The Consumer Healthcare Association

Advertising Guidance
Advertising complaint procedure for PAGB member companies

Issued: May 2021. Updated January 2022. Access: PAGB members and associate members only

Contents

1. About this guidance

This procedure applies to complaints made by PAGB member companies regarding promotional materials for products within PAGB membership, where another PAGB member is in control of the content. This includes:

- Advertising for medicines, food supplements and medical devices directed at consumers
- Advertising for medicines directed at health professionals
- Public relations materials for medicines at the point when the company relinquishes editorial control

For further detail on materials within the remit of this procedure please see the sections related to what each Code and Guideline covers in the respective documents.

2. Informal query

PAGB's copy clearance service includes the provision of telephone and email advice on advertising queries. Members are encouraged to use this service if they have queries about advertising for medicines, medical devices and food supplements, and/or interpretations of the

Codes, guidelines and legislation that advertising must comply with. If members have queries about any competitor advertising they may enquire informally via this service. PAGB is able to provide an explanation for PAGB approved advertising and provide an informal opinion on advertising that it has not pre-vetted.

In cases where medicines or food supplements advertising directed at consumers has not been pre-vetted in accordance with PAGB procedures the member will be contacted and asked to explain why the material was not approved. PAGB may request that the member's internal processes are amended and/or the advertising withdrawn as considered appropriate. If the member wishes to continue using the ad, it will be reviewed by copy clearance. If the advert is approved for use by PAGB, the complaint can proceed to Phase 1 of the complaints process.

Materials approved by members as part of a tool kit are considered PAGB approved. Where a complaint relates to tool kit materials PAGB will assess whether the ad is compliant with the agreed tool kit claims. If it is deemed compliant the complaint will progress as usual. If the material is non-compliant it will be dealt with using the compliance actions outlined in the tool kit process.

3. Phase 1 – intercompany dialogue

When PAGB member companies have concerns about advertising for OTC medicines, self care medical devices or food supplements they should write to the advertising company to outline the areas of their concern and advise PAGB by supplying a copy of the complaint to advertisingcomplaints@pagb.co.uk.

To allow advertisers to adequately address the concerns raised, the complainant must provide information detailing the precise nature of their concerns including the sections of the relevant Codes, guidelines or regulations alleged to have been breached. The complaint check list in Appendix 2 is designed to help members ensure that they have included the relevant information. At this stage if the informal query process has not been used (see 2. Informal query), it should also be established whether the advertising was approved by PAGB.

Advertisers have a responsibility to reply promptly and helpfully to the enquiry and should provide justification for the claim(s) in question.

Where claims are supported by commercially sensitive data, companies are expected to, as far as possible, summarise the data that is being used to substantiate the claim(s) in question. Failure to share this information will reduce the chance of resolving the complaint during phase 1.

Members should allow 10 working days for advertisers to respond. If the complainant believes that the advertisement represents a breach of the law or a serious risk they should highlight this in their contact with PAGB.

4. Phase 2 – formal advertising complaint

If it is not possible for the companies to resolve the issue between themselves the complainant may refer the matter to PAGB as a formal advertising complaint. There is one exception for food supplements advertising where a member has opted out of approval – see Appendix 3.

Companies must have attempted to resolve their query directly with the advertiser before making a formal complaint, and the formal complaint should cover only those concerns which were raised directly with the advertiser.

Formal advertising complaints must be submitted by the company's designated signatory or other senior regulatory or medical personnel in writing to advertisingcomplaints@pagb.co.uk. When submitting a formal complaint all relevant information and documents must be attached. PAGB will confirm receipt of formal complaints to both the complainant and the advertiser within 48 hours. If the complaint is not completed or submitted correctly it will be returned to the complainant.

The advertiser should provide any response to the alleged breaches in writing to PAGB (advertisingcomplaints@pagb.co.uk) within 5 working days. This response should include any additional material that is commercially sensitive that it has been unable to share with the complainant.

