Guidance on the vetting of promotional material for medicines (Updated 2023)

This document provides advice to companies who are submitting material for medicines to MHRA for vetting prior to issue. We strongly recommend that you read the following information and advice on the vetting process. It covers various common issues and arrangements in relation to advertising in Great Britain and Northern Ireland and is designed to help ensure that the vetting exercise is carried out efficiently.

Additional guidance on MHRA vetting is also provided in the Blue Guide.

Overall considerations

Summary of Product Characteristics (SPC)

Where the marketing authorisation (MA) has not yet been granted, we are prepared to look at advertising in anticipation provided the SPC of the product has been substantially agreed. The review is undertaken on the understanding that no materials will be issued until the applicable UK territory MA has been granted, and that all advertising materials will be amended as needed to reflect the final approved SPC applicable in the territory where the product is being advertised.

UK territories

Where a product is licensed separately in Great Britain and Northern Ireland, we would normally expect all advertising materials to include MA details (MA holder and MA numbers) for both territories so that they are suitable for use across the whole UK. If this is not the case, please submit all items for both territories. However, items that differ from those previously reviewed only because of different MA numbers or MA holder details do not need to be submitted for vetting. If a sequential launch is planned in different UK territories, MHRA will normally review materials for the first launch only. It is your responsibility to ensure that advertising that is specific for one territory is not used UK-wide or in a territory where the product is not licensed.

Orphan medicines

For these products, you should submit a single key promotional piece that represents the thrust of your campaign for our review. If a launch press release is planned, this should also be submitted for vetting.

1. Timescales

As soon as it is available, and even if it is only provisional, please let us have information on your planned timetable including a timeline of when and what type of promotional material will be used, highlighting key dates. This information will help us to plan and manage the review.

The timetable should include for every piece: a clear description of the proposed items using terminology that is understandable outside that used by your company; proposed use; intended audience; and length in number of pages (approximately or where known).

We require a minimum of 3 weeks' notice for the initial submission.

2. Scope of vetting

Promotional materials

You need to plan to submit all advertising and promotional materials that form part of the advertising campaign and ensure they are included in your timetable.

Promotional meetings targeting UK Persons Qualified to Prescribe or Supply (PQPS) must be clearly identified as such in the proposed materials from the outset.

Non-promotional materials

These include:

- Press releases and any media-engagement activities related to the product
- Patient-support materials outside those mandated by a Risk Management Plan (RMP)
- Training materials for PQPS outside those mandated by a RMP
- Advisory boards
- Non-promotional meetings targeting UK PQPS, which must be clearly identified as such in the materials

3. What vetting does not include

You do not need to submit the following materials:

- Items used within the company for internal training purposes
- Materials that are part of a RMP; we may ask you for a brief description of mandated RMP items to support our review of vetting materials
- Promotional support items or training aids for administration of the medicine
- International meetings that are not specifically targeting UK PQPS. Involvement of a UK speaker at an international meeting would not be reviewed
- Market research
- Disease-awareness campaigns or disease-specific materials
- Technology or formulary appraisals

These materials must meet statutory and self-regulatory requirements.

4. How to submit materials

All material you submit for review must have undergone a full set of internal quality control, compliance checks, and sign-off before submission to us. Further prior copy approval may be required for: over-the-counter products (eg, by The Proprietary Association of Great Britain); TV adverts (by Clearcast); and radio broadcast (by Radiocentre).

We strongly recommend that a key promotional piece such as the detail aid is submitted for vetting first so that the MHRA can review the main messages to be used in the promotional campaign. This approach should aid clearance of subsequent pieces. Materials must be submitted for assessment one at a time: you should not submit an item until you have received our comments on the previously submitted piece. This approach enables us to

stagger the review and gives you time to consider our comments appropriately in any future material.

Every piece of material submitted for vetting must be accompanied by the following information in the body of the email:

- A clear description of the item and its proposed use
- Intended audience
- Length of document
- Supporting documentation, references, and the SPC. The PIL must also be included for public-facing materials

Some activities will require you to submit a range of supporting information in order for us to determine its suitability (eg, meetings and advisory boards). These documents must be submitted at the same time in a discrete package for assessment to take place. Please refer to the checklists at the end of this guidance document.

For all items, please submit colour mock-up PDF versions that closely reflect the proposed finalised piece.

All material should be submitted by email with a read-receipt requested to ensure successful delivery. Consider using the “Reduce File Size” option within your PDF software, or splitting the items in different emails sequentially numbered in the subject line.

Submissions should be sent to your allocated named advertising assessor, copying advertising@mhra.gov.uk. To send multimedia material (eg, mp4 files), please contact us using this email addresses to obtain a secure transfer link to ensure safe receipt of these files; please note we are unable to receive multimedia files through any other route, including other file-transfer services.

References: Please ensure that the most up-to-date references are sent with each piece. It should be clear which reference corresponds to a particular citation.

Review of advertising cannot start without the SPC and supporting references or information, as applicable.

5. Outcome of review

The vetting invite letter outlines target timelines for review. Where this target may not be met, we will inform you of the expected delay.

