

WHO launches taskforce to fight counterfeit drugs

WHO will launch a taskforce in late 2006 to fight a thriving multimillion-dollar illegal trade in counterfeit drugs, vaccines and other medical products.

The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) aims to put a stop to the deadly trade in fake drugs, which studies suggest kill thousands of people every year.

“We need to help people become more aware of the growing market in counterfeit medicines and the public health risks associated with this illegal practice,” said Dr Howard Zucker, Assistant Director-General for the Health Technology and Pharmaceuticals cluster of departments at WHO.

The taskforce will encourage the public, distributors, pharmacists and hospital staff to inform the authorities about their suspicions regarding the authenticity of a drug or vaccine. In a parallel move, the taskforce will help governments crack down on corruption in the sections of their police forces and customs authorities charged with enforcing laws against drug counterfeiting. Drug manufacturers will be encouraged to make their products more difficult to fake.

The key members of the taskforce will be national drug regulatory authorities and law enforcement agencies. WHO will also seek the involvement of other international organizations, nongovernmental organizations, pharmaceutical manufacturing and wholesaling industry associations, patient advocacy groups and health-care professionals.

The taskforce will meet for the first time in mid-November in Germany. “We will decide on concrete projects and deliverables. We will decide who will do what and according to what deadlines,” said Dr Valerio Reggi from WHO’s Health Technology and Pharmaceuticals

cluster of departments, who will coordinate the taskforce.

The idea of setting up this taskforce was approved at a meeting in Rome in February but it is the latest initiative in a long campaign.

For almost 20 years, WHO has been fighting drug counterfeiting since it became a major threat in the 1980s. “The problem was first noticed by the pharmaceutical industry. They saw that their own products were being copied,” said Reggi, who has worked on drug regulation at WHO since 1989.

An estimated 1 in 4 packets of medicine sold in street markets in developing countries could be fake.

In mainland southeast Asia, artesunate, a vital antimalarial drug, is commonly faked. An

international study conducted by Nick White and his colleagues and published in *Tropical Medicine and International Health* in 2004 found that 53% of artesunate tablet packs sold in the region did not contain artesunate.

Although it is difficult to obtain precise figures, the Food and Drug Administration in the United States of America estimates that worldwide sales of fake drugs exceed US\$ 3.5 billion per year, according to a paper published in the journal *PLoS Medicine* in April 2005. The Center for Medicines in the Public Interest in the USA predicts that counterfeit drug sales could reach US\$ 75 billion globally in 2010 if action is not taken to curb the trade.

Counterfeit drugs are found everywhere, but sub-Saharan Africa is particularly affected. “The dismantling of the health-care system in most African countries has created the vacuum into which counterfeiters

have been able to slip,” said Reggi.

In Africa, drugs are sold through the informal economy in large open-air markets alongside fruit and vegetables. “People may realize the risk that they take, but there’s no other place to buy drugs,” he said. “Hospitals can’t buy directly from the pharmaceutical companies for many reasons, including cost and the small quantities they need. So they buy drugs from local suppliers who sometimes are not even licensed by the local authorities. Some of these people may be selling fake drugs, either knowingly or unknowingly.”

According to WHO, drugs commonly counterfeited include antibiotics, antimalarials, hormones and steroids. Increasingly, anticancer and antiviral drugs are also faked.

Counterfeiters take inert ingredients such as chalk, and even dangerous chemicals, package them convincingly and sell them to consumers. Such drugs may have no therapeutic effect and can be toxic.

In common with illegal narcotics, fake drugs are trafficked across borders, hidden in items such as teddy bears, or labelled as animal feed. Having escaped detection by customs authorities, the drugs are repackaged in the destination country.

“We will follow-up reports so that people who tell us about suspected counterfeit drugs are motivated to report again in the future.”

Dr Valerio Reggi from WHO’s Health Technology and Pharmaceuticals cluster of departments.



Many studies have documented the impact that counterfeit drugs can have on patients' health, as well as the way they undermine health systems. Reggi cited the case of a counterfeit iron preparation that has killed pregnant women in Argentina in the last two years. Hundreds of children in Bangladesh suffered kidney failure and many died due to a fake paracetamol syrup diluted with diethylene glycol, according to a study published in the *BMJ* in 1995.

