How TRIPS are enhancing inequalities
The case of access to HIV/AIDS drugs

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Foreword : what is this paper about ?

- The Inequalities under observations are the ones between
  - Northern and Southern citizens (PVVIH and patients under treatment)
- Encompassing mainly
  - Access to drugs, namely Antiretroviral Treatments (ART)
  - … and some related issues

- Pharmaceutical patents are thus at the heart of the issue here debated
- Key dates and issues
  - 1994 and the signing of the TRIPS
  - 2005 and the end of the deadline for DCs to comply with TRIPS requirements

Issues to be discussed

- 1. Pharmaceutical patents : an old and very controversial issue
- 2. The signing of the TRIPS and its Meaning
- 3. TRIPS Before and After 2005 : their impacts on access to HIV/AIDS drugs
- 4. Where do we stand : a short assessment of current inequalities
- 5. Concusions

1.
Pharmaceutical Patents And Public Health

Pharmaceutical patents : An very old but still controversial question

Since the establishing of the very first patent systems (Fr, USA, England : late 18th century), pharmaceutical patents were at the heart of hot controversies opposing :

- A « public health » vision excluding drugs and pharmaceutical molecules from any kind of private appropriation
- A proprietary and individualistic vision recommending the granting of patents to inventors of pharmaceutical molecules in the same way than for any other ”inventors”

Patent controverises
Lessons from history

- In most developed countries patents pharmaceutical molecules were not introduced before the 1960's
  - FRANCE : From 1844 to 1968 patents on therapeutic molecules were prohibited
  - Switzerland : 1977, Norway 1992…
- Patents on processes were eventually granted only if it existed at least one other route to (free of any kind of patent right) to process the same molecule
- The granting of patent never was the only way envisaged by policy makers to incentivize inventions ("prizes", buying of useful inventions through public money, … were also of common use)
- In most IPR laws : provisions regarding "compulsory licenses"

What about the South ?

Until the mid 90's (and the siging of the TRIPS)

- The right was recognized to countries with different levels of development to establish different patent systems

- …In full compliance with the Paris Convention :
  - No or very "weak" patent protection in most DCs
  - No patenting of pharmaceutical patents in most DC's : India, Brazil …
- Patent issues (and controversies) were put under the aegis of WIPO

2.

The changes introduced by the TRIPS

The New Constraints Generated by the TRIPS

The signing of the TRIPS (1994) meant

- The extension at the world Level of patent protection provisions designed for the firms of the most developed countries (patenting of therapeutic molecules, 20 years length protection …)

This "upward harmonization" of IP protection

- Negated the differences in national capabilities to provide access to medicines, a provision that was at the basis of the former Treatise (WIPO, Paris Convention…)

Key consequence

- The TRIPS have put an end to the right of developing countries to produce and/or import generics drugs, at low costs to satisfy the needs of the poor

Pharmaceutical Patents Regimes under the TRIPS

The signing of the TRIPS under the aegis of WTO have given birth to a series of new constraints, regarding access to treatments in DC's and LDC's

- Some Articles (Art 28 to 31) states the right to use « compulsory licenses », especially in case of « health emergency »

- Art 31f seems to prohibit the « imports » of generic drugs, even for the countries lacking of the technical capabilities required to produce the drugs localy

  … but : the working of these clauses were never clarified in a satisfactory manner…

- 2001 and the "Doha Declaration" opens some room for DC's and LDC's but the Declaration has never been enforced as an international law (see Genova 2002)

How it happened ?

- First unsuccessful tentatives under the aegis of WIPO (one country, one vote principle)
- After this failure, the negotiations were put in the context of WTO (alias Uruguay Round)
- Combination of
  - « Aggressive unilateralism » (Baghwati, 1991) by the use of « Super » and « Special 301 » of the Omnibus Trade and Competitiveness Act (1988) …
  - with Multilateral negotiations : period of the Uruguay Round…
- The passage from WIPO to WTO as the key factor explaining the adoption of the TRIPS

3.

