Appendix 8

Guidance on review of advertising by an Independent Review Panel

1. Introduction

1.1 The MHRA on behalf of Health Ministers may serve a "minded to" notice on a company advising it that it is minded to determine that an advertisement, if published, would be in breach of the legislation on advertising medicines (see regulation 305 of the Human Medicines Regulations 2012 (SI 2012/1916 as amended – the Regulations)). This note outlines the procedure for requesting a review of such a notice by an Independent Review Panel (IRP).

1.2 The MHRA will normally contact a company informally to advise them that there are some concerns about a particular advertisement. This may be a result of routine monitoring by the Advertising Standards Unit or as a result of a complaint received by the MHRA. The company will be asked for comments and may be asked to supply other promotional material for the product before being given the MHRA's opinion on the acceptability of the original advertisement. There are in the advertising legislation powers to require copies of advertisements, including advance copies, to be supplied to the MHRA.

1.3 This guidance provides advice on what steps you need to take if your company receives a "minded to" notice and explains the review procedure.

2. When to ask for a review

2.1 If the MHRA has raised concerns with you that cannot be resolved informally, the MHRA may issue a "minded to" notice under regulation 305 of the Regulations. The notice will set out the reasons for MHRA's position and will be supplemented by any relevant supporting evidence and assessment reports. You will be informed in the notice of your right to make written representations prior to the making of a final determination by the MHRA (acting on behalf of Health Ministers), provided these are made within 21 days.

2.2 Any representations made will be referred to an Independent Review Panel in order for them to give advice to the MHRA as to the determination which should be made. The Panel is designed to provide a rapid and independent review of the matters at issue, should you request it, prior to a decision being made by the MHRA on an advertisement. It does not replace or substitute the legal right to apply for a judicial review.

The Independent Review Panel does not have the remit to consider any other advertising issues.

2.3 The panel will normally consist of three persons, a legally qualified Chairman, a medically or pharmaceutically qualified person and a person with experience in consumer affairs. The members will not represent any particular organisation but will use their experience in giving advice to the MHRA. If the case concerns advertising for a traditional herbal medicine, an additional member with relevant specialist expertise may be chosen by the Chairman. The Panel will be served by a Secretariat provided by MHRA and made up of officers who have no involvement in the assessment of advertising material.

2.4 Panel members will be required to follow the Code of Practice on Relations within the Pharmaceutical Industry and accordingly declare any interest in any matter before the Panel and withdraw from any matter in which they have a conflict of interest.

3. What to do

3.1 Where the "minded to" notice includes a requirement that the advertisement should not be published pending the withdrawal of the notice, you must comply with the requirement until the review is completed or the earlier withdrawal of the notice.

3.2 If you wish for a review, you must reply to the notice within 21 days of the date of the notice setting out in a written representation why you consider that the advertisement would not be in breach. The letter should be addressed to the Secretary to the Independent Review Panel at the address given in section 6 of this guidance. The MHRA will require six copies of the representation.

3.3 You should provide full details of why you believe the advertisement would not be in breach and include all additional information which you consider will support your views. This submission should be limited to addressing the specific issues raised in the notice only but should include all the points you wish to raise before the Panel. There will be no automatic right to an oral hearing but if you feel that an oral hearing would help you to present your case, you may include a request with your written representation giving reasons.

4. What happens next?

4.1 Your written representations will be forwarded to the MHRA Advertising Standards Unit for review. If you have included in your written representation any relevant information which was not available to the MHRA during earlier negotiations, and which could have materially affected the "minded to" notice, the advertisement will be reconsidered.

If appropriate, a revised "minded to" notice will be served, restarting the process. Alternatively the MHRA may notify you that one or more of the grounds set out in the notice are withdrawn and no longer at issue before the Panel. The MHRA will also consider whether, in the light of representations made, the "minded to" notice should be withdrawn without referring the matter to the Panel.

