PATIENT SAFETY

Translated from ***Rev Prescrire*** **June 2005; 25 (262): 461**

We deserve to know the truth about the safety of our prescription drugs

We reprint below a call from Nuria O'Mahony to sign an Irish petition for accountable and transparent pharmacovigilance agencies. All European citizens should be concerned by this petition as the Irish drug regulatory agency contributes to drug approval in the EU through the 'mutual recognition procedure'.

"If you want an independent body to ensure that all drug information is not only publicly available but also acted upon promptly to PROTECT THE PUBLIC from drug induced HARM in Ireland. Sign this petition."
http://www.thepetitionsite.com/takeaction/444384374?ltl=1110811898

"We the undersigned are angered that the Irish Medicine Board (IMB) is failing consumers. Consumers have a right to expect full and impartial information about the potential risks and adverse effects of prescription medications. We are calling for a new robust independent regulatory framework to ensure that information is not only publicly available but also acted upon promptly. This new body should have full independent powers to withdraw, investigate drugs and warn patients and physicians about dangers of drugs in Ireland. The experience of consumers must be central to a modern system for the licensing and regulation of prescription drugs and that reports of adverse reactions by consumers must be given at least as equal weight by the regulator as the clinical trials data supplied by pharmaceutical companies.

We demand such an independent safety regulatory body (totally separate from the pharmaceutical industry and the IMB –100% funded by industry with 6 out of a 100 staff working on pharmacovigilance, conflict of interest scientists and staff paid by industry or holding industry shares) to be set up for post-marketing of the drugs in Ireland funded by the State with public representation and their only mandate would be TO PROTECT THE PUBLIC.

This petition also demands a mandatory clinical trial register open to all where ALL data is available to the public and physicians alike to make INFORMED DECISIONS about treatment for each individual weighing up the REAL risk as well as the REAL benefits. A "FAIR ACCESS TO CLINICAL TRIALS" ACT should be passed in Ireland to require all clinical drug trials to be made available to the public. This bill would ensure that any potential safety risks would be made KNOWN to physicians, researchers and consumers. Allowing the NEW SAFETY REGULATORY BODY to prevent future incidents like VIOXX°, SSRIs and many other drugs to cause HARM to patients because of lack of information and lack of action taken to withdraw the drugs soon enough after the findings were known.

The IMB, which was set up to protect the public, has ended up protecting the pharmaceuticals instead reneging its mandate. This body is not accountable to the public. We are concerned that the government has too cosy a relationship with the industry it is supposed to REGULATE!!! Costing innocent lives for financial gains.

We hereby demand immediate action from your government to rectify this scandalous situation."