

During clinical trials, essential medicines are the best comparators

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Except their therapeutic indications, essential medicines (EM) have other functions. In this note we evoke the comparator function which must be assigned to them.

If for a given indication, they have actually a profit/risks ratio more favorable than the other medicines, the indications of which they share, they are logically the best choices as the reference medicines during comparative clinical trials. Any new candidate medicine to reach the market will thus have to give evidence compared with EM of reference - either of a bigger profit, or lesser risks, or both at the same time. And it in a repeated way, during clinical trials on sufficient and independent randomized series of patients.

Any things implying the rigor of the methodical conditions concerning the biases which the clinical researchers have for task to avoid. This comparator function has to be one of due major criteria by ethics committees worried of performing scrupulously their office.

This requirement will allow any new medicine to reach step by step the status of EM, which in the term of a trial series would show better results than one EM of the list. Any other way of making would be detrimental to the participating patients in the essays and more still detrimental to all the patients to whom would be prescribed a medicine to the questionable merits.

Ethics committees and associations of sick will have to use vigilance to prevent the incorrect essays by referring every time necessary to the existing EM list.

EM are also strategic substances. Today we observe that more and more multinationals outsourced the production of medicinal active substances. The place occupied by producers in India, in China or in Brazil increases year by year. Little by little the western industries let escape their production capacities and their knowhow.

This exposes seriously the populations of our countries in case of political and/or economic crises to the risks of disruption of supplies¹. What would be less important for not essential medicine, would have a vital importance for the EM. It is necessary to constitute thus immediately safety stocks and to re-localize the production of the active substances of the list of EM in the European countries. The competent public authority has to on this subject exercise responsibility from now on.

¹ Matières premières pharmaceutiques, Mondialisation et Santé publique,
http://www.acadpharm.org/dos_public/Recommandations_MatiEres_premiEres_pharma_Conseil_22.06.2011_%28VF%29.pdf