The complaint, together with the advertiser's response and documentation submitted to PAGB at the time of approval, if applicable, will be considered by representatives of the Senior Management Team at PAGB who will determine the complaint and provide both parties with the findings in a PAGB formal advertising complaint report. This report will detail any action required by the advertiser to address adverse findings. This stage will be completed within 10 working days.

PAGB may seek advice from the Committee of Advertising Practice (CAP) on matters of misleadingness or consumer understanding.

If a complaint is upheld, PAGB may require one or more of the following:

1. Company audit of its own internal advertising sign off
2. Amendment to advertising
3. No further distribution, publication, or broadcast of the advertising or promotional materials
4. Withdrawal of materials from the market
5. Publication of a corrective statement.

The sanction(s) imposed will depend on the nature and severity of the breach.

Advertisers will be informed about the timelines for implementation of amendments or corrective actions including audits of other materials – especially websites which may need to be amended in the light of an upheld complaint. PAGB will seek assurances from companies that corrective actions will be taken as requested. Failure to comply with any sanctions will be reported to the PAGB Board.

Complaint summary reports will be published in PAGB's weekly newsletter 'This Week' and on the PAGB website once the final determination has been made. Please note that the final determination could be an appeal ruling (Phase 3). In the event of an upheld complaint of a PAGB approved advertisement, PAGB will review its internal processes and/or interpretation of the Codes. PAGB will notify members of any changes to the interpretation of the Codes using 'This Week' and publishing guidance on the PAGB website.

5. Phase 3 – appeal

If either party disagrees with PAGB's decision on a formal advertising complaint, they may seek an objective review of the case by the PAGB Advertising Complaints Appeal Panel (the Panel).

Requests for an objective review of cases must be received by PAGB within 10 working days of the PAGB decision. If PAGB believes that the advertisement represents a breach of the law or a serious risk immediate action may be requested prior to the outcome of the appeal. Otherwise, companies are not required to comply with the decision of the Senior Management team until the final determination of the Panel.

Phase 3 is the final stage of the PAGB advertising complaints procedure. Requests for a review of cases by a Complaints Appeal Panel may be initiated by the company's designated signatory or other senior regulatory or medical personnel and must be submitted in writing to advertisingcomplaints@pagb.co.uk within 10 working day of receipt of PAGB's decision. The Managing Director / General Manager must be copied in on the letter. Within 48 hours both the advertiser and the complainant will be informed that a review by the Panel has been requested.

The materials submitted for Phase 2 by the complainant and the advertiser together with the PAGB formal advertising complaint report and decision will form the basis of the review by the panel. No new evidence or materials will be considered; however, both the advertiser and complainant may provide any comments on the PAGB ruling ahead of the panel review. This should be submitted no later than three working days following PAGB notification of the request of a Panel review.

The Panel will be assembled within five workings days of receipt of the appeal. The Panel will make their decision within 15 working days of receipt of the appeal. If the advertising is found to be in breach of the Code or guideline the advertiser must work with PAGB to withdraw or amend any relevant advertising. The severity of the breach, potential risk to consumers and media type will be considered when considering a suitable timeframe.

A complaint summary report will be published in PAGB's weekly newsletter 'This Week' and on the PAGB website once the final determination has been made.

The costs associated with PAGB complaint appeal panels will be borne by the appellant company if the Panel dismisses the appeal and agrees with the PAGB Senior Management Team decision.

PAGB will bear the cost where the Panel upholds an appeal and disagrees with the PAGB decision in Phase 2.

The costs of convening the Panel will be in the region of £1,500 - £2,000.

5.1. Complaint Appeal Panels

In order to ensure the independence of a Complaint Appeal Panel, PAGB has a pool of experts from which to select panel members to consider a particular case.

Panel members are PAGB Board members and experts in the following disciplines: OTC medicines, medical devices and food supplements industry, marketing, advertising, clinical/medical and law. All members selected for the panel will be required to confirm that they have no competing interests in the outcome of the appeal.

