Q&A: prequalification

In May and August 2004, WHO removed five antiretroviral products from its list of prequalified medicines.

What has happened? In May and July 2004, WHO ran a series of inspections of contract research organizations and/or laboratories (CROs) as part of its continuing monitoring of prequalified medicines. The CROs had been contracted by manufacturers to carry out tests to prove the bioequivalence of medicines submitted for prequalification, in accordance with WHO requirements. Bioequivalence tests are clinical trials conducted in healthy volunteers to find out if the concentration of a generic medicine in the blood of a patient is equivalent to that of the originator product. During the inspections, two CROs were not found compliant because of serious discrepancies between the original results compiled by the CROs and the results presented to WHO by the manufacturers.

Which products were delisted? The five antiretroviral products removed from the list for lack of bioequivalence were:
- lamivudine 150 mg plus stavudine 40 mg and nevirapine 200 mg tablet (Ranbaxy Laboratories Ltd, Dewas, India; aluminium strip of 10 or 60 in box);
- lamivudine 150 mg plus stavudine 40 mg and nevirapine 200 mg tablet (Ranbaxy Laboratories Ltd, Dewas, India; aluminium strip of 10 or 60 in box);
- lamivudine 150 mg plus zidovudine 300 mg tablet (Cipla Ltd, Turin, India; blister pack of 60 or 100);
- lamivudine 150 mg tablet (Cipla Ltd, Turin, India; blister pack of 10);
- lamivudine 150 mg plus zidovudine 300 mg tablet (Cipla Ltd, Mumbai, India; blister pack of 10).

What does the delisting mean for the other products on the list? All products on the list have been assessed through: evaluation of data in the product dossiers on efficacy, safety, quality and bioequivalence; inspection of manufacturing sites for compliance with good manufacturing practices; testing of product samples at independent laboratories for compliance with product specifications. However, following the findings of non-compliance in relation to the five products mentioned, other CRO inspections will be conducted for prequalified products and if these inspections find non-compliance in the CRO, the related products will be suspended until the manufacturers can provide unequivocal evidence of bioequivalence from compliant laboratories.

Recruitment of “3 by 5” country officers in full flow

The first phase of recruitment for “3 by 5” Country Officers is underway, with the aim of having all officers in country and operational by end 2004.

Nineteen international HIV/AIDS experts are being recruited in the first phase of the process. These “3 by 5” country officers will provide technical support to countries in scaling up HIV/AIDS treatment and prevention programmes as part of activities to reach the “3 by 5” target to get three million people living with HIV/AIDS on antiretroviral treatment by the end of 2005.

The country officers recruited during this first phase will cover 19 countries across all WHO regions: Burkina Faso, Cambodia, Cameroon, Central African Republic, Djibouti, Egypt, Kenya, Malawi, Mozambique, Myanmar, Nigeria, Russian Federation, Sudan, Swaziland, Uganda, Ukraine, United Republic of Tanzania, Zambia and Zimbabwe.

Officers for the Russian Federation and Ukraine have already been deployed and have started work in their respective countries. In addition, over the last few months, new staff have been recruited to support “3 by 5” activities in a number of other countries, including in Azerbaijan and Uzbekistan.

A “3 by 5” country officer induction meeting is being planned for late October 2004 during which new country officers will join other WHO staff and partners in a team-building, orientation and skills-building programme.

The second phase of recruitment for additional officers will start within the next few months as additional funds become available.

Beth Magne-Watts

The “3 by 5” target – 3 million people on antiretroviral treatment by the end of 2005 – has helped to mobilize action across all levels of WHO and in the broader international community to scale up access to treatment and care for the millions of people living with HIV/AIDS who need it urgently. For its part, WHO has developed simplified approaches to clinical management, health-care provider training, and monitoring and evaluation which are being implemented in many countries. The drug prequalification project and the AIDS Medicines and Diagnostics Service offer services which are helping to guide countries in their choice of safe, affordable and high-quality medicines, and to improve their procurement and supply management. In addition, WHO has documented our technical support efforts at country level by placing more than 20 senior staff in our country offices specifically to provide close and continuous support to national scale-up efforts, including both prevention and treatment. We are doing more to foster new partnerships, for example, through our innovative programme to support treatment education and literacy by and for people living with HIV/AIDS in their own communities. And through the new HIV/AIDS and Malaria Systems Platform, we are strengthening our efforts to ensure that scaling up of the response to HIV/AIDS not only saves lives and prevents transmission of HIV, but also helps to build stronger health systems as a whole.

