



Patients First!

Gilles Van Cutsem, MSF

Access Campaign: 1999-2010

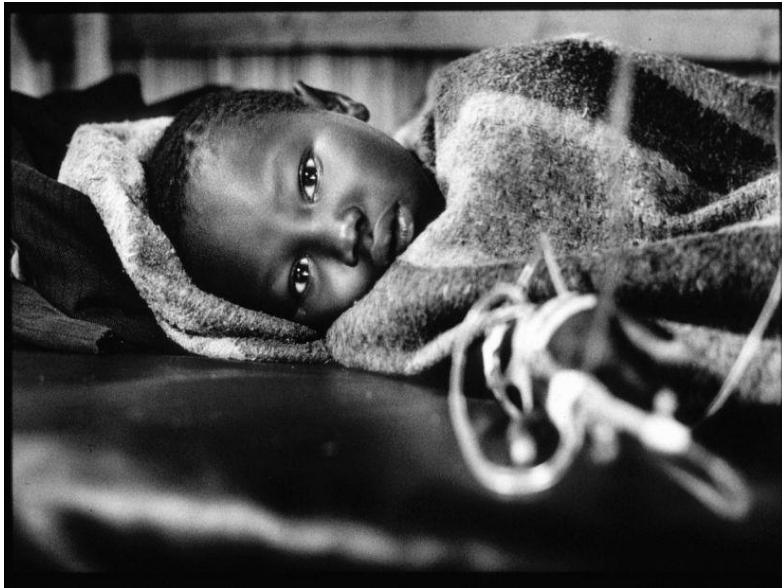
CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

Bearing Witness

“We are not certain that by speaking we will necessarily be able to save lives, but we know for certain that silence kills.”

James Orbinski

*Former President, MSF International Council
1999 Nobel Peace Prize Acceptance Speech*



*Western Cape, South Africa
HIV/AIDS*

*Northern Uganda
Sleeping Sickness*



Khayelitsha



'Aids drugs made me well again'

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and JO-ANNE SMETHERHAM

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The brand-name medicines, which cost R1 400 a month, even with discounts offered by drug companies, are still too expensive.

But Damane, 35, from Khayelitsha, has had access to less expensive generic versions, imported from Brazil, and he credits the drugs with restoring his health.

"I am now well," he told a packed news conference in Johannesburg yesterday as he held up a plastic pill box. It has one pill compartment for each day of the week, helping him take his Aids medicines on schedule.

Damane, a nervous smile showing under his blue base-

ment Action Campaign (TAC), Cefam and Coasta - pointed to the findings yesterday to urge the government to set up pilot projects to provide the drugs to symptomatic Aids patients in each province. They also referred to the results to support their argument that the government should follow Brazil's lead and make its own low-cost generic versions of the drugs.

"It is difficult, but it is feasible in developing-country conditions," said Mark Heywood, TAC secretary.

The government did not comment on the activists' calls. It said the MOC would check whether the Brazil import was legal.

The drug companies that own the patent rights to the drugs do not have plans to sue the activists. Peter Moore, medical director at GlaxoSmith-Kline, said the company would wait for the MOC to act.

Rehringer-Ingelheim spokesman Kevin McKenna said he was not surprised at the developments.

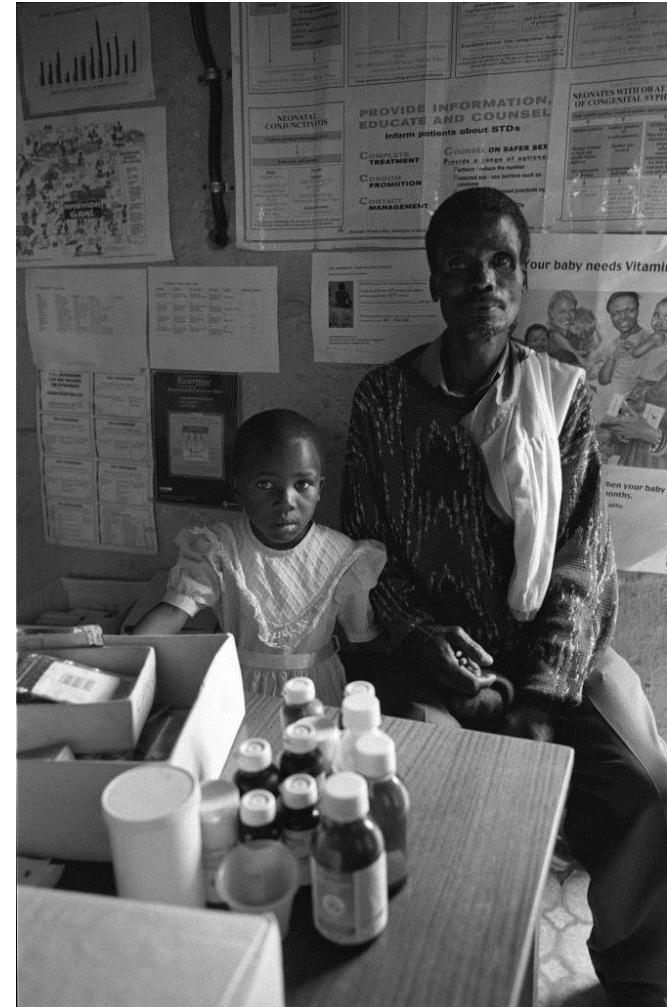
"I don't think we're falling off our chairs at the moment,"





