Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

MEDICINES AND DEVICES ADVERTISING LIAISON GROUP
12 October 2017
G-3 at 2:30pm
MHRA

Attendees

Etta Logan	PMCPA	
Kate Howlett	PAGB	
Janet Taylor	CAP	
Elizabeth Erwin	CAP	
Jenny Ackers	HFMA	

MHRA

Beryl Keeley	(Chair)
Dan Runciman	
Aisha Dewangree	(Note)
Sarah Tang	

Apologies

Niamh McGuinness	Clearcast
Al Damon	Radiocentre

MHRA welcomed those attending including Sarah Tang, the new representative for MHRA Devices Division and Elizabeth Erwin from CAP. Following discussion at the last meeting, the remit of this group had been extended to include advertising of devices. The new name will be Medicines and Devices Advertising Liaison Group.

1. Agreement of Agenda

The agenda was agreed.

2. Minutes of last meeting – 8 November 2016

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

3. Matters Arising

Transfers of value

PMCPA reported that the 2016 data were published on 30 June 2017. ABPI's press release on the day announced that the data showed a significant increase in the number of healthcare professionals who had consented to disclose details of

payments and benefits for collaborations with the pharmaceutical industry. The data can be accessed from both the ABPI and PMCPA websites.

Essential information in advertising

MHRA outlined briefly proposals to amend the current legal requirement to include prescribing information in advertising for prescription medicines. In this short form advertising the detailed prescribing information would be replaced with a direct link to a specified website that would provide the required essential information. The short form advertising was already authorised for established over the counter medicines

PMCPA informed the group that the Authority was still consulting its members and that a meeting would be scheduled in the near future to discuss the way forward.

4. Reclassification of medicines for OTC sale

Malaria, erectile dysfunction, others

MHRA gave a short presentation on latest development in this area. Following consultation with stakeholder groups a streamlined reclassification process had been introduced and included a new consultation process and timetable for national major and standard reclassifications. This year several products have been reclassified in different therapeutic areas including malaria prophylaxis, psoriasis and allergic rhinitis. Reclassification of other products proposed for osteoarthritis (knee) and erectile dysfunction were in the pipeline. Last year no products were reclassified.

Innovative over-the-counter medicines reclassified for the first time from prescription only to pharmacy sale or from pharmacy to general sale can be advertised to both healthcare professionals and the public. These products in general require MHRA vetting of advertising prior to issue. This enables the agreement of principles to ensure advertising conveys key messages for safe use of the medicines in a new therapeutic area. Principles for the advertising of malaria prophylaxis were discussed as an example.

5. Advertising of devices

Future statutory regulation

MHRA provided a brief overview of developments in this area. The new Medical Devices Regulations came into force on 25 May 2017 with a transitional period of three to five years. They will prohibit the use of any text, names, trademarks, pictures and figurative or other signs in advertising that would mislead the user or the patient about the device's intended purpose, safety and performance.

Guidelines governing the advertising of medical devices were already in place and included general principles about false impression, misleading claims and off label

use. Implementation was still at a planning stage and issues about process and compliance would need to be explored further with self-regulatory bodies such as ASA/CAP.

MHRA would welcome comments from colleagues and would also be happy to work with ASA, PAGB and Trading Standards to achieve a consistent approach and encourage good practice.

Self-regulation update

PAGB outlined that they represented the manufacturers of branded over-the-counter medicines, self-care products and medical devices. PAGB had undertaken a scoping exercise in 2016 which indicated that their members wanted to be responsible advertisers and supported guidelines that promoted a level playing field for advertising of self-care devices. The association would be happy to share details with MHRA and CAP/ASA and proposed working collaboratively with other regulators to promote good practice. Interested parties agreed to exchange contact details to take this forward.

6. Advisory Boards

Advisory boards (ABs) were an area of major current concern for both MHRA and PMCPA. Healthcare professionals should not be paid to attend advisory board meetings where medicines were promoted. PMCPA reported that there were a range of activities including marketing surveys and proposed capturing all similar activities where payments were made under the umbrella of advisory boards.

MHRA mentioned a recent AB where journalists were paid to listen to promotion for a new prescription medicine and informed the group that colleagues in the Republic of Ireland were also currently looking at ABs. MHRA had also talked to other international colleagues in Europe about this issue. PMCPA stated that their guidance on advisory boards were being adopted throughout Europe and that the same rules would apply for ABs to healthcare professionals, journalists and others. The authority would generally advise caution to its members planning to host ABs.

7. Guidance and Codes of Practice

Proposed changes and consultations

MHRA invited members from each organisation to update the group about their respective Codes of Practice.

PMCPA planned to issue a new Code in 2018 for the 60th anniversary of its establishment. Some changes were expected including requirements for scientific meetings and presentation/use of data. They were consulting their members at

present and would be consulting MHRA in due course about the proposed changes to the Code.

PAGB planned to review their guidelines on food supplements and devices next year.

CAP/BCAP were currently reviewing the health and beauty sections of their codes and were coming towards the end of the process. They had already consulted on the proposed changes.

HFMA – No change.

MHRA's Blue Guide was last updated in 2014. The guidance on services (Appendix 6) was being looked at. MHRA would welcome comments and proposals from colleagues.

Advertising of nicotine products

CAP and BCAP were currently consulting on proposals to change the rules in both Codes about advertising of e-cigarettes. The change would remove the prohibition to include health claims about smoking cessation in e-cigarettes advertising provided they can be substantiated and are not misleading.

The consultation would close on 16 October. Guidance would be issued in due course.

8. Areas of current concern

Botulinum toxin advertising

MHRA continued to receive complaints about advertising of these products to the public. A large number of the complaints related to advertising on social media and came from various sources but mainly from competitors.

PMCPA stated that the authority also received many complaints about advertising of Botulinum Toxin products to the public. They would normally advise complainants to refer the cases to the relevant authorities.

Homoeopathic products

The number of complaints about homeopathic medicines has gone down although a steady trickle of complaints was still received in the Agency. MHRA mentioned a case that required joint action with their Borderline colleagues.

Other issues around the table

PMCPA reported that they had received a high number of complaints from non-contactable sources and a lot of these were from smaller companies and were about new and complex issues. The Authority was also carrying out a lot of company audits.

HFMA had not seen a lot of advertising about traditional herbal remedies lately.

ASA/CAP had received complaints about bio identical hormone replacement therapy (HRT) and medical devices but not a lot about homeopathic medicines. The complaints related mainly to efficacy and safety claims.

PAGB informed the group that their members had raised concerns about the behaviour and compliance of companies that were not members of the Association. PAGB was looking into this and would explore ways of working with others.

MHRA mentioned that they had threatened a company currently under sanction by the ABPI/PMCPA with MHRA vetting of all their advertising should the company fail to improve their compliance with the Code.

9. Any Other Business

MHRA move to Canary Wharf

MHRA expected to move to Canary Wharf next year. The next meeting might be held at the new premises.

PAGB would also be moving to new premises the following day (13 October 2017).

Advertising Seminars 2018

The next MHRA advertising Seminar was scheduled for February 2018. Discussions were ongoing about the format – seminar or webinar or both. MHRA hoped that PMCPA, PAGB and ASA would join them again this year.

PAGB reported that they had received positive feedback from their members about MHRA's last webinar.

Advertising Standards and Outreach Unit
AIMS - VRMM
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