

# **Delivering High Standards in Medicines Advertising Regulation**

Fifth Annual Report  
September 2009 – December 2010

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

## **Foreword**

I am delighted to welcome this, the fifth annual report of the MHRA Advertising Standards Unit. It covers a slightly longer time period than before and continues the developing story of effective regulation through clear guidance and proportionate action to prevent and correct misleading advertising. Setting proportionate standards and effectively underpinning self regulation remain the cornerstones of the Agency's role.

Action on breaches of the law is important but high quality guidance is key to helping advertisers to comply with the law and avoid complaints. I welcome the recent initiatives on guidance for advertising traditional herbal and homeopathic medicines and the impact of transparency and guidance on reducing complaints.

The flexibility of Codes of Practice to respond to changes in stakeholder expectations is reflected in the changes this year to the ABPI Code of Practice for the pharmaceutical industry to outlaw most promotional gifts for health professionals.

The law is a much harder thing to change. The current MHRA review of medicines legislation provides a once-in-a-generation opportunity to ensure that the law on advertising continues to address the challenges of modern communications media not dreamt of when the law was first passed in 1968.

This year we have also welcomed the judgment of the European Court of Justice that actions taken by the National Health Service to ensure appropriate use of funds are not caught by the restrictions placed on pharmaceutical companies and others who seek to promote sales of medicines.

In 2011, we look forward to working with European colleagues on proposed changes on information to patients and with UK regulatory bodies, the pharmaceutical industry and other advertisers to ensure continued high standards in advertising for medicines to support their safe use.

**Kent Woods**  
**Chief Executive**

# Contents

Chapter 1	Setting the scene
Chapter 2	Listening and responding
Chapter 3	Protecting public health
Chapter 4	Working with others
Chapter 5	Legal perspective
Chapter 6	Future directions

References

Abbreviations

# 1

## Chapter 1 – Setting the scene

*Maintaining transparency in how medicines advertising is regulated in the UK*

This is the fifth annual report of the MHRA Advertising Standards Unit, designed to promote transparent regulation of medicines advertising in the UK. Separate chapters cover action on complaints, vetting of advertising prior to issue, working with others to ensure effective regulation and forthcoming changes to the legal framework.

In 2010 the decision was made to switch to publishing a report for each calendar year. This report therefore covers the 16 month period from September 2009 to December 2010. The next report will cover activities in 2011, and will be published in early 2012.

### **Five year perspective**

It is now five years since the Government issued its response<sup>1</sup> to the Health Select Committee report, *The influence of the pharmaceutical industry*<sup>2</sup>, in September 2005. In the Government's response a commitment was given to increase transparency in the regulation of medicines advertising and to the publication of annual reports. The first report covered the year since the response was published, from September 2005 to August 2006.

The five year milestone is a good time to review the progress that has been made in safeguarding public health through effective regulation of medicines advertising since 2005. The commitment made to vet advertising for all new active substances has led to an increase in the numbers of products vetted to about 50 per year. This has been accompanied by a significant reduction in the numbers of complaints investigated about advertising for these products, suggesting that this preventive action has been successful. Details of the work of the Agency in vetting of advertising can be found in chapter 3 of this report.

Over the same period, there has been a significant increase in the numbers of complaints about suppliers advertising prescription only medicines as part of the treatment services they offer; for example clinics offering treatment with botulinum toxin for lines and wrinkles, or erectile dysfunction treatment services. Most of these cases relate to advertising on the internet, reflecting its increasing importance as a communication medium. Details of the steps the Agency has taken to manage this activity and increase transparency are provided in chapter 2 of this report.

## **The Advertising Standards Unit in the MHRA**

Responsibility for advertising regulation sits within the Vigilance and Risk Management of Medicines (VRMM) division of the MHRA. The Advertising Standards Unit is currently part of the Information for Public Health Group, which also covers regulation of statutory product information. During the year proposals were made to realign the division to better meet business needs and public health responsibilities. This will expand this group to cover wider issues around access to medicines and outreach and professional education. Grouping all these related outward facing activities will produce synergies and improved service for stakeholders, as well as enhanced public health protection.

The advertising team uses the expertise of assessors from the VRMM and Licensing divisions to review advertising materials. The team also works closely with other colleagues across the Agency as required to provide a joined-up service. This includes working with the Herbal Policy team on matters relating to traditional herbal medicines, with the Enforcement Group on cases where advertising is linked to illegal supply of medicines and with the Borderline team where medicinal claims are made for products that do not have a marketing authorisation.

In November 2010 the Agency moved to new offices in Buckingham Palace Road, a stone's throw from London Victoria station. Our new offices are open-plan with limited storage facilities for paper records. In preparation for this move, we have switched to completely electronic communication and filing systems. Our current policy is to retain full electronic records of actions on complaints for seven years after completion of the case. Records of vetting are only retained for two years after completion of the exercise in the expectation that any complaint about the claims made would be received within this period.

### **Serving our stakeholders**

Transparency is a key aspect of our service to stakeholders and the Unit has taken a range of actions in the last year to increase openness of our work in regulating medicines advertising. These have included:

- Published outcome reports for 34 complaint and scrutiny cases on the MHRA website, including lists of companies supplying botulinum toxin products who have amended their advertising.
- Regular monthly updates on performance of vetting posted on the MHRA website.
- An annual seminar for industry on current hot topics in advertising regulation, with examples of good and bad advertising.
- A range of published guidance including new advice for journalists and patient organisations on how to keep out with the advertising controls when talking about medicines.
- Close working with self regulatory bodies to ensure consistent standards.

Information about all these actions can be found on the MHRA website<sup>3</sup> at [www.mhra.gov.uk](http://www.mhra.gov.uk). The website also includes general information and guidance about regulation of medicines advertising and the MHRA Blue Guide, *Advertising and promotion of medicines in the UK*<sup>4</sup>.

This year has seen a significant increase in the number of enquiries coming in to our dedicated mailbox, [advertising@mhra.gsi.gov.uk](mailto:advertising@mhra.gsi.gov.uk). The team does not have the resources to offer a review service for individual advertisements prior to issue but is always ready to provide advice on compliance with a specific point of law or whether advertising for a new product will need to be submitted for vetting.

# 2

## Chapter 2 –Listening and responding

### *Taking action on misleading advertising to safeguard public health*

The MHRA receives complaints and referrals from various sources including members of the public, healthcare professionals and other interested parties who have concerns about medicines advertising. Complaints can be made using the complaint form on the MHRA website<sup>3</sup>, by sending an email to the advertising mailbox or by post. In addition to the concerns raised, we find it helpful when complainants provide a copy of the advertisement with details of where and when it was published.

Details of how we investigate complaints are given in a Fact Sheet which is available on the MHRA website<sup>3</sup>. The Fact Sheet is also provided to all complainants and advertisers to inform them of what to expect from our investigation. An outcome report summarising the case is generally published on the MHRA website on conclusion of our investigations.

### **Action on complaints**

This reporting period, from September 2009 to December 2010, has been a very busy time for the Advertising Standards Unit. There has been a further significant increase in the annual number of complaints received, with one third more than the previous year. Details are provided in the table below. The figures in brackets in the right hand column show the numbers during the 12 month period for September 2009 to August 2010, to allow comparison to the previous figures which compare years from September to August.