The impact of TRIPS on inequality in access to Drugs

Nature and Dynamics of HIV/AIDS treatments

- Since 1996 : **Combinations of 3 antiretroviral drugs**
  - Stop the progression of HIV disease.
  - ***A medical revolution*** *: allowing a significant increase of the survival and quality of life of people living with HIV* *(mortality and mobidity)*
  - *But,* ***strong side effects*** *and high level of* ***toxicity*** and drug **resitances** due to HIV mutations

A constant need of several therapeutic combinations and new drugs (To manage treatment fealure ; to decrease side effects/toxicity and to increase efficacy)

- **First** ⇨ **second** ⇨ third ⇨ …… line treatments
- **New** first/New second/New third/… line treatments

The pre 2005 period

Patent, Prices and Access to ART in the South

The 90's : very difficullt beginings

- **Prohibitive cost** of first line patented ARV provided by multinational compagnies (around 10 000 USD/per/year)
- **No access** at all in the South, except for few very riche people !
- WHO recommandations were restricted to « prevention »

  - ART in the south considered as « **non cost-effective** »

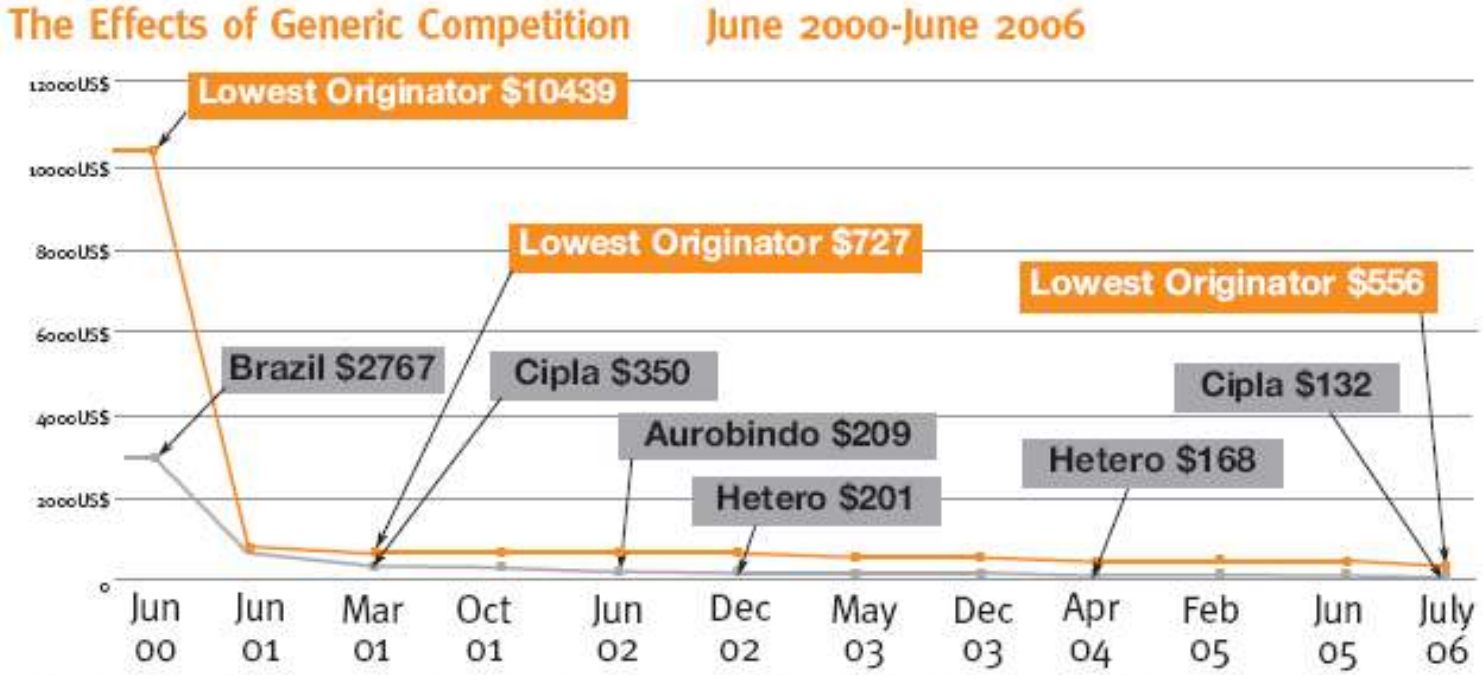
The early 2000's : first successes

- First **low-cost generic versions** of unpatented ARV in the South
- AII "**preferential pricing**" policy from multinational pharmaceutical companies
- Establishing of the **GFAMT**

➢ Launching of the first ART Programs in many countries of the south

Pre-2005 : Generic competition and spectacular decreases in prices of first Line ARV therapies

Graph 1: *Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year.*



Generic competition has shown to be the most effective means of lowering drug prices.

