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# Pharmacists have key role in fighting global health risks, says FIP president

Nearly 2,000 pharmacists from 95 countries met at the World Congress of Pharmacy, the 64th congress of the International Pharmaceutical Federation this week. **Graeme Smith** and **Pamela Mason** report the first days' proceedings

It is the duty of pharmacists to be key players in policies intended to control the spread of new diseases, said Jean Parrot,of France, President of the International Pharmaceutical Federation (FIP), during the congress opening ceremony on 5 September.

The world community is growing faster and faster, he said, and all human societies, all individuals, regardless of their nation or culture now live in a world in which risks become global.

Life in a global community requires stringent management of common goods and one of these common goods is health. Consequently, the actions taken to fight health hazards should involve everyone.

"Our own duty as health care providers is at stake," said Mr Parrot. "How shall we answer our children in the future if they say to us we had the information but what did we do?"

At the height of the SARS epidemic in Asia in 2003, pharmacists' contribution was clearly recognised and acknowledged. Pharmacists were at the front line to answer the public's questions and contribute to their education on health, hygiene and even the environment. But also — maybe above all — pharmacists quite naturally constitute an observatory that can effectively contribute to the collection of necessary data for epidemiological monitoring and even the detection of emerging epidemic areas, he said.

After all, the spread of emerging infectious diseases is a major hazard. Epidemics have never been stopped by borders, and the increase in international travel and trade contributes to an immediate spread of such diseases.

During the SARS episode, several national pharmaceutical associations presented data that proved crucial in the disease's evaluation. "How will pharmacists of tomorrow become organised for more active participation in the health watch," he asked. "Each of us, in our respective countries, can think about the procedures that need to be developed with health authorities in order to anticipate the management of such crises."

Jean Parrot: pharmacists at the front line during the SARS epidemic

**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

## HIV/AIDS

Mr Parrot turned to the HIV/AIDS problem. AIDS is the world's leading cause of death in adults. In 2003, there were 2.9 million deaths and 4.8 million new infections around the world. Moreover, only around 7 per cent of the six million people suffering and needing treatment have access to antiretroviral drugs.

Access to health care and drugs is not effective today. This results, said Mr Parrot, in particular, from a lack of health professionals trained to provide pharmaceutical care to patients with complex treatments. However, several steps had been taken and were having an impact. Funding has increased through the World Bank, the International Monetary Fund and UNICEF, for example. Also, more and more non-governmental organisations are proposing and organising action where it is needed. Another favourable development is that pharmaceutical companies have agreed to lower the prices of antiretrovirals and tests for detecting AIDS in developing countries. Indeed, prices have been reduced by half and may continue to fall. Furthermore, some global businesses are implementing specific programmes in endemic areas for treating employees and their relatives.

"But there is still a long way to go," Mr Parrot emphasised. "We have yet to find practical ways in which to optimise financial assistance closest to the cultures, values and organisation of the countries receiving it. It is necessary in response to a concern about health effectiveness to monitor carefully the proper allocation of supplies. And services for dispensing treatments sometimes still have to be created."

A major problem is that in the countries most severely affected there is a shortage of health care personnel qualified to distribute medicines effectively according to needs. "The training of health care staff is, therefore, of the utmost importance," Mr Parrot declared. "Pharmacists should be placed at the front lines in order to evaluate needs, to organise distribution and to train health care teams."

"The funding parties expect a lot from us," he continued. "After all, our skills are essential to ensure that a secure logistic organisation exists to supply the population and to assist patients through their treatment."

As part of that expectation, FIP has produced a website which is intended to be an international network on HIV/AIDS for pharmacists (see p339). Mr Parrot asked all national pharmaceutical associations to take action in the area of HIV/AIDS.

"Let our colleagues, together with the representatives of international anti-AIDS programmes, seek the means to optimise the use of all resources available to support patients' health care in their countries," he said. "But we must also remember that prevention remains a priority. Pharmacists must make sure they adopt an active role in this regard and participate in national programmes already under way. My wish is for every community pharmacy in the world to reserve a dedicated space in the shop window for displaying information on health and hygiene that is relevant to local need."

