What are the regulations relating to data disclosure to patients? Current and future perspectives

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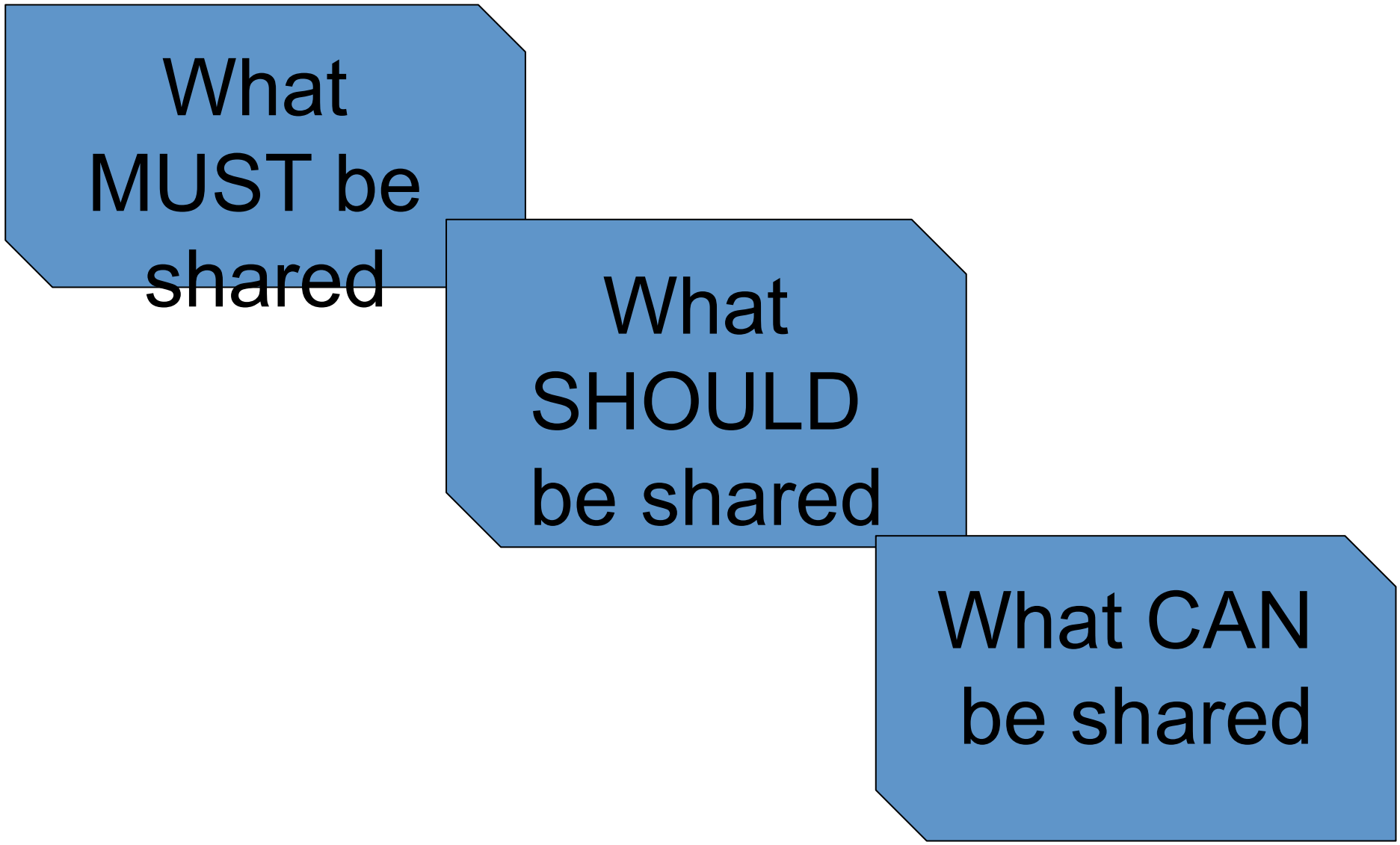

What MUST be shared
What SHOULD be shared
What CAN be shared

International Federation of Pharmaceutical Manufacturers & Associations

European Federation of Pharmaceutical Industries and Associations

Japan Pharmaceutical Manufacturers Association

Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases[1]

Updated November 10, 2009

The innovative pharmaceutical industry[2] is committed to the transparency of clinical trials that are sponsored by our member companies.

International Federation of Pharmaceutical Manufacturers & Associations

European Federation of Pharmaceutical Industries and Associations

Japan Pharmaceutical Manufacturers Association

Joint Position on the Publication of Clinical Trial Results in the Scientific Literature

The innovative pharmaceutical industry[1] is committed to the transparency of clinical trials that are sponsored by its member companies.

