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The New EU Pharma Package: Impact of proposed rules on information to patients

May 28, 2009

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European Federation of Pharmaceutical Industries and Associations

Overview

- Current situation in the EU
- Need for change
- Proposal for reform – aim, objective, key elements
- Impact in practice
- Outstanding key elements that need to be defined
- Potential outcomes
- How to monitor and sanction the information provided to patients?
- Case Study: Industry Self-Regulation in Practice in UK
- Outlook for the Proposal: What's next?

Current situation in the EU

- Directive 2001/83 excludes pharmaceutical companies from providing promotion to patients concerning prescription-only medicinal products
- EU Member States' national measures transposing the Directive's provisions on information to patients is not harmonized and lacks consistency
- The amount and type of information available to patients varies considerably among Member States
- Approaches by Member State authorities to regulation of information to patients ranges:
  - From Public-Private partnership in Sweden between the authorities and the industry's trade association intended to provide comprehensive web-based information to patients through FASS…
  - Through UK providing more adapted versions of the SmPC on the web and the possibility of broad 'reference information'
  - To very restrictive policy in France where prescription medicines information is only available through health professionals

Need for change: Identified Issues

- EU citizens are increasingly interested in their own health and available treatment options
- Internet provides enormous amount of information on prescription-only medicinal products and treatment options
- … however some of the information is of questionable quality and from dubious sources potentially endangering EU citizens health and safety
- Unequal access to internet and language barriers creates inequalities to access to health information in the EU
- Pharma companies are often not permitted to provide information because it is interpreted to be advertising
- … however they are ultimately responsible for the use of their products
- The current legislation does not provide for any consistent useable distinction between information and advertising

Current proposal for reform

- On 10 December 2008 the European Commission adopted a proposal to address the current situation
- The Commission proposes to:
  - **Harmonise** the information that companies are permitted to provide to the general public concerning their prescription-only medicines;
  - while **maintaining the ban** on advertising.
- The aim is to:
  - Provide equal access to reliable and understandable information on medicinal products
  - Ensure the conditions for equal access to information to all citizens in the EU
  - Eliminate the risks resulting from unreliable and/or illegal sources of information publicly available in Internet

Objectives of the proposal

- Ensure functioning of internal market
- Better protect health of EU citizens
- Provide a clear legal framework for companies governing the provision of information on prescription-only medicines to the general public to enhance rational use
- Ensure that Direct to Consumer Advertising remains forbidden
- EU-wide standards of high quality
- Address different needs and capabilities of patients
- Allow companies to provide in an understandable way objective and non-promotional information about benefits and risks of their medicines
- Monitoring and enforcement measures to ensure compliance with quality criteria while avoiding unnecessary bureaucracy

Key elements of the proposal

- Companies are permitted to provide objective and non-promotional information on their prescription-only products
- The information should be based on the summary of product characteristics, patient information leaflet and labelling that is
- … already officially approved by the competent authorities (EMEA/Member States)
- Information provided to patients can not go beyond or contradict these officially approved elements
- … and should be **reliable, objective, understandable, up-to-date, evidence-based and suited for the patients' needs**
- Permitted information channels would include: internet websites, printed media and written answers to requests for information from the general public

What will the Commission proposal mean in practice?

