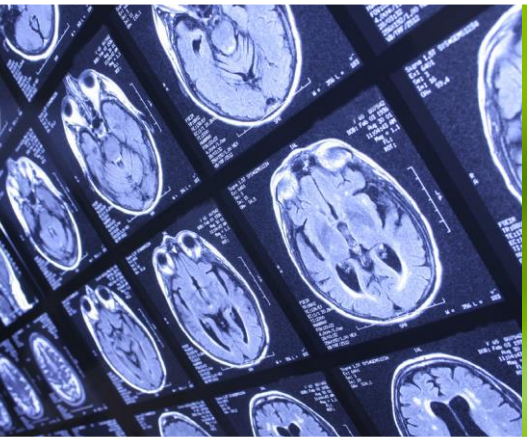
Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Delivering High Standards in Medicines Advertising Regulation

2021 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 16th report and covers the 2021 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 has been located within the group responsible for Access and Information for Medicines and Standards (AIMS) in the Vigilance and Risk Management of Medicines Division (VRMM). The MHRA is undergoing some changes in structure and in 2022, the unit will move to the Authorisation Lifecycle group within the Healthcare Quality and Access (HQA) Directorate.

This change recognises the importance of continued close working between the advertising team and MHRA colleagues in other areas including assessors involved in licensing medicines, in the Population Health and Innovative Medicines teams of the new structure, and with the Borderline team. The team will also continue to work closely with the Enforcement team, positioned in the Safety & Surveillance part of the new Agency structure.

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 2021, these have included:

- Publishing on our webpages outcome reports for complaint and scrutiny cases.
- Our Blue Guide, Advertising and Promotion of Medicines in the UK, and its 8 stand-alone guides, available on our webpage.
- Individual advice for advertisers including a dedicated mailbox for enquiries, advertising@mhra.gov.uk. Although the team cannot 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.
- An annual webinar 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 2021, we received a total of 144 complaints—a reduction of over a third from last year's total of 227. The reduction is almost entirely due to fewer cases involving advertising for botulinum toxins, reflecting successful joint working with the Advertising Standards Authority (ASA) on advertising for these products.

Complaints received 2019–21

Year	2019	2020	2021
Complaints received	213	227	144
Investigations initiated	207	81	53
Complaints referred to other MHRA Units	0	0	2
Complaints referred to another body (e.g., Advertising Standards Authority; Prescription Medicines Code of Practice Authority)	6	146	89

Consistent with previous years, a high proportion of complaints we received concerned the advertising of prescription only medicines (POMs) to the public by cosmetic clinics and other service providers, including online clinics and pharmacies. The proportion of complaints that relate to advertising on social media continues to rise and the majority of cases we investigated related to online treatment service providers (third parties) offering POMs and/or unlicensed medicinal products for prescription.

We were able to refer the majority of cases about advertising for botulinum toxin products, prescription-only weight-loss treatments and injectable vitamin products on social media to the ASA for action. This resulted in a further sizeable reduction in the number of MHRA investigations in 2021, down to 53 from 207 in 2019 before the joint action started. More information about this joint initiative with ASA is given in chapter 4.

The MHRA fully supports use of self-regulatory systems and encourages companies to firstly use intercompany dialogue and the appropriate 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.

Looking at the sources of the 53 complaints we investigated, the majority of cases we received were from members of the public (26) and competitors (22). One case arose from MHRA scrutiny of published advertising.

The table below shows that in 2021, MHRA resolved a total of 62 advertising complaints.

Outcome of complaint investigations 2019–21

Year	2019	2020	2021
Medicines advertising cases resolved	237	92	62
Advertisements withdrawn	68 (29%)	45 (49%)	49 (89%)
Corrective statements required	1	0	0
Summary reports published	29	27	23

The lower number of complaints resolved in 2021 compared with 2020 reflects the reduction in investigations initiated. The majority of these cases were upheld and resulted in withdrawal of, or changes to, advertising (89%). Where appropriate and when no potential risk to public health is identified, we continue to conclude simple cases with advice on changes needed to advertising and a reference to our published guidance on consumer websites.

In 2021, 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 2021 we published a total of 23 summary reports. We do not publish on our website individual reports on complaint cases where clinics and other service providers have promoted POMs or unlicensed medicines (or both) to the public: rather, for transparency and in order to encourage regulatory compliance, we publish 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 media, and we investigate referrals from colleagues in the Agency or other regulatory authorities.

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 the Proprietary Association of Great Britain (PAGB) and the General Pharmaceutical Council (GPhC).