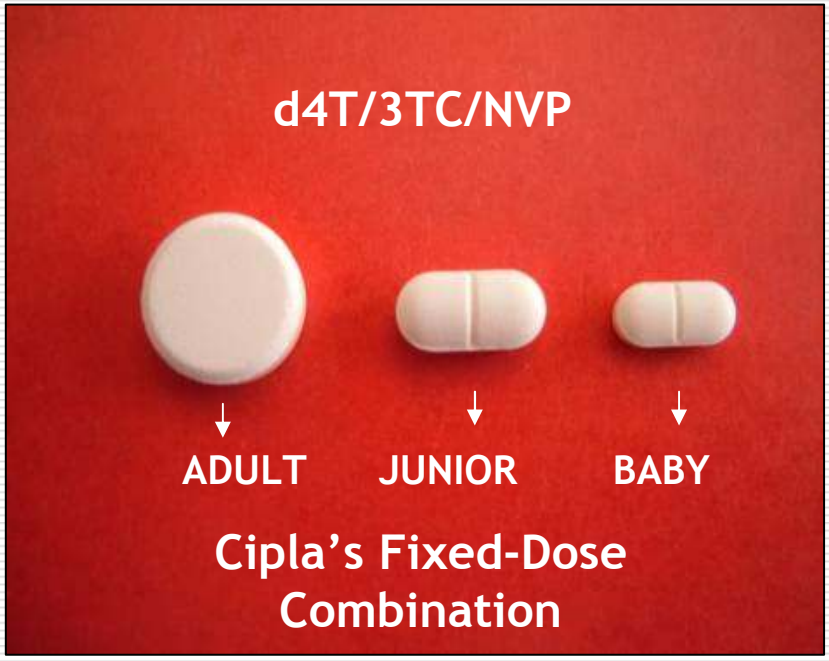
Innovative treatments from the South: The first fixe-dose Combination in HIV/AIDS

Today : (estimated) half of all patients on ARVs in developing countries depend on Indian generic ARVs

- **A major innovation** :

Triomune from Cipla Ltd : the first 3 in 1 combination

Made possible because of the exclusion of drugs from patent rights in India until 2005



