# Delivering High Standards in Medicines Advertising Regulation

Annual Report
January – December 2013

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

# Contents

# 1

## Chapter 1 – Introduction

This, the eighth annual report of the MHRA Advertising Standards Unit, covers the calendar year 2013. It is designed to promote transparency in the regulation of medicines advertising in the UK. Separate chapters cover action on complaints, vetting of advertising prior to issue and working with others to ensure effective regulation.

**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.
- 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 at www.mhra.gov.uk.

# 2

## 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 by 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 provided in a fact sheet which is available on the MHRA website.

### Action on complaints

In 2013 the MHRA received 283 complaints. This was slightly more than the number received last year (237), but lower than the peak in 2011 (357). Details are provided in the table below.

***Complaints received***

| Year | 2011 | 2012 | **2013** |
|---|---|---|---|
| Complaints received | 357 | 237 | **283** |
| Investigations initiated | 328 | 232 | **272** |
| Complaints referred to other MHRA Units | 16 | 3 | **6** |
| Complaints covering matters already being investigated | 11 | 1 | **4** |
| Complaints being investigated by another body (ASA, Trading Standards or PMCPA) | 2 | 1 | **1** |

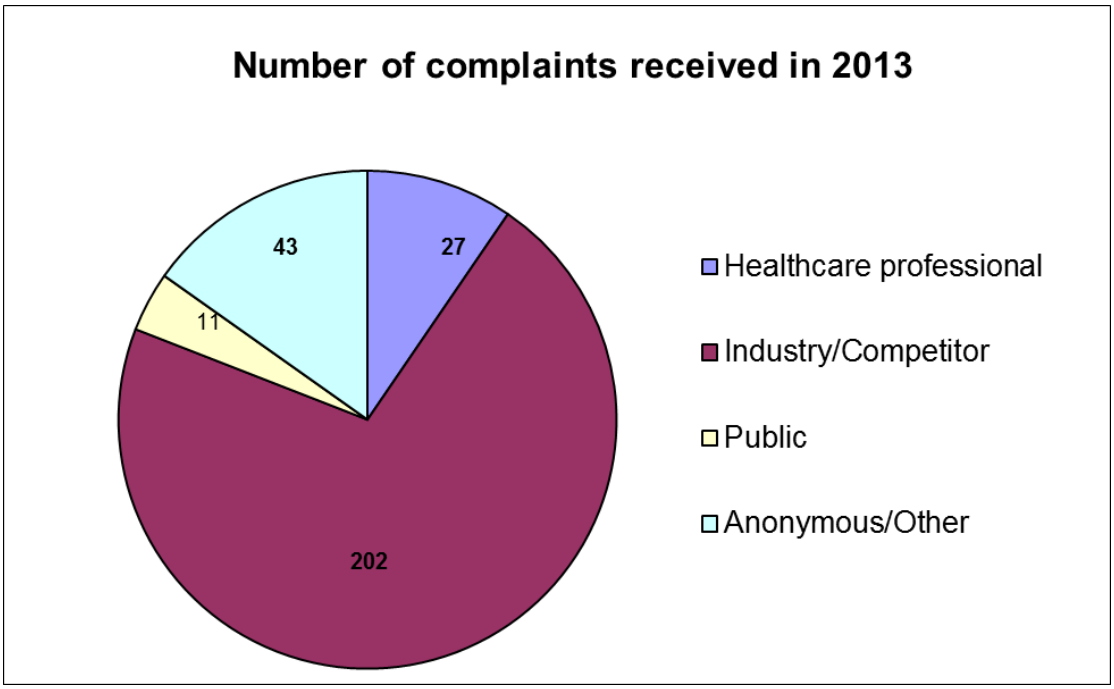
Consistent with previous years, a high proportion of complaints received were about advertising of botulinum toxin products and other prescription only medicines (POMs) to the public. The 2013 increase was largely attributable to a group of complaints about advertising of homeopathic products received from one campaigning organisation.

The MHRA operates a targeted approach to action on clinics and other services offering treatments involving botulinum toxin products and other POMs. This focusses primarily on material on the home pages of clinic websites. The aim is to ensure that customers who are seeking general information on the internet about a clinic or potential treatments are not presented with overt advertising for POMs.

The advertising of treatment services was mainly on websites but we saw an increase in the number of complaints about advertising on social media such as Facebook and also received our first Twitter complaints in 2013. Social media cases now account for more than 10% of our complaints.

