Alexander Roussanov

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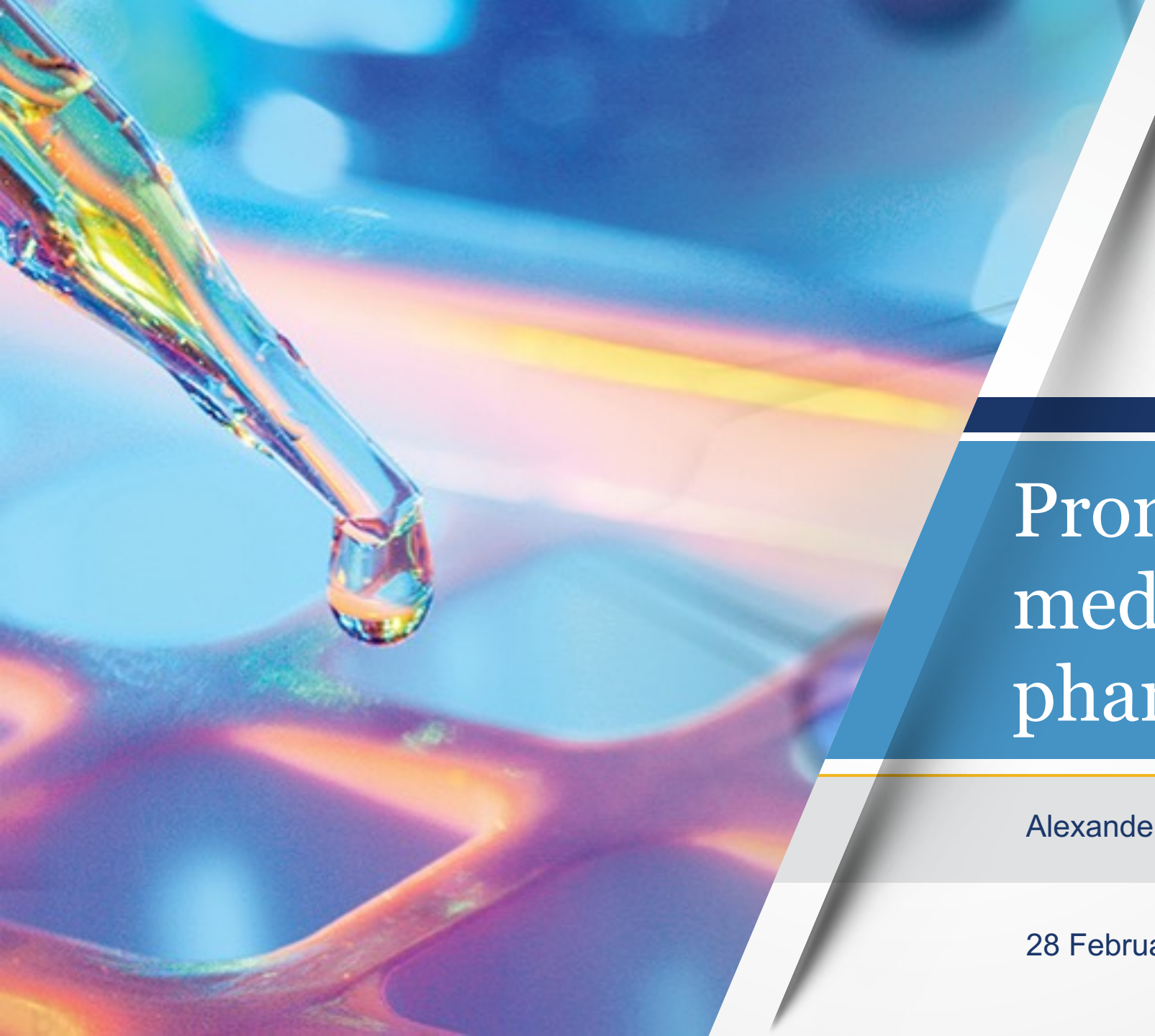

