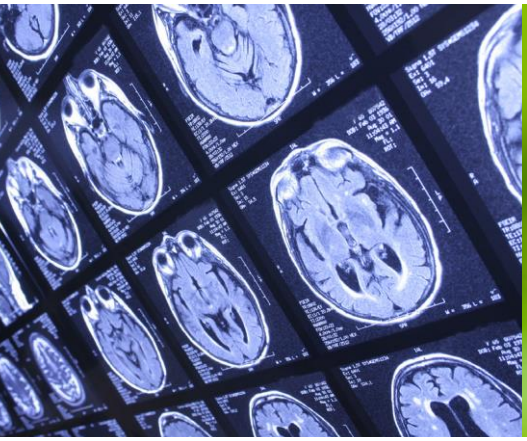
Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Delivering High Standards in Medicines Advertising Regulation

2019 Annual Report



27 February 2020

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

Produced by Advertising Standards & Outreach Unit, MHRA

Contents

1. Introduction

Since 2006, the MHRA has published an annual report on the regulation of medicines advertising to promote transparency. This is our 14th report and covers the 2019 calendar year. The report includes details of our action on complaints; vetting of advertising before issue; and 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).

The advertising team continues to work closely with MHRA colleagues in other areas including assessors in the Licensing Division, and with 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 2019, these have included:

- Publishing on our webpages outcome reports for complaint and scrutiny cases, and reporting on vetting performance.
- Our Blue Guide, Advertising and Promotion of Medicines in the UK, and its eight stand-alone guides, available on our webpage. We completed an administrative update to the Blue Guide in July 2019 and took the opportunity to add new information to the guide for medicinal treatment service providers about new General Pharmaceutical Council guidance and the Distance Selling Logo.
- Individual advice for advertisers including a dedicated mailbox for enquiries, 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.

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; sending an email to the advertising mailbox; or by post. For us to be able to investigate, the complaint needs to be accompanied by a copy of the advertisement or a link to where it can be found.

Action on complaints

In 2019, we received a total of 213 complaints—a 35% increase on last year's figure of 158, reversing an overall downward trend in recent years. The rise was made up of similar increases in all categories of complaints.

Complaints received 2017–19

Year	2017	2018	2019
Complaints received	155	158	213
Investigations initiated	153	157	207
Complaints referred to other MHRA Units	1	1	0
Complaints referred to another body (e.g., Advertising Standards Authority; Prescription Medicines Code of Practice Authority)	1	0	6

Consistent with previous years, a high proportion of complaints we received concerned the 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. 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.

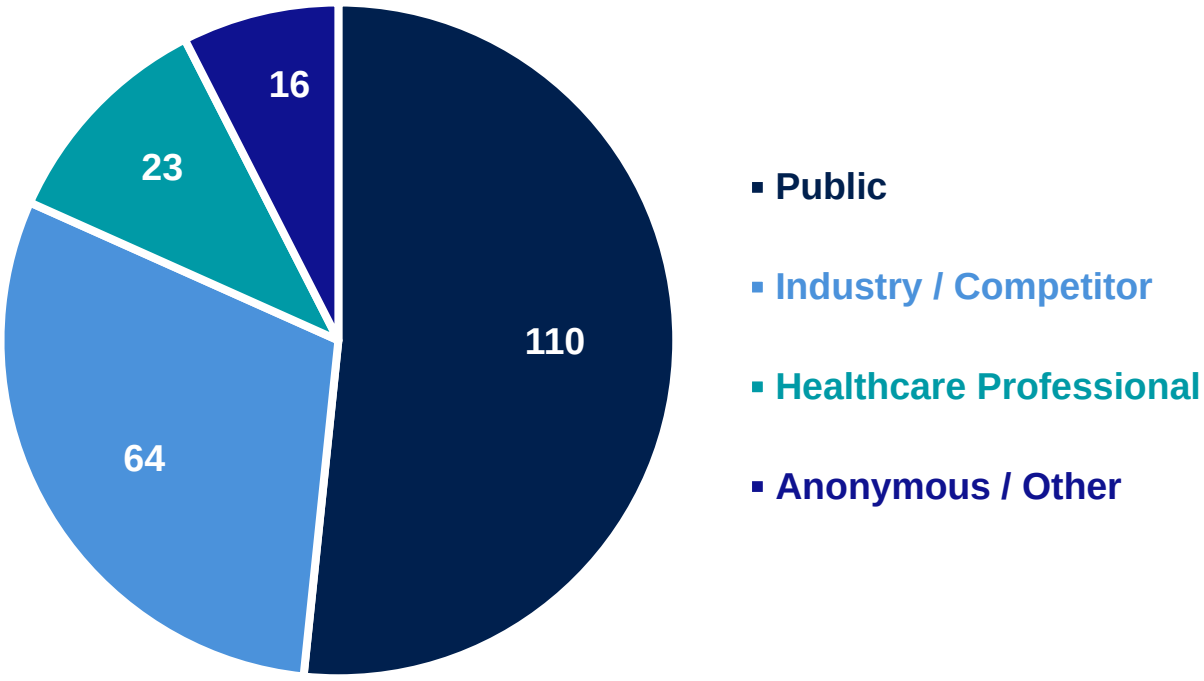
Several complaints and other referrals about advertising for slimming clinics were referred to the Advertising Standards Authority (ASA) because as well as potentially promoting POMs they also included problematic claims about clinic services that fell outside the MHRA's remit to regulate claims about medicines.