It is anticipated that increased awareness of the legal requirements and the actions being taken by the Advertising Standards Authority (ASA) will continue to improve compliance with medicines advertising regulation in this area and we will expect to see further decrease in numbers of complaints in the coming year. Individuals with a concern about medicines advertising on company websites or social media can also complain to the ASA.

***Sources of complaints received in 2013***




Nearly three quarters of the complaints received in 2013 originated from competitors. The majority of these related to advertising of botulinum toxin and other prescription only medicines to the public by third parties. When we take action against one clinic, this often generates several further complaints. Those who have been the subject a complaint in turn complain about their competitors to ensure a level playing field so that they are not disadvantaged.

During the year the Agency only received a small number of competitor complaints about prescription only medicines from marketing authorisation holders as these are mostly investigated by the Prescription Medicines Code of Practice Authority (PMCPA) under the self-regulatory regime.

The rest of the complaints were received from the public and other organisations and anonymous sources (often competitors) with the lowest number of complaints received from members of the public. Members of the public generally tend to raise any concerns they may have about the advertising of over the counter medicines with the ASA.

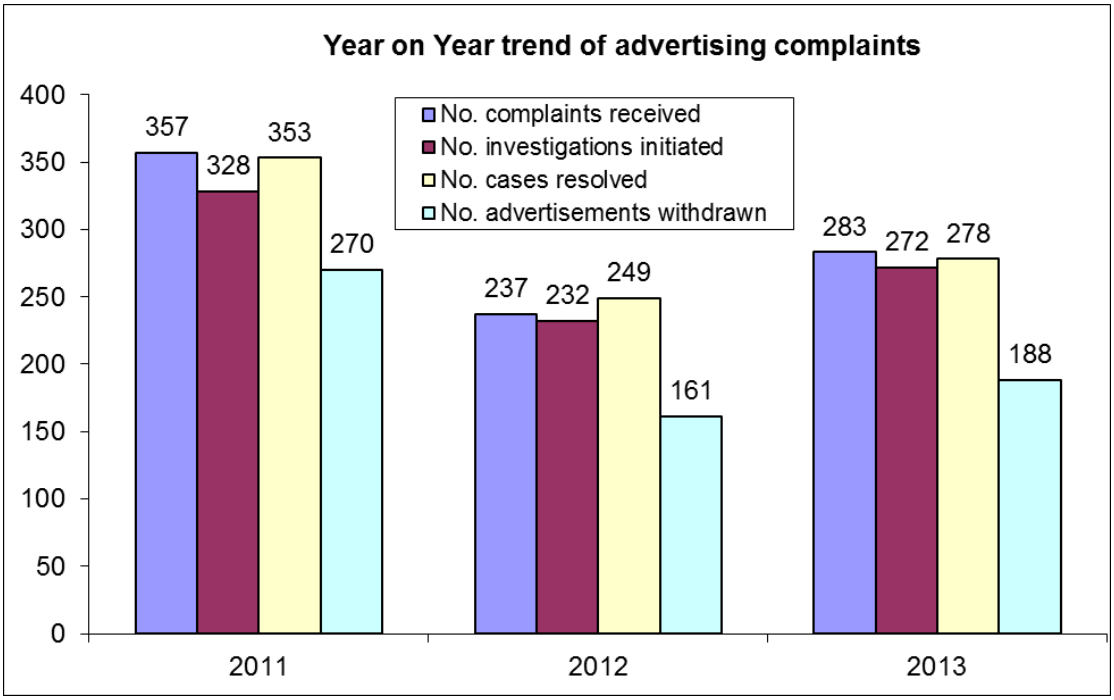
***Outcome of complaint investigations***

| **Year** | 2011 | 2012 | **2013** |
|---|---|---|---|
| **Medicines advertising cases resolved** | 353 | 249 | **278** |
| Advertisements withdrawn | 270 [76%] | 161 [65%] | **188 [68%]** |
| Corrective statements required | 1 | 2 | **0** |
| Summary reports published (excludes enforcement cases) | 28 | 18 (covering 20 cases) | **30** |

During 2013 we resolved 278 advertising complaints in total, a slightly lower figure than the number received (285) but a higher number than cases resolved in 2012. The proportion of cases that were upheld (68%) was similar to last year (65%). Where appropriate and when a potential risk to public health is not identified, the move continues towards concluding simple cases with advice on changes needed and a reference to our published guidance on consumer websites.