Registry:
- All company sponsored trials in patients
- Within 21 days of first enrolment

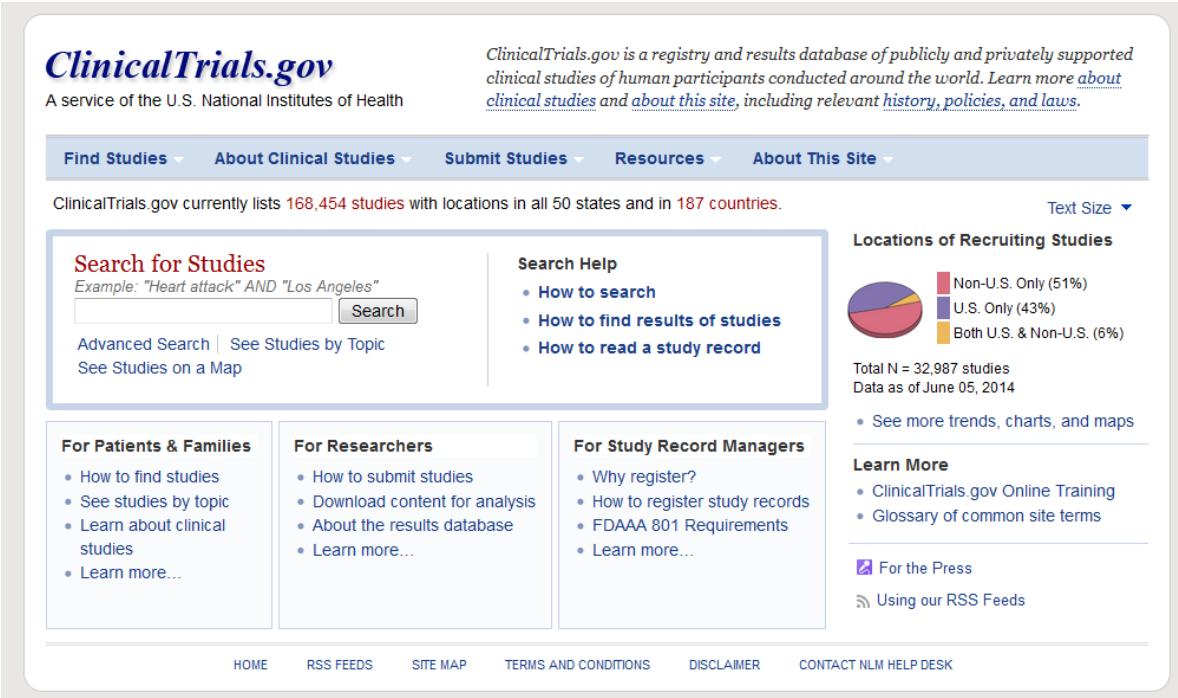
Results database
- All completed trials in patients
- Commercially available products
- Within 1 year of trial completion

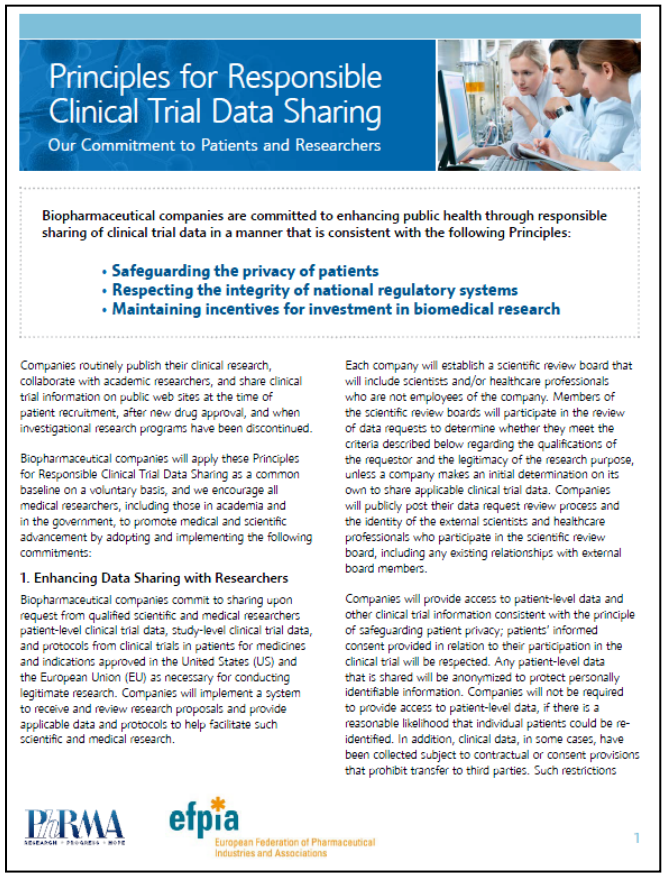
Publication
- All company sponsored trials 'considered'
- Minimum submit phase III and 'clinically important'
- Including discontinued investigational products
- With 12 – 18 months of approval / trial completion

