



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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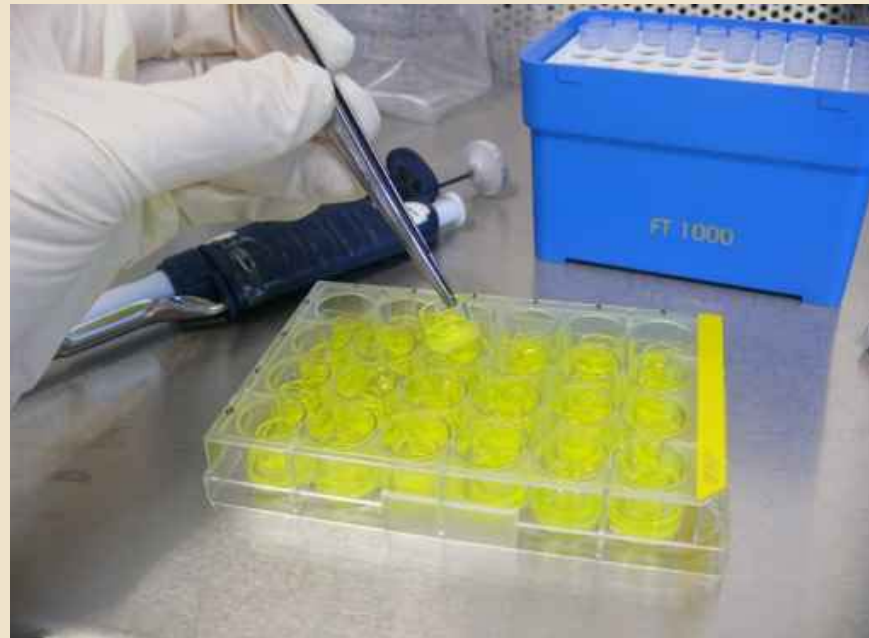
## Strengthening innovation capacities in DC II:

- **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)