Each Complaint Appeal Panel will comprise three members with relevant expertise to adjudicate on the case and will always include experts from the relevant industry sector and marketing/advertising. A chair will be selected from the three members.

Additional experts will sit on cases raising particular issues and requiring specific expertise e.g. disputes on interpretation of clinical studies will always have the views of a clinician who is familiar with the PAGB Code, medicines' law and the relevant therapy area. Medical advice will not be taken from any of the PAGB's medical advisors who have already been involved in the approval process of the claims.

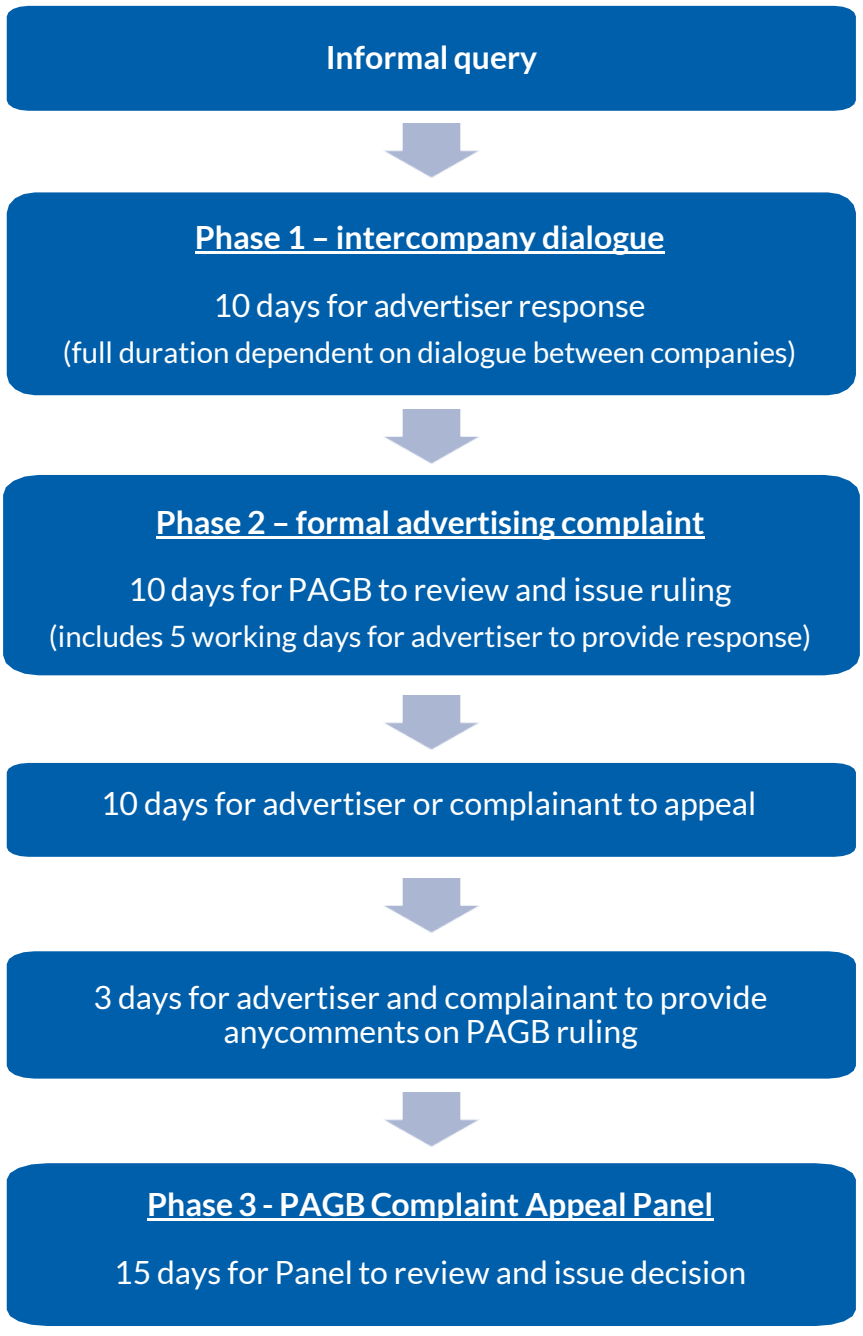
6. Non PAGB member advertising

PAGB can provide advice on complaints relating to non-member advertising but will only take action on behalf of PAGB in circumstances relating to wider industry issues. Please see the External Complaints document for guidance on processes for reporting non-compliant advertising materials created by non-member companies across the three membership categories.

