Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Minutes

Title of meeting	Medicines & Devices Advertising Liaison Group (MDALG)		
Date	21 October 2019	**Time**	2:00 pm
Venue	Medicines and Healthcare products Regulatory Agency (MHRA) 10 South Colonnade, Canary Wharf, London E14 4PU		
Chair	Beryl Keeley	**Note**	Jinal Patel

Attendees		
	Beryl Keeley	MHRA
	Claire Tilstone	MHRA
	Dan Runciman	MHRA
	Jinal Patel	MHRA
	Gavia Taan	MHRA
	Charlie Gill	MHRA
	Etta Logan	PMCPA
	Laura Kelly	PAGB
	Al Damon	Radiocentre
	Cherie Leung	ASA/CAP
	Beth Irwin	ASA/CAP
	Gwyneth Massey	HFMA
	Sarah Lepak	BHTA
Apologies	Niamh McGuinness	Clearcast
	Janet Taylor	ASA/CAP

1. Welcome and agreement of agenda

1.1 MHRA welcomed those attending and introduced Claire Tilstone as the Advertising Standards and Outreach Unit Manager and Jinal Patel who has replaced Aisha Dewangree as the new Advertising Assessor. Introductions were made around the table.

1.2 The agenda was agreed.

2. Minutes of last meeting – 24 November 2018

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

3.1 Concerns had been raised around the essential information in TV advertising. ASA have since provided new CAP guidance addressing this area.

3.2 PMCPA had noted the comments reported by MHRA of HCPs receiving large volumes of correspondences from pharmaceutical companies. PMCPA has flagged this issue to companies.

4. Social media influencers

4.1 ASA provided background to their guidance on medicines and influencer marketing to present further clarification to the recent Sanofi UK – This Mama Life ruling. The intention of the ruling was not to determine "what constitutes a celebrity", but it identified celebrity for the purpose of the CAP code and that the person was paid because of their celebrity to promote a medicine. The guidance also makes clear that it is the nature of the relationship between an influencer and their audience that would determine that individual as having an influence because of their "celebrity", rather than their traditional 'celebrity' status or popularity.

4.2 PAGB mentioned that initial confusion around potentially quantifying an influencer's status based on number of followers had been clarified in the ASA guidance published after the ruling. There has been case work around influencers using their channels with a brand sponsorship. PAGB will be issuing further guidance for their members on use of social media.

4.3 MHRA mentioned that it was important to consider the Human Medicines Regulations 2012 wording when determining the use of influencers to recommend a medicinal product: Regulation 289(c).

5. Guidance for treatment service providers

General Pharmaceutical Council (GPhC) Guidance

5.1 MHRA reported that the GPhC, who regulate pharmacies, had published guidance for registered pharmacies providing a service at a distance in April 2019. The new guidance: states that a medicine and its quantity should not be able to be selected prior to consultation; requires service providers to carry out risk assessments, identity checking; and introduces specific categories of medicines that are not eligible to sell online. The overall message is that medicines are not an ordinary item for commerce and must not be treated as such.

5.2 MHRA and GPhC are working on a joint statement setting out our roles in this area. GPhC have a wider remit to ensure the safe supply of medicines while the MHRA focus in this context is on ensuring treatment service providers are not promoting POMs to the public. GPhC has taken recent enforcement action and inspect online services.

Erectile dysfunction services

5.3 MHRA have received several complaints regarding websites offering treatment services in erectile dysfunction, by means of a proactive push of their services on their social media platforms supported by images or wording that clearly indicates that a POM will be supplied. We have advised treatment service providers that their advertising should reflect the treatment service provisions as outlined in our guidance in Appendix 6 of the Blue Guide. Details of such cases are published on our website. There have also been a few complaints regarding the advertising of other services such as hair loss, however the promotion of products has not been as overt as for ED treatment services.

5.4 ASA mentioned that they have also received a number of complaints regarding the advertising of erectile dysfunction treatments. They will feedback to MHRA on the outcome. ASA and MHRA will liaise with the MHRA regarding their case work in this area.

