

WORLD CONGRESS OF PHARMACY AND PHARMACEUTICAL SCIENCES

President urges pharmacists to rise to the challenge of therapeutic leadership

A stirring performance of the can-can celebrated the opening of the 62nd Congress of the International Pharmaceutical Federation, which took place in Nice, France, from September 1 to 6. The first of our reports summarises the speech of the outgoing president of the federation, Dr Peter Kielgast, and highlights the keynote address by Dr Oscar Arias Sánchez, former president of Costa Rica



In his final congress speech as president of the International Pharmaceutical Federation, Dr Peter Kielgast called on pharmacists to take a “reality check”, break free from their usual wait-and-see attitude and demonstrate that they are the ideal health care professional to take on the therapeutic leadership role made necessary by the powerful combination of information technology and gene technology that would be the basis for future pharmaceuticals development.

Empire builders of the future will not be warriors and cartographers exploring geographical terra incognita, he said: they are the scientifically literate. Within health care, new empires are to be built by those cartographers who are able to read and combine the two new maps that mankind possesses: the computer chip and the genome. “Learning to read these maps and to combine them will lead to a new paradigm in health care. The future of the pharmaceutical profession is closely linked to what new knowledge these maps will result in with regard to the prevention and treatment of diseases,” said Dr Kielgast.

Speaking to around 3,000 delegates from 110 countries on September 1, Dr Kielgast began by looking at the current situation in health care, in which, he said, cost containment has become a big political issue just about everywhere, no matter what proportion of gross domestic product health care costs consume. He said that drugs have increasingly been a popular target for cost-cutting measures because their costs are often seen in isolation from the costs of the rest of the health care system. And, since drug costs tend to increase as a proportion of total

health care costs, there are many attempts to stem the costs of drug use without consideration of how this affects costs in other parts of the system.

However, many of today’s costs will go down: home care and telemedicine will replace much of the expenses of institutional care, and many new drugs will dramatically decrease costs for certain illnesses, as has happened with the treatment of peptic ulcers. Against this stand three cost drivers. The first of these is demographics. More people are living longer so total health care costs per capita go up. Second is the coming explosion of opportunities, through the mapping of the human genome, to minimise the risk of illness and to cure illness. The third driver is the advent of the more educated and demanding consumer.

So what impact will this have on the pharmaceutical profession? “So far,” said Dr Kielgast, “we have seen both a negative impact and a positive impact.”

The negative one is that cost-cutting measures hit the profession and have resulted in new forms of medicines distribution. The positive one is that there is a growing demand for the pharmacist’s expertise, which has resulted in a shortage of pharmacists just about everywhere, in both developed and developing countries.

However, a powerful combination of information technology and gene technology will drive development in health care in the years to come and this will require a therapeutic leadership role to be filled. The question is, said Dr Kielgast, who will take up

that leadership role? He believed that pharmacists are ideally placed to grasp it. But before they can, they will have to stand back and take a reality check on the profession.

Pharmaceutical care, for example, has been the subject of much enthusiasm from the pharmaceutical profession. But its implementation has been modest. Many sound scientific projects have demonstrated the value of pharmacists taking broader responsibility, but pharmaceutical care is still not an integral part of any health care system.

“I am not saying that pharmaceutical care, understood as taking responsibility for outcomes, is wrong,” he said, “but without a covenant with various stakeholders, especially patients and payers, it is not going to work.”

Dr Kielgast foresaw that no single player would be in a position to monopolise the process of drugs in use. This process will consume so much of the available resources that no single profession will be left alone to do it, he believed. Collaborative models will have to be implemented, but providing leadership for the process is another matter.

In spite of the lack of breakthrough for pharmaceutical care, Dr Kielgast was firmly of the opinion that no profession is better positioned to initiate leadership than pharmacy. “We know drugs, how they work, their dangers, their costs and the complexities of their distribution and use,” he said.

But leadership is not an innate skill. It is provided by education and nurtured by the right upbringing. Leadership is not nurtured by protection, and the protective measures



Peter Kielgast: does pharmacy have the knowledge to meet the challenges?

that have surrounded the pharmaceutical profession in the past have not been the best fertiliser for entrepreneurship.

