

## Deadlock on access to cheap drugs at global trade negotiations

At the end of 2002, the United States rejected a compromise proposal aimed at giving developing countries without local manufacturing capacities access to affordable life-saving drugs. At a December meeting at the World Trade Organization (WTO) in Geneva, negotiators of several of the 144 WTO members expressed their regret about the failure to reach an agreement by the intended deadline, which was the end of last year. Eduardo Perez Motta, Chairman of the WTO Trade-related Aspects of Intellectual Property Rights (TRIPS) Council and author of the compromise proposal, even apologized to sufferers from diseases in the developing world for the failure to come up with a viable solution. Meanwhile, in an attempt to reinvigorate the stalled negotiations, European Union (EU) Trade Commissioner Pascal Lamy put forward another compromise solution.

The bone of contention is the export of generic versions of drugs protected by patent to developing countries that lack manufacturing capacity to produce the generics themselves. At their fourth conference in Doha, Qatar, in November 2001, WTO ministers adopted a Declaration on TRIPS and public health. The agreement, usually referred to as the Doha Declaration, allowed poor countries to produce urgently needed drugs even if the drugs in question are under patent protection, a procedure known as compulsory licensing.

Even back then, however, WTO negotiators admitted there was a shortcoming in the Doha Declaration: the contentious paragraph 6 the Declaration bluntly states that “members with insufficient or no manufacturing capacity could face difficulties in making effective use of compulsory licensing ... We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002”. This is because, according to TRIPS guidelines, drugs made under compulsory licence are intended predominantly for

the domestic market, that is, not for export.

But the recent TRIPS Council meeting failed to deliver one, even though a compromise proposal, drafted and circulated by Perez Motta, was on the table. At the end of lengthy argument, the United States was the only country that refused to endorse the proposal. The US delegation considered the compromise — which did not restrict the range of diseases covered — to be too broad in scope, and insisted that instead the agreement should be limited to drugs for HIV/AIDS, malaria, tuberculosis and similarly infectious epidemics. According to a statement by the United States trade representative Robert Zoellick, issued on 20 December, such a focus on infectious diseases would reflect the original intentions of the Doha Declaration.

That is not the way Ellen T’Hoen of Médecins sans Frontières (MSF) sees it. “Already in Doha the United States tried to limit the scope of diseases,” she pointed out. “None of those proposals of theirs made it through those negotiations. As a matter of fact, paragraph 4

of the Doha Declaration is very clear about this point: no limits [in terms of disease range]. In a way these attempts open up the whole Doha Declaration again.” For T’Hoen the latest developments represent a “tragic U-turn in the health–trade debate.”

T’Hoen is not alone in her critique. Celine Charveriat of Oxfam says: “The fact that the European Union and the United States argued that developing countries should not have access to affordable generic drugs for asthma and diabetes, which kill and debilitate millions in these countries, proves that profits still come before people’s lives and that the WTO has powers totally beyond its competence.”

The United States interpretation of the Doha Declaration also raised eyebrows at WHO. “Our understanding of the Doha Declaration is that it is fairly inclusive,” says Jonathan Quick, head of Essential Medicines at WHO. “The idea of either the WTO or the WHO having a single global list [of diseases] is difficult to reconcile with the changing and diverse epidemiology of the world.” That is why, in a statement on 17 Sep-

### WHO supports EU proposal for cheap drugs

WHO would not like a fixed list of diseases to break the WTO deadlock [see adjacent story], as it is too inflexible, says Jonathan Quick, of WHO’s Essential Drugs and Medicines Policy department. The Organization already publishes a priority list of its own — the Essential Medicines List, already in its tenth edition, but, Quick told the *Bulletin* “It was never intended to be a global standard — it’s a model that’s meant to be adapted. It contains some 325 drugs, about the number least-developed countries can buy; middle-income countries typically use 600; high-income countries 1200. The bottom line has to be flexibility.”

“The way WHO operates, ultimately countries decide what is of importance to them; we provide advice, the best possible data, top-flight key data. Last April for example we said these are the best 12 antiretrovirals for HIV/AIDS, and these the first, second and third most effective combinations; but we would not say: ‘Therefore these are the only drugs you can buy.’”

