**THE REGULATOR'S APPROACH TO THE SAFELY AND EFFICACY OF NEW MEDICINES HINDERS THE DEVELOPMENT AND SUPPLY OF NEW AGENTS : NO**

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Regularly some committees or councils such as the Council for International Organizations of Medical Sciences provide some guidelines concerning the development and supply of new agents. They encouraged that manufacturers and regulators will endorse and adopt a systematic approach to the evaluation and reporting of the balance between benefits and risks of a marketed medicinal product with a suspected major safety problem.
Strategies are recommended for improving communication between, and the sharing of action by, regulators and manufacturers, designed to strengthen decision-making in the interest of public health. Although evaluation and decisions are made on behalf of the at-risk population from a public-health perspective rather than that of the individual patient, the needs and perspectives of the different stakeholders and constituencies affected are carefully taken into account. Although each instance of a safety issue is unique, all parties will adopt consistent practices in analysis and reporting.
A benefit-risk evaluation should always be conducted relative to no therapy or to properly chosen comparator drugs and other treatments; to facilitate comparison between alternatives, standard graphical riskprofile representations are routinely used. It will normally not be sufficient to evaluate only the effect of the new problem (‘‘signal’’) on the benefit-risk relationship; a re-examination of the entire safety profile, or at least of the most prominent/important adverse drug reactions relative to other treatments, is recommended.
Deciding the appropriate action subsequent to a benefit-risk evaluation requires ‘‘good decision-making practices’’; in the assessment and decision-making processes the basis and rationale of decisions should be transparent and inter-agency cooperation should be encouraged. Decisions are also highly heterogeneous among countries but the comparisons are difficult. Some decisions can be considered as conservative or opportunistic. In many countries, new legislation also foresees that competent authority may at any time ask the holder of the marketing authorisation to forward data demonstrating that the risk-benefit balance remains favourable in order that the risk-benefit balance may be continuously assessed.
However despite the economic crisis, we considered that most of the decisions are rational, ethical and in the interest of the public health in US and Europe and in most of the emergent countries.