Dr Jack C. Chow, Assistant Director-General, HTM
DID YOU KNOW?

About 8 million Africans are coinfected with HIV and TB. Without TB treatment, HIV-positive people with active TB can typically die within months. For every 10 000 per day.

**Facts and figures on TB/HIV coinfection**

What are the figures for Africa?

- An estimated 25 million Africans are now living with HIV.
- About 8 million Africans are coinfected with HIV and Mycobacterium tuberculosis, the organism that causes TB.
- While the risk of TB for an HIV-uninfected individual is 5-10% in her/his lifetime, it is 5-10% per year for the HIV-infected person.
- In 2002, WHO estimated that there were 2.35 million cases of TB in Africa, of which 950 000 were treated under DOTs programmes. Of the treated patients, 243 000 (25%) were estimated to be HIV positive.
- The number of TB cases is rising dramatically by 4% a year as a result.
- In some regions of Africa, three out of every four TB patients are HIV infected.
- 31% of deaths caused by TB, in people of all ages in Africa are HIV related.
- Without TB treatment, HIV-positive people with active TB typically die within months.
- National TB programmes in Africa are currently treating only about 40% of HIV-positive people with active TB; the remaining 60% receive either poor-quality treatment or none at all.

**Why is more collaboration important?**

- Improved collaboration between TB and HIV/AIDS programmes will save the lives of TB and HIV patients, and lead to more effective control of both diseases.
- If infected with TB, HIV-positive people can be given prophylactic treatment (usually isoniazid) to prevent development of active TB disease.
- TB patients can be offered an HIV test: research shows in many settings that they are very likely to accept a test.
- TB programmes can make a major contribution to identifying eligible candidates for antiretroviral treatment and to reaching the “3 by 5” target. Antiretroviral treatment is now the WHO standard of care for HIV-infected TB patients.
- The estimated cost for 2004 to institute collaborative TB/HIV activities in 34 countries with 90% of the TB/HIV burden is US$ 300 million, including the step-wise provision of antiretroviral treatment to HIV-infected TB patients.

Glenn Thomas

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**Challenge and opportunity in China**

"The downward trend of tuberculosis in China is undeniable," says Dr Daniel Chin. But the battle must still be fought before victory is declared.

Set aside SARS and avian influenza. Discount even HIV/AIDS. The one communicable disease taking the largest number of lives in China is an age-old foe: TB. Every year, about 1.4 million people in China are hit with TB, more than any other country except India. And every day in China more than 400 people die of the disease. The word “tragedy” is often overused. But in this case it truly does apply, because TB is both preventable and treatable.

Dr Daniel Chin heads WHO’s TB programme in China, and he knows this reality better than most. Since 1995, he has been working with WHO and the Government of China to reduce the number of TB cases and deaths. Between 1991 and 2000, WHO’s DOTS treatment programme had significantly reduced TB as a health problem in China. In a recent article in The Lancet,1 it is estimated that in 2000, in the parts of China where DOTS was introduced – in all, those provinces have a population of more than half a billion – there were 660 000 fewer cases of TB than there would have been without the programme.

Those sort of numbers should be good enough to warm the heart of any public health practitioner, but Chin knows it’s too soon to claim victory. “The downward trend of tuberculosis in China is undeniable, but only in the half of China with an established DOTS programme. This means we have to quickly scale up DOTS for the rest of the people. If we’re going to meet our goals, we’re going to have to push even harder to find and cure more patients.”

The goals weighing on Chin are significant: one of the United Nations Millennium Development Goals (MDGs) is to halve the prevalence of TB by 2015, compared with the 2000 level. “The implementation of DOTS has in half of China in less than 10 years resulted in substantial reduction in the prevalence of TB. For me, this shows that the MDG for tuberculosis is achievable,” Chin says. China is now in the process of expanding DOTS. The Government has committed to reach 100% DOTS coverage for all of China’s 31 provinces, municipalities and autonomous regions. And it has not pulled back from striving to meet WHO’s goal of a 70% case-detection rate and 85% treatment success by the end of 2005.