Review of key cases

Looking at the types of cases investigated, 5 complaints were upheld against marketing authorisation holders: 2 in the prescription sector and 3 in the over-the-counter (OTC) medicines sector. In the prescription sector, 1 case concerned an advertisement for a medical device that promoted a POM to the public, and 1 case concerned promotion of unlicensed medicines (specials) to prescribers.

In the OTC sector, the cases were: promotion of a pain product targeted at healthcare professionals that did not contain the required statutory particulars; use of a celebrity social media account to encourage use of a medicinal product; and MHRA scrutiny review of a traditional herbal remedy, the advertising for which included a prohibited recommendation from a healthcare professional to use the product.

This low number of completed investigations for pharmaceutical companies 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 44 cases upheld related to online advertising by third parties such as pharmacies, clinics and other treatment service providers that supply medicines. The most common issues were: promotion of prescription only medicines to the public (including 'off-label' promotion for an indication for which the product does not have a licence); promotion of unlicensed medicines; and advertisements that did not make clear an OTC product was being promoted (see annex 3 of the Blue Guide). We published 13 summary report lists for these cases with advice on compliance to help explain the legal position.

During the review of complaints MHRA became concerned about the rising number of complaints relating to the third-party promotion of unlicensed medicines, particularly within the men's healthcare and skincare online sectors. We liaised with the MHRA Borderline Medicine Advice team and relevant self-regulatory bodies to agree principles for advertisers who wish to promote their service and consultation offer, which may result in the prescription of an unlicensed medicine in the best interests of the patient as judged by a healthcare professional supporting the service.

We continue to work closely with the MHRA Enforcement Group on casework. During 2021, we referred 2 cases for Enforcement Group action, when investigation of the advertising of the treatment service led to us becoming concerned about the overall operation of the business and its supply model. We did not need to refer any cases for enforcement action due to lack of advertising compliance in 2021.

However, where voluntary compliance cannot be achieved, the Agency is prepared to take robust action, particularly where a potential risk to public health and safety is identified. The MHRA Enforcement Group also takes 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 around 50 products each year and in 2021 MHRA vetted material for 60 medicines. This is markedly up from the previous few years.

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

- innovative reclassified medicines
- products with significant safety concerns or new 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.

The MHRA licensing assessors involved in the review of the new marketing authorisation applications or variations to existing authorisations may alert the advertising team to concerns about the potential for misleading marketing claims.

Vetting statistics 2019–21

Year	2019	2020	2021
New active substances (excluding orphan products)	20	19	34
Orphan products for rare conditions	7	12	12
Reclassified products (POM to P, or P to GSL)	2	1	4
Advertising vetted linked to previous breach	7	0	1
Other products (includes safety concerns, major new indications)	8	14	9
Total	44	46	60

In 2021 we vetted launch advertising for a total of 34 new active substances (excluding orphan products), a larger volume than last year, but with the same number of orphan products as 2020. 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; atopic dermatitis; multiple sclerosis; epilepsy; uterine fibroids; heart conditions; and the treatment of HIV. We also reviewed information disseminated on COVID-19 vaccines given a temporary supply and conditional authorisations, and for the introduction of COVID-19 therapeutics (antibodies and antivirals) in the UK.

The 12 new orphan products vetted in 2021 included new treatment options for sickle cell disease, 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 2021 and usually conducted only a single assessment for one or a small number of items for each product.

We reviewed 9 products due to safety concerns or significant changes in the indicated use in 2021, including medicines for the treatment of epilepsy, obesity, heart failure, and depression.

Advertising for over-the-counter contraceptives containing desogestrel was reviewed following reclassification of two oral products from prescription-only to Pharmacy (P) legal status. We reviewed these products to ensure that the messaging remains appropriate when the usage changes, looking specifically to ensure that the new information is accurately conveyed to the pharmacy profession and to the general public. We also assessed advertising material for 2 more reclassified products indicated for hay fever and for mild to moderate pain relief, which changed from prescription-only to General Sales List (GSL) and from P to GSL, respectively.

Following an upheld complaint to the Prescription Medicines Code of Practice Authority (PMCPA) in 2021 (Case AUTH/3335/4/20), MHRA vetted all advisory board proposals for one particular marketing authorisation holder, Britannia Pharmaceuticals (see below for vetting experience in 2021 in relation to advisory board practice).

Individual advertisements for other products were also reviewed in a proportionate manner 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 85% of items in 2021. In 10 months, we exceeded our minimum 80% target to respond within this timeframe. The overall number was strongly affected by January 2021 data, when extra work to seek DHSC and Ministerial approval of information for vaccine products given a temporary supply authorisation added to an already substantial workload and meant we achieved only 62% of items reviewed in 5 working days.