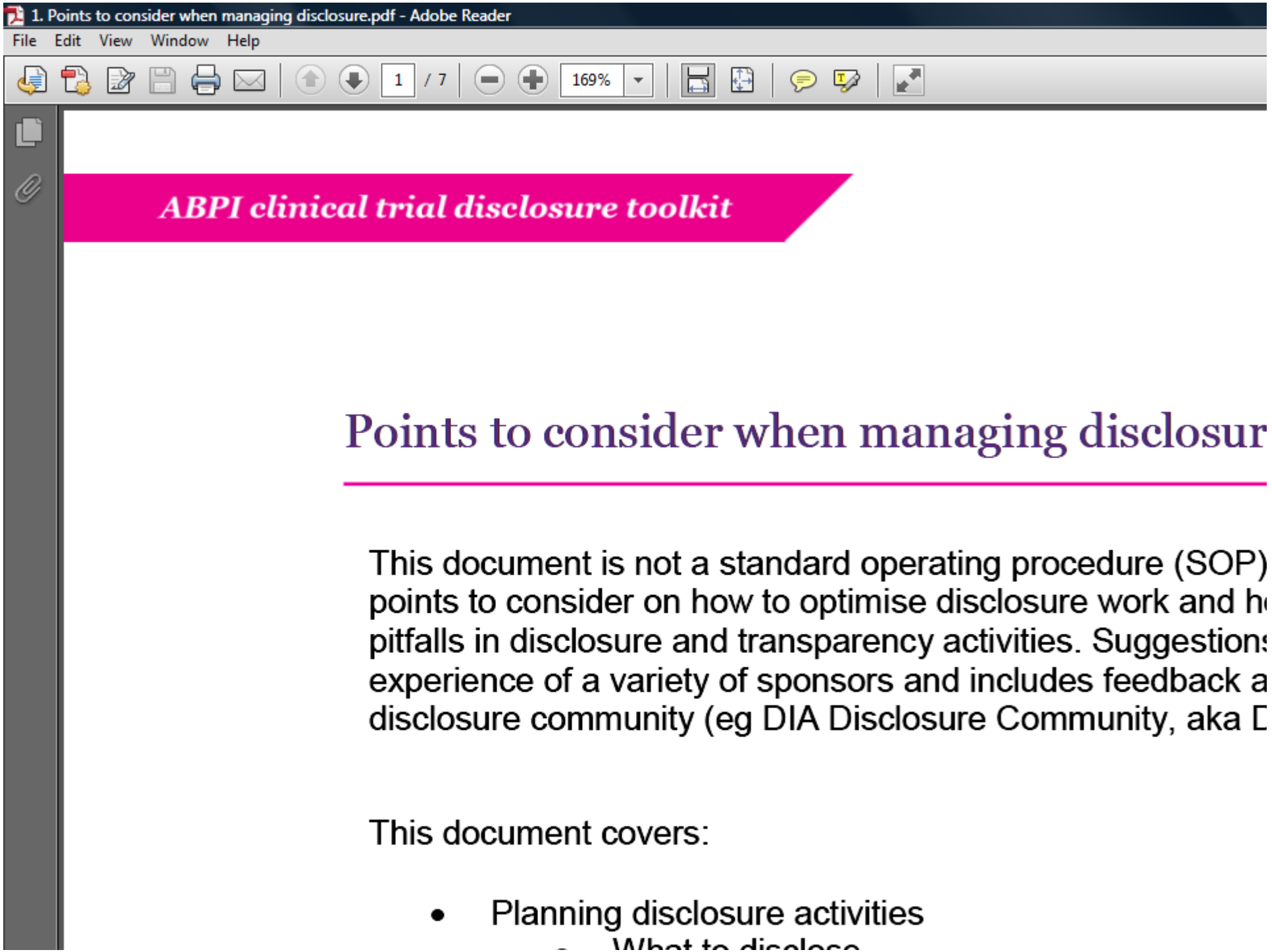
IFPMA Code; Clause 9.1:
Companies disclose clinical trial information as set out in the Joint Position on the Disclosure of Clinical
Trial Information via Clinical Trial Registries and Databases (2009) and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010) .....