For example, Dr Kielgast told the congress that even today he still could not understand why pharmacists had called upon legislators to ban e-pharmacy instead of taking control of it. "Was it lack of understanding, or was it fear of flying from pharmacy's safe and cosy nest?" he wondered. Probably, it was a bit of both, although he believed that lack of understanding was probably the main reason.

Looking to the future, Dr Kielgast said that mankind was now equipped with two powerful new maps: one composed of digital codes in the form of information technology and the other in the form of the code for the human genome. He believed that both would become more detailed and even more powerful in the years to come. With that in mind he encouraged colleagues to abandon their protectionism. "Maintaining the status quo is a questionable victory because it will blur the vision for future change," he said.

He believed that in future, as well as a need for a covenant with patients in order to secure the role of the pharmacist, alliances



will have to be forged with more business-oriented concerns, for example, the life science industry.

"I invite the leadership of that industry to a dialogue to view the front-line pharma-

cist as a partner, not as one who can be squeezed for a few more cents on filling a prescription," he said.

In a foreseeable time, we will understand how viruses, bacteria and our own bodies are programmed and how they can be reprogrammed. Although it was perhaps true that the biotechnological industries had been slower than hoped by venture capitalists in producing new medicines, it was a certainty that there would be a new generation of pharmaceuticals. "Those of us who are young enough will see a shift from acute interventions to personalised treatment and prevention," said Dr Kielgast. "The result may easily be that society will end up spending as much on drugs as we currently do on doctors and hospitals. We do not know if these pharmaceutical will look like they do today and we pharmacists must not take for granted that it will be us who will handle them unless we are willing to adapt to a new world and learn to master the combination of digital and biotechnological language," he warned.

In conclusion, Dr Kielgast said that it has become a mantra that health care and medicines in particular are too expensive, but this belief is not based on evidence. Within health care there is a strong need for leaders to document the value of medicines and he wished to encourage the pharmacy profession to undertake this leadership role and educate those who have the power to make decisions. This would require a close co-operation between science and practice. Not only will pharmacy schools have to revise and expand their pharmaceutical curricula, they will have to institute changes in teaching methods to lay the foundations for pharmacists to perform the much needed therapeutic leadership role.

Does pharmacy have the knowledge, ability and courage to meet the challenges arising from a powerful combination of IT and gene technology, or will a wait-and-see attitude prevail? Both scenarios are possible, said Dr Kielgast, and although neither will create immediate dangers, the second option will not give pharmacists a strong position in the society of tomorrow and will certainly not engender a leadership role.

Jean Parrot becomes new FIP president as Linda Stone is elected a vice-president

Taking the reins from outgoing president Dr Peter Kielgast will be Jean Parrot, of France. Mr Parrot takes up the presidency at the end of the International Pharmaceutical Federation Congress on September 6.



Jean Parrot



Linda Stone

FIP in 1994 and treasurer of the FIP bureau in 1999.

Linda Stone, a member of the Royal Pharmaceutical Society's Council and president of the Society from 1990 to 1991, has been elected a vice-president of FIP. She has

been active in FIP for a number of years. From 1994 to 1998 she was a member, then chairman, of FIP's working group on the implementation of good pharmacy practice in developing countries. She is currently the Society's designated member of FIP's council.

Mr Parrot has been president of the national council of the French Pharmaceutical Society since 1993. Also since 1993 he has been the vice-chairman of the Conseil Supérieur de la Pharmacie and of the French National Centre for Pharmacovigilance. He was elected a vice-president of

FIP 2002 awards presented

Three awards were presented during the opening ceremony. Dr Nils-Olof ("Nippe") Strandqvist, of Sweden, was the recipient of the André Bédard award, and Lifetime Achievement awards in the Pharmaceutical Sciences were jointly presented to Dr Pierre Potier, of France, and Professor Hiroshi Terada, of Japan.

Dr Strandqvist is a former president of FIP and is well known as the author of the World Health Organization's 'Good pharmacy practice'. He continues to promote GPP as a consultant in Latvia, Bosnia-Herzegovina and Norway.

The André Bédard award has been awarded by the board of pharmacy practice every two years since 1987 to an outstanding phar-

macist practitioner who has made significant contribution to pharmacy at an international level. It is awarded in memory of former FIP president, André Bédard, who was president from 1978 to 1986.

Dr Potier's work focuses on the interface between chemistry and biology. He is best known in pharmacy for his discovery of two antitumour drugs, vinorelbine and docetaxel, which have both been developed world-wide.

