

HIV/AIDS — a challenge for FIP and for the whole profession of pharmacy

Our coverage of the World Congress of Pharmacy continues with reports from **Graeme Smith** on HIV/AIDS (this page) and counterfeit medicines (p394), from **Pamela Mason** on knowledgeable patients (p392) and from **Steven Kayne** on new hospital pharmacy technologies (p396)

The scourge of HIV/AIDS is a challenge for society as a whole. Pharmacists, among all health professionals, are uniquely embedded in their local communities and have a duty to take up that challenge. So said Jean Parrot, of France, president of the International Pharmaceutical Federation, when he addressed a special symposium on September 7 about the role of pharmacy and pharmacists in improving access to and use of medicines for HIV/AIDS.

Mr Parrot said that many health care systems, especially those in resource-limited settings, are unable to respond to the increasing demands of the pandemic because of a lack of money and human resources, a lack of basic infrastructure and poor geographical access. However, he acknowledged that there is now a stronger international determination to increase human and financial resources, and to improve access to antiretroviral medicines (ARVs) and to improve provision of care in developing countries.

Some financial response exists at the international level through private foundations and non-governmental organisations, for example, but the outcome depends on the capacity of health professionals to mobilise, said Mr Parrot.

So what are the challenges for pharmacists? Pharmacists need to undertake continuing education and training on ARVs and other HIV-related treatments. They also need to mobilise themselves to participate in local projects using international HIV/AIDS funds.

The major challenges, however, are to ensure efficient logistics of ARV supply, to provide pharmaceutical care and support to patients being treated with ARVs and to achieve quality assurance throughout all programmes and processes.

Mr Parrot said the efficacy of HIV-related treatments demands quality in medicines sources (ie, there must be no defective or counterfeit medicines), safe medicines man-



Jean Parrot: pharmacists have a duty to take up the challenge of HIV/AIDS

agement (including transport and conservation) and an uninterrupted supply.

For HIV/AIDS patients, providing pharmaceutical care means optimising the treatment. Pharmacists need to explain the treatment, how to use the drug, when to take it, etc. They need to be able to detect treatment failure and give ongoing support to the patient.

Quality assurance — the heart of the process — will enable pharmacists to be trusted by possible partners as reliable health professionals. So the pharmacist should be able to evaluate his or her contribution within an HIV/AIDS project through keeping patient follow-up files, analysing patient data and evaluating patients' adherence to the treatment.

Turning to the challenges for national pharmaceutical associations, Mr Parrot said these were:

- To show determination to be involved in projects developed in their countries
- To represent the profession in national working groups in charge of devising and implementing local projects
- To develop strategies and support for training

FIP, as an international organisation, is rising to the challenges through a number of initiatives, explained Mr Parrot. It advocates the involvement of pharmacists at a global level. For example, in 1997 FIP and the World Health Organization signed a joint statement

highlighting the need for pharmacists to contribute to the prevention of HIV transmission. And, earlier this year, the World Health Professionals Alliance (of which FIP is part) issued a "wake-up call on AIDS" during the World Health Assembly in Geneva, Switzerland (*PJ*, 29 May, p678). Now, during the New Orleans congress, FIP had announced a new online resource for pharmacists working in the field of HIV/AIDS (*PJ*, 11 September, p339). This new resource, at www.fip.org/hiv aids, provides pharmacists with information (through links to many relevant international and national organisations), training modules, a forum for communication and an interactive events calendar. He encouraged pharmacists to make good use of it.

Stark statistics

Earlier in the symposium, Peter Graaff, a pharmacist in the department of HIV/AIDS at WHO in Geneva, reminded congress participants of the stark statistics surrounding the disease. He said the number of people living with HIV and AIDS worldwide amounted to 40 million. Because of this, WHO considers the pandemic to be the biggest public health crisis of modern times. He said that new infections were running at the rate of 40,000 per day; 95 per cent of these were in low to middle income countries and 2,000 were in children under the age of 15 years. In 2003, five million people were newly infected and three million people, half of whom were children, died. "The situation is worst in sub-Saharan Africa, where there are 25 million people living with HIV/AIDS and the prevalence of the disease is running an average at 7 per cent of the population," said Dr Graaff.

However, the pandemic is increasing in Eastern European and Central Asian countries. For instance, there has been a dramatic rise in HIV infection in the Russian prison population.

In general, ARV treatment rates remain low. Some 400,000 people are receiving drug treatment, representing an average of 7 per cent of those in need. "The money required to deal with prevention and treatment is staggering and will likely amount to \$20bn by 2007. But such a sum is peanuts compared with the amount of money being spent on other initiatives, for example, the war in Iraq," Dr Graaff said.

It cannot be denied that treatment works. Deaths from AIDS in Western Europe, where

Details

The World Congress of Pharmacy and Pharmaceutical Sciences was organised by the International Pharmaceutical Federation in association with the American Pharmacists Association, the American Society of Health-System Pharmacists and the American Association of Pharmaceutical Scientists. It took place in New Orleans, Louisiana, from 4 to 9 September



Peter Graaff: HIV/AIDS is the biggest public health crisis of modern times

treatment is affordable, are reducing while those in Africa are rising. However, the price of ARVs has come down tremendously recently, so there is some hope, Dr Graaff said.

He went on to update pharmacists on WHO's "3 by 5" initiative, the goal of which is to provide access to treatment for all who need it, starting with three million people with AIDS by the end of 2005. The initiative has several strategic areas:

- Providing simplified and standardised tools and guidelines on ARV treatment
- Creating the AMDS — the AIDS Medicines and Diagnostics Service — to ensure effective and reliable supply of medicines and diagnostics
- Providing rapid identification, dissemination and application of new knowledge and successful strategies
- Providing urgent and sustained technical support to the countries that need it
- Providing assistance to affected countries for capacity building and training

To achieve this, a two-pronged approach is being taken: driving the countries themselves and simplification of programmes.