TRIPS Post 2005
Key changes

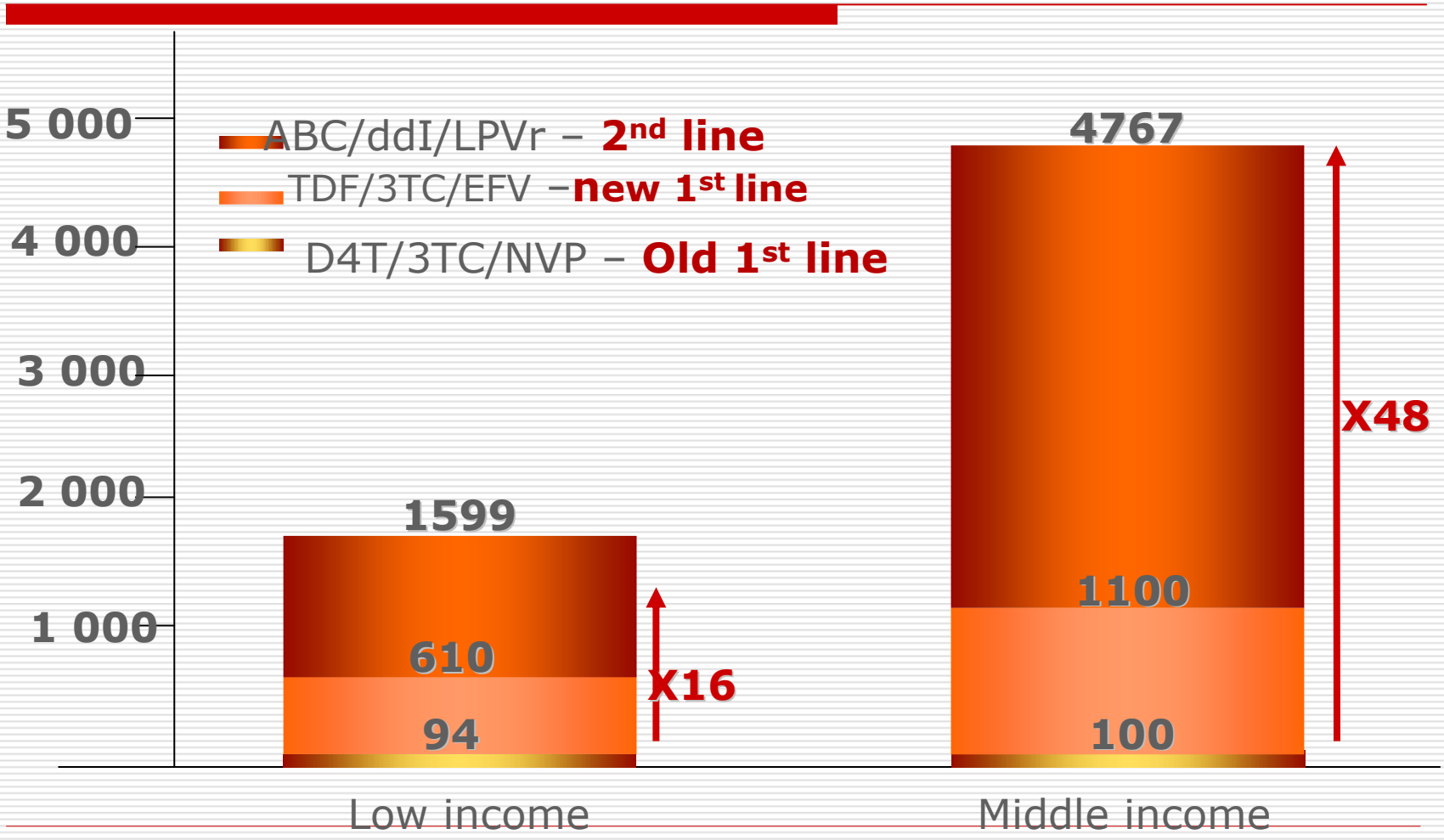
- **Increasing need** to move towards **second line** combinations (because of virus mutations)
- **Urgent need** to move towards **new first line** combinations due to the high toxicity demonstrated by the previous first line (WHO recommandations 2006 ; 2010)

But,

- Important **barriers to generic competition** (Amended Indian Patent Act 2005)
- **Soaring ARV prices** : prohibitive prices of newer first and second-line therapies