The pie chart overleaf shows the sources of the complaints we received in 2019: just over half of all complaints were from members of the public. The majority of these referrals related to advertising to the public by third parties of POMs containing botulinum toxin.
Just under a third of complaints were from competitors, usually clinics and service providers who have been subject to MHRA action on website and social media advertising, and therefore who tend to report their competitors in order to ensure a level

playing field. In previous years, a higher proportion of complaints have originated from competitors.

The change to a greater proportion of complaints coming from individuals could be due to competitors being unwilling to be identified as such.

Sources of complaints received 2019 (total 213)



In 2019 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 complaints procedure to resolve their concerns and disputes unless the advertiser has chosen not to accept the jurisdiction of the relevant self-regulatory body (see section 4). When the self-regulatory option is not available, such complaints are referred to MHRA for investigation. Cases in this category are included under ‘other’ in the pie chart.

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 we would investigate only cases where the advertiser has chosen not to accept jurisdiction of the self-regulatory body. The MHRA does not generally accept any complaint that is also under investigation by another self-regulatory body unless serious safety issues are identified.

The remaining complaints were received from healthcare professionals.

The table overleaf shows that in 2019 MHRA resolved a total of 237 advertising complaints. This is a significant increase compared to the 140 cases resolved last year. It is also more than the number of complaints received. The increase was mainly due to resolving a large number of botulinum toxin cases received late in 2018 that were carried over into 2019. We expect the numbers of cases to reduce again in 2020 and to match the number of complaints investigations started.