Describing the country-driving approach, Dr Graaff said that it was required because treatment happens in individual countries. Governments are responsible for the care and treatment of their citizens, including the poor and the marginalised. Multiple players are involved in antiretroviral therapy and in ensuring maximum provision of treatment. WHO provides technical support to governments to help them achieve this.

The simplification approach means simplifying treatment, providing a limited number of first-line treatments, providing support for fixed dose combination adherence, and simplifying procurement and supply management. He explained that WHO had established the AMDS to help countries streamline procurement and supply.

Dr Graaff said that "3 by 5" is building on opportunities created by increased global po-

litical commitment and resources, simplified treatment and testing, and more affordable pricing of ARV medicines. It is also building on partnerships with United Nations and international agencies, governments, donors, and non-governmental organisations, including faith-based organisations, researchers, people living with HIV/AIDS, the private sector, charitable foundations, communities and, of course, FIP.

Concluding, Dr Graaff quoted Lee Jongwook, director-general of WHO, who had said of the AIDS crisis: "To deliver antiretroviral treatment to the millions who need it, we must change the way we think and change the way we act. Business as usual will not work; business as usual means watching thousands of people die every single day."

He urged pharmacists to support "3 by 5", which he said is the single most important WHO initiative at present.

Developing a national initiative

In combating HIV/AIDS, prevention is better, especially when there is no cure, said Dahlia McDaniel, a community pharmacist from Jamaica. She stressed that national initiatives to fight the disease must begin today, with pharmacists confronting complacency, fear and stigma, even among themselves. "We must confront pharmaceutical and other health sectors of society, our national governments, non-governmental organisations and private sector and community groups," she said.

HIV/AIDS is currently perhaps the most researched medical and social problem worldwide and it requires relentless continuing education among pharmacists. Ms McDaniel acknowledged that pharmacists cannot all be specialists in HIV/AIDS, but the pharmacist who is up to date on the latest research findings on the disease and antiretroviral therapy can offer individuals living with HIV the expertise that is critical for adherence efforts and for the achievement of the best therapeutic outcomes.

The pharmacist is a counsellor, she said, and with the pharmaceutical care approach, patient-pharmacist interaction is increased. So skills in counselling therapy must be sharpened.

The pharmacist is a health educator and therefore should be able to promote, among other things, abstinence from sex (especially among adolescents), an increase in the age of sexual debut, the use of safer sex methods at every sexual encounter, HIV testing of women before planned conception and contraceptive use in HIV-positive women.

The pharmacist is a person with attitudes and emotions and these can be relayed or transferred to patients, Ms McDaniel told the symposium. "It may be surprising to know that health professionals, including pharmacists, are among those who are most fearful and discriminating when they face HIV or a person who has it. But can we teach ourselves how to feel about people living with HIV/AIDS?"



Dahlia McDaniel: pharmacists must practise what they preach

Pharmacists need to generate awareness in themselves about HIV: literally send themselves into situations involving HIV and examine the emotions they experience. "Then we will be in a better position regarding stigma and discrimination," she said, adding: "Maintaining appropriate HIV/AIDS education programmes will prepare us for all the other steps in a successful national initiative. We will be taken more seriously by policy makers, stakeholders, members of the health care team and the public at large."

But pharmacists cannot hope to conquer the HIV/AIDS challenge alone. HIV, on the basis of its complexity, requires a multidisciplinary and multisectoral approach, she said. "The pharmacist must be a strong link in the community of health care providers, and efforts to improve the physician-pharmacist relationship are helpful to the image and role of the pharmacist within the health care team."

Pooling energies, exchanging information and sharing skills is helpful but, since pharmacists are often marginalised within the health care team, they cannot hold their breath while waiting for opportunities to arise for interaction. "We have to step up and seize those opportunities," Ms McDaniel declared.

A way forward would be to seek membership of other professional organisations, HIV/AIDS advisory groups, voluntary associations and suchlike. Pharmacists must be represented on the committees of these organisations so that their voices are able to be heard.

Also, pharmacists are already well positioned to establish rapport with their customers, members of their local communities and citizens' associations and to help them make better decisions to prevent the spread of HIV. They should approach religious bodies, service organisations and clubs, as well as local educators and schools. "Can you imagine the impact we would have if each of us returned each year to our high school alma mater and gave a presentation on HIV and its prevention," she asked the audience.

Ms McDaniel went on to describe how she had devised a dissemination strategy for HIV/AIDS prevention. She said that applying a dissemination strategy to a serious public health concern like HIV/AIDS offers great potential for improvements in preventive health behaviour.

The first step is to analyse the problem. For the purposes of illustration, Ms McDaniel asked the audience to assume that condom use and safer sex practices have been found to be on the decline and that this is the chosen problem.

Step 2, then, is for pharmacists to update themselves on the issues that they are addressing, ie, do some research into the problem and try to find reasons why it is occurring.

Step 3 is to analyse the policy makers. Who are they? Usually they are officials in the ministry or department of health. What can they do to help alleviate the problem?

Step 4 is to decide what the aim is, based on the specific problem that has been chosen to tackle. In this case the aim would be to promote condom use and safer sex practices.

Step 5 is to design the message, which must be built on the target audience's current thoughts, feelings and needs, since persuasive communication must take the audience's perspective, said Ms McDaniel. At the same time pharmacists should take the opportunity to remind the public of their capabilities to help them in their decisions about sexual health.

Step 6 is to analyse the present policies and practice that may hinder or boost dissemination or communication. Barriers may include lack of funding, inadequate attention to HIV/AIDS and lack of commitment to a priority response by governments and policy makers. Boosts may include that there are other groups in existence with similar aims and missions. Additionally, there are funding agencies that exist, for example, some that may be prepared to pay for condoms to be given out free of charge. "Having identified real or perceived barriers and boosts to our strategy, we need to work out clearly how the barriers may be overcome," said Ms McDaniel.

