

editorial



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Medicines for tropical diseases; support through tax-incentives

Tropical diseases have the problematic feature of being endemic and a high disease burden in countries with low or moderate per capita incomes and insufficient coverage through health insurance, whereby the scope for recovering the investments in medicine research, development and production for tropical diseases is quite low [1,2]. Tropical diseases do not distinguish between well-off and poor people in tropical countries. The need to develop new medicines to cure tropical diseases remains urgent and important, with the roll back malaria program of the WHO being a key program [3]. This article discusses economic frameworks by which corporate tax-incentives may be combined with other economic mechanisms to support the discovery, development, production and distribution of medicines for tropical diseases. This would be complementary to the well-known public-private partnerships [4] and the economic frameworks for tropical diseases medicines research, based on the internal economies of disease endemic countries [5,6]. These may

be combined as partnerships/collaborations to create significant research capabilities and synergies for a broad range of tropical diseases on a long-term basis.

It may be estimated that, in a country like India, a time period of 10–12 years and a total investment of about 250–300 million US\$ would be required to discover and develop a new medicine for a tropical disease. A rule of thumb suggests that these costs would be about three-fold lower than the corresponding costs in Europe or North America. It may be considered that this may be partially achievable for large pharma companies, if they adjust the prices of their medicines by about 1% across Latin America, Africa and Asia, to generate about 25 million US\$ in revenue each year for these investments [6]. In addition to this, support through tax-incentives to offset such investments may be essential for some pharma companies with an interest in tropical diseases. The global annual sales for a single medicine for a tropical disease are likely to be below 100 million US\$, which may be barely sufficient to recover the costs of production and distribution.

Some proposals for tax-incentives have been made previously for vaccine development for the prevention of HIV, tuberculosis and malaria [7]. It is generally accepted that broader frameworks for tropical disease medicine research and healthcare in tropical countries are urgently needed, and that these countries can contribute more towards meeting these goals [3,8,9].

Over ten major tropical diseases and a larger number of minor tropical diseases are known and described [10]. The associated disease burden remains unacceptably high, in terms of disease-caused sickness, deaths, disability adjusted life years, burden on families and healthcare, and economic loss. It remains essential to discover new medicines with improved pharmacological profiles over previously discovered medicines, for clinical use as combination therapies in separate geographic regions, and as alternatives for second lines of treatment. For some tropical diseases it would be feasible to discover and develop vaccines for partial or complete protection [11,12]. Major advances in genomics and bio-informatics, and the determination of the genome sequences for many parasites/pathogens of tropical diseases by the European Bio-Informatics Institute and the Wellcome-Trust Sanger Institute, have led to the identification of unique genes and orthologues of human genes. This information serves as a basis for the discovery and development of medicines for tropical diseases.

The economic constraints and associated bottlenecks have been a major challenge for the discovery and development of medicines, vaccines and diagnostics for tropical diseases. A well-known and established framework for overcoming this, is the public-private partnerships for several tropical diseases, notably the Medicines for Malaria Venture, Global TB Alliance, Drugs for Neglected Diseases Initiative, WHO/TDR, Bill and Melinda Gates Foundation, and several other research organizations [4]. The discovery and development of artemisinin and its derivatives, by public-funded research organizations, pharma companies, and public-private partnerships is an important achievement, in discovering a new treatment for malaria [13,14]. Given the range and nature of tropical diseases, other essential and complementary approaches include public-funded and pharma-company based medicine research for tropical diseases [5,6]. It is noteworthy that during the 1970s, 1980s and 1990s several large pharma companies did engage in tropical disease medicine research, in countries such as India, under conditions of weak intellectual property protection. Given the recent changes in intellectual property and patent protection, and advances in the science and technology base in countries such as India, China and Brazil, it would be advantageous to create economic frameworks that would be suitable for tropical disease medicine research.

Economic mechanisms

It is proposed that tax-incentives will play an essential and key role in supporting medicine research for tropical diseases, whereby corporate tax-incentives for pharma and biotech companies would provide an essential economic framework to achieve cost-neutrality, as is outlined in more detail below. The time-scales and numbers are indicative of the medicine discovery and development process, which covers a ten-year period or longer, with success rates of 20% or less for preclinical and clinical research and development, respectively.

It may be suggested that when a pharma/biotech company invests in tropical disease medicine research, by committing 100–150 scientists to preclinical research and development on one or two tropical disease(s), for a period of ten years or longer (present, future), the company would deserve a tax-incentive to enable a financially neutral arrangement for this investment. Over this time period it would be feasible to discover and develop one new medicine for a tropical disease.

Similarly, it may be suggested that when a pharma/biotech company invests in tropical disease medicine research, by committing 80–100 clinicians/scientists to clinical research and development on one or two tropical disease(s), for a period of ten years or longer (present or future), the company would deserve a tax-incentive to enable a financially neutral arrangement for this investment. Over this time period it would be feasible to discover and develop one new medicine for a tropical disease.

A major hurdle for treating tropical diseases is the economic constraints that create bottlenecks for production, distribution and supply of medicines for tropical diseases. Timely access to medicines is vital, and has been discussed and emphasized by the medical and scientific communities elsewhere [3,9]. To achieve this goal, a similar economic framework may be required for the production and distribution of medicines for tropical diseases, as is suggested below.

It may be suggested that when a pharma/biotech company invests in tropical disease medicines, for the production and/or distribution of one or more medicines for a tropical disease, for a period of ten years or longer (present, future), on a regional, national, continental or global basis, then such a company would deserve a tax-incentive or other arrangements to ensure a financially neutral arrangement for this investment.

Conclusions and outlook

One may envisage that an economic framework of price adjustment and tax-incentives for pharma/biotech companies engaged in tropical disease medicine research, would create a stable economic framework on a long-term basis, which would be essential for the research, development, production and distribution of medicines for tropical diseases, on a regional, continental and global basis, and on a not-for-loss and not-for-profit basis. This would include synergies and partnerships across organizations in tropical disease medicine research for reasons of economies and scale. It is enquired whether this would be relevant for the development of vaccines and diagnostics for tropical diseases. It is widely accepted that significant improvements in health care and nutrition are essential for maintaining health, overcoming sickness, reducing birth-rates and family size, ensuring stable communities and promoting peaceful societies.

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