Fluctuations in performance throughout the rest of the year were due to factors such as: assessment complexity (particularly in relation to Covid-19 prophylaxis and therapeutics);, other Agency priorities (for example, the expert assessors who advise us were involved in licensing or safety assessments of Covid-19 vaccines and therapeutics) and a large number of products and items vetted (the launch into the OTC market for the 2 reclassified desogestrel oral contraceptives was accompanied by a substantial amount of material for professional and consumer audiences). The average number of items reviewed per month in 2021 was 36, higher than the average in 2020 which was 22.

We aim to achieve a good 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 assessment time. 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 a UK territory 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 items submitted subsequently, or where key promotional pieces are still being developed.

In 2021 we tried to target our review and concentrate on the initial pieces where our review has the greatest impact. However, the average number of items reviewed per product increased from 6 to 9 compared with the previous year. 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 70 items for a reclassified product with an extensive marketing campaign for different audiences. 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 small number of cases where we consider that substantial changes need to be made. Where revised submission is required, this is clearly stated in our response. The number of items requiring resubmission was again nearly 10% of items submitted in 2021, the same figure as that for 2020.

When either the company or MHRA need to discuss amendments to proposed advertising claims during the vetting process, these can be handled by email correspondence or 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 2021, MHRA held 1 advice meeting prior to the pre-vetting of promotional material for a product planned for reclassification of legal status. We have found that an early meeting for an innovative reclassification can significantly smooth the process of assessment of materials.

Key learning points

Our vetting experience in 2021

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

Appropriate authorised indications for each product being advertised 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 a product beyond the licensed indications, particularly where use is restricted to a specific patient group or as second-line treatment.

Accurate evidence-based 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. In addition to being capable of substantiation, claims should be able to stand alone: footnotes are unlikely to be an appropriate way to caveat or explain important information that may affect the prescribing or dispensing choice of a busy healthcare professional.

Key safety messages

Safety information required to support safe use of the product should be included as appropriate, particularly for a new product where a detail aid, for example, has a clear educational function. Such aids should include risk management messages, key contraindications, warnings and side-effects and details of any monitoring required from the product Summary of Product Characteristics.

Advisory boards

Company advisory boards should be kept to a minimum and must be strictly non-promotional, seeking only to answer legitimate business questions from the involvement of experts in a particular field that cannot be obtained by any other means. Companies should consult PMCPA guidance on advisory board practice before consideration and planning of such an activity takes place to ensure there is no risk of leading to inducement to prescribe.

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.

We are aware of 1 case where material vetted by the MHRA in 2020 was subsequently the subject of a complaint to the PMCPA in 2021. Case AUTH/3504/4/21 concerned advertising for Nilemdo

and Nustendi jointly by Daiichi Sankyo for patients with primary hypercholesterolaemia or mixed dyslipidaemia.

The Code of Practice Panel considered that some product claims read in isolation implied that these products could be added to any lipid-lowering treatments, whereas they are contraindicated with >40 mg simvastatin a day, and with any statin use in some patient subgroups. Use of footnotes to explain such contraindications was not considered appropriate for conveying important safety information to busy professionals; this was also noted for how some important posology information was presented in the material.

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 on the vetting experience suggests that the comments are generally useful and provide a new or useful 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 and, since 2016, those involved in the regulation of advertising for medical devices.

We held a MDALG meeting in 2021 to discuss current regulatory issues and to promote a common understanding and consistent high standards across self-regulatory and statutory bodies. Discussions focussed on: continued actions taken in response to the COVID pandemic; 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

The MHRA welcomed publication of an updated ABPI Code of Practice for the Pharmaceutical Industry in January 2021. We also worked with the PMCPA on guidance they published in February on advertising of products following the departure of the UK from the EU. We met with ABPI and PMCPA during 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 strongly encourage any pharmaceutical company operating in the UK to join the self-regulatory system to support their best practice through membership of a strong compliance framework.

We also monitor cases dealt with under self-regulation, particularly where audits are required by PMCPA. When needed, we regularly provide information to MHRA colleagues in the Good Pharmacovigilance Practice team to inform their inspection planning and casework.

PAGB Codes

This year, we have worked with PAGB on their guidance that aims to support OTC companies during continued digital innovations in relation to: inclusion of Essential Information in space-restricted advertising; e-commerce; and use of real-world evidence across the product lifecycle.

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

In 2021 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 continued to work together on a number of issues, including advertising of vitamin-containing injections, POMs for weight loss and botulinum toxin products for lines and wrinkles. A joint enforcement notice was issued for advertising on social media of prescription weight loss products in January. As described in chapter 2, joint working is leading 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.