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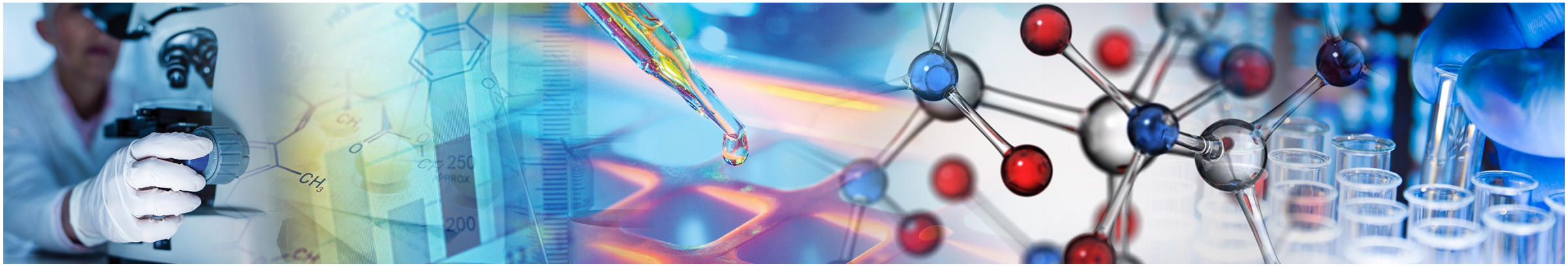
Promotion in social media – how far can pharma business go?

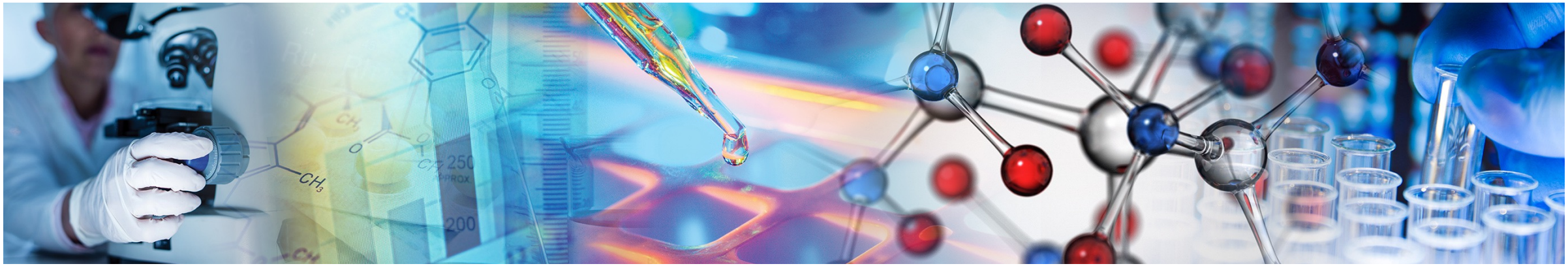
Alexander Roussanov

28 February 2024

EU and UK Legislative & Self-Regulatory Framework



Overarching principles & CJEU Rulings



Definition of Advertising/Promotion

- "**Advertising of medicinal products**" shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products (*Article 86(1), EU Directive 2001/83/EC*)
- This includes in particular:
  - advertising of medicinal products to the public
  - advertising of medicinal products to HCPs (qualified to prescribe)
  - visits by medical sales reps
  - the supply of samples
  - the provision of inducements
  - sponsorship of promotional meetings attended by HCPs
  - sponsorship of scientific congresses
- Regulation 7 of the UK Human Medicine Regulations 2012 mirrors this definition
- The EFPIA Code and national Codes establish the limits within which these activities may be undertaken

Overarching Principles

1. Promotion must be accurate, balanced, fair, objective, not misleading, sufficiently complete and capable of substantiation

