EU laws on labelling of medicines

Summary: The EU requires suppliers and dispensers of medicines to provide information either on the packaging itself or on a packaging leaflet that will enable patients to use the medicines correctly.

The objective of Directive 92/27/EEC of March 31, 1992 is to give patients clear, precise and accurate information on medicinal products so that they use them correctly. Under this Directive the following particulars must be displayed clearly on the outer packaging of medicinal products:

- The name of the product *(invented name, trade mark or name of the manufacturer)*
- A statement of the active ingredients expressed qualitatively and quantitatively
- The pharmaceutical form and contents by weight, volume or number of doses
- The list of excipients known to have an effect *(an excipient is a carrier substance in which the active ingredient has to be diluted or mixed)*
- The method of administration
- A warning that the medicinal product must be stored out of the reach of children
- The expiry date
- Special precautions for storage and disposal of unused medicinal products or waste derived from such products
- The name and address of the holder of the authorisation for placing the product on the market
- The number of the authorisation for placing the product on the market
- The manufacturer's batch number
- Instructions for use

It is also obligatory to include a package leaflet containing this information with all medicinal products unless the information required is contained on the outside of the packaging.

For more information on this directive visit:

http://europa.eu/legislation_summaries/other/l32006_en.htm