US: FDA and Clinicaltrials.gov

Europe and USA: PhRMA and EFPIA Principles






1. Points to consider when managing disclosure.pdf - Adobe Reader
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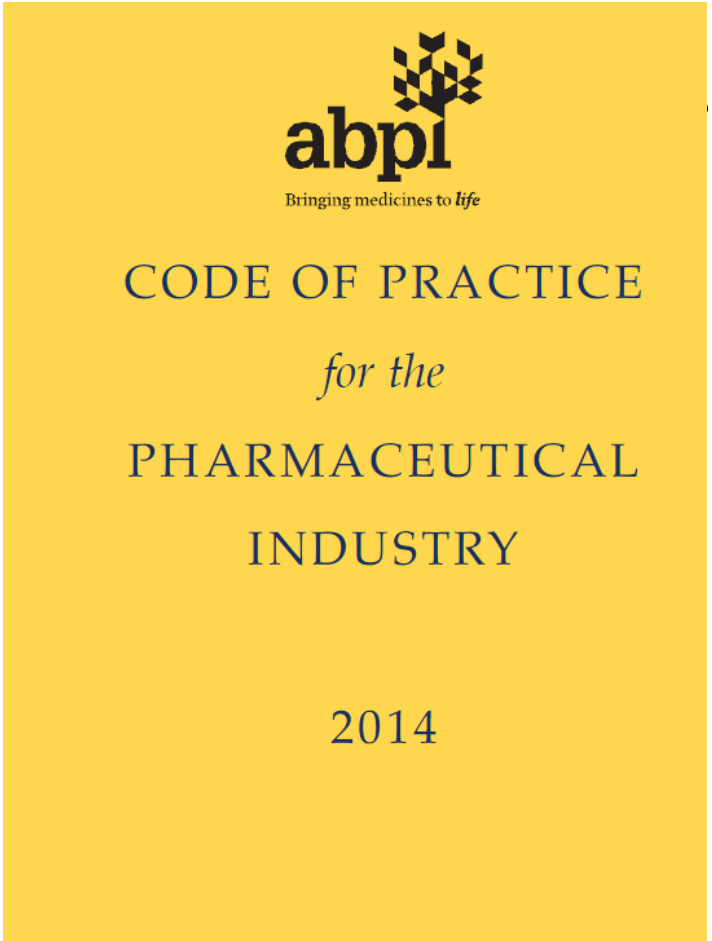
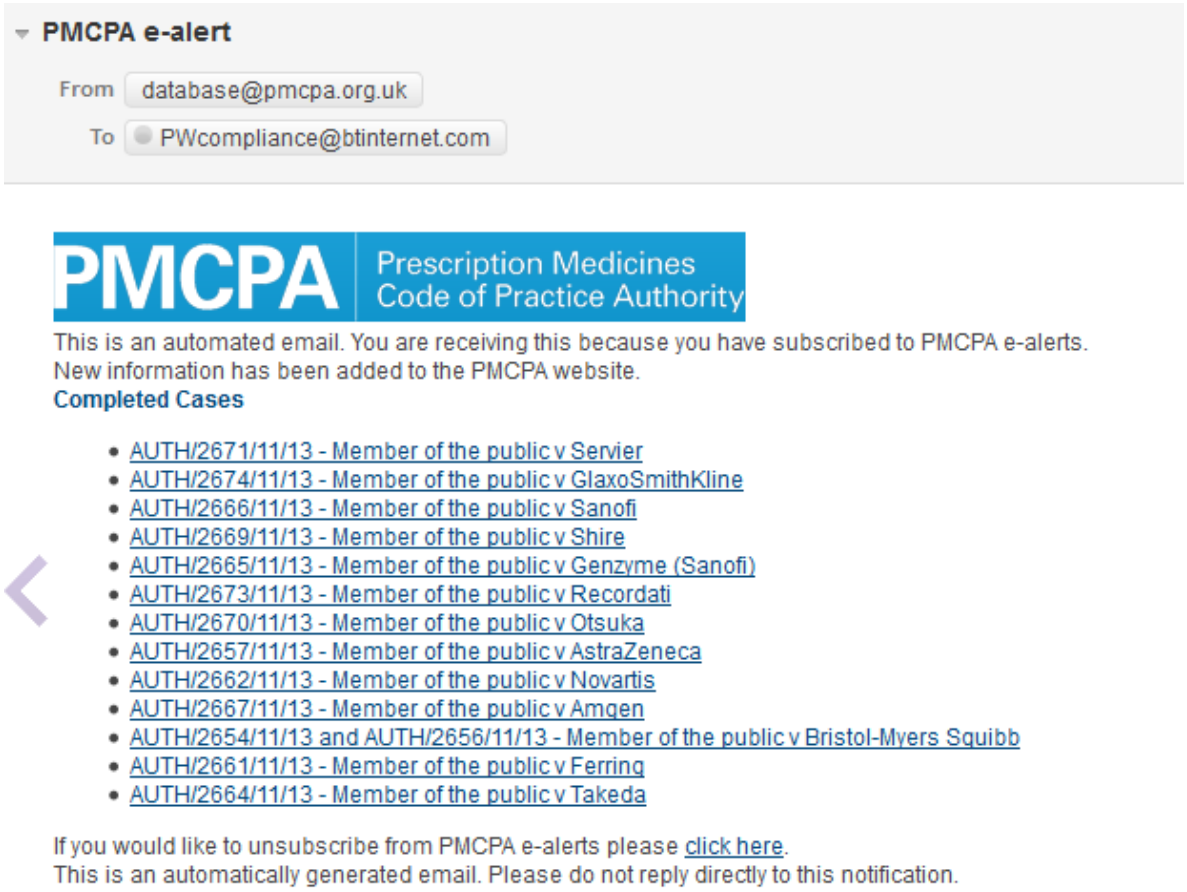
ABPI clinical trial disclosure toolkit
Points to consider when managing disclosur
This document is not a standard operating procedure (SOP)
points to consider on how to optimise disclosure work and h
pitfalls in disclosure and transparency activities. Suggestion
experience of a variety of sponsors and includes feedback a
disclosure community (eg DIA Disclosure Community, aka D
This document covers:
Planning disclosure activities