2. Promotion must be consistent with SmPC and must encourage rational use of the product

3. Companies must not provide advice to members of the public on personal medical matters

4. Prohibition of promotion of unauthorised medicines or indications

5. Prohibition of promotion of POMs to the general public

6. Prohibition on the offer or provision of financial inducements to persons qualified to prescribe or supply

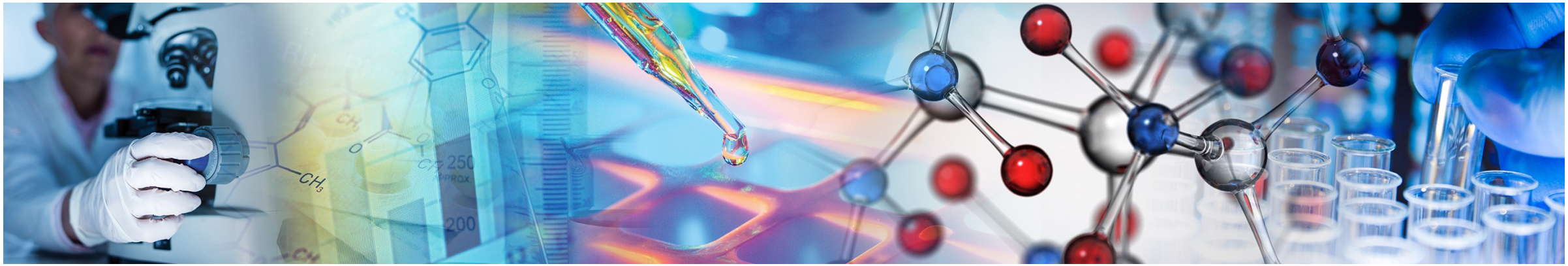
Key CJEU Ruling on Definition of Advertising

Damgaard

C-421/07

- Danish journalist posted an article online regarding benefits of an unauthorised medicinal product
- It is not necessary for the message to be disseminated by a person linked to the manufacturer or seller of the medicine, or to be disseminated in the context of a commercial activity for it to be considered as advertising

Non promotional activities



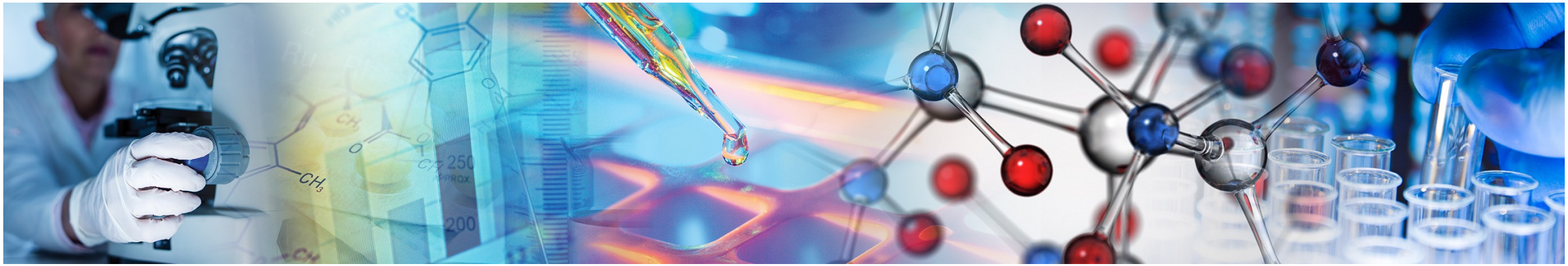
Permitted non-promotional activities pre- and post-approval:

- Legitimate scientific exchange (e.g., clinical trial results, clinical experience, published data)
  - Do not use social media
- Response to a specific unsolicited question about a particular medicinal product
  - Do not use social media
- Material relating to disease, which does not promote specific medicinal products, provided to HCPs and the public proactively
  - Social media can be used with care
- Press releases with financial/securities information exclusively for investors
  - Use of social media is risky
- Corporate communications re newsworthy information, based on national codes
  - Social media can be used with care

Clinical Trial recruitment

- Clinical trial sponsors can communicate to the public objective, factual, balanced and non-promotional information concerning clinical trials:
  - Patient recruitment websites under a separate domain name that are pre-approved by the IRB/Ethics Committee and contain basic information concerning the clinical trial and contact details of the clinical trial sites
  - Social media recruitment materials under the same conditions
  - Press releases on clinical trials intended exclusively for the investors' community in EU

Recent trends



Recent trends

The business risk in external communications may increase due to:

- Complaints about non-compliant promotion from consumers, HCPs, competitors or increased monitoring by the authorities in the UK and all EU Member States
- We also see a shift in the enforcement in the context of social media:
  - Stricter interpretation of what is considered promotion and dissemination of promotion

