Deconstructing the EU Commission's meaning of *'information to patients'*

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POLICY BRIEF

Background

Directive 2001/83/EC on the Community code relating to medicinal products for human use prohibits the advertising of prescription-only medicines to the public.

In 2001, during the pharmaceutical review, the Commission attempted to launch a pilot project authorising direct-to-consumer-advertising (DTCA) on prescription-only medicines to treat asthma, diabetes and AIDS. For public health reasons, this proposal was categorically rejected by the European Parliament and Council in 2003.

The Commission was mandated, through article 88a of Directive 2004/27/EC, to present a report in 2007 on "current practice with regard to information provision – particularly on the Internet – and its risks and benefits for patients". The Commission officially adopted and submitted the report to the European Parliament and Council on 20 December 2007. This report was highly criticised because of its poor quality, lack of clear methodology, and its surprising conclusions, favouring direct public communication by manufacturers.

During 2007, the European Commission, particularly DG Enterprise and Industry, held numerous consultations on 'information to patients'. On every occasion, the responses clearly indicated that the vast majority of stakeholders were vehemently opposed to direct-to-consumer communication by pharmaceutical companies.

In 2008, the Commission conducted a second consultation, between February and early April to address the key ideas of a legal proposal on information to patients. Again, the wider public health community unanimously stated that the pharmaceutical industry cannot be a reliable source of unbiased information due to an obvious and unavoidable conflict of interest.

Despite this opposition, the directive proposal was finally adopted on 10 December 2008 by the European Commission, as part of the pharmaceutical package. The new directive opens the door to direct promotion by pharmaceutical companies.

Key elements of the legal proposals

- Direct information from the pharmaceutical industry to the general public on prescription-only medicines is allowed; advertising remains theoretically forbidden but, as many stakeholders already explained during the consultations process, it is not possible to distinguish this "information" from "disguised advertising". The same problem was highlighted during the previous pharmaceutical review in 2001.
- Content: Article 100b outlines the content that will be allowed to be disseminated:
  - Summary of Product Characteristics (SPC) and package leaflets, as approved by competent authorities;

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- Information that does not go beyond the above mentioned but presents it in a different way;
- Prices, information on pack changes or adverse-reaction warnings;
- Information on non-interventional scientific studies or accompanying measures to prevention.

- Harmonised quality standards (are referred in art. 100d). Information should not include comparisons between medicinal products.
- Authorised channels for provision of information are outlined in Article 100c:
  - Health related publications defined by member states
  - Internet websites
  - Correspondence in response to written requests
- Obligation for Member states to establish a monitoring system (art. 100g) prior to dissemination of information, through self-regulation or co-regulation.

Major problems with the Commission's proposals

Disseminating the officially approved documents (art. 100b a) on prescription-only pharmaceuticals, namely the SPC and package leaflet on pharmaceutical companies' websites is already authorised by current EU legislation. Hence, there is no real need for changes to allow its publication on marketing authorisation holders' websites. Actions at the Member States' level would be sufficient to tackle asymmetrical enforcement.

The proposed article 100b (clauses b, c, d) raises grave concerns:

To allow the pharmaceutical industry to rewrite package leaflets (art. 100b b) and to communicate on non-interventional studies (art. 100b d) is problematic. These two possibilities will lead to the public dissemination of promotional information on prescription-only medicines. It is inefficient to have two types of leaflets circulating: one officially approved and a rewritten version produced by the manufacturer. If the officially-approved leaflet is of little use to patients, the focus must be on enforcing the existing regulations.[i]

With regard to non-interventional studies (art. 100b, clause d), even the Commission, in the public consultation on pharmacovigilance (point 3.2.5), recognised that they are "often of poor quality and frequently promotional".

Art. 100b c authorises the provision of "factual informative announcements" on prescription medicines by the industry, which are of little value for patients' treatment regimes but of enormous value as reminder adverts for their products. They are hugely effective at inflating sales through emotive branding images and messages.

Monitoring via ex-ante control by Member States using self-regulation or co-regulation procedures (art. 100 g 2) is not realistic as those with a clear conflict of interest would be handed authority over the information provided to patients and consumers. This inevitably leads to a political debate: should public authorities use their limited resources to act as law enforcers and control the pharmaceutical industry or rather be proactive and invest in validated processes towards the provision of independent and comparative information to the general public?

As the "information", as described in the present proposal would not comparative, the whole directive proposal has no added value, except for pharmaceutical companies. This is a useless exercise for both Europeans and Member States, representing additional bureaucracy and increased costs, at the expense of tax-payers and citizens.

The only real rationale for a change in the current EU legislation is the commercial benefit of expanding the marketing reach for pharmaceutical companies operating in Europe.

Another way forward: Concrete proposals to provide citizens with reliable unbiased information

- A rapid and permanent end to the confusion between the role of pharmaceutical companies and other actors in the healthcare sector;
- Recognition of the many existing independent sources of information in European Union Member States and the role of healthcare providers;
- Development and reinforcement, in each Member State, of the existing sources of reliable comparative information on available treatment options;
- Actions to ensure that pharmaceutical companies consistently abide by their obligations to provide high quality drug packaging and patient leaflets;
- Full enforcement of European regulations on pharmaceutical advertising, including measures to ensure that article 88 of Directive 2001/83/EC is not weakened or undermined;
- A guarantee of the full transparency of drug regulatory agencies, to ensure that the public has access to data on the efficacy and safety of medicines and other healthcare products, both before and after a product is marketed;
- Provisions for the direct consumer reporting of adverse drug reactions, which will contribute to improvements in the use of medicines.

Healthcare has unique characteristics. Patients are not 'simple' consumers. One of the Commission's central responsibilities is protecting the health of European citizens (article 152 of the European Treaty). Support for industrial competitiveness must not be allowed to supersede public health interests.

Increasingly frequent health scandals are ongoing reminders of the medical and legal dangers of the excessive promotion of new medicines. One cannot ignore the consequences of drug disasters for public health but also for healthcare expenditure. These include both direct costs and the cost of managing adverse events.

Many European citizens and health actors are increasingly worried by the commercialisation of healthcare. The Commission cannot continue to ignore the economic implications of deregulation and direct-to-consumer communication by pharmaceutical companies on healthcare expenditures.

To expect Member States to support these costs is irresponsible. The consequences of such measures will be onerous to all, including the pharmaceutical industry.

Executive Agency for Health and Consumers

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[1] Article 59 of Directive 2001/83/EC modified by Directive 2004/27/EC