DOTS is the internationally recommended strategy for TB control, which combines five elements: political commitment; microscopy services; drug supplies; surveillance and monitoring systems; and the use of highly efficacious treatment regimes with direct observation of treatment.

Can they do it? If not, it won’t be for lack of trying. For 2004, WHO and China’s Ministry of Health have ramped up their efforts to meet the 2005 goals. There is an issue of national pride involved too – China, with the world’s largest population, doesn’t want to be holding the world back from reaching global targets, it wants to contribute to meeting them.

“These short-term goals are tougher to meet,” Chin says. But in the end, “we have confidence China can do this.”

The DOTS programme relies on highly trained people at the grassroots level to deliver the programme needed to conquer the disease. “China has a human resource crisis in its public health programme. Without enough well-trained public health professionals, the country will not reach the MDG for TB. Fortunately, China understands this and is working to deliver the training to people to make this happen. And our funding partners are providing the financial support to bring this about. It will be a demanding few years, but my feeling is we will make this happen,” Chin said.

By “we,” Chin means China and WHO and an array of other partners. “Working together we have made remarkable progress in China’s national TB programme since 1990, and even more so in the last 2 years. That has been the result of the strong commitment from all sides of this national–international partnership.”

What’s next? “Our experience in the 1990s showed the importance of implementing a high-quality programme. With the rapid expansion of DOTS over the past 2 years, the main challenge for us has been to continue to ensure quality of the public health programme needed to deliver care and treatment to TB patients.” Despite the health challenges it’s facing, the Government understands this and is working to deliver the training to people to make this happen. And our funding partners are providing the financial support to bring this about. It will be a demanding few years, but my feeling is we will make this happen,” Chin said.

The WHO team had been focusing on decentralizing malaria control. “This was vital, because Sudan is the biggest country in Africa – one third of the United States in size. We were building capacity at the state and local level. The teams was finding long-lasting insecticidal nets their most effective prevention tool. “We saw a direct relationship between increased use of insecticide-treated nets and decreased malaria deaths,” he says. Then the violence – and vast movement of refugees – set in.

Now, fighting malaria in refugee camps has overshadowed all other efforts. “We are conducting indoor spraying with insecticides in all camps and, in concert with UNICEF,2 distributing insecticide-treated nets and the most up-to-date malaria treatment, artemisinin-based combination therapy (ACT). We’ve also been working with the Global Fund3 Project on drainage and controlling ponds and other places mosquitoes can breed. And 150 000 rapid diagnostic tests have been distributed.”

The camp crisis could not have come at a worse moment. Late summer is peak malaria season in Sudan. Mortality from all causes in the camps is high: three per 10 000 per day. “Still, the proportion of deaths caused by malaria is not higher than what we would expect under ordinary conditions at this time of year in the Sudan,” Sabatinelli says. Against a grim backdrop, it’s what he would call “a successful malaria intervention”.

Judith Mandelbaum-Schmid

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3 Internally Displaced Person.
**Sudan**

**MEET WITH...**

Name: Guido Sabatinelli, WHO Representative in Sudan

**Age:** 50 years.

**Brief biography:** A native of Florence, Italy, Sabatinelli studied medicine in Rome, with a strong emphasis on vector-borne and communicable diseases. He has been working on malaria control – chiefly in Africa – ever since.

**Hobby:** Entomology.

**Why does he what he does:** “Malaria is the most interesting disease for an epidemiologist because it involves everything – insects, humans, parasites and economics. And also, if you understand the epidemiology of the disease, you can have a huge impact.”

Before summer began this year, Sabatinelli had a good feeling about local progress on malaria. “Over a period of two years, we had seen a 30% decrease in malaria deaths in urban areas of the country, and a 50% decrease in areas where we intervened intensively,” he says.

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Mortality from all causes in the camps is high: three per 10 000 per day. “Sabatinelli says. “If infected with TB, HIV-positive people can be given antiretroviral treatment to HIV-infected TB patients. Glucocorticoids are US$ 300 million, including the step-wise provision of TB/HIV activities in 34 countries with 90% of the TB/HIV burden is now the WHO standard of care for HIV-infected TB patients. And to reaching the “3 by 5” target. Antiretroviral treatment is now the WHO standard of care for HIV-infected TB patients.

