Submission: 51

Name of organisation
Europeans for Medical Progress Trust

Stakeholder group
NGO

Country
UK

Address
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Contact Person Name
Dr Margaret Clotworthy

Role in organisation
specialist/expert

Number of employees
1 – 9

Annual turnover (in millions EUR)
0 - 10

Your organisation's geographical area of activities
national

7. In general, how do you view the measures being taken to reduce harm to patients in healthcare settings in your country?
Not at all adequate

31. How important is it for there to be a national reporting and learning system that collects, analyses and monitors information on adverse events and patient safety incidents in your country?
Very Important

32. How important is it for incident and adverse event data and the results of analyses to be evaluated and shared nationally in your country, without being used to discipline individuals?
Very Important

33. How important is it for there to be a national (or regional) organisation (institute, agency etc) that actively seeks out and tries to spread best practice and learning in your country?
Very Important

34. How important is it for the data from national (or regional) reporting and learning systems to be pooled at the EU level as a common resource for learning?
Very Important

45. How important is it for resources to be allocated to patient safety research in your country?
Very Important

46. How important is increased co-operation between EU Member States, supported by the European Community, on the priority-setting, and the commissioning, of patient safety research?
Very Important

47. How important would a database at the EU level be, which would bring together results of patient safety research and other learning and experiences, to be used as a common European resource?
Very Important

48. How important are I.T tools aimed at providing health professionals with relevant, timely and up-to-date information, such as comprehensive electronic health records, decision support systems, e-prescription support and IT-based surgery training, to efforts to reduce harm?
Very Important

49. In which areas of patient safety do you think more research needs to take place, if any? Possible areas include research on the extent of harm, the type of harm, on patient safety interventions, on the economic costs of harm, on harm outside the hospital setting and any others you feel are currently under-researched.
As a patient safety charity whose focus is on the improvement of human health by the introduction of safe new medicines, we are deeply concerned that current preclinical testing requirements are out-dated and do not reflect the current state of the art. By making (unvalidated) toxicity tests on animals compulsory, the emphasis is on ticking boxes rather than on implementing the newest & most relevant techniques. This is a waste of precious time & money, and provides the public & prescribing doctors with a false sense of security. The most recent & most dramatic instance of this was the Northwick Park hospital clinical trial disaster in March 2006 in London, where 6 healthy young men almost died after taking a new drug shown to be safe at 500x the dose in monkeys. We would like to see an evaluation, perhaps sponsored by the Innovative Medicines Initiative, to directly compare the ability of animal tests to predict human outcomes with the ability of a battery of the latest tests (microdosing, human tissues, tissue culture, microarrays, VaxDesign's MIMIC system, in silico prediction tools etc) to do so. To keep costs and time to a minimum, a panel of drugs for which both human and animal data is already available should be chosen. We believe that this would be a highly efficient & effective means of streamlining the drug safety testing process & ensure safer (& more effective) drugs reached clinical trials & ultimately patients.

50. If you answered positively to Question 47, what type of information should be held centrally?
Anonymised patient records, lifestyle information & outcomes of any trials.

60. What (further) action needs to take place in your country at the national, regional and/or local levels to improve patient safety?
Current preclinical testing requirements are out-dated and do not reflect the current state of the art. By making (unvalidated) toxicity tests on animals compulsory, the emphasis is on ticking boxes rather than on implementing the newest & most relevant techniques. This is a waste of precious time & money, and provides the public & prescribing doctors with a false sense of security. Many new technologies are already being used at various points by innovative pharmaceutical companies, because they recognise their value. The time is clearly ripe for an independent scientific evaluation to directly compare the ability of animal tests to predict human outcomes with the ability of a battery of the latest tests (microdosing, human tissues, tissue culture, microarrays, VaxDesign's MIMIC system, in silico prediction tools etc) to do so. To keep costs and time to a minimum, a panel of drugs for which both human and animal data is already available should be chosen. Industry could perhaps provide sponsorship in kind by performing some of the new tests on the chosen drugs, with further funding and statistical analysis being

provided by an independent body.We believe that this would be a highly efficient & effective means of streamlining the drug safety testing process & ensure safer (& more effective) drugs reached clinical trials & ultimately patients.

61. In which areas of patient safety should the European Community play a role in supporting Member States in their efforts to address patient safety concerns and how should this support work in practice?

The European Innovative Medicines Initiative represents the ideal mecahnism for funding / part-funding an independent scientific evaluation (as described above, Q60) to determine the most effective & efficient means of safety testing new drugs before they reach clinical trial volunteers and patients.