Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

MEDICINES ADVERTISING LIAISON GROUP
8 November 2016
R-O-507at 2:30pm
MHRA

Attendees

Heather Simmonds	PMCPA	
Dafydd Taylor	PAGB	
Kate Howlett	PAGB	
Niamh McGuinness	Clearcast	
Al Damon	Radiocentre	
Gwyneth Massey	HFMA	
Janet Taylor	CAP	

MHRA

Beryl Keeley	(Chair)
Dan Runciman	
Aisha Dewangree	(Note)
Ian Knott	

Apologies

Jenny Ackers	HFMA	Jan MacDonald
Ann Godsell	BHMA	

MHRA welcomed those attending including Ian Knott, the new representative for MHRA Devices Division. Instead of forming a new specific liaison group for advertising of devices MHRA proposed extending the remit of this group to include advertising of devices since most members were already involved in the regulation of advertising for devices. Members were invited to contact Beryl Keeley if they had any comments on this proposal.

1. Agreement of Agenda

The agenda was agreed.

2. Minutes of last meeting – 10 March 2016

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

3. Matters Arising

<u>Transfers of value</u>

ABPI's press release of 30 June 2016 announced the launch of their database disclosing transfers of value to healthcare professionals and healthcare organisations and was available on their website. PMCPA reported that the new database showed payments from

pharmaceutical companies who were members of ABPI and 55 non-member companies. The majority of healthcare professionals had given their consent for their name and information to be disclosed. There had been some coverage in the media where the discussions on disclosure were mainly about healthcare professionals who had chosen not to declare.

Disclosure of transfers of value was a European wide initiative but there were variations in its implementation around Europe. Disclosure of transfers of value for medical devices under the ABHI Code is under consideration.

Advertising of nicotine products

CAP launched their consultation on new rules and guidance on the non-broadcast advertising of e-cigarettes in September 2016 in order to amend their Codes. The proposed guidance represented their interpretation of the European Tobacco Products Directive (TPD) and its implementing legislation in the UK that came into effect in 2016. These prohibit most forms of advertising for e-cigarettes that are not licensed as medicines. The main questions related to health claims in advertisements and distinguishing between factual information and promotional claims.

Essential information in advertising

PMCPA reported on progress regarding ABPI's proposal to amend the requirement for prescribing information (PI) in advertising for prescription medicines. Discussions were ongoing to replace the PI with a direct link to the required essential information. The medium of advertising (e.g. print vs digital) would need to be considered to ensure healthcare professionals are able to access essential information. There might be a need to run two systems at the same time for a while. PMCPA would consult MHRA on their proposals.

The short form advertisement where the detailed prescribing information was provided on a specified website instead of in the actual advertisement itself was currently authorised for established over the counter medicines. PAGB reported that member companies were proactively ensuring full information was available for new products.

4. Advertising of devices

Devices for self-care

PAGB gave a slide presentation to update the group on developments since the last meeting. They were currently looking at advertising of devices for their members and focusing on three treatment areas - head lice, topical pain and eczema/dry skin - in a pilot scheme. They hoped to extend their review of all self-care products in membership by early 2018. Claims in advertisements would need to be evidence based and in line with the device's technical documentation and Notified Body assessment.

PAGB had been working on the development of guidance with the trade association that already regulates the advertising of OTC self-care medical devices to the public in the Netherlands. PAGB planned to review their Advertising Guideline, which had last been updated in July 2016 following consultation and the outcome of the Judicial Review in May 2016. Advertising of devices to healthcare professionals would be considered in the future.

MHRA invited Clearcast to update the group about the outcome of their Judicial Review. Clearcast reported that the High Court had ruled that Clearcast's decisions on television advertising preclearance were not subject to Judicial Review and that Clearcast was justified in requiring evidence to substantiate advertising claims even where an EC certificate has been granted. The Court also confirmed that since Clearcast did not perform "functions of a public nature" its decisions on advertisements were not subject to Judicial Review and clarified that claims for products certified under the European Medical Devices Directive were still subject to UK Advertising Codes.

MHRA stated that they were working with manufacturers to achieve compliance and supported collaborative work with self-regulation and local Trading Standards services as this would be beneficial to all parties and would promote a level playing field. MHRA added that where any risk to public health was identified there were measures in place to stop the supply of any device. MHRA would also be prepared to take enforcement action if necessary.