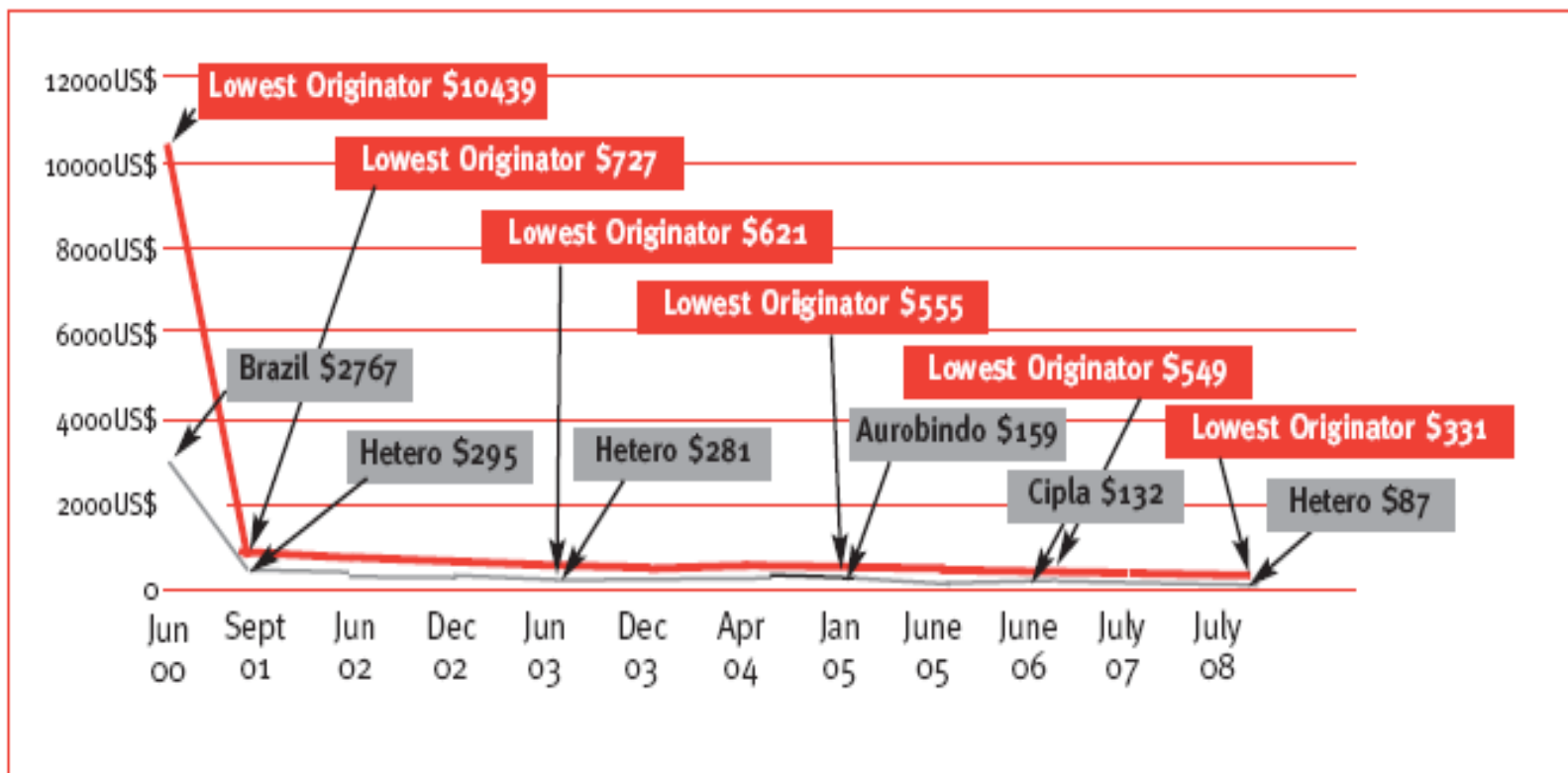


The role of the health worker is to see the patient before her and get the patient what she needs.



“Generics fuel AIDS Program” (WSJ 31 July 2008)

CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES



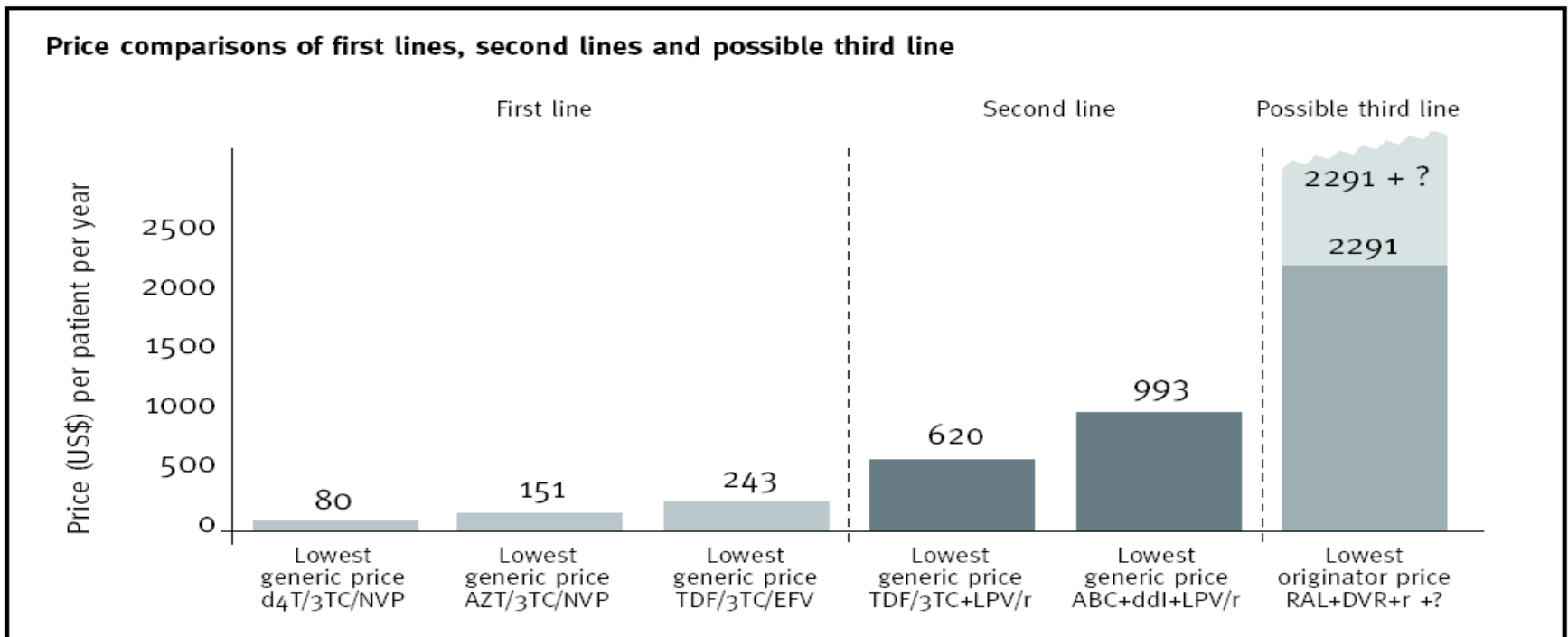
A black and white photograph of a man sitting on a bed in a dimly lit room. He is looking out a window on the right side of the frame. The room has a simple, possibly institutional or temporary, appearance with a window and a bed. The lighting is dramatic, with strong shadows and highlights from the window.