Step 7 is to determine who the stakehold-

ers are. Stakeholders may include the programme's target audience; in this case, for example, women aged 14 to 19 years and their partners, commercial sex workers and their clients and all condom non-users. They may include public sector and private sector organisations, the mass media, and non-governmental organisations. "Each organisation that can play a role in the programme has to be analysed to identify its strengths and weaknesses for health communication activities," Ms McDaniel said. And the first question to be addressed is whose behaviour needs to change in order for the programme objectives to be achieved.

Concluding, Ms McDaniel suggested that before pharmacists embark on any programme involving HIV/AIDS prevention they should individually practise what they preach. "How many of us practise safer sex? How many of us know our HIV status? How many of us care to know? I believe that we will be more convincing in our efforts against HIV/AIDS if we believe what we say to the extent that we practise it," she said.

Ways of overcoming barriers to care in a group of inner city patients with HIV/AIDS

Ways of overcoming barriers to care of inner-city patients with HIV/AIDS were described by Madeline Feinberg, director of pharmacy at Chase Brexton Health Services (CBHS), Baltimore, Maryland. She explained that although there was in her situation excellent access to drugs for HIV/AIDS, psychological and social problems faced by patients could present huge barriers to achieving good therapeutic outcomes.

She described an adherence programme at CBHS. All patients are eligible to be enrolled in the programme, which begins with patients meeting a nurse, who is an educator with HIV expertise, at least once. The patients learn the basics of HIV disease, how the antiretroviral medicines work, the concept of resistance and how the effectiveness of the medication is measured. The patient's readiness to take medicines is assessed by the nurse during these meetings. Patients are also assessed for mental health problems or addiction issues that may not have been addressed and which may present barriers to good medication adherence. "On occasion," said Dr Feinberg, "the nurse and the patient may agree that the patient is not ready to start a regimen if it is determined that he or she will not be successful until other problems are addressed. Patients will continue to be closely monitored and will be reassessed at a later date once other barriers are eliminated or reduced."

When the patient has demonstrated an understanding of the reason for good adherence to the ARV regimen, the nurse sets up a medication schedule for the patient, illustrating it, if necessary, with pictures and calendars to show how the medicine is to be taken. The pharmacy is then informed and the medicines are dispensed, one month's supply at a time. The pharmacy department tracks medicine pick-up dates, ensures that blood tests are carried out if required and sets a date for the next medicine pick-up one week before the patient is due to run out. Pharmacy staff telephone patients to remind them of pick-up dates. "Most patients like the reminder calls, although some do not want to be called for confidentiality reasons. Medicine pick-up dates are tracked by the pharmacy and by the nurses. Doctors can view an electronic patient record and use the pharmacy pick-up date as an adherence marker. Basically, we are the gatekeepers," said Dr Feinberg.

Patients are monitored closely by the nurse, the doctors and the pharmacy until the viral load becomes undetectable on two consecutive occasions, or until it



Madeline Feinberg: psychological and social barriers to regimen adherence

is deemed that the patient has achieved and maintained the lowest viral load possible that can be expected on the regimen. For most patients, this takes six months, said Dr Feinberg. If the viral load goes up or fluctuates, patients are continued in the adherence programme. When it is determined that the patient no longer requires close tracking, he or she is "graduated" from the adherence programme. At that point, the pharmacy is the only department that continues to track medicine pick-up dates.

"Currently, there are 282 patients in the adherence programme of whom 138 are active patients and 144 are 'graduates'. Since the adherence programme's inception five years ago, there have been more than 600 patients who have gone through it," Dr Feinberg said.

Patients who are unable to organise their medicine bottles or select the correct number of tablets receive their medicines in a dosage aid prepacked by the pharmacy staff.

There is also a group of patients who need long-term support in managing their medicines. Such patients prepack their own medicines under the supervision of a nurse and are eligible to join a support group known as "Club Med". It meets twice weekly for members to fill tablet boxes and to share experiences under the auspices of the adherence nurse and a mental health therapist.

Finally, Dr Feinberg described the most intensive level of adherence support for HIV patients at CBHS: directly observed therapy. This is funded privately and through the city of Baltimore and provides two patient advocates who bring medicines direct to patients' homes daily or twice daily, seven days a week.

The patient advocate also transports the patient to the health centre for blood tests or for doctors' appointments. "This intensive programme is reserved for highly treatment-experienced patients with significant mental or physical disabilities who have exhausted other options for treatment and would not be able to self-administer medicines," said Dr Feinberg.

Concluding, she said that CBHS pharmacy is continuing to develop programmes designed to ensure that medicines use is optimal. She added that, because of financing arrangements for prescription drugs in Maryland, the pharmacy is able to generate revenue surpluses which can be applied to innovative programmes in the health centre that will improve patient outcomes.

Pharmacists must not be seen as pill pedlars — despite new OTC medicines

Whether or not the increased availability of over-the-counter medicines is a threat to patient safety was considered at a practice symposium, entitled “The increasingly knowledgeable patient”, on 8 September. The impact of advertising medicines to patients and the influence these issues have on the role of the pharmacist were also discussed.

Two speakers addressed the issue of the increased availability of non-prescription medicines and the implications of this for the patient, the pharmacist and public health. Nicholas Popovich, professor and head of the department of pharmacy administration at Chicago school of pharmacy, identified several issues in relation to patient safety. First of these is the potential risk from self-medication. He described a US survey, which found that one third of Americans have taken more than the recommended dose of an OTC medicine. Two thirds take more than the recommended number of tablets at a single time, three fifths take the next dosage sooner than recommended on the label and two fifths take more than the recommended number of doses per day.