### ***Complaints received***

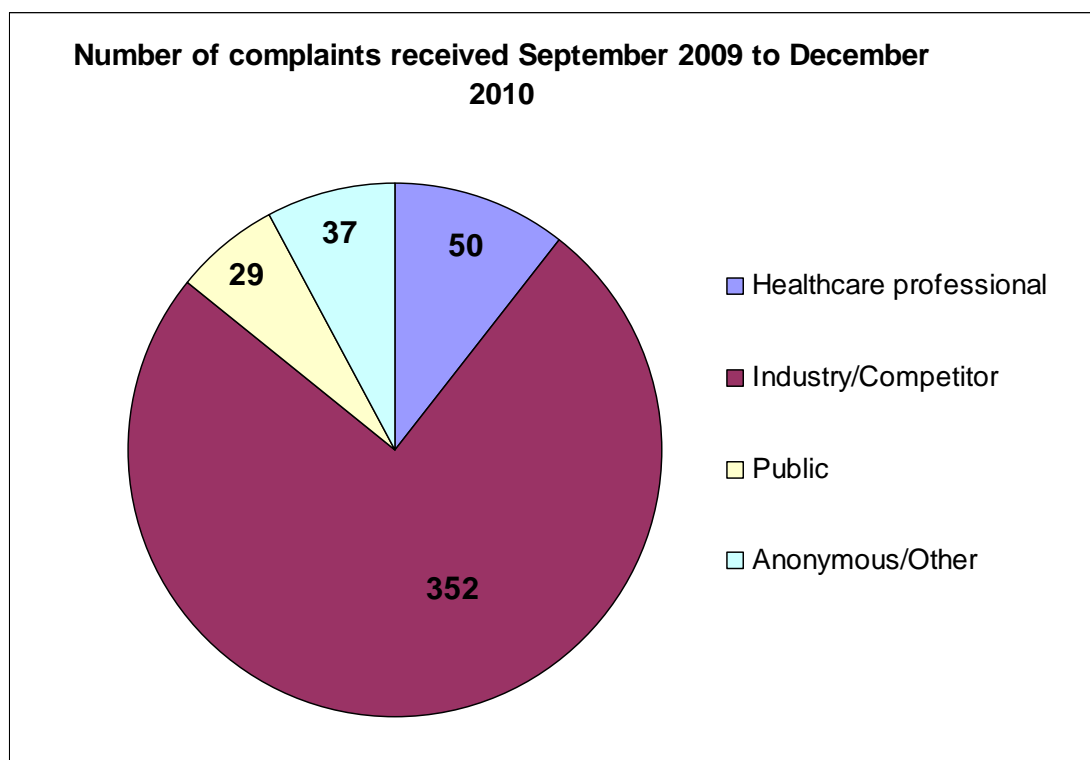
	September 2007 to August 2008	September 2008 to August 2009	September 2009 to December 2010 *
Complaints received	190	277	<b>468 (369)</b>
Investigations initiated	178	268	<b>437 (343)</b>
Complaints referred to Agency colleagues	5	5	<b>29 (24)</b>
Complaints covering matters raised previously	5	1	<b>2 (2)</b>
Complaints investigated by PMCPA or ASA	2	3	<b>0</b>

\*Figures in brackets show the total for the 12 months from September 2009 to August 2010

The continued marked increase from the previous year (277) was mainly due to a rise in the number of complaints received about advertising of botulinum toxin products and other prescription only medicines to the public by cosmetic clinics and service providers such as online pharmacies. A large number of these complaints originated from competitors who had themselves been subject to MHRA action and wished to ensure a level playing field.

Occasionally complaints received at the MHRA relate to matters that fall outside the scope of the medicines advertising legislation. We make every effort to ensure that the complaint is dealt with appropriately. We can either refer the case to another responsible organisation such as the Advertising Standards Authority (ASA) on the complainant's behalf or advise them as to where to direct their complaint. Unusually, there were no cases where the MHRA received a complaint submitted to both the Agency and another self-regulatory organisation.

### ***Sources of complaints received September 2009 to December 2010***



About 75% of the complaints received between September 2009 and December 2010 were received from competitors. A large proportion of the cases related to advertising of botulinum toxin to the public and advertising of other prescription only medicines (POMs) by third parties, mainly on websites.

Around 43% of the remaining complaints came from healthcare professionals with the rest originating from the public, other organisations and anonymous

sources. This shows a significant increase in complaints received from healthcare professionals compared to previous years.

Excluding the competitive third party POM advertising complaints, about a third of the complaints received were shared equally by the public and anonymous and other organisations. The remaining two thirds were split fairly equally between industry competitors and healthcare professionals. Very few cases related to competitor complaints about prescription medicines by marketing authorisation holders since these are usually dealt with under the self regulatory system.

### ***Outcome of complaints***

	September 2007 to August 2008	September 2008 to August 2009	September 2009 to December 2010 *
<b>Medicines advertising cases resolved</b>	172	249	<b>444 (331)</b>
Advertisements withdrawn	116 [67%]	189 [76%]	<b>386 [87%] (276 [83%])</b>
Corrective statements required	2	2	<b>3 (2)</b>
Summary reports published (excludes enforcement cases)	35	25	<b>34 (25)</b>

\*Figures in brackets indicate the total for the 12 months from September 2009 to August 2010

In the 16 month period, we resolved 444 advertising complaints. The chart below indicates the trend for complaints received and cases resolved for the last three years.

## Trends in complaints from 2007 to 2010



This reporting period shows a significant increase in the proportion of cases upheld out of the total proportion resolved, from 76% last year to 87%. The figure reflects both the marked increase in the number of enforcement cases and more streamlined procedures. If the first review of a complaint indicates that there may not be a case to answer and there is not a significant public health risk, we usually provide an initial response to the complainant explaining our published policy and the legal requirements. Unless complainants request us to take the case further and institute a formal investigation, we do not record these cases as complaints.

During this reporting period enforcement cases resolved totalled 408 (304 for 12 months), significantly more than the total number of complaints we received last year. Enforcement cases are dealt with in association with the MHRA's Enforcement Group. Cases resolved by the Advertising Standards Unit are not reported separately on the MHRA website to ensure consistency across this shared responsibility.

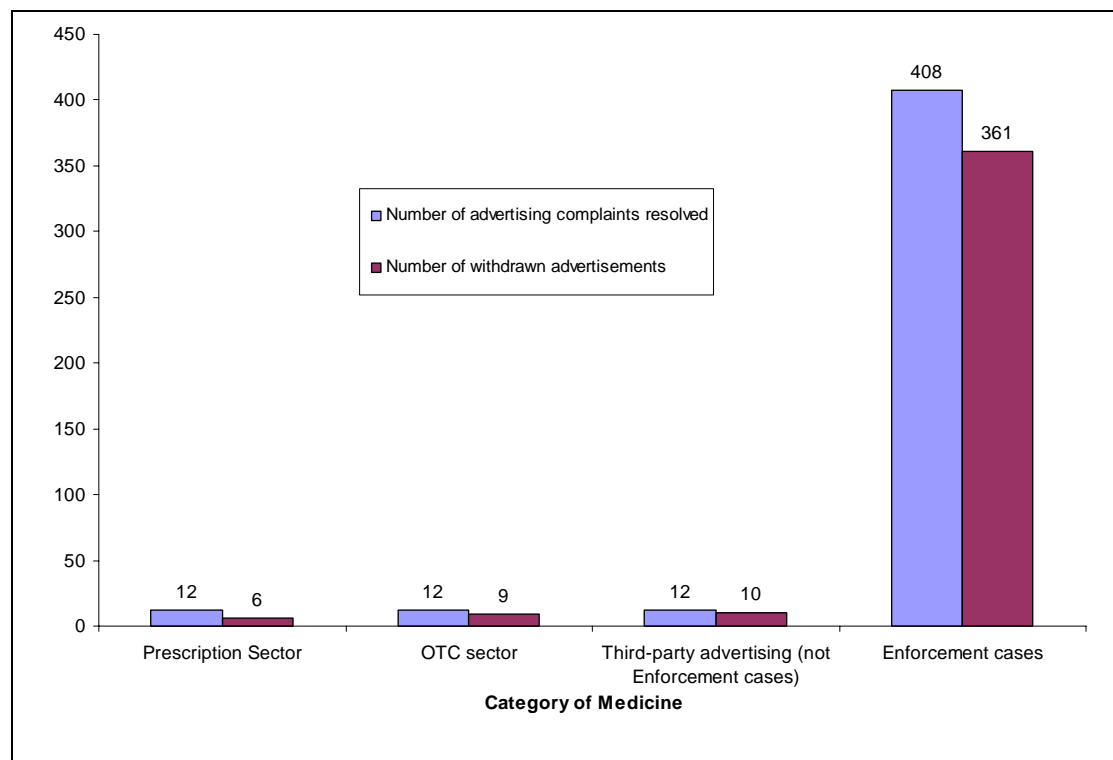
These cases were mainly concerned about the advertising of POMs to the public, for example, by clinics offering wrinkle treatments that make promotional references to botulinum toxin and websites and on-line pharmacies promoting and supplying treatment services for various conditions including erectile dysfunction, weight loss or swine flu.

