Venous thromboembolism and the pill

Learning from the past: a response from The Committee on Safety of Medicines

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Dr Benagiano’s opening debate (Benagiano, 1998) raises several important issues. His suggestion—that regulatory authorities should only act after publication of the relevant data,—would, if accepted, seriously endanger public safety. For it is, of course, regulatory authorities and not the editors of scientific journals who are ultimately responsible for protecting the public health. Failure of a regulatory authority to act in the face of a hazard, merely because the relevant data had not been published, would have unfortunate public health consequences and could be tantamount to negligence.

Dr Benagiano appears to be unaware that modern drug regulation incorporates a process of peer review which goes far beyond that of any scientific journal. The UK’s Medicines Control Agency (MCA) and Committee on Safety of Medicines (CSM) have, collectively, scientific expertise that would be the envy of any journal editor. Moreover, writing as someone who has been involved in the peer review process on many hundreds of occasions, the time and effort expended by the CSM and MCA in reviewing important new evidence is an order of magnitude greater than that involved in peer review for a journal.

It is, obviously, preferable for the regulatory position to be coordinated with publication of the data so that the evidence is available to all. This is, indeed, our policy to do so wherever possible, and I am grateful to journal editors for facilitating this. Last year, for example, we were able to ensure that the publication the meta-analysis of Hormone Replacement therapy and breast cancer (Collaborative Group on Hormonal Factors in Breast Cancer, 1997) Breast cancer and hormone replacement therapy: collaborative reanalysis of data from 51 epidemiological studies of 52 705 women with breast cancer and 108 411 women without breast cancer. Lancet, 350, 1047–1059

Committee on Safety of Medicines, London, UK.

References


