





A challenge to independent information: The Information to Patients' Directive

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This presentation arises from the Developing Rational Use of Medicines in Europe project, which has received funding from the European Union, in the framework of the Health programme.



What is HAI Europe?

- European branch of a not-for-profit global network
- Established in 1981
- Made up by consumers, public interest NGOs, health care providers, academics, media and individuals
- Europe office: Amsterdam, The Netherlands
- Works to promote access to essential medicines and their rational use



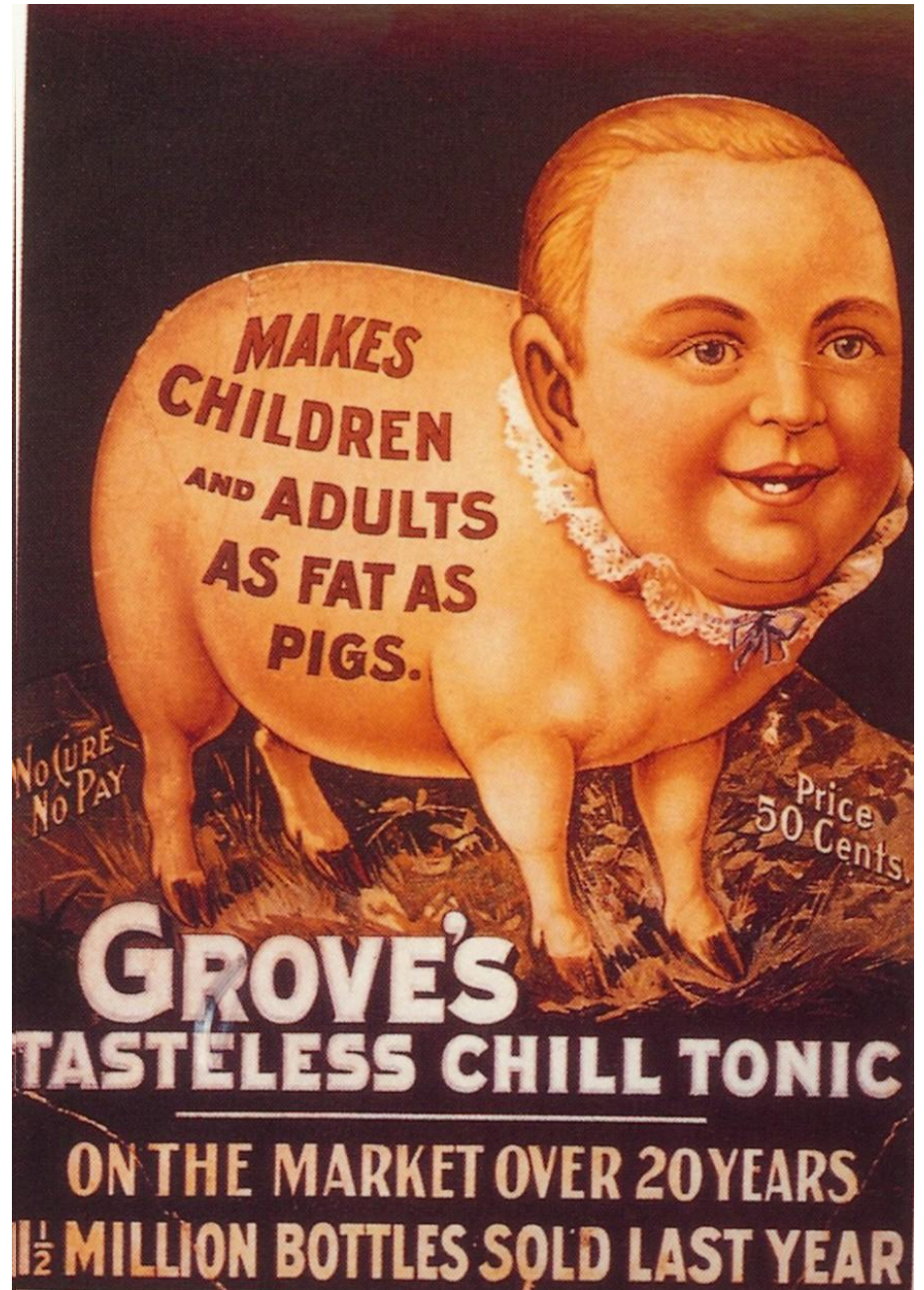
What this presentation covers...