In the same survey, seven out of 10 consumers believed exceeding the recommended dose would bring quicker relief. Patient misadventure is exacerbated by selective reading of labels and also by product line extensions. It is all too easy for patients to take more than one product containing the same ingredient, he added.

OTC product changes

Roger Walker, consultant in pharmaceutical public health and professor of pharmacy practice at Cardiff University, highlighted some of the OTC product ranges in the UK, such as Anadin, Beechams, Benadryl, Canesten and Nurofen, where there are several products under each brand. Moreover, 32 UK OTC items have “Plus” in their name and 38 are named “Extra”. Some names are misleading, for example, Sudafed has been reformulated and no longer contains pseudoephedrine.

“Names of medicines are certainly an issue,” he said. “While wider access to medicines is advantageous for patients, names and labels do not always help them.”

Increased availability of OTC medicines also has implications for pharmacy practice. In Professor Popovich’s opinion, pharmacists must be educated to be “OTC practitioners”. They must have a thorough understanding of indications, doses, side effects and interactions. In addition, a knowledge of complementary medicine is becoming increasingly important. There is also a need to counsel in



a culturally sensitive manner in an area of the pharmacy set aside for consultations.

Professor Walker commented that dealing with new OTC medicines is nothing new for pharmacists, although “mystery shopper” research has identified clear deficiencies in the system. Nevertheless, many studies have shown that pharmacists do give good advice. A study in Wales in 2003 found that malathion was the most common head lice preparation recommended by pharmacists, but not by doctors. Given the increased resistance to all head lice preparations with the exception of malathion, this study shows the significant role that pharmacists can and do play in public health.

Professor Walker went on to raise several public health issues in relation to wider access to OTC medicines. These include increased health inequalities, drug resistance (eg, head lice and antifungal preparations), contribution to road accidents (eg, antihistamines) and falls in older people, the potential for incompleteness of medical records and the risk that patients may take medicines not appropriate for them. Another issue is that of increasing access to medicines outside of pharmacies. “This increases the risk of hazard warning notices being ignored in that it is much easier to withdraw a product if it is sold only in pharmacies,” he said. “Moreover, simple advice, such as the need to crush tablets, may be missed.”

Wider use of medicines may also undermine the need to make lifestyle changes. “Pharmacists have a public health remit and must not be seen as pill pedlars,” Professor Walker declared.

He raised another public health issue,

which was the accessibility of pharmacies and whether people are willing to use them. A recent study carried out in Ebbw Vale, in South Wales, investigated the habits of people enrolled into a scheme which gave them access to free OTC medicines. Of the 1,824 households in the study, only 452 used the scheme for free medicines. The majority of these people were under 10 years of age or older people.

Public health issues associated with OTC medicines discussed by Professor Popovich included the need for more extensive public awareness programmes. A US survey found that, while 65 per cent of people will ask the pharmacist about a prescription medicine in an average week, only 37 per cent of patients ask about non-prescription medicines. He also suggested that the US might need a transitional or counselling class of medicines (similar to UK pharmacy only medicines). This could become increasingly important in the light of deregulation of more potent medicines (eg, emergency hormonal contraception, simvastatin), which often require close monitoring. Another issue that must not be forgotten is that of complementary therapies, such as dietary supplements. Increasing numbers of people use these therapies and they have the potential to interact with both OTC and prescription medicines. *Ginkgo biloba*, for example, interacts with anticoagulants, increasing the tendency to bleeding.

Self-care, including non-prescription medicines and complementary therapies, will continue to become increasingly important in the US health care system, Professor Popovich said. Consumers, pharmacists, regulatory agencies and manufacturers play a vital role in ensuring the safe, appropriate and effective use of non-prescription medicines. Professor Walker added that we must be certain that we are really helping patients. “Wider access to OTC medicines is better for patients but, as pharmacists, we must make sure that we have the skills to empower patients to use these medicines properly,” he said.

Direct-to-consumer advertising

Jenelle Sobotka, manager of pharmacy relations at Procter & Gamble, Cincinnati, Ohio, US, gave a presentation on direct-to-consumer (DTC) advertising, which has been allowed in the US for medicines since 1985. The Food and Drug Administration (FDA) produces guidance for industry, which states that advertisements must present a fair balance of information on effectiveness and risk.

Since 1989, annual DTC advertising spending has increased from \$12m to

\$2,700m. Currently, the US and New Zealand are the only developed countries that allow DTC advertising of prescription-only medicines. The European Union has an experimental scheme in place where manufacturers are allowed to provide consumers with information on treatments for diabetes, AIDS and asthma via pamphlets and web-sites.

DTC advertising has increased awareness of new drugs among American people. Discussing a 2002 consumer survey, Dr Sobotka explained that out of 943 respondents, 77 per cent said that DTC advertisements made them aware of new drugs. This encouraged them to have better discussions with their doctors and take a more active role in their health. However, only 10 per cent of patients reported that DTC advertisements caused them to expect the doctor to prescribe that medicine. When asked whether advertisements provided enough information, 59 per cent said they did not give enough information about risks and adverse effects, and 40 per cent said they did not give enough information about possible benefits. Patients said they often looked for further advice on their own. The doctor was identified by 89 per cent of people in the survey and the pharmacist by 51 per cent as key resources for additional information.

In another 2002 survey, in this case conducted by the FDA among 500 physicians, more than half thought that DTC advertisements do not provide enough information for patients to understand who should use the medicine, its limitations and possible risks and side effects. Doctors believe that DTC advertisements confuse patients about relative risks and benefits. The doctors in the survey were evenly divided in their opinions about the overall impact of advertisements on their patients and practice. Thus, one third thought adverts had a positive influence, encouraging better patient discussions and more educated and involved patients. A third believed advertisements had no effect on patients, while a further third thought they had a negative ef-

fect, causing patients to want unnecessary treatment and increasing the time spent on consultations.