We have found over the years that increasing action on the part of the MHRA in this area drives a further increase in complaints as offenders who have been the subject of complaints in turn complain about their competitors. To manage this increase within our existing resources, we have made changes in our handling of botulinum toxin cases. We have streamlined our

procedures to reduce the number of letters sent out. We now provide more information to complainants about our actions to avoid accusations that we are targeting individuals. We have also increased transparency by publishing on the Agency website a list of clinics that have revised their advertising following MHRA action on complaints received since January 2010. Updated lists are now published monthly with the reports of other complaint cases.

Following these actions, we have seen a notable drop in the number of these complaints, with the rate in the last four months of 2010 nearly down to the rate in 2008-9. We anticipate that this reduction will continue.

***Advertising complaints by category of medicine September 2009 to December 2010***



Apart from the cases dealt with in association with the Enforcement Group, we publish the summary outcome reports of all cases on the MHRA website on completion of each investigation. During the period ending December 2010, we published 34 summary reports for complaint cases, 25 of which were over the 12 month period. This was similar to the previous year.

We required the issue of three corrective statements (a measure of the seriousness of the complaint) during this reporting period. The first related to a complaint about a promotional mailing regarding Azzalure which promoted the product outside its authorised indication for glabellar lines (vertical lines between the eyebrows).

The second corrective statement was required for the promotion of an unlicensed medicine for premature ejaculation in a Lloyds Pharmacy press release announcing the start of a new medical advice and treatment service

for men with premature ejaculation. The press release clearly promoted the product rather than the service and gave rise to considerable coverage of the product's availability in the press. As well as the correction required by Lloyds, journalists were also contacted about their responsibilities in ensuring that prescription medicines are not promoted to the public and referred to recent MHRA guidance.

The third corrective statement related to a DHB Oral Healthcare advertisement distributed to dentists, offering free chocolates and gift vouchers with purchases of medicines. Under the medicines advertising regulations gifts must be relevant to the practice of medicine (including dentistry) or pharmacy.

All the corrective statements are published on the MHRA website<sup>3</sup> as part of the summary report of the complaints investigated. All complaint cases were resolved through voluntary agreement with the companies concerned during this reporting period without resort to statutory procedures.

### **Monitoring of advertising**

Another key function of the MHRA is to monitor medicines advertising directed at both healthcare professionals and the public. We routinely scrutinise a selection of widely read publications and take appropriate action as and when required on any potential breach of legislation. We also encourage all our Agency colleagues to bring to our attention any advertising that they may be concerned about.

As a result of MHRA monitoring and internal referrals from colleagues, we identified 12 potential breaches of medicines advertising legislation during this period, a return to more usual levels after the low number of cases last year (3). The potential breaches were varied, ranging from advertising of unlicensed medicines or indications to misleading and exaggerated claims. Corrective statements (reserved for serious cases with public health implications) were also required in three of these cases. Summary reports on all 12 cases have been published on the MHRA website<sup>3</sup>.

### ***Outcome of scrutiny and internal referral cases September 2007 to December 2010***

	September 2007 to August 2008	September 2008 to August 2009	<b>September 2009 to December 2010 *</b>
Advertisements withdrawn	11	3	<b>12 (11)</b>
Corrective statements	1	0	<b>3 (2)</b>

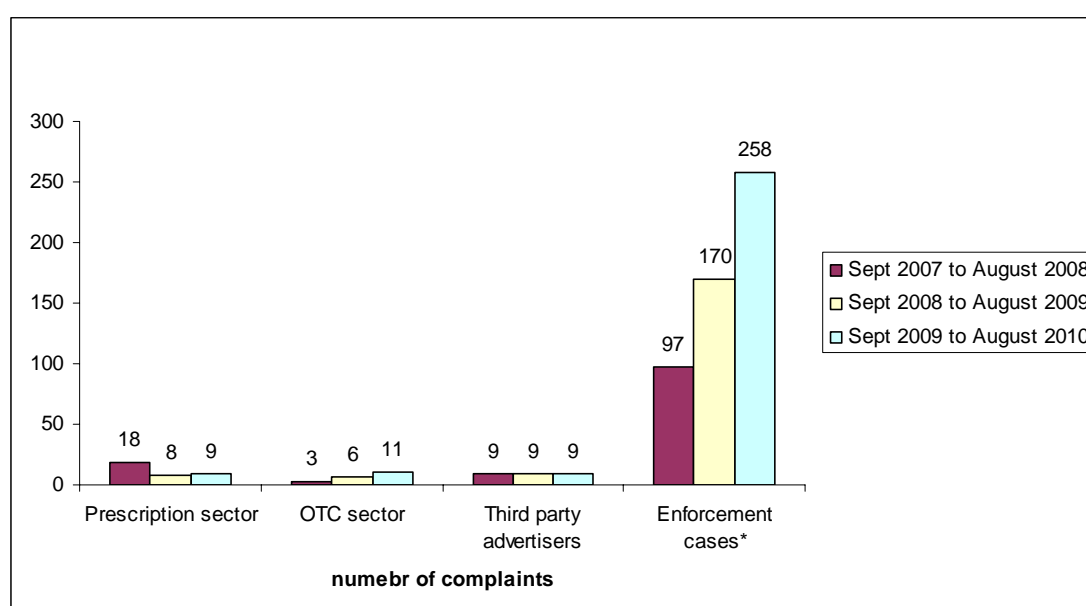
\*Figures in brackets indicate the total for the 12 months from September 2009 to August 2010

## Key issues in advertising complaints and monitoring

The graph below provides an overview of the number of advertising cases upheld by the MHRA in the past three years. It covers both internal monitoring and complaints. The information is broken down by sector as follows:

- prescription only medicines,
- over-the-counter medicines, including traditional herbal medicines,
- advertising by third parties such as supermarkets or pharmacies, and
- cases dealt with in association with the MHRA Enforcement Group.

### *Upheld cases by category of medicine for 2007 to 2010*



## Advertising of prescription medicines to healthcare professionals

Notable among the cases reported during 2009–10, the MHRA upheld two serious cases about advertising for medicines that did not hold a valid marketing authorisation. The Lloyds Pharmacy case is discussed above.

In exceptional circumstances companies may disseminate limited factual information to health authorities or budget-holders about novel medicines where their introduction is expected to have significant cost implications to help in planning their expenditure over future years. We investigated one case where the company was considered to be using this as an excuse for promoting their product before grant of a marketing authorisation.