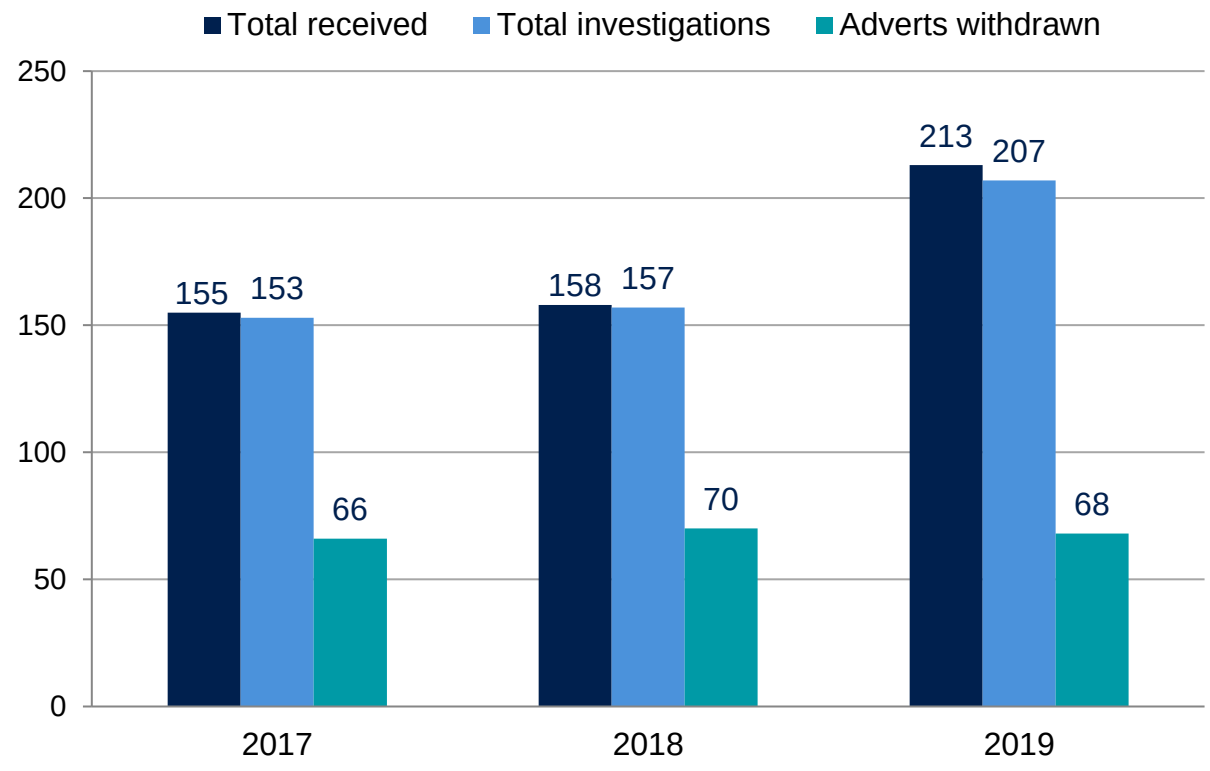
The proportion of cases that were upheld and resulted in withdrawal of, or changes to, advertising (28%) was lower than last year (50%). Where appropriate and when a potential risk to public health is not identified, we continue to conclude simple cases with advice on changes needed and a reference to our published guidance on consumer websites. Most botulinum toxin cases are resolved in this way so the higher proportion of these cases resolved in 2019 has reduced the proportion upheld.

Outcome of complaint investigations 2017–19

Year	2017	2018	2019
Medicines advertising cases resolved	132	140	237
Advertisements withdrawn	66 (50%)	70 (50%)	68 (29%)
Corrective statements required	0	0	1
Summary reports published	14	13	29

The chart below shows trends for complaints received and cases resolved for the last 3 reporting years. The numbers for 2019 show a significant increase from those for 2017 and 2018, in line with the increase in complaints received.

Trends in complaints 2017–19



This year all complaint cases were concluded through voluntary agreement with the companies concerned, so we did not need to resort to statutory procedures. There was only 1 complaint case where misleading advertising was considered to be 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 7 formal scrutiny cases in 2019. Action taken in 6 cases led to amendment or withdrawal of the advertising. In the prescription sector, cases included: promotion of generic medicines before marketing authorisations were granted; advertising unlicensed ‘specials’; and failure to state the indication clearly.

As part of a wider MHRA review of opioid products, we also reviewed advertising for tapentadol in 2019.

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 Proprietary Association of Great Britain (PAGB).

Review of key cases

The graph overleaf provides an overview of the number of upheld advertising cases over the last 3 reporting years. It covers both internal monitoring and complaints and is broken down by sector as follows:

