The ITP Support Association Platelet Reprint Series

No. 9 – Accessing information on drugs

Platelet article reprinted from: **Sept 2010**

Title: **Accessing information on drugs**

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If you want to access information about a medicine you can access it electronically at www.medicines.org.uk. This is the electronic Medicines Compendium (eMC); a database run by a not for profit company called Datapharm Communications Limited (Datapharm). The eMC was launched in 1999 and has become a trusted website for reliable information about medicines. This compendium is free to use; Datapharm works with pharmaceutical companies, the NHS, and other organisations to provide reliable information about medicines.

Apart from Patient Information Leaflets (PILs), the database contains Summaries of Product Characteristics (SPCs) and Medicines Guides. The PIL is the leaflet that is included in the pack with every pack of medicine that you receive. The PIL is a summary of the SPC and is written for patients. Beware of the side effects listed as they relate to all the adverse events seen, even if the event was very, very rare. Newer PILs should list adverse events by how common they are, for example a very common event is seen in 1 in 10 people taking a medicine.

An SPC tells healthcare professionals, such as doctors, pharmacists and nurses, how to prescribe and use a medicine correctly. An SPC is based on clinical trials that a pharmaceutical company has carried out, and gives information about dose, use and possible side effects. Also available for some medicines are Medicine Guides. These documents are aimed at non-medical professionals and an independent team of pharmacists writes them. These documents should be easy to understand for everyone.

All the information on the eMC website comes directly from pharmaceutical companies. Many (about 160) pharmaceutical companies subscribe to the eMC and they pay Datapharm to publish their information on the eMC website. The process for adding the information is as follows:

- The pharmaceutical company drafts a Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL), using all the up to date information about their medicine.
- The UK or European medicines licensing agency - the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA) - then checks and approves the information ensuring that it is correct and approved.
- The pharmaceutical company publishes the approved SPC and PIL on the eMC website.

To ensure that the Medicine Guides are independent, unbiased and non promotional, the guides are written using a set of guidelines that have been approved by an independent board that oversees the process. These guides should be a useful resource for patients and their carers. The easiest way to locate information is by using the search box at the top of the home page. Type in the name of the medicine you are interested in, this can be a generic name or a brand name of the medicine. For example:

intravenous immunoglobulin (brand names Flebogammadif, Privigen, Gammagard, Kiovig, Octagam and Vigam-S);

thrombopoietins (brand names Nplate and Revolade).

If you are being prescribed a medication, ask your doctor for a copy of the Patient Information Leaflet if you want to read about the drug before you are given a full prescription (or if you don't have access to the internet to look it up later). To get leaflets in large print, Braille or as an audio CD, call the RNIB Medicine Information line on 0800 198 5000.

Platelet article reprinted from: **September 1999**

Title: **Unlicensed Medicines**

Author: **Dr. Clive Dash, Medical Director, BPL.**

The licensing process for medicines involves the manufacturer providing information to the licensing authorities (in the UK this is the Medicines Control Agency, MCA). The information comprises method of manufacture, quality control measures as well as the results of clinical trials. The licence is granted on the basis of product quality, efficacy and safety.

The main criticism of 'off-label' use (as it is sometimes called) is that the product information and specific use have not been 'peer reviewed', that is evaluated objectively by independent experts. A disadvantage of this strict approach is that the outcomes of the groups of patients in clinical trials are assessed statistically. Within the large group of patients in any clinical trial, there will be a variety of responses. In their day-to-day work, doctors are treating individuals and may feel that an individual would be better treated with an unlicensed product or unlicensed dose. This is the main reason for the unlicensed use of a product.

Licensed products for unlicensed uses

The common situation is prescribing of a licensed product for a medical condition which is not mentioned in the prescribing information and therefore it is outside the licence (so called, off-licence use). In this case, quality of the product is assured. Doctors have the freedom to prescribe any product for any patient if they believe that benefit is probable and that undue hazard is unlikely. Doctors form an opinion about the usage of a product in an unlicensed condition either from the mode of action of the product or from clinical reports published in medical journals or presented at medical meetings.

In many situations, there is a significant amount of information to support their action, even though the condition is not a licensed indication. The only way a product can become licensed for any medical condition is for the manufacturer to compile the information and send it to the licensing authority. If this is not done, the condition will remain 'unlicensed'. This situation is frequent for relatively old products.

Even with new products, there is a time delay from the manufacturer conducting the study, compiling the results and having it approved by the licensing authority. During this time any use of the product is 'off-licence'. In addition, a product may be licensed for a condition in one country but not (yet) licensed in, for example the UK. This situation arises because of the difference in timing of sending documents to each licensing authority and the speed at which the documents are reviewed by them.

A specific type of unlicensed use has been mentioned in the news media recently, namely use of certain products in children on the basis of clinical trials in adults. In general, clinical trials are always started in adults before children (unless the product is aimed specifically at an illness confined to children). The ethics of conducting clinical trials in children are complex and have reduced the enthusiasm of many doctors to do studies in this age group. The expected effects in children have been drawn from the studies in adults.

Unlicensed products

A less common situation is the use of a product which has not been licensed for anything - anywhere! A doctor can request a supply for a specific patient or patients. This is referred to as the 'named patient' system (proper term is 'Particular Patient Scheme'). The doctor will usually have found out about the product from the medical journals or meetings. The scheme is run by the manufacturers but controlled by the licensing authorities and subject to their audit. A medicine prescribed in this way could be at any stage of clinical trials. The manufacturer has to take responsibility for the quality of the product and the doctor for its use.

Summary

The unlicensed use of a medicine may occur under different conditions. In all situations the manufacturer is responsible for the quality of the product, whereas the doctor is responsible for the clinical use of the product, such as deciding which patient might benefit and what dosage to use, although sometimes this is discussed with the manufacturer. Therefore, the manufacturer would be

liable for any fault in the product; the doctor should be able to justify his clinical decisions if challenged.