If a country considered it needed to import generics for some condition, according to the European Union (EU) proposal WHO’s role would be to provide evidence and advice on the magnitude of the disease, and to recommend treatment — “on or off patent”. The legal steps would then be up to WTO.

There had been discussions with the EU but “some of the specific phrasing” of the EU proposal “can be read differently from what we’d intended. For example, we were not involved in that list of diseases. But we are completely behind this effort to bring this business to a harmonious closure.”

Speaking to *BioMed Central* ([www.biomedcentral.com](http://www.biomedcentral.com)) Quick added “We’d like a solution that’s sufficiently robust to be good 10, 20, 30 years from now”. Disease patterns shift with time. No one was predicting AIDS 25 years ago. So “from a public health point of view you’d like a flexible agreement.”

“It’s important to step back and ask what’s the dynamic” of the [WTO] problem, said Quick. “Basically the concern of some countries is that it is an open door to break all patents, and what’s needed is an assurance that it won’t be. And the European Union’s hope is that WHO could provide enough reassurance that things can proceed.” ■

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tember 2002, WHO described desirable solutions to the “paragraph 6 problem” as having a “broad coverage in terms of health problems and the range of medicines.”

But according to MSF, Oxfam and other nongovernmental organizations (NGOs), even the Perez Motta proposal would have been insufficient to meet the real needs of the developing world. In an open letter to WTO delegates, the NGOs urged developing countries to reject the draft. “Nobody was happy with it,” T’Hoen says. “The procedures it proposed are so complicated that it would have led to a paper solution, not a practical one.”

So for T’Hoen the December failure is not entirely bad news. “This offers an opportunity to go back to the drawing board and hammer out something that is better.” An ideal solution, T’Hoen adds, should be drafted like the Amendment 196 to the European Medicines Directive, which the European Parliament adopted last October and which states: “Manufacturing shall be allowed if the medical product is intended for export to a third country that has issued a compulsory licence for that product.” T’Hoen says “That’s it — a very nice and simple solution. No strings attached”.

Another initiative to break the current deadlock was launched by EU Trade Commissioner Pascal Lamy in early January. Blaming a “lack of trust” between the United States and developing countries for the failure, Lamy suggested WHO should be actively involved in the process. “When there is too much mistrust in the game you have to call on a third party, and the WHO is a trusted party,” Lamy said at a press conference in Brussels.

Lamy presented a list of infectious epidemics, covering more than 20 diseases “generally recognized as those which have the most damaging impact on developing countries”. Lamy stressed, however, that this was not intended to be a restrictive list; with any other disease or health issue, affected countries should ask WHO to assess the severity of the situation and make recommendations as to how to respond to the problem. Lamy said he was convinced that his proposal “will be able to break the deadlock and rapidly achieve a final agreement”.

WHO’s Jonathan Quick considers the Lamy initiative “reasonable” [see Box].

The next deadline is approaching fast. WTO Director-General Supachai Panitchpakdi recently said the aim would be to reach an agreement by the first meeting of WTO’s governing General Council scheduled for 10 February in Geneva. Jonathan Quick is hopeful that a solution will be achieved before too long. “The ‘spirit of Doha’ has been tested, that is for sure; people are looking at the part of the glass that isn’t full yet. But in fact much of the key content [of the Doha Declaration] is there and has been very helpful,” he says. ■

*Michael Haggmann, Zurich*

## Donors are distorting India’s health priorities, say protestors

International donors are driving India’s national health agenda in the wrong directions, says a growing movement of Indian health policy experts and nongovernmental organizations (NGOs). For example, although AIDS mortality is still low in the country, there is an excessive focus on HIV/AIDS prevention, with little linkage to primary treatment, they say. Meanwhile, grassroots concerns and larger immediate public health needs are being ignored, they claim.

The recent visit of the Microsoft tycoon Bill Gates, with his US\$ 100 million grant for AIDS prevention in India, sparked the debate. At that time, the view of the Government of India and part of the Indian media was that they should not “look a gift horse in the mouth”. Public health experts, however, argued that this was a myopic approach that failed to recognize grassroots reality.