Following completion of this case, the MHRA had received allegations from an anonymous source that the company was continuing to promote its unlicensed medicine to healthcare professionals. In the absence of any actual evidence of promotion, the MHRA took a compliance approach and asked the Prescription Medicines Code of Practice Authority<sup>5</sup> (PMCPA) to

investigate the allegations. The PMCPA upheld the complaint (case AUTH/2327/6/10).

We also took action on four cases of products advertised outside their authorised indications. We regularly monitor cases investigated under the self regulatory system and became aware of the promotional activities of a company following review of a completed case<sup>5</sup> (case AUTH/2231/5/09). The Authority had ruled that exhibition panels displayed at a British Society for Haematology meeting promoted unlicensed indications for the product. The MHRA was concerned at the apparent non-adherence of the company to MHRA advice and general principles already agreed during the period of vetting for the product. We wrote to the company to remind them of their ongoing obligations and reviewed subsequent materials to ensure they did not promote unlicensed use of the product.

The MHRA generally does not take action on a case already investigated by the PMCPA but in 2010 we took action for the first time on a case which had been the subject of PMCPA ruling<sup>5</sup>. The survey was found to be promoting unlicensed use of botulinum toxin products in the guise of a survey. An associated payment of a cheque for £35 to recipients of the survey as recompense for “anticipated help in this study” was ruled not to breach the ABPI Code by the Appeal Board on a technicality (case AUTH/2274/10/09). The MHRA disagreed with the ABPI Appeal Board ruling and considered that a payment made in association with a promotional questionnaire was an inducement and in breach of the medicines advertising legislation.

We made a formal determination in this case and sought advice from the Independent Review Panel on Advertising. The survey was found to be an advertisement that promoted an unlicensed use of botulinum toxin products to doctors and the associated payment amounted to a prohibited financial benefit in breach of the Advertising Regulations. A corrective statement was required to be sent to all recipients of the survey.

We also took action on a disease awareness website aimed at the public that exaggerated the impact and prevalence of testosterone deficiency syndrome and promoted the use of testosterone replacement therapy to the public.

### **Advertising of over-the-counter medicines**

During this reporting period we saw a significant increase in the number of complaints upheld on OTC medicines compared to last year. Four of the seven upheld complaints related to traditional herbal medicines (THMs). The main concerns were that advertising of the THMs suggested that efficacy had been demonstrated when registration of the products is based on long-standing use as a traditional remedy.

To promote compliance the MHRA issued guidance on consumer advertising for registered traditional herbal remedies. We are also working with the self-regulatory bodies for OTC products to ensure that self regulation is equally effective in the herbal sector and we are encouraging manufacturers of these

products to become members of trade associations to help bring their advertising into regulatory compliance. Generally a condition of membership of the organisations requires all consumer advertisements to be vetted prior to publication.

One case of particular interest that was upheld during the year concerned an OTC antihistamine. It was alleged that “Fast acting hay fever relief” claims relating to a branded loratadine product were not supported by adequate evidence. The complainant, a competitor company, initially tried to resolve the concerns raised with the marketing authorisation holder (MAH). But having not obtained a satisfactory result, the complaint was then referred to the Proprietary Association of Great Britain (PAGB) for arbitration who ruled in favour of the MAH. The complaint was then submitted to the MHRA. We reviewed the existing data and concluded that on the balance of all the evidence available there was inadequate evidence to show that symptomatic relief would be achieved within about 30 minutes of taking the product.

This specific complaint generated further regulatory action by the MHRA. All marketing authorisation holders for loratadine products were informed that the fast-acting claim was no longer acceptable in advertising and should not be used in their advertising. In addition to this colleagues in the Patient Information Quality Unit are taking action to ensure no fast acting claims are included on the labelling of loratadine products.

### **Third party advertising**

During this reporting period there has been a small increase in the number of upheld cases concerning third-party advertising. These cases in general involve pharmacies or other suppliers who advertise the service they provide or the range of medicines on offer.

As an example, we investigated a complaint from a healthcare professional about an offer of Botox as a competition prize in a woman’s magazine – advertising of a prescription only medicine to the public. The magazine promptly withdrew Botox as a competition prize.

We received a small number of complaints and referrals about sale of excessive quantity of OTC analgesics containing paracetamol. The MHRA has made it clear that it strongly discourages the sale of large quantities of analgesics because it undermines the intention of the Government’s pack-size restrictions to minimise toxicity in overdose. The retailers committed to adhere to the voluntary restriction on selling more than two packs of analgesics per transaction in line with the MHRA guidance - *Best practice on the sale of medicines for pain relief* – which was published in December 2009. In order to safeguard public safety the MHRA is keen for advertising and promotion of medicines to be responsible and of the highest standard particularly in the area of self-medication and not encourage consumers to purchase medicines that they do not need.

Summaries of the outcomes of all the above cases are published on the MHRA website.

### **Enforcement actions**

We have noticed a considerable increase in the number of complaints received and handled under the agreement with our Enforcement Group during this reporting period. Generally parties that have been the subject of a complaint in turn complain about their competitors. Most cases were dealt with by negotiation with the party concerned.

When required, the Advertising Standards Unit also provides specialist advice and statements when advertising offences, usually in association with offences under the legislation on supply of medicines, are being considered for prosecution.

The MHRA successfully prosecuted a case relating to the online advertising of prescription only and unlicensed medicines by William Parsons, a pharmacist now retired. Parsons was found guilty by a jury and was sentenced to 9 months imprisonment suspended for two years and 150 hours unpaid community work. He also faces confiscation proceedings.

In another case where a doctor had previously been convicted of advertising offences, the General Medical Council investigated Dr Dinesh Maini and gave him a warning.

### **Feedback and audit of complaints**

We regularly audit a selection of complaint cases to identify learning points, improve our internal procedures and make future investigations more timely and efficient.

The last audit of a selection of complaint cases identified some measures that should improve our procedures. To avoid any delay in the investigation of complaint cases, particularly of those cases that pose a risk to public health, we ensure that acknowledgements for receipt of communications requiring action are received from the company. It is essential that correspondence about important issues reaches the appropriate responsible person in the company concerned.

During the year, we have completed the move to electronic record keeping in our strategy to go paperless, particularly with regard to our recent move to new premises. We also review cases at time of closure to ensure all outstanding actions have been completed and that our records are complete and up-to-date.

# 3

## Chapter 3 – Protecting public health

### *Targeted vetting of advertising before issue*

Proactively reviewing advertising prior to issue helps to reduce the chance of misleading messages about medicines being published and distributed. Taking a risk-based approach, the MHRA vets advertising for innovative prescription and over-the-counter products prior to launch. We also target products linked to particular safety concerns and cases where previous advertising has been in breach of the Advertising Regulations.

The table below provides a summary of our vetting activities over the last three years. The figures in brackets in the right hand column of the table below show the number of products vetted during the 12 month period for September 2009 to August 2010, to allow comparison to the previous figures which compare years from September to August.

