Transparency of Clinical Trial Data on Medicines in the EU

Introduction

Estimates indicate that 5% of all hospital admissions are caused by an adverse drug reaction (ADR)1 and that ADRs are the fifth most common cause of hospital death.2 Discussions on the safety of medicines have intensified due to recent drug withdrawals in Europe. Two of the cases relate to the recommendation of the European Medicines Agency (EMA) to withdraw the diabetes drug benfluorex (Mediator®)3 and the decision by the French medicines regulatory agency to withdraw cyproterone acetate/ethinyl estradiol (Diane 35®).ii 4 5 6 These decisions were taken because of associated adverse health events.

This policy paper argues that deficiencies in the current model for reporting scientific research increase patients' exposure to the risk of an adverse drug reaction.7 Prevailing practices of 'publication bias' – i.e. studies are published or not depending on their results- and the selective non-reporting of outcomes within published studies prevent the full effect of a medicine from publicly known. 8 In fact, reporting bias, a common phenomenon in biomedical literature, results in the overestimation of the benefits of a medicine and an underestimation of the harms. 9 10 It is estimated that only half of all studies first presented as abstracts have been published in full11 and that positive trial data is twice as likely to be published when compared to negative results.12

Reviews of previously unpublished, detailed, clinical trial data by independent researchers have often contributed to a better understanding of the risk-benefit profile of medicines.13 14 15 For example, the independent meta-analysisiii of trials for the diabetes medicine rosiglitazone (Avandia®), which included unpublished trial data, was critical in demonstrating that the risk of myocardial infarction (heart attack) and cardiovascular induced death were significantly increased.iv 16 Independent reviews of clinical trial data are therefore of utmost importance in medicines safety assessment. Indeed, they can bring additional insight onto pharmaceutical therapies and thereby contribute to evidence-based medicinev.

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