Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Minutes

Title of meeting	Medicines & Devices Advertising Liaison Group (MALG)		
Date	24 September 2018	**Time**	2:30 pm
Venue	Medicines and Healthcare products Regulatory Agency (MHRA) 10 South Colonnade, Canary Wharf, London E14 4PU		
Chair	Beryl Keeley	**Note**	Aisha Dewangree

Attendees	Beryl Keeley	MHRA
	Aisha Dewangree	MHRA
	Dan Runciman	MHRA
	Gavia Taan	MHRA
	Ryaka Poonawala	MHRA
	Etta Logan	PMCPA
	Laura Kelly	PAGB
	Simon Scott	Radiocentre
	Celia Pontin	ASA/CAP (Conference line)
	Gwyneth Massey	HFMA
	Phil Brown	ABHI
Apologies	Niamh McGuinness	Clearcast
	Janet Taylor	ASA/CAP

1. Welcome and agreement of agenda

1.1 MHRA welcomed those attending including several new representatives: Gavia Taan and Ryaka Poonawala (MHRA Devices Division), Laura Kelly (PAGB), Simon Scott (Radiocentre), Celia Pontin (CAP) and Phil Brown (ABHI). Introductions were made round the table.

1.2 The agenda was agreed.

2. Minutes of last meeting – 12 October 2017

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

3. Matters arising

Essential information in advertising

3.1 MHRA provided the background to proposals to amend the required information in advertising for prescription medicines to healthcare professionals (HCPs). A short form advertising was already authorised for established over the counter medicines and MHRA had stated its willingness to consider industry proposals for prescription medicines.

3.2 PMCPA reported that due to their heavy workload in the last 18 months they had not yet been able to bring forward proposals to amend the Code where the law allows flexibility and were still considering the options for further changes that may require legislative changes.

3.3 MHRA stated that the process of making any change to legislation could take up to a year.

Transfers of value

3.4 PMCPA reported that ABPI had published on their website the disclosure of payments data for 2017 on 30 June 2018. The data showed a dip of 16% in disclosure about the identity of recipients. This was linked to procedural issues as companies prepared to comply with the Data Protection Act that came into force in May 2018.

3.5 ABPI is working with NHS England to encourage disclosure by HCPs.

3.6 ABHI (Association of British HealthTech Industries) mentioned that their Code of Ethical Business Practice covered transparency and conflict of interest but they did not publish disclosure data.

Press advisory boards

3.7 MHRA provided the background on a case it had investigated where journalists were paid to attend an advisory board and listen to the advertising of a new unlicensed prescription medicine. MHRA's view was that there was no justification for paying journalists in the public media to advise on consumer materials and that the advisory board was designed to promote an unlicensed medicine to the attendees. The company was required to issue a corrective statement to the journalists that attended the advisory board. A report of the case had been published on the MHRA website.

3.8 Advisory boards had been an area of concern for both MHRA and PMCPA and other regulatory authorities in Europe. Regulatory action and PMCPA guidance had led to a reduction in UK cases.

4. Advertising of medical devices

Regulation of medical devices

4.1 MHRA provided the background to this for new colleagues and reported on recent developments. Devices Division were considering how to implement the Regulation provisions regarding the advertising of medical devices in the UK. The Regulation must be implemented on 26 May 2020. MHRA stated that they wished to work closely with other self and regulatory bodies such as ASA, PAGB and ABHI to take forward implementing the new advertising provisions.

4.2 MHRA was aiming to establish a group to provide an opportunity for all stakeholders to collaborate in taking this forward. MHRA stated that they strongly supported self-regulation which was well established in the UK. PAGB would be celebrating the centenary of its formation in 2019 and PMCPA have just achieved the sixtieth anniversary of their founding.

4.3 ABHI informed the group that they were the trade association that looked after manufacturers of health technology. They worked closely with the medical technology industry to develop and improve medical devices in order to achieve compliance. As a condition of membership ABHI required companies to adhere to their Code of Ethical Business Practice. Non-members may also sign up to the ABHI Code.

4.4 ABHI also mentioned that they investigated complaints, mainly from competitor companies. Cases that could not be resolved by ABHI were referred to a panel for review.

4.5 PAGB had been involved in self-regulation of self-care medical devices for several years following agreement with its members. They previously worked from a Guideline that was based broadly on their medicines Code, but have developed a new Code which is more principle based and reflects the MDRs. Subject to final approval, it was planned that this Code would come in force in January 2019 and would require one person at the company to be responsible for compliance.

