DSW Fast facts

Fighting Poverty-Related and Neglected Diseases

Strengthening Product Development Partnerships (PDPs)

Suffering on an Epic Scale

Every day more than 35,000 people die of preventable and treatable diseases such as AIDS, tuberculosis, malaria and 14 other tropical diseases named by the World Health Organisation (WHO). Tuberculosis and malaria alone claim around three million lives each year. People in developing countries are particularly badly affected by these poverty-related and neglected diseases. Millions of people in these countries have no access to medical advances in diagnosis, prevention and treatment, for example the latest vaccines. Health and development are closely linked which is why these diseases exacerbate poverty among the world's poorest people.

At present, only a fraction of the funding available for research and development (R&D) in healthcare goes towards creating new technologies to combat diseases in developing countries. The available resources are not sufficient to develop new diagnostic methods, means of prevention and medications such as microbicides, and vaccines, all of which are urgently needed to fight these diseases.

The neglected diseases include tuberculosis, malaria, HIV/AIDS and 14 tropical diseases listed by the World Health Organisation (WHO): Buruli ulcer, chagas disease, cholera and diarrhoea epidemics, dengue fever, Guinea worm, endemic in-fectious diseases (e.g. endemic syphilis), sleeping sickness, leishmaniasis (kala-azar, black fever), leprosy, elephantiasis, river blindness, bilharzia, worm infections and eye inflammations that can lead to blindness. HIV/AIDS is not a neglected disease in the strict sense, but research into vaccines, microbicides and medications for children is considered to be neglected.

Unlike rare diseases that primarily affect people in industrialised countries, the poverty-related and neglected diseases almost exclusively affect people in developing countries.

Little Incentive for Research

Pharmaceutical companies lack economic incentives to develop products that specifically address the needs of developing countries. Also public funding for research is mainly targeted towards diseases that affect rich countries. Health research for the poorer regions of the world tends to be neglected because of their limited purchasing power and the high costs of developing medical products. The figures back this up: out of 1,556 new active substances that were developed between 1975 and 2004, only 21 were intended for treating neglected diseases including tuberculosis and malaria. Health experts at the Global Forum for Health Research talk about the "10/90 gap": only 10 per cent of the world's resources for health research are being applied to diseases that affect the poorest ninety per cent of the world's population.

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Fighting Poverty-Related and Neglected Diseases

With the Millennium Development Goals (MDGs) the United Nations has also called for immediate action against neglected diseases – not just to improve people's quality of life but also to reduce poverty and enable economic growth. The MDGs emphasise the point that global partnerships need to be formed and supported, something which applies to scientific progress and developments in healthcare as well. There is a compelling need to close the "10/90 research gap" in order to achieve the health-related Millennium Goals (MDGs).

Product Development Partnerships offer Solutions

The establishment of Product Development Partnerships (PDPs) signalled a key change in the international research environment for neglected diseases. PDPs have been formed to promote research and development with the aim of rapidly making resources available in the fight against tuberculosis, malaria, other neglected diseases and HIV/AIDS. PDPs are normally based on a network structure in which different stakeholders work together: academic institutes, public research facilities and non-governmental organisations (NGOs). The advantage of a partnership of this kind is that the parties involved can each contribute their particular expertise in the different development phases of a specific product.


Foto: Iris Möker, DRK

There are now over 26 PDPs around the world, with different product portfolios. Some have specialised in fighting a particular disease and in one form of intervention, while others pursue Research and Development for several neglected diseases at once. PDPs typically operate on a not-for-profit basis. Their work is financed mainly by foundations – including The Bill and Melinda Gates Foundation – and by governments.

Special Features of International Product Development Partnerships include:

- **International portfolio management:** Unlike individual research projects, PDPs are able to utilise resources internationally where there is the greatest promise of success at any given time. After reviewing the success of individual projects the PDPs can redeploy financial resources effectively between projects if needed.
- **Tailoring the supply to meet the demand:** The aim of PDPs is to make a finished product available to developing countries at the best possible price. There are various ways of achieving this, such as giving away the patent, price agreements, technology transfer for production in developing countries, etc.

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- **Expertise:** PDPs have product development expertise which they expand by hireing former employees of the pharmaceutical industry as well as renowned researchers and doctors in industrialised and developing countries. PDPs also employ local staff in their clinical research centres, resulting in capacity building and knowledge transfer.

Product Development Partnerships have been extremely successful over the last ten years and have made great progress in researching and developing new products. Achievements include setting up a product pipeline, obtaining approvals and successfully launching new products. Studies show that PDPs are extremely cost-effective and that promising product candidates are taken through the various development stages more quickly than would have been possible in the private or public sector alone.