The chart below shows trends for complaints received and cases resolved for the last three reporting years. The graph for 2013 illustrates the overall increase from the last year.

***Trends in complaints from 2011 to 2013***



All complaint cases this year were concluded through voluntary agreement with the companies concerned, without the need to resort to statutory procedures. Also, there were no cases of misleading advertising sufficiently serious to require the issue of a corrective statement.

During 2013 we resolved a total of 262 enforcement cases (those dealt with in association with the MHRA Enforcement Group) compared to the 229 resolved in 2012. These cases mainly concerned advertising of POMs to the public, including clinics offering treatments for lines and wrinkles that made promotional references to botulinum toxin products and online clinics and internet pharmacies promoting POMs and unlicensed medicines for various medical conditions. In addition to these, a small number of cases involved advertising of homeopathic remedies, including some unlicensed products.

The MHRA has been increasing its focus on advertising for homeopathic products in the past few years and in 2013 this has resulted in a higher number of complaint cases. Our initial approach when we became aware that standards were not consistent across the sector was to develop clear guidance. We published Homeopathic Medicines: Guidance on advertising for advertisers and suppliers of homeopathic medicinal products in 2011 to raise awareness and explain the specific legal requirements for advertising of homeopathic medicines to the public and to homeopathic practitioners. We subsequently wrote to a number of companies, requesting them to review their advertising to ensure they were meeting the legal requirements. During this reporting year, MHRA received a significant number of complaints in this area, mainly from one campaigning organisation, and took further action to achieve regulatory compliance.

We continue to publish summary outcome reports of cases on the MHRA website on completion of our investigations. During 2013, we published 30 summary reports. Fifteen of these covered 16 complaint cases about POM and OTC products and third party advertising.

In order to be consistent with the approach taken by the MHRA Enforcement Group across a shared responsibility, we have not routinely reported other complaints on the MHRA website except in specific cases where we consider that it will encourage compliance. We already publish a monthly list of clinics offering wrinkle treatments that have revised their advertising following MHRA action on complaints. This year, a limited number of lists of other enforcement cases completed by the Advertising Standards Unit have also been published. Of these, one dealt with advertising for other POMs and two with action taken to ensure that homeopathic medicines were promoted within the terms of their authorisation or registration.

Increased awareness about the restrictions and voluntary compliance have led to fewer cases having to be referred for Enforcement Group action. But where voluntary compliance cannot be achieved the Agency is prepared to take robust action, particularly where a potential risk to public health and safety is identified. The Enforcement Group was successful in closing down

over 1200 illicit websites advertising and / or selling counterfeit and unlicensed medicines in 2013.

**Scrutiny of published advertising**

As well as taking action on complaints, we also monitor published advertising in a selection of widely-read journals and encourage colleagues to refer to us medicines advertisements that they consider to be misleading. In 2013, we issued five reports for cases identified by the MHRA as a result of an initiative to check that companies had implemented changes to the statutory wording in abbreviated advertisements. Eight marketing authorisation holders were found to have failed to implement the change in a range of healthcare professional journals. One other report concerned the advertising of an unlicensed homeopathic product.

As part of our actions to address concerns arising from a US legal settlement in 2012, MHRA carried out a targeted inspection review of one company's controls on the provision of information about the off label use of medicines. A full report on the outcome of the investigation was published on the MHRA website. This is the first time the MHRA has used its statutory powers to inspect advertising compliance and was designed to ensure that confidence in the strength of the UK regulatory system could be maintained. The MHRA expects that this would only be done again very rarely and is encouraging the industry to consider whether a self-regulatory approach could be developed.

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**

As a consequence of MHRA's vetting programme and investigation of complaints under the self-regulatory system, the long term downward trend in the number of advertising cases in the prescription sector has continued in 2013. There were only two complaint cases upheld. All the other cases related to failure to implement the wording change for abbreviated advertisements.

