Improving Health Care in Africa

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IFPMA
International Federation of Pharmaceutical Manufacturers & Associations

VFA
Verband Forschender Arzneimittelhersteller e.V.

About IFPMA

- International Federation of Pharmaceutical Manufacturers & Associations, based in Geneva
- Non-Profit, Non-Governmental Organisation in relations with WHO and other international agencies
- Represents pharmaceutical industry associations & companies from developed & developing countries, including VFA
- IFPMA member companies are research-based pharmaceutical, biotech and vaccine companies, often having generic and self-medication medicines

Documenting Growing Industry Help for Developing Countries

2007 Report Shows Increased Industry Activities in Developing World

Section	 2006	 2007
HIV/AIDS	24 programs	52 programs
Malaria	11 programs	13 programs
Tuberculosis	12 programs	13 programs
Tropical Diseases	8 programs	19 programs
Vaccine Preventable	9 programs	10 programs
Child & Maternal		17 programs
Chronic Diseases		11 programs

- Access & Capacity Building separated from R&D programs
- For HIV/AIDS, also ARV Access, Mother & Child programs
- Color-coding for therapeutic areas

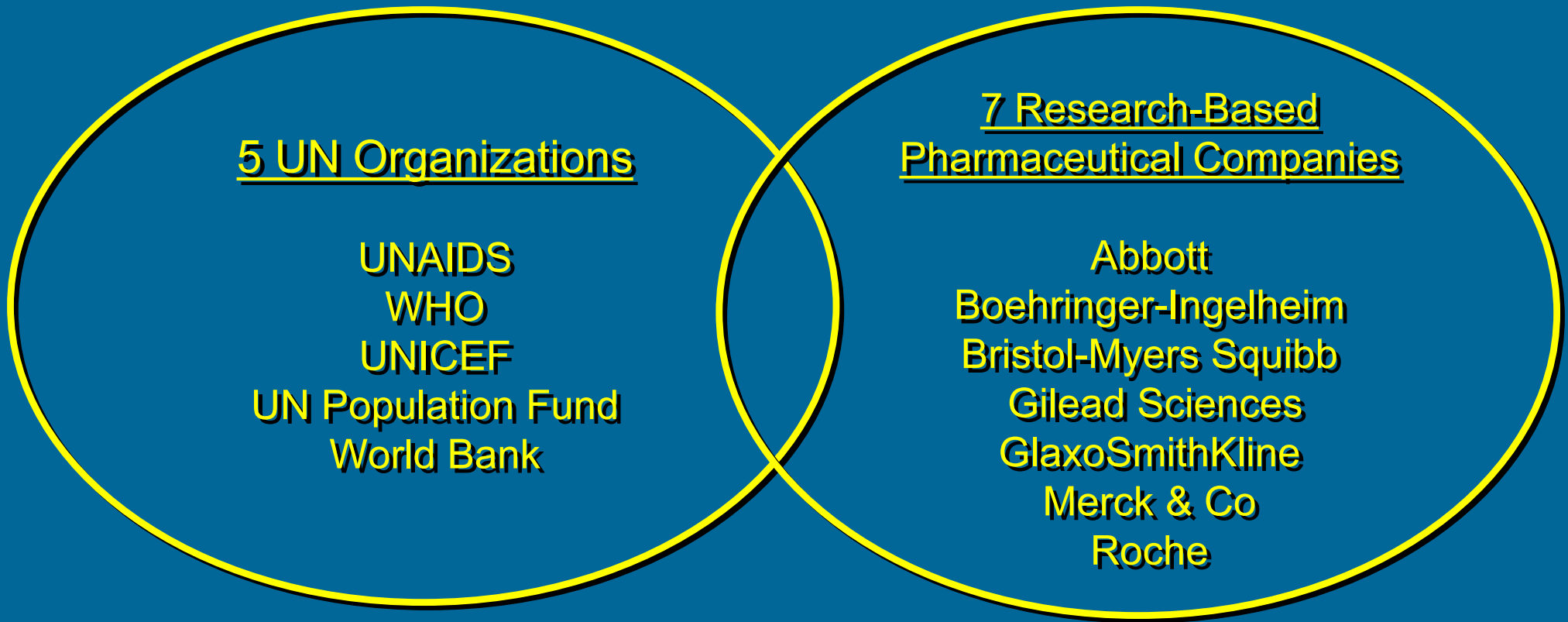
HIV / AIDS

- 39.5 million HIV+, worldwide, 2006
- 24.7 million HIV+, sub-Saharan Africa, 2006 (63%)
  - 1.1 million more than in 2004
- 2.1 million HIV deaths in sub-Saharan Africa, 2006
  - 0.2 million more than in 2004