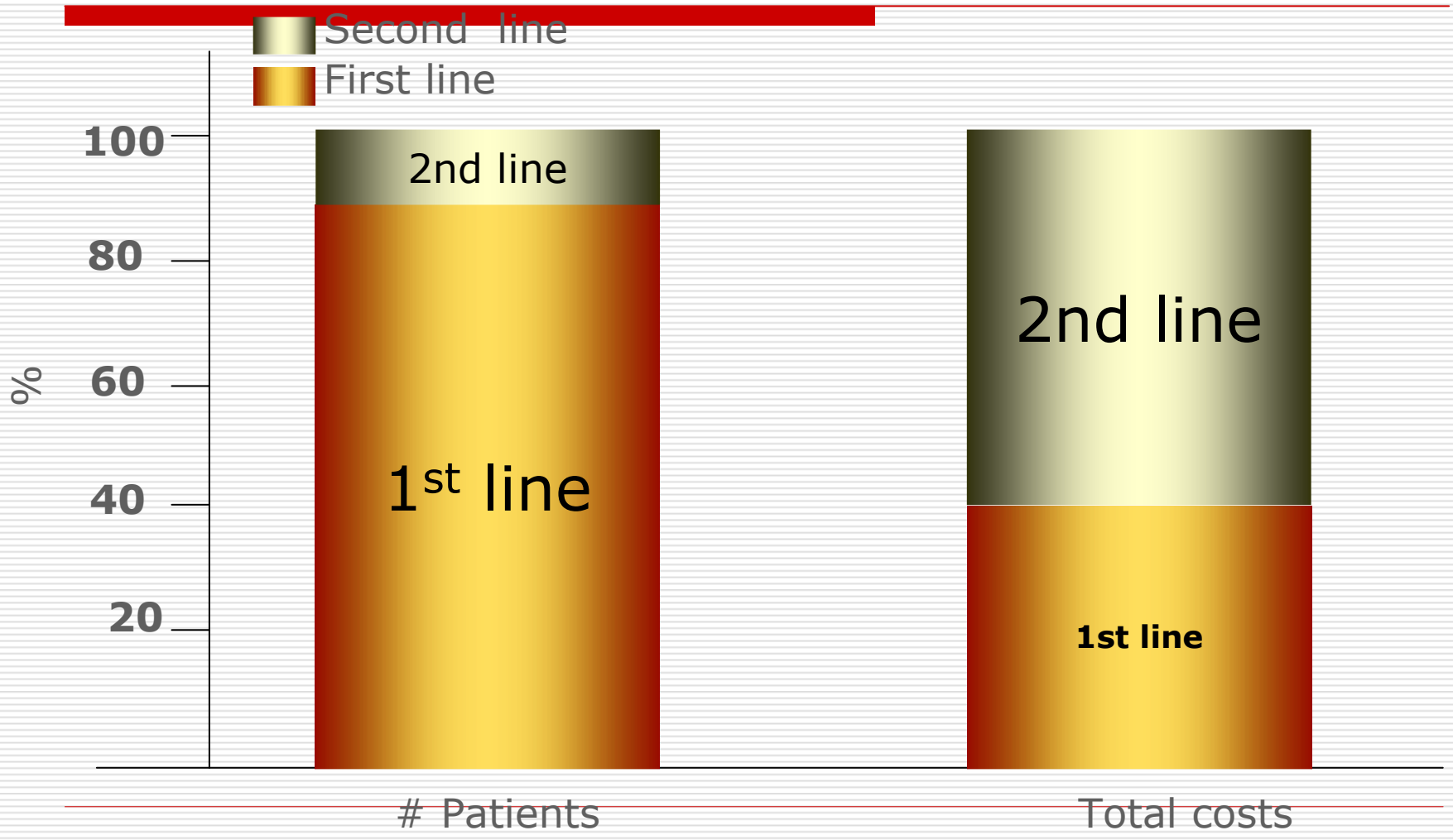
Soaring of the price ART

(WHO Global Price Reporting Mechanism , Oct.2008)