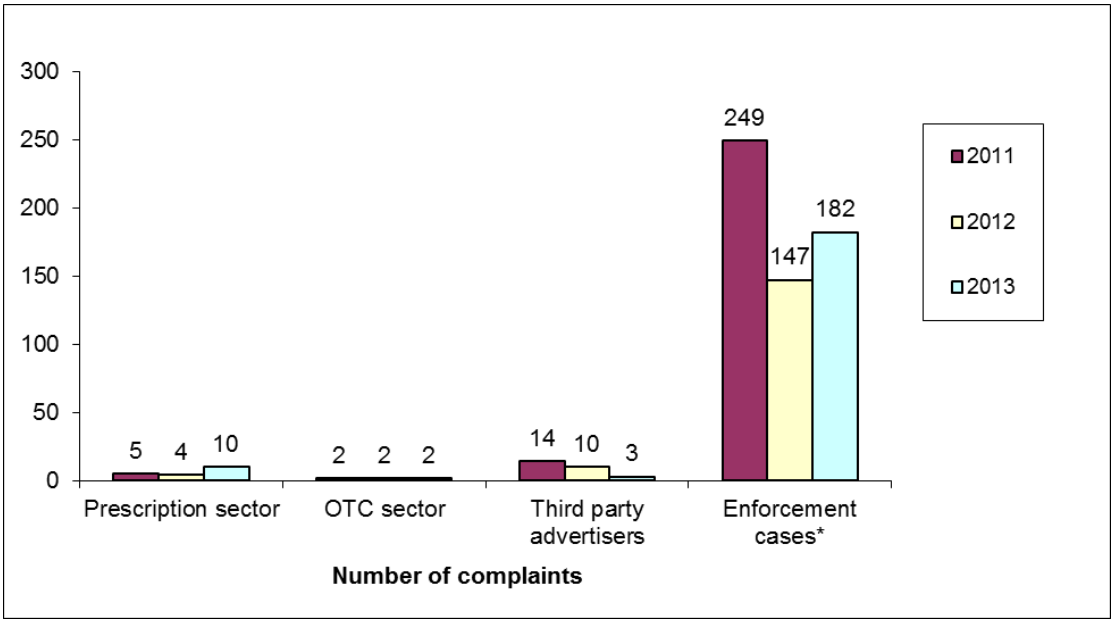
Since the Proprietary Association of Great Britain (PAGB) reviews all proposed advertising to the public by its members, the number of upheld cases each year in the OTC sector is very small. One of five cases was upheld in the year. It concerned a traditional herbal medicine where the advertising failed to make it clear that product was a traditional herbal remedy registered on the basis of traditional use rather than demonstration of efficacy.

The number of upheld cases concerning third-party advertising continues to reduce. The three cases in 2013 included two online treatment service providers and a leaflet for an unlicensed treatment for MS supplied by a pharmacy.

The graph below provides an overview of the number of advertising cases upheld by the MHRA in the last 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 complaint & scrutiny cases by category of medicine 2011-2013***




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 - *Best practice on the sale of medicines for pain relief*. Where appropriate we draw the attention of other retailers to the guidance, as part of a complaint investigation or informal action. One case reported on the website involved the purchase of 96 tablets of aspirin in a single transaction.

Looking at trends over the last few years, it is clear that our focus on prior vetting on the basis of risk, our tailored guidance for advertisers in various sectors and the action we have taken on complaints in the past has served to make complaints investigation a reducing proportion of our regulatory work.

# 3

## Chapter 3 – Vetting advertising before issue

The MHRA reviews advertising prior to issue for a small number of products each year to reduce the potential for issuing misleading messages about medicines. In choosing products, we take a risk-based approach. We choose to 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.

***Vetting Statistics for 2011 to 2013***

| Year | 2011 | 2012 | **2013** |
|---|---|---|---|
| New active substances (excluding orphan products) | 29 | 19 | **33** |
| Orphan products for rare conditions | 2 | 8 | **7** |
| Reclassified products (POM to P) | 3 | 1 | **0** |
| Vetted after action on previous breach | 2 | 0 | **0** |
| Other products (includes safety concerns, major new indications) | 15 | 12 | **9** |
| **Total** | **51** | **40** | **49** |

