FRIDAY MARCH 2nd 2012

NEW STUDY BY THE IRISH PATIENTS ASSOCIATION FINDS PATIENT SAFETY COMPROMISED

A focus on off-label medicines, and why more regulation is needed

On March 2nd 2012, the Irish Patients Association (IPA) releases the findings of a new pan-European study of 150 patient groups in the area of **off-label prescribing***. 'Off-label prescribing' occurs when a doctor prescribes a medicine—the safety and efficacy of which has not been established for a specific use.

Doctors prescribe off label when they need to support the medical needs of patients (including children) who have life-threatening conditions for which no other (or limited) therapies are available.

The practise of prescribing off-label for economic reasons has yet to be quantified, but a June 16th 2011 article in the Irish *Medical Independent* offers an example of the approach: some consultant ophthalmologists are treating wet age-related macular degeneration (AMD) with a drug which is licensed for colorectal cancer. The branded drug available to treat AMD is more expensive.[1] Another problem in the area of off-label prescribing is that some drug companies have also been accused of trying to sell more of their products off label.

Until this Irish Patients Association study was completed, no one knew whether patients were typically informed when the products they were prescribed were off-label. Similarly unknown was whether patients were being told about the extra rigour required to self-monitor the effects of off-label medicines—or whether patients then knew what to do if they experienced side-effects from the off-label medicines. The results of this study clearly indicate that off-label prescribing is an overlooked and unregulated area of medicine—mainly because doctors are able to practise it in a discretionary manner.

WHAT THE IPA STUDY HAS FOUND

The IPA study began as an online survey of 150 patient groups throughout Europe— which, together, represent the interests of around 1 million European patients with varying medical conditions. All of the respondent patient groups were familiar with the practise of off-label prescribing, and represented patients who had received off-label prescribing. The study has found the following:

- **69% of the study's respondent patient groups say that off-label prescribing is an important component of the doctor's repertoire of treatment and care**, particularly for patients who only have limited treatments available to them (for example, patients with a rare type of cancer).

- **90% of the respondent patient groups say that patients have a right to informed consent**
- **medication**. While most respondent groups support the practise of off-label prescribing, many also believe that patients should be fully informed about the fact that a prescription is off label. Nearly two-thirds (66%) of the groups say that not all patients are aware that they have been prescribed an off-label medication. More than one in five (12%) of the groups say that no patients are aware of being prescribed an off-label medicine.
- **Only 42% of the respondent patient groups say that patients are informed about what to do if side-effects should occur with an off-label medicine**. Off-label drugs (like all medicines) can cause side-effects. 23% of the respondent groups say that patients prescribed off label have reported experiencing side-effects.
- **72% of the respondent patient groups think that drug regulators should make a greater effort to monitor the use off-label medicines in their country**. 65% of the respondents believe that monitoring of off-label medicines by regulators should take place at a European level.

WHAT THE IRISH PATIENTS' ASSOCIATION IS CALLING FOR

At the moment, patients prescribed an off-label licensed product are subject to poor monitoring and surveillance. The findings of this IPA study indicate **a real need for better regulation of off-label prescribing**. The IPA therefore calls for better regulation.

The IPA believes that ...

"Learning in healthcare should not be driven by harm.

In other words, reform and change in our healthcare systems

should not be preceded by funerals, or by injury to patients."

The IPA notes that patients expect their doctor to select—with the patient's consent—the best-possible course of treatment. Furthermore, states the IPA, every patient has a fundamental right to be informed about the treatment they receive, as well as to participate in the decisions made about their clinical and medical options. Patients should be fully informed and warned of the risks (as well as of the benefits) of treatment, and should be instructed in how to recognise possible side-effects.

Addressing the launch of the Report Anna Moran External Affairs Manager from Fighting Blindness added **that** *"Proven safety and efficacy should be the only concern of any treatment debate. In situations where an off-label drug could possibly be prescribed, we would urge frank and open dialogue between patients and doctors about all treatment options and potential risks. Safety comparisons, notwithstanding efficacy similarities, are not yet powerful enough to make conclusions that should alter public policy. In essence, we want to aim for the gold standard of care, found in evidence based medicine; cost savings should not trump safety concerns in ocular disease any more than in any other disease area*

Off label prescribing, too, should not be exempt from following these fundamental rules.

*** The IPA online survey of patient groups was initiated in May 2011. The study was administered by UK-based research and publishing body, PatientView. The IPA would like to thank Novartis for providing an educational grant to support this study into off-label prescribing. 150 patient groups participated in the study, drawn from 25 European countries (including Ireland). The patient groups specialise in a broad spectrum of therapeutic conditions, and represent the interests of about 1 million European patients.**