Programme cost and regimens

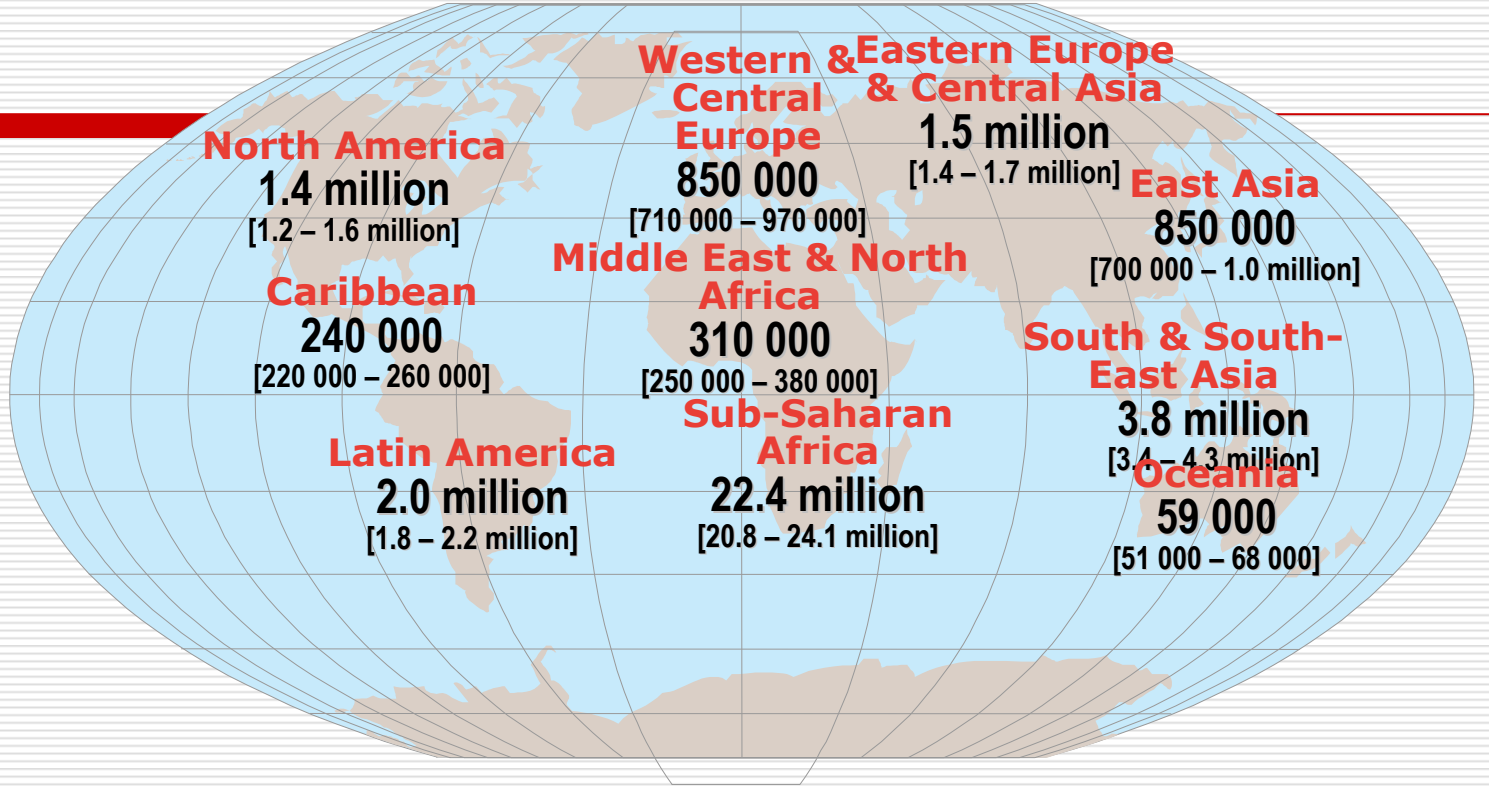
(source : WHO Global Price Reporting Mechanism, Oct.2008)



