Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MEDICINES ADVERTISING LIAISON GROUP
10 March 2016
R-M-426(A) at 2:30pm
MHRA

Attendees

Etta Logan	PMCPA	**MHRA**	
Sophie Fairweather	PAGB	Jan MacDonald	(Chair)
Niamh McGuinness	Clearcast	Beryl Keeley	
Al Damon	Radiocentre	Aisha Dewangree	(Note)
Gwyneth Massey	HFMA	Ranulf Barman	(Part)
Janet Newell	CAP		

Apologies

Dafydd Taylor	PAGB
Jenny Ackers	HFMA
Ann Godsell	BHMA
Helen Darracott	PAGB

MHRA welcomed those attending. Apologies were noted.

1. Agreement of Agenda

The agenda was agreed.

2. Minutes of last meeting – 8 July 2015

The finalised minutes had been circulated and agreed. They were subsequently published on the GOV.UK website.

3. Matters Arising

Recent events

MHRA informed colleagues about recent events. The annual Advertising Seminar was held in February. There were two sessions covering prescription medicines and guests from some other Member States attended. PMCPA participated in both sessions.

A Webinar - an Agency first – on over-the counter medicines (OTC) was also held in February. The topics covered included labelling as well as advertising. PAGB took part in the webinar.

The tenth Annual Report on medicines advertising regulation had also been published on the Agency website.

Roles of self-regulation and statutory regulation

MHRA reported on latest developments following the decision of two pharmaceutical companies to withdraw from the jurisdiction of the PMCPA whilst continuing to abide by the ABPI Code in all other respects. MHRA continued to vet all advertising for one of the companies.

MHRA had met with a third company that had also decided to withdraw temporarily from the jurisdiction of the PMCPA. In this particular case the withdrawal was mainly based on data protection issue relating to third party handling of disclosure reports with regard to transfer of values to healthcare professionals. The company would be publishing details of financial transactions with healthcare professionals and organisations on their own website.

MHRA stressed the importance of self-regulation in the UK which was well established and was older than the statutory system and encouraged PMCPA, with ABPI, to ensure that self-regulation continued to be accepted by companies operating across the prescription only medicines sector, irrespective of whether they were ABPI members or not.

PMCPA hoped these companies would come back into self-regulation in the future.

Transfers of value

PMCPA reported on the new requirements in the ABPI Code for disclosure of payments to individual healthcare professionals and healthcare organisations. The deadline for pharmaceutical companies to disclose details of transfers of value to named health professionals, other relevant decision makers and health organisations made during 2015 on a central platform is 30 June 2016. The publication of these disclosures was expected to generate interest.

4. PAGB and devices for self care

PAGB reported on developments since the last meeting. Most of their member companies with self-care devices had agreed to bring their products into membership. PAGB had also invited other medical device manufacturers to join. As a condition of membership, companies would be required to submit their device advertising to the PAGB for vetting. Initially this would cover skin care, headlice and topical products, since complaints to the PAGB had been mainly in these three categories. PAGB planned to issue guidance on advertising medical devices in order to promote

consistent standards. PAGB would request input from the MHRA, particularly the Devices Division, and would review this approach in 2017.

Clearcast also pre-vetted devices advertising. They did not accept any claims without evidence and asked about PAGB's processes. PAGB informed colleagues that they would be looking at data for devices when reviewing claims in advertising. MHRA pointed out that the device Directives did not cover advertising but stated that where medicines and devices were promoted together, care would need to be taken not to mislead about the nature and use of the products.

Action: To circulate the draft guidance to colleagues for comments. [PAGB]

5. Essential information in advertising

MHRA gave a brief presentation on this topic which was also covered at the recent MHRA Seminar. The changes to the legislation allowed advertising for OTC medicines to include simplified information and digital advertisements to include a link to the SPC instead of including the full product information in the advertisement. It was estimated that this change had led to significant annual savings across industry.

Following an approach from ABPI, MHRA had sought informal views from healthcare professionals (HCPs) on how useful they found the essential information. HCPs would generally look at advertisements that were relevant to their area of practice and wanted access to detailed information. They had raised concerns that some links in digital advertisements were not live or accessible.

Irish colleagues had also expressed an interest in this issue. But it would be up to industry to research this area and come up with proposals based on their findings.

Action: To circulate the slide presentation to colleagues. [MHRA]

6. Advertising of nicotine products

MHRA reported that there was still no medicinal e-cigarette product on the market although two nicotine products (an inhaler and e-cigarette) had been granted marketing authorisations.

ASA reported that they had received a lot of enquiries about the non-medicinal consumer products particularly with regard to the different regulations in England and Scotland. There were concerns about indirect promotion where advertisements for consumer products that did not contain nicotine included a link that would lead to information on nicotine products. Changes would be made to the CAP and BCAP Codes on 20 May when the Tobacco Products Directive comes into force.

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 had updated their Code. The 2016 edition was available on their website.

PAGB had no plans to update their Codes.

CAP/BCAP did not have any plans to update the medicines rules in their Codes.

BHMA had not issued any new Code.

HFMA hoped to update their Code later this year. They expected to discuss revisions to the Code at a meeting at the end of March.

MHRA's Blue Guide remained unchanged.

Action: To circulate the revised Code to colleagues. [HFMA]

8. Areas of current concern

MHRA gave a brief slide presentation to provide an overview of some of the recent issues and cases relating to OTC medicines. MHRA mentioned guidance on advertising of emergency hormonal contraception (EHC) that the Agency had developed when the first product was launched. MHRA also highlighted an example of use of the term 'powerful' when the SPC stated that the active ingredients had mild or slight effect.

MHRA reported that the number of complaints about OTC medicines had gone up. PAGB also mentioned that they had seen a significant increase in the number of advertising materials vetted.

Advisory Boards

Following the headlines in the press about allegations of inappropriate payments and hospitality being offered to healthcare professionals, the subject of advisory boards was also covered at the 2016 Seminar on medicines advertising. MHRA had worked with PMCPA who had issued further guidance.

PAGB planned to look at this issue and would consider amending their healthcare professional Code if necessary.

Advertising Traditional Herbal Remedies

MHRA had also taken action in a small number of cases where claims in advertisements for traditional herbal remedies had implied 'efficacy', included misleading claims or did not make clear that the product was registered based on traditional and long established use.

Natural claims

This was an area of common concern. Advertising should not suggest that the safety or efficacy of a product is due to the fact that it is natural or herbal or that a product did not have any side-effect. PAGB reported that they had communicated guidance and their concerns to companies.

Advertising of POMs to the public

MHRA continued to receive complaints about advertising of POMs to the public. This included an increasing number of complaints relating to social media. PMCPA reported that they had received some complaints mainly from whistle-blowers.

Other issues around the table

PAGB stated that they were setting up a formal complaints procedure and panel to deal with intercompany complaints. HFMA also received regular intercompany complaints.

ASA reported that their new procedures in focusing on three major complaint issues in seemed to be working.

PAGB and HFMA stated that retailers were asking for references on advertisements for medicines and food respectively for evidence of claims. PAGB had met with a major retailer to discuss this matter.

Action: (i) To circulate the slide presentations to colleagues. [MHRA]

(ii) To circulate the EHC guidance to colleagues. [MHRA]

9. Any Other Business

None.

Advertising Standards and Outreach Unit
AIMS - VRMM
March 2016

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