



Advertising Complaint Procedure

for PAGB member companies

March 2016

Review date: February 2017

Terminology

The Codes PAGB Medicines Advertising Codes of Practice

The Panel PAGB Advertising Complaints Appeal Panel

Informal Query Phase

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 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.

Phase 1 – Intercompany Advertising Complaint

When PAGB member companies have queries about advertising for OTC medicines, self care devices or food supplements they should write to the advertising company to outline the areas of their concern and advise PAGB by copy of the complaint.

In order 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 or regulations alleged to have been breached. The [complaint check list](#) is designed to help members ensure that they have included the relevant information. At this stage it should also be established if the advertising has been 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 contact PAGB simultaneously.

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. Companies must have attempted to resolve their query directly with the advertiser before making a formal complaint. 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 the

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. At the same time the PAGB copy clearance team will review the advert in light of the complaint and write up a report. The complaint together with the advertiser's response and the PAGB copy clearance report will be considered by PAGB's Chief Executive and Deputy Chief Executive 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 an agreement cannot be reached between the PAGB Chief Executive and Deputy Chief Executive the complaint will automatically proceed to Phase 3 (it will be sent straight to the Complaints Appeal Panel).

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

- i. Company audit of its own internal advertising sign off
- ii. Amendment to advertising
- iii. No further distribution, publication or broadcast of the advertising or promotional materials
- iv. Withdrawal of materials from the market
- v. 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. Failures to comply with any sanction 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 need to 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.

Non PAGB member advertising

Where a formal advertising complaint concerns a non-member company's advertising PAGB will review the advertising and if it is believed that it is in breach of advertising

codes and regulatory requirements PAGB's senior management will write to the advertiser detailing the complaint and offering to assist in resolving the dispute within 48 hours. Information about PAGB membership and the copy clearance process including PAGB's role in the self-regulation of advertising will be provided. In the event of this offer being refused or if no response is received within five working days the matter will be referred to the PAGB Board which will have a further five working days to decide if PAGB should make a complaint direct to the relevant regulatory or enforcement body (MHRA, ASA or Trading Standards).

Phase 3 – PAGB Advertising Complaints Appeal Panel

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. Companies are expected to comply with the decision of the PAGB Chief Executive and Deputy Chief Executive pending 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 copy clearance report and 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 to the PAGB Administration Manager no later than three working days following PAGB notification of the request of a Panel review.

The Panel will be assembled within five working days of receipt of the appeal. The Panel will make their decision within 15 working days of receipt of the appeal.

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 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.

PAGB Advertising Complaint Appeal Panels

In order to ensure the independence of a PAGB Advertising Complaints Appeal Panel