4. Where do we stand ?

Some key indicators related to inequal acces

Adults and children estimated to be living with HIV, 2008

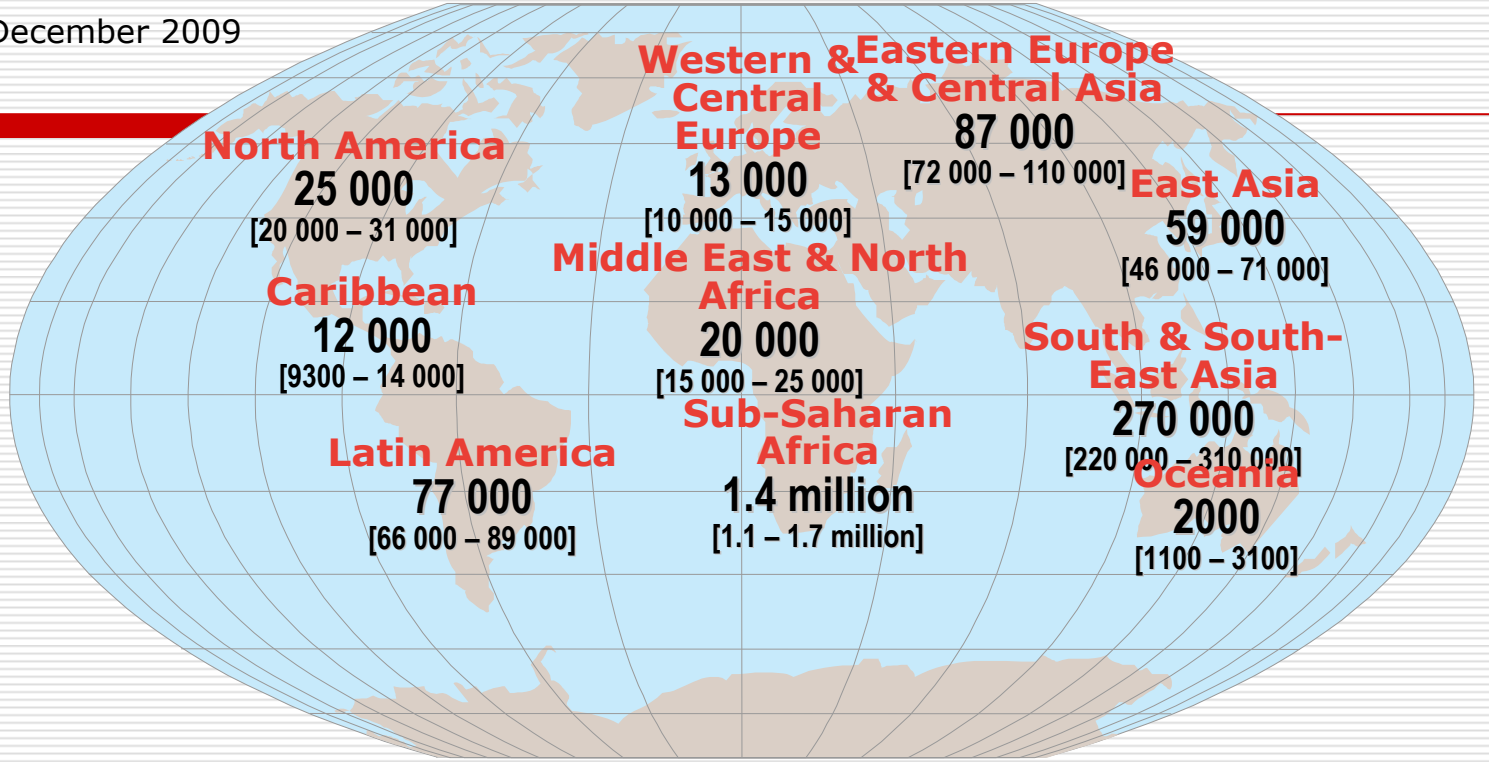


Total: 33.4 million (31.1 – 35.8 million)

