Editorial: the pharmaceutical package of the European Commission: empowerment for patients?

Benedikt Buchner

Angaben zur Veröffentlichung / Publication details:

Buchner, Benedikt. 2009. "Editorial: the pharmaceutical package of the European Commission: empowerment for patients?" *European Journal of Health Law* 16 (3): 201–6. https://doi.org/10.1163/157180909x453044.

Editorial

The Pharmaceutical Package of the European Commission: Empowerment for Patients?

1. The Pharmaceutical Package

On 10 December 2008 the European Commission presented its pharmaceutical package as a "renewed vision for the pharmaceutical sector".[1] The Commission believes that the pharmaceutical sector in Europe faces enormous challenges: lack of innovation, increasing globalisation, the rise of counterfeit medicines and many other problems. These challenges are to be addressed with a package of measures in order to re-establish the EU as a key location for pharmaceutical innovation. The EU is to be restored to its former role as "the pharmacy of the world".[2] The Commission takes the view that not only the pharmaceutical industry but also — and above all — European patients will benefit from this initiative. According to Commission Vice President Günter Verheugen, all the proposals contained in the Commission's pharmaceutical package build "on the needs and interests of patients" for whom safe, innovative and accessible medicines should be available.[3]

2. Legal Proposal on Information to Patients by Pharmaceutical Companies

The Commission's proposal to amend the provisions of Directive 2001/83/EC[4] on the advertising of and information on medicinal products is a key part of the Commission's pharmaceutical package. According to the proposal, the extensive prohibition of information on prescription-only medicines, as provided by Article 88 of Directive 2001/83/EC, is to be relaxed and pharmaceutical

---

1) Safe, innovative and accessible medicines: a renewed vision for the pharmaceutical sector, IP/08/1924, 10 December 2008.
2) *Id.*
3) *Id.*
4) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

DOI: 10.1163/157180909X453044

companies are to be allowed to disseminate information on prescription-only medicines. The Commission takes the view that pharmaceutical companies are a valuable source for high-quality information to "empower patients, allow informed choices and enhance the rational use of medicinal products."[5]

In accordance with Article 100a of the Commission's proposal, Member States are to allow pharmaceutical companies to disseminate information on prescription-only medicines. This new freedom of information is, of course, subject to some restrictions. Only certain types of information, as specified by Article 100b of the proposal, may be disseminated, e.g., the summary of product characteristics, labelling and package leaflet of the medicinal product, or the content of the former presented in a different way. Not all information channels may be used; the dissemination of information by television or radio is generally prohibited in accordance with Article 100c of the proposal. In addition, the content and presentation of information have to fulfil a number of quality criteria which are specified by Article 100d. Last but not least, various methods of monitoring and control are to prevent pharmaceutical companies from abusing the newly gained freedom of information at the expense of patients.[6]

Although the dissemination of information by pharmaceutical companies is thus regulated and restricted in many ways, the Commission's proposal, if adopted, will bring about a fundamental change of information culture in the pharmaceutical sector. In view of the limited resources of all other actors in the healthcare system, it may be assumed that pharmaceutical companies will eventually become the central mediators for information on prescription-only medicines. The main source for information on medicinal products will then be provided by those who also have a natural interest in increasing the sales of these very products. It is to be expected that pharmaceutical companies will make use of these opportunities.

3. Patients as Empowered and Proactive Healthcare Consumers

The Commission's promotion of entrepreneurial freedom of information has met with ready acceptance, even more so because it is supported by the argument of the empowered patient. In the course of the pharmaceutical package initiative the Commission, like many others before, has discovered patients as empowered and proactive consumers. According to the Commission's point of view, the empowered patient plays an increasingly active role and has therefore a right to be informed and be given access to information about his health, medical conditions

---

[5] Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use, COM/2008/0663 final, 10 December 2007, 5.2 (10).

[6] Cf. Art. 100g et seqq. of the proposal.

and the availability of treatments: "Patients are no longer simply taking what is prescribed for them, but are increasingly involved as managers of their health".[7] The Commission takes the view that the public authorities are not able to adequately serve the empowered patient's need for substantial information, which should therefore be provided by pharmaceutical companies in order to ensure that any important information is available to the patient who can then communicate with his physician at an equal level.