The Accelerating Access Initiative (AAI) Partnership, 2000-2007

Vision Statement

The AAI effort is undertaken to progressively enhance the capacity of countries to increase access to, and use of, sustainable, comprehensive and quality HIV/AIDS interventions across the entire spectrum of prevention, treatment, patient care and support



AAI Objectives

- To accelerate sustained access to appropriate interventions and affordable HIV-related medicines and diagnostics for developing countries and those hardest hit by the epidemic
- Reach significantly greater numbers of people in need through new alliances involving committed governments, private industry, UN, development agencies, NGO's and people living with HIV
- Establish and support a context of a broader framework of care, treatment and support with respect for human rights, equity, transparency and accountability

Six Key Principles of the AAI

1. *Unequivocal and ongoing political commitment by national governments…*
2. *Strengthened national capacity…*
3. *Engagement of all sectors of national society and the global community* -- including governments of developing and industrialized donor countries, international NGOs, industry, other segments of civil society (particularly people living with HIV) and multilateral organizations…
4. *Efficient, reliable and secure distribution systems* are necessary to ensure that medical supplies and other consumables procured by the public sector or NGOs are made available to people who need them at the appropriate contact points within health systems…
5. *Significant additional funding from new national and international sources…*
6. *Continued investment in research and development by the pharmaceutical industry:* innovative new treatments for HIV/AIDS and other diseases affecting the developing world -- the best hope for new and better future medicines and vaccines ... …Therefore intellectual property rights should be protected, in compliance with international agreements, since society depends on them to stimulate innovation.

