

Country case study

Access to medicines in Uganda: intersections with poverty

Medicines, as global commodities, are vulnerable to market forces and the legislated constraints imposed by international trade and patent regulation, as well as to country-level import/export taxes, tariffs, and regulations. Just as these larger issues are contextualized within the current global macroeconomic situation, issues of accessibility, availability, and appropriateness will also be contextualized within a constellation of culturally significant factors (such as economic status, gender roles, stigmatization of diseases, geographic location, and ethnicity). These socioeconomic features will largely determine the ability of specific individuals and families to access the medicines that are available in any given location. Therefore, ensuring access must be understood as the processes of making medicines available through regulation, importation, distribution, and safe prescribing and of identifying and removing the barriers that must be locally defined and addressed. This case study seeks to integrate some of these features within a comprehensive frame of reference, one that more closely aligns to the integrated experience of individuals and communities. This is a very brief examination of these issues, based on existing data. A detailed description and analysis for any country or specific region within a country would require a report substantially larger and more in-depth than is possible here.

In 2002, the Ugandan Ministry of Health, in partnership with Health Action International Africa and the World Health Organization, completed the *Uganda Pharmaceutical Sector Baseline Survey* (Uganda 2002b). This proved to be a valuable resource for the UN Millennium Project Working Group on Access to Essential Medicines when it met in Kampala, Uganda, during the summer of 2004. This document and the input from various other agencies and individuals during the course of the meeting and afterward provided the task force members with valuable insight into the issues of access to medicines

in Uganda. We wish to thank Mr. Joseph Serutoke, Essential Drugs Advisor, Essential Drugs and Medicines Policy, WHO Country Office in Uganda, for his informative presentation during the meeting. Mr. Serutoke was also instrumental in our access to reports published in Uganda and elsewhere and he provided valuable feedback in the formulation of recommendations. Thanks are also in order to Kevin Burns of Partners In Health, who conducted extensive research for the development of this case study.

Uganda

Uganda is a landlocked, equatorial East African country that borders the Democratic Republic of Congo, Kenya, Rwanda, Sudan, and Tanzania, with Lake Victoria making up much of its southern border (map A1.1). Following a long period of, at times, violent political turmoil, Uganda developed a democratic constitution in 1995, and held presidential and parliamentary elections in 1996 and 2001. The current president is Yoweri Museveni, in office since 1986.

The United Nations estimates the population of Uganda at 24.2 million (2004) with 88 percent living in rural areas (table A1.1). Classified as a low-income country by the World Bank, Uganda is also classified as a Least Developed Country by the United Nations. Per capita income (using the Atlas method) was reported at \$240 in 2003, reflecting a continuing decrease. As of 2002 Uganda's total external debt amounted to \$3.8 billion. This heavy debt service is one reason the country struggles to provide social services in adequate quantity and quality (Sachs and others 2004). The economy depends largely on agriculture, with 80 percent of Ugandans deriving their livelihoods from this sector. Currently, it is estimated that 35 percent of Ugandans live on less than a dollar a day and are unable to meet their basic requirements.

Displaced populations

There continues to be isolated unrest in the northwestern region of the country where a long and violent conflict has continued for 18 years. Almost the entire population of the Acholiland region (estimated at 1.8 million people) has been displaced into poorly equipped relocation camps. Relying on international agencies for the most basic necessities, this large population of displaced people is increasingly vulnerable to sickness and disease and without reliable access to medical services or essential medicines.

Burden of disease

Like many countries in Sub-Saharan Africa, the issue of universal access to medicines has taken on a renewed urgency and visibility in recent years due to the AIDS, TB, and malaria epidemics (table A1.2). However, these three diseases are not the only ones confronting people in this or any other part of the region. "Diseases of modernity"¹ such as adult-onset diabetes, hypertension,

Map A1.1

Uganda: Population density, 2000

People per square kilometer

Source: Center for International Earth Science Information Network (CIESIN) and International Center for Tropical Agriculture (CIAT). Copyright Trustees of Columbia University, City of New York.

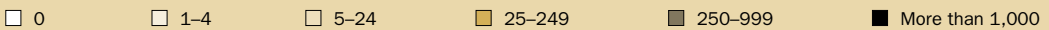
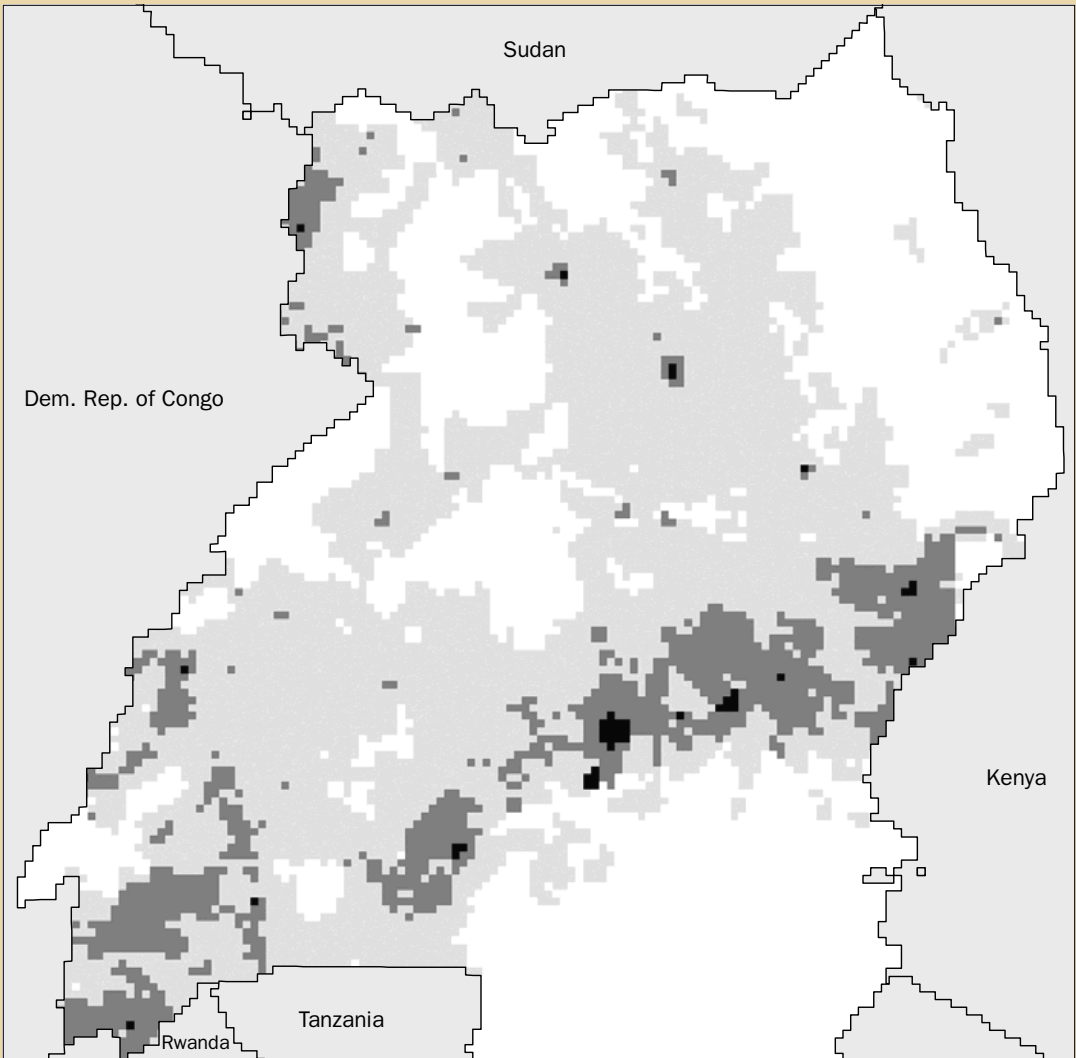


Table A1.1**Uganda: select socioeconomic indicators**Population in 2004:
24.2 million

— Not available.