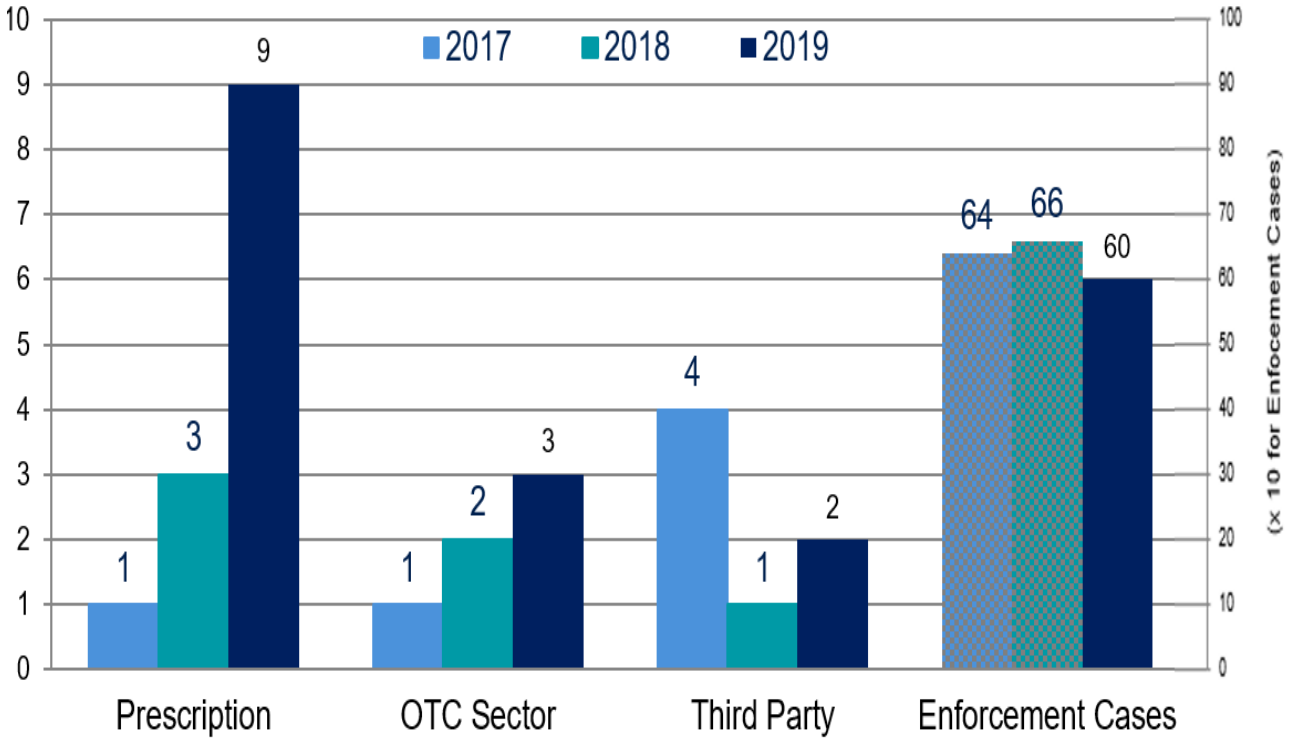
Prescription medicines
Over the counter medicines
Advertising by third parties such as pharmacies, clinics and online suppliers
Cases dealt with in association with the MHRA Enforcement Group

In 2019 the number of upheld cases concerning POMs advertised by manufacturers increased from 3 to 9. Although concerning, the number is still very low since the vast majority of complaints are dealt with under self-regulation; 4 cases related to companies that have chosen not to be part of the self-regulatory system. The number of upheld cases each year in the over the counter (OTC) sector remains low since PAGB reviews, prior to issue, all consumer advertising from their members.

Upheld cases of interest included: failure to keep materials up to date; failure to identify sponsorship clearly; and promotion of a medicine on a disease awareness website. The case where a corrective statement was required related to off-label promotion, and whereas in most cases MHRA receives a single complaint about an issue, in this case we received separate complaints from 9 healthcare professionals.

In the OTC sector, the upheld cases concerned: a potentially confusing claim relating to paracetamol for an ibuprofen product; promotional retweets by the manufacturer of an OTC product; and a claim for a co-codamol product that did not promote rational use. The third party cases related to a price promotion for sildenafil, and to promotion of finasteride by a hair loss clinic.

Upheld complaint & scrutiny cases by category of medicine 2017–19



In 2019 we upheld a total of 60 enforcement cases. This term is used to refer to cases that involve promotion of POMs to the public. MHRA's Enforcement Group may also take action on cases that include promotion but they do not report on individual cases. The total was similar to 2018 when 66 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. We continue to work closely with the MHRA Enforcement Group on casework, but we did not need to refer any cases for enforcement action because we were able to achieve compliance in 2019.