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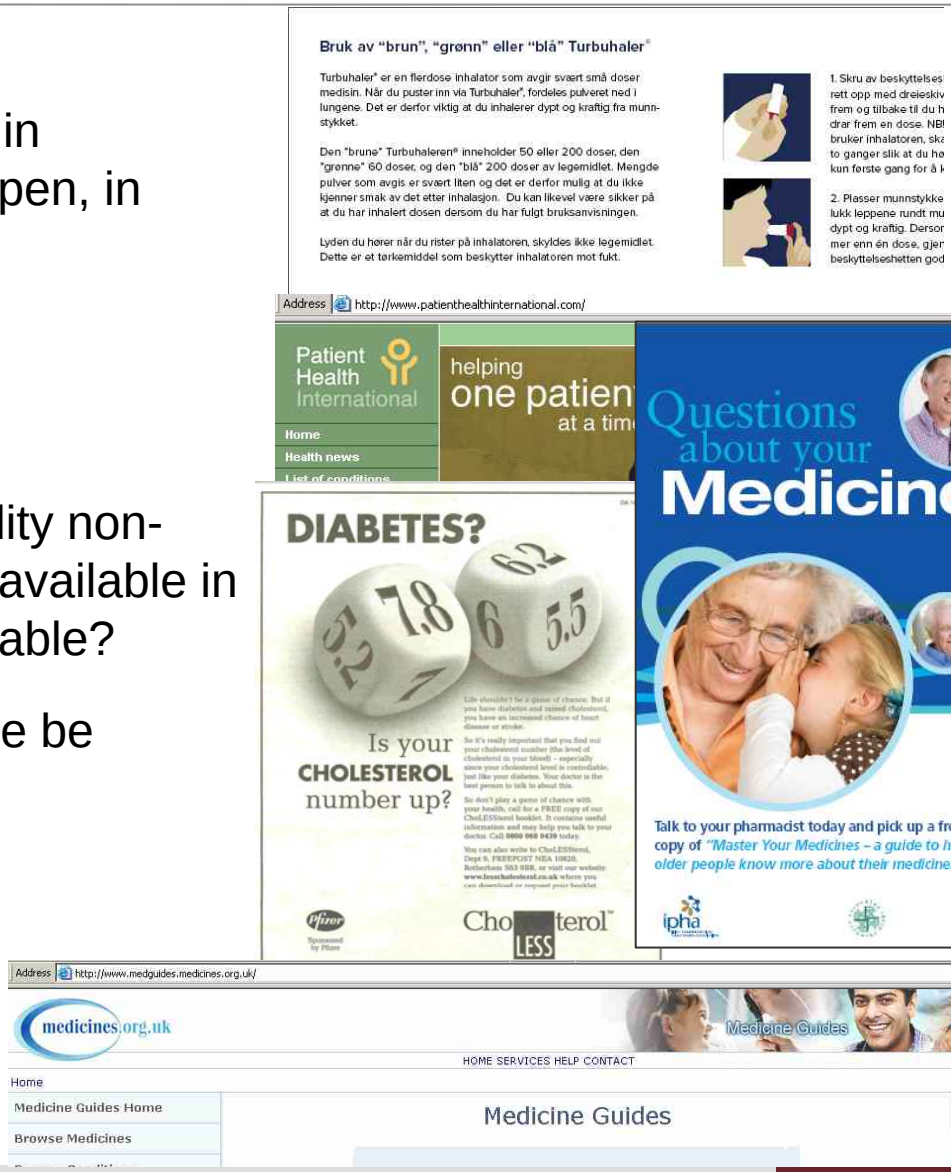
- Will the necessary improvements in information provision actually happen, in practice, in all countries?
- What is prohibited?
- What is permitted?
- Will bureaucracy lead to high quality non-promotional information currently available in some countries becoming unavailable?
- Can harmonisation to best practice be achieved?



General observations

- The proposal should be welcomed
  - After years of debate, this provides a step forward to improve access to information and reduce current inequalities
- A narrow proposal within the wider “Information for Patients” debate
  - Applies only to pharmaceutical companies – not to other information providers
  - Covers only information on prescription medicines for patients and the public
- Vigorous implementation will be needed by Member States
  - To achieve coherence and best practice information across Europe
- The proposals present no additional possibilities in some countries
  - Some currently available information may have to be withdrawn
- Need for clarification of details
  - To ensure new legislation is workable and meets its objectives

Advertising versus Information: Categories of information

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- The distinction between advertising and non-promotional information is well described in the Commission proposal
  - Identifying categories of permitted information and channels works well
  - The advertising v. information distinction can be further clarified through the guidelines, code and experience

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- However, no legal definition of the distinction between advertising and information
  - Defining by experience hides risks and gives arguments to stakeholders opposing the proposal
  - The European Court of Justice already takes a strict approach to the distinction between information and advertising (See ECJ Damgaard case C-421/07 from 2 April 2009)
  - Advertising would be any information that influences or could, potentially, influence consumers' behavior and encourage the consumption of the product

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C-421/07 Damgaard

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- Hyben Total marketed in Denmark. Related information material prepared by a journalist, Mr Damgaard.
- Sales of the product were halted in 1999. Mr. Damgaard continued to provide information on his own website about the product and of its availability as a food supplement in other EU Member States.
- The Danish authorities considered this violated the EU ban on advertising of non-authorized medicinal products
- Mr Damgaard claimed that he had no connection with the manufacturer, no commercial interest in the product and simply provided information
- **European Court Decision -**
  - dissemination of information by independent third parties not excluded from the EU definition of advertising.
  - absence of any links between the communicator and the manufacturer had no impact on this definition.
  - dissemination of information on the properties and availability of a product could influence consumers' behavior and encourage its consumption.

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Advertising versus Information: Channels of information

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- The concept of “pull versus push ” is useful
  - Could be developed further in the text or in the proposed guidelines
  - Classical "push" mass media are not appropriate for unsolicited information dissemination
  - New technology must be considered
- Print material (brochures, leaflets etc) are and remain important
  - Particularly for those without internet access
- Need for clarification of ‘health-related publications’
  - And an understanding of how Member States might interpret this

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Key elements yet to define

- Approval, monitoring and sanction
- Principle of mutual recognition
- Ways to ensure uniform high level of quality information in EU
- Addressing different needs and capabilities of patients (language, access to technology)
- Provision of legal definition to distinguish between information and advertising?
- Printed media as a permitted channel: how to define health-related publication in a harmonized way throughout Member States?

