The need to promote independent research on drugs

In their interesting review, Bergman et al. [1] analyze the difficult situation of investigator-initiated trials (IIT), discuss the reasons that put independent research at risk, and suggest possible solutions. Among the barriers to IIT, we share the view that ‘growing bureaucratic hurdles hamper clinical development’ and that there is a need to take active actions to reduce this burden. We are also aware of the growing cost of clinical research as an explanation of the reduced support for IIT by pharmaceutical companies.

In discussing possible examples of the contribution that can be provided by the public sector, the program on independent research on drugs setup by the Italian Medicines Agency (AIFA) in 2005 is mentioned. We have been involved, with various roles, in designing and running the program in the first 4 years of activity [2]. Two issues stemming from our experience may be of note here: the focus/areas of interest and the funding mechanism of a program on independent research.

Despite the several thousand clinical studies started every year to evaluate the efficacy and safety of drugs, there are questions of relevance for clinical practice which are insufficiently dealt with or nonaddressed. Even though frequently discussed, the situation depends not only on conflicts of interest that are specific of the pharmaceutical sector but also on a more general problem of ‘market failure’. There are in fact clinical areas where we lack research simply because there is no commercial interest: the expectation for economic return for the research investment is insufficient.

The cases of rare or neglected diseases, generic drugs, as well as the comparisons of drugs versus nondrugs interventions are examples from everyday practice.

Regardless of the main cause for inadequate (commercial) funding, the net result is that many pragmatic studies that should be conducted for the best interest of patients are simply not carried out. There is thus a need for direct public funding to support independent research. In the model developed by AIFA, pharmaceutical companies were required to contribute 5% of their promotional expenses to a fund for independent research on drugs.

Several reasons might justify this model. The investment on noncommercial independent research also improves research capacity that often represents a limiting factor for industry-sponsored research. Some research objectives may be relevant to patent drugs (e.g. small subgroups of nonresponders, ancillary pharmacogenomic studies, long-term evaluation of safety) and only a specific company may commercialize the results. Even when no specific company may exploit the results, as in the case of generic drugs, it is still the pharmaceutical sector that will globally benefit from the new knowledge.

In any case, aside from the specific arrangements so far implemented in different countries [3, 4], the general principle to be stressed is that health care systems should recognize their duty to incorporate financial support to health care research as part of their fundamental mission. How this can be done may vary in different health care contexts but the point is that academic researchers should not be left alone in this endeavor.

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