

Safeguarding Public Health



Maintaining High Standards in Medicines Advertising Regulation

Annual Report September 2006 – August 2007

Providing Expert Advice for Healthcare Professionals

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**Advertising Standards Unit
Vigilance and Risk Management of Medicines
Medicines and Healthcare products Regulatory Agency**

Foreword

I am delighted to welcome this second Annual Report from the MHRA's Advertising Standards Unit. It sets out in a transparent way how we have worked to promote and maintain high standards for the advertising of medicines in the last year. This work supports one of the MHRA's aims—to keep watch over medicines and take any necessary action to protect the public by ensuring that advertising promotes safe use.

I said last year that effective regulation targets high-risk areas and so it is particularly pleasing to see the reduction in serious breaches of the legislation in the prescription sector in the last year and to be able to associate that with the increased focus on targeted vetting of advertising by the MHRA.

But the control of advertising is not just the responsibility of the MHRA. It relies on a long established system of self-regulation and the statutory role of the MHRA underpins this. The collaboration over the past year documented in this report makes a major contribution to maintaining consistent standards.

The ultimate responsibility for high standards in advertising rests with each advertiser and the information and advice on best practice in this report merit close scrutiny by all sectors of the industry. Advertising is an important way of communicating about medicines and advertisers need to ensure that recipients are provided with enough information to prescribe, supply or use the advertised product appropriately.

High standards in medicines advertising are supported through targeted vetting and rapid, proportionate action on complaints by the MHRA and working with other regulators to ensure that regulation of advertising is consistent, transparent and effective. But there is also a need for a commitment from all parts of the pharmaceutical industry and other medicine suppliers to each ensure that their advertising maintains the highest standard.

Kent Woods
Chief Executive

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Chapter 1 – Continuing progress

Promoting transparency and openness in the MHRA's regulatory role

Introduction

This second annual report of the MHRA's Advertising Standards Unit (ASU) shows how we have worked to safeguard public health by ensuring that all advertising for medicines complies with the law.*

The legal requirements for the advertising of medicines include the quality standards that advertising must:

- Comply with the particulars in the Summary of Product Characteristics for the product.
- Promote the rational use of the product by presenting it objectively and not exaggerating its properties.
- Not mislead.

They also cover the ways that companies may promote their products, including the supply of samples and gifts and inducements to health professionals to prescribe or supply medicines.

The Advertising Standards Unit in the MHRA

The ASU has a dual responsibility covering both policy and case work on advertising. The Unit is located within the MHRA's Vigilance and Risk Management of Medicines (VRMM) division. VRMM aims to protect public health by promoting the safe use of marketed medicines and to support this with high quality product information.

When reviewing advertising, we work closely with colleagues in other parts of the Agency, particularly the Licensing division to make best use of the expertise on new products developed in the Product Lifecycle Assessment Teams from their review of marketing authorisation applications. Within VRMM, specialist advice is available from the Therapeutic Review group, and also from the Pharmacovigilance Risk Management group when the focus is on a safety issue. We also work with the Enforcement and Intelligence group to take action when serious breaches of the law have occurred.

* The Medicines (Advertising) Regulations 1994 and the Medicines (Monitoring of Advertising) Regulations 1994 (SI 1994/1932 and SI 1994/1933, both as amended). Together these implement the requirements of Title VIII of European Directive 2001/83/EC.

Serving stakeholders

VRMM has an outward focus to protect the health of the public and to support the prescribing and supply of medicines by health professionals. We therefore welcome complaints about misleading advertising from health professionals and the public, and we are keen to hear about any concerns with advertising. We also work closely with industry to ensure that advertising is right first time for products that are thought to present a higher risk to public health should advertising be misleading.

Implementation of Health Select Committee recommendations

The impetus for publication of an annual report on the work of the ASU was part of the Government's response to the 2005 report of the House of Commons Health Committee on *The influence of the Pharmaceutical Industry*¹. Our second annual report highlights the practical implementation of several recommendations of the Committee. A key recommendation accepted by the Government was to vet advertising for all new active substances before their issue.

Evidence to date suggests that this measure has reduced the incidence of advertising that is not compliant with legal requirements, and that the number of complaints to the MHRA or the self-regulatory body (the Prescription Medicines Code of Practice Authority, PMCPA) about advertising for prescription only products has reduced. Moreover, a reduction in the number of corrective statements required for misleading advertising for a particular product suggests fewer serious complaints that highlighted a potentially significant risk to public health.

Promotion of transparency

This report forms part of a range of regular measures to promote openness and transparency in the regulation of advertising, including:

- Detailed guidance for advertisers, the Blue Guide², and full information about how we regulate available on the MHRA website³.
- Publication of reports of individual complaint cases on the MHRA website³, with additional measures such as corrective statements where misleading information could pose a risk to public health, and press releases to highlight significant issues.
- Publication of statistics on vetting performance and articles on current issues in advertising in MAIL⁴, the MHRA medicines updating service.
- Hosting an advertising seminar for industry, and participation in other events to explain the legal requirements to industry.
- Regular liaison with other regulatory bodies including the PMCPA, PAGB and ASA to promote a common understanding of legislation.
- Advertising cases feature regularly in the MHRA's new safety alert bulletin, Drug Safety Update⁵.

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Chapter 2 – Listening and responding

Taking action on misleading advertising to safeguard public health

The MHRA welcomes complaints and referrals from health professionals and the public that highlight concerns about advertising for medicines in the UK. Details of how to complain can be found in chapter 2 of the Blue Guide² and a complaint form is available on the MHRA website³.

How do we take action on complaints?

An initial review of every complaint is carried out within 24 hours of receipt and a letter sent to the company concerned, which highlights the matters cited in the complaint (in an anonymised form). A response from the advertiser to the letter is normally required within 7 days, but if a serious risk to public health is perceived the MHRA may require immediate action by the company. The complaint is then reviewed by the Advertising Standards Unit using expert advice if required and an outcome negotiated with the company. The complainant is given details of how we investigate complaints at the outset and receives a report of the outcome on completion.

