

GlaxoSmithKline & malaria

Malaria is a public health problem in more than 90 countries and 40% of the global population is vulnerable to this potentially deadly disease. Around one million children die from malaria each year in Africa alone and resistance to the most commonly used and affordable anti-malarial drugs is developing rapidly.

A global health crisis needs to be tackled on a global scale, with the co-operation of governments, non-governmental organizations (NGOs) and private sector companies, as well as many other groups (see Figure 1). The fundamental problems of poverty and poor health systems cannot be addressed unless all sectors work together.

In fact, in recent years significant progress has been made to increase access to medicines in the developing world, and there is a growing sense of partnership between the different sectors involved. GlaxoSmithKline (GSK) remains at the forefront of this effort, and is the only company conducting research and development into the prevention and treatment of all three of the World Health Organization's (WHO's) top priority diseases – HIV/AIDS, TB and malaria.

Facing the Challenge

In June 2001 GSK published *Facing the Challenge*¹, a

document that outlines the contribution we make to improving healthcare in the developing world.

GSK's contributions include drug donation and preferential pricing programmes, the development of new medicines specifically for diseases prevalent in these areas, community partnerships with governments and NGOs, and a unique vaccine programme.

All these initiatives reflect the spirit of partnership needed to address the problems of malaria.

Preferential pricing

GSK has been offering substantial discounts on vaccines to governments, charities and agencies for public health programmes for nearly 20 years, and has been offering preferential prices to governments of developing countries for our HIV/AIDS anti-retroviral treatments since 1997. We believe that more can be done and so we have extended our preferential pricing offers to more products, countries and customers. This includes making anti-malarials available at sustainable preferential prices to all of the Least Developed Countries of the world and all of sub-Saharan Africa. GSK's commitments on preferential pricing are detailed in *Facing the Challenge*¹ and are summarized in Figure 2.

Vaccines

Global immunization is one of the most successful public health initiatives ever, and GSK leads the way in this field, as the world's largest vaccine manufacturer and one of the principal donors of vaccines. In conjunction with two other manufacturers, we have given 100 million doses of polio vaccine to African countries. In addition, as part of the Global Alliance for Vaccines and Immunization (GAVI), GSK's combination vaccine, Tritanrix HBTM, is being provided to African countries at a cost discounted by more than 90%.

No vaccine has yet been licensed to protect against malaria – the plasmodium parasites are highly complex, and are able to adapt quickly to the immune system's defences. However, in early 2001, GSK Biologicals and the Malaria Vaccine Initiative (MVI) joined forces to accelerate the development of a vaccine that has shown promising early results against malaria. Phase I trials of this compound have been underway in The Gambia for four years, and Phase II clinical trials have recently been expanded to children in Mozambique.

Other initiatives

In partnership with the World Bank, Oxford University and Lucknow University, we are providing millions of doses of albendazole for the largest randomized clinical trial ever undertaken. The project will involve 1.2 million children, and will assess the impact of early de-worming on long-term childhood survival.

Medicines for malaria

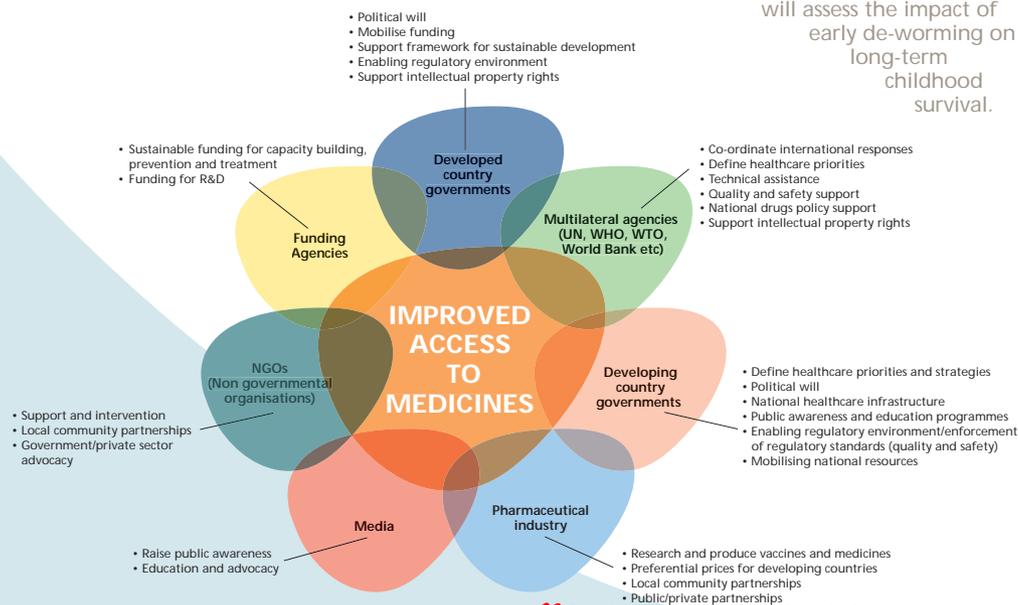
GSK already supplies 30 million malaria treatments per year in Africa at preferential prices, and we are now expanding this scheme to include our full range of anti-malarial medicines.