The estimated cost for 2004 to institute collaborative TB/ HIV activities in 34 countries with 90% of the TB/HIV burden is US$ 300 million, including the step-wise provision of antiretroviral treatment to HIV-infected TB patients.

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DOTS is the internationally recommended strategy for TB control, which combines five elements: political commitment; microscopy services; drug supplies; surveillance and monitoring systems; and the use of highly efficacious treatment regimens with direct observation of treatment.

The MDGs are to provide universal access to TB care by 2015. “The challenge is great, but so is the opportunity,” Chin says. “The will is clearly there, as is the money. Donors are holding steadfast in their commitments to funding TB control, which combines DOTS with improvements in TB surveillance and monitoring to ensure the quality of the treatment regimens with direct observation of treatment.”

What’s next? “Our experience in the 1990s showed the importance of implementing a high-quality programme. With the rapid implementation of DOTS over the past 2 years, the main challenge for us has been to continue to ensure quality of the public health programme needed to deliver care and treatment to TB patients.”

Despite the health challenges it’s facing, the Government has not lost sight of TB. The Government increased its central funding for TB in 2004 from US$ 5 million to around US$ 30 million. And donors are holding steadfast in their commitments to funding DOTS. The will is clearly there, as is the money.

“My feeling is we can do this.”

Can they do it? If not, it won’t be for lack of trying. For 2004, WHO and China’s Ministry of Health have ramped up their efforts to meet the MDGs. There is an issue of national pride involved too – China, with the world’s largest population, doesn’t want to be holding the world back from reaching global targets, it wants to contribute to meeting them.

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3. Internally Displaced Person.
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**What has happened?** In May and July 2004, WHO ran a series of inspections of contract research organizations and/or laboratories (CROs) as part of its continuing monitoring of prequalified medicines. The CROs had been contracted by manufacturers to carry out tests to prove the bioequivalence of medicines submitted for prequalification, in accordance with WHO requirements. Bioequivalence studies are clinical trials conducted in healthy volunteers to find out if the concentration of a generic medicine in the blood of a patient is equivalent to that of the originator product. During the inspections, two CROs were not found compliant because of serious discrepancies between the original results compiled by the CROs and the results presented to WHO by the manufacturers.

**Which products were delisted?** The five antiretroviral products removed from the list for lack of proof of bioequivalence were:

- lamivudine 150 mg plus stavudine 40 mg and nevirapine 200 mg tablet (Cipla Ltd, Kurkumbh, India; blister pack of 10);
- lamivudine 150 mg plus stavudine 40 mg and nevirapine 200 mg tablet (Ranbaxy Laboratories Ltd, Dewas, India; aluminium strip of 10 or 60 in box);
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- lamivudine 150 mg plus zidovudine 300 mg tablet (Cipla Ltd, Vikhroli, India; blister pack of 10).

**What does the delisting mean for the other products on the list?** All products on the list have been assessed through: evaluation of data in the product dossiers on efficacy, safety, quality and bioequivalence; inspection of manufacturing sites for compliance with good manufacturing practices; testing of product samples at independent laboratories for compliance with product specifications. However, following the findings of non-compliance in relation to the five products mentioned, other CRO inspections will be conducted for prequalified products and if these inspections find non-compliance in the CRO, the related products will be suspended until the manufacturers can provide unequivocal evidence of bioequivalence from compliant laboratories.

Advice and guidance to countries using these products can be found under “News and media” at: http://www.who.int/mediacentre/prequal/Daniela Bagozzi

**Q&A: prequalification**

**How is it possible that products that were delisted in August had been prequalified before?** Until recently, the assessment of bioequivalence data (supplied by the manufacturer) was part of the standard procedure for prequalification: there was no regular on-site inspection of the CROs that carried out the bioequivalence studies. This reflected common practice in many national drug regulatory authorities. On 1 May 2004, however, European Commission (EC) Directive 2002/10/EC came into force, demanding that countries carry out such inspections. Given WHO’s commitment to the highest standards, the EC Directive prompted inspections of the CROs carrying out bioequivalence studies (starting with products for priority diseases), which ultimately led to the delisting of the above products.

**Recruitment of “3 by 5” country officers in full flow**

The first phase of recruitment for “3 by 5” Country Officers is underway, with the aim of having all officers in country and operational by end 2004.