Action on complaints in 2006–07

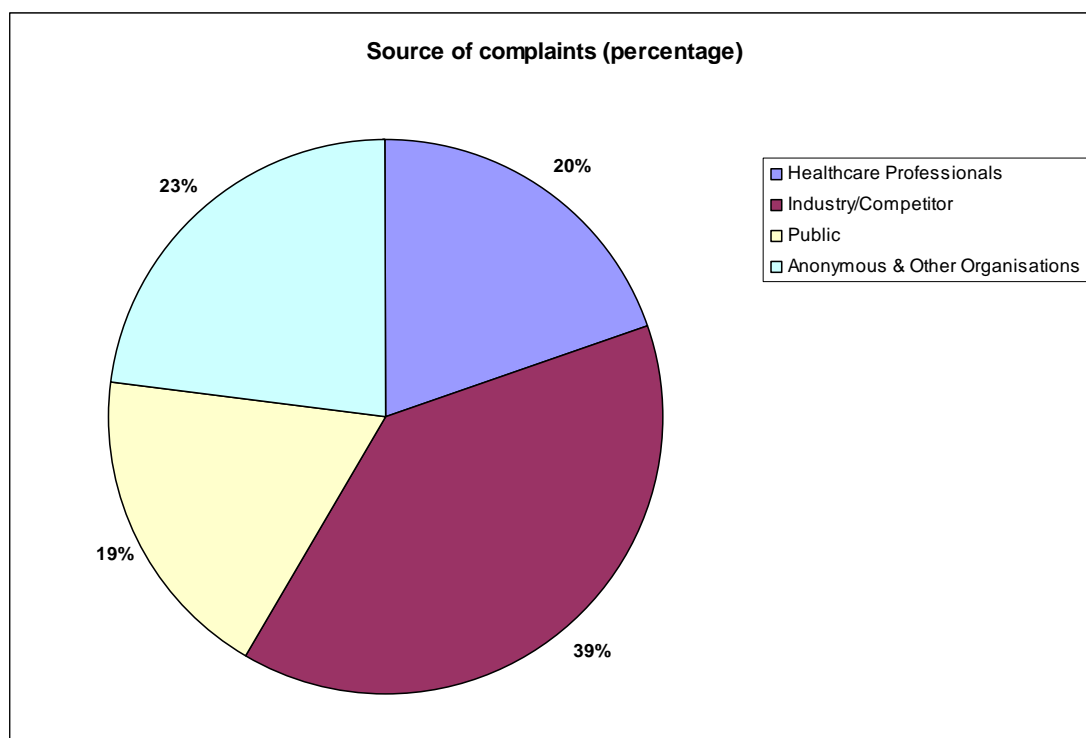
In 2006–07, we received 199 complaints about medicines advertising—a 16% increase from last year (172 complaints). The increase is accounted for entirely by an increased number of complaints about advertising for botulinum toxin products for cosmetic use. Most of these complaints are submitted by suppliers against whom action has been taken, to ensure a level playing field with their competitors.

Complaints received September 2006 to August 2007

	Sept 2005 to August 2006	Sept 2006 to August 2007
Complaints received	172	199
Investigations initiated	136	171
Complaints not relating to medicines advertising	6	2
Complaints referred to Agency colleagues	16	18
Complaints covering matters cited in previous complaint	14	3
Complaints under investigated by another body (PMCPA/ASA)	Not available	5

When the PMCPA or ASA are investigating a case, the MHRA reviews whether there is a potential serious risk to public health from the advertising, and if so the case is progressed in parallel. If no serious risk is identified, then the MHRA monitors the progress of the case by the self-regulatory body.

Complaints came from various sources, including competitor companies, health professionals, and the public.

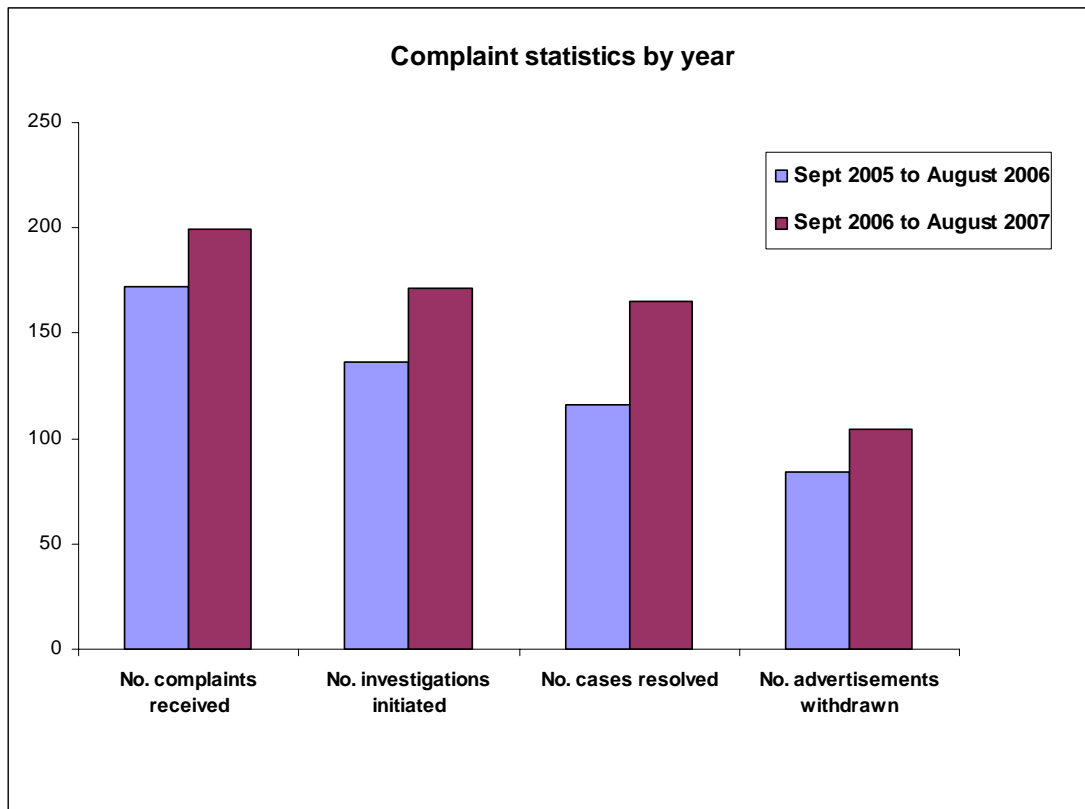


We resolved 165 complaint cases during the year from September 2006 to August 2007. Consistent with last year, about half the complaints were resolved within 1 month. Reports on all cases (except enforcement actions) were published on the MHRA website³ at the close of the investigation.