- Policy discussions in Europe: History of Events and Actors at play
- What are the changes proposed in the Information to Patients directive?
- Unbranded 'disease awareness' campaigns in Europe
- A word of caution

La Revue Prescrire - 25 years of independent medicines' evaluation

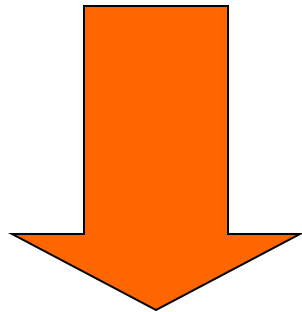
- Bravo : 0,30 %
- Real advance: 2,34 %
- Offers some benefit: 6,81 %
- Can help : 14,60 %
- Nothing new : 69,02 %
- Innacceptable : 3,18 %
- No decision: 3,83 %

In 1900...



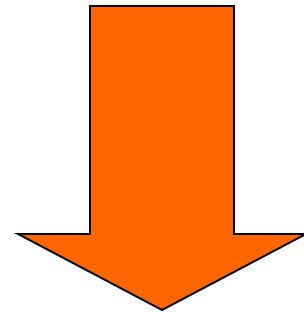
Drug Promotion – a conflict?

Public Interest



Rational use of
medicines

Pharmaceutical
Industry Interest



Maximize sales and
returns to
shareholders



2001 - Proposal for change of EU advertising laws

- EU Commission proposed a pilot project to allow direct-to-consumer advertising in Europe for asthma, diabetes and AIDS drugs
- **What was said:**

“This is not direct to consumer advertising. We are not introducing advertising for prescription drugs. What we want to do is, as a test case...to make sure that validated and patient oriented information can be made available...”

– *Commissioner Erkki Liikanen, July 2001*

What was written

Better information

The Commission considered appropriate to abandon the strict prohibition of advertising of prescription-only medicines, since there is a growing interest and knowledge among the general public for information on medicinal products.

Memo 01/267 Reform of Pharmaceutical Legislation

Brussels, July 18, 2001

Proposed legislative change included:

- “public advertising of 3 classes of products...”
- Amendment to Article 88, which prohibits advertising of prescription drugs to the public;
- No explicit exclusion of any form of advertising, in any media.

The proposal was overwhelmingly rejected

- By the European Parliament in 2002: **494 to 42**
- And again by the EU Council in 2003.

...5 years down the road...



European Political Landscape

- Pharmaceuticals still governed by DG Enterprise
- New, vocal and heavily industry-supported patient groups came into play
- One more high-level group: Pharmaceutical Forum
- Similar initiative: now disguised as information to patients

Proposed directive on Information to Patients

- Companies would be able to disseminate:
 - The information contained in the SPC and package leaflet, but presented in a different way
 - Prices, information on pack changes and adverse-reaction warnings
 - Information on non-interventional studies
- Authorised channels:
 - Internet
 - In “health-related publications” – To be defined...
- Specifically rejects comparative information

Déjà vu?



Information «» Advertising

What is prohibited under current EU legislation?

EU Directive:

- Article 88 (a) prohibits **advertising** of prescription drugs to the public
- Article 86 (2) allows information on diseases, as long as there is no direct or indirect reference to a specific product

MAIS DE SEIS SEMANAS
SEM FUMAR E AINDA NÃO
ME ENERVEI COM NINGUÉM.

Deixe de fumar sem dramas.
Consulte o seu médico.



Pfizer Campaign Portugal, 2007

More than 6 weeks
without smoking and no
arguments yet.

Stop smoking without
dramas, visit your
doctor.

What is left unsaid:

Pfizer has a product to
sell: varenicline
FDA and EMEA warnings
on side-effects:
depression, suicidal
ideation, emotional
changes