### ***Vetting statistics for September 2007 to December 2010***

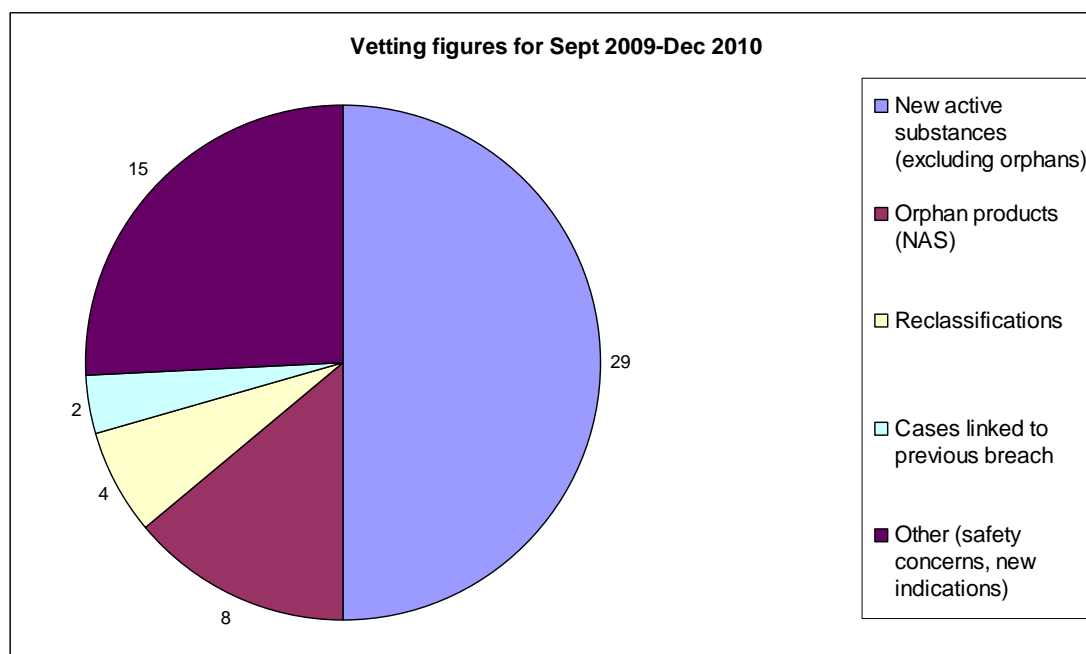
	Sept 2007 to Aug 2008	Sept 2008 to Aug 2009	<b>Sept 2009 to Dec 2010 *</b>
New active substances (excluding orphan products)	28	31	<b>29 (25)</b>
Orphan products for rare conditions	8	6	<b>8 (7)</b>
Reclassified products (POM to P)	5	5	<b>4 (3)</b>
Vetted after action on previous breach	1	0	<b>2 (2)</b>
Other products (includes safety concerns, major new indications)	15	13	<b>15 (13)</b>
<b>Total</b>	<b>57</b>	<b>55</b>	<b>58 (50)</b>

\*Figures in brackets show the total for the 12 months from September 2009 to August 2010

During the period from September 2009 to December 2010 the MHRA vetted advertising prior to issue for 58 medicines. Comparing the 12 month time periods of September 2008 to August 2009 and September 2009 to August 2010, the number has decreased slightly from 55 to 50 products. Prior to 2008, the number of products vetted had steadily increased for several years as the MHRA increased its reliance on targeted vetting and met its commitment to review launch advertising for all new active substances. Since then, the number of products vetted had reached a plateau until this year.

The decrease during the past year reflects a reduction in the number of new active substances granted a marketing authorisation by the European Medicines Agency (EMA). The numbers of other products vetted have stayed at similar levels to the previous year.

### **Types of products vetted**



In 2009-2010, we vetted advertising for 37 **new active substances** during the 15 month period. This is identical to the previous year but comparing 12 month periods (September 2009 to August 2010) the number decreased. These included launch advertising for some significant new and innovative products, including the first cannabinoid medicine to be licensed in the treatment of spasticity due to multiple sclerosis and the first in a new class of drugs for patients with chronic obstructive pulmonary disease. We also reviewed advertising materials for the first advanced cell therapy product to be licensed in the EU, an autologous chondrocyte implantation product used to repair knee cartilage.

The total number of new active substances vetted includes eight **new orphan products**, not significantly different from the number for the same period last year. Orphan products are indicated for rare medical conditions with a very small patient population. The Agency adopts a proportionate approach for assessing advertising for orphan products as the marketing campaign is usually limited and targeted at specialist prescribers. We typically focus our review on a single key piece or small selection of advertising material. Orphan products vetted in the year included a new medicine to treat the rare bleeding disorder, idiopathic thrombocytopenic purpura.

The number of **reclassified products** vetted each year has generally been consistent during the previous three years. This reflects the Government

encouragement of wider availability of medicines when there is adequate evidence of safety in use.

We vet the advertising for innovative products that are reclassified to over the counter sale through pharmacies and occasionally when switched to general sale medicines available through multiple retail outlets. Vetting helps to ensure pharmacists and consumers receive appropriate messages about the products when they are launched. The three cases this year included Flomax Relief, the first over-the-counter product for benign prostatic hyperplasia in men. A shared care model was agreed for this product, where initial supply for up to six weeks through a pharmacy came with a requirement to seek a medical diagnosis before further supply of the product.

Similar numbers of products were also vetted for other reasons. These products were selected based on **safety concerns, major new indications, and significant new combinations**.

The 15 other products vetted included cases referred by MHRA colleagues who reviewed the application for a new licence or variation to an existing licence and had concerns about how the product may be marketed. They also included products referred for vetting due to concerns about emerging safety information. In these cases, our review was particularly focussed on the safety messages conveyed in advertising to prescribers.

During the past year, the MHRA vetted the advertising of two products where **breaches** of the ABPI Code of Practice<sup>6</sup> or of legislation were found. Both arose from our regular scrutiny of cases reported by the PMCPA. See Chapter 2 for further information on these cases.

In the first case, we decided to vet the advertising for a new indication for Botox for use in chronic migraine following allegations that Allergan were promoting use in migraine before the indication was authorised. The PMCPA and MHRA upheld this case and ruled breaches of the Code and legislation. We chose to vet the advertising for this indication, to ensure future promotional activities complied with the Regulations.

An anticoagulant medicine was also vetted because of a breach of the ABPI Code for promoting unlicensed indications. In this case we were concerned that the principles agreed during the initial vetting of the product at launch had not been adhered to by the company so we requested to review any further similar materials to ensure that unlicensed uses of the product were not promoted.

Individual advertisements for other products were also reviewed as required as part of actions on upheld complaint and scrutiny cases, to ensure that misleading messages were corrected.

The number of scientific advice meetings has remained the same as the previous year (4). When the MHRA needs to discuss amendments to proposed advertising claims, these are now more often dealt with by

teleconference. Advice meetings are available when companies request them and prove a useful way to explore issues raised in advertising proposals.

### **Educational Materials**

The MHRA reviews all materials associated with the advertising campaign for a product, as well as any other related materials. Marketing authorisation holders often commit to provide educational materials as part of their risk management plan. When products are subject to vetting, these educational materials are also submitted to the Advertising Standards Unit. The materials should be educational in nature and non-promotional as they are intended to ensure doctors and patients have the information they need for safe prescribing and use of the product.

During the year we have sometimes had to remind companies that the primary purpose of these materials is education rather than promotion and that the inclusion of overtly promotional messages may detract from the important safety information that needs to be conveyed. Conversely, we have also had to remind companies that the provision of risk management materials does not absolve them from the need to include safety messages in the detail aid.

### **Advertising Standards Unit Performance**

During the reporting period, our target to respond on advertising pieces submitted for vetting within five working days was achieved 92% of the time, which is about the same as last year. During the course of the 15 months, our minimum target of responding within 5 working days for at least 80% of pieces was achieved in all but two months. The variations in the levels reflect our fluctuating work loads. Counterintuitively, it is often when we have a lower volume that the figures decrease, as a delay on one batch of materials due to assessor commitments has a larger effect on the percentage figure.