"The taskforce will coordinate all the organizations involved in combating the manufacture and trade of counterfeit medicines," said Reggi.

After assessing current national laws on drug counterfeiting, and advising governments on how they might be tightened, the taskforce will attack the corruption that stops the law from being enforced, said Reggi. "We want to explain to corrupt officers that they should not accept bribes because the fake drugs they let through could end up poisoning their own families," he said. Closer cooperation between police, customs services and health-care providers is also required.

Enforcement officers would like to be able to identify fake drugs on the spot. But sometimes it is impossible to do so without laboratory analysis. "We could make packaging resistant to forgery by using the security devices we find on modern banknotes," said Reggi. Drugs also need to be readily traceable from the point of manufacture to the point of sale.

"We are working with government agencies and manufacturers to create a database of products," Reggi said. "Each packet of medicine will have a unique number that could be tracked with widely available and relatively inexpensive technology. This would make it possible to check whether a medicine is genuine at any point in the distribution pipeline."

Reggi hopes that the taskforce will encourage consumers and health-care providers to report anything suspicious. "We will follow up reports so that people who tell us about suspected counterfeit drug transactions receive feedback and are motivated to report again in the future." ■

William Burns, *Geneva*

Nigeria leads fight against "killer" counterfeit drugs

Nigeria has been at the forefront of global efforts to fight counterfeit drugs since Dora Akunyili took over the National Agency for Food and Drug Administration and Control (NAFDAC) in 2001. To crack down on counterfeits, her first move was to stamp out corruption within her own agency as far as possible.

In five years Akunyili, a 52-year-old professor of pharmacology, has attained celebrity status in Nigeria because of her uncompromising stand against corruption. "We have been rebuilding NAFDAC from a moribund government agency to [one that meets] international standards," she told the *Bulletin*.

Nigeria is ranked as one of the most corrupt countries in the world, according to Transparency International. Before Akunyili took over, staff abused their position to extort money from honest manufacturers at the same time as taking bribes from counterfeiters in return for access to the Nigerian medicines market. Akunyili fired the most corrupt of her officers. To encourage honesty among her remaining 3000 staff and to boost morale, she offered incentives such as training abroad, improved facilities and a better working environment.

Akunyili told the *Bulletin*: "The level of corruption we had in 2001 cannot in any way be compared to what we have now. It has decreased to almost zero. But it is still a problem. We cannot rule it out completely."

The Nigerian agency is now a key player in reducing the manufacture and distribution of counterfeit medicines in West Africa. It has the support of the Food and Drug Administration and the Environmental and Occupational Health Science Institute at Rutgers University in the United States of America, among other regional and international agencies including WHO.

According to Akunyili, drug counterfeiting was first reported in Nigeria as early as 1968, "So people have been dying in this country from the effect of fake drugs since the early 1970s". In 1995, Nigeria reportedly donated 88 000 doses of meningitis vaccine to its neighbour Niger, but before the authorities realized that these vaccines were fake, about 60 000 people had been "inoculated". Akunyili said that when she took office in 2001, fake drugs were openly circulating in her country.

Her efforts have led to increased public awareness about counterfeit drugs and tougher surveillance at Nigerian customs. She says that the number of fake drugs in circulation in Nigeria has been substantially reduced, although she and everyone else involved in fighting the illegal trade admit how difficult it is to quantify the problem

and therefore measure their success. Still, there is plenty of anecdotal evidence that her measures have had an impact: shopkeepers no longer dare to sell counterfeits openly for fear of being reported to the authorities. Criminals behind the trade have left Nigeria and set up business in other countries, she says. Now governments across West Africa are working closely with Nigeria to crack down on the illegal trade.

How did Akunyili do it? In 2001, most Nigerian consumers were oblivious to the danger of counterfeit drugs. "Fake drug dealers used to thrive mainly because of a lack of awareness". The agency broadcast jingles on radio and television to make the public aware of the dangers and to encourage people to report suspicious drugs. It also regularly publishes lists of counterfeit products in the newspapers. Last year, fake drugs worth about two billion *naira* (US\$ 16 million) were voluntarily handed over by counterfeiters or seized after tip-offs from the public.

