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Info-Document :	**AEMH 13-036**
Title:	**Geographic distribution of clinical trials (EMA Report)**
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Purpose :	**Info-documents disseminated by the AEMH European Liaison Office do not necessarily reflect the opinion of the AEMH and its Board. Info-documents are meant to inform, to raise awareness, to alert, to launch a debate, to incite taking action,.....**
Distribution :	**AEMH Member Delegations**
Date :	**Sent by e-mail 07-05-2013**

EMA report on geographic distribution of clinical trials supports need for revision of European clinical trial legislation

The European Medicines Agency (EMA) issued a report in April on the geographic location of clinical trials for which marketing authorisation applications were submitted to the Agency. The report reveals that over 60% of patients were recruited outside of the European Economic Area (EEA) and Switzerland for pivotal trials. Data is also available for orphan medicinal products and will be made available soon. What does this mean for European Union-based rare disease patients?

The EMA report shows that in the original 15 EU Member States, plus Norway, Iceland and Liechtenstein, clinical studies decreased from 32% to 19% during the period of observation (2005-2011). Consequently, rare disease patients living in these countries and other EU Member States are being deprived of opportunities to participate in clinical studies. The report supports fears that research is being syphoned away from Europe due to the complex, expensive administrative procedures required under Directive 2001/20/EC (the Clinical Trials Directive) which delineates the conduct of clinical trials in the EU.

Leading European medical research organisations, including the European Science Foundation and the Academy of Medical Sciences, are campaigning for reforms to the Clinical Trials Directive, asserting that it hampers research into potentially lifesaving treatments while adding nothing to the patient safety it is supposed to enhance. The Clinical Trials Directive has been blamed for increasing the costs and time to launch trials due to burdensome and complex bureaucracy, and thus driving medical research out of the EU.

Consequently, in July 2012, the European Commission adopted a Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. This process of revision is currently underway. A Draft Report was published in January 2013 and 713 amendments were tabled by the 26 February deadline, including a key Amendment proposed by EURORDIS that assists the reporting Member State and the Member States concerned to provide a well-informed assessment of their application by consulting the Scientific Advice Working Party (SAWP) of the EMA. Considering that expertise for each of the over 6000 rare diseases identified to date is frequently scarce at national level the SAWP is best placed to provide the necessary expertise. The revised Clinical Trials legislation will be put to the vote by the Environment, Public Health and Food Safety Committee of the European Parliament on 29 May. Plenary vote is anticipated in June 2013.

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