Public more positive than doctors

Dr Sobotka then went on to discuss another study, which compared the opinions of doctors and members of the public. Overall, the public had more positive views about DTC advertising than the doctors. Of the doctors surveyed, only 9.8 per cent thought that DTC advertising was a positive step in health care, while 29 per cent of the public thought it was. Doctors believed that advertising increased overall drug consumption and changed patients' expectations of their doctors. Eighty per cent said it led patients to ask for specific medicines and 64 per cent thought it motivated patients to seek medical care. Among the public, however, these figures were 13 and 10 per cent, respectively.

Recent statements from US medical associations indicate that they support product specific advertising but it must follow specific guidelines as to educational content and fair balance, and when to refer the patient to the doctor for further information. A 2004 statement by the American Pharmacists Association (APhA) supports DTC advertising for specific conditions treatable by prescription and OTC medicines, but it opposes misleading claims or promotional efforts that encourage indiscriminate use of medicines.

The APhA recognises pharmacists' responsibility to provide appropriate responses to patient enquiries stimulated by DTC advertising and recommends that health care professionals, including pharmacists, receive information on DTC advertising campaigns before this information is made available to consumers.

In a further presentation on DTC advertising, Roberto Lopez Linares, of International Action for Health, Peru, said it was necessary to be clear about whether such advertising is really educating and empowering patients or merely making

people feel ill, encouraging them to seek an intervention and generate sales for manufacturers.

"Patients need to be knowledgeable and active participants in their health care, and pharmacists can help them to achieve this," he said.

However, pharmacists in Latin American countries are not well regulated, he said. Although pharmacies are the most frequently visited places for health care, there is often no pharmacist present, they will sell almost anything without a prescription and commercialism is a strong feature. This approach needs to be changed. Pharmacists have an important role in promoting health, not illness. Their training needs to be improved and the type of information received by both pharmacists and public should be better regulated. The goal must be the benefit of patients. "There is a big challenge in front of us and pharmacists can play a critical role," he concluded.

Next year's congress takes place in Egypt

The next International Pharmaceutical Congress will take place in Cairo, Egypt, from 5 to 8 September, 2005. It will be held in association with the Syndicate of Pharmacists of the Arab Republic of Egypt. The congress theme will be: "The right medicine to the right person — can we guarantee it anywhere in the world?" The usual programme of practice and science symposia, excursions and social events is being arranged.

The 2006 and 2007 meetings will take place in Salvador, Brazil, and Beijing, China, respectively.

Further information is available from FIP Congresses & Conferences, Andries Bickerweg 5, PO Box 84200, 2508 AE The Hague, The Netherlands (e-mail congress@fip.org) and at www.fip.org.

Meeting reports

Timing and submission *The Pharmaceutical Journal* welcomes submissions about meetings and conferences. Please contact the editorial department before sending in a report, ideally before the meeting takes place, to check that it is not already being covered and to discuss the length of the report. Photographs are also welcome, provided they are of publishable standard.

Reports should be sent in by e-mail or on disk. If the meeting is newsworthy, the report should be sent in by the Tuesday immediately after it takes place to ensure immediate publication. All reports should be sent within two weeks of the meeting to guarantee publication within a month of the meeting. Reports submitted later than this will not always be published in full in *The Journal*. It may be necessary to publish an abbreviated version in print and post the full report on *PJ Online* (www.pjonline.com).

How to prepare a report Readers need to be encouraged to read reports, so start the report with the most interesting item, not with details of what, where and when the meeting occurred.

Concentrate throughout the report on the most newsworthy contributions to a meeting, such as valuable information that has not already been publicised or strongly worded opinions voiced by influential speakers. Reports that repeat

what readers already know or cover old issues will not be interesting. Write about what people actually said rather than what they talked about. Ask speakers for copies of their talks or notes. Do not submit reports that are just lists of speakers' topics; they are of no value to the reader. Instead of writing "Professor Plum gave a fascinating account of continuing professional development," readers will want to know exactly what Professor Plum said that was so fascinating.

Do not give every speaker an equal number of words. With the exception of keynote speakers if someone says nothing of interest, then do not report it, however well-known the person. If the keynote speaker says nothing of interest, consider how valuable a meeting report will be.

Advice for photographers *The Journal* is unlikely to publish more than two or three photographs from most meetings, so it is best to concentrate on the main speakers. The ideal time to take photographs is at the beginning of each address, while the speaker is still involved in introductions and is likely to be looking out at the audience rather than staring down into his or her notes. Take several shots of each speaker and always aim to be as close as possible to the podium, even if it means obstructing the view of the audience for a short time.

What FIP and WHO are doing to fight the problem of counterfeit drugs

Counterfeit drugs are a global problem, Jane Nicholson, an industrial pharmacist from the UK, told the congress. Mrs Nicholson, who is the convenor of an International Pharmaceutical Federation Board of Pharmaceutical Practice working party on counterfeit medicines, was speaking at joint symposium of FIP and the Pharmaceutical Forum of the Americas on 9 September. She said that the working party had been set up in 2003 and is currently considering ways to:

- Promote a central reporting structure for incidences of counterfeit drugs
- Identify unreliable wholesalers
- Persuade governments to provide robust legislation against, and tough penalties for, counterfeiters
- Create awareness of the issue among pharmacists and other health care workers and patients
- Collect data through collaborations with pharmacists and medicines testing laboratories
- Publicise the training materials that are available for pharmacists and inspectors

So far the working party had produced a reporting form for use when counterfeit medicines are found in pharmacies (see *PJ*, 10 July, p70), which it is trying to encourage national pharmacy organisations to make available on their websites.

The working party has also already asked national pharmacy organisations to identify unreliable wholesalers in a letter sent out in January, after the US Food and Drug Administration had identified the practice of medicines passing through multiple wholesalers as a potential weak link in the medicines supply chain.

