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SYMPOSIUM

Conference theme: experience of a unit of pediatric oncology with drugs, prescription, observance and market

Corruption of the pharmaceutical life cycle. How to get out?

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Since the first drug disasters (sulphonamide, thalidomide) governments established control systems meant to protect their populations from the occurrence of future drams.

Unfortunately frequent serious health scandals (recently Vioxx and Mediator) shows that these control systems are no longer effective. Each time, whistle doctors gave the warning while official agencies have been slow to withdraw .No decision to withdraw Vioxx issued by an agency! Ten-year delay in the withdrawal of Mediator!

This lack of agencies is not accidental or due to incompetence or sclerosis but is structurally linked to a philosophy of cooperation with labs rather than control, exacerbated by corruption at all levels.

Loss of safety objective :

In 20 years the philosophy of state control for the population safety has faded in favour of cooperation with industry. Thus the USA "Medicine Act" formalized the primacy of the interests of big Pharma on drug safety. It required procedures for authorisation of drug on the market are the fastest possible. To facilitate this new object, many "employees" of the Food and Drug Administration are officially hired and paid by drug companies.

Similarly political decision has given senior responsibilities in the administration of the drug, to people who came from industry arguing their jurisdiction without regard to their objectivity. The influence of these reforms transformed the primary objective of the agencies. The interests

of the industry became predominant, safety forgotten. This practice is the contrary as precautionary principle: it requires little proof of efficacy and safety, to allow the commercialisation of a drug but it requires evidence of serious toxicity off the market!
Fear of retaliation (legal or illegal) laboratories paralyzes agencies when withdrawal is discussed. The policeman is afraid of the possible offender!

Corruption at all stages :

30 years ago representatives of the authority should not receive any additional compensation for their public activity or had to pass an ethics commission to ask for permission. After stopping their public labour, they should not work in companies they had previously controlled. These precautions dictated by common sense were intended to ensure the neutrality of the state and independence of decisions of their representatives.

Since the liberal reform of our societies, the liberal public-private mix became a bible and conflicts of interest increased, severely affecting the public interest mission. It corrupts all steps of the medication.

Therapeutic trials promoters are paid largely by the laboratories and their judgement severely altered in favour of the drug. Similarly statisticians analyzing the trial know they must not seek scientific truth, but demonstrate the effectiveness of the product, in order to retain their customers. The corruption potential of the raw data are possible and frequent when the trial does not fulfil its real purpose, it could nevertheless affirm the effectiveness of the product.

In all democratic countries, the open court is public and contradictory. But current judgments of medicinal authorisation are secret (nor the basis for approval, neither debates published). In democratic countries judges are paid by the state and shall in no case have any connection with any of the parties. In licensing committees as those for pricing and reimbursement rates, no expert is independent from laboratories.
How to be surprised when new drugs are reported innovative although a positive balance between risk effectiveness.

Pharmacovigilance conflicts of interest at least partly explain the "serious failure of the drug safety surveillance system" identified by the scandal in the French IGAS mediator report (2011)

How to clean up the drug chain :

Principles are simple, known a long time ago. Implementation needs courage to face very powerful and well organized lobbying.

The basic principle: the public safety outweighs the interest of the pharmaceutical industry. This requires a strict application: a potential dangerous drug should be removed from the market as a precaution

Trials to obtain a marketing authorization must not be the exclusive property of industrial but a joint industrial-patients property included associations-drug agencies and social security.

The authenticity of a clinical trial for a marketing authorization should no longer be doubted. It must declared as open, be certified by an annual registration on the model of the company deposit accounts (minimum number of patients included, age, sex, and characteristics). Any exclusion from one trial must be declared and the reasons.

No expert from a government agency should have any links with the industry. Declaration of conflict of interest is useful, but experience shows no efficacy. Commission French members of AFSSAPS who claim that their links with industry reflect merely their "high expertise" and do not corrupt their decisions have been unable to refuse the marketing authorization of Vioxx or mediator. Doctors who lacked the data file for regulatory approval, or means of investigation, early recognized and published their doubts about the effectiveness and safety of drug killers and predicts their future withdrawal.

More than a few structural adjustments, while necessary (separate authorization and removal agencies) the reform should focus on the eradication of conflicts of interest, which no useful expertise could justify.