Fact or Fiction?
What Healthcare Professionals Need to Know about EU Pharmaceutical Marketing

Workshop organised
In
collaboration with UAEM
Galway, September 2016

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Health Action International
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• Universities Allied for Essential Medicines

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  – European Commission
    (Consumers, Health, Agriculture & Food Executive Agency)
  – Open Society Foundation
  – Camino Stiftung
Outline:

• Acronyms and Definitions
• Identifying Conflicts of Interest
• How Promotion is Regulated
• Self- Regulation
• Impact of Pharmaceutical Promotion
• Promotion Imperative
• Promotional Strategies Used by the Pharmaceutical Industry
• The Way Forward
A Few Acronyms & Definitions:

HAI = Health Action International
WHO = World Health Organization
EML = Essential Medicines List
RUM = Rational Use of Medicines
OTC = Over the Counter
DTCA = Direct to Consumer Advertising
KOL = Key Opinion Leader
IPHA = Irish Pharmaceutical Healthcare Association
HPRA = Health Products Regulatory Authority
TLA = Three Letter Acronym
Identifying Conflicts of Interest

“A conflict of interest is a set of circumstances that create a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.”

United States Institute of Medicine, 2009
“...few doctors accept that they themselves have been corrupted. Most doctors believe that they are quite untouched by the seductive ways of industry marketing men [and women]; that they are uninfluenced by the promotional propaganda they receive; that they can enjoy a company's 'generosity' in the form of gifts and hospitality without prescribing its products. The degree to which the profession, mainly composed of honourable and decent people, can practice such self-deceit is quite extraordinary. No drug company gives away its shareholders' money in an act of disinterested generosity.”

Mike Rawlins,
National Institute for Health and Care Excellence
Does promotion affect prescribing?

How much influence do sales representatives have on your prescribing?

- A lot: 1%
- A little: 38%
- None: 61%

n=102 internal medicine residents

Steinman et al (2001)
Does promotion affect prescribing?

How much influence do sales representatives have on other physicians' prescribing?

- A lot: 51%
- A little: 33%
- None: 16%

n=102 internal medicine residents

Steinman et al (2001)
Impact of pharmaceutical promotion on clinical practice

- No evidence of net improvements in prescribing
- Negative outcomes associated with the interactions between physicians and the pharmaceutical industry:
  - Inability to identify wrong claims about a medication;
  - Rapid prescription of a new drug;
  - Increased prescription rate;
  - Prescribing fewer generics, but more expensive medicines with no added therapeutic value.

(Spurling et al., 2010; Wazana, 2000; Norris et al., 2005)
Early Influence

- Pharmaceutical promotion surrounds health professionals from early in their career
- Exposure starts during the academic period…
- …however most students do not obtain adequate education on how to critically appraise pharmaceutical promotion

85.2% of medical students recently surveyed in France (n=2,101) reported feeling inadequately educated about conflicts of interest arising from interactions with the pharmaceutical industry.

(Etain et al., 2014)
The Promotion Imperative

- **Accountability to Share Holders** = to make money
- **Poor Innovation** = not much therapeutic advantage
- **Me-Too Medicines** = more of the same
- **Disease Mongering** = ‘new’ non-diseases
- **Incentivised R&D Modelling** = markets not needs
True innovation or just marketing?

Prescrire Ratings, 2000 to 2014 (N=1432)

- Nothing New (51%)
- Possibly Helpful (20%)
- Not Acceptable (14%)
- Offers an Advantage (7%)
- Real Advance (2%)
- Bravo (0%)
- Judgment Reserved (6%)

(Prescrire, 2015)
Unlike conventional marketing strategies, the DOL model incorporates early-stage development and the late generic period.
A 2009 inquiry by DG Competition, European Commission, shows that between 2000 and 2007, originator pharmaceutical companies spent only 17% of their turnover on R&D worldwide, but 23% on marketing and promotional activities during the same period.

(European Commission, 2009)
Regulations on Pharmaceutical Promotion
What protects doctors from unethical behaviour by pharmaceutical companies?

- Legislative frameworks for advertising to healthcare professionals are in general fairly permissive.
- Managing rather than banning situations that have shown to have a negative impact on clinical practice.
- National regulatory authorities “delegate” responsibilities to self-regulatory bodies.
- Industry’s process of self-regulation is inherently flawed.
How Promotion is Governed in EU

• EU legislative framework
  - Directive 2001/83/EC Relating to medicinal products for human use

• Individual national laws incorporating EU provisions
  - e.g. in Ireland the Medicinal Products (Control of Advertising) Regulations 2007

• Voluntary codes of conduct (self-regulation)
  - e.g. Irish Pharmaceutical Healthcare Association (IPHA) codes
Medicinal Products (Control of Advertising) Regulations 2007- Key Provisions (I)

• Advertisement is understood as:

  “Any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.”