Source: World Bank 2004b.

	1999	2000	2001	2002	2003
Rural population (percent of total population)	—	87.9	—	87.8	87.3
Roads, paved (percent of total roads)	—	6.7	—	—	—
<i>Literacy rate</i>					
Adult female (percent women > 15 years)	—	—	—	59.2	—
Adult male (percent men > 15 years)	—	—	—	78.8	—
Youth female (percent women ages 15–24)	—	—	—	74.0	—
Youth male (percent men ages 15–24)	—	—	—	86.3	—
Primary education completion rate, girls (percent of relevant age group)	—	—	—	61.7	—
Primary education completion rate, boys (percent of relevant age group)	—	—	—	72.9	—
School enrollment, tertiary, women and girls (percent gross)	—	—	2.23	—	—
School enrollment, tertiary, men and boys (percent gross)	—	—	4.26	—	—
GDP per capita (Atlas method, current \$)	—	280	—	—	240
Percent of population living below \$1 per day (1990–2001)	—	—	—	—	35
<i>Income share</i>					
Held by lowest 20 percent	5.9	—	—	—	—
Held by highest 20 percent	49.7	—	—	—	—
Unemployment, women (percent of female labor force)	8.0	—	—	—	—
Unemployment, men (percent of male labor force)	6.7	—	—	—	—
Labor force, women (percent of total labor force)	47.6	—	—	—	47.5
Labor force, children ages 10–14 (percent of age group)	44.1	—	—	—	42.9

and cardiovascular disease join an array of infectious and parasitic diseases that are almost unheard of throughout the developed world, including hemorrhagic dengue, yellow fever, filariasis, leishmaniasis, onchocerciasis, trypanosomiasis, Rift Valley fever, and schistosomiasis.²

Until 1995 AIDS was the greatest health challenge facing Uganda, in addition to malaria and other diseases. In 1996 there was a substantial decline in the national HIV/AIDS prevalence rate, from 20 percent in 1991 to 6.5 percent in 2001, which made Uganda a model example internationally in combating HIV/AIDS. In this regard, Uganda moved ahead of the international target for the [Millennium Development Goal] on HIV/AIDS. Whereas it aims at halting and beginning to reverse the spread of AIDS by 2015, Uganda met this target in 1996, almost twenty years ahead of schedule. However, the important challenge is that complacency seems to have set in, which might cause a reversal in the downward trend. Recent evidence reveals that the prevalence rate increased from 6.1 percent in 2000 to 6.5 percent

Table A1.2**The burden of three major infectious diseases in Uganda**

— Not available.

a. Reported per 100,000 population.

Source: WHO 2004c.

	2000	2001	2002
Total TB prevalence ^a	544	—	—
TB incidence (all cases) ^a	377	—	—
TB mortality ^a	61	—	—
HIV prevalence (15–49 years) ^a	5.8	5.4	—
Estimated AIDS-related deaths	—	84,000	—
Estimated number of people living with HIV/AIDS	—	—	—
Adults	—	600,000	—
Children (0–14 years)	—	110,000	—
Percent of adult (15–49 years) TB cases that are HIV positive	—	24	—
Malaria mortality ^a	151	—	—
<i>Clinical cases reported</i>			
Older than 5 years	—	—	1.16 million
Younger than 5 years	—	—	720,298

in 2001. Although awareness of HIV/AIDS is widespread, knowledge of ways of avoiding the virus are not as well known. According to the 2000 Uganda Demographic and Health Survey, 13.4 percent of Ugandans did not know any programmatically important way to avoid HIV/AIDS (Sachs and others 2004, p. 188).

In a 2004 report on Uganda (WHO 2004c), the WHO cited the 1995 *Burden of Disease Study* and *The Uganda Demographic and Health Survey* (Uganda 2001), which showed that 75 percent of years lost to premature death are due to 10 preventable diseases. More than 60 percent of the total death burden was attributed to perinatal and maternal conditions (20.4 percent), malaria (15.4 percent), acute lower respiratory tract infections (10.5 percent), AIDS (9.1 percent), and diarrhea (8.4 percent). Others include tuberculosis, malnutrition, anemia, intestinal worms, trauma/accidents, skin infections, and dental health.

Poverty in Uganda

Poverty remains Uganda's major development challenge. The growth the country recorded in the 1990s initially led to a reduction in poverty from 56 percent in 1997 to 35 percent in 2000. However, by 2002 poverty had increased to about 38 percent (Sachs and others 2004). Uganda's government has been in the forefront of developing policies to reduce poverty. It was one of the first countries to prepare a comprehensive strategy for poverty reduction using a participatory approach. During 1995–97 Uganda developed the Poverty Eradication Action Plan to create a framework for poverty eradication by 2017. The revised plan (2000) was presented as its Poverty Reduction Strategy Paper (PRSP). Among other reasons, this was done to comply with the eligibility requirements for future debt relief under the Highly Indebted Poor Countries

(HIPC) II Initiative of the World Bank and IMF. Within this framework, the government of Uganda has developed a review process every three years as well as focused strategies to address poverty reduction in every sector of the government. The Poverty Eradication Action Plan has been used as a major guide to allocation of resources within the government (Uganda 2002a).

Part of the review process includes Participatory Poverty Assessments in which the members of 12 districts (out of the 56 districts in the country) report on the progress and impact of the government's poverty reduction strategies on their lives, families, and communities. These assessments bring together representatives from the Ministry of Finance, Planning, and Economic Development, district authorities, civil society organizations (both NGOs and academic institutions), and donors. In the Second Participatory Poverty Assessment Process (Republic of Uganda 2002), the most frequently cited cause of poverty was poor health and diseases. Improving access to essential medicines within the context of expanded and improved health services will be a key component in any effort to reduce poverty and inequality (table A1.3).

Health sector

Resources (both human and financial) as well as access are two major challenges within the health system. It is estimated that at least 53 percent of the population lives less than 5 kilometers from a health facility, with a range from 9 percent in parts of Kitgum (near the northern border with Sudan) to 100 percent in Kampala. In 2002 42 percent of approved posts in the public health sector were filled by trained workers, up from 33 percent in 1999. The human resource needs in Uganda remain significant and long-term planning for scaling up nursing and medical education is a key component of Millennium Development Goal planning.

There are only about 270 qualified dispensers or pharmacy technicians in Uganda. The current educational system produces, on average, 15 a year. At this rate, it will take Uganda over 50 years to achieve a ratio of one pharmacy technician for every 20,000 people. The situation with registered pharmacists is even worse: with an output of 10 per year, and with only 171 registered pharmacists in Uganda, it will take the government over 90 years to reach a ratio of one pharmacist for every 20,000 Ugandans (Kibumba 2002).

President Museveni initiated a major policy change in March 2001 when he abolished user fees in government health units. The public response was immediate and resulted in a dramatic change in the health system, with poor people benefiting disproportionately—the lowest quintile captured 50 percent of the benefits (Deininger and Mpuga 2004). Currently, other countries are considering this policy. The effects on direct health services and outcomes became apparent almost immediately and included healthcare reforms that were introduced and accelerated to meet the new demand. In addition to illustrating the restrictive impact of user fees, the increase in use has highlighted infrastructure

Table A1.3**Select health-related indicators in Uganda**

— Not available.