Viewed from this perspective, the Commission's proposal is a compliment to us all in our role as empowered patients. While the extensive ban on information on prescription-only medicines was based on the assumption that we are not able to deal with a complex product like the medicinal product and it should therefore be the physician who informs us and then makes the choice for us, this scepticism has given way to a quite contrary view: the concept of the empowered patient which is based on the belief that we as patients are able to deal with complex information and are thus entitled to this information, irrespective of its source.

It is difficult to disagree with such a benevolent concept and to run the risk of being accused of state paternalism by pleading for the retention of the extensive ban on medicinal information. However, the Commission and all other advocates should be prepared to be asked what their general confidence in the empowered patient and his rational behaviour in everyday life is based on. Supporters of the concept of the empowered patient generally fail to explain their confidence, and it seems that empowerment is a given fact for them which requires no further explanation.

4. The Fiction of Empowerment

The legal concept of the empowered patient is based on the hypothesis of the rational and egoistic individual who strives to maximise his personal benefit in a rational way, who obtains information, and is able to process this information in an optimal way.[8] This hypothesis of the rational and egoistic individual has always been *the* central paradigm of economic theory, although it receives increasing criticism as cognitive psychology and social psychology have found much evidence that shows that the behaviour of human beings is frequently not fully rational.[9]

In everyday life, people are in fact subject to a multitude of rationality deficits and their behaviour is at best of "bounded rationality". Evidence has shown that

---

[7] Draft report on current practices with regard to the provision of information to patients on medicinal products, 19 April 2007, p. 12.

[8] H.B. Schäfer, C. Ott, *Lehrbuch der ökonomischen Analyse des Zivilrechts* (Berlin, Heidelberg, New York: Springer, 2005), p. 64.

[9] D. Kahneman and A. Tversky, Rational Choice and the Framing of Decisions, 59 *The Journal of Business* (1986) 251-278.

most of us regularly overestimate ourselves and our own abilities.[10] In consequence, we lack the ability to realistically judge in which situations we cannot understand information and should therefore leave the information processing and the decision to a competent third party, i.e. to our physician. Many of us also act irrationally because we are influenced by the so-called framing of information: depending on the ways in which information is presented, our interpretation of it varies to a large extent. When patients are advised on whether to undergo a high-risk operation or not, empirical evidence shows that the rate of patients deciding to undergo the operation is significantly higher if they are told that there is a survival rate of 70 % than if they are told that there is a mortality rate of 30 %.[11] It is the way in which information is presented that ultimately decides the behaviour of patients in a specific situation.

People generally experience difficulties in dealing with probability and in particular with low probability.[12] This is frequently a prerequisite for a rational decision, though, and particularly so in the case of medicinal products which always involve probability considerations: the probability of side effects, the probability of a cure or the probability of not experiencing a relapse. There are innumerable further barriers to rational information processing: the problem of too much information ("information overload"); the problem of selective perception of information — the focus is on desirable information while undesirable information is suppressed as far as possible; the problem of the emotional processing of information, especially in case of illness; and last but not least the problem that patients are faced with highly professional enterprises who are aware of all these irrationalities and will make use of this knowledge in their marketing efforts.[13]

Patients are thus not fully, but at best limitedly empowered, their rationality is a limited one, and there can be no justification for ignoring this limited rationality. The standard argument of the empowered patient therefore cannot sufficiently legitimate the relaxation of the ban on information on prescription-only medicines.

5. Patient Empowerment through Better Information?

If the objective is indeed patient empowerment, this will not be achieved by a mere increase of information but only by the *improvement* of information on

---

10) D. Griffin and A. Tversky, The Weighing of Evidence and the Determinants of Confidence, 24 *Cognitive Psychology* (1992) 411-435.

11) B.J. McNeil, S.G. Pauker, H.C. Sox and A. Tversky, On the Elicitation of Preferences for Alternative Therapies, 306 *New England Journal of Medicine* (1982) 1259-1262.

12) Schäfer and Ott, *Lehrbuch*, p. 69.

