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ORIGINAL, GENERIC MEDICINES AND COPIES, BROTHERS BUT NOT TWINS. STATE OF THE ART IN 2009

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The difficult daily practice of the generic medicines as used in a public hospital led us to assess the reality of the generics identity to the original.

The notion of generic medicine appeared by 1950. Only 30 years later, appeared the first official definition in France (1981). "By generic medicine it is understood any copy of an original medicine for which the production and the marketing are made possible, in particular by the fall of patents in the public domain, at the end the legal period of protection" .

The generic medicines are not 100 % identical to the original. From a chemical point of view (molecule) the two medicines are perfectly alike but concerning the effects of the generic, differences can arise: faster or slower action, and /or more or less effectiveness.

According to current rules, the company that produces the original has to refer to previous toxicological, pharmacological and clinical studies. For the copy instead, the company has only to produce a review of the scientific literature giving evidence of the safety and efficiency of the product.

The generic medicines have be demonstrated as "essentially similar to the original medicine" (Directive 2004 / 27 / CE 31).

The statistical "Estimate point" and its 90 % confidence interval have to fall within an interval from 0.8 to 1.25 (generic medicine versus original).

BUT .. for medicines with a narrow therapeutic margin such as anti-epileptics, oral anti-coagulants, various types of contraceptives, anti=asthmatics, antibiotics, antidepressants, anticonvulsants, anti-hypertensives, anti-arrhythmics, and anticoagulants, the 90 % confidence interval has to be situated between 0.9 and 1.11.

For medicines with a wide therapeutic margin, the 90 % confidence interval can be situated between 0.75 and 1.33!

BUT.... the same active principle can exist in the form of different salts .The pharmacokinetics can be identical for any kind of salt but not always (in particular propoxyphene, pilocarpine, lincomycine, penicillin G) and the different salts may feature a different availability.