PAGB's Codes of Advertising Practice, guidelines and additional guidance are available at www.pagb.co.uk/codes-guidance. Log in to the members' area to access the full range of guidance. For more information, contact info@pagb.co.uk.

Appendix 1: PAGB advertising complaint procedure flowchart and timelines

All stated time frames are in working days.



Due to the responsive nature of PAGB's services we may be unable to process complaints according to timelines laid out in this guidance document. PAGB also recognises that in extenuating circumstances members may request extensions, which will be considered on a case-by-case basis.

If PAGB is unable to meet the timelines we will inform the parties to the complaint. In these instances, PAGB will outline the timelines that will apply to this individual complaint.

Appendix 2: Formal advertising complaint checklist

When submitting a formal advertising complaint, complainants must include the following:

- Cover letter
- The advertisement that is the subject of the complaint
- Relevant correspondence between the complainant and the advertiser
- Complaint table:
  a. where and when the advert was published and whether it has been approved for publication by PAGB
  b. the claim(s) and/or points of issue
  c. the alleged breach(es) of the codes or legislation (quote rule)
  d. written explanation detailing why you believe the advert contravenes Code or regulatory requirements
  e. any evidence or data you have which supports your position (e.g. previous PAGB, MHRA or ASA adjudication, data to contradict the claim)

Appendix 3: Food supplements approval system

The review of food supplements advertising differs from medicines in that members do not have to obtain approval in all circumstances. PAGB assessors highlight any claims within copy considered non-compliant, or at risk of non-compliance. As certain elements of food supplements legislation can be open to interpretation, PAGB has a system which evaluates risk and gives members the option to proceed without approval on certain points.

In the event of a complaint on a point where the advertiser has opted out of approval, the options of an informal query and intercompany dialogue are still open to the complainant. PAGB will assist as far as possible in securing a resolution through these avenues. However, should the member choose not to amend its advertising, the complainant made need to progress its complaint with the Advertising Standards Authority.

Appendix 4: Compliance Action

If a complaint is upheld, members should be able to demonstrate that they are taking action to remove the non-compliant material in a timely manner. Timelines may vary dependent on circumstances and the severity of the Code breach, but the below provides an indication of actions likely to be required.

Online content

Materials under direct member control should generally be amended or removed within one working week. Where external platforms have a level of control over placement, the member should be able to demonstrate that they have instructed them to take action within the same time frame.

Television and radio

Once a final decision is issued on complaints relating to broadcast ads, members should replace non-compliant material which has been supplied to broadcasters wherever possible. PAGB recognises that this may not be possible when ads are due to run imminently. The non-

compliant materials should not be supplied to broadcasters following the decision or run again until suitable edits have been made and the copy approved by PAGB where applicable.

Print

Once a final decision is issued on complaints relating to print ads, members should replace non-compliant material which has been supplied to publishers wherever possible. PAGB recognises that this may not be possible when ads are due to run imminently; recalls are unlikely to be required for materials that have already gone to print. The non-compliant materials should not be supplied to publications following the decision or published again until suitable edits have been made and the copy approved by PAGB where applicable.

Point of sale

PAGB understands that point of sale materials can be in place in retailers for long periods of time, which may present barriers to swift updates. Members should contact retailers to request that they replace or remove non-compliant materials within a reasonable period, usually four weeks. While members cannot guarantee that retailers will take direct action, they should be able to demonstrate that they have contacted them as requested and made best efforts to have the material withdrawn.