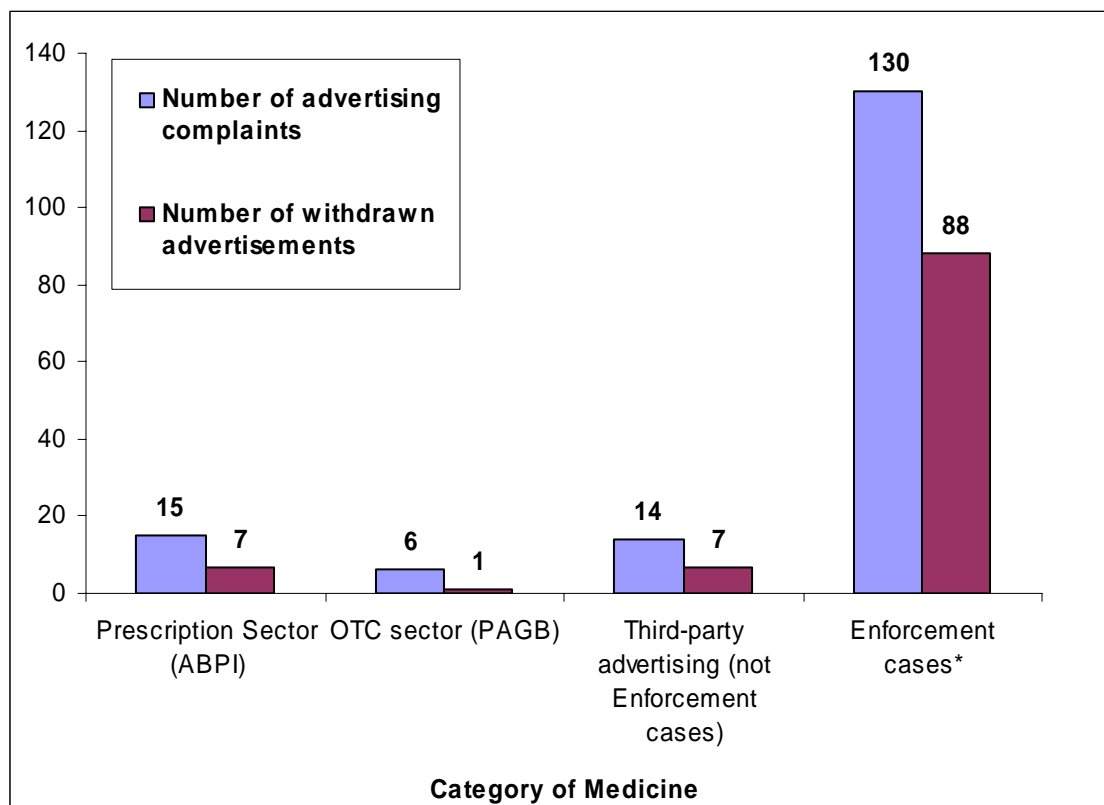
Outcome of complaints September 2006 to August 2007

	Sept 2005 to August 2006	Sept 2006 to August 2007
Medicines advertising cases resolved	116	165
Advertisements withdrawn	84 (72%)	104 (63%)
Corrective statements	6	2
Statutory procedures initiated	2	0
Statutory determinations	1	0
Referred to PMCPA	1	2
Summary reports published*	46	35

*Includes all cases other than enforcement cases.



Advertising complaints by category of medicine September 2006 to August 2007



*Cases dealt with in association with the Enforcement Group and not separately reported on the MHRA website.

During the year, two cases were referred to the PMCPA for action under the ABPI Code of Practice. One concerned allegations about the number of calls made by sales representatives to health professionals, and the second was a reference to “MHRA advice” in an advertisement that was considered to be misleading.

Two corrective statements were required this year. The first concerned misleading advertising by Alk-Abello for a hay fever treatment which failed to make clear that treatment should be initiated only by physicians with experience in treatment of allergic diseases. In a second case, Merz Pharma had supplied promotional samples of an unlicensed medicine to a group of doctors. These statements are included as part of the summary report of these cases on the MHRA website³.

The statutory procedure was not invoked in any cases during the year and all cases were settled by agreement with the company concerned. The statutory procedure, under the Medicines (Monitoring of Advertising) Regulations 1994, gives a company the opportunity to make written representations where the Secretary of State is minded to determine that there has been a breach of the regulations. In practice, these representations are put to an independent review panel who then advises the Secretary of State.

Monitoring advertising

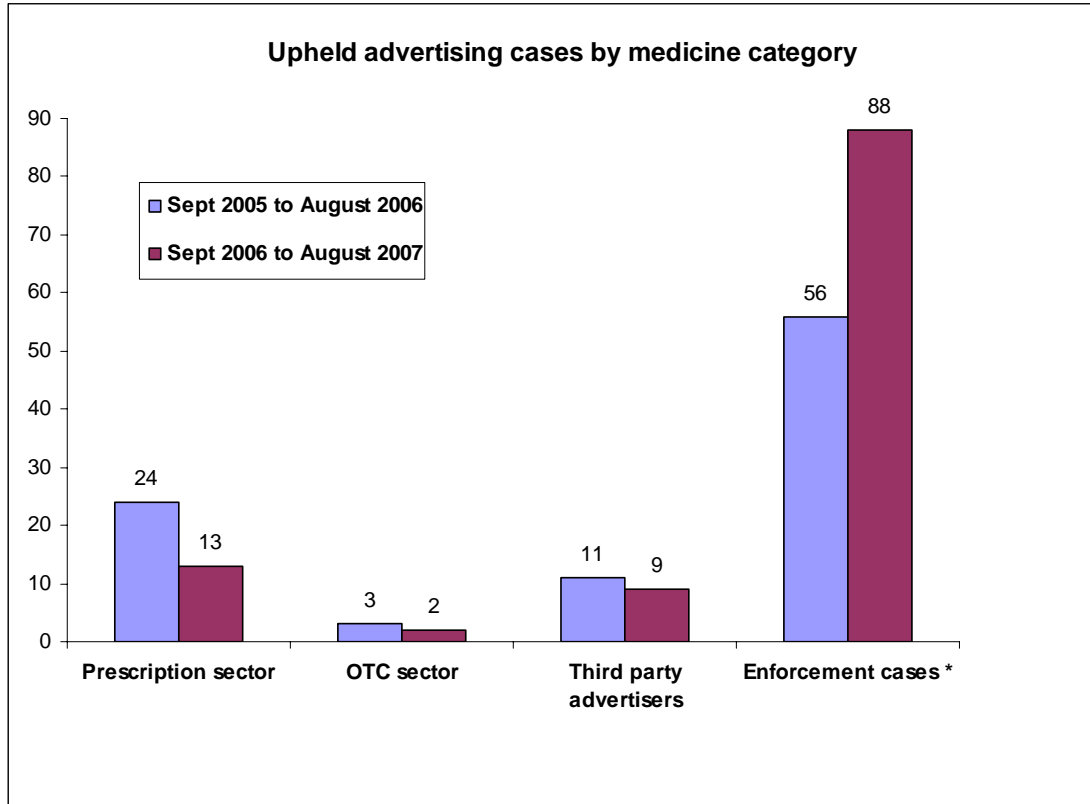
The Agency monitors published advertising in a range of journals and publications for health professionals and the public. We also encourage Agency colleagues to refer any concerns about advertising to us for investigation. During the year, eight advertisements were withdrawn as a result of our monitoring—a slight fall from the eleven cases reported last year, reflecting the result of greater emphasis on targeted vetting by the Unit this year. All cases that resulted in action were reported on the MHRA website³.