TODAY:

- needs remain enormous

AIDS is still an under-resourced emergency: drug costs, availability of diagnostics, and domestic and international policies can mean the difference between life or death

Need for newer drugs: switch to new regimens to keep people alive



Antiretroviral Treatment Scale-Up: Fixed Dose Combinations and the Absence of Patent Barriers

- Triomune (3TC, D4T, NVP) is a FDC produced by Cipla. It only exists in generic form.
- Only possible to create Triomune FDC because India's patent laws before 2005 did not recognize product patents for the 3 drugs.
- Initial cost of \$350 pp/py (2001) and now \$87 pp/py (2009).

Pediatric Drugs

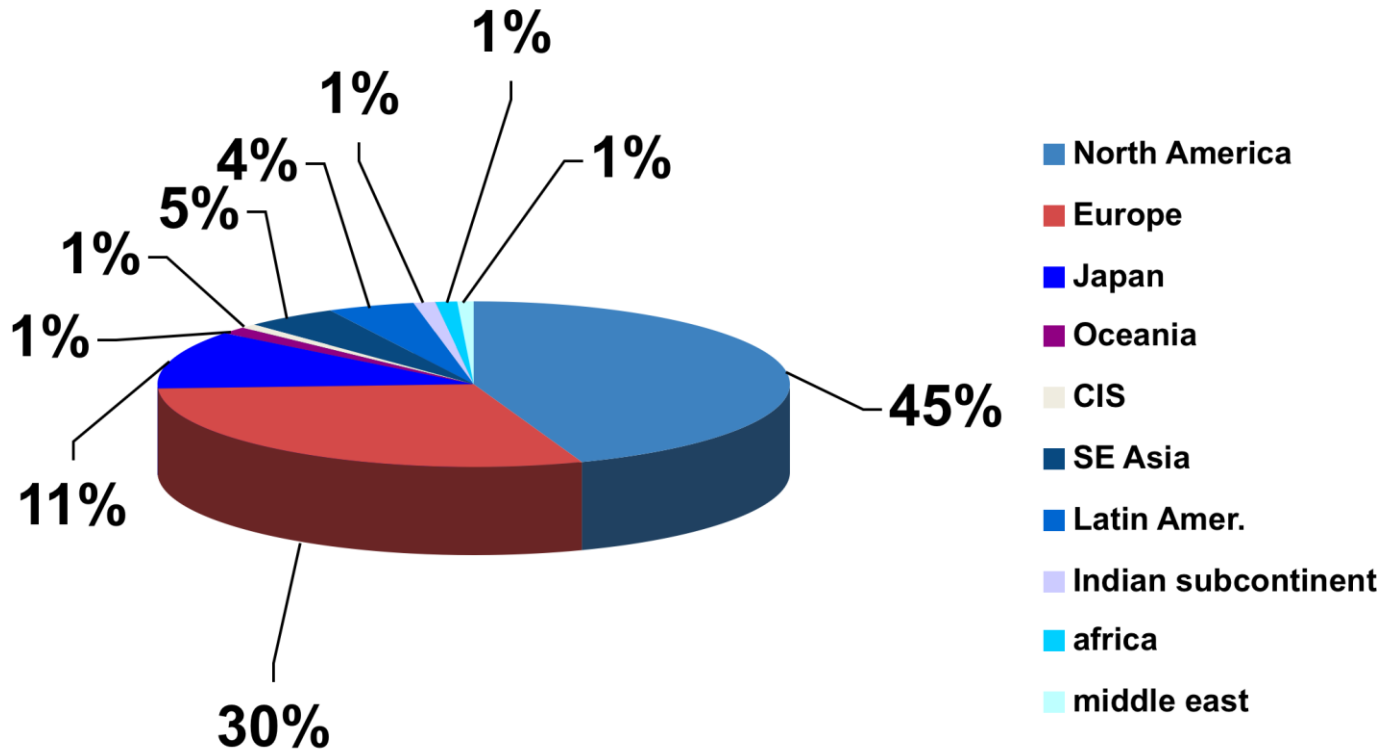
- Of 22 approved ARVs
 - 6 have no pediatric indication
 - 7 have no pediatric formulations available
- Need for immediate testing
 - Raltegravir
 - Tenofovir
 - Efavirenz (< 3 yo)
 - Darunavir (< 6 yo)

Patents severely reduce access to:

- **FDCs**
 - First-line regimens: need for TDF-based triple combinations
 - Second-line regimens: LPV/r or ATZ/r, Darunavir/r
- **Pediatric ARVs**
 - Of 22 approved ARVs: 6 have no pediatric indication, 7 have no pediatric formulations available
 - Patent barriers not the only issue: need additional incentives (i.e., clinical trials, funding for purchase to guarantee market)
- **New classes of drugs**
 - Would otherwise be blocked for 20 year patent term
 - **Integrase inhibitors:** raltegravir, elvitegravir
 - **Entry inhibitors:** maraviroc (MVC)
 - **New booster to avoid ritonavir monopoly :** GS 9350, SPI 452

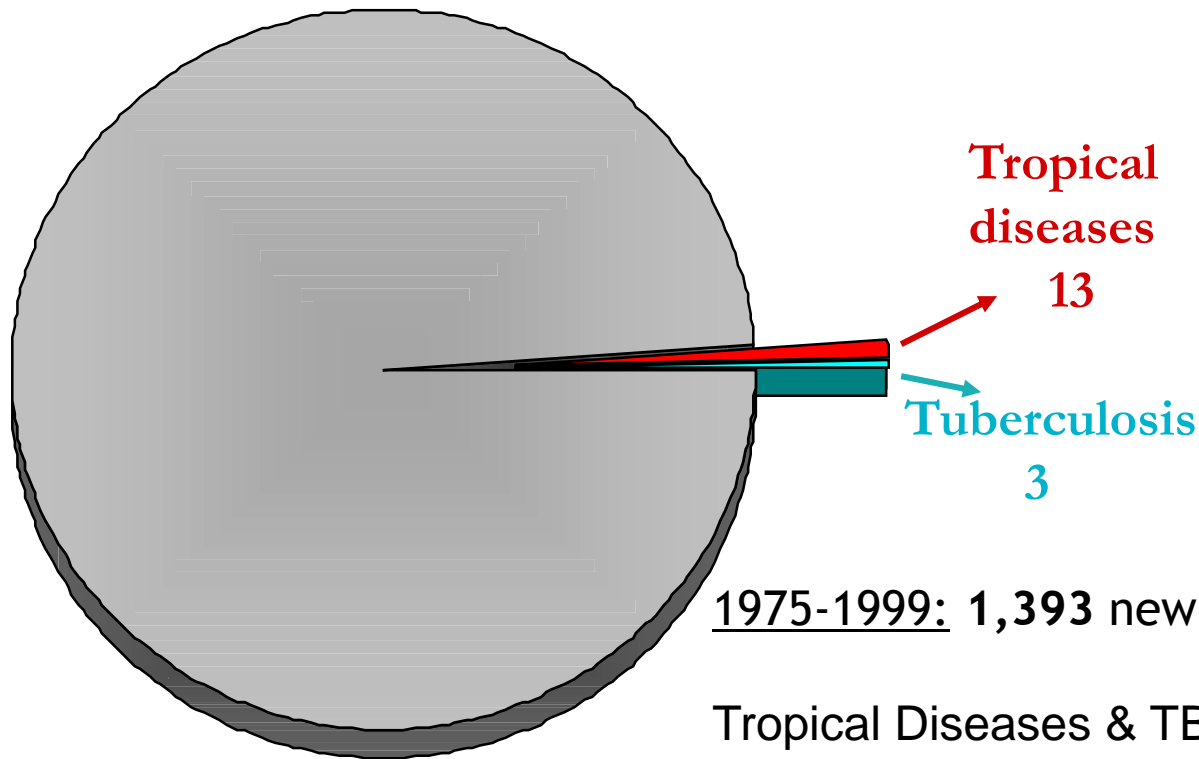
Worldwide Pharmaceutical Market, 2005

Monopoly pricing encourages market-driven rather than needs-driven R&D.



Neglected Diseases: The R&D Barrier

**Very little research on medicines for diseases only
affecting poor countries**



10% / 90% access gap:

10% of the world expenditure on health R&D is spent on health conditions that affect 90% of the global disease burden (GDB)
(Committee on Health Research and Development)

1975-1999: 1,393 new chemical entities marketed

Tropical Diseases & TB account for 12% of GDB
179 new drugs developed for cardiovascular disease (11% GDB) (Trouiller, et al., *Lancet* 2002)



**A paradigm shift is needed:
changing global rules
to prioritize people's health
needs over profit**



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activist groups announced it had imported the medicines from Brazil in violation of drug-company patent rights but with the full blessing of the Medicines Control Council (MCC).