Akunyili has hit back at the counterfeiters directly too. There is tough surveillance at ports and airports where medicines enter the country. The authorities inspect shops and markets where medicines are sold. As of June 2006, Akunyili said she had secured convictions for 45 counterfeiters with 56 cases pending. The Nigerian authorities recently opened a laboratory in Port Harcourt that analyses medicines for authenticity. Another is being set up in Calabar.

"Fake drugs were not only killing people [but] the drugs were also killing businesses. So millions of lives have been saved. Industries have been revived," she said, referring to the damage counterfeiting does to public trust in companies and their products.

Despite Nigeria's efforts, Akunyili said: "We are not there yet. Even 1% fake drugs is not good enough, because every life is important." Akunyili said she has asked the Nigerian parliament to amend existing legislation to make penalties tougher, so far without success. "The penalty for a fake drug producer or importer ranges from 5000 to 10 000 *naira* (US\$ 40–80), or between three months and five years imprisonment." The other problem is that the law is not always enforced properly: the counterfeiter may avoid jail, and fines can be insignificant compared with the huge profits from the illegal trade.

But Akunyili says that the biggest challenge her agency currently faces is the open-air drug market in the city of Onitsha in south-eastern Nigeria. She believes that the bulk of fake drugs distributed in Nigeria originate there. Police raids have been unsuccessful because market traders attacked law enforcement officers. "Our officers literally had to escape [to avoid] being lynched". But Akunyili is determined. "If they defeat us, they have defeated Nigeria."

Abiodun Raufu, *Ibadan*

Free access to journals gives Kenyan science a boost

A joint initiative between WHO and about 90 scientific publishers has transformed patient care at a university hospital in Kenya, where students and their teachers have Internet access to the latest research findings. The programme is benefiting a whole generation of scientists across the developing world.

Dr Hilary Rono shudders to think what life for him and his colleagues in the medical profession — particularly in developing countries — was like before the Internet. Rono is just about to complete his masters degree in ophthalmology at the University of Nairobi.

The Internet has been key to his studies, especially the Health InterNetwork Access to Research Initiative (HINARI). The WHO programme is a gift to academic institutions in developing countries, providing them with free online access to 3300 scientific journals. This gives researchers like Rono access to the most up-to-date information for research, but also information that can be used to improve clinical management of patients.

HINARI has transformed Rono's ability to check the latest trends in the management of trachoma and other eye diseases: "It's very easy for me to handle cases at the university hospital. ... Because of HINARI, my colleagues and I are able to provide the latest medical care for our patients here in Nairobi, instead of having them taken to the developed world for treatment."

The fact that the latest medical research is just a mouse click away is a major boon for practitioners in developing countries. Before HINARI, practitioners used to go to the library to refer to books and journals, most of which were way out of date. Dr Rono's lecturer Dr Stephen Gichuhi recalls that as an undergraduate in the 1990s: "You were considered well read if you had seen a five-year-old copy of the *New England Journal of Medicine*".

"It is often said that by the time a book rolls out of the press, the information is already outdated. But for those in the medical profession and practising in the developing world we were left with no option but to use such information," said Gichuhi.

Gichuhi has just finished a Mas-

ters degree dissertation using HINARI and says many of his colleagues are also benefiting from the programme.

As a leading institution in East and Central Africa, the University of Nairobi receives students from across the African continent, some of whom are from countries with limited access to the online journals that are now needed for effective research and patient care.

However, thanks to HINARI, these students can work successfully at the university and later take the same knowledge back home with them. Gichuhi said students

and doctors were able to follow some of the latest trends in medical care, such as evidence-based medicine, thanks to HINARI.

Coupled with this, some students, doctors and lecturers use the programme for general reading as well as planning and doing research. Some of them use HINARI in the office and — those who have Internet access — also from home. Since HINARI is relatively new, however, it is too early to say whether it is helping people publish papers more easily.

"It normally takes between six to eight months to publish and we were introduced to this programme only last year," Gichuhi said, adding that the people who use HINARI are overwhelmed by the choice and range of journals to which they can submit work.

