as large print, Braille, pictorial, or languages other than English) then it cannot be deemed ‘high quality’.”

Group specialising in brain cancer. *The participant answered in a personal capacity*. “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).”

Alzheimer’s Society (Selby and York Branch). “This information should be accessible in a variety of formats.”

Herpes Viruses Association. *The participant answered in a personal capacity*. “It is shocking to learn that adverts can go beyond what has been shown and peer-reviewed!”

Patient Information Forum. *The participant answered in a personal capacity*. “[Question: I did not realise companies made advertising claims that had not been conveyed to the drug regulator.] And I’m supposed to be in the know!”

Tony Gavin of Leukaemia CARE. *The participant answered in a personal capacity*. “NONE OF THE ABOVE! [Question: ‘Companies should be obliged to publicise data to support any claims (unknown to the MHRA)’; ‘Companies should be obliged to publicise data only when claims

(unknown to the MHRA) seem dubious or outlandish’; ‘Companies should make the data on claims (unknown to the MHRA) easily available to the public on request’; ‘Companies should make not make claims that are unknown to the MHRA’; ‘I did not realise that companies made advertising claims that had not been conveyed to the drug regulator’; ‘The current situation is about right.’] 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!!”

PPIF (Windsor, Ascot and Maidenhead). *The participant answered in a personal capacity*. “What is the cost to the MHRA if they are to investigate all data on claims?”

British Heart Foundation. *The participant answered in a personal capacity*. “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.”

PPIF. *The participant answered in a personal capacity*. “I think this is a frightening situation, and should not have been allowed—ever.”

PPIF (East Kent and Coastal). *The participant answered in a personal capacity*. “All data published must be backed by research trials, giving names of investigators, and full details of the trial.”

Diabetes UK. “All claims should be presented and known to the MHRA, and all negative findings also.”

Group specialising in HIV/AIDS. *The participant answered in a personal capacity.* “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).”

Group specialising in brain-related conditions in children. *The participant answered in a personal capacity.* “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).”

Group specialising in diabetes. *The participant answered in a personal capacity.* “This should be strictly enforced.”

PPIF (Chesterfield PCT). “We are not qualified to comment specifically, but believe that considerations of safety must predominate over commercial interests.”

Which? “This question is confusing and unclear. What does it mean to ‘publicise data’? All claims in marketing and information material should be supported by published data enabling anyone using (or prescribing) a drug to follow-up and check details of statements and claims. Furthermore, all claims should be in keeping with the marketing authorisation awarded for the product.”

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum). “We consider both to be valid.”

WHICH TYPES OF INFORMATION SHOULD BE MOST PROMINENT IN DISEASE-AWARENESS CAMPAIGNS?

Continence Foundation. *The participant answered in a personal capacity.* “The treatment should be referred to, but in the context of balanced information about any non-pharmaceutical treatments for the condition.”

Herpes Viruses Association. *The participant answered in a personal capacity.* “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.”

Arthritis Care. *The participant answered in a personal capacity.* “Need to be aware of drug companies 'constructing' new diseases.”

Insulin-Dependent Diabetes Trust. “I am not opposed to disease-awareness campaigns. But, in answering this question, I am assuming that the question refers to disease-awareness campaigns produced and funded by the pharmaceutical industry.”

UK Coalition of People Living with HIV and AIDS. “This type of advertising can be confusing to people. A typical example is GSK's current television advertising that looks more like a public-information film, with a dentist giving expert advice on sensitive teeth (and which the ASA admits has been the source of several complaints). Yet, this is an advert for a toothpaste, that takes advantage of many people's inability to get access to proper dental advice through lack of NHS dentists. It also implies that the only cure is the toothpaste—when, if the toothpaste doesn't work, patients will need to find a way of seeing a dentist anyway. Again, the downside is ignored in favour of the 'wonder preparation' being marketed by the industry.”

PXE Support Group (PiXiE). *The participant answered in a personal capacity.* “When in an emergency, or when [the condition is] life-threatening.”

Tony Gavin of Leukaemia CARE. *The participant answered in a personal capacity.* “I would also like the campaign to have its sponsor named (even if just by carrying the company logo).”

Group specialising in multiple sclerosis. *The participant answered in a personal capacity.* “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.”

Polychondritis Educational Society. “Public awareness is vital in many diseases. However, to use it as a platform to sell medication should be discontinued. Disease-awareness campaigns and advertising should be directing people to see their doctors for the correct diagnosis and treatment plans, and promoting self-diagnosis and self-treatment.”

Highland Users Group. “The campaigns are needed, but we worry that the drug companies benefit from these.”

Anaemic Society. “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.”

PIIF (East Kent and Coastal). *The participant answered in a personal capacity.* “Disease-awareness campaigns are vital to patient responsibilities for their own health.”

Group specialising in mental health. “How is it transmitted? Incubation?”

Group specialising in diabetes. *The participant answered in a personal capacity.* “All advertising should be educational to potential users of the product. Not all medications are suitable for all people. ‘The miracle cure’—one-size-fits-all—should be removed from advertising.”

PPIF (Chesterfield PCT). “We are not qualified to comment on this topic.”

Which? “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’ [see <http://medicines.mhra.gov.uk/ourwork/advertpromed/disawcam.pdf>; accessed September 6th 2005]. The published MHRA guidance goes on to say: ‘The primary purpose of a DAC must be to increase awareness of a disease or diseases, and to provide health educational information on that disease and its management. It should not promote the use

of a particular medicinal product or products’.”

Mind (Basildon). *The participant answered in a personal capacity.* “All.”

Group specialising in severe mental illness (especially schizophrenia). *The participant answered in a personal capacity.* “This is on the basis that we are talking here about drug company-sponsored campaigns.”

EUROPA DONNA—the European Breast Cancer Coalition (UK Forum). “I do not think that the answer can be limited to those [considerations] above. For example, depending on the condition, information about key aspects should be given—not necessarily information about all aspects. But this would surely include symptoms and treatment. I don’t feel that we can answer.”

PPIF (Central Liverpool PCT). “Should be done by the DoH, not by companies with special interests.”

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