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28.02.2005

GUIDELINE ON SIMILAR BIOLOGICAL MEDICINAL PRODUCTS (CHMP/437/04)

Comment of the European Kidney Patients' Federation (CEAPIR)

The European Kidney Patients' Federation-CEAPIR welcomes innovation and advances in medicine. CEAPIR is open to the introduction of the concept of similar biological medicinal products if they add to the well being and treatment of patients.

From the kidney patient perspective, quality, safety, efficacy, documentation and information issues are of paramount importance and essential. The concept touches a new area where experience is only developing.

In this respect kidney patients are worried; Biosimilars might "not work" exactly the same way as the drugs prescribed today (differences in safety and efficacy). It should be obvious that for chronic patients, like kidney patients, medicines are an essential part of their treatment. We can't afford the slightest changes, mistakes or misunderstanding.

Our main question is; how can we be assured that changes in the manufacture of Biosimilars will not affect safety and efficacy of the therapeutic molecule?

Kidney patients demand that the submission of extensive data including clinical trials and pre-clinical tests should be requested for each Biosimilar (same criteria as for referral product).

How to assure that patients really get informed in the case of a substitution of an original product by a copy product?

Patient safety first! A drug can be substituted, a patient(s' health) cannot.

Signed Executive Committee
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