Professor Terada's research focuses mainly on drug-protein interactions and mechanisms of actions of drugs based on their chemical and physicochemical properties. He is a former president of the Pharmaceutical Society of Japan.

Next year in Sydney

The World Congress of Pharmacy and Pharmaceutical Sciences next year will take place in Sydney, Australia, from 4 to 9 September 2003. The theme will be "Developing a new contract between pharmacy and society (risk management and improving outcomes)".

The 2004 Congress will visit New Orleans in the United States. Also in 2004 there will be a World Congress of Pharmaceutical Sciences in Kyoto, Japan, in May 2004.

Details of all these meetings are available from FIP Congresses and Conferences, Andries Bickerweg 5, PO Box 84200, 2508 The Hague, The Netherlands, and at FIP's website (www.fip.org).

Pharmaceutical companies must do more to help the world's poor, says Nobel peace laureate

Pharmaceutical companies must make a moral and logistical distinction between cost recovery and profit. Indeed, in certain cases, the drive for profits must be placed behind the duty to alleviate human suffering and improve human life.

Such was the plea of Dr Oscar Arias Sánchez, former president of Costa Rica (1986–90) and 1987 Nobel peace laureate, who delivered the opening session's keynote address.

Dr Sánchez explained that, among the many needs of the developing world, the scourge of tropical diseases is a major source of suffering and early death. Tropical diseases continue to kill the poor because there

is not enough research into treatments, cures and vaccines for these diseases.

Research into vaccines for malaria, tuberculosis and AIDS, which are three of the biggest killers of the world's poor, could be financed in many different ways. It is not a burden that pharmaceutical companies should have to shoulder alone. Public-private partnerships could be a way forward.

Left to their own devices, the poor countries of Africa, Asia and Latin America would never be able to solve these problems. This is not for lack of talent; rather, it is a lack of resources. Indeed, much of the scientific talent of the developing world finds its way to the United States, Europe

and Canada, said Dr Sánchez, because there are research grants and fully equipped laboratories.

"We know that the gulf between rich and poor has been widening in recent years, but we also have to recognise that the gulf in scientific output and technological innovation is even greater than that in income," he said. "As a result, I am convinced that the responsibility for researching poor peoples' diseases belongs squarely on the shoulders of those working in wealthy countries."

Dr Sánchez concluded by asking pharmacists to open dialogue with policy makers and build up public-private partnerships for the good of the world's poor.

The redefinition of regulation: culture change, culture shock

The redefinition of regulation of health professionals in the United Kingdom since the publication of the Kennedy report has meant a shift in the balance as far as self-regulation is concerned. That change gives the pharmacy profession tremendous opportunities to develop its quality assurance processes in a positive way. However, this means a culture change, which has been a culture shock for many pharmacists, Ann Lewis, Secretary and Registrar of the Royal Pharmaceutical Society told the congress.

Miss Lewis was speaking at a pharmacy practice symposium on "Competency and self regulation" on September 2.

She said that in most people's minds regulation meant discipline and the maintenance of a register and standards for education and conduct. But post-Kennedy, the concept of regulation has become much wider. The Kennedy report, she explained, outlines 12 components of regulation. These include establishing competence, committing to a programme of life-long learning and training, introducing revalidation for continuing practising rights, improving quality through audit and through clinical governance, promoting good practice, and carrying out research to underpin and carry forward the latest innovative thinking into practice development.

"In effect," said Miss Lewis, "post-Kennedy, regulation becomes competence assurance and includes all of these aspects. We believe the integrated role of the Royal Pharmaceutical Society in regulation and professional leadership through the integration of our regulatory and professional body functions fits us well to undertake the role of a modern regulator."

Miss Lewis believed that the change in the culture of regulation presents the opportunity to move from a negative regulato-



Ann Lewis: modern regulation is much more consistent with true professionalism

ry system which concentrates on discipline and policing to a more positive one which is more supportive and in which continuous quality improvement is the cornerstone.

"It is," she was sure, "much more consistent with the true meaning of professionalism and with pharmacists' aspirations to do the best for their patients."