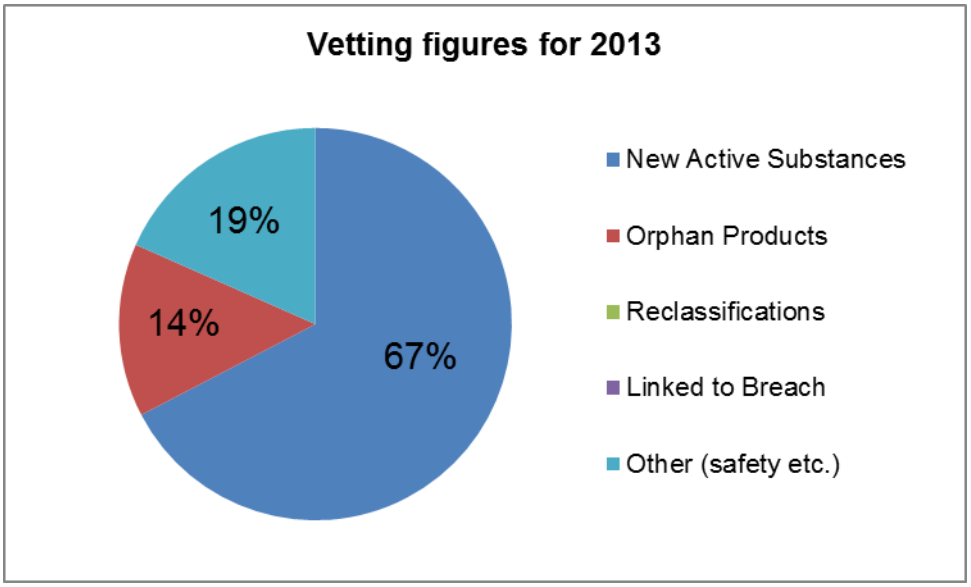
We aim to vet around 50 products each year. The 20% reduction in number of products vetted during 2012 was due to an unexpected fall in the number of new active substances and levels appear to have returned to usual levels in 2013.

In 2013 we vetted advertising for 40 **new active substances**. These included launch advertising for some significant new and innovative products, including products for the treatment of patients with multiple sclerosis, breast cancer, HIV and a vaccine for Meningitis B.

This total number of new active substances vetted included seven **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 2013 included new treatment options for idiopathic pulmonary fibrosis and specific rare forms of cancer.

Following the launch of a streamlined reclassification procedure in late 2012, we expected to see an increase in the number of **reclassified products** vetted. Although the MHRA has held an increased number of scientific advice meetings in this area, this has not yet fed through to granted applications and in 2013 we did not vet any material for reclassified products.

***Types of products vetted***




There has also been a small decrease in the number of products vetted for other reasons over the past three years. These products were selected based on **safety concerns, major new indications**, and **significant new combinations**. The nine products vetted in 2013 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.

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. This was also the case in 2012 and we would attribute this to a better understanding of the requirements for promotional material from experience of vetting as well as the effect of the vetting process itself.

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.

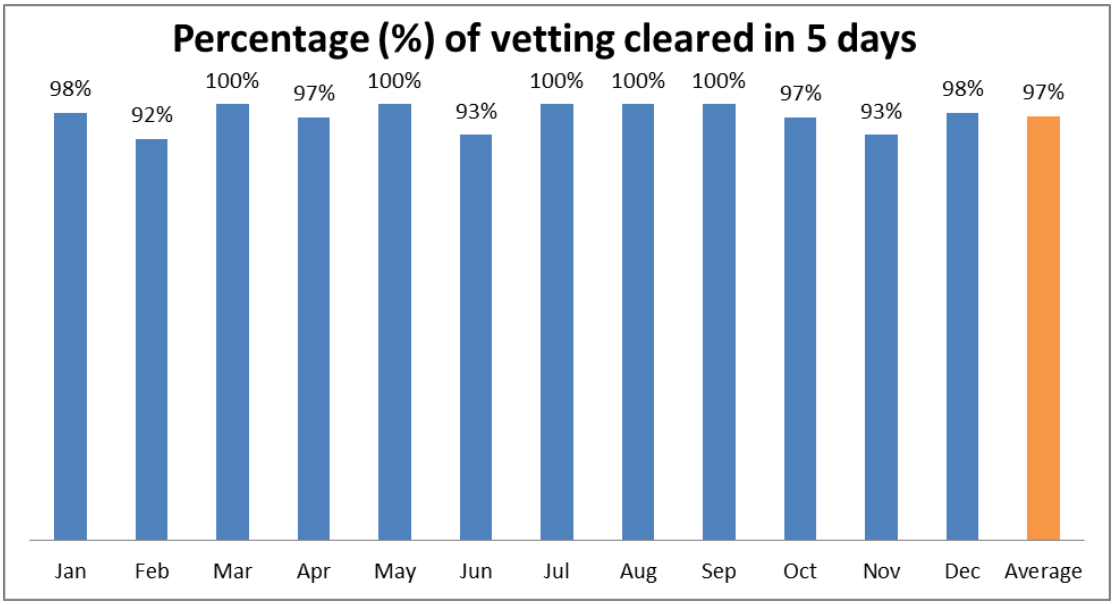
**Advertising Standards Unit Performance**