Source: World Bank 2004b.

	2000	2001	2002
Annual growth rate (percent)	—	—	3.0
Life expectancy, female (years)	—	—	50.8
Life expectancy, male (years)	—	—	47.9
Infant mortality rate (under 1 year)	—	—	82
Maternal mortality ratio per 100,000 live births	880	—	—
Births attended by skilled health staff (percent of total)	—	39	—
Malnutrition prevalence, weight-for-age (children under 5 years)	23	—	—
Immunization DPT (percent of children 12–23 months)	53	—	72
Immunization measles (percent of children 12–23 months)	56	—	77
Health expenditure per capita (US\$)	14	14	—
<i>Health expenditure</i>			
Public (percent of GDP)	3.1	3.4	—
Private (percent of GDP)	2.5	2.5	—
Total (percent of GDP)	5.6	5.9	—
Improved sanitation (percent of population with access)	79	—	—
Rural (percent of rural population with access)	77	—	—
Urban (percent of urban population with access)	93	—	—
Improved water source (percent of population with access)	52	—	—
Rural (percent of rural population with access)	47	—	—
Urban (percent of urban population with access)	80	—	—

problems as health facilities struggle to meet the increased demand for services. The government of Uganda recently found that lack of medicines is now identified as the most serious problem in health units (Republic of Uganda 2002).

There are 56 districts with an administrative structure for healthcare consisting of five levels, encompassing health centers I–IV (village, parish, sub-county, and county) and the district/general hospital. There are 11 referral hospitals (which also act as district hospitals in the areas where they are located) and 2 national referral hospitals (Mulago and Butabika). Mulago and Mbarra Hospitals also act as university teaching hospitals (Uganda 2002b). The Ministry of Health reports that there are 104 hospitals (57 government, 44 NGO, 3 private), 250 health centers (179 government, 68 NGO, and 3 private), 2 palliative care centers (1 government, 1 NGO), and 1,382 other healthcare facilities (989 government, 352 NGO, and 41 private).³

The Poverty Eradication Action Plan of 1997 was followed by the National Health Policy (NHP) in 1999, and the Health Sector Strategic Plan (HSSP

2000/01–2004/05) in 2000. Both the NHP and the HSSP focus on the Uganda National Minimum Healthcare Package, which is the basic package of services goal to which all Ugandans have access. The revised National Drug Policy (2001) aims to contribute to the attainment of a good standard of health, through ensuring the consistent availability, accessibility, and affordability of essential medicines of appropriate quality, safety, and efficacy, and by promoting their rational use.

Access to medicines

A five-year National Pharmaceutical Sector Strategic Plan for fiscal 2003–07 has been developed. The overall per capita minimum expenditure for basic healthcare provision is estimated to be \$28 per person. Current spending is estimated to be a small fraction of this. Funding for medicines in 2002/03 was \$1.20 per capita, which is only one-third of the estimated \$3.50 per capita needed (excluding the pentavalent vaccine that is currently donated and anti-retrovirals). The midterm review concludes that this shortfall poses a serious threat to sustained availability of essential medicines and health supplies, and hence to the delivery of the Uganda National Minimum Healthcare Package (Caines and others 2003, p. 10).

The National Medical Stores is the government agency charged with procuring, storing, and distributing essential medicines and supplies to the public sector. The missionary hospitals get their medicines and health supplies from Joint Medical Stores. Only when medicines and equipment are out of stock from the National Medical Stores can public health facilities obtain them from elsewhere, including the Joint Medical Stores.

Currently there are five large-scale and five small-scale pharmaceutical manufacturers. There are 2,939 public sector health facilities from which medicines may be dispensed, 215 private pharmacies, and 2,600 drug shops. Of the private pharmacies, nearly 80 percent are in the three major towns of Kampala, Jinja, and Mbarara (Uganda 2002b).

More than 90 percent of pharmaceuticals are imported into Uganda, with less than 10 percent produced locally (UNIDO–AAITPC 2001). Uganda's imports of medicines in 1999 amounted to \$73,776,000; domestic production of medicines was valued at \$7,440,632. Most pharmaceutical and health products are imported by the National Medical Stores (UNIDO–AAITPC 2001).

As of 1999 the WHO estimated that in Uganda 50–79 percent of the population had sustainable access to affordable medicines.⁴ The Ugandan Pharmaceutical Sector Baseline Survey found that only 47 percent of surveyed public health facilities had more than 75 percent of key medicines available. One out of three facilities storing medicines were found to have “not adequate” storage, leading to medicines of “poor or doubtful quality.” Given that at least 53 percent of the population lives more than 5 kilometers from a health facility and that 35 percent of Ugandans live on less than a dollar a day, the actual

percentage with access to essential medicines remains to be clearly defined. In the second Participatory Poverty Assessment, medicines shortages were reported at all sites.

Importation issues

Strategies to enhance the ability of the Ugandan government to procure medicines at the best price could include differential pricing (adapting prices to the purchasing power of governments and households), bulk purchasing, competition, and skillful negotiation (WHO and WTO 2001). Mechanisms for differential pricing are actively supported by the WHO and include voluntary negotiated agreements with companies, voluntary licensing with multiple producers (“licensed competition”), compulsory licensing, and patent waivers (Quick 2003). The Commission on Macroeconomics and Health strongly supports “differential pricing in low-income markets as the operational norm, not the exception” (CMH 2001).

Another option available to Uganda as a feature of its status as a Least Developed Country is to invoke TRIPS flexibilities and the suspension of pharmaceutical patents as described in the Doha Declaration on TRIPS and Public Health (WTO 2001). The Doha Declaration, issued at the November 2001 WTO ministerial meeting, supports the right of member states to implement the TRIPS agreement in a manner that promotes public health and access to medicines for all. To fully take advantage of differential pricing, Uganda must retain its ability to issue compulsory licenses to a company in another country (CMH 2001).

After 2005, all member countries of the WTO except Least Developed Countries are required to put into force a patent system that includes both product and process patents. A 2001 review summarizes three studies that predict pharmaceutical price increases of 200 percent or more with full implementation of TRIPS requirements in developing countries (Scherer and Watel 2001). A 2002 report by the United Kingdom’s Commission on Intellectual Property Rights also echoes this concern (UK Commission 2002).

In Uganda, new patent law legislation has been drafted that would make it harder to access generic medications—a key component of differential pricing. This legislation includes legal provisions that criminalize patent infringement, granting data exclusivity to prevent the registration of generic versions of a medication for a specified length of time, linking patent status with drug regulatory authority approval, and granting patent protection for new uses of previously patented products. The proposed legislation goes beyond what is required by the TRIPS agreement.

Full differential pricing, including access to generic medicines, would have a huge impact on the amount of medicines Uganda will be able to procure. An estimated 100,000 of the 530,000 Ugandans living with HIV need anti-retroviral medicines. Minister of Health Jim Muhwezi recently announced

that government negotiations and generic antiretrovirals have helped to reduce the treatment costs from \$1,500 per person per month to \$30 per person per month. This has resulted in an immediate increase in antiretroviral access to almost 20,000 people, with a projection of 60,000 people having access to these medicines on the arrival of projected donor funds.⁵

In addition to inadequate fiscal resources for procuring essential medicines and health supplies—currently it is estimated that only a third of what is required is being made available—institutional and human resource capacity to manage pharmaceutical supplies and service provision are inadequate. The issue of utilization, defined by one Ugandan expert as “poly-pharmacy and overuse of antibiotics and injections as well as inappropriate self-medication” is also a problem.