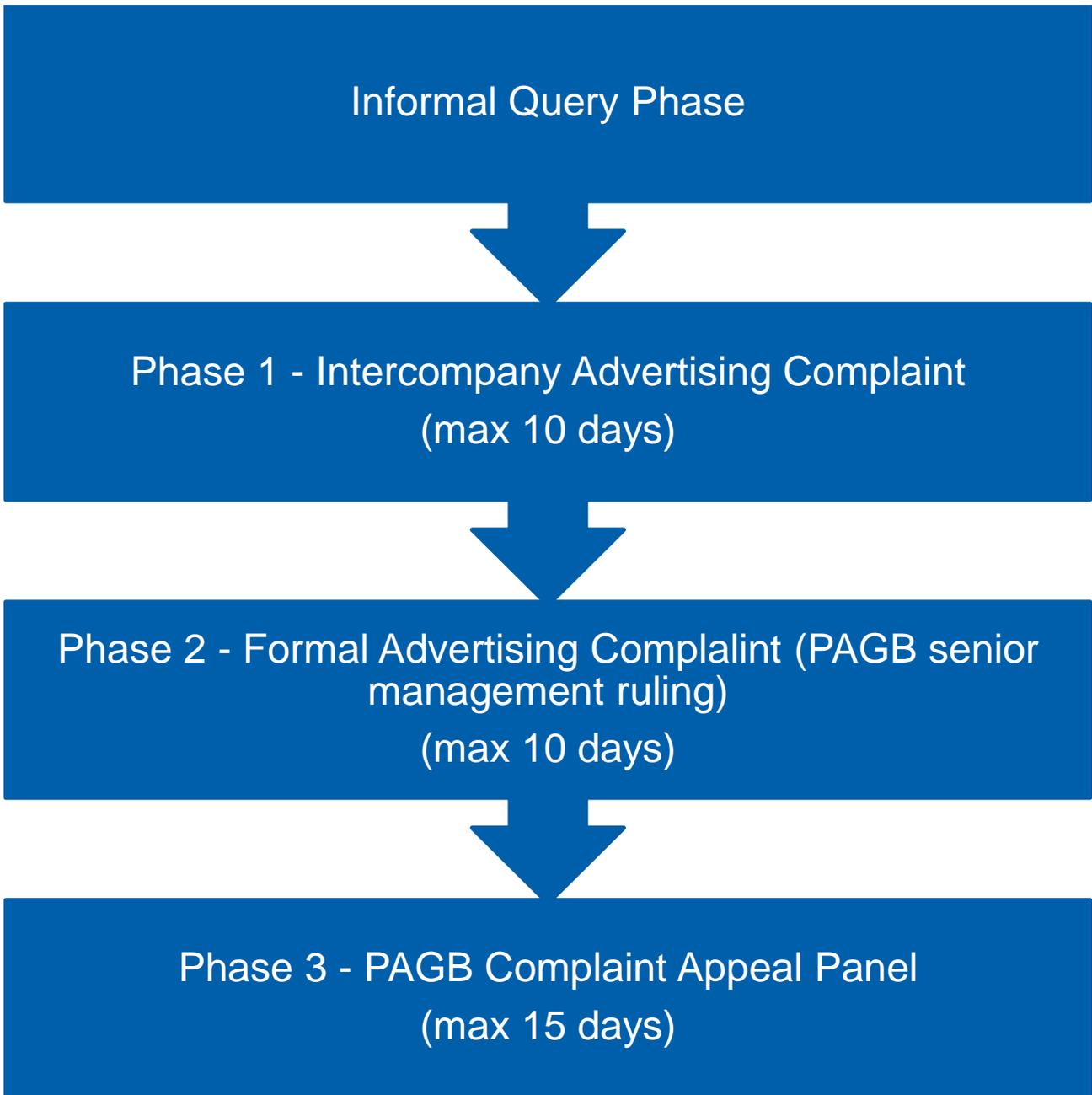
PAGB has a pool of experts from which to select panel members to consider a particular case.

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. 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.

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.

Annexes

PAGB Advertising Complaint Procedure Flowchart



Timelines

Due to the responsive nature of PAGB's advertising copy clearance service we may be unable to process complaints according to timelines laid out in this guidance document. 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.

Phase 1 – 10 working days

Phase 2 – 10 working days

Phase 3 – 15 working days

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)

Internal PAGB Guidance

Responding to complaints

Respond with an email to acknowledge receipt of the complaint (within 48hrs)

Standard email

For example: This email is to confirm that PAGB has received your complaint. PAGB will look into the alleged breaches of the code – quote claim and rule and respond in writing by [date].

PAGB Formal Advertising Complaint Report

To contain a MHRA/ASA style write up of the Formal Advertising Complaint Report with PAGB decision.

All Formal Advertising Complaint documents submitted by the Complainant will be attached.

Summary Report for Publication

A summary report of the complaint will be written for publication in PAGB's 'This Week' email newsletter and on the PAGB website. This summary report will contain sufficient detail for companies to understand the nature of the complaint and the arguments put forward by all the parties but it will not divulge any information of a commercially sensitive nature, Details of the decision, sanctions and undertakings will be provided.

Coding for complaint filing

Brand – Date (of complaint) – Product – Rule of alleged breach – XXCom

If multiple rules being breached include each with dashes eg 17-43-47

Powermol 151222 soluble tabs 17-43-47 MXCom