Delivering High Standards in Medicines Advertising Regulation

Annual Report
January – December 2012

Advertising Standards Unit
Vigilance and Risk Management of Medicines Division
Medicines and Healthcare products Regulatory Agency
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Abbreviations
Chapter 1 – Introduction

This is the seventh annual report of the MHRA Advertising Standards Unit, covering the calendar year 2012. It is 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.

Transparency

Transparency and access to clear advice is a key aspect of our service to stakeholders and the Advertising Standards Unit continues to take a range of actions to promote openness of our work in regulating medicines advertising. These have included:

- Publishing outcome reports for complaint and scrutiny cases on the MHRA website\(^1\).
- Regular monthly reports on vetting performance on the MHRA website.
- An annual seminar for industry on current hot topics in advertising regulation, with examples of good and bad advertising from our casework.
- Advice for advertisers including a dedicated mailbox for enquiries, 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.
- Close working with self regulatory bodies to ensure consistent standards.

Information about all these activities can be found on the MHRA website\(^1\) at www.mhra.gov.uk.
Chapter 2 – Reviewing published advertising

The MHRA receives complaints and referrals from various sources including members of the public, healthcare professionals, competitor companies and other interested parties who have concerns about medicines advertising. Complaints can be made using the complaint form on the MHRA website, by sending an email to the advertising mailbox or by post. Details of our procedures for investigating complaints are given in a fact sheet which is available on the MHRA website.

Action on complaints

The number of complaints received in 2012 was 237, a reduction from the higher numbers seen in the last two years and a return to previous levels. Details are provided in the table below. We changed our reporting period in 2011 so the figures in brackets in the first column show the numbers during the 16 month period from September 2009 to December 2010 for completeness.

<table>
<thead>
<tr>
<th>Complaints received</th>
<th>September 2009 to August 2010*</th>
<th>January to December 2011</th>
<th>January to December 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complaints received</td>
<td>368 (468)</td>
<td>357</td>
<td>237</td>
</tr>
<tr>
<td>Investigations initiated</td>
<td>343 (437)</td>
<td>328</td>
<td>232</td>
</tr>
<tr>
<td>Complaints referred to other Agency Units</td>
<td>24 (29)</td>
<td>16</td>
<td>3</td>
</tr>
<tr>
<td>Complaints covering matters already being investigated</td>
<td>2 (2)</td>
<td>11</td>
<td>1</td>
</tr>
<tr>
<td>Complaints being investigated by ASA or PMCPA</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

*Figures in brackets show the total for the 16 months from September 2009 to December 2010.

As in previous years, a high proportion of complaints received were about advertising to the public of botulinum toxin products and other prescription only medicines by cosmetic clinics and other internet service providers such as online clinics and pharmacies. It is mainly a reduction in these cases that has driven the overall reduction in numbers seen in 2012. As well as
increased awareness of the legal requirements, this reduction is probably also closely related to the extension of the remit for the Advertising Standards Authority (ASA) which occurred in March 2011. Since that date, individuals with a concern about advertising on company websites can also make a complaint to the ASA. They have dealt with a number of cases relating to advertising of medicines, particularly botulinum toxin products and homeopathic medicines.

For any complaint, if the first review indicates that there may not be a case to answer and there is not a significant public health risk, we may provide an initial response to the complainant explaining our published policy and the legal requirements. Unless the complainant specifically asks us to take the case further and institute a formal investigation, we do not record these cases as complaints.

As a matter of policy and to ensure appropriate use of resources, the MHRA does not conduct a second investigation into any complaint that has also been submitted to a self-regulatory organisation unless we identify a serious safety issue.

**Sources of complaints received in 2012**

<table>
<thead>
<tr>
<th>Source</th>
<th>Number of Complaints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare professional</td>
<td>5</td>
</tr>
<tr>
<td>Industry/Competitor</td>
<td>23</td>
</tr>
<tr>
<td>Public</td>
<td>175</td>
</tr>
<tr>
<td>Anonymous/Other</td>
<td>34</td>
</tr>
</tbody>
</table>

Nearly three quarters of the complaints received in 2011 came from competitors. A large proportion of these cases related to advertising of botulinum toxin to the public and advertising of other prescription only medicines (POMs) by third parties, mainly on websites. Very few cases relating to competitor complaints about prescription only medicines by marketing authorisation holders were received since these are usually dealt with under the self regulatory system.
The remaining complaints were fairly evenly split between the public and other organisations and anonymous sources (often competitors) with an unusually low number of complaints from health professionals in 2012.

