Social Media and Pharma
What can we do?

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Social Media and Pharma Compliance: Agenda

The basis for making our judgements on acceptability

- Codes and regulations relating to advertising, information and interactions with health professionals and the public
  - A complex international web.
  - Control systems
- Is it advertising?
  - Or non-promotional information for patients or HCPs?
- European Information to Patients legislation proposal
  - What can we learn

Social media – compliance practicalities

- Information and advertising
- R&D communications
- Pharmacovigilance
Online social media such as Facebook, Twitter, and YouTube are a “gold mine” where the “sky is the limit” for drug companies, a marketing expert has said.

The benefits of “social CRM” (customer relationship management), ... include the ability to direct patients to branded drug sites, recruit patients into clinical trials, and to collect business intelligence on patients and healthcare providers.

they also give drug companies the ability to improve the credibility of their message by packaging promotional material as personal experience and effectively to disguise marketing messages as independent, third party assessments, which are then spread across social networks.

.. concern about the industry’s use of unbranded websites that fail to disclose information about financial sponsors; the lack of information about drugs’ harms or side effects; and the failure to draw a clear line between websites or chats initiated by companies and other online discussions of their products.

a “sophisticated and largely stealth medical marketing apparatus . . . Designed to promote the use of specific brand drugs and influence consumers,” by using “unfair and deceptive advertising practices.

..a professor of medicine ...told the BMJ that the move of drug and device companies into the realm of social networking poses a threat to public health.
Rules ... And more

Compliance ...

• Important that Pharma’s utilisation of social media is compliant with regulations and codes

.... And Ethics

• Social media activities have the potential to enhance, or significantly harm, Pharma’s desire to be a responsible and trusted partner working towards solutions to healthcare challenges
N.B. This overview identifies some major standards but does not aim to be comprehensive.
International and national industry codes are becoming more aligned.
ABPI UK code

- The case reports and guidance available in the UK provide a good insight into the practical application of European and global principles.
  - Including guidance on digital media
- The ABPI code incorporates requirements of:
  - UK law
  - European directives
  - EFPIA European codes
  - IFPMA international code
  - WHO ethical criteria
  - .... And ethical considerations
Drug Giant AstraZeneca to Pay $520 Million to Settle Fraud Case
Justice Department Alleges Pharmaceutical Firm Illegally Marketed Schizophrenia Drug
Control mechanisms

• Approval for release
  • EU directive 2001/83
    • “Scientific service in charge of about the medicinal products which he places on the market.” (article 98)
    • Regulatory authority may pre-vet advertising
  • European Codes:
    • “.. a medical doctor or, where appropriate, a pharmacist … responsible for approving any promotional material before release.”

• Action after release
  • Regulatory Authority action
  • Prosecution by Regulatory Authority
  • Code of Practice complaints – publicity and penalties
  • Internal company procedures
Information to Patients: Current situation in the EU

• Dir. 2001/83 prohibits pharmaceutical companies promoting prescription-only medicinal products to the public

• EU Member States’ implementation of the Directive is not harmonized and lacks consistency

• The amount and type of information available to patients varies considerably among Member States
The Original Commission Proposal

• A narrow proposal that would fill a gap in current legislation
  • Regulates only pharmaceutical companies and covers only information on prescription medicines for patients
  • Driven by different national approaches and the internet
  • Presents no additional possibilities in some countries
• Highly controversial
  • Member states refused to discuss the details in Council
  • European Parliament took a constructive approach
• The proposal is now dropped – but what can we learn about Pharma and their role in communicating about prescription medicines?
Council: Why were Member States against the information to patients proposal?