6. ASA and MHRA action on other areas of service provision

6.1 ASA mentioned that they have been working closely with MHRA's Borderline team on complaints regarding linics promoting IV drips containing vitamins and other ingredients using medicinal claims. ASA is planning to publish guidance on the advertising of these IV drips.

6.2 ASA and MHRA also both have casework regarding weight loss clinics and alleged promotion of prescription only weight loss injections on social media platforms. MHRA and ASA will work closely on a joined up investigate approach and the publication of any subsequent guidance.

6.3 Advertising of Botox has been a high priority which has led to an ASA compliance project driven by particular concerns with individual practitioners. ASA are discussing this issue with social media platforms to see if they can help identify and take action against non-complaint practitioners who advertise POMs to the public.

6.4 Radiocentre asked if there are any restrictions on who can administer Botox. MHRA said the medicine would be administered on the instruction of a person qualified to prescribe or supply (PQPS), with no legal restriction on who could administer the product as long as the prescriber thinks it is clinically appropriate.

7. Medical Devices update

Implementing Regulations

7.1 MHRA presented examples of cases that involve misleading advertising. Cases included where one company made claims beyond those allowed within their certification approval, a case which went to judicial review by the ASA and a case which was referred to MHRA by the ASA.

7.2 MHRA provided a brief update on the new EU Device Regulations, which apply from May 2020, which now makes MHRA responsible for enforcing against misleading claims. Going forward, the aim is to have a more formal relationship with ASA, to ensure that misleading advertising of devices is dealt with appropriately.

7.3 There was also a discussion about how notified bodies approve devices and standards that must be met by notified bodies under the new Regulations.

7.4 PAGB expressed their interest to be involved in ASA discussions around devices, as this may affect their members.

8. Medicines safety updates

8.1 MHRA have published a recent drug safety update on paraffin containing products. The ignition risk is well known for paraffin containing products, however the risk cannot be ruled out for paraffin free products and thus warnings will be placed on all emollients. Input on risk minimisation and communications has been sought from stakeholders.

8.2 The opioid expert working group has been set up to advise the Commission on Human Medicines (CHM). This is in the light of growing concerns about overuse and misuse of opioid medicines. The group are reviewing current data on the use of both POMs and over the counter medicines, considering the benefit risk profile and whether there is a need to strengthen any warnings. Any implication for medicines advertising to consumers will be considered and implemented following the outcome of the review.

9. Update to Guidance

9.1 PMCPA outlined timelines for updates to the ABPI Code of Practice and also to their website.

9.2 PAGB are planning to update guidance on food supplements, social media and e-commerce.

9.3 HFMA plan to make updates to parts of their code but this will not affect sections relating to medicines.

9.4 BHTA will also be updating their guidance and information on their website.

9.5 MHRA Devices do not plan further guidance on advertising.

9.6 MHRA Medicines have made administrative updates to the Blue Guide, with the addition to appendix 6 of details about GPhC guidance and distance selling logos.

9.7 MHRA has prepared a new version of the Blue Guide that would be published if the UK leaves the EU without a deal. However, EU exit does not substantially affect the national Regulations for medicines advertising so this only includes minor revisions.

10. Current Issues

10.1 MHRA has exchanged emails with PMCPA to ensure the appropriate Yellow Card reporting wording is included in promotional material to HCPs.

10.2 PMCPA has received an increased volume of complaints in particular about social media platforms such as LinkedIn and provision of information about POMs, for example, by pharmaceutical company employees. MHRA will email details of a similar case involving a Galderma employee.

10.3 PAGB has received a number of social media and e-commerce queries. They explained that PAGB do not approve all the advertising placed on these platforms by their members.

10.4 HFMA also have casework on social media platforms.

10.5 BHTA has been liaising with an online seller to establish who takes responsibility on a product that is non-complaint but is not registered in the UK.

10.6 Radiocentre has seen an increase in the number of advertisements for CBD oil and E-cigarette products.

Advertising Standards and Outreach Unit
AIMS - VRMM
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