General Pharmaceutical Council (GPhC)

This year, we have forged a stronger connection with the GPhC through a series of meetings with compliance and inspector staff to share information (under the terms of a Memorandum of Understanding between MHRA and GPhC) where there are potential wider compliance concerns about the marketing and promotional activities of pharmacies that operate at a distance. This joined-up working has enabled both organisations to consider what action to take at the right time to ensure that the health of members of the pubic who choose to obtain medicines online is safeguarded in lines with the principles of both the GPhC and MHRA.

Medicines and Medical Devices Act

In February, the Medicines and Medical Devices Bill became law as the Medicines and Medical Devices Act 2021. The Act gives enabling powers to amend the advertising provisions in Part 14 of the Human Medicines Regulations. The Act requires that any future advertising changes would be subject to the affirmative procedure in Parliament.

UK exit from the EU

Following the departure of the UK from the EU, we have continued to support Marketing Authorisation Holders to comply with the requirement to accurately reflect the licensing position in a geographical territory and the new licence categories for Great Britain and Northern Ireland in advertising.

We have taken a pragmatic approach where possible to ensure a minimum burden on companies without compromising the accuracy of promotional materials.

Coronavirus legislation

Following regulations 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, we have continued to support a limited number of companies whose products had been granted such an authorisation. This has served to exempt them from the ban on advertising of an unlicensed medicine when Health Ministers considered that limited information from the manufacturers of the products was necessary to support the wider pandemic emergency campaign. Such information typically included basic company website information steering to government product information, and technical product administration videos and posters for healthcare professionals or the NHS.

5. Future direction

Putting patients first: a new era for our agency

As outlined in the MHRA's Delivery Plan 2021–23, we are committed to the protection and improvement of public health through innovative regulation based on excellence in science. To realise this continued ambition, our organisation is undergoing transformation to ensure it is fit for the future. The plan includes a deliverable to develop and deliver our future strategy and approach for access to medicines and devices, and it is within the new Healthcare Quality and Access (HQA) Group that the Advertising Unit will now sit. The operational functions of the Unit as defined in this Annual Report will not change overall, and we remain committed to playing our part to ensure appropriate regulation of the information that accompanies bringing a product to, or having a product on, the market in the UK.

Annual webinar

Our annual Hot Topics in Medicines Advertising Regulation webinar provides an opportunity to feed back to industry. Our session for 2022 covers POMs and OTC medicines, with contributions from the PMCPA and PAGB to give a broad overview of advertising regulatory actions in 2021.

Vetting

We will continue to focus our resources on vetting of advertising for in the region of 50 selected products to promote a "right first time" approach, and to protect against misleading messages. We regard this approach as very successful in supporting high standards and in reducing the number of complaints. We will aim to achieve these reviews within our published 5-day standard for response time for industry to ensure timely availability of information about innovative medicines.

We will continue to work with HQA colleagues responsible for licensing medicines to ensure timely review of advertising for products authorised through the available pathways for innovative products.

We will carry on supporting the UK government pandemic response not only by supporting with vetting company launch campaigns for Covid-19 therapeutics that are given a Marketing Authorisation, but also by working, as needed, with MHRA and DHSC colleagues to ensure timely and accurate information about further vaccines or emergency products 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 in a proportionate manner and will work with PAGB and the companies concerned as required to ensure clear messages to the public and pharmacy staff about the appropriate use of products.

Where we receive intelligence that raises potential concern about company compliance or about the requirement for people to be aware of particular safety messages for a given medicine, we will take appropriate action to ensure that advertising and promotional activity for any affected product appropriately reflects the current knowledge of its efficacy and safety.

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 in a timely fashion and by the most appropriate body.

We will continue to share intelligence or any concerns about a particular advertiser to the relevant professional body (such as the GPhC). Working closely with such bodies will continue to be integral to ensuring good advertising compliance among third party advertisers such as distance-selling pharmacies and treatment-service providers/clinics.

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 2022.

We will continue to work with the ABPI and PMCPA to ensure the self-regulatory process continues to be seen as independent, and we plan to review the Memorandum of Understanding we have with the ABPI and PMCPA. We will work with them as the updated Code of Practice continues to bed in. We will continue to encourage companies with business in the UK who are not members of the self-regulatory system to join. We will also conduct periodic reviews of compliance for companies that have declined to join the self-regulatory system.

We will also pursue as may be required 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 done over the past few years.

We will continue to support PAGB to ensure that their Code and regulatory role remain an effective safeguard 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.

Since the enactment of the Medicines and Medical Devices Act 2021, we will 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 for 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.

In 2022 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
GSL	General Sale List – medicines available from general retailers
GPhC	General Pharmaceutical Council
HFMA	Health Food Manufacturers' Association
HQA	Healthcare Quality and Access
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