Before HINARI, most of them only targeted well-established journals that were unlikely to publish articles from developing countries.

With the expansion of the choice of journals available to students and staff at the university's department of ophthalmology, usage has increased — a situation that has been helped by continuous in-house promotion by the university authorities.

Currently, users can access HINARI from four computers but

Gichuhi said that at least 10 more "would be welcome". The university also plans to offer wireless connections so that users can access HINARI from their laptops.

Gichuhi and Rono agreed that HINARI could be improved. Gichuhi said that the archiving of information online does not always include some diseases that are still a major problem in the developing world.

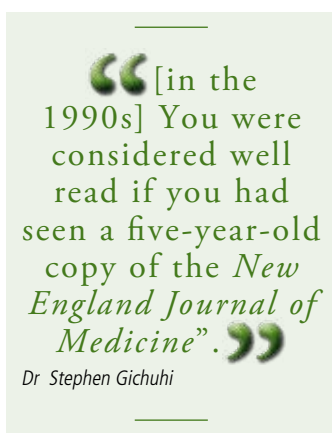
About an hour's flight from Nairobi, in the coastal town of Kilifi, HINARI has made a quieter but no less significant impact. Established in 1989, a joint programme between the Kenya Medical Research Institute and the Wellcome Trust, the Kilifi unit is a research leader in Africa.

"We're quite a different beast to most [institutions that] use HINARI in Africa in that we're very well resourced," said Dr Greg Fegan, the unit statistician.

Even before HINARI, the Kilifi library subscribed to 34 scientific journals in print and 11 others online. Fegan said that 80 scientific staff and students use the system regularly and that HINARI is one of their 10 most-visited websites. At Kilifi, they have over 100 computers on their network and about six networked laser printers.

Before HINARI, the system for obtaining articles in scientific journals at the institute was cumbersome and slow, according to librarian Alex Maina Mwangi.

But while access is no longer an issue with HINARI, institutions like the University of Nairobi and the Kilifi research centre are facing



Alex Maina Mwangi, librarian at the KEMRI-Wellcome Trust Research Programme, teaching colleagues how to use HINARI.

Alison Talbert, KEMRI-Wellcome Trust Research Programme.

mounting costs for high-quality print-outs of articles containing vital information in colour-coded figures and micrographs. ■

Tom Osanjo, *Nairobi*

Free access to journals is key to development goals

In a major coup for access to information in developing countries, publishers have renewed their commitment to a WHO programme that provides free access to more than 3300 scientific and medical journals.

The decision by a group of about 90 publishers in July was intended to help developing countries move closer to achieving the Millennium Development Goals (MDGs).

The publishers initially agreed in 2001 to provide free access for two years, then extended the deal for a further three until this year. Now the scheme will run until at least 2015, the target date for the MDGs.

The move addresses a pressing need in developing countries for better access to up-to-date scientific evidence so that governments can make informed decisions on health policy that, in turn, can lead to an improvement in people's lives.

Under the WHO programme, known as the Health InterNetwork Access to Research Initiative, or HINARI, institutions in 69 countries with a gross national product (GNP) per capita of less than US\$ 1000, as determined by the World Bank in 2001, are eligible to receive free full-text access to more than 3300 biomedical and clinical journals.

Institutions in a further 44 countries with a GNP per capita of US\$ 1000–3000 can also access the scheme, but pay only US\$ 1000 per year. This revenue is used for training in eligible countries.

"Getting connected to HINARI is easy. All users need is a computer linked to the Internet and a username and password, which their library can supply," said Barbara Aronson, Programme Manager for HINARI. "Everyone at eligible institutions can use the system, including students."

While other free-access journal schemes exist, HINARI is unique in its breadth of coverage. Included are English-language titles such as *Nature*, *Science* and the *Lancet* as well as journals published in French, Portuguese, Spanish and other languages.

