European Medicines Agency: an unacceptable choice

Regulators should give priority to trials versus established treatment instead of placebo.

When a new drug is introduced to the market, healthcare professionals and patients want to know how it compares with existing treatments. Unfortunately, data submitted by the company to support its marketing application rarely provide satisfactory answers to this question.

Patients and healthcare professionals are increasingly demanding that all new drugs be compared with standard treatments before they are authorised. Yet, in late 2010 the European Medicines Agency (EMA) launched a public consultation in which it proposed to make this type of comparison the exception, while placebo-controlled trials would become the accepted norm (1).

EMA’s proposal ignores patients’ needs. Not only does EMA’s position ignore current scientific standards which recommend that clinical trials compare a new treatment with the best existing option rather than with placebo, but it also flies in the face of the World Medical Association’s Declaration of Helsinki which states in article 32 that: “The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:

1. European Medicines Agency “Reflection paper on sound methodological reasons the use of placebo is deemed ethical and one or more established treatments are increasingly demanding that all new drugs be compared with standard treatments before they are authorised.” www.emsa.europa.eu accessed 27 April 2011: 7 pages.

The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or

Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subjected to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option” (2).

An unacceptable step backwards. There is a considerable divergence between the EMA’s proposal and international scientific and ethical principles. The Medicines in Europe Forum, Association Internationale de la Mutualité, the International Society of Drug Bulletins (ISDB) and Prescrire call for firm rejection of the EMA proposal (3).

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