… **those elements could define the outcome of the proposal**

Outcome: Best-case scenario

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- Improved access for all EU citizens to non-promotional health and medicines information in their language when they seek it:
  - Patients provided with access to quality and understandable information
  - Empowered and informed patients would make rational use of medicinal products with better outcomes and use of resources
- Industry recognized as trusted source of information
  - Without undermining the role of healthcare professionals and patient groups
  - Companies know best their products and are ultimately responsible for them
- Harmonization to current best practice across the EU and establishing greater legal certainty
- Optimal and flexible mechanisms for approval, monitoring and sanction to avoid unnecessary burden:
  - Self-regulation with binding industry codes – monitoring and sanction by industry bodies
  - Ex-post control of content by authorities and sanctions where needed

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Outcome: Scenarios to avoid

- Introduction of US-style DTC-Advertizing in the EU
  - Mass-media should not be allowed as channels for information to patients (TV/Radio already deleted)
  - Provision of information through health publications must be carefully defined and regulated
- Heavy and burdensome system of approval and monitoring of information
  - Pre-vetting of information by the Member State authorities should be avoided as it would create significant administrative burden and could compromise access to information
  - Information would be based on SmPC and PIL's, thus already approved
  - Information already available on websites in one Member State should be allowed without prior approval in other Member States after translation (application of the principle of mutual recognition)
- Maintaining of the status quo
  - The current situation is unacceptable, as affirmed by the Commission and most of the stakeholders

Outcome: Scenarios to avoid (2)

- Potential (unexpected) restrictions on information already legally available in EU/some Member States:
  - Medical information responses to HCPs
  - Information for stockholders
  - Information on clinical trials, HTA information etc (as permitted in UK 'reference information')
  - Responses to patient organizations e.g. about medicines in development
  - Information designed for children
  - Inform to patients that health may be affected by not taking a medicine (e.g. prophylactic medicines)
  - Audiovisual and new media information to support concordance
  - Oral answers to patients from medical information departments

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How to monitor and sanction the information provided to patients?

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Standards of Information

- Sensible and robust quality standards already in the proposal
- Additional requirements could be appropriate
  - Eg requirement to provide or link to Package Leaflet text
- EFPIA has already adopted information quality principles (2006) and has been developing a 'theoretical' code of practice
- Question the cross reference to the standards on OTC promotion
- Comparisons banned
  - Agree that information should not promote comparative merits
  - Some comparative information may be included in SmPC

Monitoring and enforcement

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- Need for reasonable and robust systems to ensure that company communications are
  - of a high standard
  - do not constitute advertising.
- No need for routine pre-vetting controls: Ex-post monitoring should be the general rule
  - Routine pre-vetting involves duplication of controls, unnecessary 'red tape' and potentially less or delayed availability of information
  - Could only be applied in countries in which their constitution does not prohibit 'censorship'
  - Proposal text is unclear on what constitutes acceptable alternatives to authority pre-vetting
- Is it appropriate to treat centrally approved products differently?
  - In one country companies will interact with different bodies for different products

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Monitoring and enforcement (continued)

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- A code of practice should play an important part in ensuring information is of high quality and non-promotional
  - backed up by regulatory controls
- Proposal could be enhanced by requiring doctor/pharmacist (scientific service) approval of all material
- Best practice in certain countries should be built upon
  - Eg UK code of practice /regulatory system

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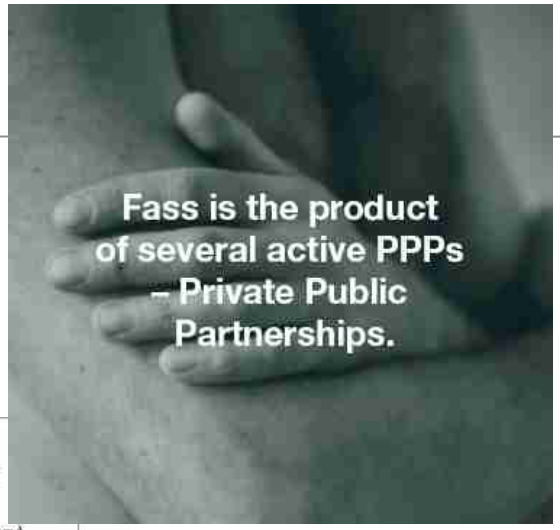
FASS – the Swedish Medicines Information Engine



- Summary of Product Characteristics (SPCs – human and veterinary)
- Package inserts (human and veterinary)
- Fass (The Medicines Compendium for healthcare professionals)
- Fass Vet. (The Medicines Compendium for veterinary use)
- Patient-Fass (The Medicines Compendium in layman language)
- My Fass
- Packages and prices
- Reimbursement status
- Medicines and the environment
- Alerts on changes of product information
- Interactions
- Treatment recommendations in case of overdose
- Identification of tablets and capsules
- Text to speech
- How to order package inserts in Braille
- Safety information
- Information on research and development
- The Medicines University
- Access to global information on clinical trials (the clinical trials portal of IFPMA)

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EFPIA "Principles & Guidance Notes"

