

GOVERNANCE

BASEL INSTITUTE ON GOVERNANCE

Conference «Access to Life-Saving Medication – Innovative Solutions» | September 7 2006 | UBS Training- and Conference Center Basel

Two markets, two rules?

Dr Yves Champey, Chair of the Board of Directors, Drugs for Neglected Diseases Initiative

There is not much debate on the fact that neglected diseases do not represent a market, while the question of the need to consider having a different set of rules for the development of new drugs in developing countries or at least for the development of new drugs for neglected diseases is a true debate.

Two Markets?

If there were a market for neglected diseases or even more generally for innovative drugs in developing countries, one would know it. Several large, medium or small companies would have developed an activity in the area. The medicines invention, production and marketing are organized around the satisfaction of a solvable need. Industrialized countries have developed through the last century important and efficient public or private social security systems, which have made possible to give access to innovative drugs for all patients. This has been a source of immense progress in developed countries, in all fields of medicine.

When discussing developing countries and access to drugs one must distinguish access to drug for a very small proportion of its population from the very difficult or impossible access for the rest, too poor to buy drugs. This becomes dramatic when discussing neglected diseases like malaria, tuberculosis, AIDS, sleeping sickness, Chagas disease and a long list of other tropical diseases.

Efforts, which have developed in the last ten years to modify that situation, do not call for

“ Market regulation “ but for other publicly funded mechanisms for buying existing drugs. Still the strong research and development incentive for R and D brought by rich markets do not exist in the pharmaceutical industry and a few PDPs have come in existence to fill that need for research and development of new drugs.

Two Rules?

Should we then conceive different sets of rules for the development of new drugs for developing countries or more specifically for neglected diseases? No!

One must keep in mind that the production and refinement of regulatory rules have been and are conceived for the protection of consumers. This is the main mission of all regulatory authorities, national or international. This is what ICH is about with, in addition the acceleration of the development process by avoiding all duplication of development work.

If different sets of rules were to be conceived, it should not be at the expense of safety or the quality of proof of efficacy. All experiments carried out for drug development are scientific activities whose characteristics are to be reproducible and predictive of an activity, or safety, or efficacy. Changing the rules could not happen if these permanent objectives are not satisfied.

If changing the rules for the development or the registration of new drugs in developing countries was to be considered, it will have to be on clear and well-documented proposals.

Should we devise processes to facilitate drug development for neglected diseases? Yes

One rule seems to be undisputable: that of the division of responsibilities between public and private research. The very serious situation with the lack of innovative drugs for neglected diseases calls in fact for a different involvement of public resources. Shouldn't public research play a more active role in drug discovery or drug development? Several countries, Brazil, India, China are entering in the field of drug research. Developed countries should help building consortia on genomics, medicinal chemistry, and molecular pharmacology in order to build true drug discovery programs for neglected diseases.

Registration authorities, with the governments they are representing must play a more active role in supporting, helping, and advising those companies or PDPs active in the field. Simplification of applications, ethical decisions on clinical trials, common registration by multiple countries...