During the reporting period, our target to respond on advertising pieces submitted for vetting within five working days was achieved 97% of the time, up from 93% last year. Our minimum target of responding within five working

days for at least 80% of pieces was achieved every month. Monthly achievement ranged from 92% in February to 100% in 5 other months.

The figure below shows the proportion of advertising pieces vetted within five working days each month in 2013.

***Vetting performance in 2013***




We seek advance notice from companies about the proposed timetable for submission of advertising to help us to plan the vetting process with medical assessors internally. This is vital if we are to meet our target of five working days and thereby to avoid potential delays for the product launch. Occasionally we need to renegotiate submission dates when large volumes of advertising arrive for assessment unexpectedly. We recognise that timetables are subject to change but ask that companies keep us informed of when they expect to submit initial materials. When 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.

The average number of items reviewed per product has remained fairly constant each year and was around 10 in 2013. The number of items reviewed can vary dramatically between products, from a single piece for an orphan product or safety related vetting to more than 20 for some new actives. The mix of products therefore influences this figure as much as improvement in the quality of submissions.

When the MHRA needs to discuss amendments to proposed advertising claims during the vetting process, these are usually dealt with by teleconference but we did hold one formal chargeable scientific advice meeting in 2013. Advice meetings are available when companies request them and have proved a useful way to explore issues raised by the MHRA in response to advertising proposals submitted.

In 2013 there was one instance where a company 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 2013 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.

- **Comparisons**
  Comparisons with other products should not ‘cherry pick’ favourable findings without setting these in the context of the overall study results. Presenting efficacy comparisons without including details of relevant differences in safety is likely to mislead.

- **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**

One of the advertising outcomes of the Government's Red Tape Challenge focus on medicines regulation in April 2012 was a commitment to assess the impact of vetting on the quality of advertising and promotional materials. To achieve this we carried out a review of all new products vetted in the first eight months of 2012.

The aims of the review were to assess:

- the extent to which vetting of advertising contributes to raising standards for advertising and promotion of medicines, and
- whether vetting is being targeted on the most appropriate categories of products.

We focused our survey on the review of the first substantial item to be submitted for each product, usually the detail aid. The majority of the claims for a product are normally included in this item and it is unusual for major issues to arise subsequently. Where the detail aid was not the first item submitted, earlier items were checked to ensure we captured all of the major issues.

Our review covered promotional material for 20 products. For 14 of these products, we identified at least one significant issue where information in materials submitted may have failed to adequately inform prescribers as to the benefits and risks associated with use of the product. All materials had minor issues where improvements could be made to the advertising but there was not considered to be a significant risk that prescribers would be misled or uninformed as to the appropriate use of the product. The results are tabulated below:

***Results of review of 2012 vetting cases***

| **Reason for vetting** | **No. of products** | **No. (%) with significant issues** | **No. with minor Issues** |
|---|---|---|---|
| **New active substance*** | 11 | 7 (64%) | 11 |
| **Orphan product** | 6 | 5 (83%) | 6 |
| **Safety** | 3 | 2 (67%) | 3 |
| **Total** | 20 | 14 (70%) | 20 (100%) |

*Excluding orphan products

The significant issues raised in the cases reviewed were as follow:

- Indication (2) – one concerned insufficient differentiation between the indicated use and secondary effects and the second a lack of clarity that the product was indicated for use with another therapy.
- Claims (7) – these included exaggeration of comparative claims, particularly where differences were not statistically significant, a lack of clarity that data were derived from volunteer or *in vitro* studies, unclear presentation of NICE advice, an exaggerated usability claim and a misleading image.
- Safety (5) – these included exaggerated claims for manageability of ADRs and failure to include adequate information on key SPC warnings, significant ADRs or risk management measures.

These issues were more around omission of information from the body of the advertisement that could be found in the small print, rather than the provision of actively misleading information. Nevertheless, the initial impression gained could have exaggerated the benefits or safety of the product.