Nineteen international HIV/AIDS experts are being recruited in the first phase of the process. These “3 by 5” country officers will provide technical support to countries in scaling up HIV/AIDS treatment and prevention programmes as part of activities to reach the “3 by 5” target to get three million people living with HIV/AIDS on antiretroviral treatment by the end of 2005.

The country officers recruited during this first phase will cover 19 countries across all WHO regions: Burkina Faso, Cambodia, China, Côte d’Ivoire, Egypt, Georgia, Guatemala, India, Indonesia, Kenya, Kyrgyzstan, Lao People’s Democratic Republic, Lesotho, Lithuania, Myanmar, Nigeria, Russian Federation, Sudan, Swaziland, Uganda, Ukraine, United Republic of Tanzania, Zambia and Zimbabwe.

**Officers for the Russian Federation and Ukraine have already been deployed and have started work in their respective countries. In addition, over the past few months, new staff have been recruited to support “3 by 5” activities in a number of other countries, including in Azerbaijan and Uzbekistan.**

A “3 by 5” country officer induction meeting is being planned for late October 2004 during which the new country officers will join other WHO staff and partners in a team-building, orientation and skills-building programme.

The second phase of recruitment for additional officers will start within the next few months as additional funds become available. Beth Magne-Watts

**Welcome!**

As the Assistant Director-General of the World Health Organization (WHO) for HIV/AIDS, tuberculosis and malaria (HTM), I am pleased to present the first issue of the HTM newsletter. It will provide our readership and stakeholders with a continuing overview of WHO’s current projects and research in the area of HIV/AIDS, TB and malaria. It will also aim to inform you about progress made in countries towards effectively controlling the three diseases.

Collectively, HIV/AIDS, TB and malaria kill at least six million people annually, a toll that is growing, especially in resource-poor countries. When Dr Lee Jong-wook, Director-General of WHO, took office in July 2003, he established the HTM cluster to accelerate action and better coordinate our efforts to tackle these global epidemics. The formation of HTM also demonstrates an increased level of commitment to work closely with organizations and partnerships dedicated to confronting these diseases.

In the first year of HTM’s mission, we have made excellent progress towards our key objectives and have identified several major challenges ahead.

**HIV/AIDS** - The “3 by 5” target – 3 million people on antiretroviral treatment by the end of 2005 – has helped to mobilize action across all levels of WHO and in the broader international community to scale up access to treatment and care for the millions of people living with HIV/AIDS who need it urgently. For its part, WHO has developed simplified approaches to clinical management, health-care provider training, and monitoring and evaluation which are being implemented in many countries. The drug prequalification project and the AIDS Medicines and Diagnostics Service offer services which are helping to guide countries in their choice of safe, affordable and high-quality medicines, and to improve their procurement and supply management. However, we need to bolster our technical support efforts at country level by placing more than 20 senior staff in our country offices specifically to provide close and continuing support to national scale-up efforts, including both prevention and treatment. We are doing more to foster new partnerships, for example, through our innovative programme to support treatment education and literacy by and for people living with HIV/AIDS in their own communities. And through the new HIV/AIDS and Health Systems Platform, we are strengthening our efforts to ensure that scaling up of the response to HIV/AIDS not only saves lives and prevents transmission of HIV, but also helps to build stronger health systems as a whole.

**Malaria** - This disease kills more than one million people a year, of which 75% are African children and it is the number-one cause of childhood mortality. We are promoting the use of the new generation of artemisinin-based combination therapy and enhancing country capacity to make the change as quickly as possible. We are working with the private sector and nongovernmental organizations on promoting the use of long-lasting insecticidal nets that are effective for several years.

**Innovation** - An effective fight against the three diseases requires mutually supportive programmes that are appropriately designed, culturally relevant and implemented in a strategic manner. Resilient health workforces, logistical and management capacity, and well-crafted economic incentives are needed to start, maintain and expand these programmes at national level. We have created a new department - Strategic Planning and Innovation - to identify innovative practices and programmes holding potential for wide adaptation and implementation.

Our efforts to control these pandemics comprise a central pillar of WHO’s commitment to attain the Millennium Development Goals to collectively reduce poverty, hunger and disease. We will continue to work in concerted action with our partners across the global health landscape to make a fundamental difference towards mitigating and ultimately halting these diseases of poverty.

**Dr Jack C. Chow, Assistant Director-General, HTM**