## Developments in Europe

Turning to Europe, Mr Parrot explained to the international audience how the European Union had enlarged to 25 countries on 1 May. The European internal market allows for the free circulation of individuals, goods, services and capital which is conducive to the development of businesses. He told the meet-

ing of his hope that a legal framework which will help to maintain the quality of health services, including, in particular, community pharmacies, will be defined in the near future.

"The interests of patients has governed the establishment of national regulations currently in force which allow for adequate service to local communities. An approach of pharmaceutical services that would be based only on the principles of ordinary commerce — in the name of maximum competition in the EU internal market — could drastically change this situation. Let us be careful about the health consequences that a blind, ie, strictly economic, deregulation could have in the field of health care," he said.

## Counterfeit medicines

But there is also a global concern that must be addressed, said Mr Parrot: that of counterfeiting, which is likely to develop more and more rapidly as international trade increases still further.

"Counterfeit products clearly pose a significant risk to public health. Our pharmaceutical organisations, along with public authorities and all others concerned must unite to fight this insidious evil more effectively," he said.

Counterfeiting yields large profits to unscrupulous traders who take advantage of the numerous drug distribution systems and flaws in border controls to infiltrate markets. In addition, the purchase of drugs via the internet can open another door to these counterfeits, evading any control.

Because of the difficulties in distinguishing counterfeit medicines from real ones, it is necessary to find technical solutions that will strengthen the ability of drug distribution systems to guarantee the quality of products provided to patients. "At the global level, control laboratories should be linked together so as to be able to follow up exported drug batches, although I am aware that this is difficult to implement," he said.

## New roles

Mr Parrot went on to talk about new roles for pharmacists in health systems. He explained that, early on, FIP had declared itself in clear terms to be in favour of the development of pharmaceutical services. "We insist that close co-operation of health professionals is necessary for improved efficiency of care," he said.

This policy has had good results. "We can congratulate ourselves that health authorities in a growing number of countries entrust pharmacists with a prescribing role so that they can follow up certain patients and see to repeat dispensing for chronic treatments. Pharmacists thus go well beyond their traditional role."

Also, some national authorities have entered into agreements with their pharmacists to bring them into the "fee-for-service" era. Such a thing was exceptional in the 1990s but is now beginning to take ground for the greater benefit of health care quality. It may, for example, be based on formal collaboration between doctors and pharmacists, said Mr Parrot.

Finally, in some countries all patients have a "personal medical file" indexing their health and treatment data. "Pharmacists must have access to the therapeutic part of this file and add their data to it," demanded Mr Parrot.

At the international level, the World Health Professionals Alliance, of which FIP is a founding member, intends to encourage just such co-operation, as it demonstrated at its inaugural meeting in Geneva, Switzerland, earlier this year (see *PJ*, 29 May, p678). Thus the process has begun. "Through the WHPA, we have an instrument that can be the common mouthpiece for our respective professions towards internal organisations," said Mr Parrot.

**Opening ceremony participants were treated to the sound of New Orleans jazz**

## Pharmaceutical sciences

Concluding his address, Mr Parrot turned to the pharmaceutical sciences, a sector of activity that is both vast and specialised, he said. On any continent, there exist research teams with highly specialised knowledge. International collaboration is therefore essential for them to exchange information. "New disciplines which result from this collaboration are essential for enabling pharmaceutical research to be directed towards new axes of development. This is how we will create the drugs of the future," he said. At the same time and on several continents traditional medicines are being updated and developed. They are beginning to be evaluated in accordance with the wishes of the World Health Organization in order to promote traditional, often plant-based, local resources. The aim is to save money in the overall management of health care in these countries.

"FIP has a duty to respond to such initiatives," said Mr Parrot. "We must also make sure that they are incorporated into a strictly scientific and pharmaceutical framework open to all researchers and that their inevitable globalisation does not produce a new market for quack medicine."

# John Bell receives FIP's André Bédat award

The André Bédat award for 2004 was presented to John Bell, FRPharmS, a community pharmacist in Sydney, Australia, during the congress opening ceremony on September 5. The award is FIP's premier award for a pharmacist who has made an outstanding contribution to international pharmacy. It is presented biennially.

Mr Bell is immediate past-president of the Commonwealth Pharmaceutical Association and is a member of the Order of Australia.