ABPI Code of Practice 2014



13.1 Companies must disclose details of clinical trials in accordance with the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature.

Case reports published today at 00.47 on several clinical trial disclosure cases



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PMCPA Prescription Medicines Code of Practice Authority

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New information has been added to the PMCPA website.

Completed Cases

- AUTH/2671/11/13 - Member of the public v Servier
- AUTH/2674/11/13 - Member of the public v GlaxoSmithKline
- AUTH/2666/11/13 - Member of the public v Sanofi
- AUTH/2669/11/13 - Member of the public v Shire
- AUTH/2665/11/13 - Member of the public v Genzyme (Sanofi)
- AUTH/2673/11/13 - Member of the public v Recordati
- AUTH/2670/11/13 - Member of the public v Otsuka
- AUTH/2657/11/13 - Member of the public v AstraZeneca
- AUTH/2662/11/13 - Member of the public v Novartis
- AUTH/2667/11/13 - Member of the public v Amgen
- AUTH/2654/11/13 and AUTH/2656/11/13 - Member of the public v Bristol-Myers Squibb
- AUTH/2661/11/13 - Member of the public v Ferring
- AUTH/2664/11/13 - Member of the public v Takeda

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Disclosure: Paul Woods acted as a consultant to PMCPA with respect to certain aspects of these cases

ABPI Code cases based on published paper

Case Summary:

- An anonymous, contactable member of the public complained about the information published as 'Clinical Trial Transparency: an assessment of the disclosure results of company-sponsored trials associated with new medicines approved recently in Europe'.
- The study was published in Current Medical Research & Opinion (CMRO) on 11 November 2013. The study authors were Dr B Rawal, Research, Medical and Innovation Director at the ABPI and B R Deane, a freelance consultant in pharmaceutical marketing and communications. Publication support for the study was funded by the ABPI.
- The study surveyed various publicly available information sources for clinical trial registration and disclosure of results searched from 27 December 2012 to 31 January 2013. It covered 53 new medicines (except vaccines and fixed dose combinations) approved for marketing by 34 companies by the European Medicines Agency (EMA) in 2009, 2010 and 2011. It included all completed company-sponsored clinical trials conducted in patients and recorded on a clinical trial registry and/or included in a European Public Assessment Report (EPAR).
- .....

EU Clinical Trials Regulation

Information from Clinical Study Reports of trials should not generally be considered commercially confidential :

- All drug trials in Europe to be registered before they begin on the publicly accessible EU clinical trials register.
- A summary of the results from these trials to be published on the register within a year of the trial's end.
- A summary understandable to a lay person of what was found in the trial to be published on the register.
- Clinical Study Reports to be made publicly available, where they are produced.
- Establish a new publicly accessible EU clinical trials register, to be set up and run by the European Medicines Agency.
- All trials used in support of an application to run a new clinical trial must be registered or have published results.