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- Quality Criteria: Principles for high quality information by companies + "guidance" to illustrate possible application in practice
  - Demonstrate industry's will to make proactive, constructive and responsible contribution to current debate
- Invite all providers of health information to apply same high standards
- Adopted by EFPIA Board in November 2005

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Industry Ethical Framework

Proposed

Code: Relationships with Patient Organisations
2007

CODE : PROMOTION OF MEDICINES AND INTERACTIONS WITH HEALTHCARE PROFESSIONALS
2007 revision

Code: Health Information For Patients

Implementation in 32 European countries

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Case Study:

Industry Self-Regulation in Practice - UK

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ABPI Code (UK)
Coverage of 'Relations with the General Public and the Media'

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- Do not advertise prescription-only medicines
- Information must be factual & balanced
- Pro-active Information; Reference information; Reactive Information;
- Disease awareness or Public health communications
- Certified by Medical Signatories
- Statements must not encourage members of the public to ask for a specific prescription only medicine
- Patient organisation interactions: Transparent (on company website), written agreements, meetings, certification …
- Refuse requests for advice on personal medical matters
- Companies responsible for their PR agencies
- Public access to Internet sites

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Cases from the May 2007 ABPI 'Code of Practice Review'

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CASE AUTH/1957/2/07

ANONYMOUS MEMBER OF THE PUBLIC v SANOFI-AVENTIS

Statements to the public about Lantus

The anonymous mother of a diabetic child alleged that an athlete had promoted Lantus (insulin glargine) to members of the public during a local hospital fun day which she and her son, a type 1 diabetic, had attended. The matter was taken up with Sanofi-Aventis.

The complainant explained that while the children were playing, she was invited, with the other parents, to a presentation on sports and insulin, which interested her a lot, as her son was a keen footballer. One of the speakers gave a very impressive presentation on his sporting successes. The complainant was very interested in how well he managed to control his sugars. He kept referring to an insulin called Lantus and how good it was. The complainant also looked at his website and was very impressed.

I can race 100% just like everyone else'.

The Panel considered that, given the arrangements that existed between them, Sanofi-Aventis was responsible under the Code for statements made by the speaker at the meeting in question. If it were otherwise then the effect would be for companies' support of patients known to be positive about their products to be used as a means of avoiding the restrictions in the Code.

The Panel noted that it had not been provided with either a copy of the presentation or a transcript of what had been said at the fun day meeting although from the complaint it was clear that the speaker had commented positively about Lantus. The Panel considered that the balance of probability was, that during his talk, statements were made by the speaker

CASE AUTH/1819/4/06 *NO BREACH OF THE CODE*

MEDIA/DIRECTOR v ROCHE

Newspaper article about Herceptin

An article entitled 'The selling of a wonder drug' which appeared in the g2 supplement to The Guardian on 29 March criticized Roche's promotion of Herceptin (trastuzumab). In accordance with established practice the matter was taken up by the Director as a complaint under the Code.

The article alleged that Roche, or its public relations agency, tried to use a patient as part of its marketing strategy. It was also alleged that Roche organized a think tank for journalists paying each £250 for their time and giving them dinner in an expensive restaurant. The journalists were asked for their opinions on how best Roche could get stories into the media about its medicine for breast cancers that had spread to the bones.

The Panel noted that the article referred to a conversation between a named breast cancer patient and the spokeswoman from Roche who was reported [illegible] we're running a big campaign to [illegible]rceptin ...' and 'Either we could find

not provide information for publication. Confidentiality agreements were signed. [Note: Roche subsequently admitted that, due to an error, confidentiality agreements had not in fact been signed on this occasion.]

The Panel noted that again the accounts differed. Roche had not provided information to the journalists for publication, it had sought advice from them. On the basis of the information before it, the Panel considered that the activity did not constitute advertising prescription only medicines to the general public nor did it consider that information about medicines had been made available to the public either directly or indirectly. Thus the Panel ruled no breach of the Code.

With regard to the actual meeting the Panel noted that the supplementary information to the 2006 Code specifically stated that meetings for journalists had to comply with the Code. This was a requirement newly introduced into the 2006 Code. The relevant

CASE AUTH/1942/1/07

MEMBER OF THE PUBLIC v JANSSEN-CILAG

Disease awareness campaign on schizophrenia.

A member of the public complained about a schizophrenia advertisement placed by Janssen-Cilag in the Big Issue magazine. The advertisement told readers, *inter alia*, that 'Schizophrenia can be very difficult to live with. But the good news is, with modern treatments there's now a real chance of recovery. So it's very important to discuss with your doctor the choices available'.

Janssen-Cilag produced Risperdal (risperidone) and Risperdal Consta (long acting risperidone for intramuscular injection), an atypical antipsychotic.

The complainant alleged that the claim 'the good news is, with modern treatments there's now a real chance of recovery' was misleading and untrue. There was an implied association between visiting the doctor to discuss choices and the modern treatments available from Janssen-Cilag.