**Outcome of complaint investigations**

<table>
<thead>
<tr>
<th></th>
<th>September 2009 to August 2010*</th>
<th>January to December 2011</th>
<th>January to December 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines advertising cases resolved</td>
<td>331 (444)</td>
<td>353</td>
<td>249</td>
</tr>
<tr>
<td>Advertisements withdrawn</td>
<td>276 [83%] (386 [87%])</td>
<td>270 [76%]</td>
<td>161 [65%]</td>
</tr>
<tr>
<td>Corrective statements required</td>
<td>2 (3)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Summary reports published (excludes enforcement cases)</td>
<td>25 (34)</td>
<td>28</td>
<td>18 (covering 20 cases)</td>
</tr>
</tbody>
</table>

*Figures in brackets indicate the total for the 16 months from September 2009 to December 2010

In the year we resolved 249 advertising complaints, slightly higher than the number received as cases ongoing at the start of the year were concluded. A lower proportion of enforcement cases were upheld, reflecting a move to conclude simple cases with advice on changes needed and a reference to our published guidance. The chart overleaf indicates trends for complaints received and cases resolved for the last three reporting years. The figures for 2012 are very similar to those for 2008/9 (not shown).
Apart from the cases dealt with in association with the Enforcement Group (see below), we publish the summary outcome reports of all cases on the MHRA website on completion of each investigation. During 2012, we published 18 summary reports covering 20 complaint cases, slightly less than in previous years (28 in 2011).

Four further reports were issued for cases identified by the MHRA as a result of our monitoring of published advertising. These included two proactive reviews, relating to concerns about opioid usage and to a US legal settlement. Neither review identified any breaches of the legislation.

We required the issue of two corrective statements (a measure of the seriousness of the complaint) in 2012. The first related to a wholesale supplier to doctors in general practice who offered prohibited inducements to encourage orders. The second related to an advertisement for a traditional herbal medicine that claimed efficacy for an unlicensed indication.

During 2012 a total of 217 enforcement cases (those dealt with in association with the MHRA’s Enforcement Group) were resolved. 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 internet pharmacies and other clinics promoting treatment services for various conditions including erectile dysfunction, weight loss or hair growth.

We have found over the years that MHRA actions in this area drive a further increase in complaints as offenders who have been the subject of complaints in turn complain about their competitors to ensure a level paying field.
Increased awareness about the restrictions has led to fewer cases having to be referred for Enforcement Group action.

To encourage compliance, we do publish on the Agency website a monthly list of clinics offering wrinkle treatments that have revised their advertising following MHRA action on complaints. Other enforcement cases resolved by the Advertising Standards Unit are not reported on the MHRA website, in order to be consistent with the approach taken by the Enforcement Group across this shared responsibility.

All complaint cases were resolved through voluntary agreement with the companies concerned this year, without the need to resort to statutory procedures.

We also provided advice and dealt informally with a range of other cases, including issues referred to us by colleagues and other regulators such as the ASA.

**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 reporting years. It covers both internal monitoring and complaints. The information is broken down by sector as follows:

- prescription medicines;
- over-the-counter 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 2009/10 to 2012**

![Graph showing upheld cases by category of medicine for 2009/10 to 2012]
Three of the four cases reported during 2012 that concerned prescription only medicines all concerned advertising for medicines by companies holding manufacturing licences but where they did not hold marketing authorisations for the products (‘specials’ manufacturers). The long term downward trend in the number of advertising cases in this sector, stimulated by the MHRA’s vetting programme, has continued in 2012.

Since the Proprietary Association of Great Britain\textsuperscript{5} (PAGB) reviews all proposed advertising to the public by its members, the number of upheld cases each year in the OTC sector is very small. One of the two cases in the year concerned updating information on a company product website and the other a traditional herbal medicine.