Citing preliminary results from a pilot project in Khayelitsha, the activists said the Aids drugs had reduced the presence of the virus in people's bloodstreams to undetectable levels after less than one year of treatment. They said patients were getting off their deathbeds and returning to productive work and family lives.

"We literally resuscitated people," said Eric Goemaere, who heads the Aids clinic run by Médecins Sans Frontières (MSF) in Khayelitsha.

The preliminary results of the Khayelitsha pilot study - which has reported findings for 85 patients taking the Aids medicines - are the first evidence from a township clinic in South Africa that the Aids drugs can be taken on a long-term basis and can have the same dramatic effect in improving health as they have had in industrialised countries.

ment Action Campaign (TAC), Oxfam and Cosatu - pointed to the findings yesterday to urge the government to set up pilot projects to provide the drugs to asymptomatic Aids patients in each province. They also referred to the results to support their argument that the government should follow Brazil's lead and make its own low-cost generic versions of the drugs.

"It is difficult, but it is feasible in developing country conditions," said Jark Heywood, TAC secretary.

The government did not comment on the activists' calls. It said the MCC would check whether the Brazil import was legal.

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Multi-Tiered ARV Access

Drug	Patent Expiry
Darunavir	2013
Atazanavir	2017
Fosamprenavir	2018
Etravirine	2019
Maraviroc	2019
Raltegravir	2022

Access if you can afford it....

Was the last decade of rapid scale-up only a mirage?

THIS PANDEMIC
IS WORSE THAN THE
HOLOCAUST DOCTOR
DENIALIST PLEASE!! GIVE
US ANTI-RETROVIRAL THERAPY
WE WILL DO COUNSELLING
FOR FREE!!!



Some Ongoing Operational Challenges

CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

- **Adult regimens (HIV/AIDS and TB)**
 - New and adapted first-line regimens that are better tolerated, easier to use, even more potent
 - Affordable, accessible, adapted second- and third-line regimens
- **Pediatric formulations (HIV/AIDS and TB)**
 - FDCs for infants and low-dosage or breakable tablets for children
 - Clinical trials for children for new drugs
- **Tools to diagnose and manage TB/HIV co-infection**
 - New drugs and diagnostics
 - Additional research into drug interactions between preferred ARVs and common TB drugs
- **Field-adapted lab monitoring tools**
 - Rapid, low-tech, semi-quantitative tests to monitor efficacy, detect treatment failure, diagnose OIs, monitor community resistance patterns
- **Affordable and appropriate vaccines**
 - Vaccines for priority diseases developed and made timely available in poor countries

Some Ongoing Political Challenges

CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

- **“TRIPS Plus” agenda:** pressure to relinquish TRIPS flexibilities
- Continued **price reductions** needed
- Continued **scaling up** of access to existing drugs needed - political commitment at developing country and donor levels
- Implementation of the **Doha Declaration** and the use of **TRIPS safeguards**
- Political actors must address the question of **where the affordable generics will come from** now that TRIPS implemented in pharmaceutical producing countries (i.e., post-TRIPS in India): need for developing country production capacity, technology transfer
- **Human resources!** Commitment to **health systems strengthening**
- Increased **resources and coordination** from donors needed (fulfillment of commitments)
- **Political will from national governments** in developing countries needed to develop and implement strong health care initiatives
- **Public and donor financing for the development of new tools** needed (operational research and R&D); WHO will need to take leadership role
- Support for **innovative financing and R&D mechanisms** (prize funds, patent pools, R&D Treaty)

What can you do?

Learn. Read. Inform yourself.

Communicate

Post on social media about FTPL!

- Tweet @the_dti to @FixPatentLaw and use #Pharmagate !
- Tweet at the conference to turn in the survey!
- Retweet the attached tweets that @MSF_southafrica will be posting throughout the week!

- Identify new issues and write about them
- Sign the linezolid letter
- Write: to the press; articles; to civil society
- **Encourage people to fill out the survey and turn it in at the TAC stand #29!**
- **Attend one of the events with Fix the Patent Laws speakers**

Because patients cannot wait 20 years for the right drugs.
And we know what they are.



For more information, please visit: www.msfacecess.org.