In October 2006, Merck Sharp & Dohme Ltd. was suspended from ABPI membership in relation to a nurse audit programme where the offer of nurse advisors to review treatment of hypertensive and diabetic patients in GP practices was linked to promotion of Cozaar (losartan). The MHRA subsequently reviewed all advertising for this product and materials that included misleading comparative claims were withdrawn.

Action taken by the US Food and Drug Administration alerted us to a potential problem with another advertisement. Advertising for Nasonex (mometasone) in both the USA and UK cited a study that compared physical characteristics such as taste and scent to suggest that patients preferred the product to a competitor. In practice, patient preference would also be influenced by how well the product worked, which the supporting study did not assess. The advertising was therefore considered to be misleading because it did not make clear the basis of the comparison.

Key issues in advertising complaints and monitoring

The chart below shows the breakdown by sector of complaint and monitoring cases where a breach of the regulations was identified, for the current year (September 2006 to August 2007) compared with 2005–06.



*Cases dealt with in association with the Enforcement Group and not separately reported on the MHRA website.

Advertising of prescription only medicines to health professionals

The overall number of complaint cases upheld for prescription only medicines has fallen by nearly half from 2005–06 to the present year. Eight of fifteen complaints about advertising for prescription only medicines were upheld in the year—a fall from last year (53% upheld vs 65% in 2005–06). This reduction can be attributed mainly to the increase in vetting of launch materials for innovative products and for other cases where there is a substantial safety concern, an initiative designed to ensure that potential breaches are prevented before publication.

It is particularly noticeable that the number of corrective statements has decreased: from eight to two. Correction is required when a misleading advertisement is considered to pose a serious risk to public health. So this decrease suggests that there have been fewer serious breaches, likely to be linked to the increase in vetting for key products (see chapter 3).

One particular case highlights the need for companies to review continually their advertising in the light of current information on the balance of risks and benefits for their products, and to take appropriate action if new safety data become available. Advertising for Zyvox (linezolid) highlighted favourable

efficacy results from a comparative study with vancomycin. At the time, Pfizer was in discussion with the MHRA about emerging concerns about the safety and efficacy of Zyvox compared with vancomycin in a clinical trial in patients with catheter-related infections. Pfizer promptly suspended all advertising that contained this claim.

Three cases this year related to advertising before the granting of a Marketing Authorisation. Such advertising is illegal. MHRA action frequently includes preventive steps such as a requirement to submit advertising and allied materials for vetting before they are issued. The companies involved were Novartis, Merz Pharma (Xeomin case described above), and Huntley Pharmaceuticals.

Advertising for OTC medicines and services

The small number of upheld cases for adverts for OTC medicines (two) again reflects the effectiveness of vetting carried out by the main trade association, the Proprietary Association of Great Britain (PAGB) as part of industry self-regulation. Unusually, we dealt with one complaint this year under older legislation that governs products granted product licences of right, the Medicines (Labelling and Advertising to the Public) Regulations 1978. The company withdrew a reference to the MHRA in advertising on their website.

Upheld cases on offers by third-party suppliers of medicines such as supermarkets or wholesale suppliers were broadly in line with the previous year. The most cited company was Superdrug plc. An initial case involved an in-store magazine that featured endorsement of medicines by a pharmacist, exaggerated claims, and had missing or illegible statutory information. Two further cases of superlative claims on shelf edgers swiftly followed, highlighting a lack of appropriate procedures. The company subsequently visited the MHRA to demonstrate that it had implemented additional procedures and training designed to ensure that: all responsible staff were aware of the legal requirements; advertising materials were checked thoroughly before issue; and that misleading advertising could be withdrawn rapidly and completely from its stores.

Enforcement actions

Cases in this category are handled in association with the MHRA Enforcement Group and those managed by the Advertising Standards Unit are not individually reported on the MHRA website. They mainly relate to the advertising of prescription only medicines to the public, such as clinics offering wrinkle treatments that made promotional references to "Botox". The increase in the number of these cases in the current year is noted above and reflects an increase in competitor complaints following MHRA action.

Notably, this year has also seen the first use of two legal routes to enforce the regulations that govern the advertising of medicines.

First, action was taken under the legal provisions available in the Medicines (Monitoring of Advertising) Regulations 1994 to take out an injunction against persistent advertising in breach of the legislation. In April 2007, Martin Simon

Hickman was jailed for 3 months for failure to comply with the terms of an injunction taken out by the MHRA to prevent advertising and supply of unlicensed medicines and prescription only medicines to the public through websites operated by MSH World Traders Ltd.

Second, a criminal conviction was obtained against Peter Tomlinson whose company Healthwise Clinic Ltd persisted in advertising prescription only medicines to the public despite action taken first by the Advertising Standards Unit and then a caution by the MHRA Enforcement Group. Advertising materials, including leaflets and a website, promoted prescription only medicines to the public. The defendant stated that the business was no longer in operation at the time of the court hearing and was given a conditional discharge for 2 years and ordered to pay costs. Although advertising offences had previously been cited in criminal cases as a subsidiary to the main supply offences, this case was the first time a conviction was secured for advertising offences alone under the 1994 regulations.

These cases demonstrate the commitment of the MHRA to enforce the legislative prohibition on the promotion of POMs to the public.

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Chapter 3 – Protecting public health

Proactive vetting of promotions for significant products to ensure advertising is right first time

In the year to 31 August 2007, the MHRA vetted the advertising for 48 products before issue. We target our prior vetting on innovative new products and those where there is a significant safety concern or previous advertising was misleading. Such action aims to promote high standards and reduce the potential for misleading advertising in these critical areas. This includes vetting of advertising before launch for all new products authorised after 1 November 2005. This requirement was introduced in response to a recommendation in the Health Committee report on the pharmaceutical industry¹.