Skip your period campaign by Bayer Schering in The Netherlands, 2007



Menstruatie verschuiven

Bayer HealthCare
Bayer Schering Pharma

1. Uitstellen menstruatie bij pilgebruiksters

Merk pil

Yasmin®	Uitstel:	geen stopweek, direct doorgaan met nieuwe strip
	Duur:	zolang als gewenst
	Opmerking:	geen afname betrouwbaarheid
Femodeen®/ Minulet®		Zie het advies bij Yasmin®
Microgynon® 20/ Lovette		Zie het advies bij Yasmin®
Microgynon® 30/ Stediril® 30		Zie het advies bij Yasmin®
Marvelon®		Zie het advies bij Yasmin®
Mercilon®		Zie het advies bij Yasmin®
Trigynon®/ Trinordiol®	Uitstel:	geen stopweek, doorgaan met de derde fase uit de nieuwe strip. Dit zijn de 10 gele dragees. Voor langer uitstel doorgaan met Microgynon® 30
	Opmerking:	geen afname betrouwbaarheid

Leaflet distributed at pharmacies

What is left unsaid:

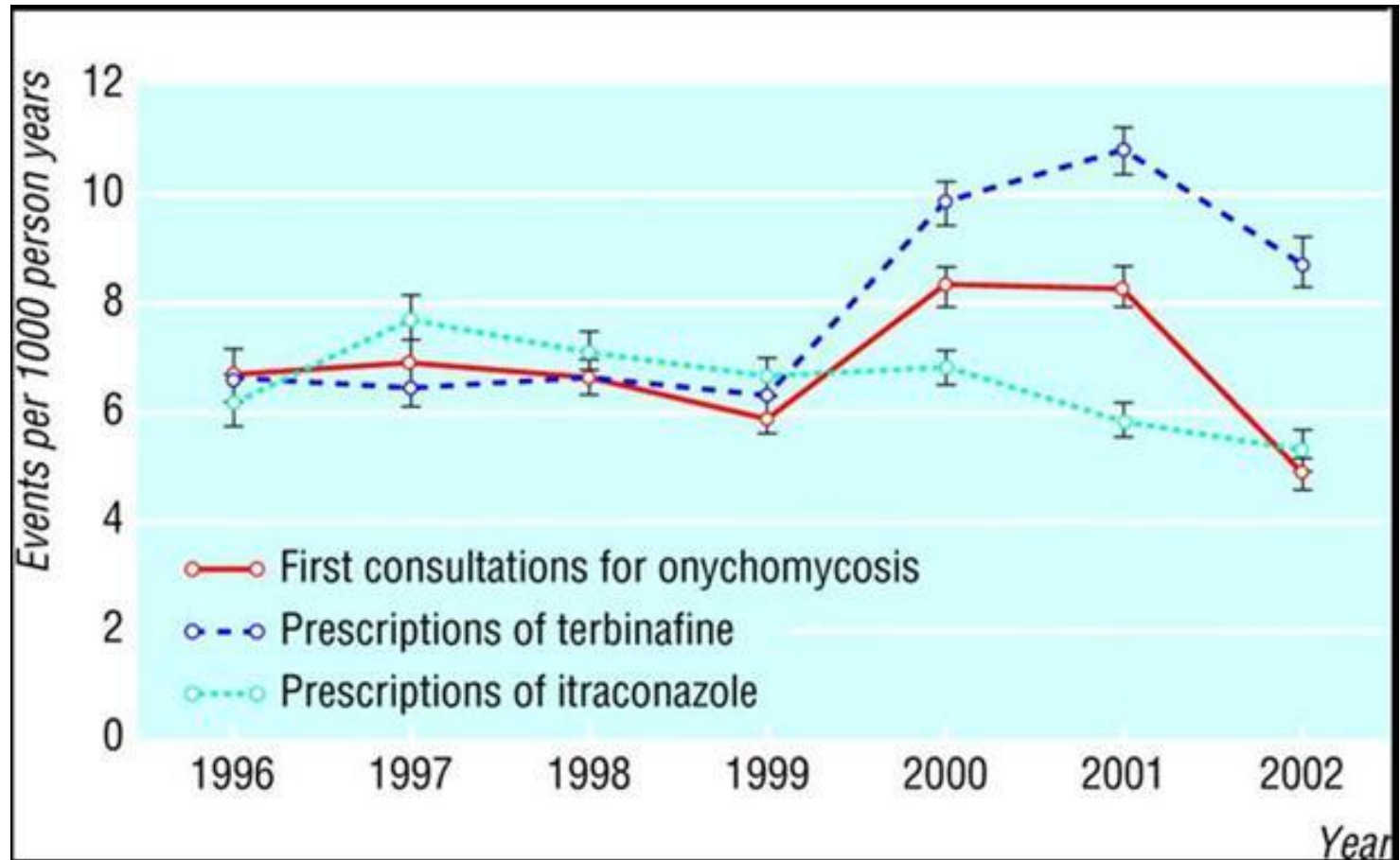
- DTCA: Illegal
- Direct reference to products which have been approved for specific indications
- Positive comments about company's medicines
- Suggested product is under FDA scrutiny: concerns about side-effects – DVT - company made unsupported claims in advertising

