Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

MEDICINES ADVERTISING LIAISON GROUP
8 July 2015
R-G-2 (Ground Floor) at 2:00pm
MHRA

Attendees

Heather Simmonds	PMCPA	**MHRA**	
Dafydd Taylor	PAGB	Jan MacDonald	(Chair)
Niamh McGuinness	Clearcast	Beryl Keeley	
Jenny Ackers	HFMA	Aisha Dewangree	(Note)
Ann Godsell	BHMA	Dan Runciman	
Janet Newell	CAP	David Olszowka	(Part)

Apologies

Al Damon	Radiocentre
Andy Taylor	CAP

MHRA welcomed those attending. Apologies were noted.

1. Agreement of Agenda

The agenda was agreed.

2. Minutes of last meeting – 25 September 2014

The finalised minutes had been circulated and agreed. MHRA were making arrangements to publish them on the GOV.UK website shortly.

3. Matters Arising

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

MHRA stated that the European Commission report on the shortcomings of statutory information about medicines had been completed but was not yet in the public domain. It was understood that the report did not make any recommendations relating to non-statutory information or advertising that would be of relevance to this Group.

Implementation of changes to essential information in advertising to healthcare professionals

MHRA asked colleagues for their views on the impact of the changes to the legislation that allowed advertising for some medicines to include a short form of the essential information or a link to the prescribing information or the product SPC rather than including the full information in the advertisement.

PAGB reported that their members had started to use the new format and were content.

PMCPA noted that the changes only applied to digital advertisements for prescription products but reported that they had been welcomed by companies.

Website transfer to www.gov.uk and MHRA branding

MHRA reported that the transfer of information from the MHRA website to GOV.UK had been completed. MHRA content had been rewritten to meet Government Digital Service content design principles and style. Some colleagues reported they were experiencing difficulties with finding information on the GOV.UK website. This would be reported to the Communications Division.

MHRA informed the group that, following a recent rebranding, the Agency should be referred to as the Medicines and Healthcare products Regulatory Agency.

PAGB and devices for self care

PAGB announced that they had invited member companies with self-care devices to bring these products into membership but that not all manufacturers had joined so far.

They planned to introduce guidance on advertising devices by the end of the year to promote consistent standards and would request input from the MHRA, particularly the Devices Division. Clearcast stated that they did not accept any claims without evidence.

PMCPA asked whether this move would be in competition with the Association of British Healthcare Industries (ABHI) Code. This was not PAGB's intention and they saw the two approaches as complementary. PAGB would keep the group informed on progress.

4. Roles of self-regulation and statutory regulation

MHRA introduced this topic and stressed the importance of self-regulation in the UK which was well established and was older than the statutory system. MHRA provided information on the decision of two pharmaceutical companies to withdraw from the jurisdiction of the PMCPA, although both continued to abide by the ABPI Code in all other respects. The withdrawal of these companies from PMCPA oversight had led to an increase in MHRA's vetting of advertising. It was important for ABPI and PMCPA to

strive to ensure that self-regulation continued to be accepted by companies operating in the sector, regardless of whether they were ABPI members.

5. Advertising and regulation of nicotine products

MHRA reported that the Department of Health Consultation on implementation of the revised Tobacco Products Directive (2014/40/EU) had been published. The closing date for responses was 3 September 2015. By November 2015 the outcome of the consultation would be well developed. The Directive must be implemented into UK legislation by May 2016.

The directive included provisions relating to advertising, including a ban on cross border advertising. Scotland had consulted separately on restrictions on advertising e-cigarettes. CAP was carrying out a review of how these could be implemented.

MHRA would be responsible for regulating nicotine products.

ASA reported that current complaints were mainly about how e-cigarettes were presented. They had recently ruled on a complaint from MHRA where information on a website was found to breach the CAP Code.

Action: To circulate the link to the consultation to colleagues. [MHRA]

6. 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 planned further revisions of their Code in 2016.

PAGB reported that they had published updated Codes recently.

CAP/BCAP expected to make minor changes only to the Codes.

BHMA had not issued any new Code.

HFMA continued to update their guidance but did not have a new Code available.

7. Areas of current concern

Prioritisation Principles

ASA informed the group that this was work in progress. They planned to maximise the use of their resources by focusing on key issues and restricting the number of points raised in a complaint to three.

PAGB announced that they were also looking at their procedures.

Tissue salts

MHRA explained the regulatory position on tissue salts. Tissue salt products would not normally be considered to be medicines provided there was no reference to the terms 'homeopathic remedy', and/or 'homeopathy' and/or 'homeopathically prepared', no numerical value for the potency e.g. 6X and/or the word 'potency' itself and no indications for use in a medical condition. Any tissue salt product which included any of these types of claim would be likely to be classified as a medicine and would require a marketing authorisation or homeopathic registration before it could be advertised.

Traditional Herbal Remedies (THRs)

MHRA presented information on principles for advertising THR products based on recent casework and drew attention to a recent upheld complaint about a TV advertisement for a THR product.

Logo for online sellers

MHRA provided an overview of the legislative requirement for a common EU logo to be displayed on websites selling medicines to the public at a distance. The logo would inform buyers that the website was a safe supplier and allow them to verify this on the MHRA website in the UK. With effect from July 2015 the logo would need to be clearly displayed on websites selling human medicines online to the public. The legislation also laid down specific provisions for on line sales of medicines. Sellers would also be required to comply with the E-Commerce Directive.

[Post meeting note: Further details on implementation of the new EU logo are available in MHRA guidance published on the GOV.UK website. https://www.gov.uk/guidance/register-for-the-eu-common-logo]

Advertising of POMs to the public

MHRA informed colleagues about Operation Pangea VIII. Counterfeit and unlicensed medicines and devices worth £15.8 million were seized in the UK as part of the global operation. The UK operation also resulted in 1,380 websites being closed down, 339 of which were domestic sites.

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

Forum on Advertising Medicines (FOAM)

MHRA reported on the third meeting of European colleagues responsible for regulating medicines advertising in June. Discussions this year focused on inspecting for

compliance with topics ranging from inspection of company procedures and records, vetting advertising materials and reviewing websites to attending promotional meetings and checking hospitality costs and other benefits. Delegates also shared practical approaches to a range of topical issues including materials for patients, samples and who is defined as qualified to supply medicines.

8. Any Other Business

PMCPA informed the group of the requirement under the ABPI Code that transfers of value made by the pharmaceutical industry to healthcare professionals and healthcare organisations in 2015 would need to be disclosed within the first six months of 2016.

Advertising Standards and Outreach Unit
AIMS - VRMM
July 2015