- EMA: Draft data sharing policy – debate over access and redaction

From : http://www.alltrials.net/news/europe-votes-for-clinical-trial-transparency/

What SHOULD be disclosed

- The moral judgement on clinical trial data disclosure
  - Who 'owns' the data? Morally / Legally
    - The company?
    - The participants?
    - The investigators?
    - Everyone?
  - A utilitarian calculation?
    - The greatest good to the greatest number of people?

Pharma communications with patients and the public - what can be shared?

- The current regulatory situation and the European proposals for change
  - What have we learnt?
- Current possibilities for communication
  - Keeping within the codes and regulations

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 medicines information available to patients varies considerably between Member States
- No consensus on what companies may provide in different countries
- No special regulatory category for Patient Organisations
- No special regulatory category for patients prescribed a treatment

The European Commission Proposal on Information to Patients

- An attempt to harmonise national interpretations
- A narrow proposal that would fill a gap in current legislation
  - Regulates only pharmaceutical companies
  - 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, in effect, refused to discuss the details
- Now appears to be as good as dead
  - .. But we have learnt some lessons

EUROPEAN COMMISSION

Brussels, 10.2.2012
COM(2012) 48 final

2008/0256 (COD)

Amended proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2001/83/EC as regards information to the general public on medicinal products subject to medical prescription

Council: Why are Member States against the information to patients proposal?

Inappropriate

- "Not an appropriate way of providing patients with objective and unbiased information"

Lack of a clear distinction

- between "information" and "advertising" .

Monitoring mechanisms

- will be costly and will create administrative burdens

Relationship between patients and health professionals

- might be changed in a way that is counterproductive for the patients' health

Such information should be given

- by competent authorities, health professionals or independent bodies
- not by the pharmaceutical industry

Constitutional grounds.

- Conflict with national legislation on freedom of expression

Budgets

- Negative consequences caused by unjustified increase in medicines usage


EUROPEAN COMMISSION

Brussels, 10.2.2012
COM(2012) 48 final
2008/0256 (COD)

Amended proposal for a

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.

Is it advertising to the public? ABPI Code

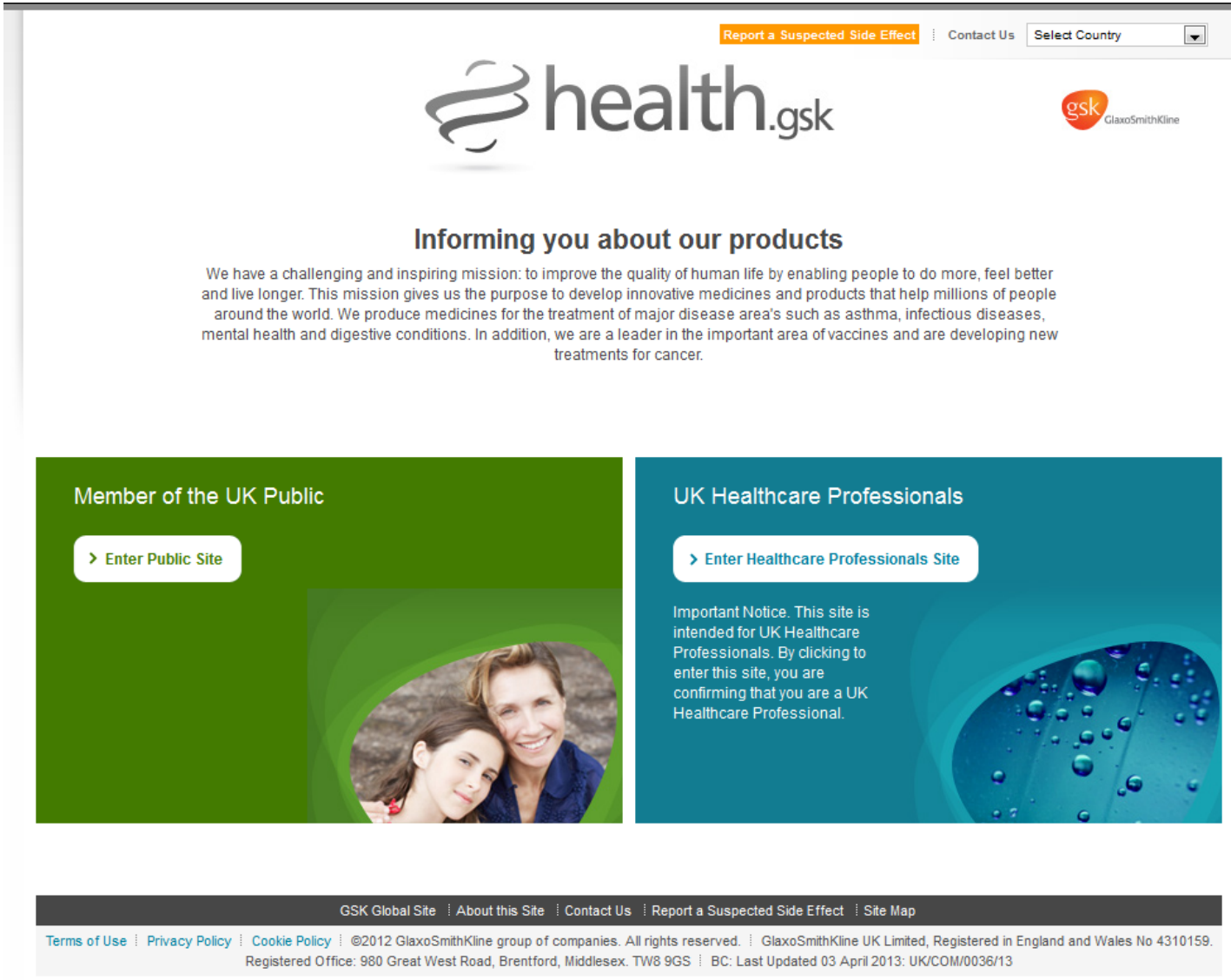
- Information about prescription only medicines made available to the public (directly or indirectly) :
  - Must be factual, balanced and not misleading.
  - Must not raise unfounded hopes of successful treatment