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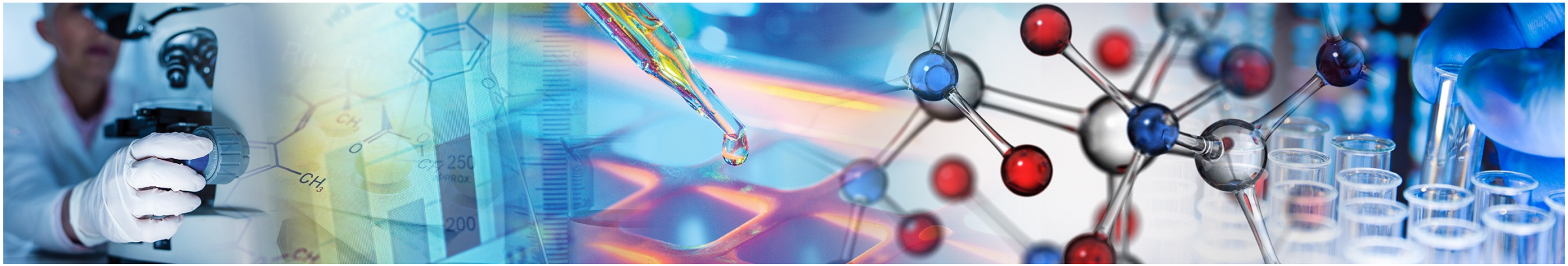

Social Media

Use of Social Media: Challenges

- Particular challenges with use of digital channels include:
  - **Immediacy of communication**
  - **Breadth of audience**
    - Challenges limiting communications
    - Promotion of POMs or unlicenced medicines to the public
  - **User generated content**
    - Data privacy
    - Pharmacovigilance
      - Ensure social media platforms are monitored for PV purposes or restrict comments
      - Signpost users to where they can report adverse events
    - Compliance with legislation/ Codes
      - Removal of inappropriate content

Activity found to be problematic: UK decisions

71 PMCPA cases referring to LinkedIn:

- The “liking” or “applauding” of a post by a company employee constitutes proactive dissemination of that post to all of the connections of that employee – both HCPs and non-HCPs
- A job title or description of the role of an employee which includes names and indications for use of medicines → may amount to promotion of that product.
- Posts including information intended for HCPs may be promotion of a POM to members of the public → lack of control!

12 PMCPA cases referring to Instagram:

- Pictures of a friend on private account, who is also a KOL in a therapeutic area of interest to the employee’s company → resulted in a finding of failure to maintain high standards

41 PMCPA cases referring to Twitter/X:

- Linking to a tweet could constitute proactive dissemination of the tweet
- Unrestricted access to twitter account may result in promotion of POM to public
- A tweet need not mention the product by name to be considered promotional
- Limitation on characters means compliance with requirement to provide prescribing information etc is not possible

EU and UK legislation and guidance

EU

- Directive 2001/83/EC – no reference to social media
- EFPIA Code 2019 – express reference that Code applies to promotion via social media
- **EFPIA and IFPMA joint guidance on social media and digital channels 2022**

UK

- HMR 2012 – no reference to social media
- ABPI Code 2021 – "*companies should take particular care if they use social media*" to avoid promoting POMs to the public
- PMCPA guidance about digital communications 2016
- PMCPA decisions (multiple!)
- **PMCPA guidance on social media 2023**
- PAGB social media guidance 2021

PMCPA Social Media Guidance 2023

- PMCPA Social Media Guidance provides detailed guidance on various topics:
  - Links
  - Hashtags and Tagging
  - Responding to misinformation/correcting inaccuracies
  - Signposting vs posting/sharing/re-sharing
  - Corporate news and announcements
  - Professional profiles and job advertising
  - Disease awareness for the public
  - Patient support
  - Meeting advertisements
  - Product and pipeline milestones
  - Working with social media influencers
  - Promotion to HCPs and other relevant decision makers
  - Clinical trial recruitment

Use of Social Media: General Principles

- Communications and promotion of medicinal products using social media are subject to the same rules as traditional forms of advertising
- Transparency and responsibility:
  - Content posted on social media (including by third parties on behalf of the company) should include a clear statement about the company' involvement
  - Company is responsible for activity of employees and agents:
    - If a EU/UK-based employee interacts/engages with a post such as 'liking', this is disseminated to their connections/followers, then it would likely be subject to the EU/UK promotional rules
    - Could include activity on a personal social media account
  - Company needs to have clear policies and provide regular training about social media.
    - Completion of training should be monitored.