We identified a significant issue with promotional items for nearly two-thirds of new active substances vetted and the proportion was similar for products vetted for safety reasons, although the number in this latter category was small.

One of the questions we wanted to investigate was whether we could cease vetting of orphan products to reduce the regulatory burden. In fact, orphan medicines showed the highest proportion of products with significant issues. The MHRA already takes a proportional approach for assessing advertising for orphan products and, based on these results, we do not intend to change this. Orphan products are often developed by smaller companies with relatively limited experience in promoting medicines and this may help to explain the relatively high number of issues identified through vetting.

Another question was whether our requirement to see non-promotional materials such as press releases could be relaxed. Although promotion of prescription only medicines to the public is prohibited, as a matter of policy we agree that companies may issue a press release to announce the launch of an innovative new product. These must be factual, balanced and non-promotional in content. Half of the press releases vetted had issues identified in relation to content that was deemed promotional. Again, we do not propose any changes to our current practice.

We found that most of the issues were identified at an early stage of vetting and we will seek to ensure that we minimise the duration and number of items reviewed in the future.

The overall result of the survey was that 70% of the products vetted in the survey period had promotional material containing at least one significant issue that had the potential to mislead prescribers. This clearly indicates the need for pre-vetting, that it is indeed adding value and that the current

targeting is achieving the aim of raising standards for advertising and promotion of medicines.

**Measuring quality**

One of the regular methods we use to assess the quality of vetting assessment is to monitor upheld complaints about advertising vetted by the MHRA. When complaints concerning vetted advertising are upheld by either the MHRA or the PMCPA, these are reviewed closely for learning points for future vetting.

The MHRA is aware of four products where material vetted by the MHRA was subject to complaints in 2013. This is a similar number to previous years and a small proportion of the overall number of pieces vetted in the year. All four relate to complaints upheld by the self-regulatory Prescription Medicines Code of Practice Authority and each case is described below.

**Lyxumia (lixisenatide)**
This concerned claims that Lyxumia was 'the only once-daily prandial GLP-1 receptor agonist', that 'a positive addition can make all the difference' and there was 'strong evidence supporting the use of Lyxumia as add-on to basal insulin' The PMCPA ruled that all three claims were misleading and exaggerated the benefits of the product.
PMCPA case AUTH/2600/4/13

**Flutiform (fluticasone/formoterol)**
This concerned claims for comparable efficacy between Flutiform and Seretide that did not reflect Flutiform's more restricted indication and the limitations of the data used to support the comparisons. The PMCPA ruled that these were misleading.
PMCPA case AUTH/2570/12/12

**Picato (ingenol mebutate)**
This concerned the claim that Picato is 'the revolutionary, shortest duration, patient-applied actinic keratosis treatment'. The PMCPA ruled that this claim exaggerated the properties of the product by failing to make the indication and time to effect of treatment clear.
PMCPA case AUTH2583/3/13

**Seebri Breezhaler (glycopyrronium bromide)**
This concerned a general claim that 'reductions in exacerbations can reduce mortality rates' and a table detailing the endpoints of two studies. The PMCPA ruled that both were misleading.
PMCPA case AUTH/2588/3/13

The MHRA reviewed the above material again to ensure that the points raised in the PMCPA's assessment would be taken into account for future vetting cases.

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.

# 4

# Chapter 4 – Working with others

### Medicines Advertising Liaison Group

During 2013, we have worked closely with the other bodies involved in the regulation of medicines advertising on a range of issues in order to ensure a common understanding and consistent high standards across self regulatory and statutory bodies. One formal meeting of the Medicines Advertising Liaison Group (MALG) was held during the year. Discussions focussed on topics of current concern, including use of digital communications media in advertising and advertising for homeopathic and nicotine replacement products. We also had a number of informal contacts with MALG colleagues on issues arising from casework.

During the year the PMCPA consulted on and published a new edition of the ABPI Code of Practice for the Pharmaceutical Industry. The amendments were designed to incorporate the requirements of the new European EFPIA Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations and changes to the existing EFPIA Codes. The opportunity was also taken at the invitation of the MHRA to include additional statements about adverse reaction reporting for patient materials, in line with new pharmacovigilance requirements for statutory information. The MHRA was fully consulted during this process and welcomed the changes made to the Code.

