Delivering High Standards in Medicines Advertising Regulation

2018 Annual Report

28 February 2019

Advertising Standards & Outreach Unit
Vigilance and Risk Management of Medicines Division
Medicines and Healthcare products Regulatory Agency
# Contents

1. **Introduction** 2  
   Transparency 2  

2. **Investigating published advertising** 3  
   Action on complaints 3  
   Scrutiny of published advertising 5  

3. **Vetting advertising before issue** 8  
   Type of product vetted 8  
   Advertising Standards Unit performance 10  
   Key learning points 11  
   Measuring quality 12  

4. **Working with others** 13  
   Medicines and Devices Advertising Liaison Group 13  
   PAGB Codes of Practice 13  
   ABPI Code of Practice 13  
   European Forum on Advertising Medicines (FOAM) 14  

5. **Future direction** 15  
   Annual webinars 15  
   Complaints 15  
   Vetting 15  
   Supporting self-regulation 15  
   International work 16  

**Abbreviations** 17
1. **Introduction**

The MHRA has published an annual report on the regulation of medicines advertising since 2005-6 to promote transparency. This is our 13th report and covers the calendar year 2018. The report includes details of our action on complaints, on vetting of advertising before issue and on how we have worked with others to ensure effective regulation.

Advertising regulation is included within the responsibilities of the Advertising Standards and Outreach Unit. The team sits within the group responsible for Access and Information for Medicines and Standards (AIMS) in the Vigilance and Risk Management of Medicines Division (VRMM). During 2018, the MHRA Head Office moved to a new Government Hub building in Canary Wharf. Our correspondence address is now:

MHRA Advertising Standards and Outreach Unit  
10 South Colonnade  
London  
E14 4PU

The advertising team continues to work closely with MHRA colleagues in other areas including Licensing Division assessors and the Enforcement and Borderline teams in the Inspection, Enforcement and Standards Division.

**Transparency**

Transparency and access to clear advice is a key aspect of our service to stakeholders. We continue to take a range of actions to promote openness of our work in regulating medicines advertising. In 2018, these have included:

- Publishing on our webpages [outcome reports](#) for complaint and scrutiny cases, and reporting every month on vetting performance.
- Individual advice for advertisers including a dedicated mailbox for enquiries, [advertising@mhra.gov.uk](mailto:advertising@mhra.gov.uk). Although the team does not have resource to offer a review service for individual advertisements before issue, we are always ready to provide advice on compliance with a specific point of law or on whether advertising for a new product will need to be submitted for vetting.
- Annual webinars for industry on current hot topics in advertising regulation, with examples of good and bad advertising from our casework and contributions from self-regulatory bodies.
- Close working with self-regulatory bodies to ensure consistent standards.

Information about advertising regulation and all these activities can be found on the page [Advertise your medicines](#) within the MHRA section of [www.gov.uk](http://www.gov.uk).
2. Investigating published advertising

Among its key functions MHRA has a legal obligation to investigate complaints about medicines advertising. We receive complaints and referrals about advertisements from many sources including members of the public, healthcare professionals, competitor companies and other interested parties. Any concerns and complaints can be made to MHRA by using the online complaint form, by sending an email to the advertising mailbox or by post.

Action on complaints

In 2018 MHRA received a total of 158 complaints, a similar number to last year’s figure of 155 and in line with the overall downward trend in recent years.

Complaints received 2016-18

<table>
<thead>
<tr>
<th>Year</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complaints received</td>
<td>171</td>
<td>155</td>
<td>158</td>
</tr>
<tr>
<td>Investigations initiated</td>
<td>166</td>
<td>153</td>
<td>157</td>
</tr>
<tr>
<td>Complaints referred to other MHRA Units</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Complaints being investigated by another body (ASA / PMCPA)</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Consistent with previous years, a high proportion of complaints received concerned advertising of botulinum toxin products and other prescription only medicines (POMs) to the public by cosmetic clinics and other service providers including online clinics and pharmacies. Most of these complaints were mainly about advertising for botulinum toxin products on websites and social media including Facebook, Instagram and Twitter.

We also investigated a small number of other complaints ranging from advertising for over the counter medicines and homeopathic products, to unlicensed medicines for prescription.

Members of the public generally tend to complain to the ASA about the advertising of medicines. In 2018 the proportion of all complaints received by MHRA from members of the public increased from around a third to a half. The majority of these related to advertising of prescription only medicines containing botulinum toxin to the public by third parties. This is unlike previous years when most complaints originated from competitors.

