EFVV
EUROPEAN FORUM FOR VACCINE VIGILANCE

PRESS RELEASE

European patient groups call for tougher vaccine laws

European patient groups are calling for a mandatory surveillance system for routine vaccines after safety concerns at the end of the EU Immunisation Week (April 23-30, 2011). This would include training for GPs to recognize adverse vaccine reactions; a campaign to boost public awareness of how to report vaccine side effects, and vaccine status of hospital patients to be routinely taken on admission.

The World Health Organisation (WHO) supported the European Immunisation Week as a chance to promote widespread vaccination. However, on April 21, the WHO's Global Advisory Committee on Vaccine Safety (GACVS) stated that further investigation is needed on possible links between narcolepsy and vaccination. Swine flu vaccine [Pandemrix] in 2009–2010 caused nine times as many narcolepsy cases as expected in children (Finland and Sweden). WHO noted that narcolepsy has never before been associated with vaccines.

EFVV, the European Forum for Vaccine Vigilance, is calling on member states, WHO and the EU Environmental Committee for Public Health and Food safety (ENVI) to mandate surveillance systems for vaccines. "We urgently need to establish surveillance systems that analyze diagnosis made at outpatient visits and hospitalizations for at least one year post-vaccinations so that statistically significant links can be identified and assessed for causality," says Dr Meryl Nass, Microbiologist.

The gold standard of double blind placebo tested (where the placebo is benign) is never afforded to vaccines and there is never a control group in vaccine testing. Professor David Salisbury, Director of the UK Immunization program, confirmed to EFVV spokeswoman Anna Watson, that vaccine placebos in safety tests were other vaccines and that control groups were considered unethical in the case of vaccines.

"In the absence of double blind trials, surveillance in the community is essential as vaccines may not have been tested for interactions with other drugs, or on certain population groups such as pregnant women," said Ms Watson. "Phase IV trials, known as Post-Marketing Surveillance Trials are vital, especially considering that Adverse Drug Reactions (ADRs) are the fifth leading cause of death in Europe," she said.

"Patients can report ADRs in most European countries now but most people are not aware of this. In theory doctors and health professionals should be encouraged to complete Yellow Cards, for the Medicines and Healthcare products Regulatory Agency (MHRA). However, as vaccines are considered 'established medicines', doctors are not required to report side effects unless there is prior association or effects are life-threatening. These guidelines mean that most potential side effects from vaccines are going unreported. Additionally, GPs have very little training in spotting adverse drug reactions," said Ms Watson.

As vaccine manufacturers are not liable in a civil action for damages arising from a vaccine-related injury or death, market forces are weak in this area. It is the view of the EFVV that the Vaccine Damage Payment Fund, or its European equivalent, should be calling for Mandatory Active Vaccine Surveillance to fulfill a responsibility to vaccine safety. Parents, patients and health professionals should be supported in vaccine safety initiatives. As vaccine programs continue to increase, so should our vigilance say the EFVV.

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For more information, further quotes, case studies or photographs please contact:
Xxxxx
T:0 9999999999999
E: xxxxx@gmail.com

Notes to Editor

EU Immunisation Week 23-30 April "Prevent, Protect, Immunize"
http://eiw.euro.who.int/page/what-is-eiw

Dr. Nass is a board-certified internist who has authored many publications, testified before Congress, and spoken before medical organizations regarding the problems of vaccinations and Gulf War syndrome. New Adverse Reactions from Vaccines – Surveillence needed by By Meryl Nass, M.D.

When there is no prior association, diseases occurring in temporal relationship to vaccination are generally felt to be coincidental. Therefore, they are not generally reported to voluntary reporting systems like the UK Medicines and Healthcare products Regulatory Agency (MRHA) or the U.S. Vaccine Adverse Event Reporting System (VAERS).

If no data collected, and it remains unknown whether vaccination increases the incidence of most diseases, particularly rare diseases.

Other examples of vaccine problems:

2010 suspension of Fluvax in Australia and New Zealand that "caused two or three hospital admissions due to febrile convulsions for every hospital admission due to influenza prevented," scientists wrote.

1999 suspension of Rotavirus vaccine that caused 22 times the expected incidence of intussusception as expected (United States).

Currently Gardasil results in an average of 6 times more reports of ADRs and hospitalizations to VAERS (*Vaccine Adverse Event Reporting System*) than any other vaccine.