Position of the Medicines in Europe Forum (MiEF) and of the Association Internationale de la Mutualité (AIM) on the

REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC
CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION Draft November 2010

The Medicines in Europe Forum (MiEF) and the Association Internationale de la Mutualité (AIM) will not comment all the points submitted for consultation. We prefer to focus on a few key points and general principles of upmost importance for patients and care givers.

Our comments are referring to part 2 of the concept paper (1).
We do believe a « *risk-adapted approach* » should be enforced as proposed by the Commission and we agree with the general principle of « *harmonised proportionate requirements* » (consultation item n° 9).
Indeed there should be such "proportionate requirements" but we believe this should not be limited to the sole aspect of risk for the patient (consultation item n° 12): the public health relevance, the level of medical need, the equipoise, and the benefit-risk ratio should be duly taken into account in this approach. Because there is no rationale, from the scientific and ethical points of view, of accepting trials whose aim is trivial, obvious, or useless for any therapeutic advance for the patients, whatever the risk.
Clinical trials, because they involve human beings, should be considered as exceptional and duly motivated by the search of important knowledge for medicine and/or for better diagnostic or therapeutic tools.
As regards consultation item n° 11, in MiEF and AIM's opinion, the « *detailed provisions* » of the « *risk-adapted approach* » referred to in section 2.2 are too important as to be simply up-dated by delegated acts (they should not be considered as purely technical). MiEF and AIM prefer instead that they should be a matter of legislation and not of comitology.

Eventually, we agree with consultation item n° 17 about clinical trials in third countries and would like to underline that indeed it's really time to ensure that all clinical trials used to obtain drug approval in Europe are consistent with the best scientific and ethical criteria, being performed in Europe or elsewhere.

Yours sincerely
MiEF and AIM

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1- http://ec.europa.eu/health/files/clinicaltrials/concept_paper_02-2011.pdf