Two science awards were also presented. The FIP 2004 Pharmaceutical Scientist award was presented to Toshio Honda, of Japan. Professor Honda's research focuses on the synthesis of biologically active compounds towards the development of new medicines.

FIP's Lifetime Achievement in the Pharmaceutical Sciences award for 2004 was presented to Stig Agurell, of Sweden, whose original research on cannabis led to the first analytical method to assay tetrahydrocannabinol blood levels after marijuana smoking.

**John Bell: outstanding contribution to international pharmacy**

# Drugs will be tailored to the individual and biological proteins in the future

In the future, drug treatment will be increasingly and confidently tailored to the individual through the help of specific diagnostics, for example, genomic information and biological markers of disease susceptibility and progression. So said Malcolm Rowland, of the Centre for Applied Pharmacokinetic Research, University of Manchester, UK.

Professor Rowland was addressing a professional symposium, entitled "New drug therapies and the impact on the patient/pharmacist partnership", on 6 September.

He added that many new drugs (especially biopharmaceutical agents) will be given parenterally and targeted for specific diseases experienced by relatively few patients presenting at specialist centres. "The pharmacist will need to adapt to this changing pattern in order to be seen by the patient as part of the health team," he said.

He believed that package inserts and supportive data would need to become more informative. He also foresaw that interactive, web-based systems, using sophisticated modelling tools, would become available. These would link patients and data to pharmacists, other health professionals and pharmaceutical companies in order to guide clinical management better. "Research," he said, "is driving modern drug development to be increasingly mechanistic and predictive. Exposure-response relationships, coupled with modelling and simulation, are becoming the bedrock for quantitative decision making."

These approaches, coupled with diagnostics, are helping to inform the appropriate therapeutic dosage window for both the patient population and the individual patient.

## A disease approach

There is also a movement from a drug/target-oriented approach to a disease approach for the development of new drug treatments. By that he meant that diseases are being redefined. For example, whereas patients used to be described as having asthma, now the asthma is subdivided according to the biomolecular pathways involved in the disease, and this would define future treatment approaches.

It is already happening, he said. For example, etanercept is a recombinant soluble tumour necrosis factor that "captures" excess TNF, which plays a significant role in the pathology of rheumatoid arthritis. Unlike non-steroidal anti-inflammatory drugs, etanercept actually impedes disease progression.

There is also trastuzumab for the 25 to 30 per cent of women who develop breast cancer because of an over-expression of the HER2 protein; trastuzumab is ineffective against other breast cancers.

**Daan Crommelin: new parenteral formulations needed for proteins**

A third example is imatinib, which has been developed specifically for patients with chronic myeloid leukaemia caused by a genetic defect arising from the translocation of DNA between chromosomes 9 and 22.

"All these new medicines are coupled with a diagnostic marker and have fewer adverse effects than alternative drug treatments," said Professor Rowland.

This is the future of drug treatment. And it has come about since the realisation that the traditional "one-size-fits-all" approach is untenable. For example, many drugs are not effective in all patients: beta-blockers do not work in 15 to 35 per cent of patients; tricyclic antidepressants do not work in 20 to 40 per cent of patients; and interferons do not work in 50 per cent of patients.

## Proteins

Protein drugs are set to play a huge part in the future of drug treatments and how they could be delivered to the patient was discussed by Daan Crommelin, of the Utrecht Institute for Pharmaceutical Sciences, the Netherlands.

Professor Crommelin said that the growth rate in the use of therapeutic proteins is high at 24 per cent. Why? "The answer is that their success rates in terms of therapeutics are much higher than those of chemical entities." And there are other issues to consider: the medical aspects — their indications are for serious diseases and they meet previously unmet medical needs; the economic aspects — they constitute a relatively small but fast growing market; and the pharmaceutical aspects — they are delicate, complex molecules that are generally active in the microgram range, which means that they are difficult to deliver to the patient.

The main problem with delivery is that biopharmaceuticals are large, hydrophilic molecules so they are hard to get through membranes. Currently, needles are used. But their disadvantages have led scientists to look at other routes: oral, rectal, nasal, etc. "Every orifice of the body has been tried," said Professor Crommelin. The pulmonary route has shown some success with the delivery of insulin. But, said Professor Crommelin, the bioavailability is around 10 per cent — ie, 90 per cent of the drug is lost. "Can any health care system afford that," he asked.

