GENERIC MEDICINES AND COPIES, THE QUESTIONING OF THE PRECAUTION PRINCIPLE

Dr Nicole Delépine, MD , paediatrics' oncologist, chief of the paediatric oncology unit , University Raymond Poincaré (APHP) hospital in Garches, France
Dr Salwa Alkhallaf, MD, paediatrician, paediatric oncology unit, University Raymond Poincaré (APHP) Hospital in Garches, France
Dr Zahia Lankri, MD, paediatrician, paediatric oncology unit, University Raymond Poincaré (APHP) Hospital in Garches, France
Dr Hélène Cornille, MD, onco-paediatrician, paediatric oncology unit, University Raymond Poincaré (APHP) Hospital in Garches, France

On March 31st, 2004, generic medicines acquired a real legal status in the EC directive 2004 / 27 /CE.

Nevertheless, in spite of officially considering the patient as the centre of the reflection, the reality "demonstrates that the development of the generic medicines and their usage mainly takes advantage of a certain economic opportunism" (Sandrine Barthelmé).
The Directive of March, 2004 defines the generic medicine and specifies the procedure for requesting the Marketing Authorisation (MA) with the clear intention of easing this procedure for the applicant.

The incentives in favour of the generics are mainly of pecuniary nature (subsidies to the doctors, bonuses in the replacement for the pharmacists, return on investment for the industrialists).
The procedure is widely intended to favour the multiplying of generics by Industry in order to benefit from all possible economic opportunities.

A new applicant has the possibility of requiring from the original laboratory making the princeps, communication of the original MA file, to be used as a starting point for obtaining a new authorization. But this laboratory is obviously not interested (nor requested) in supplying the results of the preclinical and clinical tests from the file of MA of its generics.

The legal regime of the generics has been built to be the most flexible and the least forcing possible, for the new actors (industrialists, public authorities), in spite of the existing brands and patents regulations.
It has been built in an unusual way: starting from the economical goal before defining the means to reach it.
This approach appears to question the precaution principle as the foundation of the sanitary safety, in particular for what regards the evaluation of the risk involved.
The notion of risk is what conditions and dimensions the precaution principle.
In the medicine based on generics, the evaluation of the risk is reduced to its simplest expression. This is a non-sense, in complete contradiction with the policy implemented by the same political entities, for instance to address the H1N1 risk