Dear Peter,

Following on from the last Pharmacovigilance meeting and the European Patients' Forum presentation please find what we hope will be useful comments to this important debate.

The European Patients' Forum expressed views on behalf of patients in the form of a power point presentation which is described as follows.

- **Patients views on safety of medicines**
- **Urgent safety issues**
- **Reporting suspected adverse reactions and patients**
- **Communication on the safety of medicines**
- **Transparency/protecting individual data/commercial confidentiality**
- **Views Experiences of community system**
- **Patients contributions to Community Pharmacovigilance**
- **Strengthening the System**

Starting with the premise that no individual or organisation sets out to develop and promote a bad medicine or medical device, it does not alter the fact that when devices and medicines come to the market, comparatively little is known about their safety profile until they have been exposed to a much wider range of diverse people than can be undertaken in the current clinical trials regime. (The surveillance of side effects is of greater importance with fast track procedures,) so, unless appropriate audit and quality management systems are in place to ensure the reporting of the same, this will put greater risks onto patients and the perceived benefits of the medicine or device will be diminished.

It is evident that with adverse drug reactions being attributed as the fifth largest cause of deaths in hospitals and the level of reporting adverse reactions being extremely low (Salutest, the Lancet, UK National Audit Office) it has been quantified that a rate of reporting for adverse reactions to patients is between 10-25%. Of these documented cases the side effects are generally established observations.

Within all our member organisations there is evidence and examples of where medicines or devices that come to market, experience of them by health professionals is limited with adverse events being poorly understood, and that after marketing authorisation new adverse reactions, new toxicities and interactions are discovered, some of which are extremely harmful to the individual by possibly "curing the disease and killing the patient".

Therefore comprehensive risk assessments need to prioritise the benefits and be a priority in an auditable process to establish the comparison of benefits verses side effects to existing medicines or medical devices. This needs to be followed up by unambiguous reporting mechanisms that are standardised and easy to use for patients and health professionals alike.

A popular view expressed by the media is of manufacturers and regulators not being transparent on drug safety issues and those same organisations viewing information on risks, as a block to law suits, and not emphasising the educational aspects of preventing risks. There appears to by a tradition of secrecy on the risk information given to health professionals and patients and one questions, if the balance is too far in favour of commercial confidentiality?

With industry spending between 500 – 800 million Dollars on each new medicine coming to market, it may not be surprising that phase IV trials are limited. However, more of these long term studies would permit a greater evaluation of side effects and long term toxicity of treatments, hopefully leading to less of complications in the real diagnosis of problems and more effective treatments. A way forward may be to provide a joint pool of funding from both the industry and national governments to fund the development of phase IV trials and assessments.

Although currently overall drug surveillance systems work reasonably well in some EU countries, there are areas for continuous improvement needed: Notification of adverse events by healthcare professionals through statutory and mandatory processes should be considered, delays in the analysis of data needs to be improved, this could be developed by a proactive surveillance system introduced amongst informed stakeholders, with a greater and broader access to information for all.

The way forward is to improve the current system by creating a greater and a more inclusive method of information provision and dissemination with patients' organisations being wholly involved throughout:

By using the Eudra-Vigilance data base and by giving access to patients and healthcare professionals to the information will aid a greater shared understanding and knowledge, which will enable trust to be developed by all stakeholders, and real choices being made based on timely and pertinent information that is reliable.

By the establishment of proactive surveillance systems of Pharmacovigilance internationally would also help ensure a streamlining of recommendations into a single coherent system.

Where patients' organisations can be particularly involved is by helping in the development of public information campaigns, through an identified regulatory body and national agency websites, health centres and patient organisations at pan European and national levels. They could help ensure the importance of reporting and in the training of healthcare professionals, along with partnerships being established to ensure Pharmacovigilance bodies and

patient organisations define and develop communication strategies and policies as to when, how and what to communicate in order to ensure the correct use of medicines and medical devices.

The development of pertinent patient information leaflets which are designed to convey potential and actual adverse reactions of medicines, and who they should contact in the event of an incident or reaction occurring. In the case of new medicines some form of identifier to inform both healthcare and patients that the drug is a new product would also be useful as an increased warning and awareness for increased observations being needed.

One key area for the strengthening for the Pharmacovigilance system is in the initial reporting mechanisms from patient to healthcare professional and beyond. Because reporting is low, and because the perception from healthcare professionals is one of a ‘blame culture’ in organisations, and the associated competing demands on their time, a mandatory system should be used that eliminates blame, and recognises the importance of reporting in the interests of overall patient safety. Healthcare Chief Executives and healthcare Professional leads should have written into their contracts a clause which makes them accountable for such systems being implemented and reported within their Boards in a transparent way.

Patients and carers must be involved proactively in the regulators role of following up adverse events through a system of prospective surveys for new medicines that come onto the market. There should be an established model on consumer reporting through the use of toll free numbers, website feedback and from return slips on patient information leaflets.

Improving the transparency of information by allowing access to healthcare professionals and patients is crucial, by giving them the tools to do their jobs effectively and efficiently in the form of all information on the safety of medicines and devices. This will enable them to discuss with the patients and enable the patient to make better choices for the treatment they choose. In general most patients are aware that there are drug reactions and risks, but they have a right to know what these might be, and make the choice on the overall benefits by taking the medicine or using the device, thus providing a better compliance to treatment options and the prescription instructions.

The regulators database should be available to healthcare organisations, healthcare professionals, patients’ and consumers. It must allow feedback to healthcare professionals on timely information with good methods of circulation of information, thus allowing them to have confidence in the system that provides an added value to them in identifying adverse reactions and the treatment options for individual patients.

It is evident that the process for obtaining information on medicines needs a thorough assessment in order to reveal the unexpected side effects during their development. Additional research is required that tracks patients using specific medicines over a longer period, with the aim of tracking potential adverse reactions and any other difficulties with the use of medicines and

devices over time in a larger and more diverse population including gender and cultural differences.

In Concluding the interests of patient safety outweighs commercial interests, and all data in this respect should be made available to protect the patient in the public interest.

The way forward must be to create a climate of trust between patients, health professionals, regulators and industry; this can only be achieved if we all passionately believe that the goal is safe, affordable and accessible medicines to enhance quality of life. And to recognize when mistakes happen and systems fail – (which they will). We all learn together to put them right through continues improvement without blame. (However, only if we can believe we have worked together from the start in an open, honest and transparent way that is easily auditable by all).

I hope these comments will be of use in establishing a revised and improved framework.

Best wishes and kind regards

Don

Don Marquis
Consultant

(Collated response on behalf of European Patients' Forum)