The advertisement led to a website (oneinonehundred.co.uk) sponsored by Janssen-Cilag which the complainant alleged promoted a prescription-only medicine as 'long acting injections' was underlined twice, and 'atypical antipsychotics' was underlined three times. This underlining re-reinforced the link between long-lasting injections and atypical antipsychotics. The complainant noted that Risperdal Consta was the only atypical

epilepsy, depression and bi-polar disorder, this link within the site was deeply sinister; it was an attempt to condition patients with schizophrenia to the possibilities of 'pace-makers for the mind', ie neuroleptics delivered direct to the brain by surgical implant, in the not too distant future.

The Panel noted that the advertisement had been published in the lay press. Schizophrenia was a chronic condition. The Panel considered that some lay people, particularly those who knew very little about schizophrenia, might assume that recovery meant elimination of the illness, particularly as the advertisement referred to a 'real chance' of recovery in the context of 'modern treatments' and described this as 'good news'. The advertisement was misleading in this regard. A breach of the Code was ruled.

The Panel noted that whilst the advertisement referred to modern treatments there was no direct or implied reference to a specific medicine. There were several 'modern' treatment choices. The Panel did not consider that the statement at issue promoted a specific prescription only medicine to the public or would encourage patients to ask their health professional to prescribe a specific prescription only medicine. No breach of the Code was ruled.

The Panel noted that throughout the website certain

CASE AUTH/1936/12/06

PARAGRAPH 17/DIRECTOR V SCHERING HEALTH CARE

Advertisement to the public and a website

During the consideration of Case AUTH/1921/11/06 the Panel was concerned about an advertisement feature issued by Schering Health Care and published in the Marks & Spencer magazine, Christmas 2006. The advertisement was headed 'Time for you to take control' and was about long acting reversible contraception (LARC). A highlighted box of text described various LARC methods available. The first was the intrauterine system (IUS), which readers were told released 'progestogen where needed, so you only absorb a low dose of hormones' and was even more reliable than the pill. Comparable data, where appropriate, was not given for any of the other LARC methods referred to (implant, injection and intrauterine device (IUD)). The Panel was concerned that by giving more positive data about the IUS than the other methods the material was not balanced and some women might be encouraged to ask their doctor or other health professional to prescribe that method. The Panel noted that Schering Health Care marketed, Mirena (levonorgestrel), the only IUS available in the UK.

The Panel was further concerned about the content of the Schering Health Care website www.modernmotherhood.co.uk referred to in the advertisement. The home page featured a box 'The GP is in!' which linked readers to frequently asked questions about LARC and to the real life experiences of five mums. Each of the women

website only related to women using the IUS that section was not balanced. Schering Health Care should have ensured that each type of LARC was represented by case studies. The material would encourage women to ask for the IUS which in effect would be a request for Mirena. The Panel ruled a breach of the Code.

COMPLAINT

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Experience from the ABPI Code (UK)

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- Complaints about consumer communications considered in great detail and ruled on
- Well established adjudication body with independent and lay membership
- Leads to a continuously refined understanding of what is, and what is not, acceptable
  - Beyond the words in the legislation and code
- Commitment from companies to comply

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Public-private partnerships providing patient friendly information

