

**IPCRG and EFA submit comments to the European Commission Consultation:
An Assessment of the Community System of Pharmacovigilance**

On 12 May 2006, the International Primary Care Respiratory Group (IPCRG) and European Federation of Allergy and Airway Diseases Patients' Associations (EFA) submitted comments to the European Commission's Public Consultation regarding "An Assessment of the Community System of Pharmacovigilance".

IPCRG and EFA are very pleased about the opportunity to comment on the current EU pharmacovigilance system and agree with the core recommendations¹ in the EU-commissioned study "*An Assessment of the Community System of Pharmacovigilance*" conducted by the Fraunhofer Institute².

In their submission, both organisations welcome moves towards a common pharmacovigilance database, but point to potential shortfalls of adverse event monitoring: many databases prove challenging, since the recording is often haphazard and dependent on the prescribing physician recognising a connection between the intake of the medication and an adverse event which might occur only a considerable time afterwards. Such event monitoring would, for example, not have picked up less clearly linked events such as an increased risk of asthma deaths in association with the sole (i.e. without combining them with inhaled steroids) prescription of long-acting beta agonists. It is also likely to under-report problems associated with the use of medicines that are either unlicensed, as it is often seen in paediatric practice, or used beyond their licensed dosages. This can be noticed, for example, in the high and unlicensed dosages of inhaled steroids as well as older nasal steroids for infants.

IPCRG and EFA would therefore propose proactive methods to evaluate the safety of all newly licensed medications and also of those with any existing concerns. In so doing, greater consideration should also be given - to how to make use of patient organisations, given that patients are currently an underutilised source of adverse event reporting. Furthermore, primary care networks should be included and supported, since adverse events may only be noted in primary care settings, even if a drug is prescribed predominantly in specialist practices.

Finally, IPCRG and EFA would advocate greater consistency of internal actions of the European Medicines Agency (EMA) at working party level, as well as a streamlining of the liaison with national regulators.

Both organisations look forward to receiving feedback from the European Commission on their comments and learning about next steps.

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http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance_acs/docs/acs_consultation_final.pdf

² Fraunhofer Institute Systems and Innovation Research in collaboration with the Coordination Centre for Clinical Studies at the University Hospital of Tuebingen



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