Alka Gogate, director of the Mumbai AIDS Society, says that those who have direct contact with this reality recognize the importance of ensuring that AIDS funds are used to strengthen general health services, even while ensuring care and support for AIDS patients. There have been several meetings on this issue with the deans of public hospitals in the city, she said. She claimed that it was “well recognized” that if primary health services were neglected, the huge load of infectious disease patients would be pushed onto the city’s tertiary services — which cannot cope with this pressure.

The top killers in India were classified in the 1994 survey of the Indian Registrar General as: “senility or old age” 21.2% (1.8 million); “cough” 19.3% (1.6 million); “circulatory disease” 11.2% (940 000), and “causes peculiar to infancy” 9.6% (810 000).

The epidemiology of HIV/AIDS in India has recently generated heated controversy between the Government of India and international agencies. India urgently needs a new system of disease surveillance, according to Anish Mahajan, AIDS researcher with a Chennai-based AIDS support group and Brown Medical School in the US. The present system extrapolates data from high-risk groups, and has no community-based information from the private sector — which is the country’s largest health provider.

The National AIDS Control Organization (NACO) estimates that four million people suffer from HIV infection in India. AIDS is not reported as a cause of death in the death registers, but NACO states that between 1986 and November 2002 there were 42 411 cases of full blown AIDS in the country. NACO also claimed that the epidemic is now plateauing because of its efforts. Others are sceptical, and reliable data, that all sides can agree, are urgently needed.

As for finance, according to the Central Government’s Expenditure Budget for 2000–01, India’s health and welfare budget was some US\$ 1.2 billion. The disease control programme received some US\$ 170 million, around 14% of this. AIDS and sexually transmitted diseases got some US\$ 30 million, 2.5% of the health and welfare budget.

But the current donor interest in HIV/AIDS in India is boosting HIV/AIDS spending by approximately an additional US\$ 80 million a year, causing spending on this one disease to reach US\$ 110 million a year, thus making HIV/AIDS the main target of India’s spending on disease control.

Moreover all AIDS funding is routed through NACO and state AIDS Societies, bypassing state health departments, so contributing little to improving the country’s struggling health system.

Meanwhile, says Ravi Duggal, a health policy researcher at the Centre for Health and Allied Themes, Mumbai, treatment budgets are barely adequate to

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HIV prevalence levels remain comparatively low in most countries of Asia and the Pacific. That, though, offers no cause for comfort. In vast, populous countries such as China, India and Indonesia, low national prevalence rates blur the picture of the epidemic.

Both China and India, for example, are experiencing serious local epidemics that are affecting many millions of people. India's national adult HIV prevalence rate is less than 1%, but an estimated 3.97 million people were living with HIV in India at the end of 2001 — the second-highest national figure in the world after South Africa. HIV prevalence among women attending antenatal clinics was higher than 1% in Andhra Pradesh, Karnataka, Maharashtra, Manipur, Nagaland and Tamil Nadu.

New behavioural studies in India suggest that prevention efforts directed at specific populations (such as female sex-workers and injecting drug users) are paying dividends in some states, in the form of higher HIV/AIDS knowledge levels and condom use. However, HIV prevalence among these key groups continues to increase in some states, underlining the need for well-planned and sustained interventions on a large scale. ■

cover 25–30% of TB cases, even though most AIDS patients in India die because of AIDS-related TB, and TB remains a major killer by itself.

"International donor influence in the Indian health system is disproportionate to the amounts of money they have contributed," says Duggal. "The foreign component in our overall health and welfare budgets is not more than 10%, but the advice and influence affects more like 90% of our spending."

Western and Indian government perceptions can differ widely not only from each other but from grass-roots realities, several studies have shown. A survey of published studies by Ramila Bisht, a senior lecturer in the department of health services at Mumbai's Tata Institute of Social Sciences, found that donor funding between 1985 and 1995 for specific disease programmes did not match evidence of the prevalence of these conditions in the community. For instance, despite being a major killer, TB was not a priority for funders until the 1990s, she says.

Moreover, most international aid is not neutral, Duggal complains: it comes as soft loans with policy conditions attached, such as the introduction of user fees in government hospitals, policies that might attract more private sector participation in health, and emphasis on "vertical" health programmes.

