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IPJ

The Official Journal of FIP

Evidence: Measurable, Tangible and Powerful
Is there enough for the value of the pharmacist?

A Comprehensive Future
With conventional, complementary and alternative medicines practice

The Future of Pharmacy
Will currents priorities ultimately bear succes?

Evidence to Reengineer Pharmacy

But can pharmacists build on the facts to ensure a valid future?

advancing pharmacy and science to the benefit of the patient

IPJ
Official Journal of FIP

The International Pharmaceutical Federation/ Federation Internationale Pharmaceutique (FIP)

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International Pharmacy Journal

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Dear Reader

Do we, as pharmacists, have it within us to reengineer our profession? And can we secure our future without validating our present, or even more so, our presence?

Traditionally, the December Issue of the IPJ brings readers highlights and insight into the immediately previous FIP Congress; this edition is no exception. Yet our higher aim in compiling these pages is to link the Congress, its Sessions and discussions and its participants – you – to the goal of seeking answers to the most pertinent issues facing pharmacists and pharmaceutical scientists. And from there, go on to ask ourselves if we can move from anecdote and evidence to reengineering the future of pharmacy.

As such, this 'Congress' issue of the IPJ welcomes reports from probing Sessions and Workshops from the recent FIP Congress in Beijing. Examined, amongst others, are the value of the pharmacist – and evidence for it; health systems financing and expanding pharmacy practice; a timely look at pharmaceuticals in the environment; as well as an update on the FIP-WHO Global Pharmacy Education Consultation, all encompassing the central theme of *"From Anecdote to Evidence, Helping Patients make the best use of medicines"*.

But perhaps more importantly, 2008 will see FIP moving forward with these issues, inviting pharmacists and pharmaceutical scientists to discover how we can best take what we have learnt and reengineer the profession for the maximum benefit for all. From events such as the 1st Global IMPACT Forum to the World Health Professions Conference on Regulation and the Global Hospital Pharmacy Conference, alongside such ongoing FIP projects as Pharmacy Education, Patient Safety and Safe Medicines, FIP will make known the potential of our knowledge, culminating with the 68th FIP Congress in Basel, Switzerland, where all will be engaged in *Reengineering Pharmacy Practice in a Changing World*.

This editorial began with not only valid questions, but *necessary* questions; the answers to which were teased forth from the sessions and discussions of the 67th FIP Congress in Beijing China, and for which further direction is hoped to be gained from what is to follow in 2008.

We invite you now to read of what is preparing us for the future.

Myriah Lesko Editor
Lowell Anderson Co-Editor

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Evidence: Measurable, Tangible and Powerful

Is there enough for the value of the pharmacist?