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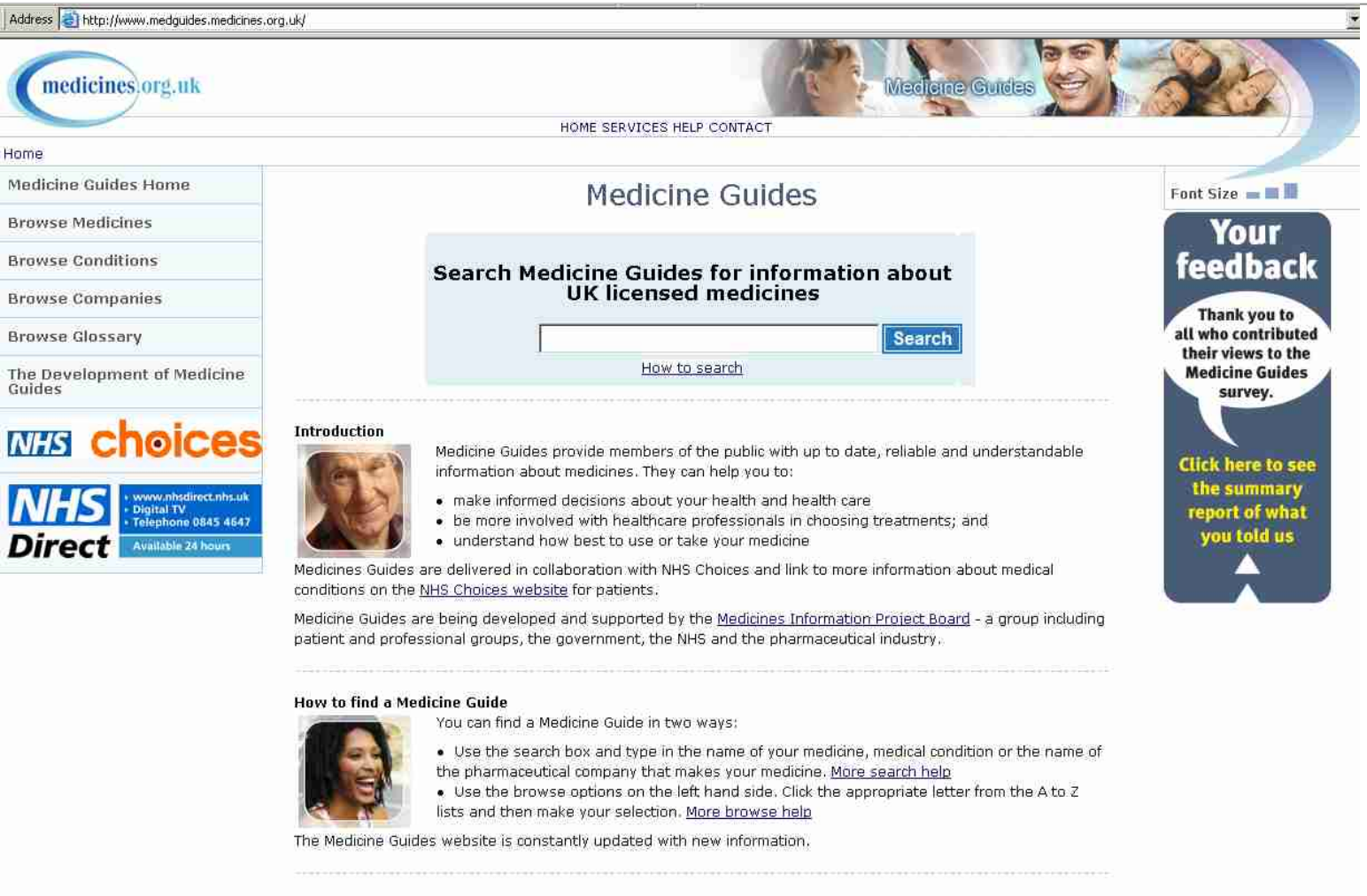

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Public-private partnerships providing patient friendly information

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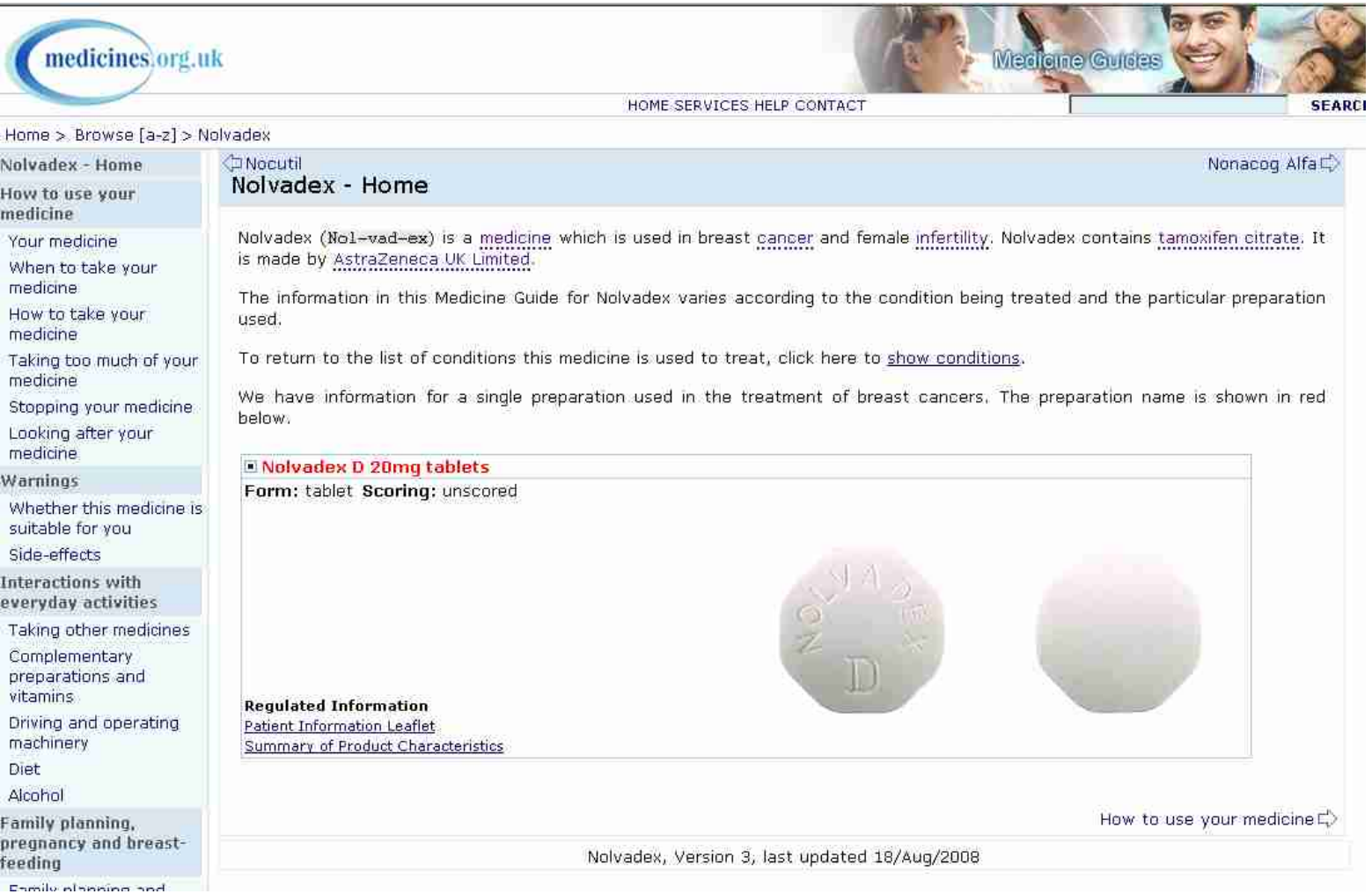