During this year only around a third of complaints were received from competitors, usually clinics and service providers who have been subjected to MHRA action on website and social media advertising, and therefore tend to report their competitors in order to ensure a level playing field. This reduction could be due to competitors being unwilling to be identified as such.
In 2018 we received a very small number of inter-company complaints from marketing authorisation holders. This is in line with previous years as most pharmaceutical companies use the self-regulatory regime to resolve their concerns and disputes unless the advertiser has chosen not to accept the jurisdiction of the relevant self-regulatory body. When the self-regulatory option is not available such complaints are referred to MHRA for investigation.

The MHRA fully supports use of the self-regulatory system and encourages companies to firstly use inter-company dialogue and the self-regulatory regime to resolve medicines advertising issues where appropriate and would only investigate cases where the advertiser has chosen not to accept the jurisdiction of the self-regulatory body, or where safety issues are identified. The MHRA does not generally progress any complaint that is under investigation by another self-regulatory body unless safety issues are identified.

As the pie chart above shows the remaining complaints were received from healthcare professionals, other organisations and anonymous sources.

The table overleaf shows that in 2018 MHRA resolved a total of 140 advertising complaints. This is a slight increase compared to the 132 cases resolved last year.

The proportion of cases that were upheld and resulted in withdrawal of, or changes to, advertising (50%) was the same as last year (50%). Where appropriate and when a potential risk to public health is not identified, we continue to conclude simple cases with advice on changes needed and a reference to our published guidance on consumer websites.
Outcome of complaint investigations 2016-18

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines advertising cases resolved</td>
<td>172</td>
<td>132</td>
<td>140</td>
</tr>
<tr>
<td>Advertisements withdrawn</td>
<td>98 (57%)</td>
<td>66 (50%)</td>
<td>70 (50%)</td>
</tr>
<tr>
<td>Corrective statements required</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Summary reports published (exc. enforcement cases)</td>
<td>27</td>
<td>14</td>
<td>13</td>
</tr>
</tbody>
</table>

The chart below shows trends for complaints received and cases resolved for the last three reporting years. Numbers for 2018 were very similar to those for 2017.

Trends in complaints 2016-18

This year all complaint cases were concluded through voluntary agreement with the companies concerned, so we did not need to resort to statutory procedures. Furthermore, there were no complaint cases of misleading advertising sufficiently serious to require the issue of a corrective statement.

Scrutiny of published advertising

In addition to investigation of complaints, we also scrutinise published advertising in selected journals and other media, and we investigate referrals from colleagues in the Agency or other regulatory authorities.
We resolved two scrutiny cases in 2018. The first case, which was brought to our attention by another regulatory authority, related to a media advisory board for a medicine that had not yet received a marketing authorisation; we considered that this advisory board was designed to promote an unlicensed medicine to the attendees (mainly journalists). The company concerned was required to issue a corrective statement to the journalists that had attended the meeting. The second case concerned an advertisement displayed in a pharmacy for an over-the-counter medicine. The MHRA considered that the advert did not promote the rational use of the medicine and it was withdrawn.

During the year we also provided advice and dealt informally with a range of other cases and issues referred to us by the public, companies, colleagues and other regulators such as the ASA and PAGB. These included a small number of referrals about the sale in retail outlets of an excessive quantity of OTC analgesics containing paracetamol.

Review of key cases

The following graph provides an overview of the number of upheld advertising cases over the last three reporting years. It covers both internal monitoring and complaints and is broken down by sector as follows:

- Prescription medicines
- Over the counter medicines
- Advertising by third parties such as pharmacies, clinics and online suppliers
- Cases dealt with in association with the MHRA Enforcement Group

Upheld complaint & scrutiny cases by category of medicine 2016-18

In 2018 the number of upheld cases concerning POMs advertised by manufacturers remained very low since the vast majority are dealt with under self-regulation. The number of upheld cases
each year in the OTC sector remains low since PAGB reviews prior to issue all consumer advertising from their members.

Upheld cases of interest included the advertising of a POM on an online publication that was not wholly or mainly directed at prescribers and suppliers of medicines; advertising of unlicensed medicines in a newsletter on the manufacturer’s website and an inaccurate e-mail communication about a POM that was sent to selected healthcare professionals from what purported to be a news source.

In the OTC sector, the single upheld case concerned a tweet by the manufacturer of an OTC product that MHRA considered constituted an implied recommendation by a celebrity.