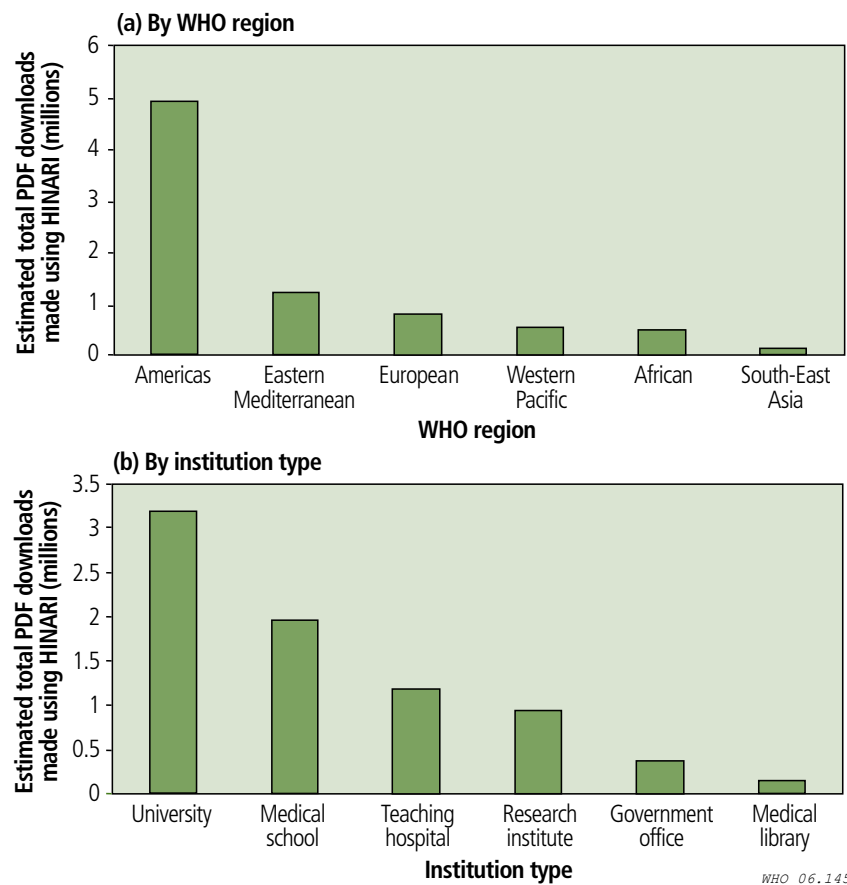
Although primarily aimed at researchers at universities and public health institutes, HINARI is available in government offices as well as hospitals and nursing schools.

WHO set up HINARI after researchers from developing countries attending a WHO workshop in Anney, France, in 2000 said that they did not have adequate access to many key journals because the subscriptions were too expensive.

"The number one priority for them was 'get us access to the priced journals'," Aronson said, referring to the international journals with high subscription charges, particularly for institutions in developing countries.

"So we went to a few publishers and said 'could we have free access to your journals for

Who is using HINARI?



Journal articles are often downloaded through HINARI as portable document format (PDF) files. The downloading estimates presented here serve as a rough guide to HINARI usage. They are divided according to (a) WHO region and (b) institution type and cover the period from May 2003 to June 2006. They incorporate data from the majority of countries entitled to use HINARI. Only the top six institution types, based on number of downloads, are shown. Other users include national libraries and schools of public health, dentistry, pharmacy and nursing.

Source: HINARI, 2006.

10 institutions per year' to test out whether this works".

The *BMJ* lent the project a staff member, Maurice Long, who knew many of the key science, technology and medical publishers well. Long organized the first meeting with six of the biggest journal publishers in New York City in 2000, and has been liaising with the publishers ever since.

"We just said 'look, this is the situation of the poor countries of the world'. And the publishers said 'OK, that group should get the journals for free'. They were immediately receptive to the idea". Currently, Aronson estimates that the market price for the entire package would be US\$ 2.4 million per institution.

With the help of Yale University in the United States of America, WHO set up the authentication server that routes download requests to the publisher's own servers, which hold the articles. The system went live in January 2002 and usage has grown since.

"By our best estimate there were one million articles downloaded in 2003. In 2005, it was 3.5 million. By the end of this year we could

get as high as five million," Aronson said.

Connectivity is the hitch that stops more people from taking advantage of the scheme. Users in developing countries often don't have computers, fast Internet connections and the dependable electricity supplies that are needed to download articles.

