Medicines & Healthcare products Regulatory Agency

MHRA

Guidance on the vetting of promotional material for medicines
(Updated November 2020)

This leaflet provides advice to companies submitting promotional 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.

Please do not hesitate to contact your advertising assessor by phone or email if you have any questions about the vetting process.

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.

We aim to agree a date for submission of the main promotional items as early as possible to ensure that we are able to plan and manage the review and complete it within the target time.

If a minimum of two weeks' notice is not provided for the initial submission the MHRA may need to pause assessment for two weeks and may be unable to meet published target times.

2. What does vetting include?

You need to submit all advertising and promotional materials that form part of the advertising campaign

You are also required to submit non-promotional materials such as press releases and associated media material and items for patient support. This also includes any social media material, whether or not promotional.

You should submit material for all meetings about your medicine, whether promotional or non-promotional, including presentations, agendas and details of hospitality. For any advisory board please also include the number of attendees and detailed justification for the business purpose of the meeting and for each attendee.

For promotional support items or training aids, you should notify us about items you plan to use but do not have to send specimens for review.

Where the marketing authorisation (MA) has not yet been granted, we are prepared to look at advertising in anticipation provided the Summary of Product Characteristics (SPC) of the product has been substantially agreed by the MHRA or through the centralised route. The review is undertaken on the understanding that no promotional materials will be issued until the applicable UK marketing authorisation 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: We recognise that promotion of new orphan products may be limited considering that their use is usually restricted to very small patient populations. The MHRA has therefore decided to adopt a proportionate approach for this category of medicines. For these products, you should submit a single piece or small selection of advertising material that represents the thrust of your campaign for our review.

3. What vetting does not include

You do not need to submit materials that are only used within the company, including those used for internal training purposes.

As part of a Risk Management Plan (RMP), MA holders often commit to dissemination of educational material that provides additional information to physicians and/or patients. Materials that are formally identified as part of the RMP do not have to be submitted to the Advertising Standards Unit for vetting. All RMP material for UK use should be submitted directly to RMPallocation@mhra.gov.uk. The RMP assessor in the Benefit Risk Management Group will inform you about the outcome of their review in accordance with their target response time.

4. How to submit materials

All material you submit for review must have undergone a full set of internal quality control and compliance checks and sign-off prior to submission.

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. Once these are agreed, other derivative pieces can then be quickly cleared when subsequently submitted. While we prefer this option, if you do plan to submit several pieces at once, it is particularly important that you let us know well in advance. Where a high number of items are submitted together and accompanied by substantial supporting data, additional time may be needed for review

When submitting material for vetting, you should include a description of the item and its proposed use (if not obvious) along with any supporting documentation, references and the SPC(s).

Please submit colour mock-up PDF versions that closely reflect the proposed finalised piece. In some cases we are prepared to look at proposed text and provide initial comments, provided formatted items are subsequently submitted for a full review. Please note that review of the formatted item may give rise to additional concerns.

All material should be submitted by email with a read-receipt requested to ensure successful delivery. Attachments to any single email should be limited to 25MB. It should be possible to reduce the size of most PDFs to within this limit using the “Reduce File Size” option within your PDF software.

Submissions should be sent to your advertising assessor copying advertising@mhra.gov.uk. To send multimedia material (eg, mp4) files, please contact us using the above email addresses to obtain a 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.

We are unable to accept submissions on removable media devices such as USB memory sticks or CDs.

If the electronic version is of an unusual file format please discuss this with your advertising assessor to ensure it can be opened. It is not usually necessary to submit hard copies of material.

File Naming: Files names should be short and hyphens or underscores should be used to separate words. File names cannot include the following symbols: ~ " # % & * : < > ? / \ { | } " * : < > ? / \ |

References: It is more convenient to provide the complete set of numbered core references for your promotional campaign, rather than providing repeat references with each piece of promotional material. Please make sure that you cross refer for each individual piece and make clear which number of the core reference list applies for each promotional piece.

Review of advertising cannot start without the SPC and supporting references.

5. Outcome of review

We are committed to a target of five working days to give our opinion on each individual promotional item submitted for review. In certain circumstances this may not be possible, for example due to the unavailability of expert assessors, emerging urgent safety priorities or the large volume of material submitted. Should this be the case 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; or
- 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 need to provide the final version for our records. If any of our comments are not clear to you, you wish to clarify a specific point or 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.

Performance statistics on vetting of advertising materials are also published on our website. These show the percentage of pieces of advertising submitted each month where the MHRA has provided a response to the company within the target response time of 5 working days.

6. Further scientific advice

Most concerns are resolved through correspondence or clarification over the telephone with your advertising assessor. There are occasions, however, when this may not be possible due to the complexity of the issues. In such cases, we are happy to discuss these issues or concerns informally with you by pre-arranged teleconference or formally at a meeting. Where the MHRA has substantial

comments on the material submitted and serious concerns about the advertising material, a face to face discussion may prove helpful. A scientific advice meeting can be arranged so that MHRA advertising and specialist assessment staff may help you to understand the Agency's views and the changes needed to the material. This is most beneficial once outstanding concerns have been identified following MHRA assessment of the material. The MHRA charges a fee for such meetings. You should give us notice of at least 1-2 weeks. Details of how to request a meeting are available from the MHRA website.

Occasionally companies may wish to have a scientific advice meeting to discuss their advertising campaign at the start of the vetting process. 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 two weeks before the meeting to allow for MHRA review and an initial written response. If the initial response gives only minor comments, you may wish to cancel the meeting.

7. Duration of vetting

The vetting period usually lasts for approximately two to three months but this can vary depending on the quality and timing of the initial promotional material submitted, subsequent revisions and other relevant factors. The Agency will inform you in writing when the vetting period has come to an end.

8. Top Tips on vetting material

We have identified six key learning points during our review of advertising for new products. You should carefully consider the following when preparing and submitting material for MHRA vetting:

- **Indication:** The authorised indication 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, particularly where use is restricted to a specific patient group or as second line treatment.

- **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.

- **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.

- **Accurate Claims:** Claims should be supported by the balance of evidence available and include sufficient information to allow the reader to judge the importance of the claim for themselves. Primary endpoints should be presented prominently and relevant limitations of secondary or exploratory findings explained. Associated graphics should not exaggerate the benefits of treatment.

- **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. Presenting 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.

- **Materials for the Public:** Promotion of prescription only medicines 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. Press releases shouldn't use emotive or alarming language or raise unreasonable patient expectations. Likewise, patient materials must be consistent with the patient information leaflet and not contain promotional claims.

9. "Right first time" should be the objective

We aim to make the vetting exercise smooth and swift. We can achieve this by working closely with you, with careful planning and submission of advertising and promotional material of a high standard.

MHRA Advertising Standards & Outreach Unit
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