5. 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 no plans to update their Code in 2017 but would issue a new Code in 2018 to coincide with the 60th anniversary of the trade association. Proposed areas for updating were under consideration and would be looked at by PMCPA's workshops.

PAGB would review the rules on testimonials and would consider including guidance on online reviews and star ratings (e.g. Amazon) in future Code updates.

CAP/BCAP would update their Codes following consultation. The proposed changes were mainly intended to clarify points on specific issues on health and slimming.

BHMA - No report.

HFMA have updated their Code but have not yet published it on their website. A digital version would be circulated to colleagues.

MHRA's Blue Guide was updated in 2012 when the medicines legislation was consolidated and in 2014 following changes to prescribing information for OTC medicines. There were no immediate plans to amend the Blue Guide.

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

6. Areas of current concern

Health professional endorsement

During the investigation of several complaints MHRA had become concerned about the use of the MEDIFact format in TV advertising. MHRA considered that this format could potentially

mislead the public by suggesting endorsement by healthcare professionals, in breach of medicines advertising legislation. Following discussions with the advertiser and PAGB changes were made to the advertisements and general principles had been agreed.

Advisory Boards

MHRA had worked with PMCPA to agree updated guidance on advisory boards. PMCPA stated that additional guidance would also be included in the international IFPMA code.

PMCPA mentioned the NHS England consultation, Managing conflicts of interest in the NHS which had just closed and which covered issues such as gifts, hospitality and sponsorship. These issues were also relevant to medicines advertising regulation.

MHRA reported that following PMCPA's investigations of three advisory board complaints the Agency took follow-up action and required the marketing authorisation holders to issue corrective statements to those healthcare professionals who had attended the advisory board meetings. The summary reports of the cases were available on the MHRA website.

Multiple Sales of Analgesics

MHRA reported on the action it had taken following the publication of articles in the BMJ and Chemist and Druggist about multiple sales of analgesics in retail outlets. The articles provided evidence that some retailers were not adhering to the MHRA Best practice guidance on the sale of medicines for pain relief. Some of the sales allegedly exceeded the legal limit of 100 tablets of paracetamol or aspirin per transaction, above which level the supply became subject to prescription control.

MHRA had met with the British Retail Consortium (BRC) to discuss the issues raised. BRC had agreed to work with their members to ensure that they and their staff were aware of the legal and voluntary restrictions and understood that they were in place to protect vulnerable individuals. MHRA had also written to all retailers identified by the article authors. MHRA remained concerned about multiple sales of analgesics in the small number of discount retailers that still did not adhere to the MHRA best practice guidance. Since the guidance did not have the force of law, the Agency was not in a position to take statutory action to prevent such practices. But MHRA would consider whether further regulation was necessary should there be evidence of a significant risk to public health. Any further evidence of illegal sale of these medicines would lead to MHRA enforcement action.

Advertising of POMs to the public

MHRA reported that they had received fewer complaints about advertising of POMs to the public recently. CAP mentioned that they were currently looking at incentives to purchase based on price. MHRA considered that information about comparative prices could be useful to consumers who had already received a prescription.

MHRA also mentioned the recent Operation Pangea undertaken by MHRA Enforcement Division that led to the seizure of medicines and closure of illegal advertising websites.

ASA Botox Project

CAP informed colleagues about their proposed compliance project on botulinum toxin injections. It is intended to address concerns about the advertising of these prescription only medicines to the public. CAP planned to work with the MHRA to ensure that all advertisers are aware of the relevant legislation and Code rules to enable them to achieve compliance.

Other issues around the table

PAGB stated that their formal complaints procedure and panel to deal with intercompany complaints has been recently used by member companies.

Radiocentre reported that they had recently reviewed several disease awareness campaigns.

HFMA mentioned that most of the issues that they had dealt with related to health claims for non-medicinal products.

PMCPA have seen an increase in the number of complaints received from last year. They had also requested more corrective statements than in previous years. They are focusing on education and guidance.

MHRA continued to receive a low level of complaints about advertising for homeopathic medicines.

7. Any Other Business

None.

Advertising Standards and Outreach Unit
AIMS - VRMM
November 2016