A recent conference of the Asian Social Forum in Hyderabad saw several Indian health NGOs such as Swasthya Panchayat, Lokayan, and the Centre for the Study of Developing Societies, coming together to analyse what they considered to be the negative impact of the Indian AIDS programme, which they said had been shaped by the "monolithic, homogenizing nature of

the response shaped by the perspectives of the 'north'".

According to these NGOs this approach has isolated HIV/AIDS from other public health problems, and promoted technological and managerial solutions while ignoring the social and cultural roots of the problem.

"Unless we strengthen the primary health care base we won't go anywhere," says Sheela Rangan of the Pune-based Centre for Health Research. "There is an urgent need to build management systems, fill vacant posts and train front-line health workers in comprehensive care, so they understand the linkages between diseases."

"The emphasis on AIDS works to the detriment of other communicable diseases, which could stage a resurgence," claims Bisht. "We need to integrate AIDS funds into strengthening the general health services. Improving the primary health system will have an impact on a range of killer diseases, including AIDS." ■

Rupa Chinai, *Mumbai*

## Leprosy elimination in India inches closer

India has recently been oscillating between good and bad news in its bid to defeat leprosy. The Indian government has effectively curbed the disease in many parts of the country, but health experts believe that it may not be able to "eliminate" it from India within the next three years as planned. Elimination has been defined for the purposes of the global campaign to defeat leprosy as bringing the prevalence down to below one case per 10 000 people.

The government announced in December 2002 that it had brought down the leprosy prevalence dramatically from 57.6 per 10 000 people

in 1981 to 4.2 per 10 000 people currently. According to government figures, there were 440 000 leprosy patients in the country in April 2002. "We hope to eliminate leprosy by 2004-05," said Ashok Kumar, the head of the Leprosy Division of the government of India's health services.

Though this figure for the country as a whole may make elimination seem well within reach, the situation in some parts of the country is more daunting. In the eastern state of Orissa, the prevalence per 10 000 people had decreased from 23.9 in 1998 to 8.9 in 2002, which is impressive but still more than twice the national average. In the state of Jharkhand in eastern India, the prevalence was 12.95 per 10 000 people, more than three times the national average. Going down another level, there could be areas within Jharkhand with a prevalence of 20 or more per 10 000 people.

"There are some states where the prevalence is very high," said Serge Manoncourt, the Medical Officer for Leprosy at WHO's Regional Office in New Delhi "and in some parts of those states the figures are higher still." The focus of the government was on the southern region initially, because it was there that the prevalence was highest in the 1980s. The campaign is now being intensified in the east, where three states — Bihar, Jharkhand and Orissa — have a prevalence of more than 8 per 10 000 people.

Leprosy was already recognized as a major public health problem in India in the 1950s, but the real prospect of solving it came only in 1991, after the World Health Assembly had approved a global strategy to eliminate leprosy by the year 2000. It was the advent of an effective treatment in the form of multidrug therapy that had made this possible. With a loan from the World Bank for 1993–94, the government launched an intensive national campaign against leprosy, focusing on early detection and treatment.

The campaign included a comprehensive mass awareness programme. Groups of trained personnel visited schools and village market squares to spread messages about leprosy treatment. Radio and television messages stressed that leprosy was curable. "We had to tell the people that leprosy was not a curse inflicted on them by the gods but a disease that could be treated very easily," said Kumar. Meanwhile "the Indian Government has been ensuring that people have access to free medicines at a health centre near their



WHO/TDR, L. Maurice

A cured leprosy patient from India's leprosy-endemic eastern seaboard with her child.

house," said Kumar. The campaign was effective and the prevalence rate plummeted.

The government is now in the second phase of the campaign funded by the World Bank, which ends in 2004. In this phase, leprosy treatment — which up till now has been the responsibility of a separate department — is being integrated with general health services. Personnel at public health centres have been trained to detect early signs of leprosy. General State, district and village health authorities are now being drawn into the programme. ■

Bishakha De Sarkar, *New Delhi*

## US obesity grows 74% in a decade

A nationwide, randomized telephone survey by the US Centers for Disease Control and Prevention has shown a fat 5.6% growth in obesity in the United States in the single year 2001–02, and a massive 74% since 1991. Type two diabetes is following the same track (*Journal of the American Medical Association*, Vol. 289, 1 January 2003, p. 76-9).