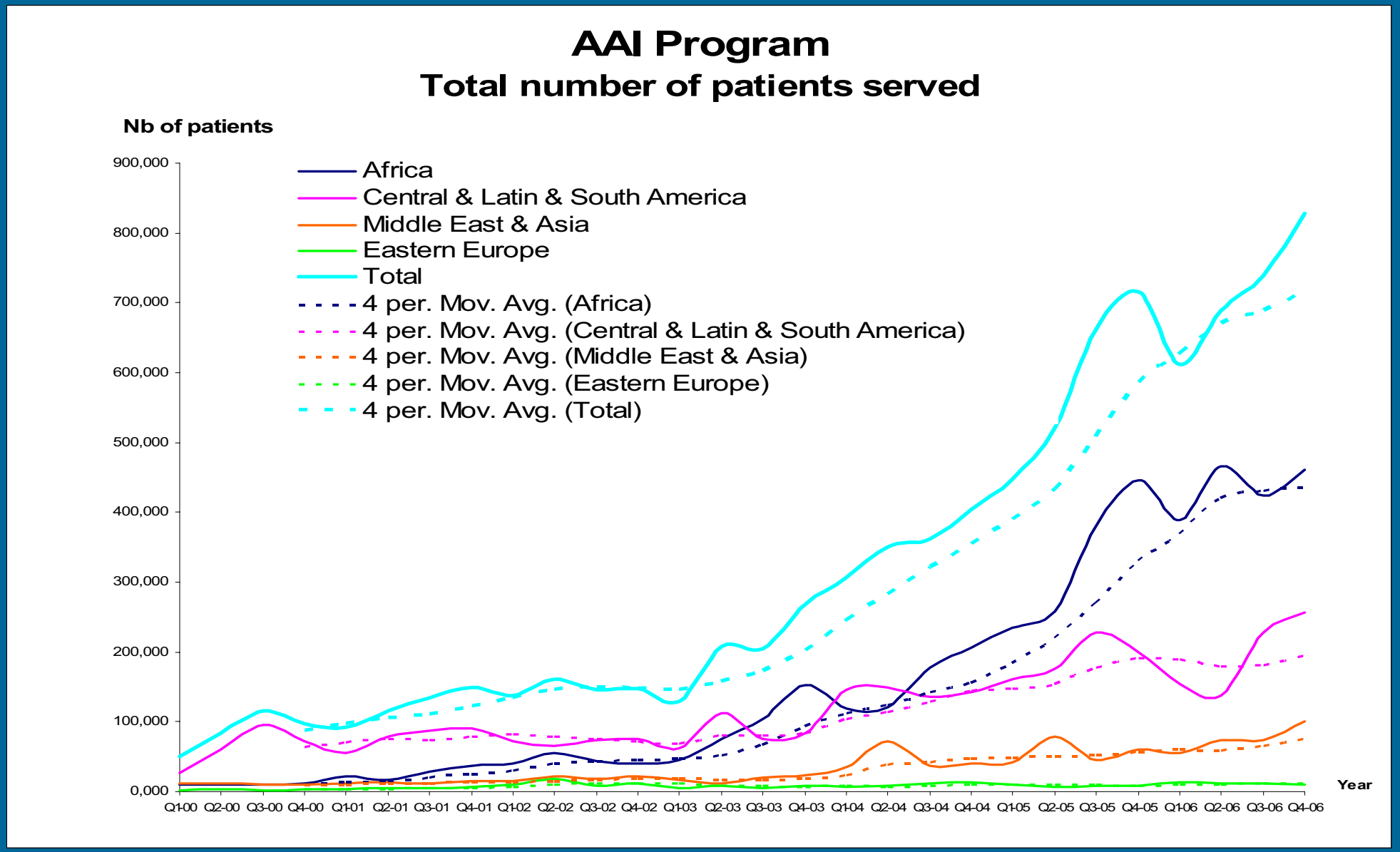
How AAI Functions

- AAI is a country-led process, responding to the priorities and needs identified at the national level
- Companies each commit independently to preferential pricing in these countries

Timeline

- **May 2000** – AAI launched
- **2002** – AAI Companies sign letter of intent with Economic Community of Western African States and Caribbean Community to expand access to care and treatment through AAI
- **2003** – Health Ministries of 6 Central American countries reach individual agreements with AAI companies
- **End of 2003**: doubling of number of patients on therapy to 150,000
- **November 2004** – 80 countries indicated interest in AAI
  - 49 countries have developed national plans to improve access within AAI
- **2007** – Announcement of new patient numbers through Q4 2006

Est. Number of Patients on AAI Company ART – Q4 2006



NB: AAI is the only organisation with such a broad set of data, representing 7 years history of access to treatment in developing countries

Key Data Elements

- More than 827,000 people were receiving at least one ARVs supplied by the 7 AAI companies at the end of 2006
- This number has doubled in the last 2 years
- In Africa alone, patient number increased by 120% over the last 2 years
- The number of treated patients with ARVs supplied by the AAI represents more than 40% of the total number of patients treated in the developing world as estimated by WHO in their report "*Towards universal access*" (April 2007)

Challenges to Access in Resource Limited Settings

- Limited basic infrastructure, particularly in rural environments
- Limited health care infrastructure & equipment
- Limited human resources/ limited training / capacity
- Food security / clean water
- Psychological and social issues
- Treatment & monitoring costs
- Danger of inappropriate use of ARVs: multi-drug resistance
- Compliance with therapy
- Logistical challenges of supply chain management

Ongoing Need for AIDS Medicines Innovation

Key Issue: There is no cure -- or vaccine -- for HIV/AIDS

Resistance to existing drugs is developing, and will continue to develop

- Need for <u>new drugs</u> – beyond 1st and 2nd line therapies
  - Better control of the infection
  - Management of resistant virus

- Need for <u>easier administration</u>
  - Once/twice a day medicines
  - Fixed dose combinations / Co-pack options
  - improved paediatric formulations

More than 20 ARV's are available to patients now and over 30 more are in the human clinical trials

- **Need for a <u>vaccine</u>** – of approximately 75 new medicines in clinical trials, <u>15 are vaccines</u> in the "pipeline"

The AAI Companies' Commitments are long-term

Malaria

- ~1 million deaths/year in sub-Saharan Africa (90% of total)
- Majority of victims are children under 5 years

Malaria: Access & Capacity Building

- Roll Back Malaria (1998)
  - WHO, UNICEF, UNDP, World Bank, endemic states, NGOs, Academia,
  - GlaxoSmithKline, Novartis, sanofi-aventis
  - Global Coordination, Advocacy, Forecasting, Research
- GlaxoSmithKine (2003)
  - No-profit prices for antimalarials for all Global Fund projects
  - Education (8 African states) and “Mobilising for Malaria” advocacy program
- Novartis (2001)
  - No-profit prices for antimalarials for all Global Fund projects
  - Education & Advocacy, plus Capacity Building in Tanzania
- Pfizer (2006)
  - Education & Training for health workers (3 African states)
- sanofi-aventis (2001)
  - No-profit prices for antimalarials
  - Training & Education for health workers & public

Tuberculosis

- Worldwide, ~1,500,000 people died of TB in 2005
- In Africa 544,000 people died from TB in 2005 (34%)