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Company Internet information on its medicines

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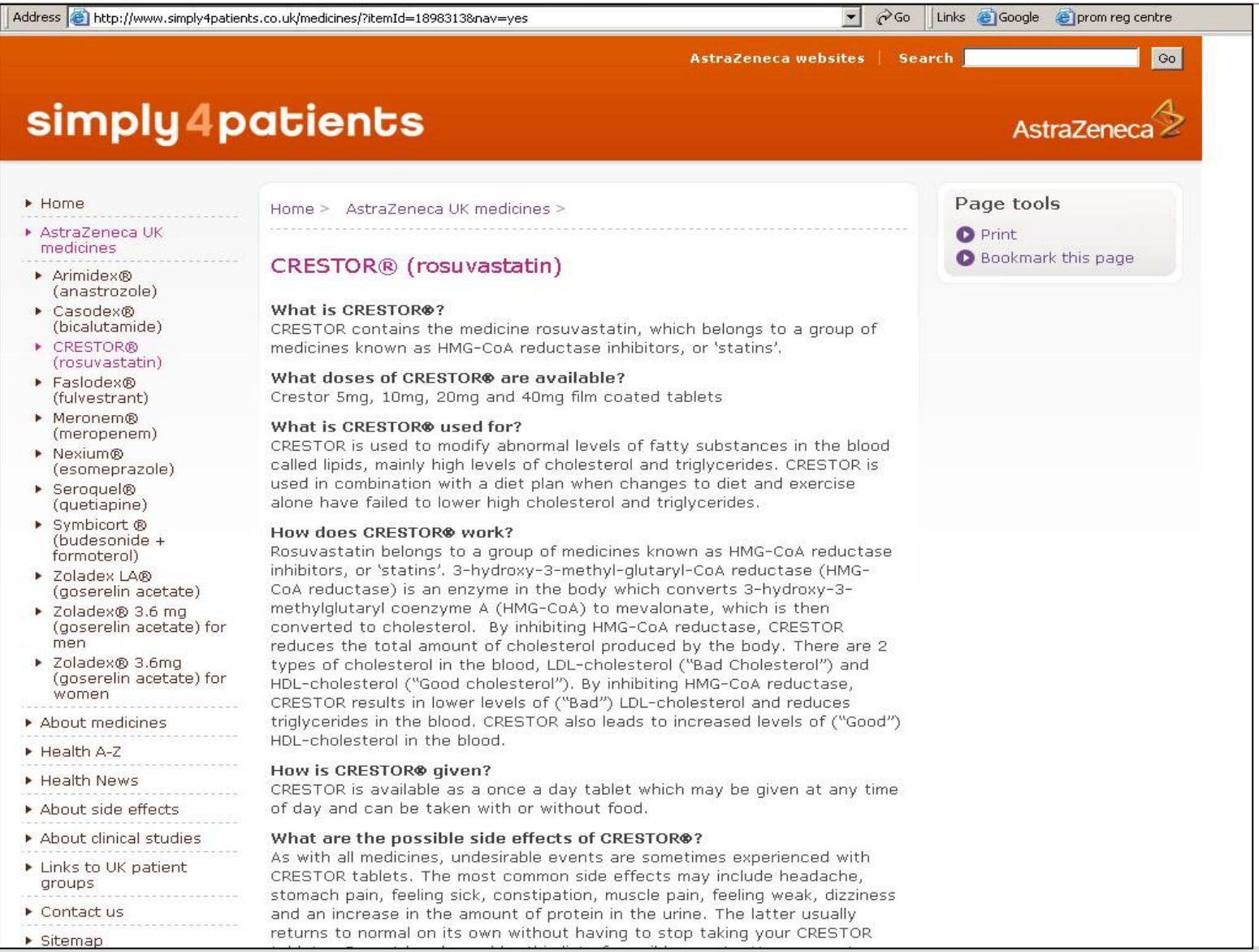

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Outlook for the Proposal:

What's next?

