



*Italian Embassy  
London*

## **Science Seminar Series 2008**

Under the auspices of the Italian Medical Society of  
Great Britain

**Professor Silvio Garattini**  
**Director, Istituto "Mario Negri"**  
**Milano, Italy**

### **"The Bias of Pharmacological Clinical Trials and the European Legislation"**

Randomized clinical trials are the best way to obtain evidence in medicine but unfortunately trials for drug evaluation suffer a number of limitations. Scientific literature has reported a number of biases, generally connected with the large-scale financial interests characterizing the medicinal products market. Exclusion of the elderly, women and children, small numbers of patients, use of non-inferiority or equivalent designs, lack of therapeutically sound end-points, differences between protocols and conduct of the trial, selective publication of positive rather than negative trials, and conflicts of interest are some of the biases that will be described in the lecture. In addition, the effects of the European legislation on the activity of the regulatory agencies will be discussed, with particular focus on the lack of any requirement to show 'added value' and the excess of confidentiality in the procedure for approving new drugs.

Silvio Garattini is founder and director of the Mario Negri Institute for Pharmacological Research. Former President of the UICC Committee on Antitumor Chemotherapy, of the European Organisation for Research and Treatment of Cancer (EORTC), and of the European Society of Biochemical Pharmacology. Former consultant to the WHO and a member of the Committee for Proprietary Medicinal Products of the EMEA. Fellow of the New York Academy of Sciences, of the American Association for the Advancement of Science, a Honorary Fellow of the Royal College of Physicians, London, and a member of numerous other Italian and international scientific societies

**Tuesday 10<sup>th</sup> June 2008**

**6:00 pm**

**Italian Cultural Institute  
39 Belgrave Square  
London SW1 8NX**

**Tea and coffee will be  
served from 5:30 pm**

**There will be an  
opportunity to meet the  
speaker after the  
seminar at 7:00pm**

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