In 2018 we resolved a total of 65 enforcement cases (those dealt with in association with MHRA’s Enforcement Group), similar to 2017 when 64 cases were resolved. These included a variety of issues from advertising of POMs to the public, including by clinics offering treatments for lines and wrinkles and unlicensed homeopathic remedies. During 2018 we referred one case for Enforcement Group action where we were unable to achieve compliance.

The MHRA Enforcement Group takes robust action, particularly where a potential risk to public health and safety is identified. In 2018 Enforcement Group investigations led to the successful prosecution of a person for the manufacture and sale and supply of an unlicensed medicine advertised as a ‘miracle cure’. Details are available here. The Advertising Standards Unit continues to provide support for prosecution cases as required.

We continue to publish summary outcome reports of cases on the GOV.UK website on completion of investigation. In 2018 we published a total of 15 summary reports. For consistency with the approach adopted by our Enforcement Group across this shared responsibility, we do not publish on our website individual reports on complaint cases relating to the promotion of POMs to the public following MHRA action. But for transparency and in order to encourage regulatory compliance, we continue to publish on the Agency website regular lists of clinics offering wrinkle treatments that have amended their advertising after MHRA action on complaints and occasional lists of other enforcement cases. Eight such lists were published during the year.

The listing of an advertiser related to specific advertising action taken by the MHRA on a particular date should not be viewed as endorsement of the ongoing practices of the service or future content of its website.
3. Vetting advertising before issue

Each year MHRA performs a targeted review of advertising prior to issue for a small number of products. This is to ensure that advertising is right first time and compliant with the legislation, thus preventing misleading messages and any potential negative impact on public health and safety.

Type of product vetted

We aim to vet advertising prior to issue for around 50 products each year but in 2018 MHRA only vetted material for 37 medicines. This is down from the 2017 number (45) but in line with the 38 products vetted in 2016. These fluctuations reflect the general trend for fewer new active substances being authorised at a European level.

We use the same risk-based approach to choose vetting candidates each year. Advertising for new active substances is always reviewed before launch. We select other vetting candidates by using a risk-based approach and these may include:

- innovative reclassified medicines,
- products that raise significant new safety concerns or have significant new indications or new combinations of active substances, and
- products where there may have been previous breaches of Part 14 of the Regulations by the marketing authorisation holder.

Vetting statistics 2016-18

<table>
<thead>
<tr>
<th>Year</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>New active substances (excluding orphan products)</td>
<td>17</td>
<td>22</td>
<td>13</td>
</tr>
<tr>
<td>Orphan products for rare conditions</td>
<td>10</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>Reclassified products (POM to P or P to GSL)</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Advertising vetted linked to previous breach</td>
<td>6</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Other products (includes safety concerns, major new indications)</td>
<td>5</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>38</td>
<td>45</td>
<td>37</td>
</tr>
</tbody>
</table>

In 2018 we vetted launch advertising for a total of 27 new active substances, again, fewer that last year but similar to the number vetted in 2016, although the ratio of orphan products to other new active substances varies. The number included innovative products for a wide range of medical conditions including various cancers, rheumatoid arthritis, asthma, migraine and type 2 diabetes.
The 14 new orphan products vetted in 2018 included new treatment options for cystic fibrosis, spinal muscular atrophy, X-linked hypophosphataemia, stem-cell treatments for eye damage and complications of Crohn’s disease. Since orphan products are indicated for medical conditions with a very small patient population, marketing is usually limited and targeted at specialist prescribers. We continued with our proportionate approach and only assessed a limited number of items for each product.

We reviewed five products due to safety concerns in 2018, including medicines for the treatment of epilepsy, morning sickness, headache/migraine and an anaesthetic, and three products were reviewed following significant changes to their indication. The MHRA licensing assessors involved in the review of the new marketing authorisation applications or variations to existing authorisations alerted the advertising unit to concerns about the potential for non-compliant marketing claims that may be made.

We vetted promotional material for one reclassified product in 2018, a treatment for erectile disfunction switched from prescription only to pharmacy sale. We ensured that advertising to the public was consistent with the licensed indication and that material intended for pharmacists and their staff reflected key elements of the risk minimisation material.