Another problem with biopharmaceuticals is that their circulation times in the body tend to be short. What is needed, Professor Crommelin said, are new parenteral formulations which can increase the half-life of the drug and ensure site-directed delivery, or drug targeting.

## Pegylation

One way to increase half-life is pegylation, whereby a drug molecule is combined with polyethylene glycol in such a way that the drug's clearance by glomerular filtration is reduced and receptor uptake sites are masked, thus increasing the drug's half-life. For example, the pegylated form of interleukin-2 circulates much longer that the non-modified drug. "Clearly, pegylation improves the performance of drugs and so reduces the number of injections that patients have to endure," said Professor Crommelin.

Other approaches being studied are enclosing drug molecules in microspheres, in order to reduce the rate of drug release, and enclosing the drug in a dextran-based hydrogel. Since proteins like water, their release from such hydrogels can be manipulated so that 100 per cent can be released over a period of two weeks.

Professor Crommelin had a warning, however. Great care needs to be taken when modifying proteins because it could lead to problems of immunogenicity.

# How pharmaceutical services are provided to patients around the world

Community pharmacists are vital for any health care system, whether rich or poor, said João Gonçalves de Silviera, of Portugal, when he introduced a professional symposium entitled "The patient and the pharmacist in different health care systems" on 6 September. They are the most accessible health care professionals and the ideal contact point for the patient. Indeed, community pharmacists throughout the world are rapidly becoming the first and last health care providers contacted by the patient during an episode of care.

In a presentation about the practice of pharmacy and patient care around the world, Jeff Luce, IMS Health, US, said that pharmacists share a common goal of providing the best possible care for their patients. There are, however, significant differences in the practice environments and health care systems in which pharmacists provide this patient care. Several factors consistently impact on pharmacists' ability to provide quality patient care, he added. These include time, cost of medicines for patients, access to medicines information, pharmaceutical and medical knowledge and the health care environment.

To illustrate these issues, Mr Luce considered six countries: Germany, France, the UK, Japan, the US and Canada. Beginning with Germany, he highlighted the fact that there are currently no pharmacy chains and owners can own no more than three pharmacies. However, discussions are taking place on the prohibition of chains, and they may eventually be allowed. Reference pricing is used to control the prices of medicines, substitution by the pharmacist is allowed and parallel imports are used to secure better prices. Self-medication is being increasingly encouraged, with potential cost savings for the German Sick Fund and, since over-the-counter medicines can be sold only in pharmacies, this has huge implications for pharmacy practice.

In France, again, there are no pharmacy chains. Social security and employer plans pay for patients' medicines, and patients carry an insurance card for health care services, including prescription medicines, for which they have to make a small co-payment. Efforts to raise co-payments is meeting with considerable resistance and there is little generic substitution, although this is growing. Reference pricing, which will be phased in by 2005, has been developed to reduce drug costs.

Mr Luce went on to describe pharmacy practice in the UK with its mixture of chains, supermarkets and independents. He drew attention not only to the aim of the UK government to expand the role and responsibility of pharmacists, but also to the recent

Philip Davies: remuneration might be better tied to advice

Consumers' Association survey, which indicated that pharmacists may not be providing adequate patient advice on medicines. He also mentioned Walmart Asda's recent announcement of a change in the pharmacy management structure designed to give pharmacists more time to talk to patients about their medicines and health.

In his discussion about Japan, Mr Luce said that both prescribing and dispensing had historically been the responsibility of doctors, and it is only recently that these two processes have begun to be separated. Known as *bungyo*, this separation is becoming increasingly common with the result that pharmacy chains are opening in Japan. *Bungyo* is driving major changes in pharmacy in Japan, including increasing patient co-payments as well as reducing the gap between the market costs of medicines and their reimbursement price. Generic use has historically been quite low but is now increasing.