It will mean inviting more public intervention in pharmacy's institutions and processes. However, there are those, she said, who oppose such intervention, believing it will somehow weaken pharmacy's institutions and diminish the Society's ability to support the profession. But lay input into the Royal Pharmaceutical Society's Council through its three Privy Council nominee members had been to the strength and benefit of the Society.

"Not infrequently, the insight of those outside the profession can be greater than those within," she said. "Enhanced lay involvement should certainly strengthen our

authority and the moral force in the relationship between the profession and the public. It will also enhance our success in acting in the interest of the public where those interests are for the public good."

Concluding, Miss Lewis said that those who travel to foreign lands may have to rethink their values and redefine their principles. Some may experience culture shock. In a similar way, the change of the attitude of the public and the impact of that on pharmacy's perceived freedom to regulate its own affairs may be felt as "regulation shock" by some. But for those bold enough to explore unknown territory, there could be treasure in store.

In the same congress session, Dr Phil Schneider, of Ohio State University, expanded on Miss Lewis's point about continuing professional development being an integral part of modern regulation. He stressed that CPD is much more than continuing education. It is more like a quality assurance system that involves five steps: self-appraisal, the development of a personal plan, taking action to implement the plan, documenting the improvements in competence that resulted, and evaluating the impact of all of that on practice. It is an ongoing cycle of improvement, he said.

He told the congress that FIP had made several recommendations surrounding CPD: for example, that national learning needs should be established through pharmacy associations, schools of pharmacy and education providers. But pharmacists would need to be motivated to undertake CPD, perhaps through models of career planning. A change in attitude is needed to increase pharmacists' enthusiasm. Dr Schneider firmly believed that participation in CPD would increase pharmacists' career satisfaction and choices, and that would ultimately be good for improvements in patient care.

International perspective on safety issues

Awareness of problems in relation to the safety of medicines is increasing. The challenge to pharmacists is to increase their knowledge of processes known to reduce medication errors and to contribute to interdisciplinary methods of preventing and solving these errors. Four speakers at a board of pharmaceutical practice symposium on 2 September looked at the safety of medicines from the patient and the regulatory perspective and described the challenges of ensuring the safety of two specific types of products — herbal medicines and biotechnology products.

In explaining the patient's view, Dr Kevin Moody (Health Action International, The Netherlands) said that consumers have a right to safe medicines, but for them, safety means more than preventing and managing medication errors. Patients welcome attention to adverse reactions, but safety also means receiving the right diagnosis, a treatment that works and the health outcome that is hoped for.

Demands on patients to accept financial and moral responsibility for their health are growing, he said. In return they expect (and have a right) to be actively involved in their care, and reporting of medication errors should be part of this involvement. In any case, patient reports could add information to health professional reports. Health professionals report relatively few adverse events, partly because they consider the event to be insignificant (eg, a headache) or well known, or they fear being blamed.

INVOLVING PATIENTS

Involving patients in reporting helps to validate their role in assuming the risks associated with taking medicines. It is also of benefit to health care professionals in that they are not solely responsible for reporting and it has the potential to reduce their workload. By adding information to databases, patient reporting could also enhance rational drug use. Moreover, the quality of reporting is richer and also first-hand.

However, there are potential problems with patient reporting. First, there is a need to distinguish between regular side effects and errors. Secondly, health professionals may not trust patients to interpret their own complaints. Thirdly, not all countries have a highly literate population and the availability of appropriate information, Dr Moody said.

He went on to say that the structure for patient reporting needs careful consideration. Ideally, the responsible body should be independent (neither government nor industry), the reporting procedure should be simple, available on the internet and provide a channel for feedback. Collected data should be shared both within and among countries in case "action" was needed. Patient reporting systems are most effective within an existing "official" report-

ing system to verify causality and should be seen as part of a pharmacovigilance system, he concluded.

Vaiyapuri Subramaniam (Food and Drug Administration, United States) provided a regulatory perspective and described how pharmacists contribute to patient safety through the FDA's drug quality reporting system (DQRS). With this system, which began in 1988, safety information on medicines is voluntarily disseminated through MedWatch. Reports are related to the appearance of the medicine and classified into three groups: imminent or serious health hazard (priority 1), potentially significant (priority 2) and routine follow-up (priority 3).

