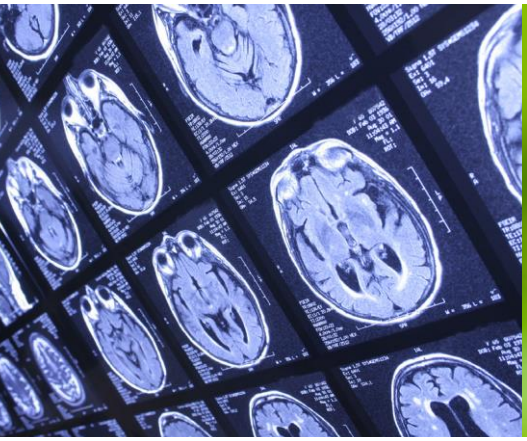
Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Delivering High Standards in Medicines Advertising Regulation

2020 Annual Report



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

Produced by Advertising Standards & Outreach Unit, MHRA

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1. Introduction

Since 2006, the MHRA has published an annual report on the regulation of medicines advertising to promote transparency. This is our 15th report and covers the 2020 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 2020, 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 updated to the Blue Guide in November 2020 to reflect the departure of the UK from the EU and changes arising from pandemic legislation (see chapter 4 for details).
- 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 using the online complaint form, or by sending an email to the advertising mailbox. 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 2020, we received a total of 227 complaints—a similar number to last year's figure of 213.

Complaints received 2018–20

Year	2018	2019	2020
Complaints received	158	213	227
Investigations initiated	157	207	81
Complaints referred to other MHRA Units	1	0	0
Complaints referred to another body (e.g., Advertising Standards Authority; Prescription Medicines Code of Practice Authority)	0	6	146

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. 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.

Following work with the Advertising Standards Authority (ASA) we were able to refer the majority of cases about advertising for botulinum toxin products on social media to the ASA for action. This resulted in a sizeable reduction in the number of MHRA investigations in 2020, down to 81 from 207 in 2019. More information about this joint initiative with ASA is given in chapter 4.

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. The MHRA would not investigate a complaint that is also under investigation by another self-regulatory body unless serious safety issues are identified.

Most pharmaceutical companies do use the self-regulatory complaints procedure to resolve their concerns. When the self-regulatory option is not available or if the advertiser has chosen not to accept the jurisdiction of the relevant self-regulatory body, complaints are referred to MHRA for investigation. One complaint referred to MHRA by the Prescription Medicines Code of Practice Authority (PMCPA) was investigated in 2020.

Looking at the sources of the 81 complaints we investigated, similar numbers were received from healthcare professionals (28), the public (28) and competitors (25).

The table below shows that in 2020 MHRA resolved a total of 92 advertising complaints. This is a significant decrease compared to the 237 cases resolved last year.

Outcome of complaint investigations 2018–20

Year	2018	2019	2020
Medicines advertising cases resolved	140	237	92
Advertisements withdrawn	70 (50%)	68 (29%)	45 (49%)
Corrective statements required	0	1	0
Summary reports published	13	29	27

Just under half of these cases were upheld and resulted in withdrawal of, or changes to, advertising (49%). 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.

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 were no complaint cases where misleading advertising was considered to be sufficiently serious to require the issue of a corrective statement.

We continue to publish summary outcome reports of cases on the GOV.UK website on completion of investigation. In 2020 we published a total of 22 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 service providers who have amended their advertising after MHRA action on complaints. 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.

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 3 formal scrutiny cases in 2020 where action taken in these cases led to amendment or withdrawal of the advertising. These included advertising for a homeopathic Coronavirus product, a traditional herbal remedy and an adrenalin autoinjector product.

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

Looking at the types of cases investigated, only one complaint was upheld against a marketing authorisation holder in each of the prescription and OTC medicines sectors. This reflects the preference for prescription medicines cases to be investigated under self regulation, and the work of the PAGB to review advertising for OTC medicines by their members prior to publication. The remaining cases related to advertising by third parties such as pharmacies, clinics and online suppliers of medicines. The most common issue was promotion of prescription only medicines to the public. We published summary reports for 7 of these cases with advice on compliance to help explain the legal position.

