Essential medicine and pharmaceutical innovation

Jean-Claude Salomon (February, 2015)

Will the publication in our country of a list of essential medicine (EM) have an incidence on the pharmaceutical innovation[1]?

If this publication remains a fact isolated, flooded in the considerable mass of the publications, we can undoubtedly answer negatively. If it is accompanied and followed by efforts arranged to make, well know the begun process and its possible consequences, we think that this list of EM can be a real factor in the resumption of this innovation gradually broken down since the beginning of 1980s

Two orders of facts are to be considered.
1-These EM, selected by the clinicians for their benefits / risks ratio the most favorable to the patients in 95 % of the pathological situations, are going to stand out as reference[2] medicine in the comparative clinical trials[3]. Today these essays are designed to favor by all means the innovative value of a medicine, which is very rare and the objective advantages for the even rarer patients[4]. This carries an indisputable damage to the patients who agree to participate in these essays. Later this damage will be echoed on all the patients who would take this new medicine, in case it would obtain an AMM (marketing authorization). Regrettably until now, neither committees of ethics and protection of the patients, nor the commissions of AMM intervened in the choice of reference medicines, for lack of having had such a list of trustful reference medicines[5].
2-The existence of a list of EM will also intervene in a less direct way. The innovation depends not only on the possibility of using the most recent techniques during the research, but also of the diversity of the questions and of the hypotheses which the researchers study. The EM are those which managed to stand out in the face of the multiplicity of more recent drugs, conceived in a scientific context, certainly more recent, but unconfirmed by the facts on the clinical ground. The historians of the medicine, of sciences and ideas will have the task to help us to understand why the period between 1935 and 1975 was so rich in authentic innovations. The list of EM will thus be for them a valuable document to find the particular conditions of the major inventions.

We shall return later on the likely consequences of the application of the concept of EM on the pharmaceutical innovation, because good spirits will not miss to announce that they are going to sound the knell of an already dying innovation. Nothing is less certain.

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[1] According to the International Company of the Independent Reviews on the medicine, the term of innovation recovers three concepts: 1-the commercial concept which indicates(appoints) any product recently marketed; 2-the technological concept which relates to the industrial innovations 3-the concept of therapeutic progress which takes into account the new treatments which bring a profit to the patients by comparison to the existing treatments Here we take into account only this last concept.

[2] Reference medicine, in a comparative clinical trial, is medicine prescribed to the patients of the control groups.

[3] Tries(Essays) of phase III, during the authorization requests of launch on the market.

[4] The agencies of medicine in the various countries, or the European Medicines Agency, have no criterion for the choice of reference medicine presented in the files of the comparative clinical trials today.

[5]It is necessary to note that the commission of AMM in France is seized with the file only after the clinical trial. It is put in the presence of a fait accompli. It is during the writing of the protocol that the choice of the reference medicine must be justified, if it is not one of the EM, on the optimal conditions (doses, duration of prescription...) for the patients.