Pharmacists are the main source of reports, he said. In 2001, hospital pharmacists contributed 42 per cent of reports and community pharmacists 18 per cent. The remainder came from patients (8 per cent) doctors (7 per cent), nurses (3 per cent), pharmacy technicians (1 per cent) and others (21 per cent). The main problems reported in 2001 were due to packaging (33 per cent), labelling (12 per cent) and lack of effect of the drug (12 per cent) with the rest made up of defects such as physical change to the medicine, reconstitution difficulties, tampering with the packaging and general deterioration. In other words, these were "textbook complaints", Mr Subramaniam concluded, and pharmacists had demonstrated that they could contribute to product safety by participating in this system.

Markus Veit (German Central Institute for Pharmaceutical Research) discussed some of the problems in ensuring the safety of herbal products. Several safety issues have come under the spotlight recently, including toxicity (eg, hepatotoxicity of kava), adverse effects (eg, anaphylactic reactions with chamomile) and interactions (eg, St John's wort, garlic).

The safety of herbal products is closely tied to product uniformity and batch-to-batch consistency. Consistency has to be achieved with all the constituents of a herbal product, including the active principles, active markers, accompanying constituents (eg, inorganic salts, carbohydrates, amino acids) and constituents with potential negative impact (eg, allergens, toxins).

To achieve such consistency requires control and standardisation of the preparation process. This means characterising and defining the plant material used, together with all the chemicals used in the production process. Each step of the process — from cultivation, harvesting and drying through to extraction, production of the finished product, packaging and storage — has to be standardised. Specification limits and ranges for impurities have to be set.

Mr Veit went on to say that safety and uniformity for herbal products should be harmonised globally. At the European Union level, a directive is currently under discussion in which there are three cate-

gories of herbal medicinal products: traditional use, well-established use and new entities. Traditional use means use of 30 years within the EU or 15 years in the EU and 15 years elsewhere, and a list of ingredients, doses and permitted claims for this category will be defined.

According to the directive, traditional use products (because they are predefined) will have to satisfy only standards of quality — not efficacy or safety. Products in the well-established use category and new entities will have to satisfy standards of quality, efficacy and safety. However, for well-established use products, evidence for efficacy and safety could be derived from bibliographic material (eg, post-marketing studies, epidemiological studies, studies conducted with similar products) and not just clinical trials. Widely accepted scientific monographs such as those from the Europe Scientific Co-operative on Phytotherapy and the World Health Organization for herbal drugs could be used as a basis for the safety of products with well established medicinal use, he said.

BIOTECHNOLOGY PRODUCTS

Silvio Garattini (Mario Negri Pharmacology Research Institute, Milan, Italy) discussed the safety and efficacy of biotechnology products. Biotechnology products represent an advancement because they add a new dimension to the therapeutic armamentarium. Of the 202 products reviewed by the European Medicines Evaluation Agency between 1995 and 2001, 67 were biotechnology products.

Most of these fell into four therapeutic categories — gastrointestinal, blood, anti-infectives and antineoplastics and immunomodulating agents. "It is remarkable, that no biotechnology products have yet been developed for the management of disorders of the cardiovascular system, the central nervous system and the respiratory system," he said.

Interest in biotechnology products has grown on the basis that they are more specific, less toxic and less expensive than conventional products. However, this has not proved to be true. Epoetin-beta and darbepoetin-beta, for example, are essentially "me-too" drugs with adverse reactions no different from erythropoetin. Tenecteplase and reteplase are no more efficacious than streptokinase. Desirudin and lepirudin have a safety profile similar to heparin. No difference in mortality from breast cancer has been demonstrated from a combination of trastuzumab and paclitaxel compared with paclitaxel alone.

Biotechnology products have not been adequately compared with other products. "This makes any sound evaluation of both safety and efficacy difficult, and there is a need to establish an independent European fund for clinical trials," he concluded. — *Contributed by Pamela Mason.*

How to provide patient-friendly information on paper and on the internet

The way forward for the provision and sourcing of patient-friendly information — on labels, in leaflets and on the internet — was outlined by two speakers at a symposium on 2 September.

Discussing patient-friendly labelling, Jane Nicholson (Bristol-Myers Squibb, United Kingdom), said that although there is no substitute for reading a medicine label, improving the design of that label could lead to a reduction in medication errors. Manufacturers who use the same livery with the same colours and the same text size positioned on a same-sized carton are setting up an accident waiting to happen, she warned.

