MEDICINES ADVERTISING LIAISON GROUP
25 September 2014
R-M-426 (4th Floor) at 2:30pm
MHRA

Attendees

Heather Simmonds	PMCPA	**MHRA**	
Camelia Mihaescu	PAGB	Jan MacDonald	(Chair)
Dafydd Taylor	PAGB	Beryl Keeley	
Andy Taylor	CAP	Aisha Dewangree	(Note)
		Dan Runciman	
		Clare Headley	(Part)

Apologies

Al Damon	RACC
Niamh McGuinness	Clearcast
Jenny Ackers	HFMA
Ann Godsell	BHMA

MHRA welcomed those attending. Apologies were noted.

1. Agreement of Agenda

The agenda was agreed.

2. Minutes of last meeting – 21 January 2014

The finalised minutes had been circulated and agreed. They had since been published on the MHRA website.

3. Matters Arising

<u>European report on statutory information</u>

MHRA reported that the European Commission report on the shortcomings of statutory information had not yet been published but was expected to go to the Pharmaceutical Committee and subsequently to Member States (MS) in the near future. MHRA did not expect the report to include any legislative proposals relating to statutory information or to information for patients. There were no other current European developments relating to information for patients.

4. The Human Medicines (Amendment) (No. 2) Regulations 2014

MHRA reported that the amending regulations (SI 2014/1878) were laid before Parliament on 18 July 2014 and would come into force on 1 October 2014.

Advertising to healthcare professionals

One of the changes to the legislation related to advertising aimed at healthcare professionals and other suppliers of medicines. Advertising for over the counter medicines would be able to include a link to the prescribing information or the product SPC rather than including the full information in the advertisement. A link to the SPC would also be permitted for advertisements in digital media. PAGB mentioned that they had informed their members about these changes in one of their weekly newsletters.

The Blue Guide

The MHRA had revised its Blue Guide to accommodate the regulatory changes and had also used the opportunity to make additional changes based on advertising case work. Amendments had been made following feedback from MALG members and the updated version would be published to coincide with the legal changes.

5. Introduction to Medical Devices

MHRA gave a brief presentation on the regulation of medical devices and the Agency's work in that area. MHRA was the competent authority for medical devices for the UK and was responsible for enforcing the regulations on devices. There are no 'licences' for medical devices, but rather a CE marking process. This is not undertaken by MHRA but by designated Notified Bodies, who undertake the relevant assessments and issue CE certificates. MHRA is responsible for the designation of Notified Bodies in the UK and audit them regularly to ensure compliance. The certificates are supplemented by the manufacturer's declaration that the product conformed with all of the legal requirements of the applicable EC directives (declaration of conformity).

Advertising for medical devices was regulated under consumer protection legislation by the Advertising Standards Authority. PAGB announced that they planned to expand their membership and services into the area of medical devices for self-care.

Action: To circulate links to guidance on medical devices and contact details. [MHRA]

6. Advertising and regulation of nicotine products

CAP reported that, following their consultation on the marketing of electronic cigarettes (e-cigarettes) earlier in the year, they would be publishing on their website new specific advertising rules for e-cigarettes to ensure they continued to be promoted in a responsible way.

7. Guidance and Codes of Practice

Review of Codes of Practice

MHRA invited members from each organisation to update the group about their respective codes of practice.

PMCPA reported that they had consulted about the proposed changes to the Code in summer. A paper about the proposed changes including rules on disclosure of payments to healthcare professionals and transparency would be going to the ABPI board in November for approval. Once agreed the updated Code would come into effect on 1 January 2015. PMCPA also mentioned that a new version of the ABPI examination had been accredited by Industry Qualifications.

PAGB reported that they would implement changes in advertising to healthcare professionals and advertising in pregnancy in November 2014.

CAP/BCAP reported that they had only made minor changes to the Codes.

8. Areas of current concern

Advertising of POMs to the public & Enforcement

MHRA updated colleagues on MHRA's handling of website cases. Measures leading to the removal of the website domain or merchant trading facilities are undertaken for websites considered to be supplying illegally by the Enforcement Division. Cases involving legal supply continue to be investigated by the Advertising Standards Unit before any enforcement action is taken.

ASA mentioned that advertising of prescription only medicines to the public continued to be a major issue for the Authority.

Complaint handling procedures

ASA reported that it had updated its handling procedures for all advertising complaints received from the public and industry. Details were available from the Authority's website.

ASA added that they would be launching a public consultation in October on new prioritisation principles for the Authority. These would provide guidance on use of resources and how to prioritise work.

Multiple Sales of medicines for pain relief

MHRA reported that multiple sales of analgesics remained an issue of concern. MHRA was looking at further options, including legislation to restrict multibuy promotions of analgesics.

Move to GOV.UK

MHRA reported that the transfer of the MHRA website to GOV.UK was planned for early 2015. MHRA would keep colleagues posted on progress.

8. Any Other Business

THR statement

PAGB queried whether the statutory statement relating to traditional herbal registration should be repeated in an advertisement if the indication statement was already included on the pack. MHRA advised that the law required all advertising to include the statutory statement.

Advertising Standards Unit
AIMS - VRMM
September 2014