The MHRA Enforcement Group takes robust action, particularly where a potential risk to public health and safety is identified. They also take part in Operation Pangea, an annual international enforcement initiative to target the illegal internet sale of medicines. The Advertising Standards team 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 2019 we published a total of 29 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 as well as occasional lists of other enforcement cases. 16 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

The MHRA Advertising Standards team focus their resources on a targeted review of advertising prior to issue for a small number of products each year. 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 have the capacity to vet advertising prior to issue for up to 50 products each year and in 2019 MHRA vetted material for 44 medicines. This is up from the 2018 number (37) but in line with the 45 products vetted in 2017. These fluctuations reflect a general trend for fewer new active substances being authorised at a European level.

Advertising for new active substances is always reviewed before launch. We select other vetting candidates by using a consistent risk-based approach every year, which may identify:

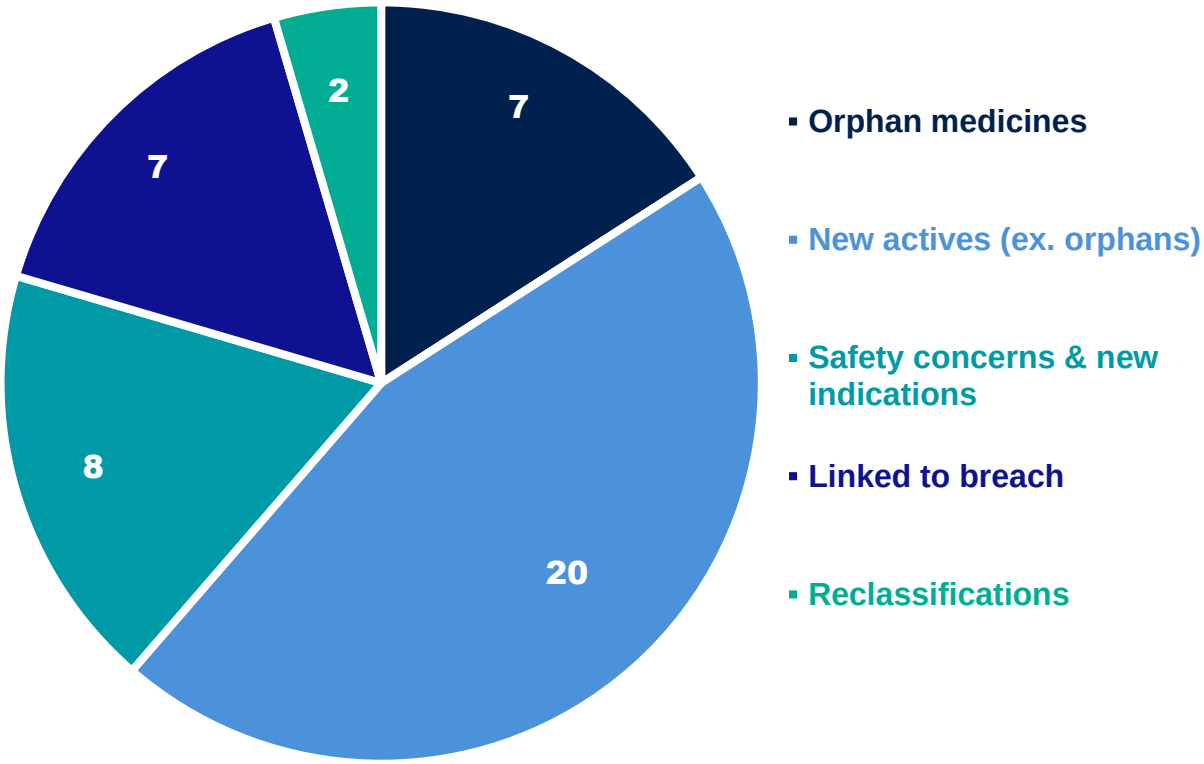
- innovative reclassified medicines
- products with significant new safety concerns or indications
- new combinations of active substances
- products where there may have been previous breaches of Part 14 of the Regulations or of the Association of the British Pharmaceutical Industry (ABPI) Code by the marketing authorisation holder.