In the past year, we vetted advertising before launch for 20 new active substances. This number is significantly more than in 2005–06 because 2006–07 is the first full year for which we have vetted advertising for all new active substances. The frequency of other types of vetting done by the MHRA is broadly similar for 2005–06 and 2006–07, although unusually only one reclassified product made available over the counter for the first time, a cold sore cream, was vetted in the current year. Together, the overall total of 48 products represents a small overall additional increase from the previous year (44 products). The table below shows the MHRA's advertising vetting activities since the introduction of this initiative in September 2005.

Vetting statistics for September 2006 to August 2007

	Sept 2005 to August 2006	Sept 2006 to August 2007
New active substances (excluding orphan products)	11	20
Orphan products for rare conditions	7	8
Reclassified products (POM to P)	4	1
Vetted after action on breach of legislation	2	1
Other products (includes safety concerns, major new indications)	20	18
Total	44	48

We have vetted advertising for several innovative products during the current year, including two new vaccines for cervical cancer, a new aid to smoking cessation and three products in a new class of diabetes treatment.

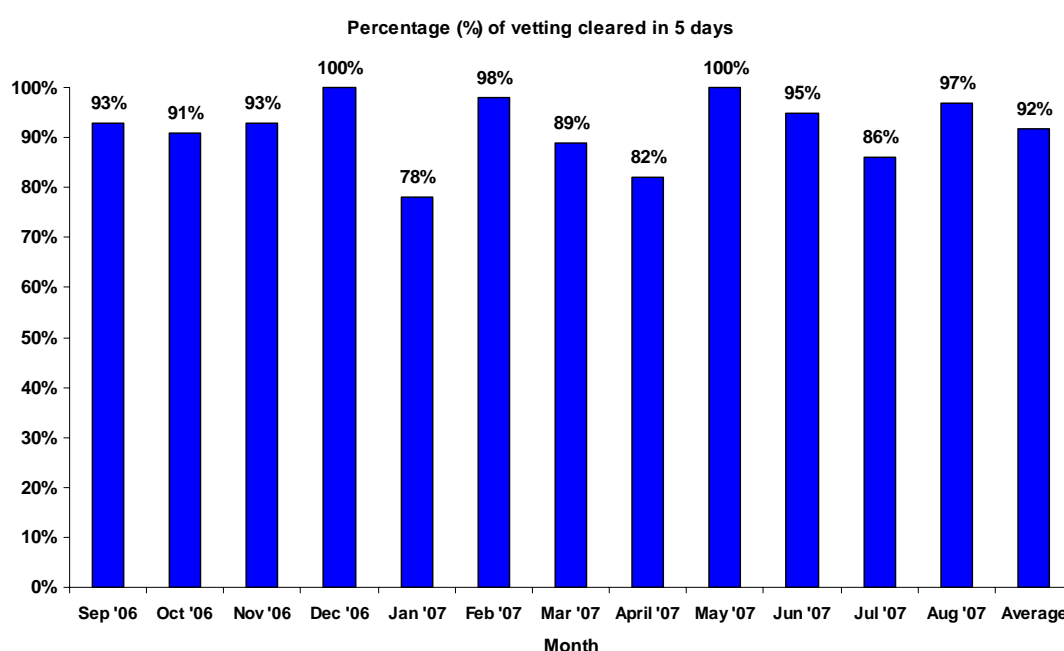
We have also vetted eighteen other products where there have been particular concerns about advertising. These often relate to safety concerns, where it is important that efficacy and safety messages are both presented in a balanced way, or where a limited indication needs to be presented clearly in advertising. Products have included a new testosterone patch, new indications for combination products used in asthma and an established antibiotic following restriction of the indication.

For orphan products for very rare conditions, we adopt a proportionate approach and review only a single submission of advertising material. This year, orphan products we have vetted include Increlex for Hunter's syndrome and Revlimid in the treatment of multiple myeloma.

We aim to cease vetting as soon as we can be assured of a high standard of advertising to support safe use of the product. For new launches, vetting lasts about 2 months, but depends on several factors such as the marketing authorisation holder's programme for development of materials and whether any problems are encountered.

Performance

The Agency has a target to respond to advertising submitted for prior vetting within 5 working days of receipt. In 2006–07, we achieved this target for 92% of pieces submitted and thus met fully our commitment given in the Government response⁶ to the Health Committee report¹ that the requirement for vetting would not cause unnecessary delay to the launch of new products. Moreover, we have significantly improved on the average 78% achievement last year, which reflects the introduction of more-streamlined procedures in 2006. The figure below shows the proportion of advertising vetted within 5 working days by month.



In the First Advertising Annual Report, the MHRA committed to undertake a survey of company experience of vetting. This took place in early 2007 and covered the 30 companies involved in vetting in 2006. The 23 replies received from 21 companies (70%) were on the whole very positive: 18 of 23 respondents rated the overall vetting experience as “good” or “excellent”, and there were no “poor” responses in any category. Full details of the survey were published in MAIL 160⁴. Companies found that scientific advice meetings were particularly valuable as an opportunity to explore MHRA views on advertising materials and potential amendments in more detail. A total of four advice meetings were held in the year covered by this report—all of which were for products that were undergoing vetting.

The Unit has also made several minor changes to improve the vetting procedures in response to comments received to ensure that the procedure continues to promote high standards in advertising without causing unnecessary delay to the marketing of new medicines. We have also updated our advice to companies at the start of the vetting process, which is available on the MHRA website³. This includes an enquiry facility to provide companies with a quick response on whether their product is likely to be a vetting candidate, to aid their launch planning.

Effectiveness

The Health Select Committee identified the vetting of advertising for all new active substances as a key area of importance to the safeguarding of public health by ensuring that advertising for new products is right first time. A direct benefit in terms of complaints avoided cannot be measured, but several indicators are available:

- The number of cases where potentially misleading advertising has been corrected through vetting before publication is not publicly available, but we are aware of a number of significant cases.
- The changes made during vetting may also be one of the factors that has led to a reduction in the overall number of complaints about published advertisements for new products upheld by the Unit and the self-regulatory body, as well as a reduced number of corrective statements (see chapter 2).
- We are aware of only four upheld complaints investigated by the MHRA or the self-regulatory body, the Prescription Medicines Code of Practice Authority (PMCPA), about the advertisements for new products vetted since November 2005. During this period, we have reviewed many hundreds of advertisements.

