

Deutsches Netzwerk Evidenzbasierte Medizin [German Network for Evidence-based Medicine]

Response to the position paper on the LEGAL PROPOSAL ON INFORMATION TO PATIENTS

The German Network for Evidence-based Medicine shares the concerns of the European Commission that high standards of patient information need to be ensured in the European Union.

Citizens and patients want and need valid, evidence-based patient information in order to

- understand their disease and its symptoms and put them into context,
- be able to weigh the harms and benefits of a treatment,
- find the best treatment that is consistent with their preferences,
- find the best therapist.¹

This information must be evidence-based, objective, unbiased, independent and understandable.^{2 3}

The proposal of the European Commission is to maintain the ban on prescription drug advertising; but at the same time it seeks to create a framework for the pharmaceutical industry for providing patients and health care professionals with information about their products and also allowing for the use of radio and television as their dissemination media.

The German Network for Evidence-based Medicine very decidedly disapproves of these plans.

The pharmaceutical industry – as was also demonstrated in a World Health Organisation⁴ study that was co-funded by the European Commission – cannot be regarded as a suitable source of independent, objective and unbiased patient information.⁵

In this context it is important to consider the following aspects:

The industry primarily pursues the legitimate aim to make profits. It hence always seeks to present its products as particularly attractive and valuable. We cannot reasonably expect the industry to provide information on its own products that would make them appear in an unfavourable light.

Even theoretically, a sharp distinction between (open-to-outcome) information and (influential) advertisement is difficult to draw. Practically, making a distinction between advertising and non-promotional information might also prove very difficult in the individual case. For a good reason the term “conflict of interest” is defined not by the outcome of an activity or

a judgement, but by the conditions that might influence this activity or this judgement.^{6 7} The pharmaceutical industry has an irresolvable institutional conflict of interest regarding the development of independent patient information.⁸

For what advocates of the pharmaceutical industry regularly call information would – from a neutral perspective – have to be unambiguously categorized as promotional material.^{9 10}

This is why we urgently advise the European Commission to give up on the plan to grant more rights concerning patient information to the pharmaceutical industry.

The German Network for Evidence-based Medicine also recognizes the necessity of ensuring consistent, high-quality patient information within the European Union.

This is why we recommend, among other things, that:

- the existing structures and institutions developing and disseminating independent, evidence-based patient information be supported, and
- the development of industry-independent drug information systems be promoted across the European Union.

Patient information should not be considered in connection with the competitiveness of the pharmaceutical industry. Rather, patient information is exclusively dedicated to the protection of patients. Hence, we recommend that the responsibility for patient information issues be assigned to the consumer rights protection division.

1. Gruhl M, Klemperer D. Nutzerkompetenz durch Qualitätstransparenz. Steuerungskriterium für das deutsche Gesundheitswesen? (User Competence through quality Transparency. A Governing Criterion for the German Health Care System?) *GGW* 2008;8(1 (January):7-16
2. Steckelberg A, Berger B, Köpke S, Heese C, Mühlhauser I. Kriterien für evidenzbasierte Patienteninformationen (Criteria for Evidence-based Patient Information). *ZAeFQ* 2005;99,(6, 07-2005):343-351.
3. Sängler S, Lang B, Klemperer D, Thomeczek C, Dierks M-L. *Patient Information Manual – Recommendations for the Development of Evidence-based Patient Information*. Berlin, 2006.
4. Norris P, Herxheimer A, Lexchin J, Mansfield P. Drug Promotion - What We Know, What We Have Yet to Learn. Reviews of Materials in the WHO/HAI Database on Drug Promotion. World Health Organisation. 2005.
5. Collier J, Iheanacho I. The Pharmaceutical Industry as an Informant. *The Lancet* 2002;360(9343):1405-1409.
6. Thompson DF. Understanding Financial Conflicts of Interest. *N Engl J Med* 1993;329(8):573-576.
7. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, 2006, Updated February
8. Emanuel EJ, Steiner D. Institutional Conflict of Interest. *N Engl J Med* 1995;332(4):262-268.
9. Holmer AF. Direct-to-Consumer Advertising -- Strengthening Our Health Care System. *N Engl J Med* 2002;346(7):526-528.

10. Bonaccorso SN, Sturchio JL. For and Against: Direct to consumer Advertising is Medicalising Normal Human Experience: Against. *BMJ* 2002;324(7342):910-911.

**Deutsches Netzwerk
Evidenzbasierte Medizin
DNEbM e. V.**

Office:

c/o Ärztliches Zentrum für
Qualität in der Medizin
Wegelystraße 3 /
Herbert-Lewin-Platz
D-10623 Berlin

fon: +49-30/4005-2500
fax: +49-30/4005-2555

E-Mail:

kontakt@ebm-netzwerk.de

www.ebm-netzwerk.de