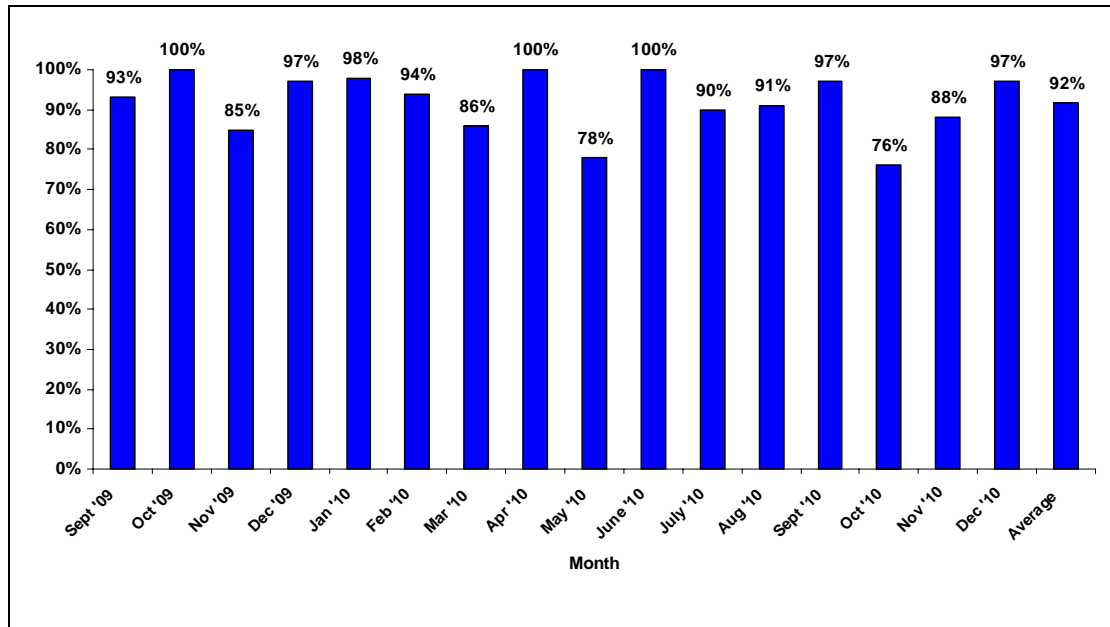
We ask that companies provide us with enough notice for us to review materials. Occasionally companies have specifically requested a shorter timeframe for review for certain pieces required urgently; we try to be flexible and accommodate this where possible.

Working closely with colleagues in other parts of the Agency and marketing authorisation holders has enabled us to plan our work loads and ensure the procedures run efficiently to reach our target turn around times.

Early contact with companies about the proposed timetable for submission of advertising is important to help us to plan the vetting process with our colleagues internally, help us meet our target of 5 working days, and avoid potential delays for the product launch. We ask for companies to keep us updated about their expected timetables and schedules for submitting materials. Occasionally we have had to remind companies of this when large volumes of advertising have arrived for assessment unexpectedly.

The figure below shows the proportion of advertising pieces vetted within 5 working days.

### **Percentage of vetting cleared within 5 days**



The vetting process can start before the grant of a marketing authorisation in preparation for a product launch. It continues until key pieces have been reviewed and the Agency is satisfied about the quality of the materials. The duration of vetting is usually about two months but it continues for longer if initial materials are not satisfactory and we have concerns about the quality of the submissions or if key advertising pieces are still being developed.

### **Working with companies**

We aim to work closely with companies to ensure the vetting exercise runs smoothly and constantly look to find ways to improve the process. We now work completely electronically, so all correspondence is via e-mail or occasionally CD-ROM for large volumes of references. This has benefits to companies in terms of reduced postal delays and courier costs but also to the MHRA in terms of electronic processing and record keeping. We also now send communications exclusively by email.

We try to ensure that points made and actions required are explained clearly and guidance is given where appropriate on measures needed to reach compliance.

During the last year, instead of a survey, we have invited feedback on vetting whenever we notify companies that vetting has finished. The small number of responses received have all been positive about the level of service and advice and flexibility on timeframes.

## Key learning points

To help advertisers, we review the main findings from vetting of advertising every year. This has identified important points and key tips that advertisers should carefully consider when preparing their materials. These are listed below:

- **Indication** – The authorised indication of the product should be stated clearly and prominently at the outset to ensure that claims are set in a clear context. Advertising should not serve to extend the use of the product beyond the licensed indication.
- **Key Safety Messages** – Safety information required to support safe use of the product should be included, particularly for a new product where the detail aid has a clear educational function. It should include risk management messages and the key contraindications, warnings, interactions and side-effects with a statement referring to the product SPC for full details, for a balanced approach.
- **Tolerability claims** - Exaggerated or categorical tolerability claims such as “reassuring” or “well documented” should be avoided when they relate to newly authorised products. It is unacceptable to refer to any medicine as “safe” in advertising.
- **Clinical Studies** – Product claims should be supported by the balance of evidence available and should not exaggerate the findings of studies with methodological limitations. The absolute effect as well as the relative change should be provided to help readers to assess the clinical relevance of findings. Care should be taken not to give an exaggerated impression of the efficacy of the product in words or pictures.
- **Materials for the Public** – Promotion of prescription only medicines to the public is prohibited. Exceptionally, companies may produce press releases to announce an innovative new product launch. These must be factual, balanced and non-promotional in content. Likewise, patient materials developed as part of risk management measures must not contain promotional claims.

Advertisers should consider these points when preparing and submitting materials to the MHRA for vetting to help the process run efficiently and aim to submit advertising that is right first time.

Review of the top tips for the last few years reveals a surprising degree of consistency. The first point to ensure the indication for use of the product is clear has remained constant since we started producing ‘top tips’.

## Measuring effectiveness

It is difficult to measure the direct impact that vetting has. The MHRA has a policy of not publicising the potential errors that are identified during vetting so we cannot directly measure the effectiveness of the vetting procedure as a whole.

We do measure the number of upheld complaints about advertising vetted by the MHRA and this can give an idea of the effectiveness of vetting. When complaints concerning vetted advertising are upheld by either the MHRA or PMCPA, these are reviewed closely as they are learning points for future vetting. They are discussed by the Advertising Action Group which includes senior medical and pharmaceutical assessors with experience of assessing advertising from across the Agency.

We are aware of two complaints about advertising vetted by the MHRA that were investigated by the PMCPA<sup>5</sup> in the last year. The first concerned promotion of Victoza (liraglutide) for the treatment of type 2 diabetes. The dosing card and press releases reviewed by the MHRA as part of the vetting procedure formed part of the complaint. The PMCPA considered the claims in the dose card implied that the product was to be used as monotherapy and the statements in the press release exaggerated the effect of Victoza on weight reduction and were promotional. PMCPA case AUTH/2222/4/09.

The second case was about the promotion of Nicorette (nicotine transdermal patch) for smoking cessation. The presentation of data in a slide presentation for healthcare professionals was considered to be in breach of the ABPI Code. PMCPA case AUTH/2324/6/10.

Reports on both cases are available on the PMCPA website<sup>4</sup>. In both cases, with the benefit of hindsight, we agreed with the PMCPA rulings.

The number is similar to previous years. It is a small proportion of the number of products vetted during this time frame. This suggests that the vetting procedure is successful in improving the standard of advertising for new medicinal products.

Vetting gives companies an opportunity to hear the MHRA view on their advertising other than in the context of a specific complaint. Feedback from companies suggests that the comments are useful and provide a new perspective. Evidence from complaint cases suggests that principles from vetting are continued in advertising after the vetting period ends and continued into subsequent marketing campaigns. Further information on complaints can be found in chapter 2.