The view from the community level

The following comments were offered from community members during the Participatory Poverty Assessment Process completed in 2002. Full reports from the 60 communities that participated are available online.⁶

They revealed that most of them had resorted to local herbs for treatment but they also revealed that the herbs had become very scarce and the situation was worse during dry season when most of the plants were burnt down. The study also revealed that some people went to traditional healers/witch doctors. However, it had been noted that often their powers did not work. The community resorted to these due to shortage of drugs in the government health centres and lack of money to go to private health clinics.

District of Kitgum, Northern Region

Area: 16,136 sq. km

2002 population: 286,122 (1.4 percent urban)

[T]he people said they still go to the government health units despite the rudeness and drug shortages. They explained that government units had equipment and facilities that were lacking in private clinics. Also, drug shortages were reported in the government health units to the extent that people said they were sent to private clinics to purchase them. They therefore go to government units for diagnosis and prescription then go for treatment in the private health units.

District of Masindi, Western Region

Area: 8,458 sq. km

2002 population: 469,796 (0.8 percent urban)

The people of Nakapelimen claimed that they took to herbs as first option for treatment because they often did not get treatment in the hospital on the account that there were no drugs most times. They

also argued that they were sometimes referred to private clinics to buy drugs and yet they do not have the cash to do that. . . .

On decisionmaking, the women say that they are not free to make independent decisions about most things—including matters of healthcare. That in spite of the fact that it was they (the women) who were responsible for treatment of the children, they had to seek for permission from their husbands to visit a health center. They said they did this in spite of most men not providing financial support for treatment. However the women of Lokileth and Naoi (villages where the nearest health facilities were NGO units) explained that they did this so that the men could sell a goat or sheep to raise some money required for payment for treatment. In Lorukumo the women explained that even when they informed them, the men they did not give any money—since even the survival of the household depend on them (the women). They explained further that since the children traditionally belong to the man, they could not take the child away from home without informing the man.

District of Moroto, North Region

Area: 14,113 sq. km

2002 population: 170,506 (0.2 percent urban)

Recommendations

The Uganda Pharmaceutical Sector Baseline Survey of 2002 includes an impressive number of specific recommendations. The following are included here because, as with many of the other recommendations, they specifically address issues of access on the community level.

1. Develop and implement strategies that ensure equitable access, affordability, and sustainable financing for health services in general and access to essential medicines in particular.
 - Advocate for increased funding to the health sector in general and for medicines in particular from the government and from focused donor support.
 - Strengthen institutional and human resource capacity for coordination and implementation of the National Drug Policy—setting up a functional and adequately staffed Department for Pharmaceutical Services within the Ministry of Health and similar structures at the local government levels and in hospitals.
2. Develop and implement interventions to address the poor availability of drugs in public health facilities.

- Strengthen institutional and human resource capacity to manage pharmaceutical supplies and service provision within the public health facilities.
 - Establish a Logistics Management Information System and a Medicines and Health Supplies Tracking System to monitor drug utilization, facilitate accurate quantification, and harmonize procurement.
3. Identify and develop interventions to address the significant increase in the number of antibiotics prescribed per patient contact.
4. Identify, develop, and continue implementing interventions to further decrease the number of patients receiving injections.
- For both (3) and (4):
- Support the formation of drugs and therapeutics committees in health facilities to coordinate the selection, procurement, and utilization of medicines at these levels, and for support for lower levels where the capacity may be limited.
 - Disseminate the Uganda Clinical Guidelines to all healthcare workers in the country and train them in their correct use.
 - Preservice training in health training institutions and continuing in-service medical training (may be as a precondition for licensure/practicing renewal).
 - Strengthened supervision, audit, and regulation of the activities of all actors involved in the use of medicines.
5. Design and implement consumer-targeted and community-based information, education, and communication campaigns to improve rational use of medicines in the community.
- Ensure that over-the-counter medicines are dispensed with adequate labeling and provide written or oral instructions that are accurate and easily understood by laypersons. The information should include the medicine name, indications, contraindications, dosages, drug interactions, and warnings concerning unsafe use or storage.
 - Conduct targeted public education campaigns that take into account cultural beliefs, illiteracy, language differences, and the influence of other social factors. Education about the use of medicines may be introduced into the health education component of school curriculums or into adult education programs, through the use of literacy courses and drama educational techniques.
 - Monitor and regulate advertising, which may adversely influence consumers as well as prescribers, and which may occur through television, radio, newspapers, and the Internet.

Conclusion

Access to a sustained supply of good-quality medicines is a critical part of addressing both the current infectious disease epidemics and the long-term quality of life and productivity of people throughout the world. As an essential component of good health, it is also a human right. Reaching the people with the least access to resources and who are conditioned by the conditions of poverty to be disproportionately vulnerable to a wide array of diseases and chronic illnesses is the challenge before us. The government of Uganda continues to move forward in its determination to address these difficult issues. The international community can do no less.

Statement of dissent by representatives of the research- based pharmaceutical industry

December 6, 2004
Overview

The Millennium Development Goals (MDG) are an important symbol of global commitment to addressing the root causes of poverty. Health is a unifying theme for the Goals because progress in basic indicators of mortality and morbidity are a prerequisite for the social advances and higher economic output that, when combined, yield better life opportunities for the poor.

As we move closer toward the 2015 target date for realization of the MDGs, the R&D pharmaceutical industry is ready to demonstrate its contribution, particularly in those areas—medicines research, clinical training, and drug delivery and distribution—where we possess unique expertise. The industry is proud of its record.

We regret that the sum total of our efforts in building practical, field-based partnerships—partnerships that work—was not recognized in the final report of the Working Group on Access to Essential Medicines. Representatives from our industry actively participated in the working group from its launch until final editing was completed last month. We endorse many of the basic messages contained in the text—in fact, we contributed much of this content in cooperation with other members. Assessment of critical needs around human resources, the importance of mobilizing political will, the slow pace of donor support, filling the enormous gaps in physical plant capacity, and resolving social biases of gender and stigma are all critical factors that must be addressed in any national strategy to increase medicines access.

We believe this because we are doing it—with our own resources, ranging from the simple transfer of people-to-people skills to technical support, supply chain management, research expertise, philanthropic grants, cash, and donated goods and services.

So the question arises: after a year of effort and a record of contribution offered in good faith, why is it that we cannot sign the report?

Let it be clear that our failure to sign is not because all our views were rejected—disagreement is part of normal life—but rather because of an enormous visionary gap between ourselves and the working group in identifying root causes of the access challenge. We do not believe that the main problem in barring medicines to the poor is patent protection, nor do we accept that individual company pricing practices are fundamental to explaining why one-third of the world's poor lack access to basic, low-cost essential medicines. An inaccurate and subjective link is forged between rights, “monopoly” pricing, and global inequities in access to medicines. Much of the text on these issues was adopted from the Task Force on Trade—a group in which industry was not represented—and inclusion of this material was never discussed with the full membership of the Working Group on Access to Essential Medicines. Hence the necessity of including a detailed rebuttal to correct what we contend are critical factual errors and underlying biases on intellectual property.

We also believe that our private sector research model is worthy of preserving rather than abandoning on the risky premise that more public investment will by itself yield miracle cures against the complex scientific challenge of fighting resistant strains of infectious disease. There is a failure to acknowledge current efforts in development of drugs and vaccines for diseases primarily limited to developing countries and an unwillingness to realistically identify research gaps and establish priorities.