4.6 ASA stated that the medical device complaints they investigated were mainly about the efficacy of products and they would generally ask for evidence. They were monitoring this area to see how it would evolve and were considering whether to produce guidance or update their Codes.

4.7 Radiocentre have considered proposed advertising about medical devices as well. Some companies had argued that the product registration was adequate evidence to support specific efficacy claims.

4.8 All regulators and self-regulators for medical devices agreed to work together.

5. Guidance and Codes of Practice

5.1 **PAGB** reported that they were reviewing their Code but did not propose major changes. It would be an opportunity to bring the Code up to date and clarify clauses on specific issues such as Internet advertising, celebrity endorsement and new types of advertising. Review of their guidance on food supplements was on the agenda for 2019.

5.2 **PMCPA** stated that a consultation on proposed changes to the Code of Practice and PMCPA Constitution and Procedures led by the ABPI was ongoing. No major changes were anticipated though some clauses relating to meetings (including those overseas), hospitality and stock market press releases would be simplified. The new Code would allow a non-medical person to be a signatory for certification of certain types of advertising material. MHRA stated that they would respond formally to the consultation.

5.3 **ASA** did not expect any specific changes to the medicine section of their Codes but were consulting on the *e*-cigarette advertising codes.

5.4 **HFMA** had no plans to update their code but were currently working on a code for botanical products.

5.5 **MHRA** were making minor changes to their guidance on how companies should submit their vetting material.

6. **Areas of current concern**

Presenting essential information in TV advertisements

6.1 MHRA was considering how safety information and limitations on product use were being conveyed in TV advertisements in the light of several recent complaint and vetting examples. There were specific requirements under the BCAP Code, including requirements to ensure the required text was readable to viewers. There appeared to be inconsistencies in some of the cases MHRA had reviewed. MHRA would refer relevant examples to ASA for informal discussion.

6.2 ASA stated that they were looking at TV advertising at present. They wanted to ensure that key messages were clear to consumers.

Casework examples

6.3 MHRA provided the background to a recent case where a retweet by the manufacturer of an OTC product was considered to constitute an implied recommendation by a celebrity. MHRA had worked with the PAGB who were clarifying their Code.

6.4 MHRA summarised two recent cases about a promotional material for OTC products displayed in the pharmacy. MHRA considered that the way the promotional statement was presented did not promote the rational use of the medicine. They had also clarified with PAGB the requirement for essential information in point of sale advertising.

Recent reclassifications

6.5 MHRA updated colleagues on latest switches. A product for erectile dysfunction was now available from pharmacies and other products were under review.

'Lifestyle' products

6.6 MHRA reported concerns about promotion on websites and social media for medicinal products for weight loss.

6.7 MHRA was also currently investigating the promotion of IV drips containing vitamins and other ingredients. There were concerns about the evidence to support the claims being made and whether the products were classified as medicines.

6.8 Advertising for these products could also fall under the remit of the ASA. MHRA Borderline and Advertising Standards Unit were planning to meet with ASA to discuss handling of these cases.

Volume of correspondence

6.9 As part of a recent consultation on medicines safety messages, MHRA had received feedback that some healthcare professionals were concerned about the high number of letters they receive from industry. A large proportion of these were promotional and because of this healthcare professionals could miss important safety communication letters.

6.10 PMCPA announced that they would look into this area. As far as they were aware marketing authorisation holders communicated with HCPs mostly by e-mail.

Current issues around the table

6.11 PAGB stated that they would be reviewing their guidance on social media and pay per click advertising in response to recent casework.

6.12 ABHI asked whether mobile apps would be acceptable for devices. MHRA stated that if apps were used as a means of communication about medicines there would need to be a robust way of updating the app if safety information changed to ensure accurate information was being disseminated. MHRA Devices would be looking at the use of apps.

6.13 ASA mentioned a recent ruling about a contraceptive app that included misleading claims. PMCPA asked whether there was a means to enable apps to be withdrawn on safety grounds.

6.14 PMCPA also added that they had seen an increase in the reference to MHRA in advertising. One case was serious and led to sanctions.

6.15 Radiocentre has seen an increase in the number of advertisements for CBD oil.

6.16 Members also queried how long documentation relating to advertisements should be stored. MHRA Advertising Standards and Outreach Unit had a policy to store documentation for advertising complaints for eight years, other items for three years and vetting for two years. ABHI's retention policy was for the lifespan of the products plus two years.

7. **Any Other Business**

7.1 The next meeting would be scheduled in 6-12 months.

Advertising Standards and Outreach Unit
AIMS - VRMM
November 2018