The upheld complaints concerned:

- Acomplia (rimonabant for weight management), July 2006—an advertisement failed to set the effects of the product on cardiometabolic risk factors in the context of the indication for promotion of weight loss. PMCPA case AUTH/1871/7/06;

- Exubera (inhaled insulin for diabetes), January 2007—a claim that the product “maintains long-term glycaemic control” was not supported by adequate evidence. PMCPA case AUTH/1944/1/07;
- Grazax (grass pollen extract for hay fever), February 2007—claims made in the advertisement did not make clear the restrictions on the use of the product; made claims based on selective data; and did not make the extent of pre-treatment clear. MHRA had asked the company to make the restrictions clear and required a corrective statement;
- Gardasil (cervical cancer vaccine), April 2007—MHRA considered that the claim “reduces the incidence of pre-cancerous vaginal lesions” was misleading because the reduction was not statistically significant.

Reports on every case are published on the MHRA³ or PMCPA⁷ website.

Learning from experience

A review of advertisements reviewed in 2006-7 highlights several key learning points:

- The authorised indication for the product should be clearly stated at the outset to ensure that the claims are set in clear context.
- Advertising for a new product has an educational function and should include key safety information to ensure prescribers are aware of precautions and monitoring necessary before prescribing the product.
- If use of a product in a specific area is mentioned, a balanced picture of all the requirements should be presented. For example, if a claim is made that no dose adjustment is required in moderate renal impairment but there is a need for extra monitoring in this group, then both messages should be stated.
- When reporting on clinical studies, advertising should indicate the absolute effects as well as the relative change to enable an assessment of the clinical relevance of findings. Secondary endpoints should be set in the context of the overall primary outcome of a study.
- Claims based on ongoing studies must comply with any information in the SPC on the study. For example, if the SPC states that the effects of the product are comparable to X, then a superiority claim cannot be made when new data become available until the SPC is updated.

The first two points were also cited in last year’s report and reflect the aim of the Health Select Committee in recommending vetting for new products. We ask all advertisers to consider carefully these points to enable the vetting process to work smoothly.

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Chapter 4 – Working with others

Working closely with other regulatory and self-regulatory bodies to promote understanding of the legal requirements and to set high standards in medicines advertising

Medicines Advertising Liaison Group

We continue to work closely with other bodies that regulate medicines advertising in order to promote high standards and a common understanding of the regulations. The Medicines Advertising Liaison Group (MALG) met twice during the year to discuss areas of common interest such as traditional herbal medicines (THMs—see below) and topical issues arising from casework such as the use of text messages to advertise medicines or provide motivational support to encourage patients to continue with treatment.

We also continue to work with individual bodies with whom we have common interests. We have held discussions with the Prescription Medicines Code of Practice Authority (PMCPA) on the effectiveness of the new ABPI Code of Practice restrictions. This work has focussed on improving our liaison with the PMCPA in dealing with cases (see chapter 2) and on measures to promote reporting of suspected adverse drug reactions via the Yellow Card scheme. The latter arose from the introduction of a new requirement to highlight reporting mechanisms for suspected adverse drug reactions in advertising. MHRA has held discussions with ABPI and PMCPA about measures and revisions to the Code to ensure that this initiative does not adversely affect the existing reporting by health professionals to the Yellow Card scheme, which forms an important part of the MHRA pharmacovigilance system.

Traditional Herbal Medicines (THM)

During the year the MHRA has worked with other regulatory bodies through MALG and the Herbal Forum (a group of companies and trade associations for herbal products) to promote a common understanding of the legal requirements for advertising of THMs licensed under the new Registration Scheme⁸. These products are registered for the treatment of minor conditions on the basis of evidence that they have traditionally been used for at least 30 years. No proof of efficacy is required – nor does it usually exist. A key issue is that advertising for THMs must not mislead about whether efficacy of the product has been demonstrated. Advertising can state the registered indications but should be clear that registration is based on demonstration of traditional use for at least 30 years (including at least 15 within the EU) and should not make other claims that could be interpreted to suggest that the product has been shown to have a therapeutic effect.

Advertising for THMs has to include a statement required by law: “Traditional herbal medicine for the treatment of [indication] exclusively based on long-standing use”. This statement is potentially misleading since it could suggest that consumers need to take the product for a long time to derive a benefit. Guidance mandates adding the clarifying phrase “as a traditional remedy” at the end of the statement. The Medicines Advertising Liaison Group in August 2007 contributed to the MHRA response to the European Commission’s consultation on experience of implementing the provisions of the Directive on traditional herbal medicines (2004/24/EC)⁸, suggesting a revision to the law to provide for greater flexibility in the wording of the statement. The MHRA will continue to press for a change to ensure that the message is clear.

The Unit has also provided advice on the requirements to demonstrate that THMs and ingredients meet recognised organic standards to permit the inclusion of ‘organic’ claims in advertising and product information, and on proposals to develop an identifying symbol for the consumer to show that the product is registered as a THM.

Advertising to teenagers under 16 years of age

During the year, the MHRA reviewed a proposal to permit advertising of over the counter medicines for the treatment of mild to moderate acne directly to teenagers younger than 16 years of age. The proposal recognised that many under 16s already make independent decisions about their health care, that they may well have acne at this age and that they need to be able to access information on treatment options for their condition and on when to seek health professional advice.

UK and European law prohibits the advertising of medicines to children. In the UK, guidance defines a child as a person younger than 16 years of age. This matter is one of national discretion and in some Member States of the European Union, a different age has been chosen.

It is open to the UK to change the minimum age for advertising of any medicine—e.g. by revising the definition of a child to someone younger than 12 or 14 years of age—but, in the MHRA’s view, it is not possible to do this selectively for only some conditions or products. The MHRA concluded that the case had not been made to allow advertising of all over the counter medicines to those younger than 16 years of age. This does not prevent the offer of non-promotional information such as disease awareness materials that give an overview of the treatment options for those under the age of 16 years who have acne.

Guidance for health professionals

In 2006 there were two cases investigated by the PMCPA where ABPI member companies were suspended from membership for failing to maintain high standards in promotional activities. One case involved the provision of hospitality, and the second offered a nurse-led support service to GP practices which the company linked to the promotion of a medicine. Other similar cases where a support service is preferentially offered to practices

likely to prescribe the company's products have also been investigated by the PMCPA⁷.

The MHRA took the opportunity to write to the main regulatory bodies for health professionals to remind them of the requirements of the advertising regulations. Restrictions on gifts and other inducements to prescribe or supply medicines make it illegal for a pharmaceutical company to offer a prohibited inducement and for a health professional to accept one.

