Access to Essential Medicines as a Global Necessity

25th Anniversary of the WHO Model List of Essential Medicines Geneva, 21 October 2002

Colleagues, Friends, Ladies and gentlemen,

It is a great pleasure for me to join you in the celebration of the 25th anniversary of the first Model List of Essential Medicines. To understand the revolutionary nature of the idea behind the Model List, and the tremendous importance of this List over the past quarter century, we must take a minute to look back.

The twentieth century opened with only one widely available modern medicine: aspirin.

In the 1940's, the first antibiotic, the first mass produced anti-malarial, and the first antitubercular were introduced. The 1950s and 1960s saw the rapid introduction of oral contraceptives, diabetes medicines, and then medicines for mental illness, many infectious diseases, cardiovascular diseases, and cancer.

By the 1970s, effective medicines - though not always ideal – existed for nearly every major illness we know. Yet, for half the world's population, it was as if they were still living in the 1880s. For them, modern medicines were unavailable, unaffordable, of poor quality, or ineffectively used.

The World Health Assembly of 1975 was a watershed. This Assembly introduced the concepts of "essential drugs" and "national drug policy".

Seeing how central and everyday these concepts have become to public health, it is impressive to think that they are not much more than 25 years old.

The Assembly hoped to begin closing the huge gap between those who were benefiting from the pharmaceutical harvest of the mid-1900s and those who could not access these medicines.

It began developing this bridge by building on precedents set in Scandinavia, on the North America formulary literature, and on pioneering efforts by countries as diverse as Papua New Guinea, Peru, Sri Lanka, and Tanzania.

In October 1977, WHO produced the first Model List of Essential Drugs and, in 1978, the Declaration of Alma Ata identified "provision of essential drugs" as one of the eight elements of primary health care.

The Model List has clearly filled a need. By the end of 1999, 156 countries had a national list of essential medicines; three-quarters of these lists had been revised in the five preceding years.

Over the past few years, the Model List has developed rapidly on several fronts in response to a growing global demand for wider access to essential medicines.

The new procedures for updating and disseminating the WHO Model List were approved in 2002; a process that was strongly supported by the Executive Board and the Assembly.

In April 2002, WHO included 12 anti-retroviral medicines and the first artemether-based antimalarial medicine on the Model List.

Our new Essential Medicines Library now brings together all WHO's core evidence and normative information on all essential medicines.

The new WHO Model Formulary was issued for the first time two months ago, based on the Model List of Essential Medicines. It presents all relevant medicine information and summaries of most WHO's clinical guidelines. It is available in hard copy and as a searchable web version.

This has led to a complete renovation and re-actualization of the whole essential medicines concept. The new WHO Model Quality Assurance System has, for the first time, led to the prequalification of manufacturers and products for HIV and malaria on behalf of all UN agencies.

The last decade has seen inequities in health care increase, with reduced public budgets and increased reliance on the private sector. There is now a global cry for equitable access to essential medicines for the prevention and treatment of HIV/AIDS. This also applies for access to other essential medicines, especially those for common childhood diseases, major infectious diseases and chronic conditions such as diabetes, hypertension, epilepsy and mental disorders, which benefit from long-term treatment.

New international agreements, including the WTO TRIPS agreement and the WTO agreement on Technical Barriers to Trade (TBT), will undoubtedly affect access to medicines in developing countries. The recent UK Commission on IPR provides a very comprehensive analysis of the potential impact.

WHO is closely involved in the negotiations - and the wider debate – on intellectual property, where it is relevant for public health. The basis for our position is very clear: no clause in any trade agreement should work in a way that denies - to those who need them - access to life-saving medicines for common diseases. This applies wherever they live and whatever their ability to pay.

In accordance with this position, WHO has formulated global guidance and is giving practical advice to Member States on the consequences and possibilities that lie in the rules on intellectual property being negotiated within the World Trade Organization.

We have come a long way since 1977. But the challenges ahead are great. For too many of the world's poor people - those with an income of one or two dollars a day - nothing very much has changed at all. The onset of serious illness in the family too often leads inexorably to death, disability and impoverishment.

Thirty-eight countries spend less than two dollars per person per year on medicines, while many of these countries have large numbers of people living with AIDS. Overall health expenditure may be as little as ten - twelve dollars per person.

Inevitably, in such circumstances, the cost of care falls to the individual and the family. Few poor people have access to health insurance. They have to pay for drugs when they get sick.

Out-of-pocket payments - a large proportion of which go on medicines - constitute up to 90 per cent of total health spending in some poor countries. For many the reality is stark: no cash, no cure.