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 2020.

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.

3. Vetting advertising before issue

The MHRA Advertising Standards team focusses 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 protecting patients and the public from any potential negative impact on public health and safety.

Type of product vetted

The Advertising Standards team has capacity to vet advertising prior to issue for up to 50 products each year and in 2020 MHRA vetted material for 46 medicines. This is slightly up from the 2019 number (44), itself a return to more usual levels from a low of 37 products in 2018.

Advertising for new active substances is always reviewed before launch. We select other vetting candidates using a consistent risk-based approach every year. This may identify candidate products for review within the following categories:

- 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 of Practice by the marketing authorisation holder.

Vetting statistics 2018–20

Year	2018	2019	2020
New active substances (excluding orphan products)	13	20	19
Orphan products for rare conditions	14	7	12
Reclassified products (POM to P, or P to GSL)	1	2	1
Advertising vetted linked to previous breach	1	7	0
Other products (includes safety concerns, major new indications)	8	8	14
Total	37	44	46

In 2020 we vetted launch advertising for a total of 29 new active substances, the same as last year but with a higher proportion of orphan products than 2019. Any variation in the type and range of products coming for vetting prior to market launch reflects the number of new products being authorised in the year. Advertising was reviewed for innovative products for a wide range of medical conditions including various cancers, multiple sclerosis, ocular conditions, thrombocytopaenia and rheumatoid arthritis and the treatment of COVID-19. We also reviewed

information disseminated on the first COVID-19 vaccine given a temporary supply authorisation in the UK.

The 12 new orphan products vetted in 2020 included new treatment options for cystic fibrosis, spinal muscular atrophy and specific cancers. 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 in 2020 and usually conduct only a single assessment for one or a small number of items for each product.

We reviewed 14 products due to safety concerns or significant changes in the indicated use in 2020, including medicines for the treatment of epilepsy, asthma and stimulant laxatives. Advertising for a medical screening test patch was reviewed following reclassification from prescription only to general sale. We review these products to ensure that the messaging remains appropriate when the usage changes, looking specifically to ensure that the new information is accurately conveyed. The MHRA licensing assessors involved in the review of the new marketing authorisation applications or variations to existing authorisations alert the advertising team to concerns about the potential for misleading marketing claims.

Pleasingly, no products were chosen for review in 2020 on the basis of previous breaches of the legislation or the ABPI Code of Practice.

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 87% of items in 2020. In 11 months, we exceeded our minimum 80% target to respond within this timeframe and we achieved 100% in 8 months. The overall number was strongly affected by the December result where extra work to seek DHSC (Department of Health and Social Care) and Ministerial approval of information for the first vaccine products given a temporary supply authorisation added to a heavy workload and meant we only achieved 52% of items reviewed in 5 working days. The average number of items reviewed per month in 2020 was 22, but 69 items were reviewed in December.

We can only achieve this level of performance by working closely with companies and we provide guidance on managing the process. We ask for advanced notice about the proposed timetable for submission of advertising to help us 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 raise concerns about the quality of the material and these are not satisfactorily resolved in materials submitted subsequently, or where key promotional pieces are still being developed.

In 2020 we took steps to target our review and concentrate on the initial pieces where our review has the greatest impact. This resulted in a reduction in the average number of items reviewed per product from 11 to 6. 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. After the significant reduction in the number of items requiring resubmission seen in 2019, numbers increased again to nearly 10% of items submitted in 2020.

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. No advertising advice meetings were held in 2020.

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.

We are not aware of any cases in 2020 where material vetted by the MHRA was subsequently the subject of a complaint to MHRA or the PMCPA. Any such cases are always 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 one MDALG meeting in 2020 to discuss current regulatory issues and to promote a common understanding and consistent high standards across self-regulatory and statutory bodies. Discussions focussed on: actions taken in response to the COVID pandemic, in particular to endure action was taken on misleading advertising for treatments; the departure of the UK from the EU; and issues of current concern including advertising for lifestyle-related products and joint enforcement initiatives between the MHRA and ASA. We continue to have regular informal contact with MDALG colleagues on interpretation of the legislation and issues arising from casework.