During the year MHRA started vetting all promotional material for one particular marketing authorisation holder, Astellas UK. Following their renewed suspension from the ABPI in 2017, MHRA put the company on notice that, should they be expelled from the ABPI or be found in breach of the ABPI Code again, MHRA would require all promotional material to be submitted for review before it could be issued. Following PMCPA’s decision to uphold Case AUTH/2984/10/17, MHRA began vetting Astellas’ material in December 2018 and we have accounted for this as one product “linked to breach”.

![Pie Chart: Type of product vetted 2018]

- Orphan medicines
- New actives (ex. orphans)
- Safety concerns & new indications
- Linked to breach
- Reclassifications
Individual advertisements for other products were also reviewed as required as part of follow-up action on upheld complaint and scrutiny cases, to ensure that misleading messages were corrected.

**Advertising Standards Unit performance**

We aim to give an opinion on materials submitted for review within five working days and this was achieved for 97% of items in 2018. Every month we exceeded our minimum 80% target to respond within five working days and we achieved 100% in six months. Our lowest individual month was January, when we achieved 91%, having missed the target for 1 of the 11 items reviewed. The average number of items reviewed per month in 2018 was 22 but August and September saw a particularly busy period with 99 items reviewed.

**Vetting performance 2018**

![Percentage of vetting cleared in 5 days](chart)

We can only achieve this level of performance by working closely with companies and asking them to give us advanced notice about the proposed timetable for submission of advertising. This helps us to plan the vetting process with our medical assessors and meet our target. Sometimes we may have to renegotiate submission dates with companies to accommodate the availability of medical assessors or when large volumes of advertising are submitted without notice.

We recognise that timetables can change but ask that companies keep us informed of their expected date of submission, particularly for initial materials. Where possible we also try to accommodate companies that require expedited review for specific individual pieces.

Generally, the vetting process starts before the grant of a marketing authorisation in preparation for a product launch. It continues until key pieces have been reviewed and MHRA is satisfied about the quality of materials. Vetting usually lasts for approximately two months but may be shortened if initial pieces are of a high standard. The vetting period may be extended if initial materials are not satisfactory and raise concerns about the quality of the material or where key promotional pieces are still being developed.

In 2018 the average number of items reviewed per product remained around nine, the same as the
year before. The number of items reviewed can vary significantly between products, from a single piece or small selection of material for an orphan product, to more than 40 items for reclassified products with extensive marketing campaigns. The mix of material and the quality of items submitted can affect this figure.

We updated our guidance for vetting in 2018, providing up-to-date information and advice on the vetting process. It is designed to help ensure that the vetting exercise is carried out efficiently and includes guidance on the type of material covered by vetting, how to submit it, details about procedures and our response letters and our Top Tips to help ensure quality material. In most cases our response letters list out the specific points that should be addressed before the material is issued. Resubmission of revised material for further review is required in only a few cases where we consider that substantial changes need to be made. Where revised submission is required this is clearly stated in our response. We saw an increase in the number of items requiring resubmission in 2018 to around 8% of all items submitted. This was primarily driven by problems identified with several items for a small proportion of products, rather than a general trend across the range of products vetted.

When either the company or MHRA need to discuss amendments to proposed advertising claims during the vetting process, these are normally dealt with by teleconference. In other cases, companies may choose to request a chargeable scientific advice meeting at the start of the vetting process for their products or to help explore issues raised by the MHRA in response letters on proposed advertising. In 2018 MHRA held one advice meeting prior to the pre-vetting of promotional material for a new product combination used to treat melanoma.

Key learning points

**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, particularly where use is restricted to a specific patient group or as second line treatment.

**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, key contraindications, warnings, side-effects and details of any monitoring required from the product SPC.

**Accurate claims**

Claims should be supported by the balance of evidence available and include sufficient information to allow the reader to judge the importance of the claim for themselves. Primary endpoints should be presented prominently and relevant limitations of secondary or exploratory findings explained. Associated graphics should not exaggerate the benefits of treatment.

**Fair comparisons**

Comparisons with other products should not ‘cherry pick’ favourable findings without setting these in the context of the overall study results, particularly in non-inferiority studies. Presenting efficacy comparisons without including details of relevant limitations on prescribing or differences in safety is likely to mislead. It is unlikely that cross-trial comparison will be
sufficiently robust to support comparative claims.

**Material for the public**

Promotion of prescription only medicines to the public is prohibited. Exceptionally, companies may issue a press release to announce the launch of an innovative new product. This must be factual, balanced and non-promotional in content. Clinical trial data or comparisons should be presented as factual findings, including the population, duration and endpoints. Press releases shouldn’t use emotive or alarming language or raise unreasonable patient expectations. Likewise, patient materials must be consistent with the patient information leaflet and not contain promotional claims.