Mrs Nicholson explained that some governments do have robust laws and penalties. For example, in Thailand, counterfeiters may receive a death sentence. She added that it had been reported in the *BMJ* in August 2003 that India is planning to introduce the death penalty for the sale and manufacture of counterfeit medicines that cause grievous bodily harm. The Indian government had realised that its existing laws were posing little deterrence to unscrupulous drug dealers.

However, a major problem is that sometimes existing licensing legislation and testing systems are inadequate, Mrs Nicholson said. For example, at least 11 states in India do not have laboratories for testing drugs and in 15 states that have functional laboratories, only seven are adequately equipped and staffed.

Every country without funding for national quality assurance systems must pose a



Jane Nicholson: counterfeit drugs are a global problem

huge risk of flooding the market with counterfeit drugs, said Mrs Nicholson.

In Bangladesh, for example, there are 80,000 unlicensed drug stores and the country's drug administration authorities have 25 branches with 40 drug superintendents and inspectors. It is estimated, Mrs Nicholson told the meeting, that \$150m worth of fake medicines are produced in the country each year, often in small operations along its borders. And Bangladesh exports to 52 countries.

Another aspect of the FIP working party's work is a move to set up a website for reporting counterfeit medicine. Mrs Nicholson said she expects the website to be up and running by the end of the year. It is intended that it will have links to other relevant national websites. It will also contain photographs of known counterfeit products.

The working party is also trying to tackle sales of medicines over the internet and intends to send a letter to all FIP's member organisations urging them to make patients aware of the usefulness of the internet but reminding them to ask their pharmacist about the advice they obtain from it.

Other messages under consideration by the working party include the following:

- Governments should outline the hazards of buying drugs over the internet without consultation, pointing out the risk of side effects, of counterfeit medicine and of interactions with other drugs

- Governments should draw public attention to existing legal and regulatory frameworks relating to prescription drugs
- Governments should encourage the public to report dubious online pharmacies to the regulatory and professional authorities in their countries
- Internet service providers should filter out drug-related spam and remove illegal sites from their servers
- Patients should buy medicines only from high street or reliable online pharmacies (both of which may be regulated, as they are in Britain)
- Parents should install a firewall and e-mail spam filter on the family computer and assume responsibility for the way it is used

Mrs Nicholson said that her working party is in touch with the Pharmaceutical Security Institute, a not-for-profit membership organisation dedicated to protecting health, sharing information on the counterfeiting of medicines and initiating law enforcement actions through the appropriate authorities. The PSI collects and analyses data for use in the prosecution of counterfeiters. It also offers specialist training for law enforcement officers. FIP is looking at the possibility of using its distance learning material to help in the training of staff who handle medicines, Mrs Nicholson said.

Finally, Mrs Nicholson stressed that the activities of her working party were ongoing. "We are determined to keep bringing the subject of counterfeit medicines to the attention of members of FIP. Publicity is central to our work and we need your help to counteract this menace," she concluded.

The work of WHO

Giving the view of the World Health Organization, Eshetu Wondemagegnehu, technical officer for counterfeit drugs at WHO in Geneva, said that health is a fundamental human right. It is a state of complete physical, mental and social well-being and not merely the absence of sickness or disease. Access to safe, effective medicines is an integral part of that human right to health, which is why the promotion of human rights is one of the main purposes of the United Nations and, therefore, of WHO.

Dr Wondemagegnehu explained that WHO acts as a directing and co-ordinating authority on international health work. It assists governments, on request, to strengthen health services. It develops and promotes international standards with respect to medicines. It also supports countries in their attempts to implement national drug policies.

This is no easy task. Thousands of pharma-

ceutical products are continually moving in international commerce. So there is a need to regulate manufacture and trade in order to assure the safety of these products. However, less than 20 per cent of WHO's 192 member states have well developed medicines regulation. And about 30 per cent of the rest have no regulation or limited regulation that does not function well.

One third of the world's population has no access to regular supplies of essential medicines. Medicines are not affordable in most developing countries and the result is that thousands of adults and children die, he said.

Thus are the seeds for production of counterfeit medicines sown. Lack of access to medicines, poverty and corruption lead to the illegal manufacture and distribution of medicines. These factors also lead to smuggling and to the unregulated sale of medicines in markets and on street corners, and to the illegal packaging and relabelling of medicines to hide their source of identity. "So we get circulation of counterfeit medicines in international and national markets," said Dr Wondemagegnehu.

Medicines are attractive to counterfeiters for several reasons, he explained. They are high value items in relation to their bulk that are easy to hide and transport. The need for medicines is limitless. They do not require a huge, expensive infrastructure in order to produce them. Patients, and often prescribers and dispensers, cannot tell the difference between a counterfeit medicine and the real thing.

Producing counterfeit medicines is particularly attractive in countries where there is little or no government commitment to health care and where there are inadequate health care facilities. Medicines are expensive, and where there is no insurance system and a low per capita income, patients look for cheaper alternatives.

Often, too, in countries where counterfeit medicines are produced there is a high illiteracy rate among the population. Patients don't know their rights; they accept what governments tell them.

Absence of legislation, official corruption, weak law enforcement, inadequate inspection and surveillance and lack of capacity to detect fakes all are helpful to counterfeit medicines producers, said Dr Wondemagegnehu. So, too, is weak control at points of entry, like post offices and customs.

What can WHO do? Dr Wondemagegnehu explained that WHO is undertaking advocacy and educational programmes to increase awareness of the issue among decision makers. It is promoting rational use of medicines and developing guidelines that countries can use in their fight against counterfeit medicines. It is helping to strengthen regulatory and quality assurance systems, and training staff in the detection, investigation and prosecution of counterfeiters.