4.2 Your written representations, together with the MHRA papers, will also be provided to the Independent Review Panel (through the Secretariat). The MHRA papers will consist of the notice and supplementary evidence and assessment reports referred to in point 2.1, a copy of the advertising material and supporting references, details of the original complaint and copies of all correspondence with the company relating to the assessment of the complaint.

4.3 If you have requested an oral hearing, the Panel will decide, taking into account any MHRA views, whether an oral hearing is required in order to ensure fairness, having particular regard to the complexity of the issues in the case. The MHRA may also request an oral hearing but has stated, as a matter of policy, that it will not normally do so. When an oral hearing is to take place the hearing will be set for a time and place as notified by the Panel (taking into account any representations made by the parties). Where an oral hearing is not to take place, the Panel will inform the parties of the date on which it will settle its advice. The date of the Panel meeting will normally be within 4 to 6 weeks of the date of receipt of your written representations.

4.4 With the notification of the Panel date you will also receive any MHRA response to the points raised in your representations (see point 4.1 above) and copies of any additional MHRA papers not provided with the original “minded to” letter. The MHRA will either copy to you any of this material which did not accompany the original "minded to" letter, or (where you already have the material) will inform you of the fact that it is relying on it.

4.5 The Panel may also call for further information from either party or from an independent expert. Any material lodged with the Panel will be made available to both parties.

4.6 If an oral hearing is held, both you and the MHRA may attend to answer questions from the Panel. The MHRA will first be given the opportunity to answer any questions from the Panel. You will then be given the opportunity to answer the Panel’s questions and respond to MHRA's points at issue. Both the company and the MHRA representatives will then withdraw when the Panel begins their detailed discussion of the case leaving only the Panel members themselves and the Secretariat members.

4.7 At an oral hearing, a party may only call witnesses if the Panel, on application, considers that this is necessary in order to clarify any matter

or otherwise ensure fairness. The normal procedure of the Panel will be to consider written submissions and supporting evidence and you should include any witness statements in your written evidence, assuming that oral evidence from witnesses will not be required. The Panel may request witnesses to attend of its own motion. Either party may present all or part of its case through an in-house lawyer. However, a party may only be represented by independent Counsel in exceptional circumstances and the Panel will only accede to a request to be so represented if it concludes that, without Counsel, a party would not be able to present its case to the Panel with sufficient clarity, or otherwise so as to ensure fairness. The Panel may settle its advice without an oral hearing if you fail to appear at the date and time set for the hearing.

4.8 An oral hearing will be in private with support from the Panel Secretariat. The Panel may adjourn an oral hearing date or the date on which it will settle its advice (as the case may be) on application or on its own initiative.

4.9 The Panel will consider the advertisement for compliance with the Regulations, taking into account the papers submitted by the MHRA, the written representations received from the company, and any oral representations made by the parties. The Panel will settle its advice, if necessary, by majority verdict. The Panel's advice will be put in writing, giving full reasons, and forwarded to the Advertising Standards Unit.

4.10 Following the sitting of the Panel, the MHRA (acting on behalf of Health Ministers) will make a final determination on the advertisement taking into account the advice of the Panel. You will normally be advised of the final decision within 21 days of the Panel sitting, and will be informed of any delay and the reasons for it, if this deadline is not met.

4.11 The MHRA will notify the company of the final determination and the reasons for any determination that the advertisement would be in breach. It will include a copy of the Panel’s advice and will specifically point out any divergence between a determination that the advertisement would be in breach and the Panel's advice, and give the reasons for this.

4.12 At the close of the case, a report including the advice of the Panel and the final determination of Health Ministers will be published on the MHRA website (subject to the exclusion of any confidential material). This will also include copies of all representations to the Panel unless these have been identified as confidential by the company concerned.

5. What if I still disagree?

5.1 There is no right of appeal against the final determination that the advertisement would breach the Regulations, but you may apply for it to be judicially reviewed. If the notice of final determination requires you to refrain from publishing the advertisement and you decide to disregard the notice and re-issue the advertisement without amendment, the

MHRA may take further action. This may take the form of injunctive action to prevent the publication of the advertisement or a prosecution for an offence under the Human Medicines Regulations.