In the US, patients access medicines mainly through pharmacy chains, supermarkets, the internet and mail order. There are few independents. Health care coverage is not universal, and for many people, particularly older patients, affording medicines is difficult and sometimes impossible. This is a source of political debate in the current election campaigns. The Medicare system (the public health care programme for older people) has recently been reformed, with the advent of drug discount cards, but this is confusing for many elderly patients and may not provide them with significant cost savings, Mr Luce said. One of the striking things about US pharmacies is the choice of OTC medicines available on open shelves, not only in pharmacies but also in supermarkets and other stores, which patients can buy without any advice from a pharmacist.

In Canada, pharmacists are increasingly playing a key part in health care. Designated as "medical practitioners", they can be reimbursed for providing pharmaceutical care. Pharmacists have been proactive in exploring the appropriateness of antibiotics use, drug safety issues and also drug abuse in several provinces of Canada. Although pharmacists from many countries are exploring similar issues, Canada's approach to integrating pharmacists in key health care roles is impressive, he said.

Mr Luce concluded his presentation by emphasising that the quality of pharmaceutical care can be improved by identifying best practices and challenges in different countries. "The best patient care practices are those in which the pharmacist is the one who counsels patients on the proper use of medicines. This requires that the pharmacist is aware of all medicines the patient is taking, both OTC and prescription."

## Medicines policy in Australia

Philip Davies, deputy secretary, Australian Department of Health and Ageing, gave a presentation on the role of community pharmacy in Australia's national medicines policy. Australia's national medicines policy was launched in 1999. It aims to improve positive health outcomes for all Australians through their access to, and wise use of, medicines.

The policy has four specific objectives, the first of which is timely access to the medicines that Australians need at a cost individuals and the community can afford. Secondly, medicines must meet appropriate standards of quality, safety and efficacy. The third objective is the quality use of medicines by consumers and providers, and the fourth is the maintenance of a responsible and viable medicines industry.

The pharmaceutical benefits scheme (PBS) is an important feature of Australia's national health care landscape and plays a vital role in meeting the first objective of the national medicines policy. The scheme provides subsidies for a wide range of medicines that community pharmacists dispense.

Before a product can be listed for subsidy under the PBS, it is subjected to rigorous cost-effectiveness evaluation by an independent expert committee and the price at which the product is supplied is agreed between the government and the manufacturer. The annual cost of the scheme is about Aus$6bn (£2.5bn) which is met by government funding and patient co-payments in the ratio of five to one. The current cost of co-payment is Aus$23.70 for general patients and Aus$3.80

for concession card holders, but the price is reduced for patients who need a large number of medicines.

The pharmacist claims the balance of the price of the medicine from the government. The price paid to the pharmacist is made up of several factors. These include the cost of production of the medicine (agreed between government and manufacturer), plus 10 per cent of the cost of production (added as a wholesaler margin). However, due to discounting, actual wholesaler margins are closer to 5 per cent with the difference being added to community pharmacists' revenues. In addition, there is a pharmacy mark-up, plus a dispensing fee, together with a number of other payments for collecting patient information and providing patients with information on medicines.

There is no direct financial relationship between the government and either the wholesalers or manufacturers. The community pharmacist pays the wholesaler, which in turn pays the manufacturer. Distribution costs can account for a significant proportion of PBS spending, and in 2003/04 about 28 per cent of PBS spending was shared between community pharmacists and wholesalers. These costs, together with other parts of the pharmacist's remuneration are directly linked to the costs of the products they dispense. Because of the high-tech nature of the pharmaceutical industry, the costs of medicines have grown at a faster rate than inflation and pharmacy revenues have increased accordingly.

Mr Davies went on to question the rationale for linking payments to pharmacists and wholesalers to the price of ingredients. The most common answer is that stock-holding costs account for a significant proportion of operating costs and that, as medicines become more expensive, both pharmacists and wholesalers have increasingly large sums tied up in stock. However, money tied up in stock is less than might at first appear because pharmacies receive deliveries twice a day, most wholesalers offer extended credit and interest rates have fallen during the past 10 to15 years.

The PBS therefore allows pharmacists in Australia to have a favoured position in the health care arena. They are well funded with a large proportion of their revenue being indexed to growth in the cost of medicines. In Australia, pharmacists also face limited competition, because mark-ups and fees are uniform and there are controls on the ownership, number and location of pharmacies able to dispense subsidised medicines. Chains do not exist and the federal government has recently introduced a legislative amendment which precludes pharmacists from establishing pharmacies within supermarkets.