Vetting statistics 2017–19

Year	2017	2018	2019
New active substances (excluding orphan products)	22	13	20
Orphan products for rare conditions	10	14	7
Reclassified products (POM to P, or P to GSL)	1	1	2
Advertising vetted linked to previous breach	3	1	7
Other products (includes safety concerns, major new indications)	9	8	8
Total	45	37	44

In 2019 we vetted launch advertising for a total of 27 new active substances, the same as last year but with a smaller proportion of orphan products than 2016. The number included innovative products for a wide range of medical conditions including various cancers, psoriasis, osteoporosis, migraine and depression.

Type of product vetted 2019



The 7 new orphan products vetted in 2019 included new treatment options for amyloidosis, β thalassaemia and hereditary angioedema. 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 8 products due to safety concerns or significant changes in the indicated use in 2019, including medicines for the treatment of epilepsy, asthma and HIV. 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 misleading marketing claims.

We vetted promotional material for 2 products reclassified from prescription only to pharmacy sale in 2019; both were nasal sprays. 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 materials.

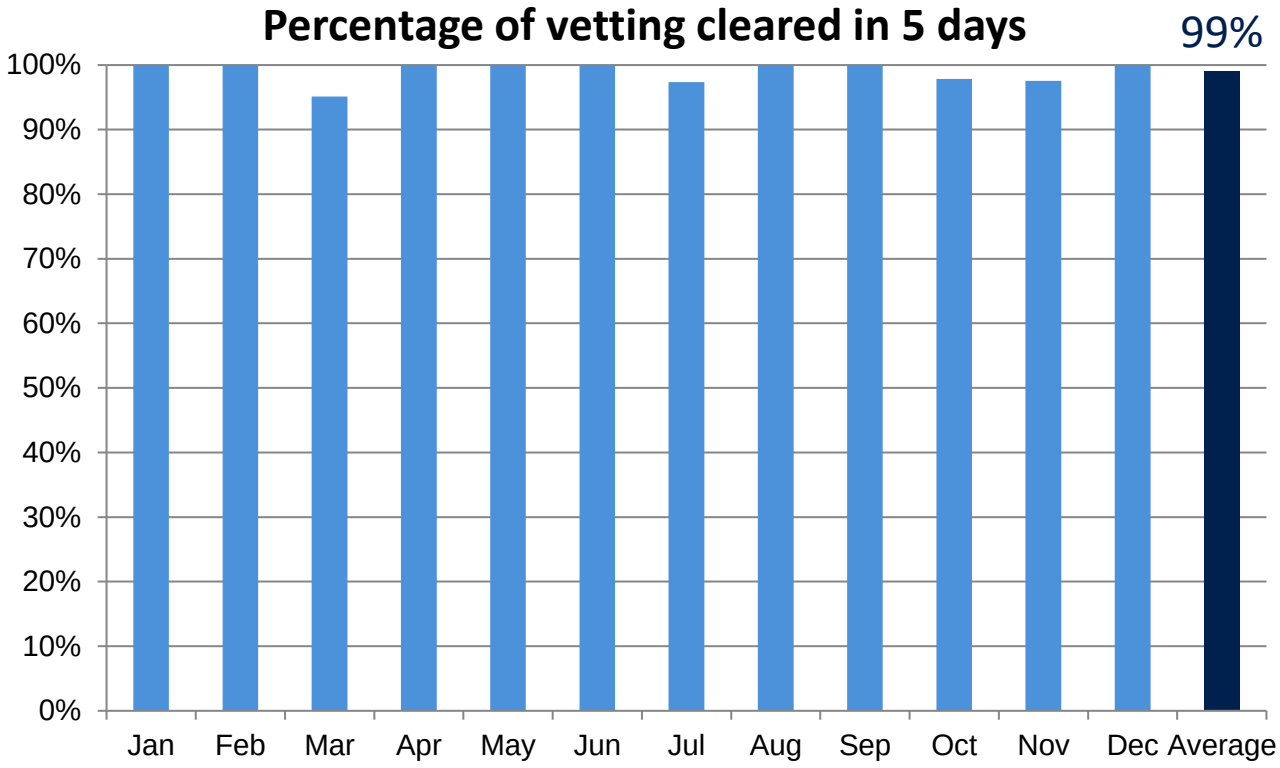
For the first half of the year MHRA continued to vet all promotional material for one particular marketing authorisation holder, Astellas UK, to ensure compliance. This action followed on from an upheld complaint to the Prescription Medicines Code of Practice Authority (PMCPA) in 2018 (Case AUTH/2984/10/17). Following Astellas' renewed suspension from the ABPI in 2017, MHRA had 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. We discontinued vetting when a further audit of Astellas by PMCPA showed sufficient improvement for the PMCPA complaint cases to be closed with no further action. This