6. Further information

6.1 Further advice about advertising policy can be obtained from:

Advertising Standards Unit
Area 3-M MHRA
151 Buckingham Palace Road
LONDON SW1W 9SZ
Tel: 020 3080 6765/6689/6717
Email: advertising@mhra.gsi.gov.uk

6.2 Further advice about the Independent Review Panel and its processes can be obtained from the Secretariat:

Independent Review Panel Secretariat
Area 4-T MHRA
151 Buckingham Palace Road
LONDON SW1W 9SZ
Tel: 020 3080 6431
Email: reviewpanelsecretariat@mhra.gsi.gov.uk

MHRA
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GLOSSARY

AA	Advertising Association
ABPI	Association of the British Pharmaceutical Industry
Advertising Regulations	The Medicines (Advertising) Regulations 1994, SI 1994/1932 as amended.
ASA	Advertising Standards Authority
ATMP	Advanced Therapy Medicinal Product
AWMSG	All Wales Medicines Strategy Group
BCAP	Broadcast Committee of Advertising Practice
BHMA	British Herbal Medicine Association
BMA	British Medical Association
BNF	British National Formulary
CAP	Committee of Advertising Practice
Cm	Command Paper
Common Name	The international non-proprietary name (INN) or the usual common name.
DAC	Disease Awareness Campaign
DH	Department of Health
eMC	Electronic Medicines Compendium – a database of SPCs and PILs for licensed medicines, see http://www.medicines.org.uk/emc/
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EU	European Union

GP	General Practitioner
GPhC	General Pharmaceutical Council
GSL	General Sale List – medicines available without a prescription in pharmacies or non-pharmacy retail outlets
Healthcare professional	As defined in regulation 8 of the Human Medicines Regulations 2012. Healthcare professionals are subject to statutory regulation by a body such as the General Medical Council or Health and Care Professions Council.
HFMA	Health Food Manufacturers' Association
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
INN	International Non-proprietary Name
IRP	Independent Review Panel
MA	Marketing Authorisation
MALG	Medicines Advertising Liaison Group
MHRA	Medicines and Healthcare products Regulatory Agency
Monitoring Regulations	The Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933 as amended.
NICE	National Institute for Health and Care Excellence
Ofcom	Office of Communications
OFT	Office of Fair Trading
OTC	Over-the-counter – medicines classified as Pharmacy and General Sale List legal categories that are available and can be purchased without a prescription
P	Pharmacy medicine – a medicine which is neither POM nor GSL available only in pharmacy outlets under the supervision of pharmacists

PAGB	Proprietary Association of Great Britain
PAR	Public Assessment Report
PGD	Patient Group Direction
PIL	Patient Information Leaflet (provided in a medicine pack)
PL	Product Licence
PLR	Product Licence of Right
PMCPA	Prescription Medicines Code of Practice Authority
Product Claim	A form of words that highlights the qualities of a medicine
Promotional Aid	A non-monetary gift made for a promotional purpose by a commercially interested party
POM	Prescription Only Medicine – a medicine for supply by prescription only
PQPS	Person Qualified to Prescribe or Supply medicines
RACC	Radio Advertising Clearance Centre
RCN	Royal College of Nursing
RPS	Royal Pharmaceutical Society
S4C	Sianel Pedwar Cymru (Welsh television broadcasting service)
SFO	Serious Fraud Office
SI	Statutory Instrument
SMC	Scottish Medicines Consortium
SPC	Summary of Product Characteristics
‘Special’	An unlicensed medicine supplied to meet the special need of a patient
TSO	The Stationery Office

THM	Traditional Herbal Medicine
USR	Urgent Safety Restriction
VAT	Value Added Tax
Vetting	Review of promotional material prior to issue (sometimes called pre-vetting)