• Includes:

  - advertising to the general public and persons qualified to prescribe or supply medicines
  - provision of inducements
  - visits by sales representatives
  - supply of samples
  - sponsorship of promotional meetings and scientific congresses
Types of medicines that can be advertised:

- All categories of authorised human medicinal products may be advertised to healthcare professionals

- Prescription-only medicines and controlled drugs cannot be advertised to the public

Approved vaccination campaigns

Health/disease awareness campaigns provided there is no reference, even indirect, to medicinal products
As a general rule, advertising must be consistent with the approved product information

Advertisements must not be deceptive or inaccurate

Specific rules applying to advertising vis a vis healthcare professionals through:

- Written materials
- Sales representatives
- Inducements and hospitality
- Free samples
Health Products Regulatory Authority:

- Monitors advertising generated by pharmaceutical companies
- Does not routinely pre-review advertising materials before their use, but reserves the right to do so in certain cases

Sanctions for non-compliance with Regulations:
- Removal of misleading advertisement
- Publication of corrective statements
- Penalties
Self Regulation

• Regulation on pharmaceutical promotion is entrenched in law…

• …but governments often “delegate” some of their responsibilities regarding the control of promotional activities to pharmaceutical industry associations

• Main self-regulatory tool in EU: EFPIA codes of conduct (2014)

• In Ireland: IPHA Codes
IPHA Codes


Complaints procedure similar to ABPI system in UK
# IPHA Codes

## Code of Practice - Disclosure of Transfers of Value

### Transfer of Value Disclosure Details

**Time Period**  
01 January 2015 - 31 December 2015

**Company**  
Allergan Pharmaceuticals

**Methodological Note**  
Download

For any queries in relation to this transfer of value disclosure, please contact: 
mli-uk_compliance@allergan.com

Last updated: 30 June 2016 09:39:17 (2 months ago)

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Why Self-regulation Doesn’t Work

- **Intrinsic conflict of interest**: Codes are created and monitored by those with commercial motivations.

- **Voluntary in nature**: ‘Opt in’ mechanism. Not automatically applicable to the whole industry but to industry association members.

- **Occurs too late**: Pre-vetting mechanisms are generally lacking; breaches spotted when damage has been done.

- **Economic sanctions too mild** and contribute to cost of administering the self-regulatory system rather than as a dissuasive mechanism.
Medical Council

- Medical Council is the regulatory body for doctors

- Guide providing guidance to doctors on matters related to professional conduct and ethics, including conflicts of interest, sources of information & good prescribing practices
Promotional Strategies Used by Pharmaceutical Industry

- Relationship-based Selling
- Use of Key Opinion Leaders
- Use of Media
- Product Information and Awareness
- Market Expansion Technique
Relationship-based Selling
Sales Representatives (I)

• One of the most effective techniques for developing personal relationships and influence prescribing behaviour

• Sales reps are highly trained in influencing skills

“It’s my job to figure out what a physician's price is. For some, it's dinner at the finest restaurants. For others, it's enough convincing data to let them prescribe confidently and, for others, it's my attention and friendship...but at the most basic level, everything is for sale and everything is an exchange”.

Shahram Ahari,
Former pharmaceutical sales rep
(Fugh-Berman & Ahari, 2007)
## Sales Representatives (II)

### Common Techniques used by Sales Representatives

<table>
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<tr>
<th>Unconscious influences on a person’s judgement</th>
<th>Use of this unconscious influence for marketing purposes</th>
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<tbody>
<tr>
<td>Experts know best</td>
<td>“Professor Z recommends medicine B.”</td>
</tr>
<tr>
<td>Peers know best</td>
<td>“Medicine B is the most frequently prescribed medicine for indication X.”</td>
</tr>
<tr>
<td>People we like can be trusted</td>
<td>Use of attractive, friendly representatives.</td>
</tr>
<tr>
<td>We should help others who have helped us</td>
<td>Use of gifts, including free samples of expensive new medicines.</td>
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| People should be consistent with their past statements | Sales representative: “Do you treat many people with indication X?”
  Doctor: “Yes.”
  Sales representative: “So you need to know about the treatments for indication X?”
  Doctor: “Yes.”
  Sales representative: “Would you like me to tell you about our medicine B for indication X?”
  Doctor: “Yes.”
  Note: this is an example of the commitment consistency technique - getting the physician to agree to successive statements that are consistent with one another, ending up at the conclusion the marketer wants, although if the final question had been asked first, the physician would probably not have agreed. Often the final statement is, “So doctor, will you try medicine B for your patients with indication X?” |

Adapted from Cialdini, 2000; Roughead, 1998 in HAI& WHO, 2009
Sales Representatives (III)

- Many healthcare professionals report relying on sales reps for medicines information.