Emphasising that he was using the Australian PBS as an illustration of the challenges faced by any government-based pharmaceutical benefits programme, Mr Davies suggested that pharmacists' remuneration might be better tied to provision of advice rather than the cost of products. However, evidence that pharmacists can be cost-effective providers of health advice is mixed. In a US study, 91 per cent of people with diabetes showed an improvement in their condition after participating in a 12-month pharmaceutical care programme. Nevertheless, a recent Australian study found that there were only two areas where disease management by community pharmacy improved outcomes — asthma and the use of anti-coagulants.

**Prafull Sheth: poor pharmaceutical services in developing countries**

Mr Davies went on to question whether there could also be scope for savings in the pharmaceutical supply chain. Can medicines be delivered from the manufacturer to the patient more cheaply? If so, the role of the pharmacist must be questioned. Are they professionals or retailers, or people who try to combine both roles?

The case for allocating the supply function to supply specialists is becoming increasingly compelling. If this happened, pharmacists could then focus on working with patients to help them use modern pharmaceutical technologies to enhance the quality and length of their lives, he concluded.

## Developing countries

In a presentation focusing on developing countries, Prafull Sheth, of the Indian Pharmaceutical Association, said that pharmacists are comfortable dispensing medicines without providing pharmaceutical care. Development of practice standards in developing countries are not seen as a priority and pharmacists' remuneration for added value services continues to be non-existent.

He went on to describe the diversity of health care systems around the world and to highlight the gaps in morbidity and mortality between developed and developing countries. Poor pharmaceutical services in developing countries are part of the problem. Thus, patients go directly to pharmacists for medicines without consulting the doctor. Most drugs are dispensed illegally without prescription by drug sellers with little or no training. Drug enforcement tends to be weaker. Pharmacists are rare in rural districts, and supply of university-trained pharmacists is low. In Indonesia and Malaysia, many drug stores are operated by traditional Chinese herbalists. Distribution, transport and storage of medicines may also be badly managed.

Improving access to essential medicines and ensuring proper procurement, pricing, inventory control, quality and timely delivery to the patient offer huge opportunities for pharmacists in developing countries. Development of standards of good pharmacy practice which are in turn delivered by properly educated and trained pharmacists in adequate numbers are vital for improving the health of the general population, he concluded.

## A US regional health plan

Richard Bruzek, vice-president, Health Partners, Minneapolis, Minnesota, described the provision of pharmacies within a US regional health plan, and the benefits for patients of collaboration with community pharmacy. The health plan he discussed was developed by Health Partners, a family of non-profit Minnesota health care organisations.

Health Partners pharmacy services include the provision of more than five million prescriptions for 600,000 members at a drug cost in excess of $300m. (In the US, the total number of prescriptions is 3.4 billion at a cost of $2.6bn.) Pharmacy services are provided partly by pharmacies owned by Health Partners and partly by a network of contracted community pharmacies.

The cost of medicines in this scheme is met partly by the patient's health insurance company and partly by patient co-payment. The system offers flexibility in that the amount of the co-payment varies depending on whether the patient chooses to have a generic ($8 per item), a branded product ($15) or an item not included in the Health Partners formulary ($30). Use of generics is promoted because these differences in patient co-payments do not remove the differences in costs between brands and generics for the insurance companies.

One of the aims of Health Partners is appropriate use of drugs and the development of a formulary. Collaboration with community pharmacists has had a significant impact on this. For example, national statistics show that first-line antibiotics are used 60 per cent of the time, while with the Health Partners plan, such antibiotics are used 86 per cent of the time in the "own pharmacies" and 71 per cent of the time in the networked community pharmacies. Similarly, use of non-steroidal anti-inflammatory drugs is 52 per cent nationally, 91 per cent in Health Partners own pharmacies and 78 per cent in the networked pharmacies. Other successes include a higher rate of generic drug use than the overall national figure, and pharmacists are paid an increased fee for high generic dispensing volume.

According to Dr Bruzek, the Health Partners plan has transformed pharmaceutical services and pharmaceutical care. Service, quality and cost have exceeded expectations, prescribing is managed at the point of care and appropriate use of medicines is ensuring maximum benefit for patients.