<table>
<thead>
<tr>
<th>Inappropriate</th>
<th>“Not an appropriate way of providing patients with objective and unbiased information”</th>
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<tbody>
<tr>
<td>Lack of a clear distinction</td>
<td>between &quot;information&quot; and &quot;advertising&quot;.</td>
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<td>Monitoring mechanisms</td>
<td>will be costly and will create administrative burdens</td>
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<td>Relationship between patients and health professionals</td>
<td>might be changed in a way that is counterproductive for the patients' health</td>
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<td>Such information should be given</td>
<td>by competent authorities, health professionals or independent bodies</td>
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<td></td>
<td>not by the pharmaceutical industry</td>
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<td>Constitutional grounds.</td>
<td>Conflict with national legislation on freedom of expression</td>
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<td>Budgets</td>
<td>Negative consequences caused by unjustified increase in medicines usage</td>
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Parliament vote

After a lengthy debate with 500 amendments, European Parliament concluded its first reading in Nov 2010

- **Changed emphasis**
  - on rights of patients to receive information - not rights of companies to provide it
- **Obligations on Member States** to provide medicines information.
- **Obligations on companies** to provide Summary of Product Characteristics (SPC), Package Leaflet etc.

Christopher Fjellner
Is it advertising?

- Advertising unlicensed products and uses is prohibited
- Advertising prescription medicines to the public is prohibited
  - Except USA & NZ
- The distinction between ‘Advertising’ and ‘Non-promotional communications’ is not clearly defined by European pharmaceutical directives
  - Different practical interpretations in different countries
  - Internet/social media communications cross national boundaries
- An attempt to harmonise national interpretations was made with a proposed ‘Information to Patients’ directive and regulation
Is it advertising?
Recent European Court of Justice conclusions
(in my own words)

**Damgaard (February 2010)**
- Dissemination of information by independent third parties not excluded from the EU definition of advertising.
- So - Information from journalists (and patients associations etc.) could be considered as advertising prescription medicines

**ABPI v MHRA (April 2010)**
- Personal incentives to prescribers to prescribe certain medicines are not a breach of the advertising regulations if they come from health authorities
- Incentives from companies remain illegal

**MSD: SPC on websites (May 2011)**
- Unadulterated Summary of Product Characteristics is not advertising
- Intent, content and practical impact are important in deciding what is and is not advertising
- Just because it comes from a company doesn't mean it is advertising.
- ‘Push’ is different from ‘pull’; passive websites do not push.
SOCIAL MEDIA:
COMPLIANCE PRACTICALITIES
Social Media – Ten Top Tips

• From a mainly European perspective
  • so no DTCA
• Remembering that content will travel across national borders
• With a practical and pragmatic approach
Tip 1: Set out clear company standards and procedures

- Tailor company standards to company organisation
  - International; Europe; National; USA
- Set out approval procedures and responsibilities
  - Identify responsible roles for content production and approval
  - Ensure international HQ materials approved at national level if necessary
  - Include all parts of the company including R&D and medical
  - Include personal use of the internet for posting company relevant information.
  - Communicate the rules effectively
- Keep complete records
  - Including dynamic content
- Monitor company related activities; check for out of date material

Implement a digital governance strategy and plan that includes compliance aspects
Tip 2: Be clear on who the content is from and who it is for.

• Prominently and repeatedly state the intended audience:
  • International; Europe; Single country
  • Health Care Professionals; Public; Patients; Lay journalists; Business press etc.
• Password protection or identity verification may be necessary if prescription medicine material is contained
• Identify clearly who the material is from
  • Company international HQ v National HQ

Include requirements on how to present the intended audience and your company identification in your digital standards
GSK Europe

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› Click here to enter the site

If you are a European Healthcare Professional

› Click here to enter the site

Important Notice. This site is intended for European Healthcare Professionals. By clicking to enter this site, you are confirming that you are a European Healthcare Professional.
German site

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Passwort vergessen? Passwort beantragen

NHL: Zuletzt aktualisiert am 10 Dezember 2010: ZINC CODE
Tip 3: Forget Twitter for product information communication

- Twitter: probably not feasible for prescription only medicine promotion to health professionals
  - The audience must be restricted to Healthcare Professionals (HCP)
  - Study alerts to HCPs are likely to be considered promotion
- Probability of re-tweeting means you can expect messages to reach beyond your original intended audience
- 140 Character number restriction means statutory information required for advertising cannot be included

Restrict Twitter use to non-product corporate business and other non-product communications
Bayer tweet breaches ABPI code