- However, information provided by sales reps is often incomplete and biased towards the benefits of the product.

- Evidence suggests that healthcare professionals would be better off avoiding such interactions.

- When confronted with sales reps, claims about medicines’ therapeutic profile should always be contrasted with regulatory & independent sources of information.
HEALTH POLICY

Pharmaceutical Sales Representatives and Patient Safety: A Comparative Prospective Study of Information Quality in Canada, France and the United States

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INTRODUCTION: The information provided by pharmaceutical sales representatives has been shown to influence prescribing. To enable safe prescribing, medicines information must include harm as well as benefits. Regulation supports this aim, but relative effectiveness of different approaches is not known. The United States (US) and France directly regulate drug promotion; Canada relies on industry self-regulation. France has the strictest information standards.

METHODS: This is a prospective cohort study in Montreal, Vancouver, Sacramento and Toulouse. We recruited random samples of primary care physicians from May 2009 to June 2010 to report on consecutive sales visits. The primary outcome measure was “minimally adequate safety information” (mention of at least one indication, serious adverse event, common adverse event, and contraindication, and no unqualified safety claims or unapproved indications).

RESULTS: Two hundred and fifty-five physicians

DISCUSSION: “Minimally adequate safety information” did not differ in the US and Canadian sites, despite regulatory differences. In Toulouse, consistent with stricter standards, more harm information was provided. However, in all sites, physicians were rarely informed about serious adverse events, raising questions about whether current approaches to regulation of sales representatives adequately protect patient health.

KEY WORDS: health policy; patient safety; primary care; health services research.

J Gen Intern Med 28(10):1368–75

INTRODUCTION

Pharmaceutical sales representatives (PSRs), and the free
Study Mintzes et al (2013)

• Findings: Less than 2% of the reported 1,692 drug-specific promotions included minimally adequate safety information

• “Minimally adequate safety information”: 

  At least one:
  – indication
  – common adverse event
  – serious adverse event
  – contra-indication

  And no:
  – unqualified safety claim
  – unapproved indications
Findings: in many cases, physicians considered the information to be of good quality and expressed their intent to prescribe the medicine.

Physicians’ stated likelihood to begin or increase prescribing as compared with before the sales visit

(n=1660; 98% of promotions)
Gift Giving

- Inducements are aimed at influencing medical education, treatment decisions and research habits
- Gifts (large and small) create sense of obligation, often unconscious, to “return the favour”

Studies show that industry inducements are associated with:
- Prescribing patterns inconsistent with evidence-based guidelines
- Reduced generic prescribing
- Increased drug costs
- Biased requests for additions to hospital formularies

(Smith et al., 2013)

Should not be perceived as a socially acceptable norm
Product Information & Awareness
Clinical Guidelines (I)

List of red flags that should raise substantial skepticism amongst guideline readers:

- Sponsor is a professional society that receives substantial industry funding.
- Sponsor is a proprietary company, or is undeclared or hidden.
- Committee chair(s) have COI
- Multiple panel members have financial COI
- Any suggestion of committee stacking that would pre-ordain a recommendation regarding a controversial topic.
- No or limited involvement of an expert in methodology in the evaluation of evidence.
- No external review.
- Non inclusion of non-physician experts/patient representatives.

(Lenzer et al., 2013)
Clinical Guidelines (II)

- Dutch health inspectorate announced 40 health professionals involved in 6 guidelines had financial links to companies affected (2009)

- Cross-sectional survey of 192 authors of 44 chronic disease clinical practice guidelines found:

  - 59% of authors had financial relationship with manufacturers of drugs in guideline

  - 42/44 guidelines – no declarations of conflicts of interest

  (Choudry et al. JAMA 2002)
Clinical Guidelines (III)

A comparison of the German S3 guidelines on the treatment of psoriasis vulgaris with Raptiva (efalizumab) with a NICE guideline developed by independent authors reveals more positive judgement by the S3 guideline  
(Schott et al., 2013)

- Safeguards to avoid conflicting situations in guideline development must be in place

- When confronted with clinical guidelines with conflicts of interest, independent sources of information can help inform optimal treatment decisions.
Free Samples

- Company strategy to increase brand awareness and sales of new (and often more expensive) medicines

- Healthcare professionals might suggest they accept samples to reduce patients’ cost barriers to access…

- …however, evidence shows that the provision of samples can lead to higher out-of-pocket prescription costs (Alexander et al., 2009)

- The provision of samples can also lead to poorer compliance with clinical guidelines
Use of Media
• Sponsored content can appear as clear product advertisements, conference updates or as information that may appear of educational/public health importance.