# 4

## Chapter 4 – Working with others

*Promoting a common understanding of the legislation and consistent high standards of practice*

### **Medicines Advertising Liaison Group**

We continue to work closely with other bodies involved in the regulation of medicines advertising to ensure a common understanding and consistent high standards across self regulatory and statutory bodies. Three meetings of the Medicines Advertising Liaison Group (MALG) were held during the period from September 2009 to December 2010. Discussions focussed on:

- the review of medicines legislation and proposals for modern sanctions for advertising;
- guidance for advertising / sale of analgesics;
- MHRA guidance for traditional herbal remedies and homeopathic products, and
- guidance on advertising products containing codeine/dihydrocodeine and nicotine replacement therapy.

During the year the ABPI consulted on and published a new edition of their Code of Practice for the pharmaceutical industry<sup>6</sup>. The MHRA was fully consulted during this process and welcomed the changes made to the Code, particularly the restrictions on gifts and increased transparency for contracts with health professionals. Small gifts bearing the name of a product will no longer be permitted and there are new transparency requirements for contracts with doctors and other health professionals who provide consultancy services to companies. The MHRA is also considering whether legal changes should be made to support these restrictions on promotional aids in support of the recommendations of the 2009 report by the Royal College of Physicians, 'Innovating for Health'<sup>7</sup>, which recommended an end to all industry gifts for doctors and their supporting staff.

The PMCPA<sup>5</sup> has also been developing additional guidance on how companies can communicate with healthcare professionals about POMs using newer digital media. The MHRA has consulted regularly with PMCPA about progress on this initiative and looks forward to publication of the guidance in early 2011.

The Committees of Advertising Practice also launched new Broadcast and Non-broadcast Codes<sup>8</sup> during the year, including new specific advice on advertising Traditional Herbal Medicines. The MHRA had earlier commented on the proposals during the public consultation phase.

In July 2009, the Committee on Human Medicines (CHM) undertook a review of abuse and misuse of OTC analgesics containing codeine or dihydrocodeine. The CHM recommended a package of measures to minimize the risk of overuse and addiction. These measures involve changes to pack sizes, indications, patient information leaflets, labelling, advertising and promotional activities. As part of this, PAGB<sup>9</sup> developed voluntary guidance restricting the advertising of these products in consultation with MALG and other stakeholders. This was issued in January 2010.

### **MHRA guidance on specific areas**

At the start of the reporting period in November 2009, the MHRA finalised its guidance on advertising registered Traditional Herbal Medicines and this was published on the MHRA website<sup>3</sup>. This advice formed the basis for consideration of complaints about THM advertising during the year. It was noticeable that after an initial batch of complaints by a single company against one other company, no further complaints about THMs were received during the reporting period.

We also updated our guidance on websites offering consumer treatment services to relax the restrictions on displaying price lists. It was envisaged that this increased transparency should promote legitimate price competition in the sector without promoting any specific product above others.

We also worked with companies who market nicotine replacement therapy to agree informal guidelines on how to promote their products in the new indication for harm reduction granted by the MHRA.

All guidance was shared with MALG members for comment in advance to ensure common understanding of the legal requirements.

Following on from the European Court of Justice<sup>10</sup> judgment in the case of Damgaard (Case C-421/07), the MHRA also prepared more general advice for journalists and patient organisations to help them to ensure that they can provide information about medicines where this is relevant to their readers, without promoting the product. The key is to keep the material factual and balanced. This guidance has been published on the MHRA website<sup>3</sup>. It is also sent to journalists when we receive a complaint about reporting about medicines in the press.

### **General sale list analgesics**

In December 2009, the MHRA published best practice guidance on the sale of medicines for pain relief. This was developed in association with stakeholders representing large and small retailers, pharmacists, trading standards officers and the pharmaceutical industry. It is designed to ensure that consumers have access to these medicines but do not buy quantities greater than needed at the time. The MHRA also undertook to publicise the guidance and attended the Trading Standards Institute's annual conference to increase awareness among trading standards officers across the UK.

## **Independent Review Panel**

A new Independent Review Panel membership was appointed in early 2010. Each member is available to serve on a Panel to consider an advertising case as the Independent Review Panel for Advertising or for a borderline case as the Independent Review Panel for Borderline Products. Training was provided on the legal requirements and procedures under each regulatory regime. A Panel met in May 2010 to consider an advertising case, only the second time an advertising panel has met since the system was set up in 1999. Details can be found in chapter 2.

# 5

## Chapter 5 – Legal perspective

*Ensuring we interpret the law consistently*

### **Review and consolidation of the UK medicines legislation**

In 2008, the MHRA started a major project to consolidate the Medicines Act 1968 and over 80 statutory instruments, many amended several times, into a single piece of legislation. This has included rewriting the advertising regulations.

The Advertising Standards Unit has worked closely with MHRA legal advisors to ensure that each provision is correctly transposed. The major changes have been to update the definition of advertising to reflect that in the Directive rather than the original definition in the Medicines Act, and a review of wording to ensure that modern digital communications media are adequately covered. Neither represents a substantive change in legal interpretation.

The second phase of this project is to review the legislation and determine whether changes could be made to simplify it and reduce the regulatory burden where this is possible within the constraints of European law. Two areas of advertising have been identified, sanctions and review of proposed determinations.

### **Sanctions**

We are considering supplementing or replacing criminal sanctions with more flexible, customised, and proportionate “administrative sanctions”, including:

- Financial penalties that regulators can issue without the need to prosecute.
- Statutory notices that require recipients to take certain action or refrain from doing something in order to comply with the law. The failure to comply with such notices can be treated as a criminal offence.
- Enforceable undertakings that require parties to take remedial action, such as compensate affected parties.

For advertising, we think that statutory notices and financial penalties will give us greater flexibility as we respond to the advertisement of prescription medicines on the internet. For example, we could issue notices that require parties involved with the illegal advertising to remove the advertisement or website. We could also issue fines where appropriate. We anticipate that this could decrease the time and work involved for both parties in obtaining compliance and reduce the number of times where a criminal prosecution is undertaken.

## **Review of proposed determinations**

The MHRA is also considering streamlining three review functions for medicines regulation: the right to be heard by a “person appointed”, the review panel for borderline medicines and the review panel for advertising. We intend to amalgamate these to establish a single overarching independent review process. There will remain certain differences between the functions (for example in relation to fees charged and timings for seeking review). We aim to keep the regulation to a minimum, and will provide detailed supporting guidance.

## **Judicial review – prescribing incentive schemes**

In November 2005, Pfizer Ltd. contacted the MHRA for clarification on the legality of certain incentive schemes operated by primary care trusts in England. The schemes offered financial rewards to GP practices in return for increasing the numbers of patients prescribed cheaper generic medicines in specified therapeutic categories. In particular some of these schemes incentivised the prescription of generic simvastatin rather than the more expensive branded Pfizer product, Lipitor (atorvastatin). The MHRA indicated to Pfizer that it was minded to determine that the specific schemes were outside the scope of Regulation 21 of the Medicines (Advertising) Regulations 1994.

The issue was subsequently taken up by the ABPI who, in December 2006, sought a judicial review of MHRA’s decision that the schemes fell outside the legislation on medicines advertising.

The case was referred to the European Court of Justice<sup>10</sup>, which published its judgment in April 2010 (case C-62/09). This found that financial incentive schemes, implemented by the national public health authorities in order to reduce their public-health expenditure and designed to encourage, for the purpose of treating certain conditions, the prescription by doctors of specific named medicinal products containing an active substance which is different from the active substance of the medicinal product which was previously prescribed or which might have been prescribed but for such an incentive scheme, were not precluded. The ABPI subsequently withdrew their application for judicial review in the UK courts.