Unbranded pharmaceutical advertising

- “Disease-mongering” – expanded disease definitions in order to increase sales
- Inaccuracies about disease prevalence, risks, potential treatment benefits
- Failure to comply with standards in WHO Ethical Criteria
- Regulatory response is generally inadequate

NOVARTIS TV ads, The Netherlands

*Ethical Criteria definition of promotion:
to stimulates sales*



Problems

- Companies have an inherent conflict of interest
- Public dissemination of promotional information about prescription-only medicines
 - Increase in consumption and costs
 - Increase in irrational use
- Reminder adverts would be allowed: emotive branding images and messages
- Checking information before release will not solve the problem
 - Big burden on public authorities
 - Waste of resources: human and financial
- Self-regulation is not a solution

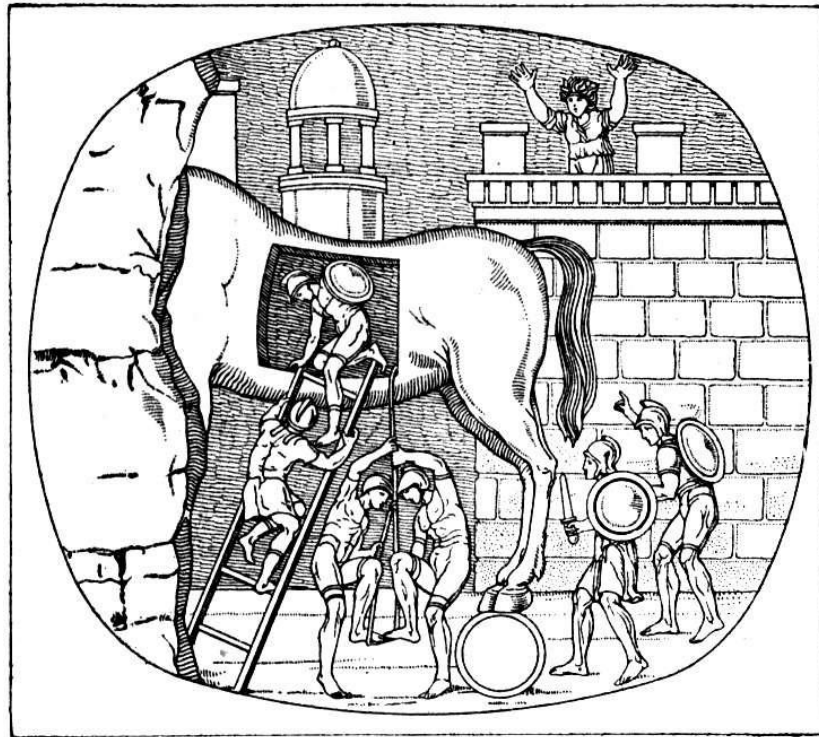
What is happening...

- Opposition from public-health related groups, consumers, payers, healthcare professionals, independent patient organisations
- EU Council expressed grave concerns
- Commission Directive is now being discussed at EU Parliament
- Essential to mobilize CSO voice: Your voice!

Public health and welfare first!

- The public needs unbiased, accurate, comparative information on the pros and cons of all treatment choices, including the option not to treat – not disguised or undisguised advertising.
- Legislation banning unethical drug promotion should be enacted and enforced.
- Industry has a clear role to play:
 - Improve quality of product information, packaging and patient information leaflets;
 - Full public disclosure of all pre- and post- market drug effectiveness and safety studies

The information to patients directive...



...is not what it seems!

Group Activities

- Break-up in small groups
- Practical Exercises
 - To critically appraise an advert
 - Each group selects one rapporteur, who then presents to plenary
- Joint Discussion

Group Exercise

- Look at the image, title and text
- Who is the target audience?
- What are the key messages?
- What is mentioned:
 - About the treatment benefits ?
 - About the treatment risks?
- What is included?
- What is missing?