accounts for 6 of the cases in the ‘linked to breach’ category. We also instigated vetting of advisory boards for one company who had a case against them upheld by PMCPA.
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 5 working days, which we achieved for 99% of items in 2019. Every month we exceeded our minimum 80% target to respond within this timeframe and we achieved 100% in 8 months; the lowest individual month was March, when we achieved 95%. The average number of items reviewed per month in 2019 was nearly 40.

Vetting performance 2019



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 2 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 2019 the average number of items reviewed per product increased from 9 to 11, reflecting an increase in the complexity of the products and claims made. 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 a reclassified product with an extensive marketing campaign. The mix of materials and the quality of items submitted can affect this figure.

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 a significant reduction in the number of items requiring resubmission in 2019 to less than 1% of all items submitted.

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 2019 MHRA held two advice meetings prior to the pre-vetting of promotional material for new products used in the treatment of breast cancer and leukaemia.

Key learning points

Our vetting experience in 2019

The following themes that are important for best practice can be identified from our experience throughout the year from vetting new materials for a range of products:

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 and side-effects and details of any monitoring required from the product Summary of Product Characteristics.

Accurate claims to support rational use

Claims should be supported by the balance of evidence available and include sufficient objective information to allow the reader to judge the importance of the claim for themselves. Data limitations should be made clear. Primary endpoints should be presented prominently and relevant limitations of secondary or exploratory findings explained. Exploratory endpoints should be set in the context of relevant findings from pre-specified endpoints. Clinical data must not be presented in such a way that a clinical benefit is implied in the absence of a sound statistical basis or a clinically important effect. Non-clinical data must not imply a clinical benefit unless data are available to show clinical relevance. Claims that relate to risk reduction should be

accompanied by absolute risk to better assess the clinical impact of a medicine. 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 POMs 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, and they should focus on absolute rather than relative differences. Press releases shouldn't use emotive or alarming language or raise unreasonable patient expectations about the benefits and safety of the product. 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, submission of 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 was one case in 2019 where material vetted by the MHRA was subsequently the subject of a complaint to the PMCPA (Case AUTH/3135/12/18). This case concerned advertising for Betmiga for overactive bladder syndrome that misleadingly implied that patients persisted on this treatment because of a favourable side-effect profile, whereas the reference cited did not include evidence to support this claim. As with all similar cases, the PMCPA report was carefully reviewed by the MHRA advertising team as a learning exercise.

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 and Devices Advertising Liaison Group (MDALG) provides a forum for close working with the other bodies involved in the regulation of medicines advertising. The remit of the group now includes the regulation of advertising for medical devices and representatives from self-regulatory bodies in the devices sector attend as members, including the Association of British HealthTech Industries (ABHI) and the British Healthcare Trades Association (BHTA).

We held a MDALG meeting in 2019 to discuss current regulatory issues and to promote 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

MHRA was pleased to support the 100-year anniversary of the PAGB and its Codes of Practice in 2019. 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 contributed an article on the development of regulation for OTC medicines since the introduction of the Medicines Act in 1966. The PAGB also consulted MHRA when they developed or updated guidance in specific areas of advertising, in particular on the use of social media influencers following a ruling by the ASA, and on piloting future models of self-regulation.

ABPI Code of Practice

A new version of the ABPI Code of Practice for the Pharmaceutical Industry came into force at the start of 2019. The main changes related to: 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 also consulted on a plan to update and recast the ABPI Code for 2020 and we held discussions with ABPI and PMCPA and presented to the ABPI Board on the future of self-regulation and the supporting role of the MHRA.

We continue to monitor the advertising of a small number of companies who have chosen for various reasons to leave the self-regulatory complaints system operated by PMCPA. 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. As discussed earlier, we intervened in 2019 in 2 cases to require vetting to support the actions taken by PMCPA. We also checked the compliance of one company whose advertising we were vetting when a complaint about material on social media was upheld by PMCPA.