ABPI Code of Practice

MHRA has regularly been consulted by the ABPI and PMCPA as the ABPI Code of Practice for the Pharmaceutical Industry is being updated and recast for publication in 2021. We also met with ABPI and PMCPA at the end of the year to hear about progress of work to ensure the arrangements between ABPI and PMCPA service continue to support and assure the independence of self-regulation.

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. We regularly provide information to MHRA colleagues in the Good Pharmacovigilance Practice team to inform their inspection planning and casework.

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

In 2020 we have continued to strengthen 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 injections, POMs for weight loss and botulinum toxin products for lines and wrinkles. Joint enforcement notices were issued for advertising botulinum toxin products on social media in January, on IV drips in April and POMs and ‘vitamin shots’ in May. As described in chapter 2, this has led to a significant reduction in the number of complaints investigated by MHRA. ASA has effective monitoring systems for medicines advertising on social media and we refer social media complaints to ASA under these enforcement initiatives.

Medicines and Medical Devices Bill

The Medicines and Medical Devices Bill was introduced in Parliament in February 2020 and we have supported its passage through each legislative stage. If enacted in 2021, this will give enabling powers to amend the advertising provisions in Part 14 of the Human Medicines Regulations. The Bill includes amendments to require that any future advertising changes would be subject to the affirmative procedure in Parliament.

UK exit from the EU

In preparation for the end of the transition period following the departure of the UK from the EU, a new edition of the MHRA Blue Guide and updated guidance on vetting were published in December. This included advice on reflecting the new licence categories for Great Britain and Northern Ireland in advertising and changes to permit limited advertising in certain types of public health emergency, as described below.

Coronavirus legislation

Regulations were made in October 2020 to permit the MHRA to grant a temporary supply authorisation for a medicine in the case of a pandemic or other public health emergency. These regulations also provided an exemption from the ban on advertising an unlicensed medicine for advertisements that have been approved by Health Ministers for a medicine to be used in certain public health emergencies including in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation. The advertising team has managed the process to obtain approval for information on these products.

5. Future direction

Annual webinars

Our annual Hot Topics in Medicines Advertising Regulation webinars provide the opportunity to feed back to industry. Planning for 2021 has been delayed due to COVID priorities and we expect there to be a single event covering both POMs and OTC medicines in May 2021. The session will include contributions from the PMCPA and PAGB to give a broad overview of advertising regulatory actions in 2020.

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 2021 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.

We will work with Licensing colleagues to ensure that timely review of advertising is carried out for products authorised through the new pathways for innovative products being made available in 2021. We will also work with MHRA and DHSC colleagues to ensure timely and accurate information about further vaccines given a temporary supply authorisation in the UK.

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. We will continue to work with ASA and other self-regulatory bodies to ensure complaints can be investigated by the most appropriate body.

Working together

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 MDALG in 2021.

We will continue to work with ABPI and PMCPA to ensure the self-regulatory process is seen to be independent and plan to complete a review of the Memorandum of Understanding we have with ABPI and PMCPA. We will work with them as they bring into effect the 2020 changes to the ABPI Code of Practice that 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 build on and extend the successful enforcement initiatives on advertising carried out in 2020.

We will support PAGB 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.

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.

Since the year end, the Medicines and Medical Devices Act 2021 has been enacted. This gives the legal powers to enable us to work with the ABPI, British Generic Manufacturers Association (BGMA) and other interested parties to develop proposals to simplify requirements for information in advertising to prescribers and suppliers of medicines 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.

The MHRA will continue to work with self-regulatory bodies to ensure advertising for medicines reflects the new licensing arrangements for medicines in the UK after the end of the transition period following the UK's departure from the EU came to an end on 31 December 2020. 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 2021 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
BGMA	British Generic Manufacturers Association
BHMA	British Herbal Medicine Association
BHTA	British Healthcare Trades Association
CAP	Committees of Advertising Practice
CQC	Care Quality Commission
DHSC	Department of Health and Social Care
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