• Low quality of journal advertising as a global issue. Misleading claims and missing essential information, including contraindications, interactions, side effects, warnings and precautions (Othman et al., 2009).

A study of German CME journals identified an increased occurrence of positive editorial commentary regarding specific medication when the journal ran ads for the same product. (Becker et al., 2011)
Journals & medical Literature (II)

• Ghostwriting and guest authorship: common practices

• Research or opinion papers published under the name of a key opinion leader (KOL)/qualified clinician – in spite no significant contribution

• Company’s contribution downplayed

• Academic authorship enhances the credibility of industry publications and masks their commercial function to promote and position a product (Matheson, 2011).
Advertisement for Amylin and Eli Lilly’s Byetta® (exenatide injection) for type 2 diabetes appeared in the August 20, 2008, issue of the *Journal of the American Medical Association* and elsewhere.

(Healthy Skepticism, 2009)
Recommended information in journal advertisements by WHO’s Ethical Criteria for Medicinal Drug Promotion (1988)

- Name(s) of the active ingredient(s) using either international nonproprietary names;
- (INN) or the approved generic name of the drug;
- Brand name;
- Content of active ingredient(s) per dosage form or regimen;
- Name of other ingredients known to cause problems;
- Approved therapeutic uses;
- Dosage form or regimen;
- Side-effects and major adverse drug reactions;
- Precautions, contra-indications and warnings;
- Major interactions;
- Name and address of manufacturer or distributor;
- and Reference to scientific literature, as appropriate.
Digital marketing (I)

- 25% of pharmaceutical marketing budget spent on digital technologies (Manz et al., 2014)

- Digital marketing changing how companies communicate with health professionals and consumers

- Increasing use of product websites, social media campaigns, mobile phone apps

- Pharmaceutical industry calls this the move towards patient-centric care …

  …from the perspective of promotions, this flags a shift away from health professionals and towards the patient as the customer
Digital Marketing (III)

- Allergan manufacturer of Lo Loestrin Fe®, birth control pill
- Launched #actuallyshecan campaign, which focuses on female empowerment using celebrity spokespeople
- Campaign leads healthcare professionals and consumers to branded and unbranded information on birth control

(Source: www.actuallyshecan.com; www.instagram.com/mirandakerr)
Market Expansion
Disease mongering (I)

- ‘Disease mongering' used to describe this process of medicalisation of natural processes

- Construction of disease and risk: natural physiological processes, such as a gradual decrease in bone density as people age, are misrepresented as diseases

- Manufactured chronic diseases mean the potential for market expansion for pharmaceutical companies promoting treatments for non-diseases

https://www.youtube.com/watch?v=RoppJ0tRLe4
"the information used contained misleading statements and omissions likely to cause medically unjustifiable drug use or to give rise to undue risks."

(Quick et al., The Lancet, August 30, 2003)
Key Opinion Leaders
Key Opinion Leaders (I)

• Common practice used to affect purchasing behaviour by associating a product with a respected person

“Key opinion leaders were salespeople for us and we would routinely measure the return on our investment by tracking prescriptions before and after their presentations. If that speaker didn’t make the impact the company was looking for, then you wouldn’t invite them back”

Kimberly Elliott, former US-based pharmaceutical sales representative (Moynihan, 2008)

• Merck study shows that KOLs provide a better return on investment to companies than the use of sales representatives (Scott & Martinez, 2005)
Key Opinion Leaders (II)

• Pharmaceutical companies engage KOLs under formal commercial agreements as product spokespeople

• Level of transparency of product endorsement may range from obvious promotion to subtle inclusion in presentations, discussions with peers/social media followers

• Experts in field also engaged in industry-sponsored conferences/CME through hospitality.