Once the review is complete, we will inform you of our views in writing by email. Our comments to you will be based on the information available to us at the time of review and will enable the agreement of general principles.

Our comments will take one of the following forms:

- We do not object
- We do not object provided specific changes are made
- Refusal. In such cases revised materials must be submitted for further review

When our letter states: “We do not object provided specific changes are made” you do not need to resubmit the material for MHRA review, but you do need to provide the final version for our records. If any of our comments are not clear to you, if you wish to clarify a specific point, or if you do not agree with our requests, please make this clear in your response.

We may also decide not to review certain items submitted and will confirm this to you in writing for each item.

The vetting period will vary depending on timing of the key material submitted and on the overall quality of all items. We will inform you in writing when the vetting period has come to an end for a particular product.

6. Scientific advice

Occasionally companies may wish to have a scientific advice meeting to discuss their advertising campaign at the start of, or during, the vetting process. Details of how to request a meeting are available from the MHRA website. To facilitate discussions on the proposed advertising at a pre-planned meeting, a key promotional piece (for example a detail aid) with accompanying supporting data and SPC must be submitted at least 2 weeks before the meeting to allow for MHRA review and an initial written response.

7. Top Tips on vetting material

To help ensure that materials have the objective of being “right first time”, you should carefully consider the following when preparing and submitting material for MHRA vetting:

- **Indication:** The authorised indication(s) of the product should be stated clearly and prominently at the outset to ensure that claims are set in a clear context. Advertising should not serve to extend the use of the product beyond the licensed indication(s), particularly where use is restricted to a specific patient group or as second-line treatment.

- **Presentation of data:** Data according to hierarchy of the study should be discussed carefully in a logical flow of information (ie, primary endpoint findings presented first, followed by secondary endpoints). The title of each page should clearly refer to which endpoint is being discussed. Measures of confidence must be reported where these data are available. Exploratory endpoints should only be discussed after slides showing primary and secondary endpoints. No claims can be made for exploratory endpoints and their limitations should be made very clear to the audience. Associated graphics should not exaggerate the benefits of treatment.

- **Accurate claims:** Claims should be supported by the balance of evidence available and should include sufficient information to allow the reader to judge the importance of the claim for themselves.

- **Fair comparisons:** Comparisons with other products should not ‘cherry pick’ favourable findings without setting these in the context of the overall study results, particularly in non-inferiority studies. Presentation of efficacy comparisons without including details of relevant limitations on prescribing or differences in safety is likely to mislead. It is unlikely that cross-trial comparison will be sufficiently robust to support comparative claims.

- **Images and straplines:** These can convey powerful messages about the properties of the product, but must portray realistic expectations for use of the product and be supported by relevant data. Pictures intended to depict a patient must be representative of the indicated patient population.

- **Key safety messages:** Safety information required to support safe use of the product should be included, particularly for a new product where the detail aid has a clear educational function. It should include risk-management messages, key contraindications, warnings, side-effects, and details of any monitoring required from the product SPC. For a new active, we do not generally consider claims for “good tolerability and a manageable safety profile” or similar to be justified at that stage in a product’s lifecycle when knowledge is limited.

- **Materials for the public:** Promotion of Prescription-Only Medicines to the public is prohibited. Patient materials must be consistent with the PIL and not contain promotional claims. You must ensure there is sufficient rationale for the preparation of company patient materials, which should not undermine the PIL or any statutory information for patients defined in a RMP.

- **Press releases:** Companies may issue a press release to announce the launch of an innovative new product in a UK territory. This release 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. Press releases should not use emotive or alarming language or raise unreasonable patient expectations. It is your responsibility to ensure that the press release accurately reflects the licensing position in UK territories at time of issue. Targeting of media outlets should also accord with licensed territory/ies.

MHRA Advertising Standards Unit
June 2023

Checklist of information required for assessment of specific materials

Advisory boards

The following should be submitted for every proposal:

a. Draft email invitation
b. Meeting agenda, with clear information on time allocated to company presentations versus discussion time with the advisors
c. Objectives of the advisory board and rationale for requiring expert advice
d. Details of hospitality
e. List of attendees, with a justification for every attendee
f. Honoraria details for all attendees
g. List of company or contractor staff to be present, with role and justification
h. Meeting slides
i. A summary of prereading required

Before submitting proposals, you must ensure internally that you are satisfied that the proposal supports a meeting that would meet statutory and self-regulatory standards for the expert group with whom you wish to engage. Advisory boards should seek to only obtain information about treatment pathways that you cannot obtain by any other means.

Meetings

The following should be submitted for every proposal:

a. Draft email invitation
b. Meeting agenda
c. Presentations where the company has been involved in their preparation. Presentations drafted independently by external speaker with no company involvement do not need to be submitted for vetting, but you must ensure it meets all statutory and self-regulatory requirements; all speakers must declare any conflicts of interest
d. Details of hospitality
e. Clear indication to us and in the materials as required to indicate whether the meeting is promotional or non-promotional