WHO, December 2009

Estimated adult and child deaths due to AIDS, 2008

WHO, December 2009



Total: 2.0 millions

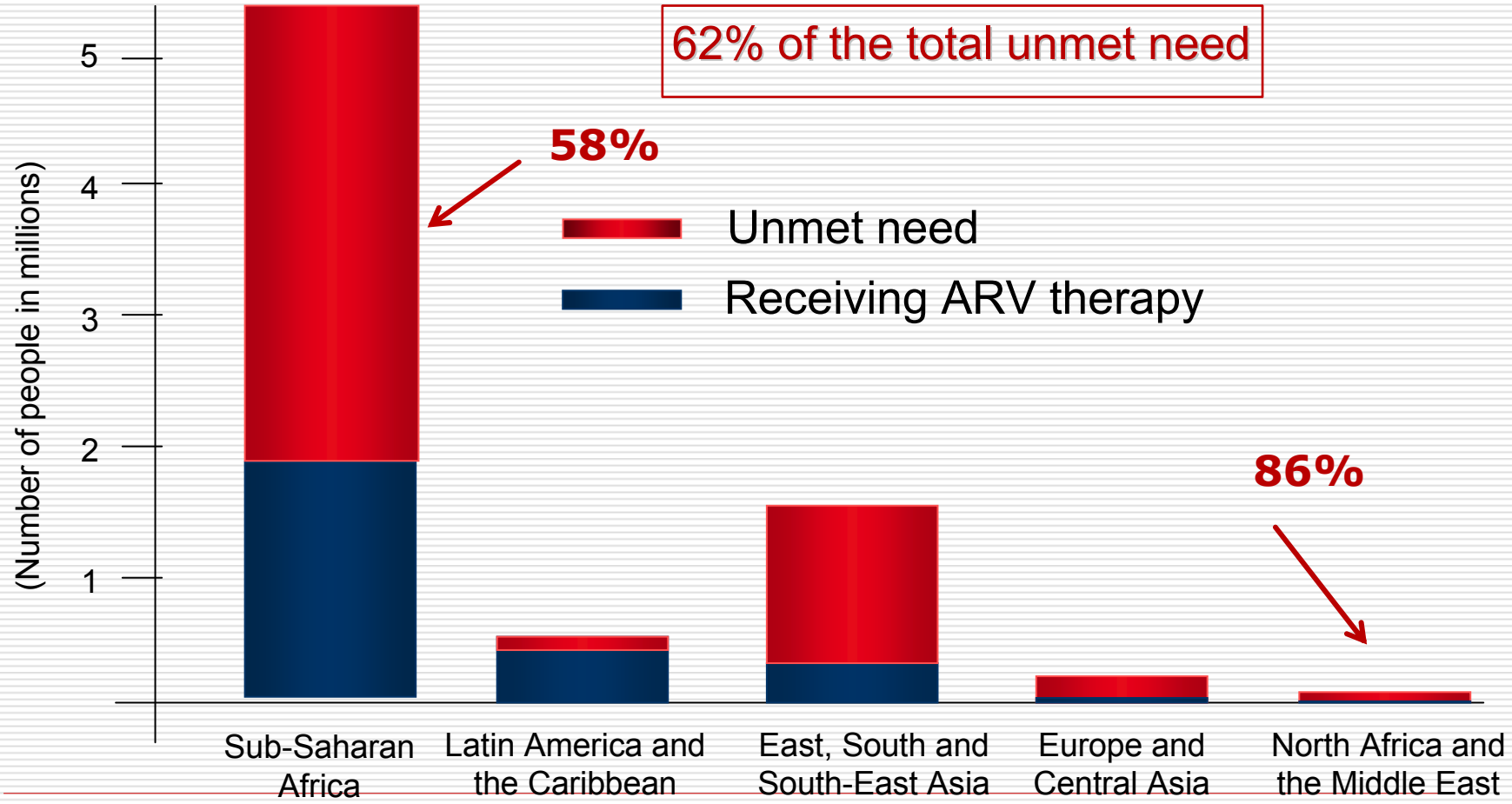
Sub-Saharan Africa : 1.4 million
North America 25 000
Western and Central Europe : 13 000

Over 7400 new HIV infections a day (in 2008)

- More than 97% are in low- and middle-income countries
- About 1200 are in children under 15 years of age
- About 6200 are in adults aged 15 years and older, of whom:
  - almost 48% are among women
  - about 40% are among young people (15–24)

WHO, December 2009

ARV Therapy: global need, December 2008



Conclusions (1/2)

Inequalities are almost every where :

- % of people in need currently benefiting from ART as regards both
  - 1st line
  - 2sd line treatments (less than 5% of people in need of 2sd line treatment currently benefit from it
- Nature of the drugs and quality of the treatment distributed
  - The cocktail distributed to the Patients of the North is carefully chosen among a list of about 30 different drugs
  - 90 % of the patients in Sub-Saharan Countries receive the same basic combination, comprising a drug (d4t) which toxicity is now established
- Monitoring tools, and effectiveness of the treatments
  - An abondant material for the building of indicators !

Conclusions (2/2)
AIDS and the « Health Paradox »

- Simple formulation :

  « The drugs are in the North, the patients are in the South !... »

- More adequate one :
  - Whilst drugs and treatments are more and more efficient and accurate … the new IP rules entering into enforcement make their access to patients of the south more unlikely than ever

"Call for action to secure universal access to antiretroviral therapy in Developing Countries"

Orsi, Carrieri, Coriat, Delaporte, Moatti, Spire, Taverne, Barré-Sinoussi

The Lancet (May 15th, 2010)

Key ideas : reopen the entry for generic producers; redesign and extend the conditions to issuing compulsory licenses