The number of upheld cases concerning third-party advertising is similar to previous years. The nine cases represent a broad range of categories from general retailers to specialist suppliers.

As in previous years, we received a small number of referrals about the sale of an excessive quantity of OTC analgesics containing paracetamol. Most retailers have committed to adhere to the voluntary restriction on selling more than two packs of analgesics per transaction in line with the MHRA guidance - \textit{Best practice on the sale of medicines for pain relief}. Where appropriate we have drawn the attention of other retailers to the guidance.

Where newspaper articles or patient organisation websites were referred to us for possible promotional claims we drew the author’s attention to our guidance on reporting to the public about medicines.
Chapter 3 – Vetting advertising before issue

The MHRA takes a risk-based approach to the proactive review of proposed advertising to reduce the potential for issuing misleading messages about medicines. We vet advertising for all new active substances when first made available as a prescription or over-the-counter medicine prior to launch. We also target a small number of other products linked to particular safety concerns or where previous advertising has been in breach of the Regulations.

The table below provides a summary of our vetting activities over the last three years. Reports before 2011 used a different reporting period from September to August and the figures in brackets in the first column of the table below show the number of products vetted during the period for September 2009 to December 2010 for completeness.

### Vetting statistics for September 2009 to December 2012

<table>
<thead>
<tr>
<th>Category</th>
<th>Sept 2009 to Aug 2010 *</th>
<th>January to December 2011</th>
<th>January to December 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>New active substances (excluding orphan products)</td>
<td>25 (29)</td>
<td>29</td>
<td>19</td>
</tr>
<tr>
<td>Orphan products for rare conditions</td>
<td>7 (8)</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Reclassified products (POM to P)</td>
<td>3 (4)</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Vetted after action on previous breach</td>
<td>2 (2)</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Other products (includes safety concerns, major new indications)</td>
<td>13 (15)</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>50 (58)</td>
<td>51</td>
<td>40</td>
</tr>
</tbody>
</table>

*Figures in brackets show the total for the 16 months from September 2009 to December 2010

The most obvious difference in 2012 was that the MHRA vetted advertising for fewer products prior to issue. The total of 40 medicines was a reduction of about 20% from previous years. The figures above show that this was made up of reductions across all areas except orphan products which returned to previous levels after a low number in 2011. In particular, there was a noticeable decrease in the number of new active substances receiving...
a first marketing authorisation. We suspect this may just be random variation since the numbers have risen rapidly since the year end.

**Types of products vetted**

<table>
<thead>
<tr>
<th>Category</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of new active substances (excluding orphans)</td>
<td>19</td>
</tr>
<tr>
<td>Number of orphan products (NAS)</td>
<td>12</td>
</tr>
<tr>
<td>Number of reclassifications</td>
<td>1</td>
</tr>
<tr>
<td>Number linked to previous breach</td>
<td>0</td>
</tr>
<tr>
<td>Other (safety concerns, new indications, etc.)</td>
<td>8</td>
</tr>
</tbody>
</table>

In 2012, we vetted advertising for 27 **new active substances**. These included launch advertising for some significant new and innovative products, including products for the treatment of patients with *C. difficile* or HIV infections, diabetes and malignant melanoma.

This total number of new active substances vetted included eight **new orphan products**. 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. Products vetted in 2012 included new treatment options for cystic fibrosis and certain specific forms of cancer.

The number of **reclassified products** vetted decreased in 2012 to one from the usual level of about three products / year. It is anticipated that the number will rebound to previous levels following the launch of a streamlined reclassification procedure at the end of 2012.

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 12 products vetted included cases referred by MHRA licensing assessors who reviewed the application for a new marketing authorisation or variation to an existing authorisation and had concerns about how the product may be marketed. They also included products referred for vetting due to concerns about presentation of safety information.
Unusually during the past year, the MHRA did not identify any instances where vetting of advertising was required because serious breaches of the advertising legislation had been found.