The General Medical Council published additional guidance for doctors on conflicts of interest in November 2006⁹. This guidance includes information on declaration of sponsorship for contributors at educational meetings.

The Royal Pharmaceutical Society of Great Britain updated its Code of Ethics and issued associated guidance on Professional Standards and Guidance for Advertising Medicines and Professional Services in August 2007¹⁰.

Independent Review Panel

The MHRA wrote to stakeholders in September 2006 to consult on a proposal to merge the Independent Review Panel for Advertising with the Independent Review Panel for Borderline Products. After careful consideration of the responses the MHRA decided to retain the two separate Panels. However, when the appointments are next due for renewal in 2009, we expect to appoint a single pool of members who will be eligible to serve on each Panel according to their expertise.

A panel for an advertising case will continue to constitute of the legally qualified chairman and two experts chosen by him from the pool of members, one representing the interests of the consumer and one with appropriate medical or pharmaceutical expertise. This arrangement equates to the previous composition of an Advertising Panel. If further special expertise is required (e.g. for a THM), then the chairman will choose a suitable additional member for the Panel to review the case. A full report of the outcome of this consultation has been published on the MHRA website³.

Information developments in the UK

As part of the MHRA's Information for Public Health Group, the Advertising Standards Unit has worked closely with colleagues and other stakeholders to promote access to high quality information about medicines for patients that is not promotional and supports their safe use. In this work, the MHRA is advised by the Commission on Human Medicines Expert Advisory Group on Patient Information¹³.

The MHRA has input into several current Department of Health initiatives that seek to improve access for everyone to quality information that people need to make choices about their healthcare. These initiatives form part of the implementation of its 2004 report, *Better information, better choices, better health: Putting information at the centre of health*¹⁴, and they include proposals for an Information Accreditation Scheme¹⁵ that will "kite mark"

producers of information to make it easier for people to judge the quality of information to make decisions about their health, health care, and social care. We commend this initiative to pharmaceutical companies that wish to produce non-promotional disease-awareness information or patient-support information: it is a way of assuring the quality of materials and signalling such quality to patients.

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Chapter 5 – Future directions

Proactive engagement in initiatives to improve further advertising standards for medicines in the UK

The year ahead

This second annual report is characterised by the effects of increased targeted vetting of advertising for key products on levels of compliance by the prescription sector, which has led to a reduction in complaints upheld and in misleading advertising that required correction. In the year ahead, we will build on this success by continuing to vet advertising for key products, supported by robust systems for timely and thorough investigation of complaints about advertising. We would expect levels of complaints in all areas and the number of products vetted to remain broadly static in the coming year.

We will continue to work closely with companies that submit advertising for vetting and ensure that they have opportunities for feedback as part of a system of continuous improvement in our procedures. Moreover, we expect to move fully to electronic working for processing of complaints and vetting in the next year, including the ability to submit vetting materials and receive responses through the MHRA portal.

New therapeutic areas

During the past year, the MHRA has consulted on innovative applications to make medicines available through pharmacies in therapeutic areas not previously recognised for self-treatment—for instance, tranexamic acid for menorrhagia and naproxen for dysmenorrhoea. If the applications are successful, the MHRA will work with the relevant companies and the PAGB to ensure high standards of advertising for these products and to develop additional specific guidance for the new therapeutic areas if needed.

Self-regulation

The ABPI plans to update its Code of Practice in 2008 to reflect developments since the last revision. These include updates to incorporate changes made in an anticipated new edition of the European Code of Practice operated by the European trade association, the European Federation of Pharmaceutical Industries and Associations (EFPIA), of which ABPI is a member. The MHRA will work with the ABPI and PMCPA to ensure that the revisions to the ABPI Code reflect best practice and take into account issues arising from casework and new developments since the current Code came into operation at the beginning of 2006. This will include revisions to address concerns raised by

the MHRA's Expert Advisory Committees on maintaining reporting of suspected adverse reactions by health professionals via the Yellow Card scheme (see chapter 4).

The MHRA will also work with other regulators and industry stakeholders such as the Herbal Forum to ensure that, as the market for traditional herbal medicines develops, regulatory guidance and scrutiny is in place to support high standards of advertising. We will continue to press at a European level for greater flexibility in the wording of the statement required by law in advertising for registered herbal products, to ensure that the message is clear and consumers are not misled.

Judicial review

In December 2006, the MHRA (acting on behalf of the Secretary of State) was the subject of an application by the ABPI for judicial review of a decision that measures taken by Primary Care Trusts to promote cost-effective prescribing of statins were not in breach of the provisions of Regulation 21 of the Medicines (Advertising) Regulations 1994. These provisions prohibit the offer of inducements to prescribe medicines to health professionals as part of the promotion of medicines. The MHRA, together with colleagues in the Department of Health who are responsible for NHS prescribing, will defend this application vigorously.

Better regulation initiatives

In March 2005, the Final Report on the Hampton Review of regulatory inspection and enforcement was published¹⁶. This review was designed to identify measures to reduce the administrative cost of inspection and enforcement to a minimum but to a level that is consistent with maintaining the UK's excellent regulatory outcomes. The recommendations of the review have been accepted by government, and all regulators (including the MHRA) are expected to comply with the set of Hampton principles.

The subsequent Macrory review of regulatory penalties¹⁷, published in November 2006, examined issues raised in the Hampton Review about the penalties available for regulatory offences in the UK. The review made several recommendations that aim to ensure that regulators have access to a flexible set of modern fit-for-purpose sanctions that can be applied in a risk-based proportionate and appropriate way as outlined in the Hampton Report. The government accepted the recommendations in the Report in full and has consulted on draft legislation to take forward key recommendations from this report.

The MHRA is currently undertaking an internal review to ensure that all its processes are Hampton-compliant. Once compliance has been demonstrated, the Advertising Standards Unit plans to work with Enforcement colleagues to investigate whether powers under the Macrory penalties system can be used to provide sanctions for advertising offences that are more readily available than court proceedings. This project will be long term and stakeholders will be consulted fully as it develops.

Information for patients - European developments

Commission report on current practice

In April 2007, the European Commission issued for consultation a 'Draft report on current practice with regard to provision of information to patients on medicinal products'¹¹. This fulfilled a requirement under Article 88a of Directive 2001/83/EC for the Commission to present a report to the European Parliament and the Council in 2007 on "current practice with regard to information provision – particularly on the Internet – and its risks and benefits for patients". Although based on a common basic principle that advertising to the public is prohibited for prescription only medicines, evidence showed that the rules and practices on what information can be available still vary significantly among Member States.

