

Letter to the Editors

Erice statement on drug innovation

The Erice Statement was developed by a group of experts from different countries meeting strictly in their personal capacities, and expressing their personal views during the international Workshop on Drug Innovation at the Ettore Majorana Centre for Scientific Culture, Erice, Sicily from May 24–27, 2007. They bring with them experience at national and international levels.

General definition

Innovation is a term that may have several meanings, that vary according to the context. The definition should incorporate the concept of an action of introducing a new product into the market, the 'innovative' object newly brought on to the market, and the potential positive effect on users. Thus, a possible definition is: 'The process of making improvement by introducing something new that should potentially yield a benefit for users, in terms of a tangible impact at the level of society'.

Definition in the drug context

An innovation in the field of medicinal products consists of a completely or partially new active substance or biological entity or combinations of such entities acting against a disease, relieving symptoms or preventing a disease through pharmacological or molecular mechanisms, and developed and made available as a medicinal product that can improve the quality of patient management and outcomes. The present definition of drug innovation may also include new indications, technological and manufacturing processes, new formulations (including combinations) and delivery systems of known drugs.

Overall value and innovation

The concept of value of a given drug should not be confused with the meaning of innovation, this being only one of the determinants of the overall value of a drug.

While the definition of innovation should be general, comprehensive and invariant across settings and con-

texts, the concept and the ratings of the 'value' of a given drug could vary among different countries (according to public health needs, disease priorities, epidemiology, health-care system organization, different economies, access to medicinal products and pharmaceutical markets), different cultural settings, population/ethnic groups with different genetic backgrounds. For these reasons, and differently from the definition of innovation, value cannot be decided on in general terms, and it can also vary over time, according to the availability of new data or new medicinal products in the same therapeutic area, or changes in priorities in public health (e.g. new health emergencies, changing epidemiology).

Evaluation of innovation

The value of innovation could be seen in relation to:

- contribution to scientific knowledge
- public health needs
- patients' needs
- social and economic needs (in relation to the social system and public and private investments for research and development)
- environmental impact

Recommendations

- Promoting valuable innovation in the pharmaceutical field is of paramount importance for patients, society, and economic systems. Such promotion should, however, not only apply to the provision of rewards to innovative authorized products through early reimbursement and/or other tools, but should also ensure support in the early stages of research and development on innovative medicinal products. This could be better achieved through public-private partnerships aiming to better define priorities for research, develop complementarities, and making it sustainable for a broader range of medical needs.

- On the other hand, the status of ‘innovative’ applied to a given medicinal product should not be considered a fixed attribute, but a condition that should be monitored and valued over time, from the preclinical to the clinical phases of research and eventually to utilization of the drug in clinical practice and its value is to be judged in terms of added value, with respect to clinical and humanistic effectiveness, as well as in terms of convenience, utility, and cost.
- An important contribution to the promotion of innovation in the pharmaceutical field could be the development of a consensus methodology to evaluate different aspects of the value of innovative medicinal products.

Actions

The panel believes that an assessment of the presence and amount/level of innovation may be useful, even in the early stages of the research and development process. This activity should be carried out using a transparent process and validated methods. At the moment, several approaches are available, but their performance and validity are often unknown, not consensual, and sometimes questionable. As one action, the panel decided to perform a systematic review of the available methods/tools for the definition of the value of innovation, undertaking an appraisal of their value in terms of availability of empirical data on validity, reliability and applicability, and a test of all selected methods on a common data set.

The statement was signed by

G. Apolone, Mario Negri Institute, Milan, Italy
M. Bassi, Smith Kline Foundation, Rome, Italy
B. Begaud, Université Victor Segalen, Bordeaux, France
I. Cascorbi, University of Kiel, Germany

C. Chiamulera, University of Verona, Italy
A. Doodoo, University of Ghana, Accra
L. Ferro, Gentium, Villaguardia (Como), Italy
G. Ghignoni, Pfizer, Rome, Italy
G. Isola, Inchgower Associates Ltd, Lenno (Como), Italy
Y. Juillet, Les Entreprises du Medicament (LEEM), Paris, France
G. Masotti, University of Florence, Italy
G. Novelli, University Tor Vergata, Rome, Italy
P. Rizzini, Smith Kline Foundation, Rome, Italy
P. Russo, Italian Medicines Agency (AIFA), Rome, Italy
V. Silano, Health Ministry, Rome, Italy
G. Tricarico, Italian League against Cystic Fibrosis, Chiaravalle (Ancona), Italy
G.P. Velo, University of Verona, Italy

For further information contact

Giampaolo Velo, Director, Clinical Pharmacology Unit, and Reference Centre for Education and Communication within the WHO Programme for International Drug Monitoring, University Hospital, Verona, Italy. E-mail: gpvelo@sfm.univr.it
Paolo Rizzini, Vice President and General Secretary, Smith Kline Foundation, Rome, Italy. E-mail: rizzini.fsk@tiscali.it

Received

11 July 2007

Accepted

20 July 2007

Correspondence

G. Velo, Director, Clinical Pharmacology Unit, and Reference Centre for Education and Communication within the WHO Programme for International Drug Monitoring, University Hospital, Verona, Italy. E-mail: gpvelo@sfm.univr.it