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

When the MHRA needs to discuss amendments to proposed advertising claims, these are usually dealt with by teleconference and we did not hold any formal scientific advice meetings in 2012. Advice meetings are still available when companies request them and have proved a useful way to explore issues raised by the MHRA in response to advertising proposals submitted.

**Advertising Standards Unit Performance**

During the reporting period, our target to respond on advertising pieces submitted for vetting within five working days was achieved 93% of the time, slightly lower than last year (95%). Our minimum target of responding within 5 working days for at least 80% of pieces was achieved in all months except for August when performance was affected by a combination of holidays and the Olympics. Monthly achievement ranged from 73% in August to 100% in 5 of the other months.

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

**Percentage of vetting cleared within 5 days in 2012**

![Percentage of vetting cleared within 5 days in 2012](chart.png)
Advance notice from companies about the proposed timetable for submission of advertising is important to help us to plan the vetting process with medical assessors internally. This is vital if we are to meet our target of 5 working days and thereby to avoid potential delays for the product launch. We have sometimes had to renegotiate submission dates when large volumes of advertising have arrived for assessment unexpectedly. We recognise that timetables are subject to change but ask that companies keep us informed of when they expect to submit materials. Occasionally companies request expedited assessment for individual pieces required urgently; we try to be flexible and accommodate this where possible.

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. It can also be shorter if initial pieces are of high quality.

On average in the past, we have reviewed about 12 items per product vetted, although this can vary significantly from a single piece for an orphan product to over 50 items for a major reclassification. This year we have noticed a decrease in the average number of items per product to about 8. We think this is probably due to a combination of a change in the mix of products vetted and a shorter vetting period because initial materials were of a high standard.

Unusually in 2012 there were two companies who omitted to send an individual item to the MHRA for review despite an agreement to vet all materials. This usually leads to extension of the period of vetting by the MHRA. Reports of these cases are published on the MHRA website.

**Key learning points**

To promote compliance, we review the main findings from vetting of advertising every year. This is used to identify important points and key tips that advertisers should carefully consider when preparing their materials. The key points from the 2012 review 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 details of any monitoring required with other key contraindications, warnings and side-effects from the product SPC.
Images and straplines – These can convey powerful messages about the properties of the product but must portray realistic expectations for use of the product and be supported by relevant data. Pictures or diagrams intended to represent a patient must be representative of the indicated patient population.

Clinical Studies – Advertising should set findings from secondary endpoints of clinical studies within the context of the primary endpoint and not ‘cherry-pick’ favourable findings. Care should be taken to present non-inferiority clearly and not to exaggerate the importance of individual differences, particularly those that are not statistically significant.

Materials for the Public – Promotion of prescription only medicines to the public is prohibited. Exceptionally, companies may issue press releases to announce the launch of an innovative new product. These must be factual, balanced and non-promotional in content. Likewise, patient materials must be consistent with the patient information leaflet and not contain promotional claims.

Advertisers should carefully consider these points when preparing and submitting materials to the MHRA for vetting to help the process run efficiently. Submitting high quality advertising from the start means the period of vetting can be reduced.

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 measure the number of upheld complaints about advertising vetted by the MHRA to give an idea of the effectiveness of vetting. When complaints concerning vetted advertising are upheld by either the MHRA or the PMCPA⁴, these are reviewed closely for learning points for future vetting.

The MHRA is aware of two complaints that were upheld in 2012 and related to advertising previously vetted. This is a similar number to previous years and a small proportion of the number of products vetted in 2012. This suggests that the vetting procedure is successful in improving the standard of advertising for new medicinal products. Each case is described below.

One complaint about advertising vetted by the MHRA was investigated by the PMCPA⁴ in the last year. This concerned a press release for Trajenta (linagliptin) in the treatment of diabetes. The MHRA reviewed the evidence for the claim ‘class-comparable efficacy’ again and agreed with the finding of the PMCPA that this was misleading and exaggerated the properties of the product. PMCPA cases AUTH/2440/10/11 and AUTH/2441/10/11.
One further complaint about advertising vetted by the MHRA was investigated by the ASA\(^3\) in 2012. This concerned advertising for Nuromol (paracetamol/ibuprofen). The MHRA had previously investigated complaints about vetted advertisements and this covered similar ground. The ASA considered that the claim made was open to misinterpretation as suggesting superiority to a single ibuprofen tablet and this could not be substantiated.