Tuberculosis: Access & Capacity Building

- Stop TB Partnership (1998)
  - WHO, *Médecins Sans Frontières*
  - AstraZeneca, Eli Lilly, GlaxoSmithKline & Novartis
  - Global Coordination, Advocacy
- AstraZeneca (2002)
  - Access & Capacity Building Programs in Central Asia, S. Africa & Uganda
- Eli Lilly (2003)
  - Technology Transfer to help China, India, Russia & S. Africa make Medicines to Treat Multi-Drug Resistant TB
  - Training & Education (with Harvard Medical School, Intl. Council of Nurses, etc.)
- Novartis (2003)
  - Donation of Fixed Dose Combination Therapy to WHO use
  - Novartis Foundation working to improve compliance, reduce
- sanofi-aventis (2002)
  - Training & Education Programs in India & S. Africa

Tropical Diseases

- Top 6 Tropical Diseases*: 100,000 deaths in 2001
- 0.2% of total deaths, all causes, worldwide
- BUT 13 million DALYs (= 0.9% of all DALYs worldwide)

* Leishmaniasis, Trypanosomiasis, Shistosomiasis, Chagas disease, Lymphatic filiarisis, Onchoceriasis

Tropical Disease: Access & Capacity Building

- Leishmaniasis (Kala Azar)
  - Gilead-WHO MoU: no profit prices for WHO to treat visceral leishmaniasis
  - sanofi-aventis: cash, price reduction program, capacity building in Brazil (2006)
- Trypanosomiasis (African Sleeping Sickness)
  - Bayer HealthCare: no profit prices for WHO use (2004)
  - sanofi-aventis: medicine donation for WHO use, capacity building (2001)
- Shistosomiasis
  - Merck KGaA: medicine donation for WHO (2007)
- Chagas disease
  - Bayer HealthCare: medicine donation for WHO use (2002)
  - sanofi-aventis: funding to WHO for disease control programs (2006)
- Lymphatic filiarisis (Elephantiasis)
  - GlaxoSmithKline & Merck & Co. & WHO: medicine donation & capacity building (1998)
- Onchoceriasis (River Blindness)
  - Merck & Co.: medicine donation & capacity building, with WHO et al. (1987)

2000-2005, R&D Pharma industry made available enough health interventions to reach 540 million people (2/3 population of sub-Saharan Africa)

Percentage of People Without Access to Quality Essential Medicines, by WHO Region, 1999

WHO Region	No. of countries	Estimated % of population without regular access to essential medicines		
		Population without access (millions)	% of WHO regional population without access	% of World population without access
Africa	**45**	**267**	**47**	**15**
Americas	35	179	22	10
East Mediterranean	22	143	29	8
Europe	46	114	14	7
South-East Asia	9	127	26	7
India	**1**	**649**	**65**	**38**
West Pacific	26	55	14	3
China	1	191	15	11
All countries	**183**	**1,725**	**30**	**100**

Source: WHO: World Medicines Situation (2004)

What is the Range of Available Prescription Pharmaceuticals?

- ***Original*** *("brand-name" innovator) medicines*
- ***Bioequivalent*** *copies of originals:*
  - *Unbranded* generics: common in US/UK/elsewhere
  - *Branded* generics: common in developing countries & parts of Europe
- ***Non-bioequivalent****:*
  - "Similars" are prevalent in Latin America, Turkey, etc.; and may be legal or tolerated
  - Substandard drugs (lack of GMP's in developing countries)
- ***Counterfeits****:*
  - totally deceptive of their origin and not regulated at all
  - includes diverted, mishandled, mislabeled medicines
  - 10 to 50 percent of supplies in developing countries

Not All Drugs Are Created Equal: Serious Quality Problems - example of Hormonal Contraceptives

44 companies in 13 developing countries studied

- All companies complied with national GMP standards
- BUT: less than 30% would meet global GMP requirements of WHO, PIC/S or any stringent regulatory authority – they could not be prequalified
- 20% of the failing companies could comply in the medium term, but only with some investment and improvements in quality management and practice
- 50% of the failing companies are manufacturing products under conditions that give cause for concern – they would take years to comply (if at all)

Source: P.Hall/UNFPA/WHO

Improving Health in Africa: Thoughts for G8

- Major barrier is lack of health infrastructure in Africa
- Health worker "Brain Drain" exacerbates problem
- Helpful actions G8 could undertake:
  - More funding for neglected diseases (G8 funding now < Gates funding!)
  - More funding for health infrastructure in Africa (targeted aid, against criteria)
  - Reduce "brain drain": IMF fund salary top-up, "no poaching" accords, etc.
  - Press Local Governments to play their part:
    - Maputo Declaration: AU states to spend 15% of budget on health
    - Only 1 does today
  - Focus on improving substandard quality of drugs and reduce trade and supply of counterfeit medicines

Vielen Dank.

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