Since 1999, GSK has been involved in a groundbreaking collaboration to develop a new and affordable treatment for malaria. LapdapTM (a combination of two existing compounds: chlorproguanil and dapsone) is effective against malaria in areas where other therapies have encountered resistance. It has been developed primarily for use in sub-Saharan Africa and will be priced at an affordable level. LapdapTM is in the final stages of development, and regulatory files will be submitted in early 2002. The project is funded through a three-way partnership between GSK, the UK Department for International Development (DFID) and the WHO. The development of LapdapTM has also involved medical teams from Liverpool University and the London School of Hygiene and Tropical Medicine, as well as collaborators across Africa.

GSK has recently built on the success of the LapdapTM collaboration by becoming involved in two further projects. These are partially funded by the Medicines for Malaria Venture (MMV) and two new anti-malarial medicines are involved:

- Chlorproguanil/dapsone/artesunate (LapdapTM plus artesunate) entered development in 2001. The combination of conventional anti-malarials with artemesin derivatives is increasingly seen as the preferred way of treating malaria while, at the same time, minimizing the risk of increasing drug resistance. The team that developed LapdapTM is also carrying out the development of this triple combination, with funding from MMV, GSK, DFID and the WHO.
- Also in development is a novel analogue of amodiaquine, based on concepts developed at the University of Liverpool. Accelerated development of this compound, with MMV funding, is due to start in 2002.

Figure 1. Shared responsibilities





Malaria is also a risk to travellers visiting malaria endemic countries. Malarone™ (atovaquone and proguanil) is a novel combination medicine that is used both for prevention and as a treatment for uncomplicated malaria. It has been widely marketed in Europe and the USA. In addition, early-stage trials are exploring the use of a novel aminoquinolone, tafenoquine, for the prevention of malaria in travellers. This drug is currently in Phase III clinical trials.

At GSK, our mission is to improve the quality of human life by enabling people to do more, feel better and live longer. We know that no single organization can produce a solution to the crisis of malaria but, while we do not

have the mandate, expertise or resources to deliver healthcare unilaterally, we have taken a leadership role in addressing the issue of access to medicines. We believe that this is both an ethical imperative and the key to business success, and companies that respond sensitively to these challenges will be the leaders of the future. Our collaborations with MMV are one part of our commitment to these goals.

We are therefore proud to be associated with this Nature Insight, which will advance understanding of all aspects of the fight against malaria, the world's most deadly tropical disease.

GSK and diseases of the developing world

Drug donation programmes

Since 1998 GSK has played a leading role in the Global Alliance to Eliminate Lymphatic Filariasis (LF or elephantiasis – a major tropical parasitic disease causing lifelong disability in 80 countries). Working closely with the WHO, its regional offices and country Ministries of Health, GSK is an active and involved partner, providing disease-prevention treatments, funding and expertise on a massive scale. In 2001, GSK shipped 45 million treatments of its antiparasitic drug albendazole to 30 countries and provided about \$1 million in partner grants.

In 2002, it is estimated that 40 countries will request more than 100 million treatments as part of this scheme, and GSK is committed to continuing this long-term programme. Donations will increase to a maximum of 400–600 million treatments per year over 20 or more years – until LF is eliminated as a public health problem – making this potentially the largest drug donation programme in history. The WHO-recommended LF elimination strategy involves simple oral co-administration of two anti-parasitic drugs (albendazole with either diethylcarbamazine or ivermectin) given to entire at-risk endemic communities annually for 4–6 years.

Figure 2. GSK's preferential pricing commitments to the developing world

- Sustainable, preferential prices for all GSK HIV/AIDS medicines
- Anti-malarial medicines also offered at sustainable, preferential prices
- Expansion of countries eligible for preferential pricing offers. The offer will apply to all Least Developed Countries (as defined by the UN) and all countries of sub-Saharan Africa – a total of 63 countries
- Expansion of customer groups eligible for preferential pricing offers, including the Global Fund to Fight AIDS, TB and Malaria
- Development of a pilot programme to assess the impact of preferentially priced anti-infectives and de-worming agents in resource-poor settings.

These new initiatives build on the leadership role taken by GSK to address the barriers that block access to medicines in developing countries and complement the company's existing commitments of continued research and development into diseases of the developing world, offers of preferential prices on medicines and vaccines, and support for community activities that promote effective healthcare

Tritanrix HB™, Lapdap™ and Malarone™ are trademarks of the GlaxoSmithKline Group of Companies.
 1 http://corp.gsk.com/community/facing_the_challenge.pdf