The PMCPA\(^4\) and ASA\(^3\) have published reports on these cases on their websites.

The MHRA also received one complaint in 2012 about advertising that had been vetted prior to issue. This concerned an advertisement for Sycrest (asenapine). A review of the advertisement reached the same conclusion as the initial assessment and the complaint was not upheld. This case is reported on the MHRA website.

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. The low numbers of complaint cases about medicines where launch advertising was vetted suggests that principles and learning from vetting are continued in advertising after the vetting period ends and into subsequent marketing campaigns.
Chapter 4 – Working with others

Review and consolidation of the UK medicines legislation

Four years ago, the MHRA started a major project to consolidate the Medicines Act 1968 and over 80 statutory instruments, including the advertising regulations, into a single piece of legislation. This project came to fruition in August, following a public consultation, when the new Human Medicines Regulations 2012 (SI 2012/1916) came into force. Part 14 covers the advertising of medicines and incorporates the content of the previous Medicines (Advertising) and Medicines (Monitoring of Advertising) Regulations.

The Advertising Standards Unit worked closely with MHRA legal advisors to ensure that each advertising provision was correctly transposed and met with stakeholders to discuss areas of concern. The opportunity was taken to update the definition of advertising to reflect that in the European Directive rather than the original definition from the 1968 Medicines Act, to update the requirements for prescribing information and abbreviated advertisements and to review wordings to ensure modern digital communications media are covered.

MHRA guidance

In preparation for the implementation of the new legislation, the MHRA also undertook a review of the Blue Guide. The existing second edition was published in 2005, the last time the legislation on advertising medicines was amended. Revisions were required to reflect the changes made in the new consolidated medicines legislation and the opportunity was also taken to reflect other developments in advertising regulation over the previous six years. All the new guidance notes on specific topics that had been developed since the second edition was published in 2005 were also incorporated into the new edition. A draft of the new Blue Guide was shared with members of the Medicines Advertising Liaison Group (MALG) and then placed on the MHRA website for comment in advance of publication.

The third edition of the Blue Guide was published when the consolidated legislation came into force in August 2012. An interactive version was also developed for the MHRA website.

Medicines Advertising Liaison Group

We 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. Two meetings of MALG were held during 2012. Discussions focussed on:

- the consolidation and review of UK medicines legislation;
- European Commission proposals on Information to Patients;
- revisions to the MHRA Blue Guide, and
- topics of current concern, including use of digital communications media in advertising and advertising for homeopathic and nicotine replacement products.

During the year the PMCPA\(^4\) and PAGB\(^5\) consulted on and published new editions of their industry Codes of Practice. These incorporated relevant changes made to the legislation and MHRA Blue Guide\(^2\). The MHRA was fully consulted during this process and welcomed the changes made to the Codes.

The PMCPA\(^4\) also published additional guidance on how companies can communicate with healthcare professionals about innovative medicines before the grant of a marketing authorisation. We welcomed the guidance as it promoted compliance with the prohibition on advertising before the grant of a marketing authorisation and addressed concerns arising from casework that some companies did not fully understand the practical implications of this.

We have worked with all the self regulatory bodies through the year to ensure that we take a consistent regulatory approach.

**Independent Review Panel for Advertising**

As part of the Government’s agenda to reduce the number of non-departmental public bodies, the MHRA has changed the status of the Independent Review Panel (IRP) for Advertising. It will now operate as an independent MHRA advisory committee. In the future, there will be a single membership panel for the IRP for Advertising, the IRP for Borderline Medicines and the Review of Medicines Panel. This will establish a single overarching independent review process for medicines. As vacancies arise, new members will be appointed to serve as required on all three Panels.

There will remain differences between the functions for each type of panel and it is not anticipated that the function of the IRP for Advertising will change in any material way. In particular we will ensure that the new panel retains the appropriate membership to provide for a legally qualified chairman and two further members as required for an advertising panel, one with expertise in the area of medicine or pharmacy and one representing the interests of the consumer.