Most important, we contend that the skeptical stance the report takes toward the industry's partnership efforts are simply counterproductive, especially when examined against the working group's own mandate: to seek access solutions that work, in cooperation with the pharmaceutical industry. The working group seems not to have recognized that today our industry is managing programs that include the single largest antiretroviral treatment program in Sub-Saharan Africa as well as the region's first clinical education and training facility focused specifically on finding innovative local solutions to the AIDS pandemic.

In short, the report fails to provide the balanced and accurate perspective necessary to stimulate fresh policy approaches that could make a real difference in the lives of the poor. To allow these inaccuracies and misrepresentations to become accepted as truth and as the basis for moving policies forward does no one any service, least of all the patients who rely most on the commitments we have made. It would significantly diminish our ability to fulfill commitments to current and future partnerships and—most importantly—our capacity to produce new drugs, diagnostics, and vaccines.

Thus we have no choice but to respectfully dissent from the working group's report and to summarize below those four areas of greatest concern.

Specific issues and areas of dissent

Role of research-based pharmaceutical companies and the importance of

public-private partnerships in access to essential medicines in developing countries

The report does not adequately reflect the true breadth of what the R&D industry actually does to fight disease and promote the health and wellness that aids development. It is critical that this be understood because much of what is recommended in the report regarding intellectual property, pricing, and innovation would, if implemented, threaten the industry's ability to maintain existing and future contributions.

The most significant contribution research-based pharmaceutical companies can make to the goal of expanding access to essential medicines is to discover and develop new medicines. Private research-based pharmaceutical companies have produced the overwhelming majority of new medicines now on the market and available to patients in all countries. Fully 77 percent of the products approved for the WHO Essential Drugs List between 1977 and 2002 originated or were substantially developed by the R&D industry. Since 1988, 22 separate HIV-related medicines have been developed by research-based pharmaceutical companies and in 2003 there were still 87 in development. Because of the rapidity with which HIV is developing resistance to existing drugs, the need and urgency for new drugs is greater than ever before.

We are heavily invested in research and development, spending approximately 17 percent or more of sales on R&D—three times more than the next high-spending industry (telecommunications), four times more than the defense industry, and four times more than all other industries (*Pharmaceutical Industry Profile 2003*, www.phrma.org). In 2003 the combined investment in biomedical research in the United States by both the public and private sectors exceeded \$70 billion, of which half (\$35 billion) originated in the pharmaceutical industry.

What is generally not understood is the essential, unique, and complementary roles that both industry-funded (private sector) and federally funded (public sector) research play in translating these advances into tangible new treatments and the interrelatedness and synergies between the two. Although scientists in research-based pharmaceutical and biotechnology companies contribute significantly to basic research and thus to increasing our fundamental understanding of disease, it is also true that federally funded investigators have traditionally conducted the bulk of basic biological research. However, the pharmaceutical industry continues to lead the way in the applied research activity that ultimately results in the discovery and development of most new medicines, i.e. the actual compound or biological entity that is the drug.

Increasingly, research-based companies are valuable partners with researchers from academia and the public sector on basic research projects. However, companies that license inventions from universities still pay the majority of the innovation's final cost and pay for all the failed efforts and blind alleys (there is a 90 percent failure rate from target identification to product launch) and the promising drugs that prove not to be sufficiently safe and sufficiently effective

to gain approval for marketing from the regulatory authorities (there is a 50 percent failure rate in Phase III) (*Pharmaceutical Industry Profile 2003*, www.phrma.org; Economist.com 4/21/03; Edwards, M.G., F. Murray, and R. Yu, *Nature Biotech* 2003(21): 618–25).

At the global level, the relationship between governments, multilateral institutions, NGOs, and the research-based industry has developed progressively. The pharmaceutical R&D industry plays a far larger role in the advancement of global health than is generally realized. The estimate for pharmaceutical companies' total foreign assistance for 2003 is just over \$2 billion. This estimate is based on the dollar value of their product donations and cash contributions for global health programs. In 2003, Partnership for Quality Medical Donation reports that its members provided more than \$1.4 billion in donated drugs, and in 2002 pharmaceutical companies' select humanitarian programs totaled \$810 million (*Improving Health in the Developing World*, PhRMA publication, January 2004).

When compared with the annual budgets of governments and international health organizations, total aid from the industry is actually the same or even higher (e.g., WHO's annual program budget of \$421.3 million; or UNICEF's annual budget of \$1.3 billion) [see "The Privatization of Foreign Aid", *Foreign Affairs*, November/December 2003, Adelman; "The Full Measure of Foreign Aid", "Foreign Aid in the National Interest: Promoting Freedom, Security, and Opportunity", Chapter 6, Adelman, USAID/W, 2002].

More recently, the industry has worked with the WHO and other stakeholders to lower the price of key medicines like antiretrovirals and those for treating MDR-TB, and has expanded donations and technical assistance programs to help fill the capacity gap. A few examples include the African Comprehensive HIV/AIDS Partnership (ACHAP) in Botswana, a collaboration of the government of Botswana, the Bill & Melinda Gates Foundation, and Merck & Co., Inc. (26,000 patients are now receiving antiretroviral therapy through ACHAP); Pfizer built Uganda's first Infectious Disease Institute in Kampala to provide a training site for physicians and technicians drawn from throughout Africa, thus seeding best practices regionwide; Bristol Myers Squibb has initiated HIV/AIDS programs in 5 South American countries which provide antiretroviral medicines, as well as inputs into health management, medical research and education, community education and outreach, and capacity-building programs for women and children.

Likewise, the UN/Industry Accelerating Access Initiative (AAI) is a cooperative endeavor of seven research-based pharmaceutical companies, UNAIDS, WHO, UNICEF, the UN Population Fund, and the World Bank. In July 2004, WHO estimated that 440,000 AIDS victims were receiving antiretrovirals in the developing world, including 136,000 in Brazil alone. Outside of Brazil nearly 50 percent of the remaining patients were obtaining their AIDS drugs through the efforts of the Accelerating Access Initiative program. And

Boehringer Ingelheim, Merck, and GlaxoSmithKline, among others, have extended voluntary licenses to generic manufacturers in South Africa so that antiretrovirals can be manufactured for Africa—an example of the kind of “patent flexibility” that the report cites as entirely lacking from the industry.

In a program to address MDR-TB, Eli Lilly and Company is transferring manufacturing technology and technical assistance to manufacturing companies in India, China, and South Africa. In addition to supporting a center of excellence for training in Russia and establishing a surveillance program in partnership with the Centers for Disease Control and Prevention and WHO, Lilly is also providing at significantly below cost two of the five antibiotics used for treating MDR-TB to the WHO.

In contrast to popular belief, the research-based pharmaceutical companies continue to play an important role in development of medicines for malaria, TB, and other diseases occurring primarily in developing countries. For example, Novartis recently established a research center for drug discovery and development for tropical diseases in Singapore, focusing initially on TB and dengue fever. When drugs are finally produced, they will be sold at no profit. Astra Zeneca has created a new discovery research facility in Bangalore, India, which will focus exclusively on TB. GlaxoSmithKline has a dedicated facility in Tres Cantos, Spain, for drug discovery in diseases of the developing world, including malaria and TB. They currently have two antimalaria drugs in development (phases I and III) and also have vaccines in clinical trials for TB and malaria. Much of this work is in association with public-private partnerships that offer a new and innovative approach to drug and vaccine development—a development barely cited in the report.

Priorities for innovation

The report neglects the important point that most diseases that disproportionately affect low-income countries can be treated or prevented with easily available existing resources, such as medicines from the WHO Essential Drugs List, of which over 95 percent are off-patent. Yet these diseases continue imposing important burdens on the health of millions of people affected, proving that the biggest challenge that remains is getting the interventions to the people who need them. Any considerations regarding the need for novel interventions and setting research priorities should therefore be made within this specific context (IFPMA 2004).

