The information to patients directive
*a rose by any other name would smell as sweet…*

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EU Policy in Action: in whose interests?
HAI Europe Seminar, 23 Oct 2009, Brussels
What is being proposed?

- An amendment to EU legislation prohibiting prescription drug advertising to the public.
- Article 88 Directive 2004/27/EC states:
  Member states shall prohibit the advertising to the general public of medicinal products which... are available on medical prescription only...
Proposed amendments to the ban

- An exception for certain types of ‘information’
  - Approved product information (already allowed!)
  - Medicines presented in the context of the condition to be treated or prevented
  - Information on measures to accompany drug use
  - Cannot go beyond the elements of the approved labelling and public version of EPAR **but can state the information in a different way**
  - Information on non-interventional studies
How would this be managed?

- Radio, TV ads with brand names banned
- Specific media allowed:
  - Internet websites
  - Health-related publications
- Stated information criteria
  - “must not contradict” approved labelling
- Pre-approval by national governments or equivalent but different mechanism
Background:
EU Commission proposal in 2001-2

- Allow advertising of asthma, diabetes, AIDS drugs
- Rejected by the EU Parliament: 494 to 42
- Rejected again by the EU Council in 2003
- Mobilisation of civil society: EPHA, BEUC, HAI
  Europe, Medicines in Europe Forum etc.

However...

- Article 88(a) called for a report back to Parliament on ‘non-promotional’ information to patients
- EU Pharmaceutical Forum working group
Stated rationale for current proposal

- Harmonisation within the EU – confusion between countries about existing rules
- Information access is currently inadequate
- **Quality** is more important than **source**
- Companies have needed expertise
- Regulation & pre-approval, prevents abuses
Unstated rationale

- The United States represents nearly half of global pharmaceutical sales
- US direct-to-consumer is a very effective marketing technique ($4 per dollar invested)
- This is a compromise solution between industry pressure within a competitive global market, and lack of EU citizenry or health ministry appetite for ‘US-style DTCA’.
Promotion or information?
A reality check
Medicines within a health context
Bayer October 2009 – English/ German

Hormone replacement therapy

- Relieves menopausal symptoms such as hot flushes and night sweats.
- Reduces the incidence of osteoporosis-related fractures.
- Relieves complaints resulting from dry mucous membranes, e.g. in vagina and urinary tract.
- Has a positive effect on mood and sensation of wellbeing. Feelings of depression, irritability and lack of drive are less frequent. Enjoyment of sex continues or returns.
- The appearance of skin and hair improves.

The many years of experience with hormone replacement therapy have produced evidence suggesting that hormone replacement therapy has additional benefits. It has been observed that combined preparations reduce the risk of cancer of the uterus or ovaries. There is also evidence indicating that hormone replacement therapy protects against colon cancer. It has been reported that memory and cognition improve on estrogen replacement therapy and that it protects against Alzheimers disease. This evidence is currently being investigated in scientific studies.

Ask your doctor whether hormone replacement therapy would be appropriate for you. In order to tailor a 'customized' treatment plan for you, your doctor will perform an individual benefit-to-risk assessment, i.e. he will weigh up the specific benefits of hormone replacement therapy in your particular case against the possible risks. Your general state of health, your medical history, your lifestyle and your age will also be taken into consideration.
‘Information’ or promotion?

“Even in the only medically valid role for hormone replacement therapy today (ie, control of menopausal symptoms), such therapy does not seem to have a clinically meaningful effect on health-related quality of life…It is difficult to presume that the benefits of routine use of such therapy for menopausal symptoms outweigh the increased risks of mortality, especially in the absence of improvement in the quality of life.”

- Apar Kishor Ganti, The Lancet, October 10, 2009
Information that does not go beyond the approved product information

Poor product choice
- Cardiac risks
- No more effective
- More expensive
Medicines in a health context
Stimulation of sales through unbranded advertising
NOVARTIS toenail fungus, the Netherlands

- 't Jong GW et al. British Medical Journal 2004;328:931
Allergy may lead to asthma. Snotty nose, stuffy nose or red, irritated eyes may be more serious than you think. Allergy is a disease that, in itself, may lead to asthma.
Stating information in a different way
“Skip your period” campaign, 2007

Leaflet distributed at pharmacies in the Netherlands

- Illegal DTCA
- Image suggests ease, satisfaction
- Recommends Yasmin (Bayer)
- Specific safety concerns, higher risks potentially fatal blood clots and potassium imbalance, than with other birth control pills.
- With continuous use, frequent bleeding between periods
Have your period less often.

Need birth control and wish you could lengthen the time between your scheduled periods?

Talk to your doctor about oral contraceptive options or visit us online.

PeriodsLessOften.ca
Pre-approval by self-regulatory bodies?

The Canadian experience
Patient autonomy or manipulation?

“An individual may come to a decision based on an assessment of the available evidence presented neutrally. This is the basis of shared informed decision-making and is fundamental to respect for autonomy. Information manipulation in contrast is a deliberate act of managing information that alters a person’s understanding of a situation in order to motivate him or her to do what the agent of influence intends.”

- Mintzes and Mangin, Future Medicinal Chemistry 2009, In press
In summary: no public health rationale for the patient information directive

- Companies have a fiduciary responsibility to shareholders – to promote sales
- The aim of the patient information directive is to increase industry profitability by driving health care choices
- There are serious risks to public safety and sustainability of health care costs
- Regulation is not an effective solution – ineffective in the US, New Zealand and Canada
- A serious problem exists with disguised advertising
- If the aim is to meet patient needs, publicly financed independent, unbiased comparative information is needed