The largest telephone poll on health ever conducted in the US reached nearly 200 000 individuals over 18 years old, outside institutions or the armed forces (where diet is effectively controlled). The "Behavioural Risk Factor Surveillance System" questioned people on their health and behaviour, including height and weight, and calculated their body mass index (BMI), which is weight

in kilograms divided by height in metres squared. Overweight is classed as a BMI of 25 to 29.9; "class two" obesity as 30 to 39.9, and "class three" obesity as 40 or over.

The prevalences represent over 20 million obese men and 30 million obese women. Extreme, class three obesity affects 1.7% of American men and 2.8% of American women, the study showed.

Some 21% — over one in five — American adults are obese, falling either into class two or three; 31% of blacks are obese, according to the study.

The prevalence of diabetes, which correlates with obesity, has risen 61% in the US since 1990, and 8% over 2000–01 alone, to nearly 8% of the population, and 11% among blacks. Among all colours, diabetes was present among 13% — one in eight — of those without high school education.

However "these rates are no doubt substantial underestimates" the authors write. Smaller validation studies where weights and heights were actually measured showed people tend to overestimate their height, and underestimate their weight, the researchers say. The overall proportion of Americans who are obese could be as high as 30%, not 21%, they say.

Previous studies by the same team showed that under 20% of American adults who were trying to lose weight were following recommendations to eat fewer calories and increase physical activity to at least 150 minutes a week. ■

Robert Walgate, *Bulletin*

## Antiretroviral misuse in Mumbai, India

Many patients who have tested HIV-positive in Mumbai are consuming antiretrovirals (ARVs) in fits and starts because of their unstable financial circumstances. The warning comes from the Indian community-based organization Sankalp and the Committed Communities Development Trust. For lack of reliable counselling, patients are unaware that once started, ARV treatment has to be lifelong and without a break.

Patients are also not briefed about the hidden costs of therapy, such as the need for regular, and expensive, laboratory tests, or the possibility of severe side-effects.

AIDS specialist Nagesh Shirgopkar says there is a strong case for use

of ARVs amongst patients whose CD4 cell count, a measure of immune status, falls below 225. Patients with such conditions have experienced a life-saving reversal of symptoms when properly treated with ARVs, but treatment involves care and knowledge as well as medicines.

This advice is being undermined by the expanding interests of pharmaceutical companies and private doctors in Mumbai. According to a senior doctor, patients are being directly approached by medical representatives of drugs firms and persuaded to start ARV courses. Apart from violating the patients' right to confidentiality, this often puts them on therapy when they don't need it, and no monitoring is done, he said.

AIDS drugs companies appear to be racing to expand their Indian markets. Given the current haphazard prescribing and consumption practices with AIDS drugs, many doctors — not just quacks — are experimenting with their own dosage and drug combinations. These factors could lead to HIV developing drug resistance. If that happens, the Indian government will face the enormous problem of how to help those who have already started on the therapy. The majority of AIDS patients in India come from the poorer strata of society, who are the most exposed to haphazard and sporadic therapy.

The rush to market ARVs and the chaotic treatment of AIDS patients was also underlined by government officials at a recent workshop in Mumbai, where they complained of a "mania for HIV testing" by doctors, in both the private and the public sector. Official policy in public hospitals in Mumbai does not encourage HIV testing unless there are clinical symptoms warranting suspicion of AIDS. But private hospitals insist on compulsory HIV testing before patient admission, even if they have no clinical symptoms of AIDS. Nongovernmental organizations have pointed out that an HIV-positive "certificate", in the absence of proper counselling and on the basis of a single ELISA test, is seen as a death sentence by the patient and his family, and this view is endorsed by an ignorant medical profession.

While India's National AIDS Control Organization (NACO) stipulates a minimum of three ELISA tests before a person can be confirmed to be HIV-positive, most patients cannot afford three tests. ■

Rupa Chinai, *Mumbai*