One of the most pressing needs is to set a clear and irrefutable priority around access to medicines to fight the three biggest killer diseases: HIV/AIDS, TB, and malaria. Millions die each year from these diseases and millions more contract them in even more deadly combinations. Both trend lines and absolute numbers for these three diseases continue to rise at alarming rates among the world’s population, and the 2 billion poorest people in the developing world experience the most direct and deadly impact.

Due to the speed at which these diseases are spreading and antimicrobial resistance is developing, failure here could render access to other medicines and related issues a moot point.

Partnerships built around public and R&D industry engagement are rising to this need. New and emerging infections have triggered substantial investment in research in infectious diseases in both rich and poor countries over the last decade. For example, the budget of the National Institute of Allergy and Infectious Diseases of the National Institutes of Health in the United States has increased from a little more than \$1 billion in 1998 to more than \$3.5 billion in 2003 (NIAID, NIH 2004). Sixty percent of this budget is dedicated to infectious and parasitic diseases relevant to developing countries (WHO 2004e). An increasing amount of their budget is to promote collaborations with scientists in other countries and to establish research centers in those countries, particularly as it relates to HIV, TB, malaria, and other parasitic diseases. The 10/90 Report on Health Research 2003–2004 (www.globalforumhealth.org) and the workshop of the Initiative on Public-Private Partnerships for Health, “Combating Diseases Associated with Poverty: Financing Strategies for Product Development and the Potential Role of Public-Private Partnerships,” indicate that substantial progress has been made in the last decade by the establishment of a new type of public-private partnership for product development, as already discussed.

A small number of diseases of the poor still need R&D investment as no effective and safe treatments for them exist. For others, medicines exist but capacity-building approaches and strategies require re-evaluation. Various attempts to prioritize the need for R&D among “neglected” diseases have led to a unanimous conclusion that efforts should be focused on the three kinetoplastid diseases: African trypanosomiasis, Chagas disease, and leishmaniasis.

Surprisingly, the working group’s report does not acknowledge this, nor does it accept that important progress has been made in both drug development and increases in public funding of basic research for these and other diseases primarily occurring in developing countries. A proper perspective is critical: so called neglected diseases often do not represent the most pressing public health priorities in low-income countries. In fact, they constitute a small fraction of the total disease burden. According to the 2002 *World Health Report*, tropical diseases accounted for only 0.5 percent of deaths in high-mortality poor countries, and only 0.3 percent of deaths in low-mortality poor countries (WHO 2002g).

Even for the truly neglected diseases, progress is being made through public-private partnerships and independent efforts. For African trypanosomiasis an initiative between WHO and three pharmaceutical companies—Aventis, Bayer, and Bristol Myers Squibb—has been established. There are several products available for leishmaniasis developed by pharmaceutical companies working with the WHO Tropical Disease Research group. For Chagas disease, Roche has donated rights and technology to manufacture benznidazole (the most effective drug for Chagas disease) to the Brazilian government.

With respect to other tropical diseases, schistosomiasis can be treated with praziquantel at a cost of 30 cents per child per year. Onchocerciasis is controllable with ivermectin, and a range of treatments is available for lymphatic filariasis. The only significant tropical disease for which there is no existing medicine is dengue fever, but even for this disease there are five compounds currently at a state of discovery and preclinical development, a further two in Phase I trials, and one more in Phase II trials (IFPMA 2004).

To conclude, there is a continuing need for new and innovative medicines and vaccines to keep pace with current and emerging health challenges. All agree that the existing healthcare inequities of the developing world require new thinking. Unfortunately, quick solutions are usually equally shortsighted and fail to understand or address the complexity of the issues, and incur disastrous and potentially irreversible long-term consequences. It requires the good-faith effort, intelligence, and commitment of all parties to the development of solid, sustainable, win-win policies from which short- and long-term strategies can be developed for intervention and relief.

Inaccuracies and biases on intellectual property and pricing

Scaled-up efforts by the public sector to support developing countries; donations or voluntary differential pricing schemes by pharmaceutical companies, when combined with safeguards against diversion; and creative use of intellectual property to promote public-private partnerships around drug discovery are all critically important to building access. The report of the working group discounts or rejects all but the first of these, but the reality is that all are inter-related—without the spur to development provided by property rights and the rule of law, donor efforts to fund medicines are likely to yield only short-term gains in health.

There is now a track record on how intellectual property rights may be properly managed to support access and economic and social development. Certainly not all questions have been answered as to how intellectual property rights should be managed in connection with procurement and all medicine development programs. None of these matters is susceptible to a “cookbook” or “one-size-fits-all” approach.

We do believe, however, that the time has arrived to put behind us whether intellectual property has a productive role to play in access and to move on to the task of making it work to play such a role (Wilder and Solovy 2004; Roy Widdus, *Product Development Partnerships on ‘Neglected Diseases’: How They Handle Intellectual Property and How This May Contribute to Improving Access to Pharmaceuticals for HIV, TB and Malaria*, www.iprsonline.org/unctadictsd/bellagio/docs/Widdus_Bellagio3.pdf).

Throughout the report there is a fundamental bias that intellectual property is a problem to be overcome rather than a tool to be managed and used to accomplish desired goals. This bias in the report is found in recommendations

to focus on the exceptions to intellectual property rights as an end in itself, rather than a necessary adjunct to a fair and functional intellectual property system. In short, the report gives far more attention and credence to the exception to the rule of intellectual property than it does to the rule itself.

This discrepancy is highlighted in the section of the report on “overarching barriers” to access to affordable new medicines and vaccines. This section was apparently added to the final report of the Working Group on Access to Essential Medicines based on discussions that took place in the Task Force on Trade.

Specifically, there is a factual reference that is not fully understandable in context—that is, “after January 2005, generic production in India and China, the source of many vital existing medicines for developing countries without productive capabilities, will be subject to TRIPS provisions.” China made substantial reforms to its patent system in 1993, including providing patent protection for pharmaceutical products, and as a new member of the WTO, its intellectual property laws had to be fully TRIPS compliant as of its WTO accession in December 2002.

This is in contrast to the situation in India, which was given until 2005 to fully comply with TRIPS. China has had a patent law that protected pharmaceutical products for over a decade, and has had a TRIPS-compliant law since 2002. Hence it is not clear what changes will be made after January 2005 in China. This problem regarding the perceived effect of TRIPS implementation on China appears in several sections in the report, including the recommendation on unaffordable prices.

The working group also states that the agreement on the waiver to obligations in Article 31(f) of the TRIPs Agreement “will be too cumbersome for developing countries to exploit.” Making such a statement is at least premature, as WTO members are only now passing legislation to implement the waiver, let alone deal with specific cases. Further, the waiver was a carefully negotiated, drafted, and unanimously agreed-upon compromise among all WTO members.

Lastly, the “major recommendation” to mandate the WHO to monitor TRIPS compliance is in our view unnecessary. The WHO role in trade and, in particular, on intellectual property matters, has been fully discussed in the World Health Assembly over the past several years. To the extent that the WHO has a role in this area, it is already being addressed and it is clear that most member countries of the WTO are reluctant to see the WHO expand its purview into this area without proper consultation and negotiation concerning the respective areas of engagement and enforcement.

With regard to industry pricing, the report states that “governments ensure TRIPS public health safeguards are in national legislation and have the expertise and will to use them.” There is no doubt that having expertise and the will to implement provisions regarding the protection of intellectual property protection are important. Indeed, for WTO members, implementing the TRIPS agreement is both required and good policy. That said, urging

the implementation of “safeguards” or “flexibilities” is narrow and insufficient. Rather, the goal should be to fully and fairly implement the TRIPS agreement as a whole—including its substantive obligations and limitations and exceptions—to achieve the legislative intent of the entire agreement.