**Red Tape Challenge**

In 2012, the MHRA participated in the Red Tape Challenge\(^7\), a Government initiative to identify unnecessary or unduly onerous legislative burdens on industry and commerce that can be removed. Medicines regulation was the
theme in March / April 2012 and comments were invited on any area where burdens could be reduced. A small number of the comments received concerned advertising. These were all carefully considered and three projects were identified to take forward.

The first area concerned the use of lay language in advertising and the content of the statutory information required for advertising to healthcare professionals. Some changes were made to the requirements for statutory information in the consolidation of UK medicines legislation and we plan to consult on further changes in Spring 2013.

The second area concerned the benefits and burden imposed by MHRA vetting of advertising. Following the extension of MHRA vetting to all new active substances in 2005 we saw a significant reduction in complaints about advertising for these products that gradually extended more widely as more companies became familiar with our vetting principles across the prescription sector. To take this further, we will undertake a review of the benefits of vetting for products vetted in 2012 in terms of potentially misleading advertising that was not published because of MHRA intervention at the vetting stage. This review will be published in Spring 2013.

The third area concerned the potential benefits of relaxing the ban on advertising to adolescents with certain conditions such as acne. This is based on European law which prohibits advertising to children. For the purposes of advertising in the UK, a child is taken to be a person under 16 years of age. The MHRA has invited the companies concerned to review whether there are any measures that can be taken within the existing legal constraints. Once this is completed, consideration will be given to the need to seek a change to European law to provide for national flexibility on the age limit.

**European co-operation on advertising regulation**

The MHRA has set up an informal forum, under the umbrella of Heads of Medicines Agencies, for the teams responsible for regulation of medicines advertising in each member state to exchange information about their work. This became operational in early 2012 following the identification of contacts in 30 member countries including all the EU member states, Norway, Iceland and Croatia. The forum acts as a virtual network with mechanisms to seek information about how issues are handled in other territories and to inform colleagues about cross border cases. Information was exchanged on a number of issues in 2012, including disease awareness campaigns, competitions and sales representatives. A meeting was held at the MHRA in London in October 2012 with 15 member countries represented. This proved a valuable opportunity to exchange ideas on the variety of regulatory tools used in different European countries and current issues of concern such as hospitality and gifts to health professionals and the use of new media in advertising.
European proposals on Information to Patients

In October 2011, the European Commission published updated proposals for legislation on Information to Patients. The Commission also took the opportunity to add proposals to strengthen the existing controls on pharmacovigilance. Following initial discussions, the Commission republished the proposals in February 2012, separating out the two strands so that the pharmacovigilance changes could proceed rapidly. Discussions between member states on the information to patients proposals did not make progress and were terminated when the Danish presidency reported to the Commission that member states had been unable to reach agreement in June 2012.
Chapter 5 – Future direction

This is a time of major change for the MHRA, as the merger with the National Institute of Biological Standards and Control (NIBSC) takes place in April 2013. This builds on the launch of the Clinical Practice Research Datalink (CPRD) in 2012 to form an enlarged Agency with wider responsibilities in supporting science and research in addition to the regulation of medicines and medical devices.

We will continue to play our part within the Regulatory Group of the new Agency. We will investigate complaints about advertising medicines and monitor published advertising, ensuring action on potential breaches of the legislation is timely and effective.

We expect to vet advertising for around 50 products during 2013 to promote a “right first time” approach and protect against misleading messages. We will again 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.

We plan to feed back to industry on the outcome of our work in 2012 at the annual seminar – Hot Topics in Medicines Advertising Regulation – in February 2013.

At a European level, we will continue to work with the Forum on Advertising Medicines group to share expertise and information on the regulation of advertising medicines, using a mixture of email exchanges and virtual meetings with a formal meeting planned for late in the year.

The European Commission is conducting a review of the shortcomings of statutory information about medicines and is due to publish a report in 2013. It is not yet clear whether this will have implications for information about medicines more widely or for advertising. The MHRA will provide input to the review and will ensure stakeholders are informed and consulted on any proposals as the Commission develops them.