Even if users can access HINARI, technical problems are common. Aronson blames these on the rocketing demand for bandwidth and related technology issues. The system is complex too, with about 90 publishers and 2100 registered institutions worldwide all trying to connect to one another. This can cause blackouts.

WHO and its publishing partners are improving the reliability of the service. Aronson said that HINARI is "working to replace our much overloaded authentication server with a better one". Recently, there was some incompatibility between HINARI and one of the big publisher's web sites. "We got the publisher's entire technology team to stop what they were doing and work with us to solve the problem." <http://www.who.int/hinari/en/>

William Burns, *Geneva*

quality of the information available. Ghys says the data improved after local health officials were trained how to use more comprehensive computer programs to produce and analyse their own information. "In the past, estimates were largely a Geneva-based exercise, with little involvement from the countries," he says. "If analysts produce their own estimates, they take it more seriously than if it 'dropped out' of Geneva."

Many countries have also expanded their surveillance systems. Until recently, HIV and AIDS estimates were based on tests of pregnant women visiting antenatal clinics, mostly located in cities. The tests were useful in tracking trends, but had limitations for measuring the actual size of the epidemic. Since 2000, a group of 20 countries in sub-Saharan Africa has conducted nationwide household surveys with HIV testing, and some have expanded their surveillance to antenatal clinics in rural areas. When they looked at their respective countries as a whole, researchers in several countries discovered that the prevalence of HIV infection was far lower than previously thought.

Some commentators say the programmes still have a long way to go. John Donnelly, who writes about global health issues for the *Boston Globe*, argues that UNAIDS and WHO have been far too conservative in downgrading their estimates. Donnelly believes that as more information is gathered, HIV/AIDS prevalence figures will continue to drop. He says that instead of downgrading the figures slowly, it would be "more honest" to admit that information from countries that haven't done nationwide health surveys is inaccurate, and to adjust the worldwide estimate based on results from those countries that have done the surveys. "The global estimate is an advocacy tool, and it [downgrading the numbers] would be a huge embarrassment," he says. "But it would help

national governments refocus their programmes."

According to Dr Ties Boerma, Director of WHO's Department of Measurement and Health Information Systems, "this may have been valid

before the 2006 Report on the global AIDS epidemic — but not any more". Nevertheless, Kenji Shibuya believes that harmonization still has a long way to go. Boerma agrees: "We won't get the truth easily".

Much more investment is needed in developing countries to improve data collection, such as national health surveys, says Boerma. But even for countries that do carry

out national health surveys, there is no guarantee of accuracy. In South Africa, for example, response rates to national health surveys are under 60% and even lower than this among the white population, making it hard to assess how representative the surveys are. Countries also rely on health workers to report diseases, but in many developing countries record-keeping and reporting are poor.

Another challenge is the availability of multiple sources of data — surveys, civil registration and health facility and administrative records. These data need to be harmonized to come up with the best possible estimates, Boerma says. Another challenge, he says, is "an inclination to overestimate" for the sake of advocacy.

Boerma admits that it may never be possible to come up with just one number when estimating the burden of a disease or the size of an epidemic, because there will always be a range of uncertainty. Moreover, although there may always be disagreements over the final estimates these often lead to constructive discussion and better information. "The best we can do is to be completely transparent," he says. "And if there is a disagreement to explain very clearly why." ■

Anita Elash, *Paris*

“The best we can do is to be completely transparent. And if there is a disagreement to explain very clearly why.”

Dr Ties Boerma, Director of WHO's Department of Measurement and Health Information Systems.

XVI International AIDS Conference in Toronto, Canada

An estimated 20 000 people descended on the Canadian city of Toronto in August for the International AIDS Conference. Participants at the meeting included scientists, health-care workers, activists and civil, political and business leaders. The conference theme was "Time to Deliver" and delegates called on the world to take whatever steps were necessary to ensure HIV/AIDS treatment and care were available for all who needed them by 2010.



Thousands of people fill the streets of Toronto to rally for AIDS treatment.



The Dance4Life group, which uses dance to raise AIDS awareness among young people, entertains the crowd during a special concert held on the opening day of the meeting.



Prevention outreach workers in the conference hall.

AIDS 2006