- Statements must not be made for the purpose of encouraging members of the public to ask their HCP to prescribe a specific medicine.

What you CAN provide - ABPI Code

- Medical information responses to unsolicited enquiries
  - But not personal medical advice
- 'Reference Information' (Library information)
  - SmPC, Package Leaflet, Medicine Guides etc
  - Study information (published or not), disease information and information about specific medicines
  - Represent fairly the current body of evidence and benefit/risk profile.
- Leaflets concerning a specific medicine
  - for HCPs to hand to a patient who has already been prescribed it
  - provided the leaflet is factual and non- promotional
- Disease awareness or public health campaigns to encourage members of the public to seek treatment for their symptoms
  - Includes advertising for trial participants
- Financial and business information for shareholders etc
- Product information for employees

GSK Europe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Serevent

salmeterol xinafoate

- Product Overview
- Safety
- Patient Videos
- Patient Information

Product Overview

What is Serevent:

Serevent contains the medicine salmeterol. It is a long-acting bronchodilator, which means that it helps the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects are usually felt within 10 to 20 minutes and last for 12 hours or more.

Use of Serevent:

Serevent is prescribed to help prevent breathing problems, which can be a result of Asthma or Chronic Obstructive Pulmonary Disease (COPD). Serevent helps to stop breathlessness and wheezing coming on and it is important to take the medicine regularly. It does not work once you are breathless or wheezy. If that happens you need to use a fast acting 'reliever' medicine, such as salbutamol.

Serevent Devices:

Serevent is available in 3 different devices:

- Accuhaler (50 microgram per dose),
- Diskhaler (50 microgram per dose),
- Evohaler (25 micrograms per actuation).

Taking Serevent:

- If you are being treated for asthma, you must always be given both Serevent and a steroid inhaler to use together.
- If your asthma or breathing gets worse tell your doctor straight away.
- You must never take Serevent on its own, without a steroid inhaler, if you suffer from asthma.

For further information on Serevent, including information on how to take your Serevent, please see the appropriate Serevent Patient Information Leaflet (PIL):

Links & Resources

- Serevent Accuhaler (PIL)
- Serevent Diskhaler (PIL)
- Serevent Evohaler (PIL)
- Medicine Guide for Serevent
- Serevent Accuhaler SPC
- Serevent Diskhaler SPC
- Serevent Evohaler SPC

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Find out more information on how you can help reduce the harmful environmental impact associated with landfill disposal of inhalers.

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Serevent

salmeterol xinafoate

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- Safety
- **Patient Videos**
- Patient Information

Serevent Patient Videos

To learn how to use your Serevent Evohaler, watch the animation below.