PMCPA Social Media Guidance 2023 – topics of interest (1)

Responding to Misinformation

- Difficult area as by correcting certain information, confirm the remaining information is accurate

- Matter of company policy

- Posting link to SmPC = reasonable, but not pointing to a sub-section as this introduces judgment

- Could refer to own reference information as long as not promotional

Corporate News

- Must be appropriate for the public

- Generally no mention of products, pipeline assets or clinical research

- In some countries, newsworthy information (e.g. clinical trial results) may be published on a time-limited basis

- May include new executive appointments, employee recognition and company awards

PMCPA Social Media Guidance 2023 – topics of interest (2)

Links

- Company responsible for content of links
- Indicate whether company material or non-company material

Hashtags

- Must be appropriate to content of post
- Claim for a POM or name of product = promotion

Disease awareness

- Purpose must be to increase awareness and provide educational info
- Timing relative to MA may be relevant to whether viewed as promotional

Product milestones

- Clear signposting of audience and self-validation
- Share news via dedicated closed groups

Example PMCPA case (1)

- **AUTH/3583/11/21 - *Complainant v ALK-Abelló* (use of Instagram by creative agency)**
  - Complaint related to an image of an ALK-Abelló advertisement for a POM, posted by a creative agency on its Instagram account
    - The image documented the success of the Agency at a named advertising awards competition
  - The contract between the Agency and ALK-Abelló:
    - Required the Agency to prepare images for launch of the relevant product
    - Included restriction of use and confidentiality provisions
    - Provided for documents and records to be returned to ALK-Abelló at the conclusion of the contract
    - No permission was sought from ALK-Abelló to use of the images in the competition
    - The contract ended 16 months before the date of the competition

- What did the PMCPA Panel find?
- Outcome of appeal?

Example PMCPA case (2)

- **AUTH/3572/10/21 - *Complainant v AstraZeneca* (Link to educational website)**
  - Complaint related to sharing of a link to an educational blood cancer website with the public via LinkedIn
  - AZ's response indicated:
    - Blood Cancer Awareness content for corporate LinkedIn and Twitter pages had been pre-approved
      - This was shared by 9 employees via their personal LinkedIn accounts
    - The link took viewers to the landing page of the Blood Cancer UK website
      - Primarily depicting Blood Cancer UK's activities
      - No product references
    - Treatment webpage was several clicks from the landing page
      - It appeared to describe all relevant treatments

- What did the PMCPA Panel find?

Key questions to consider before carrying out social media activity: PMCPA Guidance

- What is the objective of the activity?
- What content will be made available?
  - Is the content promotional or non-promotional?
  - Is the content related to medicines?
  - Does the medicine have a marketing authorisation/is the indication covered by the marketing authorisation?
  - Is the content related to educational information for the public?
  - What information is linked to and therefore forms part of the content?
- Who is the audience (for example, public, health professionals, media, investors) and is the content suitable and appropriately signposted for that audience?
- Are there licence variations between Great Britain (GB) and Northern Ireland (NI)?
- Has access been limited to the appropriate intended audience? Is interaction with the social media activity limited or controlled, and if not how does this affect the risk of the activity?
- Is the audience expected to respond or participate in discussion?
- Is the role of the pharmaceutical company clear?
- How is the content reviewed, approved and maintained?
- What are the arrangements for pharmacovigilance obligations?
- Why could it not be considered as promotion to the public?
- Is it in line with company guidance, is the company guidance clear and consistent with all applicable codes, laws and regulations?

Image from: PMCPA Social Media Guidance 2023

Do's and Don't's – Social Media

Do's

- Provide adequate training on social media
- Consider GDPR
- Think about your audience
- Consider whether you have control over end content
- Monitor discussion forums (e.g. for pharmacovigilance and inappropriate content)
- Ensure links to other websites stand up to scrutiny
- Think about how information will display on different devices
- Exercise extreme caution when sharing content posted by overseas affiliates

Don't's

- Use social media for promotion of POMs unless audience can be restricted
- Engage with other posts (internal or external) without considering content
- Engage with corporate social media channels based in other jurisdictions if these refer to products
- Forget to monitor user generated content

How is this different in the US?

- In the EU (and many other countries):
  - prescription-only medicines cannot be promoted to an audience other than HCPs (NO DTCA)
    - HCP definition may vary between EU Member States
  - patient advocacy organisations do not have a special status – they are considered consumers
  - Social media cannot therefore be used for promotion of prescription only medicinal products

- DTCA is permitted in the US

Questions?

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