There are many ways that labelling can be improved. Mrs Nicholson recommended the use of sans serif type faces because they are easier to read. She also recommended using upper and lower case lettering because part of reading was the recognition of word shapes, and these are lost when capital letters are used. However, she added that a limited use of capital letters could be helpful when products had similar names, eg, vinBLASTine and vinCRISTine. Bold type is useful for emphasis. Abbreviations should never be used.

The use of colour is important, too, she said. Critical information could be given in red, but designers need to be careful to ensure that there is a maximum contrast between text and background. For instance, red type can be hard to read on a blue background.

For maximum safety, certain text is crucial, she said. The label must contain the product's registered name followed by the generic name, the strength of the drug, its route of administration and dosage instructions. Special warnings should appear in as large a font as possible and should not be broken up by such things as graphics or logos. She added that, for easy viewing, the full name, strength and, if appropriate, route of administration should appear on three non-opposing pack faces.

Turning to patient information leaflets, Mrs Nicholson said that these frequently do a poor job of providing information to the patient in a way that is easy to understand. Leaflets produced by manufacturers are usually based on legally approved text which must be converted into lay language with the result that, rather than being informed, patients are often overwhelmed by the information available. In some countries, a third party, rather than the company,

produces the leaflet and its content is not reviewed by the regulatory agency.

Leaflets should be tested among a group of 20 patients to assess their user-friendliness, said Mrs Nicholson. That testing involves asking each patient, after they have read the leaflet, the name of the product and 14 safety-related questions. She drew atten-

tion to a European guideline which suggests that 16 of these 20 patients should be able to answer all the questions correctly.

Finally, on the subject of patient information on the internet, Mrs Nicholson said that much of what was available really constituted advertising and was of variable quality and limited usefulness. However, no one could stop people looking at such sites if they wanted to.



Jane Nicholson: patient information leaflets not always easy to understand



Andrew Herxheimer: patients need different kinds of information to make treatment choices

tion to a European guideline which suggests that 16 of these 20 patients should be able to answer all the questions correctly.

She told the congress that, for patient sites on the internet to be valuable, they need to contain:

1 The identity of the company and the sponsor of the website

1 Health education information, such as methods of disease prevention, screening advice, and information on public health

1 Balanced and accurate patient information on products marketed by the company, to include the registered text of patient information leaflets

1 The summary of product characteristics

1 Links to other websites, such as patient groups, medical research and professional bodies

She added that all websites should be subjected to internal company scientific review. Preapproval by regulatory authorities is not necessary, but national authorities should monitor such websites' contents.

Mrs Nicholson said that, in conjunction with the advice of health professionals, patient-friendly labelling in and on the

pack, and on the internet, helps to inform patients. "Well-informed patients are more likely to adhere to prescribed medication, with safer, more successful outcomes and more efficient use of health care resources," she concluded.

Dr Andrew Herxheimer (UK Cochrane Centre) focused on the sources and quality of health information.

He agreed with Mrs Nicholson that the internet was a major source of health information but that quality was often variable. He described to the congress the "Discern" criteria. This is a brief questionnaire which provides users with a valid and reliable way of assessing the quality of information on treatment choices. Pharmacists can view the questionnaire at www.discern.org.uk. According to Discern, a good publication should fulfil several criteria. It should have explicit aims and it should achieve them. It should be relevant to consumers, make sources of information

explicit and be balanced and unbiased. It should describe how treatment works and outline its risks and benefits. It should refer to areas of uncertainty and describe what might happen if treatment is stopped. It should also make clear that there may be more than one possible treatment choice and should provide support for decision making that is shared between the patient and the health professional.

However, for patients, having access to information is only half the job. "The other half is knowing how to use it and understanding that judgements must be made," said Dr Herxheimer. Patients need information and the knowledge to be able to evaluate it. To aid that in future, he suggested that basic concepts about medicines should be taught in schools.

Patients need different kinds of information in order to make decisions at different stages of medicine choice. First they need to decide whether they need a medicine at all. Then, if they do, they need information on how to use it, for how long and with what precautions. Such information often comes from written sources, but is more useful to patients if it can be explained or elaborated upon during conversation with a health professional, including the pharmacist.

In conclusion, Dr Herxheimer said that he believed that information as a rule is best obtained from independent professional sources that disclose how and from what primary sources their information is assembled.