We will take forward the Red Tape Challenge proposals for advertising in 2013 with a view to any legal changes coming into force towards the end of the year. We will also participate in the forthcoming MHRA-wide review of sanctions and penalties. These projects both feed into the Government’s regulatory priorities, for the MHRA a focus on regulatory excellence – simplifying regulation while delivering our public health outcomes - and
operational excellence – streamlining our processes while retaining the quality of our work.

We will continue to work to ensure that medicines advertising regulation is proportionate and effective and that clear guidance is available on compliance with the legislation.
References

1. 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, under How we regulate/Medicines/Advertising of medicines.
   http://www.mhra.gov.uk/Howweregulate/Medicines/Advertisingofmedicines/index.htm

   http://www.mhra.gov.uk/Howweregulate/Medicines/Advertisingofmedicines/BlueGuide/index.htm

3. Advertising Standards Authority. Details of their work and reports of cases investigated are published on the ASA website at:
   http://www.asa.org.uk/

4. Prescription Medicines Code of Practice Authority. Details of their work and reports of cases investigated are published on the Authority’s website at:
   http://www.pmcpa.org.uk/?q=cases

5. Proprietary Association of Great Britain. Details of their work are available on the PAGB website at:
   http://www.pagb.co.uk/

6. Human Medicines Regulations 2012 (Statutory Instrument 2012 No. 1916). The Regulations can be accessed at:

7. Red Tape Challenge. Details of the medicines theme are available on the Cabinet Office website at:
   http://www.redtapechallenge.cabinetoffice.gov.uk/themehome/medicine/

Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABPI</td>
<td>Association of the British Pharmaceutical Industry</td>
</tr>
<tr>
<td>ASA</td>
<td>Advertising Standards Authority</td>
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<tr>
<td>BCAP</td>
<td>Broadcast Committee of Advertising Practice</td>
</tr>
<tr>
<td>BHMA</td>
<td>British Herbal Medicine Association</td>
</tr>
<tr>
<td>CAP</td>
<td>Committee of Advertising Practice</td>
</tr>
<tr>
<td>CHM</td>
<td>Commission on Human Medicines</td>
</tr>
<tr>
<td>CPRD</td>
<td>Clinical Practice Research Datalink</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
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<tr>
<td>ECJ</td>
<td>European Court of Justice</td>
</tr>
<tr>
<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FOAM</td>
<td>Forum On Advertising Medicines</td>
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<tr>
<td>HFMA</td>
<td>Health Food Manufacturers’ Association</td>
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<tr>
<td>IRP</td>
<td>Independent Review Panel for Advertising</td>
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<tr>
<td>MALG</td>
<td>Medicines Advertising Liaison Group – includes regulatory bodies that deal with medicines advertising including PMCPA, PAGB, ASA, CAP, BHMA, HFMA, Clearcast and RACC</td>
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<tr>
<td>MHRA</td>
<td>Medicines and Healthcare products Regulatory Agency</td>
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<tr>
<td>NIBSC</td>
<td>National Institute of Biological Standards and Control</td>
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<tr>
<td>NHS</td>
<td>National Health Service</td>
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<tr>
<td>OTC</td>
<td>Over-the-counter</td>
</tr>
<tr>
<td>PAGB</td>
<td>Proprietary Association of Great Britain</td>
</tr>
<tr>
<td>PIL</td>
<td>Patient Information Leaflet</td>
</tr>
<tr>
<td>PMCPA</td>
<td>Prescription Medicines Code of Practice Authority</td>
</tr>
<tr>
<td>POM</td>
<td>Prescription only medicine</td>
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<tr>
<td>RACC</td>
<td>Radio Advertising Clearance Centre</td>
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<tr>
<td>RTC</td>
<td>Red Tape Challenge</td>
</tr>
<tr>
<td>SI</td>
<td>Statutory Instrument</td>
</tr>
<tr>
<td>SPC</td>
<td>Summary of Product Characteristics</td>
</tr>
<tr>
<td>THM</td>
<td>Traditional Herbal Medicine</td>
</tr>
<tr>
<td>VRMM</td>
<td>Vigilance and Risk Management of Medicines</td>
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</tbody>
</table>