Why is DSW Involved?

Health – The Key Issue

DSW helps people to free themselfes from poverty and to ensure that everybody has access to Sexual and Reproductive Health services. Improving healthcare in general and fighting poverty effectively are closely linked to this goal. There is also an urgent need to tackle the neglected diseases in order to bring about a lasting improvement in people's health in developing countries. One focus of DSW's work is prevention. In the context of PDPs, DSW campaigns specifically for the development of diagnostics, preventive measures such as vaccines and microbicides and medical treatment.

Focus on Girls and Women

DSW works to improve the lives of girls and women. They are often the weakest members in society and are particularly badly affected by neglected diseases including HIV/AIDS, tuberculosis and malaria. It is only possible to improve the situation for girls and women once unnecessary suffering due to these diseases and their consequences is eliminated. People need to be healthy to take control over their lives.

Experience on the Ground

Since 1995, DSW has built up a network of youth clubs for sexual education and AIDS prevention in Ethiopia, Kenya, Tanzania and Uganda. Peer educator at these clubs tell their peers how to prevent unwanted pregnancies and HIV infection. DSW staff on the ground know about the younger generation's life circumstances and aspirations, and know from experience that there are many health risks – including neglected diseases – that threaten the young people and their environment. This practical experience informs our dialogue with policy-makers in Germany and Europe.

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Presenting Product Development Partnerships (PDPs)

The International AIDS Vaccine Initiative (IAVI) was established in 1996 as the world's first Public-Private Product Development Partnership. Its mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. IAVI's scientific team researches and develops promising AIDS vaccine candidates and conducts HIV clinical trials and studies through partnerships with over 40 academic, biotechnology, pharmaceutical and government institutions that are geared to the specific requirements of developing countries.

Together with other partners, IAVI has so far evaluated six vaccine candidates in early clinical trials in eleven countries on four continents which have provided valuable insights towards the development of an AIDS vaccine. In addition to its global involvement in research and development, IAVI also supports global AIDS prevention education, the integration of local communities into HIV research and the improvement of clinical research capacities in developing countries. IAVI's programmes strengthen the bonds between communities, national governments, scientific researchers, the media and the people who are affected by HIV, and aim to secure long-term political support for the development of an AIDS vaccine. IAVI is supported by 11 national governments, the European Union, The Bill and Melinda Gates Foundation and many other companies, foundations and private individuals.

IPM is a product development partnership that aims to prevent HIV transmission by accelerating the development and availability of a microbicide for women in developing countries. Microbicides are vaginal products that are intended to meet the need for a discreet prevention method that enables women to protect themselves against HIV transmission and gain control over their own health. IPM is focused on microbicides based on highly effective antiretroviral medications, which are one of the most promising HIV prevention options that can be initiated by women.

The formulation that has reached the most advanced stage of testing so far is Dapivirine, which is currently undergoing clinical trials as a gel and as a vaginal ring. A Phase III efficacy trial is scheduled to begin in 2011. If this trial is successful, it would provide evidence that could lead to the approval of Dapivirine products for HIV prevention.

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PATH

The Program for Appropriate Technology in Health (PATH) is an international organisation that focuses on health technologies for developing countries. PATH works through various programmes that also involve 11 PDPs and are aimed at developing vaccines, diagnostic tools and health technologies such as barrier contraception methods and injection devices. In the Malaria Vaccine Initiative (MVI), for example, PATH is working with Glaxo Smith Kline to test their vaccine candidates RTS, S in Phase III clinical trials in various countries in Africa. In the Meningitis Vaccine Project, PATH worked with the Serum Institute in India to develop MenAfriVax, an affordable vaccine that was recently licensed by the Drug Controller General of India. PATH also advocates improvements in healthcare systems and has a strong presence in Africa, Asia and Latin America that enables it to maintain close relationships with policy-makers.

TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

The Global Alliance for TB Drug Development (TB Alliance) was established in 2000 to meet the urgent need for a faster and simpler treatment for tuberculosis and to develop drugs that are effective against all forms of TB including multi and extensively resistant TB and in patients co-infected with TB and HIV. The effectiveness of existing medications is limited in these respects.

The TB Alliance's mission is to develop new, improved and faster-acting treatments for TB to shorten the course of the disease and reduce TB mortality. A treatment that is affordable, simple to use and available around the world, particularly in the poorer countries that are worst affected by the tuberculosis epidemic. Since its founding in 2000, the TB Alliance has built the largest, most diverse portfolio of tuberculosis drug candidates in history. Three of these candidates are currently undergoing clinical trials.

The TB Alliance estimates that over the next five years a funding gap of around EUR 120 million will need to be filled to develop the research outcomes into products that can be used in the field.