### Red Tape Challenge

In 2012, the MHRA participated in the Red Tape Challenge, a Government initiative to identify unnecessary or unduly onerous legislative burdens on industry and commerce that can be removed. Good progress has been made on each of the three advertising projects identified to take forward.

### Benefits and burden imposed by MHRA vetting of advertising

We undertook a review of the benefits of vetting for products vetted in 2012 to assess whether the actions of the MHRA in preventing the publication of potentially misleading advertising were justified. The results of this survey are described in chapter 3. The conclusion was that the current targeting vetting is achieving the aim of raising standards for advertising and promotion of medicines.

We have also committed to reviewing the way vetting is handled for OTC products. The next time we vet advertising for an OTC product we plan to test out simplifications to our procedure that take into account of the role of PAGB in vetting materials aimed at the public.

**Simplification of statutory information requirements for advertising to prescribers and suppliers of medicines**

This proposal was designed to reduce the number of times advertising has to be revised when changes are made to the statutory information on a medicine. Further discussions were held with ABPI and PAGB during the year to identify options and obtain preliminary estimates of the cost savings to be expected. A consultation is planned in Spring 2014 on three proposals to extend the use of the abbreviated advertisement format for OTC medicines and to widen the use of the SPC as a source of information.

**Review of the ban on advertising to adolescents with certain conditions such as acne**

As a first step, MHRA invited the companies concerned to review whether there were any measures that could be taken within the existing legal constraints. It was anticipated that this would identify whether legal change was necessary and provide evidence to support any move to seek a change to European law to provide for national flexibility on the age limit. PAGB advised during the year that that this was not a current priority for the member companies concerned. The MHRA remains ready to take forward the initial review should companies request it in the future.

**European forum on advertising regulation (FOAM)**

This forum, co-ordinated by the MHRA, allows teams responsible for regulation of medicines advertising in each member state to exchange information about policy questions and other aspects of our work. Information was exchanged on a number of issues in 2013, including disease awareness campaigns, detailing using digital media and patient support programmes. A second annual meeting was hosted by the MHRA in London in November 2013 with 15 member countries represented. We also welcomed a colleague from the Canadian regulatory authority. This proved a valuable opportunity to exchange ideas on the variety of regulatory enforcement tools used in different European countries and Canada. We heard from EFPIA on their new Disclosure Code and discussed a range of current issues of concern including transparency of hospitality and gifts to health professionals and the use of social media in advertising.

# 5

## Chapter 5 – Future direction

This year has been a time of change for the MHRA, which merged with the National Institute of Biological Standards and Control (NIBSC) 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. The divisions that regulate medicines sit within the Regulatory Group of the expanded Agency. Our work in the Advertising Standards Unit fits mainly under the corporate theme of 'the role of regulation and the regulator'.

Our annual seminar – Hot Topics in Medicines Advertising Regulation – in February 2014 will provide the opportunity to feed back to industry on the outcome of our work in 2013. For the first time, the seminar will include information on complaints dealt with by the PMCPA and advertising to the public reviewed by PAGB to give a comprehensive view of regulatory action in the past year.

In the coming year, we expect to vet advertising for around 50 products 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. We will also continue to investigate complaints about advertising medicines and monitor published advertising, ensuring action on potential breaches of the legislation is timely and effective.

We will take forward the Red Tape Challenge proposals to simplify the information requirements for advertisements aimed at prescribers and suppliers of medicines, with a view to the legal changes coming into force in October 2014. This will necessitate changes to our Blue Guide and to self-regulatory Codes of Practice. We will take the opportunity to consider if any other changes to the Blue Guide are required and to review our enforcement policy for websites offering treatment services.

We will continue to work proactively with self regulatory bodies and other stakeholders to ensure consistent high standards in the coming year.

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 an annual meeting.

A European Commission review on the shortcomings of statutory medicines information medicines was due for completion in 2013 but the report is now expected to be published in 2014. It is not yet clear whether this will have implications for information about medicines more widely or for advertising.

We will ensure that stakeholders are informed and consulted on any proposals as the Commission develops them.

More widely, we will also continue to work with colleagues on initiatives that promote access to innovative medicines through such models as adaptive licensing and early access schemes.

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.

## Further information

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

2. The Medicines and Healthcare products Regulatory Agency (MHRA). The Blue Guide: Advertising and Promotion of Medicines in the UK. London: Third edition, 2012. This is available at: 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: http://www.legislation.gov.uk/uksi/2012/1916/contents/made

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

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