

Joint statement

of the
German Network for Evidence-based Medicine
(Deutsches Netzwerk Evidenzbasierte Medizin e.V.)



and the
patient advocacy group in the Federal Joint Committee
(Patientenvertretung im Gemeinsamen Bundesausschuss)



Berlin, den 30.05.2016

Position on the EUPATI Toolbox

In early 2016 the EUPATI Toolbox was published in German (EUPATI stands for European Patients' Academy on Therapeutic Innovation). It contains a collection of articles and videos designed to explain the process behind the development and approval of pharmaceuticals to patients (<https://www.eupati.eu/de/>).

Some background information on EUPATI: EUPATI is a project with funding of a total of 10 million euro over five years. The project is being supported by the European Union through a hybrid private-public sponsorship. 5 million euro have been provided by the EU, the pharmaceutical industry contributed with another 5 million euro. EUPATI defines its goal as follows: “to help patients be more educated and involved in the research and development process of new medicines by offering reliable, objective, comprehensive lay-friendly information and training on the research and development process of medicines. We will increase the capacity of patients to be effective advocates with meaningful involvement in areas like drug discovery and non-clinical testing, planning and conduct of clinical trials, regulatory affairs, assessment of safety of medicines, benefit-risk assessment, as well as principles of health technology assessment.” (<http://www.patientsacademy.eu/index.php/en/about-eupati>)

The German Network for Evidence-based Medicine (DNEbM) and the patient advocacy group in the Federal Joint Committee (G-BA) welcome the idea of making this kind of information freely available.

However, the information provided does not meet the minimum requirements for the creation of readily understandable patient information.

DNEbM and the patient advocacy group in the G-BA consider the following three aspects especially worthy of criticism:

1. There is no documentation of methodology.

A project of this size should apply international standards of methodology, documentation and publication and provide transparent documentation in the form of a readily accessible report. This is not the case, however. Those not involved with these processes have no means to independently assess whether the information was produced in an appropriate way. This transparency is absolutely essential in light of the fact that industry representatives are directly involved, thereby incorporating different interests in the process.

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Answers to the following questions should be provided and documented in a transparent way:

1. How did EUPATI select the questions that were considered to be relevant from the perspective of the “patients as laypersons”?
2. How did EUPATI search for and select the sources that were used to answer those questions?
3. How did EUPATI test the objectivity and neutrality of the information they produced?
4. How did EUPATI test the comprehensibility of their information for patients not involved in the development of the information?

2. The language and editorial style used are not suitable for a wider target audience of non-specialists.

The language used in the articles is still quite unpolished, and the text contains many technical terms with inadequate explanations. Most of the time no attempt is made to describe the scientific concepts in a way that will be understood by non-specialists.

Specifically, a number of the standards that EUPATI itself has repeatedly stated to be necessary for broader patient target groups have not been followed – in a project targeted at patients. Based on the scope of the project in terms of funding and timeframe, it begs the question why it was not possible to produce higher quality material.

3. Critical aspects of drug development and approval are not discussed.

The perspective presented in the articles largely appears to be an unreflected presentation of the current industry strategies for drug development. This means that critical aspects that could be improved through patient involvement are not mentioned. For example, there is widespread public debate concerning the fact that only some of the newly developed and approved pharmaceuticals are actually therapeutic innovations. There is no critical consideration of when a “new” pharmaceutical is a real “innovation.” And the question of what drug development really costs is ignored completely. Instead, the only figures provided are those offered by the pharmaceutical industry (“1 billion euro”).

These criticisms suggest that the funds dedicated to this project have not been used effectively. This is particularly regrettable considering that the funding of EUPATI was an historic opportunity to close actual gaps in patient knowledge, but that the final product is now of doubtful validity and usefulness due to a lack of transparency, quality and neutrality, as well as poorly communicated conflicts of interest.

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Representing DNEbM

Prof. Dr. Ingrid Mühlhauser
DNEbM Chair

Dr. Klaus Koch
DNEbM spokesperson concerning patient information and patient participation

Prof. Dr. Anke Steckelberg and Dr. Britta Lang
Members of the EUPATI Advisory Board

Representing the patient advocacy group in the Federal Joint Committee

Dr. Martin Danner
Spokesperson for the Patient Advocacy Coordination Committee

The **German Network for Evidence-based Medicine** (DNEbM) promotes the provision of health care for all citizens based on the best scientific knowledge and informed decision-making. The network is made up of researchers from medical, health care and health sciences faculties, practicing physicians and other health care professionals (www.ebm-netzwerk.de).

Patient advocacy group in the Federal Joint Committee

The legislature has officially recognized a total of four organizations of significance for the awareness of patient interests and self-help for chronically ill and disabled people.

- German Disability Council (Deutscher Behindertenrat, DBR),
- Federal Working Group for Patient Centers (Bundesarbeitsgemeinschaft der PatientInnenstellen, BAGP),
- Federation of German Consumer Organisations (Verbraucherzentrale Bundesverband e.V., vzbv), and
- German Working Group for Self-help Groups (Deutsche Arbeitsgemeinschaft Selbsthilfegruppen, DAG SHG).

These four patient and self-help organizations are currently authorized to appoint patient advocates to work together with the Federal Joint Committee.

(<https://www.g-ba.de/institution/struktur/patientenbeteiligung/>, in German)