This prejudice is evident in the section on addressing issues at the international level. In particular, there is a statement of a need to provide “new options [pertaining to exceptions and limitations to intellectual property protection], beyond those already incorporated in the TRIPS agreement.” Thus, rather than urging a full and fair implementation of the TRIPS agreement, the goal is to seek further ways to undermine intellectual property protection before it is fully established in many countries.

In this same section there is a statement that competition in the pharmaceutical field must be favored—“including unhampered competition between individual firms and between innovative companies on the one hand and generic producers on the other.” In context, it is clear that this statement calls for an elimination of intellectual property protection. That is, the goal is to achieve competition on price to enhance static efficiency, rather than competition on technologies to enhance dynamic efficiency. Put another way, it makes it clear that the goal of the authors of the report is to reject the general rule of intellectual property protection and elevate and expand exceptions and limitations on intellectual property protection to the point that it has no force or effect.

This type of absolutist position is evident where it is stated that “newer drugs will be protected by patent from low-cost competition for at least 20 years, which means that impoverished populations may (and generally will) be deprived of these medicines for that entire period.” It ignores the fact that much of a patent term (between 8 and 12 years) expires prior to commercialization in the first market. It fails to acknowledge that medicines currently under development, which will be the first ones globally introduced, already have patent terms that are expiring, and counterparts of these patents may not even exist in the Least Developed Countries. And it glosses over much of what was discussed during the proceedings in the working group and the commissioned paper by Wilder and Solovy (2004) concerning the role of intellectual property and the way in which properly functioning intellectual property systems can be made to work so as to support the emergence of new drugs, and their being taken up for generic manufacture at the end of the patent term.

Finally, it assumes a static, one-dimensional view of patents that does not admit the proper role of patents and the possibilities of the implementation of a strong patent system with built-in safeguards to prevent abuse of patents once granted.

Misperceptions about drug quality assurance and safety

In addition to improving access to medicines, the working group must accept that cooperation is necessary to ensure that medicines are both safe and

effective—and that no double standard between developed and developing countries should be tolerated. To do otherwise would be to promote practices and standards below those expected in the developed world, which would clearly be at odds with the basic human rights espoused as one of the principal recommendations of the report.

Safety in medicines has two basic aspects: minimizing the potential for harm while maximizing the potential for benefit, such as efficacy. In this context, two elements are fundamental: first, we should start with the goal of raising the standard of medicines quality for everyone, not lowering the standard for some. Second, while we know some necessary steps have been taken to improve the availability of “approved” drugs, it must be understood that, while necessary, these steps are not sufficient to ensure their quality.

Here are the facts: we know that medicine safety and efficacy are a direct result of implementing quality manufacturing practices. These practices, in turn, have implications for manufacturing costs and ultimately price; those connections and consequences are undeniable and unavoidable. Furthermore, as originator firms scale up to production-level manufacturing, some economies of scale will drive the per-unit cost down. However, many medicines are simply difficult to manufacture from a scientific or technical standpoint. Those manufacturing challenges, with their associated costs, are not diminished simply by an increased scale of production. Unfortunately, this reality results in the pursuit of manufacturing practices at odds with both safety and effectiveness—manifest in both substandard and counterfeit manufacturing operations—with disastrous results for patients.

As indicated in the report, evidence is building that the extent of problems associated with medicines safety and efficacy (such as second- and third-world manufacturing quality) is large and growing in the developing world. Whether due to poor local or regional manufacturing practices or the manufacture or importation of counterfeit products, the results are the same. Furthermore, if we wait for absolute confirmation of this alarming trend, the proof will be the thousands of individuals who have needlessly suffered or died for lack of successful treatment or because of the insidious, silent threat of microbial resistance. The working group is resoundingly silent on this issue.

The critical situation is further complicated by what we see as a considerable misunderstanding in the report about the role of the WHO in drug regulation and approval. The WHO does not “approve” drugs. That is the role of national legal and regulatory authorities that are equipped to do such work. In its prequalification system, the WHO lists those drugs it has prequalified for procurement by UN agencies. As the WHO system stands, there are no requirements to ensure that the drugs it prequalifies meet the standards of safety and efficacy established by national drug regulatory agencies in developed countries. The WHO is clear that it does not guarantee the drugs it prequalifies by issuing a disclaimer on all of its prequalified antiretroviral prod-

ucts, stating that they are “not warranted for safety and/or efficacy in the treatment of HIV/AIDS.”

In point of fact, a closer examination of detailed information from the WHO website for the prequalification system and that of the U.S. Food and Drug Administration and the European Medical Evaluation Agency highlight some significant differences vis-a-vis: 1) required clinical trials; 2) basis for legal and regulatory authority; 3) postmarketing surveillance; 4) use of scientific standards for innovator, generic, and copy drugs; and 5) basis for enforcement authority.

The research-based pharmaceutical and biotech industry affirm their strong support for rigorous product marketing reviews and manufacturing protocols that meet the highest international standards for product quality, safety, and efficacy as embodied in the International Conference of Harmonization (ICH). In our view, the WHO prequalification scheme, based on its own record, does not meet the stringent and well established standards in use among leading, highly experienced, and well resourced regulatory agencies. We note that in recent months there has been a confusing series of listings and delistings that have disrupted supply and created confusion for consumers.

With respect to the safety, efficacy, and quality of the medicines purchased by the U.S. government for treating AIDS patients, the President’s Emergency Plan for AIDS Relief explains that medicines will be “procured from reliable manufacturers,” and supports capacity to test products in the countries in which medicines are delivered. In the specific case of fixed-dose combinations (that is, the combination in a single pill of previously approved individual HIV/AIDS therapies), the U.S. Department of Health and Human Services recently announced an expedited approval process by the Food and Drug Administration that tests efficacy and safety and makes such medicines (including those of foreign companies) available for procurement by the U.S. government. As explained by the U.S. Global AIDS Coordinator and the Secretary of Health and Human Services, “drug patent issues that apply in developed nations should not impede purchase of these drugs for developing countries.”²

It should also be noted that combination copy products are among those withdrawn from the WHO prequalification list.

At this writing, we observe that the number of products approved by the prequalification scheme that have been subsequently delisted and withdrawn from the market exceeds the products that remain on the prequalified list. Hence it is puzzling to us why the working group strikes a strong note of support for the prequalification scheme approach as a tool to increase access—access yes, but at what cost?

Conclusion

We appreciate the opportunity to provide the working group with a statement of our concerns focused on these four critical thematic areas of the report.

Our industry remains committed to dialogue with all members of the working group and we welcome additional opportunities to explain our perspective as work moves to transforming recommendations into a specific action agenda. We believe that our expertise and experience, while not reflected in the report itself, remains a critically important element in ensuring the successful promotion of medicines access under real life conditions in the field. We stand ready to contribute to the ultimate aim that we all share: health for all and making a real difference in the lives of the world's poor.