Sativex tweet:
“Sativex® launched in UK for the treatment of spasticity due to Multiple Sclerosis http://tiny.cc/kiz2y.”
Bayer UK Twitter case

- Some of the ~500 Bayer twitter account followers were clearly members of the public.
- The tweets at issue were taken from the headlines of certified press releases.
- They were not themselves certified.
- Each tweet was in fact a public announcement about the launch of a prescription only medicine:
  - which promoted that medicine to the public
  - would encourage members of the public to ask their health professionals to prescribe it.
- Social media, including Twitter, can be used to provide information to the public so long as the material complied with the Code.
- Clause 2 breach.
- New procedures from Bayer to prevent repeat.
  - And other companies have also learnt.

JOURNALIST v BAYER
Tweets about Levitra and Sativex

A reporter with a healthcare publication provided a copy of an article from InPharm entitled 'Digital Pharma: Bayer UK’s Twitter slip-up' which discussed two tweets posted by Bayer Healthcare about Levitra (vardenafil) and Sativex (delta-9-tetrahydrocannabinol and cannabidiol) and the Code.

The InPharm article stated that the tweets at issue were notable compared with other UK pharma twitter accounts which signed their tweets off by medical and legal departments and were confined.
Tweet by Allergan employee to a friend referring to Botox

- Tweet from an Allergan employee, using a personal Twitter account to an individual at a patient organisation.
  - Tweet named Botox
  - Included ‘… we could do something around stroke rehab’.
- Sent privately, mistakenly and contrary to company policy.
- Seen by the friend, the friend’s followers and followers of the patient organisation.
- Breach for ‘advertising to the public’
  - Comment: Company employees need to be extremely cautious when using social media and ensure that business and personal relationships are kept very separate.
Tip 4: Provide ‘reference information’ on all your products

• ‘Reference information’ is allowed for public access under the UK code
  • including SPC, Package Leaflet, study information, specific medicine information, material supplied for health technology assessments
• It must be non-promotional so take care:
  • If selective over which medicines reference information is provided for
  • In selecting which information to provide. Positive v Negative
  • On the readability and likely understanding of a lay audience.

Take care in directing people to ‘Reference Information’ in social media interactions – it could turn non-promotional material into promotion.
Tip 5: Differentiate between ‘push’ and ‘pull’ information

• An objective, factual ‘medical information’ response to an unsolicited enquiry is not advertising
  • But can easily become promotional e.g. by introducing information that goes beyond that necessary to answer the question.
  • Responses made public e.g. on a website as a FAQ could be promotion
• Recipients of pushed information must have agreed to receive it.
  • Ensure they are aware of what they are signing up to
  • Unsolicited promotional emails etc. are not allowed.

Think about the real intent and likely effect of any posted information
Tip 6: Differentiate between Promotional and Non-Promotional Information

- Content and context is more important than who in the company is the communicator
  - R&D, medical and the CEO are capable of unwittingly producing advertising communications
- The judgements on the scientific worth and whether it is advertising are separate.
  - Highly scientific material can be promotional.

If a statement is likely to encourage the prescription of a specific medicine or a request for a prescription it’s probably promotion.
Tip 7: Set out rules and responsibilities for participating in interactive forums

- Can use social media to communicate with patients receiving a particular prescription medicine.
  - Providing it doesn’t promote a prescription only medicine
  - Information can go into more detail than when directed at the general public or potential patients
- Company run/supported/promoted discussion forums and blogs
  - Companies responsible for content
  - Must moderate the site so that the only content to appear complies with the Code.
  - Don’t sponsor sites/content that could reasonably be expected not to comply (e.g. off-label)

Identify code-trained persons to post information on behalf of the company
J&J closes UK facebook page due to comments

• More than a year after launching its Psoriasis 360 page on Facebook, the Janssen UK unit of Johnson & Johnson is closing down due to a growing number of comments that had to be removed because specific drugs were mentioned or, in some cases, offensive language was used.

Story from ‘Pharmalot’ 22nd mar 2012
Psoriasis 360 Facebook page

Hayley Kench
Also atm am using two types of sterile creams, and as u know they can only be used for about a month, my question is atm they are really helping and my psoriasis has gone down greatly, but when i have to stop using the sterile creams will it flare back up?