How to take your Serevent Evohaler

To learn how to use your Serevent Accuhaler, watch the animation below

How to take your Serevent Accuhaler

Links & Resources

- Serevent Accuhaler (PIL)
- Serevent Diskhaler (PIL)
- Serevent Evohaler (PIL)
- Medicine Guide for Serevent
- Serevent Accuhaler SPC
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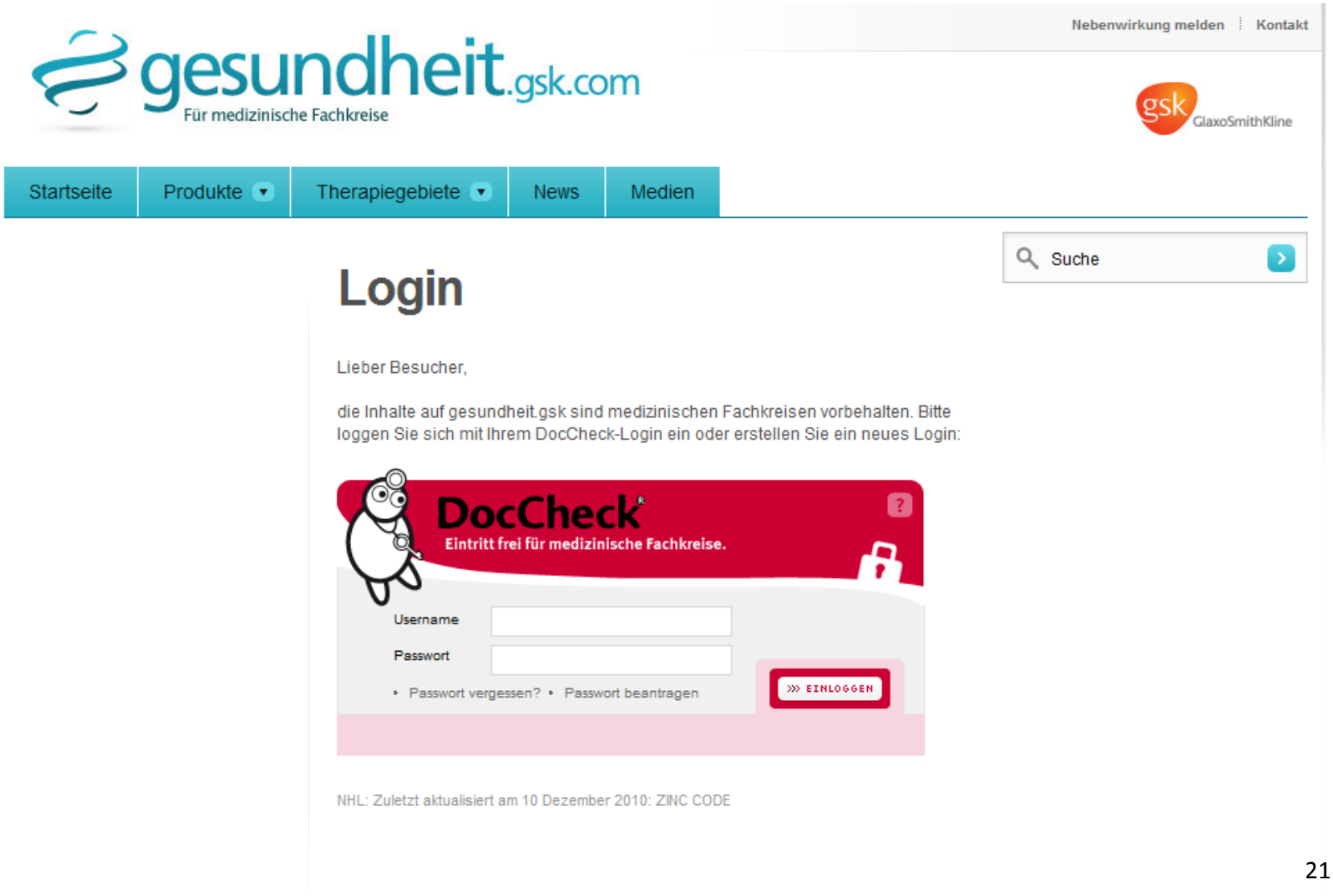
German site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So .....

- Advertising prescription medicines to the public is prohibited
- We CAN provide non-promotional medicine and health information
- Factual trial result information presented in line with disclosure sites format unlikely to be ruled as advertising
- There's no agreement on exactly where the line between advertising and non-promotional communications should be drawn
- Journalists, patient groups etc, as well as

It all adds up to a simple approach

- We CAN communicate with the public about health and prescription medicines
  - We just can't advertise to them

- And when were not sure whether it's advertising we can always ask ourselves:
  - **Intent:** Why do we want to do it?
  - **Effect:** Could it encourage a patient to ask for a medicine?