## **Price lists and ‘specials’**

Following an earlier ECJ decision, the MHRA decided to relax the restrictions on issuing price lists to ensure that price competition was not unduly restricted by the ‘specials’ regime. The specific prohibition on holders of a licence permitting the manufacture, importation and/or distribution of unlicensed medicines that prevented them from issuing a price list to healthcare professionals has been removed, provided the price list is not used to solicit orders. No product claims may be included in any price list issued.

# 6

## Chapter 6 – Future direction

*The challenge of continuous improvement in standards for medicines advertising in the UK and its regulation*

### Review of medicines legislation

Details of the proposed changes to be made for advertising as part of the review of medicines legislation are set out in chapter 5. The MHRA will be conducting a formal public consultation on all the proposed changes to the legislation during 2011. It is anticipated that the final changes will come into force in mid 2012.

In preparation for the implementation of the new legislation in 2012, the MHRA will review the Blue Guide in 2011. The most recent (second) edition was published in 2005 and several pieces of stand-alone guidance have been issued since that time. These will be incorporated into the third edition and we will ensure that stakeholders have an opportunity to comment on proposed changes. We expect to add in guidance that addresses what is permissible when using new digital media to communicate about medicines.

### Extension of ASA remit

On 1 March 2011, the Advertising Standards Authority will extend its remit to include digital media. All marketing communications on companies' own websites and in other third party space under their control, such as Facebook and Twitter, will have to adhere to the non-broadcast advertising rules as set out in the CAP Code<sup>8</sup>. The MHRA has been taking action for several years on websites that promote prescription only medicines. We welcome this new initiative and will work with the ASA and CAP to ensure that action on website cases addresses the public health concerns raised by promotion of POMs to the public.

### Homeopathic medicines

Following discussions with MHRA colleagues responsible for licensing homeopathic medicines and review of complaints received, the need was established for specific guidance on advertising homeopathic medicines. The MHRA has discussed draft guidance with a range of stakeholders including the British Association of Homeopathic Manufacturers, individual companies, bodies representing homeopaths, the Advisory Board on the Registration of Homeopathic products, pharmacists and other advertising regulators through MALG. We expect to publish the guidance in draft form in early 2011. We plan to circulate the guidance to companies we are aware of that advertise homeopathic medicines and give them a period to review their practice before

taking action to ensure legal compliance. After use for a period of around six months, we will review and finalise the guidance.

### **European Court of Justice**

The European Court of Justice<sup>10</sup> continues to receive a small number of cases concerning interpretation of the medicines advertising legislation. Judgments are expected on two interesting cases in Spring 2011.

The first is an Estonian case (Case C-249/09) asking whether all information in advertising must be included in the SPC for the product. The Advocate General's opinion is that this is not required, provided the claims are consistent with the information in the SPC. This reflects current practice in the UK.

The second, a German case (Case C-316/09), asks whether the inclusion of information from the patient information leaflet on a company website constitutes advertising. The Advocate General's opinion is that such information should not be classified as advertising where it is only available on the internet to those who actively search for it. This is consistent with the view of the UK as set out in section 5.10 of the Blue Guide.

### **European proposals on information to patients**

The MHRA continues to support in principle the European Commission's legislative proposals on information to patients<sup>11</sup> and published the outcome of a public consultation on our website in October 2009. We will work with the Commission to seek to identify a way forward that takes account of the diversity of views among member states and the focus of the European Parliament on the rights of patients to be able to access the information they need about medicines to support their safe use. In particular, we will build on the view of the European Parliament to distinguish between information "pushed" at the public, and that "pulled" or actively sought out.

### **European advertising network**

The MHRA sought agreement from the Heads of Medicines Agencies to set up an informal forum for the teams responsible for regulation of medicines advertising in each member state, to exchange relevant information about their work. We expect to make this operational in early 2011.

### **Looking ahead**

We will continue to investigate complaints about advertising medicines and to monitor published advertising, and ensure action on potential breaches of the legislation is timely and effective. We expect measures taken during the last year to reduce the increase in complaints about advertising POMs to the public by service providers.

We also expect to vet advertising for around 50 products during the year to promote a right first time approach and protect against misleading messages. We will achieve this within our published standards for response time for industry.

The MHRA will continue to work proactively with self regulatory bodies and other stakeholders to maintain high standards in the coming year.

In line with the Government's regulatory priorities, the MHRA will be focussing in the coming year on **regulatory excellence** – simplifying regulation while delivering our public health outcomes - and **operational excellence** – streamlining our processes while retaining the quality of our work. Our role in regulating medicines advertising is of course a key part of this and we will work, through the medicines legislation review project and other initiatives, to ensure that regulation is proportionate and effective and that clear guidance is available on compliance with the legislation.

## References

- 1 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](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4118604&chk=4imzAe)
2. 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>
3. A complaint form, reports of cases, general guidance and other information about medicines advertising regulation are available on the MHRA website, [www.mhra.gov.uk](http://www.mhra.gov.uk), under How we regulate/Medicines/Advertising of medicines.  
<http://www.mhra.gov.uk/Howweregulate/Medicines/Advertisingofmedicines/index.htm>
4. The Medicines and Healthcare products Regulatory Agency (MHRA). The Blue Guide: Advertising and Promotion of Medicines in the UK. London: The Stationery Office Limited, 2005.  
<http://www.mhra.gov.uk/home/groups/pla/documents/publication/con2022589.pdf>
5. Prescription Medicines Code of Practice Authority. Details and reports of cases investigated are published on the Authority's website at:  
<http://www.pmcpa.org.uk/?q=cases>
6. Association of the British Pharmaceutical Industry. Code of Practice for the Pharmaceutical Industry 2008.  
[http://www.pmcpa.org.uk/files/sitecontent/ABPI Code of Practice 2008.pdf](http://www.pmcpa.org.uk/files/sitecontent/ABPI%20Code%20of%20Practice%202008.pdf)
7. Royal College of Physicians. Innovating for Health. 2009  
<http://bookshop.rcplondon.ac.uk/contents/76673804-76c5-4ab3-89a0-92d44e45edc3.pdf>
8. CAP and BCAP Codes 2010. Details are available at:  
<http://www.asa.org.uk/Advertising-Codes.aspx>
9. Proprietary Association of Great Britain. Medicines advertising codes: Codes of practice for advertising over-the-counter medicines which are subject to a marketing authorisation 2009. Information on the Codes is available at:  
<http://www.pagb.co.uk/advertising/advertisingcode.html>

10. European Court of Justice. Case reports for each case referred to in the text can be found by entering the number into the search facility. This, together with information about the Court, can be found at:  
<http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&newform=newform&docj=docj&typeord=ALL&numaff=C-421%2F07&ddatefs=&mdatefs=&ydatefs=&ddatefe=&mdatefe=&ydatefe=&nomusuel=damgaard&domaine=&mots=&resmax=100&Submit=Submit>
11. European Commission. Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use. Brussels: Enterprise and Industry Directorate-General, 2008.  
[http://ec.europa.eu/enterprise/pharmaceuticals/patients/patients\\_en.htm](http://ec.europa.eu/enterprise/pharmaceuticals/patients/patients_en.htm)

## Abbreviations

ABPI	Association of the British Pharmaceutical Industry
ASA	Advertising Standards Authority
BCAP	Broadcast Committee of Advertising Practice
BHMA	British Herbal Medicine Association
CAP	Committee of Advertising Practice
CHM	Commission on Human Medicines
DTCA	Direct to Consumer Advertising
EC	European Commission
ECJ	European Court of Justice
EU	European Union
HFMA	Health Food Manufacturers' Association
IRP	Independent Review Panel for Advertising
MALG	Medicines Advertising Liaison Group
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
OTC	Over-the-counter
PAGB	Proprietary Association of Great Britain
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