From Chairman's Desk

Crises in pharmaceutical research

The major objective of pharmaceutical research is to invent new drugs for better therapy of existing diseases and evolving diseases, as also to improve safety profile of existing drugs so as to reduce health care costs and improve quality of life. Success rate of any new drug can only be assessed by therapeutic advantages it presents over the existing treatment available. Unless a new drug is better candidate than the existing ones, in terms of efficacy, safety and economy of therapy, ideally it need not claim any landmark advances in therapy. Rather it should be treated as another "me too" drug and nothing more. Thus the parameters for adjudging a real new drug are obvious. Hence, pharmaceutical research must culminate into therapeutically superior new medicines and not simply armed with minor clinical advantages. This line of thinking is based on the fact that although during 1978 to 1989 US FDA approved 218 drugs, out of these only 15.6% or a mere 34 could be adjudged as major therapeutic advances. In another study covering the period from 1974 to 1994 P. E. Barral reported that only one in nine(11%) new drugs were innovative, therapeutically and pharmacologically superior over the existing ones. This scenario definitely hints to real innovation crisis in pharmaceutical research, new drug discovery and hence implies wide opportunity before pharmaceutical researchers to add new dimensions to research methodology. This is no mean challenge and it can be addressed only by team work in series.

It is well established that sponsored pharmaceutical research and development mostly focuses on minor variations on existing drugs, as a result significant clinical superiority is not achieved. Moreover, they produce an epidemic of serious adverse reactions and in turn add to national health care cost, individual health problems and overall economic retardation, which is neither in individual nor national interest.

Obviously, pharmaceutical research needs new thinking, new plan and monitoring/regulatory system which certifies reproducibility and ensures zero tolerance to health hazards. These goals can be achieved only if basic research gets adequate emphasis. Of late, this has become the most neglected area because direct return is not visible to the sponsors. Private sector hardly ventures in this. Moreover, academic research is degree linked, hence priority is diluted and concentrates more on publishing papers, that too irrespective of quality of paper but simply number of papers and get the degree within stipulated time. Quality of research papers is very big question mark across the world and many scientists have published numerous papers to expose the arrangement. Thus utility of such publications is negligible and therefore, academic researches hardly contribute to drug discovery, because it also lacks research in series to correlate the previous findings and extend the work to complete next step and so on, with a view to reach to meaningful conclusion. Universities must give very serious thought to the looming crises in research arena and set the stage for better research environment which is productive by all means.

Say for example the withdrawal of rofecoxib from the market on September 30, 2004, because of concerns about increased risk of heart attack and stroke associated with long-term, high-dosage use, and definitely points out the limitations of Clinical trials of new drugs. Moreover, this is not lone drug, many drugs are withdrawn, but by the time they are off the shelves they cause more than enough damage to health and life. This scenario or state of affairs in drug discovery makes enough room for more logical approach to drug research. One school of opinion is that the real enemy of real innovation in drug research is corporate strategy and vigorous marketing, succeeding in persuading doctors to prescribe the new products. Let researchers bring some real time innovations and team work spirit in pharmaceutical research arena to ensure health safety for posterity.

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