These points should be considered by all advertisers to help ensure compliance with the regulations, but in terms of the vetting process, submitting high quality advertising from the start is likely to result in a reduced period of vetting and help the process run efficiently.

**Measuring quality**

We monitor upheld complaints about advertising vetted by the MHRA in order to assess the quality of our vetting assessments. When complaints concerning vetted advertising are upheld by either the MHRA or the PMCPA, these are reviewed closely for learning points for future vetting.

There were no cases in 2018 where material vetted by the MHRA was subsequently the subject of a complaint to the PMCPA.

Vetting gives companies an opportunity to hear the MHRA view on their advertising more generally than is the case with action on a specific complaint. Feedback from companies suggests that the comments are generally useful and provide a new perspective. The consistently low number 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. Working with others

Medicines and Devices Advertising Liaison Group

The MHRA continues to be a strong supporter and advocate of self-regulation for medicines advertising. The Medicines Advertising Liaison Group provided a forum for close working with the other bodies involved in the regulation of medicines advertising for many years. This group has been successfully expanded to become the Medicines and Devices Advertising Liaison Group (MDALG). The remit of the new group now includes the regulation of advertising for medical devices and now includes representatives from MHRA Medical Devices division and the Association of British HealthTech Industries (ABHI) as members.

One meeting of MDALG was held in 2018 to ensure a common understanding and consistent high standards across self-regulatory and statutory bodies. Discussions focussed on Codes of Practice and issues of current concern including celebrity endorsement in medicines advertising, requirements for point of sale materials and advertising for lifestyle-related products. We continue to have regular informal contact with MDALG colleagues on interpretation of the legislation and issues arising from casework.

PAGB Codes of Practice

In preparation for its 100-year anniversary in 2019, the Proprietary Association of Great Britain (PAGB) reviewed their Codes of Practice and made a number of updates. The MHRA was consulted and provided advice on our interpretation of the legislation. The PAGB also consulted MHRA when they developed or updated detailed guidance for advertising products containing specific active ingredients where there have been safety concerns, including lidocaine and codeine.

ABPI Code of Practice

The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry was 60 years old in 2018. During the year ABPI proposed amendments to the Code to come into force at the start of 2019. The main changes related to the requirements covering certification for meetings outside the UK, an increase in the permitted cost for ‘inexpensive’ patient support items and updates to reflect the increasing use of digital materials. The MHRA was consulted on the changes and, where we did not consider that a case had been made for a relaxation of requirements, we worked with ABPI to ensure that alternative safeguards were inserted in the Code to ensure high standards were maintained.

We continue to monitor the advertising of a small number of companies who have chosen to leave the self-regulatory complaints system operated by PMCPA for various reasons. They all continue to adhere to the ABPI Code in other respects and we have encouraged them to consider re-joining the self-regulatory system wherever possible.

We also monitor cases dealt with under self-regulation, particularly where audits are required by PMCPA, and are prepared to intervene if necessary to support the actions taken and ensure compliance. In early 2018, we met with Astellas UK. The company had been suspended from ABPI membership following several complaints investigated by the PMCPA and repeated adverse findings during PMCPA audits. We heard about the steps being taken to improve compliance and
change the company culture and encouraged them to continue these. We were pleased to see that they had made sufficient improvement to be accepted back into ABPI membership in June. It was a great disappointment later in the year when PMCPA informed us of another upheld complaint and a failure of Astellas to undertake a full investigation and disclose all relevant evidence to PMCPA. We had put Astellas on notice in 2017 that any further breach would result in lead to a formal request to submit all their advertising materials to MHRA for review prior to issue. This was implemented for all new advertising materials from 1 December.

On a more positive note, we noted that the guidance issued by PMCPA on advisory boards appeared to be successful in reducing the incidence of complaints about advisory boards. We continue to monitor this to ensure the improvement is maintained.

**European Forum on Advertising Medicines (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 and ask questions about other aspects of our work. The group continues to exchange information by email on issues of concern but no meetings were held in the last year. Questions asked of members in 2018 included the promotion of ibuprofen-containing products and using links to the Summary of Product Characteristics in press releases.

We also hosted a visit from a colleague from the Irish Healthcare Products Regulatory Agency to exchange information on regulation of medicines promotion.