In its response, the MHRA expressed its support for access for patients to high quality information about medicines and other treatments within the current legal framework to ensure that the prohibition on advertising of prescription only medicines directly to patients remains in place.

We recommended that the strategy for the provision of patient information to all in the European Union should be based on three pillars in line with the work already underway in the Pharmaceutical Forum (see below):

- improvement of the quality of statutory patient information, which should form the cornerstone of information for patients;
- accreditation of non-statutory medicines information based on quality criteria;
- promulgation of the concept of "information partners" such as health professionals and patient organisations to promote better access to the information.

Pharmaceutical Forum

Through its Working Group on Information to Patients, the European Pharmaceutical Forum[†] has continued to explore ways to improve the quality of, and access to, information on authorised medicines and related health areas to European patients. This initiative focuses on disease information, electronic and non-electronic dissemination of information, and the availability of supporting information in the healthcare setting to supplement the key role of health professionals.

The Forum issued a consultation on its work in March 2007¹². This venture also sought views on a set of principles on good quality information and a pilot diabetes information package developed by a consortium of Member States and industry stakeholders led by the UK.

[†] The Pharmaceutical Forum brings together Ministers from all European Member States, Representatives of the European Parliament, the Pharmaceutical industry, health care professionals, patients and insurance funds. The aim is to improve the performance of the pharmaceutical industry in terms of its competitiveness and contribution to social and public health objectives.

The consultation responses supported the quality principles, with suggestions for improvement, and were supportive in principle for the provision of information at a European level consistent with the diabetes information model. There are a number of options as to how the principles might be used ranging from full regulation of this additional information by regulatory agencies such as the MHRA to self-regulation by the sponsor of the information. These initiatives will now be taken forward by the Working Group.

The MHRA will continue to participate fully in these European initiatives to promote the availability of, and access to, good information for patients and the public about medicines, within the current legal framework that prohibits advertising to the public for prescription only medicines.

Measuring our impact

Looking forward, the most important question remains whether the work of the Advertising Standards Unit improves the quality of published advertising materials. Evidence from the past year suggests that it has—and without adverse delay to the introduction of new medicines. In the coming year, we will maintain our focus on prevention of misleading advertising by vetting for key products, and on securing effective action on misleading advertising identified through complaints and our scrutiny of published advertising.

The MHRA will continue to take swift action where any serious potential breach of the regulations is identified and where a risk to patient safety is identified.

References

1. House of Commons Health Committee. The influence of the pharmaceutical industry. London: The Stationery Office Limited, 2005. (<http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf>)
2. The Medicines and Healthcare products Regulatory Agency. The Blue Guide: advertising and promotion of medicines in the UK. London: The Stationery Office Limited, 2005. (http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dID=17493&noSaveAs=0&Rendition=WEB)
3. Full information about the regulation of medicines advertising is available on the MHRA website, www.mhra.gov.uk, under How we regulate/Medicines/Advertising of medicines. (http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=165)
4. The Medicines and Healthcare products Regulatory Agency. MAIL: the MHRA updating service for medicines. Published bimonthly on the MHRA website. (http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=380)
5. The Medicines and Healthcare products Regulatory Agency. Drug Safety Update. Published monthly on the MHRA website. (http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=1100)
6. Department of Health. Government response to the Health Committee's report on the influence of the pharmaceutical industry. London: The Stationery Office Limited, 2005. (http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4118604&chk=4imzAe)
7. Prescription Medicines Code of Practice Authority. Reports of all cases are published on the PMCPA website, www.pmcpa.org.uk. (<http://www.pmcpa.org.uk/?q=completedcases>)
8. The Medicines and Healthcare products Regulatory Agency. Details of the Traditional Herbal Medicines Registration Scheme. (http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=95)
9. General Medical Council. Ethical guidance – Conflicts of Interest. November 2006. (http://www.gmc-uk.org/guidance/current/library/conflicts_of_interest.asp)
10. Royal Pharmaceutical Society of Great Britain. Code of Ethics for Pharmacists and Pharmacy Technicians. Professional standards and guidance for advertising medicines and professional services. August 2007. (<http://www.rpsgb.org/protectingthepublic/ethics/>)
11. European Commission. Draft report on current practice with regard to provision of information to patients on medicinal products in accordance with

Article 88a of Directive 2001/83/EC, as amended by Directive 2004/27/EC on the Community code relating to medicinal products for human use. Brussels: Enterprise and Industry Directorate-General, 2007.

(http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_04/draft_info_patients2007_04.pdf)

12. European Commission. Public consultation on Health-related information to patients. Brussels: High Level Pharmaceutical Forum, 2007

(http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm)

13. Information about the work of the Expert Advisory Group on Patient Information is available on the MHRA website, www.mhra.gov.uk, under Committees/Medicines advisory committees/Commission on Human Medicines/Expert Advisory Groups/Patient Information.

(http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=962)

14. Department of Health. Better information, better choices, better health: Putting information at the centre of health. London: DH Publications, 2004.

(http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4098576)

15. Information on the Department of Health proposals for an Information Accreditation Scheme is available on the DH website, www.dh.gov.uk.

(<http://www.dh.gov.uk/en/Policyandguidance/PatientChoice/Choice/BetterInformationChoicesHealth/Informationaccreditation/index.htm>)

16. Hampton P. Reducing administrative burdens: effective inspection and enforcement. London: HMSO, 2005.

(<http://www.hm-treasury.gov.uk/media/7/F/bud05hamptonv1.pdf>)

17. Macrory RB. Regulatory Justice: Making Sanctions Effective. London: Better Regulation Executive, 2006.

(http://bre.berr.gov.uk/regulation/documents/pdf/macrory_penalties.pdf)

Abbreviations

ABPI	Association of the British Pharmaceutical Industry
ASA	Advertising Standards Authority
ASU	Advertising Standards Unit
EFPIA	European Federation of Pharmaceutical Industries and Associations
GP	General Practitioner
IRP	Independent Review Panel
MALG	Medicines Advertising Liaison Group
MHRA	Medicines and Healthcare products Regulatory Agency
OTC	Over the counter
PAGB	Proprietary Association of Great Britain
PIL	Patient Information Leaflet
PMCPA	Prescription Medicines Code of Practice Authority
POM	Prescription Only Medicine
SPC	Summary of Product Characteristics
THM	Traditional Herbal Medicine
VRMM	Vigilance and Risk Management of Medicines