Other initiatives are the organising of international conferences on the matter. WHO is also assisting countries to foster closer co-operation between regulatory authorities and



Eshetu Wondemagegnehu: thousands of adults and children die



Marv Shepherd: counterfeit medicines threat has increased

law enforcement agencies. It also serves as a clearing house for information on counterfeit medicines for its member states.

A further move is WHO's campaign against the export of medicines through free trade zones and the promotion of the concept of an international framework for the control of trade in medicines.

Finally, Dr Wondemagegnehu reminded congress participants of WHO's website on counterfeit medicines at www.who.int.

The new public health concern

Drug counterfeiting is the new public health concern, Marv Shepherd, director of the Centre for Pharmacoeconomic Studies, University of Texas, told the symposium.

Giving a perspective from the US, Dr Shepherd said that a major source of counterfeit and substandard medicines is rogue and foreign websites.

"With more and more people using their home computers to purchase pharmaceuticals from the foreign market, the threat of receiving a counterfeit pharmaceutical has increased," he said.

Dr Shepherd pointed out that there are a few countries which are the primary providers of fake drug products, and sometimes these were hard to identify because counterfeiters use what is known as "spoke and wheel" organisation. That means, he explained, that each spoke is not familiar with the others. For example, ingredients are produced in one country, the product is formulated in another country, packaged in a third and shipped to a fourth to reach their final destination.

He gave an example. In 1997, US Customs seized more than \$60m worth of counterfeit and misbranded drugs in just one raid. The products had been produced in India, packaged in California, and were being shipped to Mexico when they were intercepted. They were intended to be sold to US residents via border Mexican pharmacies, which Americans use because of easy access and lower prices.

In another example, bottles and jars were produced in California, lids came from another state and labels from Florida. The ingredients were from another country and the product was formulated in Colombia and shipped to Florida. None of the producers knew the others.

Dr Shepherd described the extent of the problem for the US. He said that it has been estimated that 20 million packages containing drugs arrive annually through the US Mail, which does not include deliveries via Federal Express, UPS or other delivery mechanisms. "This figure represents a 1,000 per cent increase in two years and it continues to grow," he said. Canadians export an estimated \$1.1bn worth of drugs to US residents and Mexico sells £800m just from its border pharmacies. "But what is troubling is that the vast majority of the pharmaceutical products coming onto the US are not approved by the Food and Drug Administration. Many are substandard products and are mislabelled."

The FDA had determined that imported products may:

- Contain no active ingredient, or too little or too much active ingredient
- Be date expired or have a false expiry date
- Be contaminated
- Have been stored at the wrong temperature or under unsafe conditions
- Be a fake or counterfeit product
- Be fraudulently or inadequately labelled
- Be a product that has been withdrawn from the US market
- Be animal drugs not approved for human use
- Be inappropriately packaged

"Counterfeit drugs continue to be a growing concern," said Dr Shepherd. "It is anticipated that the number of counterfeit drugs will continue to increase. Since 1996,

73 fake pharmaceuticals cases have been opened in the US. Legal results show 44 arrests and 27 convictions. In 2003 there were 22 fake drugs cases opened by the FDA."

He added that the extent of counterfeit drugs in the US has not been determined. Some commonly heard estimates are that it is less than 1 per cent. "However, with the proliferation of internet sites and the number of drugs entering the US from other countries, this estimate may be low," Dr Shepherd concluded.

"Good business"

Giving a view from Latin America, Rodrigo Salas Sánchez, of Costa Rica, president of the Pharmaceutical Forum of the Americas, said that counterfeiting of medicines has become more profitable than cocaine and so, for unscrupulous persons, made "good business".

According to the World Health Organization, 60 per cent of counterfeit medicines cases occurred in the poor countries of Asia, Africa and Latin America. Wherever poverty blooms — and this includes areas of developed countries — counterfeit medicines will bloom, said Dr Salas Sánchez. Medicines counterfeiting also blooms in countries where there is no legal control of medicines, a large over-the-counter trade in medicines,



uncontrolled direct promotion of medicines through the mass media, a culture of self-medication, and legally allowed dispensing by non-pharmacists.

The position of pharmacists, which varies from country to country, also has a bearing on counterfeiting, said Dr Salas Sánchez. For

example, in some countries, pharmaceutical interventions are considered merely to be an intermediation that increases the cost of medicines while limiting the access of people to them. And sometimes a pharmacist's professional image and scientific knowledge are ignored and his or her participation in political, sanitary and social areas not allowed. However, in general, the situation is improving, he said.

He added that counterfeiting is "empowered" in countries where it is not defined as a specific crime, and where weak judicial systems are overloaded, making perpetrators difficult to trace and prosecute.

Dr Salas Sánchez said that the battle against medicines counterfeiting required a multisectoral approach. "We need global solidarity to combat poverty and global solidarity to improve access to health services and good medicines," he said. "Prices for essential medicines need to be affordable, and there ought to be adequate legal prosecution of counterfeiting of medicines as a crime against life."

Finally, he said that moves towards eliminating counterfeiting could only succeed if the pharmacist is the last screen between the medicine and the patient.

Are new technologies in hospital pharmacy actually improving services?

More than 30 per cent of preventable adverse drug events occur at the administration phase of the medication process, Steve Rough, director of pharmacy at the University of Wisconsin Hospital and Clinics in Madison, told the congress. Mr Rough was discussing the impact of point-of-care bar code medicines scanning technology during a symposium organised by the International Pharmaceutical Federation's Hospital Pharmacy Section on 6 September.

The University of Wisconsin Hospital has achieved a substantial reduction in administration errors, within two months of installing a point-of-care bar code scanning application. Mr Rough said that the system, called Admin-Rx, has now replaced paper charts and has reduced errors by monitoring patient activities as well as medication planning and medicines administration in all 22 of his hospital's units.