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The way ahead: co-decision

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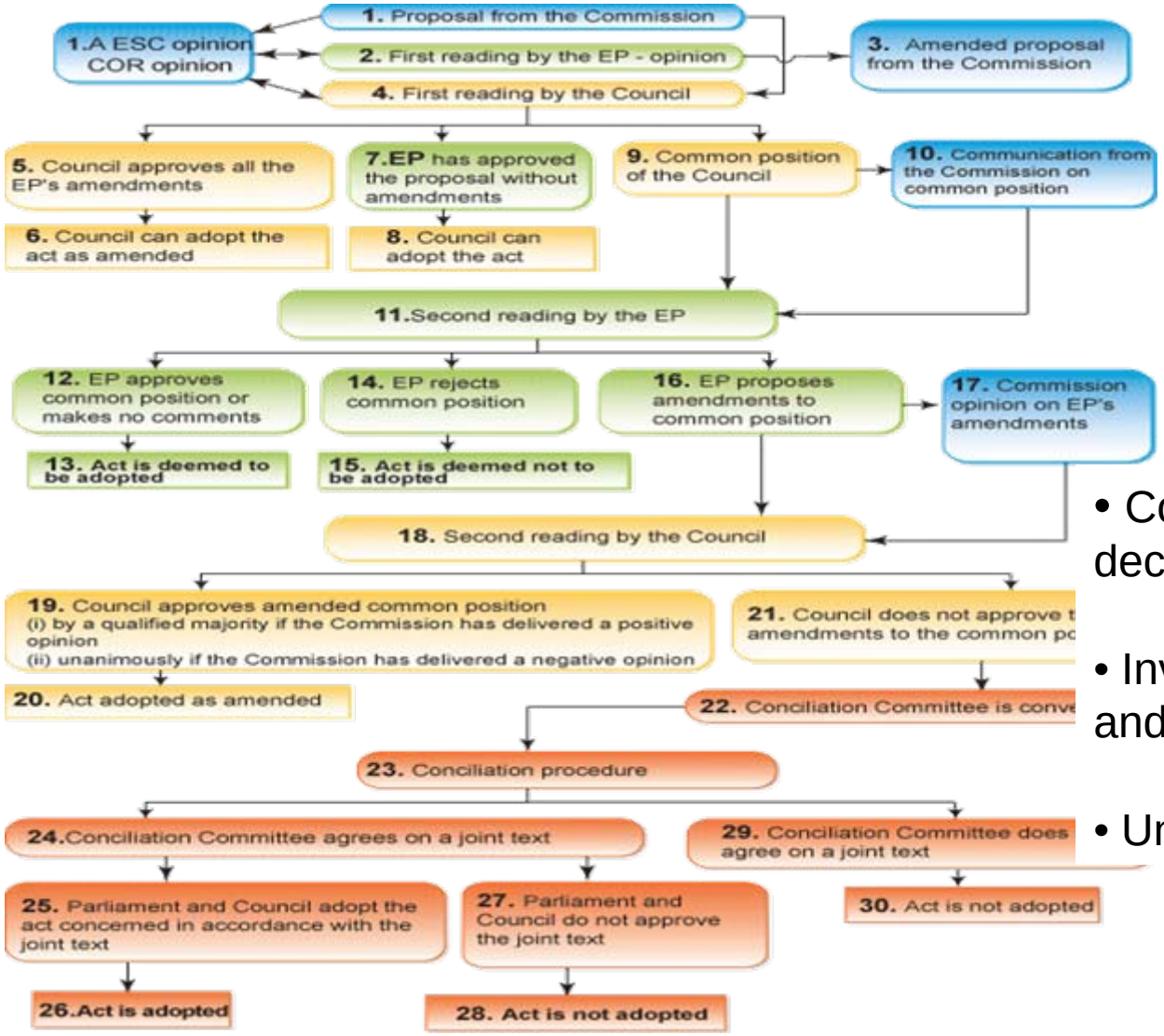

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- Complex EU co-decision procedure
- Involves Parliament and Council)
- Unpredictable results

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EU decision making

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"Laws are like sausages. It's better not to see them being made."

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Otto von Bismarck (1815 – 1898)

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Proposal: Outlook

- The proposal is part of the Pharmaceutical Package:
  - Together with the proposals on fighting counterfeit medicinal products and pharmacovigilance
  - Published together on 10 December 2008 but legislative processes are independent (one can be adopted before the others)
- Very controversial proposal:
  - Opposed by a number of Member States and various stakeholders
  - Internal divergences of position within Commission
- Current status: European Parliament competent Committee to adopt 1st reading draft report
- Progress of the legislative process further delayed by approaching European Parliament elections and appointment of the new Commission
- Unlikely approval of the text before 2010; implementation in Member States after 2012