ASA/Committees of Advertising Practice (CAP) UK Advertising Codes

In 2019 we have strengthened our links with the ASA to ensure we are able to share information about cases and direct complaints to the regulatory body best placed to investigate them. We have worked together on a number of issues, including advertising of vitamin-containing infusions, POMs for weight loss, products for erectile dysfunction and botulinum toxin products for lines and wrinkles.

General Pharmaceutical Council

The General Pharmaceutical Council (GPhC) is the body responsible for the statutory regulation of pharmacies; they also have a role in regulating advertising by pharmacies. In April 2019, the GPhC published detailed guidance for registered pharmacies providing pharmacy services at a distance, including on the internet. This guidance includes standards on how services that lead to the prescription and supply of a medicine are advertised, and on how information about medicines and their availability is presented. We have worked with them to ensure clarity for pharmacies on our respective roles, and to ensure we are able to share information about cases and direct complaints to the most appropriate regulatory body for investigation.

European Forum on Advertising Medicines (FOAM)

This forum, coordinated 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. Questions asked of members in 2019 included the review of promotional materials for OTC medicines prior to issue.

There were no relevant European Court of Justice cases which concluded in 2019.

5. Future direction

Annual webinars

Our annual Hot Topics in Medicines Advertising Regulation webinars provide the opportunity to feed back to industry. In February 2020 we are again holding separate events for POMs and OTC medicines to update on our work in 2019. The sessions include information on complaints handled by PMCPA and advertising to the public reviewed by PAGB, respectively, giving a comprehensive overview of regulatory action in the past year in each sector. For the first time, the OTC webinar will also cover advertising for self-care devices and will include contributions from MHRA Devices colleagues and the ASA.

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 2020 and to achieve this once more within our published 5-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.

Working together

We will work proactively with self-regulatory bodies and other stakeholders to support continued self-regulation and to ensure consistent high standards. We will continue to meet as MDALG. We plan to complete a review of the Memorandum of Understanding we have with ABPI and PMCPA. We will work with them as they complete planned changes to the ABPI Code of Practice in 2020 to recast the information and implement the new European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice. We will also conduct periodic reviews of compliance for companies that have declined to join the self-regulatory system.

We will also consider the development of Memoranda of Understanding with other key self-regulatory partners including ASA and PAGB. Our work with ASA will include an enforcement initiative on advertising of botulinum toxin products to address the increase in casework seen in 2019; this work will have a particular focus on social media.

After celebrating 100 years of effective regulation by PAGB in 2019, we will work with them as they review and streamline their procedures to ensure that their role remains effective for the coming

years. 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.

We will also continue work to strengthen our links with other bodies that have a role in the regulation of medicines suppliers including the General Pharmaceutical Council and the Care Quality Commission.

The MHRA continues to work on arrangements for future regulation of medicines in the UK once the UK departure from the EU and implementation period are completed. 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 2020 and beyond, we will continue to work with our regulatory partners 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

ABHI	Association of British HealthTech Industries
ABPI	Association of the British Pharmaceutical Industry
ASA	Advertising Standards Authority
BCAP	Broadcast Committee of Advertising Practice
BHMA	British Herbal Medicine Association
BHTA	British Healthcare Trades Association
CAP	Committees of Advertising Practice
CQC	Care Quality Commission
FOAM	Forum on Advertising Medicines – includes 30 members representing the regulatory authority of every EU member state, Norway and Iceland
GPhC	General Pharmaceutical Council
HFMA	Health Food Manufacturers' Association
MDALG	Medicines and Devices Advertising Liaison Group – includes regulatory bodies that deal with medicines and devices advertising including PMCPA, PAGB, ASA, CAP, BHMA, HFMA, ABHI, BHTA, Clearcast and Radiocentre
MHRA	Medicines and Healthcare products Regulatory Agency
OTC	Over the counter
PAGB	Proprietary Association of Great Britain
PMCPA	Prescription Medicines Code of Practice Authority
POM	Prescription only medicine
VRMM	Vigilance and Risk Management of Medicines