Drug prices are only part of this challenge. Access to essential medicines depends on a nucleus of key factors: rational selection, affordable prices, sustainable financing, and reliable supply systems. These four components of the strategy are inter-dependent. Lower prices attract more donor and government financing; radically increasing drug availability boosts health systems development; more effective supply systems mean greater coverage; and more coverage increases sales revenues.

High quality health care depends on choosing those medicines with the best combination of safety, efficacy, quality and health impact. Over 1500 new medicines have been introduced

during the last 25 years. Many of these represent genuine therapeutic innovations which can and should have a major public health impact. Health systems and health care providers everywhere struggle to select those drugs which best suit their needs.

New essential medicines are expensive. For example, the new artemether-lumefantrine combination for malaria is about 25 times as expensive as chloroquine, even at the preferential price negotiated by WHO for the public sector in developing countries.

Treatment of multi-drug resistant tuberculosis is about fifty times as expensive as a simple DOTS regimen.

Last week, we presented new evidence which shows that a few commonly available medicines such as statins for the lowering of cholesterol and low-doses of common blood pressure drugs and aspirin - given daily to people at elevated risk of heart attack and stroke - can save the lives of millions of people at risk of cardiovascular disease each year on a global basis. This highly effective combination therapy could be much more widely used in the industrialized world, and is increasingly affordable in the developing world.

These medicines are off-patent and relatively cheap. The drug combination would cost less than 14 dollars for each person annually. Still, it might not be affordable to poor countries facing the traditional burdens posed by communicable diseases and the growing burden of noncommunicable and chronic diseases.

The recent WHO Commission on Macroeconomics and Health highlighted the need for major new injections of resources from high income countries. It called for a major increase in the resources invested in health in the poorest countries over the coming two decades. Moreover, it argued that the old dogma which says development assistance is only cost-effective if it focuses on prevention - not treatment - is outdated. The recent developments within a number of diseases, such as HIV/AIDS, TB and malaria - and now with cardiovascular diseases - show that prevention and treatment are integrally linked. Spending money on essential medicines - and on the systems needed to deliver them effectively, equitably and safely - is a good health investment.

We need to find ways to respond to these great challenges. Essential drugs are not an ordinary commodity. Access to health care is a human right. Governments and international agencies have an obligation to see that this right is progressively realized. Access to essential drugs is part of this obligation.

The concept of essential medicines has global relevance and is a global necessity.

The Millennium Development Goals include access to essential medicines as one of 17 health indictors. The world is committed to expanding access to essential medicines and WHO is committed to supporting this goal.

WHO has two critical functions for essential medicines: to develop and promote global normative guidance, and to give technical support to Member States.

Some of the normative work and all technical support puts emphasis on promoting equity and sustainability, with a focus on fulfilling the needs of poor and marginalized populations.

WHO works with all stakeholders - both at the global level and in the countries. Besides the Ministry of Health, this includes especially the nongovernmental sector and academia.

WHO needs to remain evidence-based and totally independent from commercial interests so that we can ensure an independent development of normative work. Member States should always feel confident about the independence of our policy advise.

For our future work, this means continued support to countries, with a focus on results.

Within country support, more focus will be put on capacity building through normative information, practical policy guidance and training.

More focus will be put on supporting Member States in aspects of good governance and formulation of essential government functions, such as promoting the right mix between public and private functions and regulating the private sector.

We will continue development of the evidence base for drug selection, based in part on WHO's independence as a source of scientific information.

Scientific and normative work benefits all Member States and needs to remain independent from individual donor decisions.

It is certainly part of WHO's core functions and will remain so.

More focus will be put on strengthening the functions of district hospitals in ensuring equitable access to primary care.

Access to essential medicines is part of the progressive fulfilment of the fundamental right to health. The rights-based approach will be further developed and supported as a means of empowering NGOs and the general public in making their governments accountable.

More focus will be put on further developing and supporting health insurance as an important approach in making health care more affordable for all, and in promoting access to costeffective health care. WHO will follow a pragmatic approach to critical issues, such as affordability and the use of TRIPS safeguards to ensure access, building on good governance by countries.

The promotion of the essential medicines concept will be further intensified through close collaboration with other clusters, other UN agencies, the World Bank and NGOs.

Ladies and Gentlemen,

We are in the middle of a great struggle to increase investments in health as part of the fight to reduce poverty and achieve the Millennium Goals. We have to show that we have effective means to achieve measurable improvements in health. We need to find effective ways of delivering basic health care to all - also to the world's one billion poorest people. A key part of this challenge will be to ensure a widening access to essential medicines.

The Model List of Essential Medicines is a key tool in this work. Let us all work to make the next 25 years even more successful than the quarter century we celebrate today.

Thank you.