• Speakers might underestimate how financial incentives can bias their judgement
Key Opinion Leaders (III)

(Garcinia Cambogia, Where to Buy, 2015)

Source: Standford School of Medicine, 2015
The Way Forward

Different levels of action:

- Regulation
- Education
- Behavioural change
- Organisation/institutional change
Better Regulation

• Sound regulation in place aimed at banning, rather than framing, practices that are likely to negatively impact prescribing practices

• Pre-vetting, active monitoring of promotional activities and enforcement measures (e.g., corrective measures, naming and shaming, dissuasive fines)

• Mandatory disclosure of interactions between the pharmaceutical industry and health professionals (e.g. French & US Sunshine Acts)
Sunshine legislation

- Helps to uncover transfers of value between industry and healthcare professionals

- Helps to reveal connections between industry payments and doctors’ prescribing habits (Pro Publica, 2016)

- Can deter healthcare professionals from entering into conflicting situations
Better Education

• Quality education about pharmaceutical promotion as part of the medical curriculum & CME

• Support & recognition of independent initiatives on education of pharmaceutical promotion

• Support & recognition about independent sources of information on medicines
**Behavourial change from HCPs**

- Problem: Industry influence has become a social norm in healthcare
- Healthcare professionals must abide by high level of ethical conduct
- Importance of disassociating from situations where private interests can affect clinical judgements

Rational use of medicines requires:

- Understanding of commercial biases
- Ability to recognise and take account of the effects of misleading promotional material and activities
- Seek independent, high-quality clinical information
No Free Lunch Pledge

Become No Free Lunch Certified!

Join the growing number of health care professionals from around the globe who have made a commitment to evidence-based practice by pledging to accept no gifts from industry and to rely on non-promotional sources of prescribing information.

The pledge is as follows:

"I, ____________________, am committed to practicing medicine in the best interest of my patients and on the basis of the best available evidence, rather than on the basis of advertising or promotion.

I therefore pledge to accept no money, gifts, or hospitality from the pharmaceutical industry; to seek unbiased sources of information and not rely on information disseminated by drug companies; and to avoid conflicts of interest in my practice, teaching, and/or research."

Health care professionals who take the pledge will be included in the No Free Lunch Directory, which is searchable by specialty, city, state, and ZIP code. E-mail addresses or phone numbers will not appear on the website.
Institutional/organisational change

AMSAR Scorecard 2014

Conflict of Interest Policies at Academic Medical Centers

| Institution                                                                 | Grade | Gifts | Meals | Speaking relationships | CME | Promotional events | Scholarships and awards | Ghostwriting | Consulting | Sales reps | Device reps | Disclosure | COI curriculum | COI policy extension | Enforcement |
|----------------------------------------------------------------------------|-------|-------|-------|------------------------|-----|--------------------|--------------------------|--------------|------------|------------|-------------|-------------|-------------|----------------------|---------------|-------------|
| Edward Via College of Osteopathic Medicine Blacksburg, VA                  | A     | 🌙    | 🌙    | 🌙                     | 🌙  | 🌙                 | 🌙                       | 🌙            | 🌙         | 🌙         | 🌙          | 🌙          | 🌙          | 🌙                    | 🌙            | 🌙          |
| Stanford University School of Medicine Stanford, CA                        | A     | 🌙    | 🌙    | 🌙                     | 🌙  | 🌙                 | 🌙                       | 🌙            | 🌙         | 🌙         | 🌙          | 🌙          | 🌙          | 🌙                    | 🌙            | 🌙          |
| Pacific Northwest University of Health Sciences-College of Osteopathic Medicine Yakima, WA | A     | 🌙    | 🌙    | 🌙                     | 🌙  | 🌙                 | 🌙                       | 🌙            | 🌙         | 🌙         | 🌙          | 🌙          | 🌙          | 🌙                    | 🌙            | 🌙          |
| University of Alabama School of Medicine Birmingham, AL                    | A     | 🌙    | 🌙    | 🌙                     | 🌙  | 🌙                 | 🌙                       | 🌙            | 🌙         | 🌙         | 🌙          | 🌙          | 🌙          | 🌙                    | 🌙            | 🌙          |
Further Information

www.haiweb.org
www.politicsofmedicines.org

@HAIMedicines

HAIMedicines

Health Action International
Independent Sources of Information

Cochrane: www.cochrane.org


Drug and Therapeutics Bulletin (DTB): dtb.bmj.com

Geneesmiddelenbulletin: geneesmiddelenbulletin.com


Healthy Skepticism: www.healthyskepticism.org/global

No Free Lunch: www.nofreelunch.org

No Gracias: www.nogracias.eu
Independent Sources of Information

PharmAware: www.pharmaware.co.uk

PharmedOut: www.pharmedout.org

Prescribers’ Letter: prescribersletter.therapeuticresearch.com

Prescrire: www.english.prescrire.org

RxIsk: www.rxisk.org

Therapeutics Letter: www.ti.ubc.ca/TherapeuticsLetter

The Medical Letter: secure.medicalletter.org/

Universities Allied for Essential Medicines: uaem.org

Worst Pills, Best Pills: www.worstpills.org
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Rev Prescrire 2015. Année du médicament. 35 (376)

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