Marietta Laoudi
http://www.dailymail.co.uk/health/article-2090771/Consultants-insist-really-works-talking-emotions-clear-bad-skin.html#comments

Thought this might help!!

Consultants insist it really works but can talking about your emotions clear up bad skin?
www.dailymail.co.uk

Ruby Jaffrey suddenly developed severe psoriasis. Within weeks, 80 per cent of her body was covered with the characteristic scabs.

GotClearSkin.net (GCS)
Greetings all - we just came across this site and have subscribed to the YouTube channel for Psoriasis360 / Will be joining the community as well / so nice that we have resources such as Psoriasis360 for all of us who have "P"...
http://www.TalkPsoriasis.net/

TalkPsoriasis.net
talkpsoriasis.net
Treatments | Reviews | Social Net

Hayley Kench
Hi guys, i am currently going through light treatment and was just wondering if anyone else has had it and what sort of results they had from it?
Tip 8: Be careful and consistent if you interact with Wikipedia

- Transparency about your identity is important
- Consider Wikipedia ‘rules’
- Links to company ‘reference information’ would be OK
- All or nothing?
  - If company corrects one point does it assume responsibility for the total content of a monograph?
  - Just correcting negative information could be inappropriate

Establish company policy covering your position on Wikipedia entries for new medicines, corrections/suggestions etc.
Tip 9: Manage third party relationships according to written criteria

- Information in links provided by companies may be subject to the code
- Supporting a third party site could mean you are held responsible for the content
  - E.g. funding a site, blog etc where you expect off-label information to be provided
- It is possible for a company to sponsor material produced by a third party and not be liable under the Code for its contents
  - if there has been a strictly arm’s length arrangement between the parties.

Describe clearly the company role in third party sites
Tip 10: Remember your pharmacovigilance responsibilities extend to social media

- If a company, or an agent working on its behalf, becomes aware of an adverse reaction report it must be documented and reported to the regulatory authority.
- Implement pharmacovigilance policies and procedures for each project e.g.
  - Involve company pharmacovigilance, legal, data protection, compliance, medical information, corporate communications, market research etc.
  - Include ‘contact us’ facilities
  - Have an identified project owner – with compliance responsibilities
  - Contracts with third parties should identify their responsibilities
- Provide appropriate pharmacovigilance content on ‘sites’
  - E.g. on-line reporting forms, company contact details, links to regulatory authority reporting schemes
- If a company “listens” at non-company sites the pages should be monitored for adverse reactions for the period of the listening activity only.

EMA Guideline on good pharmacovigilance practices
June 2012

- Marketing authorisation holders (MAH) should:
  - Regularly screen internet or digital media under their management or responsibility, for potential reports of suspected adverse reactions.
  - The frequency should allow for valid ADRs to be reported to the competent authorities within the appropriate reporting timeframe based on the date the information was posted.

- Also:
  - Consider utilising websites to facilitate the collection of reports of suspected adverse reactions
  - If a MAH becomes aware of a report of suspected adverse reaction described in any non-company sponsored digital medium, the report should be assessed to determine whether it qualifies for reporting.
    - Treat as a spontaneous report.
    - The identifiability of the reporter means it is possible to verify contact details (e.g., an email address).

Advice on application of regulations and codes to social media (US & UK)

- USA: FDA draft guidance
  - Responding to off-label information requests
  - Mobile Medical Apps
    - [http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm369431.htm](http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm369431.htm)
  - Twitter etc
    - [http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm397791.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm397791.htm)
  - Wikipedia etc
    - [http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm397791.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm397791.htm)
  - Submitting ‘live’ material for regulatory approval
    - [http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm397791.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm397791.htm)

- UK: ABPI code guidance from PMCPA
  - All aspects of digital communications
    - [http://www.pmcpa.org.uk/advice/digital%20communications/Pages/default.aspx](http://www.pmcpa.org.uk/advice/digital%20communications/Pages/default.aspx)