The system was initially installed in December 2001 with a pilot project in the haematology and oncology units of the hospital. The pilot study involved eight implementation teams and took 18 months from inception to launch. After just two months of use, the hospital conducted a study and discovered that the overall medication error rate had fallen from 9.08 per cent to 1.21 per

cent. There were also dramatic improvements in medicines administration and documentation accuracy.

Of the errors observed before installation of Admin-Rx, 44 per cent involved medicines given at the wrong time, 21 per cent involved the wrong dose of a medicine, 15 per cent resulted from the omission of a medicine, 15 per cent used the wrong dosage form (for example, an injection rather than an oral formulation) and 5 per cent involved the use of an incorrect drug. Mr Rough stressed that the vast majority of these errors did not result in harmful consequences.

The great value of bar code-scanning medication applications was in catching the 3.2 per cent of "near miss" errors that might have caused serious patient harm. More than half of these errors resulted from underdosing. After the new system was installed, the prevalence of wrong dose, wrong dosage form and omission errors decreased more than 90 per cent, while medicines given at the wrong time dropped over 75 per cent.

Admin-Rx involves the use of a hand-held device that displays, receives and charts real-time patient and medication information. It also keeps a historical record of all medicines given to the patient. Before giving a patient a medicine, nurses scan a bar code on their

identification badge, a second bar code on the medicine and a third on the patient's wristband. If there are any discrepancies regarding patient, dose, method or time, an alert is generated.

Mr Rough warned that bar coding was not without some initial problems. Set up



Steve Rough: bar code scanning has substantially reduced medication errors



David Cousins: clinically important deficiencies in some computer systems

costs were high with systems costing anywhere from \$500,000 to over \$2m, excluding additional pharmacy and nursing staff. Justifying such expenditure in accounting terms was difficult.

Although patient welfare through error reduction was the prime catalyst for installing bar coding, Mr Rough said there were also potential financial rewards to be reaped. When a medication error actually harms a patient, a hospital may incur up to \$4,600 in costs for follow-up care. Avoiding 100 errors would represent a saving of almost half a million dollars that could be directly attributable to Admin-Rx.

Software interfaces that keep data flowing smoothly between bar code and other pharmaceutical systems can be difficult to create and maintain. Practical difficulties arose from bar coding labels of dispensed medicines. Standardising the system of bar coding to allow interfacing with other hospitals had to be resolved, said Mr Rough.

Finally, nursing staff faced a significant challenge in learning and adjusting to the new technology. Nursing satisfaction data from the University of Wisconsin Hospital had demonstrated a 42 per cent improvement in overall nursing satisfaction with medication documentation and administration after the implementation of bar coding.

Medicines delivery

David Cousins, head of safe medication practice at the National Patient Safety Agency, UK, said that no single automated system is appropriate for all hospital pharmacies throughout the world and it is necessary to conduct local risk assessment before investing in appropriate technology.

Even when electronic systems are chosen there could be serious deficiencies. Over 90 per cent of general practices in the UK regularly use computers for clinical care. These electronic prescribing systems contain drug

interaction alerts, and are considered useful by most GPs. However, the safety features of computing systems currently in use in about three quarters of UK general practices have clinically important deficiencies. All may fail to act in a situation when a warning is expected, thus potentially creating a hazard to patients. In particular the systems fail to warn for prescription of drugs with similar names.

Although similar problems might exist with respect to medication errors, practices differ widely and require different solutions, said Professor Cousins. In the US there are on average 231 beds in a hospital with 4.4 pharmacists servicing 100 beds while in Europe the figures are 664 and 0.8, respectively. As a result there are substantial differences in the amount of weekly pharmacy cover provided in hospitals: 101 hours in the US as against 46 hours in Europe. This means that different models of service are provided.

Professor Cousins identified three models of medicines delivery. In the first model a patient's medicines are provided centrally in individual doses and delivered to the ward for administration by the nursing staff. This is more common in the US and could be tracked with a bar coding system. The second model was more traditional: patients' medicines are dispensed from ward stocks topped up by central supplies as required. The potential for administration error is much higher here. There is a third model that is gaining acceptance in the UK that provides advantages in reducing both errors and costs. Here patients' bring their own GP-prescribed medicines into hospital and they are kept, together with hospital-prescribed medicines, in a bedside locker.

There is a case for allowing able patients to be responsible for self-medication, said Professor Cousins. Original pack dispensing complete with patient instruction leaflets is an effective alternative to unit dose dispensing and could be taken home on discharge where appropriate.

In conclusion, Professor Cousins drew attention to the lack of hard evidence on the



Makiku Kusama: warning against becoming too dependent upon IT

effect of automation on medication error rates. He called for randomised clinical trials to allow properly informed investment decisions to be made.

Problems in Japan

Makiku Kusama, of the University of Tokyo Hospital, Japan, outlined some of the perils of automation. Ms Kusama said that there have been recent developments in electronic prescribing, automatic dispensing and electronic medical records incorporating clinical pathways and therapeutic guidelines and that these have provided great benefits in reducing medication errors and promoting interdisciplinary information sharing. However, a number of new problems has emerged.

In Japanese hospitals, 30 per cent of prescribing is electronic, primarily initiated as a method of generating accurate costing information. Setting the number of characters needed to identify a drug is a trade-off between accuracy and convenience; three characters are usually required but large numbers of look-alike and sound-alike drug names cause problems in Japanese. A study in 2002 found that selection errors accounted for 0.6 per cent of medication errors, and 66 per cent of physicians in the study highlighted a line above or below the required drug on the computer selection screen. A further problem is that identity and password theft could result in the generation of false prescriptions, she said.

Filling dispensing machines with the wrong medicine is another peril of automation. The traditional final checking process can be difficult to achieve. Ms Kusama warned against becoming too dependent on IT, citing the recent power supply problems in New York that could wipe out records if not properly backed up.

Ms Kusama also expressed concern about compatibility between IT systems used in different hospitals.

