



Federal Ministry
for Economic Cooperation
and Development



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Patents and Affordable Access to Essential Medicines: A Development Issue

med4all Conference on

Equitable Licensing of Medical Research
Results

Charité - Berlin, 23-24 April 2009

Challenges and Opportunities

- Lack of innovative medicines dealing with specific disease burden and health problems in developing countries (DCs)
- Negative effects of TRIPS agreement and other patent regimes on access to medicines and national/regional industrial development in DC



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Current international developments

- **World Health Assembly (May 2008) / IGWG-Process:** Global Strategy and Global Plan of Action on Innovation, Intellectual Property and Public Health: Creation of additional and alternative incentives for R+D of innovative medicines (see below), and improvement of access to medicines through the use of TRIPS flexibilities

Objectives and Offers of The German Development Cooperation



Rationale of German Government's Approach to IPRs & Health

- Fostering pharmaceutical R&D and production in DCs by using TRIPS flexibilities, through helping countries and private enterprises in sustainable investments in the R&D and production of essential medicines

Objectives

- Improving the access to low-cost, high-quality medicines
- Fostering innovation
- Development of local/regional pharmaceutical industry in DC



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Development of local/regional industry I:

- Promotion of value chains in the pharmaceutical sector (including R&D)
- Reduction of supply-side constraints (e.g. quality, human resources, APIs)
- Technology transfer, e.g. to foster innovative capacities

Development of local/regional industry II:

- Reduction of regional trade barriers: Harmonisation of tariffs, trade and patent laws and drug registration and better access to procurement systems
- Adaptation of national patent legislation and implementation in DCs
- Use of the transition period for LDCs until 2016



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Strengthening innovation capacities in DC I:

- Strengthening innovation capacities by Public-Private Partnerships (PPPs) in galenic R&D for new health products against poverty-related, tropical and neglected diseases



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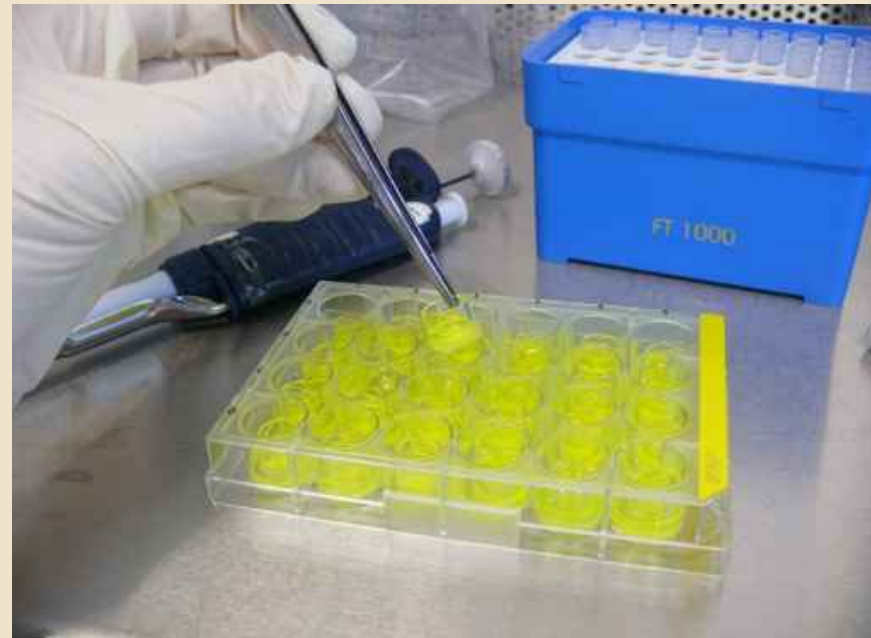
Strengthening innovation capacities in DC II:

- **Public-private product development partnerships** (PPDPs) for innovative health products:
e.g. off-patent anti-malarial developed by Drugs for Neglected Diseases Initiative (DNDi) in collaboration with Sanofi-Aventis, to be produced in Morocco

Structure and Instruments of the German Development Cooperation

We are using two existing ways:

- **Bilateral Development Cooperation (e.g. GTZ, InWEnt, KfW /DEG, PTB)**
- **Multilateral Development Cooperation (e.g. UNIDO, UNCTAD)**



Products elaborated 2006 – 2009 I

- Global market study on essential medicines for DC
- Reference Guide to Intellectual Property and Local Pharmaceutical Production in DC
- Pharmaceutical Sector Profiles in Lao, Cambodia, Bangladesh, Zambia, Zimbabwe, Lesotho, Uganda, Nigeria, Senegal, Mali, Tanzania, Ghana, and Ethiopia (for Kenya and South Africa under work)

Products elaborated 2006 – 2009 II

- Studies on the impacts of the international patent regime on pharmaceutical production and access to medicines in 14 DC
- International and regional conferences and workshops in Thailand, Senegal, Zambia, Tanzania and Ethiopia on TRIPS and local pharmaceutical research and production

Products elaborated 2006 – 2009 III

- E-learning training course on the use of TRIPS flexibilities in the field of public health in **South-East Asia** and **Africa**
- **East African Community**: Regional Programme for harmonization of trade and patent law and coordination of national activities in the EAC
- Building up national and regional roundtables and other measures for scaling up the pharmaceutical industry in Ghana and Ethiopia (in EAC and SADC under work)

Products elaborated 2006 – 2009 IV

- **Ethiopia:** Scaling up of the whole the pharmaceutical sector
- Support for the production of ARVs, ACTs and Tb-medicines in Tanzania, Kenya, Cameroun, Mocambique and Bangladesh.
- Support of pharmaceutical companies with regard to compliance with GMP-standards in Ethiopia, Tanzania, Kenya and Syria
- Training of industrial pharmacists on quality issues, including training-on-the-job

Products elaborated 2006 – 2009 V

- Building up a bio-equivalence centre for Africa in Ethiopia/Kenya (under work)
- Support of companies in the WHO pre-qualification process
- Establishment of a pharmaceutical training and research laboratory at Dar-Es-Salaam University, School of Pharmacy

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Looking Ahead: Possible Alternatives to patent based R+D



Alternative approaches I:

To secure sufficient R&D for innovative health products for fighting poverty-related, tropical or neglected diseases strong public intervention is required. The most widely discussed alternatives at this stage are:

- Multilateral public health research and prize funds: an inter-governmental fund finances inventions that have a positive effect on neglected diseases research

Alternative approaches II:

- **Patent pools:** patent holders make available to the other pool members their respective patents free of charge (possibly in combination with prize funds)
- **Patent buy-outs:** states / organizations buy patents from patentees that are unable to market the protected pharmaceutical product (lack of purchasing power)