13) Cf. e.g. B.K. Lee, W.N. Lee, The Effect of Information Overload on Consumer Choice Quality in an On-Line Environment, 21 *Psychology and Marketing* (2004) 159-183, on the problem of information overload, or A. Keselman, A. Browne and D. Kaufman, Consumer Health Information Seeking as Hypothesis Testing, 15 *The Journal of the American Medical Informatics Association* (2008) 484-495, on the problem of selective perception of information.

medicinal products. A basic prerequisite for patient empowerment is the provision of patients with high-quality information, i.e. information which is accurate, complete, and made available to an adequate extent. Whether these quality standards can be guaranteed by pharmaceutical companies seems more than doubtful; it is questionable whether the primary criterion governing the information policy of companies is really the quality of information, or rather the value of information for the sales of their own products. Pharmaceutical companies are not independent and transparent mediators of information; they cannot be compared with physicians who are only committed to the well-being of their patients. Like all other enterprises, pharmaceutical companies are profit-oriented and view patients mainly as customers, not aiming to inform them as best as possible, but to subject them to advertising in order to increase sales of their own medicinal products.

Of course, the Commission's proposal has also taken this aspect into account and therefore included a number of restrictions and quality standards for information on medicinal products provided by pharmaceutical companies. This is to ensure that only" high-quality non-promotional information" about the benefits and risks of medicinal products may be disseminated.[14] However, whether this goal can be achieved is questionable. Requirements for the quality of information like "objective and unbiased"[15] or "reliable, factually correct and not misleading",[16] may appear very convincing at first sight. However, it is frequently unclear and controversial even among experts which information can actually be defined as "unbiased", "reliable" or "factually correct" where medicinal products are concerned. There remains considerable scope for interpretation of all these and other quality criteria. Pharmaceutical companies will be prepared to use this scope in a way that first of all favours their own products.

Similar objections are also to be raised to the admissible types of information on medicinal products which may be disseminated according to Art. 100b. Some of these may be clearly defined, e.g. the "summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities" (Art. 100b (a)). Other types of information, as for example "information which presents the medicinal product in the context of the condition to be prevented or treated" (Art. 100 b (d)), are so unspecific that any information might fall under this definition. The Commission's proposal thus provides extensive freedom of information for pharmaceutical companies; this freedom might be restricted on paper, but in fact these restrictions are of marginal practical significance.

---

14) COM/2008/0663 final, 5.2 (10).
15) Art. 100d (1) (a).
16) Art. 100d (1) (e).

6. Conclusion

The Commission claims that its legal proposals take the needs and interests of European patients into account and that the relaxation of the ban on prescription-only medicines will allow informed choices and promote the rational use of medicinal products. However, this is not convincing. The general argument that patients have become more empowered and proactive consumers of healthcare cannot conceal that patients are subject to a multitude of rationality deficits. "More information" therefore cannot be automatically equated with "improved decision-making" of patients. Informed decisions and the rational use of medicinal products do not depend on the quantity, but on the quality of the information which is available. The latter cannot be guaranteed by the restrictions and quality standards imposed on medicinal information by the Commission's proposal, as these are too general and uncertain in character. Last but not least, it is not to be expected that Member States will prevent misuse of the newly gained freedom of information "through adequate and effective methods of monitoring", as provided by Article 100g of the Commission's proposal. So far, Member States do not even have sufficient capacity to monitor the extensive and thus unambiguous prohibition of medicinal information. It is unclear how they are supposed to find the financial and personal resources to attempt to manage the information flood which is to be expected if the ban is lifted and to control the quality of individual information.

The conclusion therefore is rather disillusioning. Although the Commission may present its action as a step towards more high-quality information from which European citizens will benefit,[17] the relaxation of the ban on medicinal information is rather a step in the opposite direction — towards an uncontrollable information overflow which will prevent, rather than promote, informed choices and a rational use of medicinal products.

Benedikt Buchner*
Professor of Civil, Health and Medical Law,
Institute for Health and Medical Law,
University of Bremen, Germany

[17] Citizen's Summary, Commission Communication on the Pharmaceutical Sector, 4.

*) LLM, UCLA.