There were no relevant European Court of Justice cases which concluded in 2018.
5. Future direction

Annual webinars

Our annual Hot Topics in Medicines Advertising Regulation webinars provide the opportunity to feed back to industry on the outcome of our work in 2018. In February 2019 we are again holding separate events for POM and OTC medicines. The sessions include information on complaints handled by PMCPA and advertising to the public reviewed by PAGB, giving a comprehensive view of regulatory action in the past year in each sector. The OTC webinar will also cover topical product labelling and reclassification issues.

Vetting

We will continue to focus our resources on vetting of advertising for about 40-50 selected products to promote a "right first time" approach and to protect against misleading messages. This approach has been very successful in promoting high standards and reducing the number of complaints. We expect to review a similar number of products in 2019 and to achieve this once more within our published five-day standard for response time for industry to ensure timely availability of information about innovative medicines.

Where innovative products become available to be sold in UK pharmacies for the first time, we will vet initial advertising and work with PAGB and the companies concerned to ensure clear messages to the public about the appropriate use of products.

Complaints

We will continue to investigate complaints about advertising of medicines and monitor published advertising, ensuring timely and effective action on potential breaches of legislation.

Supporting self-regulation

We will work proactively with self-regulatory bodies and other stakeholders to support continued self-regulation and to ensure consistent high standards. This will include at least one meeting of the Medicines and Devices Advertising Liaison Group. We will review the Memorandum of Understanding we have with ABPI and PMCPA and review the compliance of each company that has declined to join the self-regulatory system. We will also continue to monitor the success of measures to ensure that media and other advisory boards are not used to promote medicines.

We look forward to celebrating with PAGB 100 years of effective regulation. A group of manufacturers came together in 1919 to promote high standards in advertising for medicines, a heritage that continues to this day with the PAGB Codes of Practice and effective review of advertisements to the public for OTC products. We will also work with them on advertising standards for specific product categories subject to regulatory action to protect public health.

Building on the success of changes to simplify requirements for information in advertising to prescribers and suppliers of medicines for OTC products in 2014, we are ready to continue to work with the ABPI and other interested parties to develop proposals to extend this to the prescription medicines sector. Any proposals will need to balance burden reduction for industry with the need
for healthcare professionals to have ready access to information they need to be able to use products safely. Implementation would be likely to require a progressive combination of changes to the detailed requirements in the ABPI Code of Practice and enabling changes to the legislation. There would be full consultation on any changes.

**International work**

More widely, we will continue to work with European colleagues through the Forum on Advertising Medicines group to share expertise and information on the regulation of advertising medicines, using email exchanges with a possible meeting during the year. We will also monitor the progress of a reference to the European Court of Justice on the provision of free samples to pharmacists (Case C-786/18).

The MHRA continues to work through the implications of the UK referendum vote to leave the EU for UK medicines regulation. Procedures to regulate medicines advertising are already recognised as a national responsibility and these will continue to operate as at present in the UK.

In 2019 and beyond, we will continue to work to ensure that medicines advertising regulation in the UK is proportionate and effective to protect public health, and that clear guidance is available for advertisers to promote compliance with the legislation.
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>ABHI</td>
<td>Association of British HealthTech Industries</td>
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<tr>
<td>ABPI</td>
<td>Association of the British Pharmaceutical Industry</td>
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<td>ASA</td>
<td>Advertising Standards Authority</td>
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<td>BCAP</td>
<td>Broadcast Committee of Advertising Practice</td>
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<td>BHMA</td>
<td>British Herbal Medicine Association</td>
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<td>CAP</td>
<td>Committee of Advertising Practice</td>
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<td>CHM</td>
<td>Commission on Human Medicines</td>
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<td>European Court of Justice</td>
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<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>FOAM</td>
<td>Forum on Advertising Medicines – includes 30 members representing the regulatory authority of every EU member state, Norway and Iceland</td>
</tr>
<tr>
<td>HFMA</td>
<td>Health Food Manufacturers’ Association</td>
</tr>
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<td>MALG</td>
<td>Medicines and Devices Advertising Liaison Group – includes regulatory bodies that deal with medicines and devices advertising including PMCPA, PAGB, ASA, CAP, BHMA, HFMA, ABHI, Clearcast and Radiocentre</td>
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<td>Medicines and Healthcare products Regulatory Agency</td>
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<td>Prescription Medicines Code of Practice Authority</td>
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<td>POM</td>
<td>Prescription only medicine</td>
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<td>Statutory Instrument</td>
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<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>
</tr>
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