Summary of recommendations

Area	National recommendations	International recommendations
General principles	<ul style="list-style-type: none"> • Translate principles of human rights relating to medicines access into enforceable rights for the individual. • Make it a priority to strengthen healthcare systems, including the role of ministries of health, capacity building, and integrating public and private sector perspectives. • Explicitly recognize in policies the need to have gender-responsive policies and plans that can be measured effectively (such as using both sex- and gender-disaggregated data) for the extent to which gender is adequately considered and the outcomes substantively target women and girls and increase their equitable access to healthcare and medicines. • Protect and promote women's equal rights, with priority areas being protection from violence, equality under inheritance laws, and increased policy and financial responses to gender-based discrimination in accessing healthcare and treatment. 	<ul style="list-style-type: none"> • International organizations need to acknowledge access to medicines as a human right. • International organizations should support a competitive international pharmaceutical environment that includes generic competition. • UN agencies and the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM) should adopt policies and approaches that ensure that gender considerations are adequately integrated into all aspects of their planning, activities, and budgets.
<i>Barriers to availability</i>		
Gaps in innovation	<ul style="list-style-type: none"> • Provide policy, sustained funding, and infrastructure for biomedical research, including research on indigenous medicines, to encourage innovation driven by priority health needs. • Promote a policy environment that protects complementary and synergistic roles of publicly and privately funded research. • Promote a predictable, expeditious regulatory environment that emphasizes interventions for priority diseases. • Promote research and development for indigenous medicines. 	<ul style="list-style-type: none"> • Promote global public investment in research for priority health needs of developing countries. • Create an environment that stimulates the private sector to contribute to innovation in public health priorities. • Ensure that international standards for ethical research, such as those elaborated by the Declaration of Helsinki, are applied in all countries. • Request the WHO Commission on Intellectual Property Rights, Innovation, and Public Health to examine alternative international models to the current patent-based system for priority-setting and financing of R&D.

Area	National recommendations	International recommendations
<i>Barriers to availability (continued)</i>		
Unreliable supply systems	<ul style="list-style-type: none"> Promote all effective supply channels (public, private, NGO), giving priority to sustainable, reliable supply systems. Provide clear regulations for supply systems using international best practices, such as those established by the GFATM. Ensure that the judicial system enforces regulations and supports concrete actions against corruption and diversion. Explore pooled procurement options. 	<ul style="list-style-type: none"> Promote transparent information sharing on successful national and pooled supply strategies to enable access. Provide producers with reliable forecasts of priority product requirements. Promote international standards for procurement agencies. Provide technical assistance (WHO, GFATM, the World Bank, and others) to strengthen supply systems in developing countries.
Unsafe medicines	<ul style="list-style-type: none"> Strengthen medicines regulatory authority with political support, financing, and staff. Strengthen national systems for monitoring adverse reactions. Work with appropriate parties to monitor adverse drug events and institute no-fault systems for redressing drug injury. Design national registration systems that are simple, work in a timely manner, and include fast tracks for priority medicines; in particular, those that are WHO prequalified. 	<ul style="list-style-type: none"> Enforce compliance with international GMP. Share information about poor-quality products and producers, based on reliable and accurate data. Strengthen systems for sharing information on benefit-risk assessment and regulatory decisions (such as withdrawals of medicines from the market). Support existing adverse event monitoring. Prequalify according to the WHO prequalification project and monitor priority products and suppliers and share this information (for example, as a "white list"). Strengthen and expand the WHO prequalification project and make it a permanent and well funded function of the WHO. Strengthen national regulatory capacity through training, capacity building, information sharing, evaluation of best practices, and sustained funding.
<i>Barriers to affordability</i>		
Inadequate and unfair financing	<ul style="list-style-type: none"> Increase the public sector budget for essential medicines and ensure equitable access. Phase out user fees for essential medicines in favor of more equitable financing. Institute performance-based payment for providers. Promote good donation practices as in accord with international guidelines. 	<ul style="list-style-type: none"> Increase total international financing for essential medicines targeting the poor. Do not use loans to fund recurrent medicines expenditures. Increase development assistance for health in line with recommendations by the Commission on Macroeconomics and Health and others. This assistance should support national health policies and systems. Coordinate and simplify donor assistance procedures to make transparent the total funding flows and to reduce transaction costs for developing countries.
Unaffordable prices	<ul style="list-style-type: none"> Use a variety of tools to lower prices in developing countries ("equity pricing") including promoting generic competition, using essential medicines lists, promoting bulk procurement, negotiating equitable prices, minimizing markups, and adapting national legislation to ensure that TRIPS safeguards can be used. Ensure timely payment of suppliers to encourage lower prices. 	<ul style="list-style-type: none"> Carefully monitor the impact of TRIPS compliance by medicine-producing countries, such as India and China, on access to essential medicines in developing countries and present an assessment by 2007. Provide medicines at production cost to low-income countries and at reduced cost to middle-income developing countries. Share accurate and consistent data on producer prices, markups and profits, tariffs and taxes, and fees and other charges. Support a competitive international pharmaceutical environment that includes generic competition. Ensure that regional and bilateral trade negotiations promote international understandings that support access to medicines.

Area	National recommendations	International recommendations
<i>Barriers to appropriateness</i>		
Inappropriate prescribing and dispensing	<ul style="list-style-type: none"> • Implement national coordinating policy on activities to improve rational medicines use. • Use evidence-based treatment guidelines in teaching, monitoring, and evaluation. • Ensure responsible and ethical medicines promotion by pharmaceutical companies through government oversight. • Ensure the availability of independent and impartial information for continuing education of prescribers and dispensers. • Separate prescribing and dispensing profits. • Train, regulate, and monitor people prescribing and dispensing medicines. 	<ul style="list-style-type: none"> • International donor agencies should coordinate to support country efforts to promote rational use. • WHO should update and promote ethical criteria for medicines promotion and medicines information (for example by utilizing the Internet). • WHO should share, disseminate, and translate independent information on treatment of priority conditions for national adaptation.
Inappropriate use by households	<ul style="list-style-type: none"> • Promote culturally appropriate health literacy and community support. • Ensure availability of independent and impartial information for households using culturally appropriate means. • Mobilize and engage communities to improve use of medicines. • Regulate consumer advertising for medicines. 	<ul style="list-style-type: none"> • International health organizations and NGOs should continue to develop and disseminate health literacy information related to appropriate use of medicines for use in developing countries.
<i>Cross-cutting issues</i>		
Human resources	<ul style="list-style-type: none"> • Pay health workers an adequate wage. • Ensure sufficient numbers of trained pharmacy workers of different levels. • Continuously update and adapt to needs training curricula for prescribers and dispensers. • Develop, support, and involve the communities' own resource persons. 	<ul style="list-style-type: none"> • Support health worker training with updated international curricula. • Use donor financing to fund salary costs in poorest countries. • Institute international agreements and cooperation on health worker migration. • Through international financing agencies such as the World Bank and the GFATM and major bilateral donors, focus on training and capacity building of a substantial number of supply chain managers and other essential health workers in developing countries.
Gender	<ul style="list-style-type: none"> • Ensure women have access to accurate, gender-sensitive medicines information. • Involve women in medicines policymaking. • Promote innovative and outcome-based research on the gendered aspects of medicines access and use by women and girls and men and boys. • Collect sex- and gender-disaggregated data on access and use, which, in combination with adequate gender analysis, should inform policies, plans, and budgets. • Ensure that women and girls have equal access to medicines. • Ensure full and equitable access to sexual and reproductive health services and commodities. • Ensure that national essential medicines lists contain the core medicines and devices for sexual and reproductive health recommended by the UNFPA and WHO. 	<ul style="list-style-type: none"> • Ensure that adequate gender analysis is included in all health policymaking, strategies, and programs.
Institutional structures	<ul style="list-style-type: none"> • Create and maintain efficient national institutions required to implement law, regulation, inspection, and financing in the field of medicines. 	<ul style="list-style-type: none"> • Maintain international institutions capable of supporting the development of stable medicines access systems.