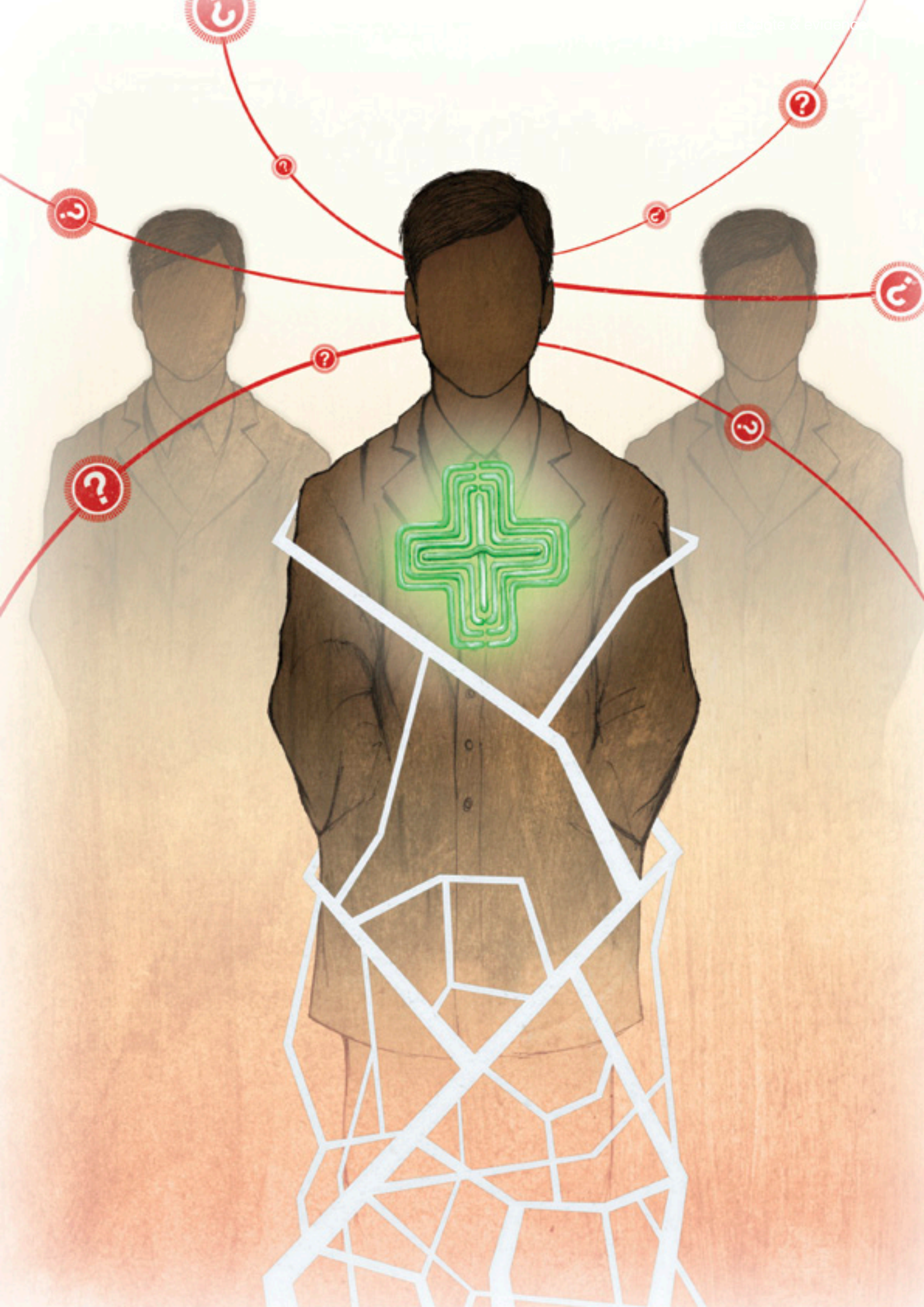
Catherine Duggan

The 68th FIP Congress in Beijing had the focus of linking anecdote to evidence to the pharmacist with the goal of better patient use of medicines. From a different angle, this theme reflects a pertinent question that continues to linger in the minds of pharmacists, which could have the power to steer the profession and global healthcare in a number of significant directions. Whilst we have some tentative conclusions and a variety of anecdotes and evidence of various levels, we still ask the question: is there truly enough evidence for the value of pharmacists?

The answer to this question could also influence governments, regulators and funders as well as wider professional expectations and requirements. Pharmacists have to deliver the value that society perceives they have: there is an increasing responsibility to make this inherent in professional development. With these factors in mind, the FIP Administrative Pharmacy Section hosted a session during the 68th World Congress that posed the question: "Is there enough evidence for the value of the pharmacist?"

The Session was set up to define the services and benefits that pharmacists can offer to society; to respond to the challenges of changes in healthcare; to describe the evidence and the value of pharmacists to the society and to develop strategies to convince policy makers of the value of pharmacists. The session was chaired by Professor Marion Schaefer from the Institute for Clinical Pharmacology in Berlin, Germany.

Representing the Belgium-based Pharmaceutical Group of the European Union (PGEU), John Chave began with a fundamental question in itself: "How should we regulate community pharmacy services to achieve optimum outcomes for society?" Throughout his talk, Chave considered approaches to pharmacy regulation in Europe that influence the supply of non-prescription medicines as well as the trends towards deregulation of the pharmacy sector. How pharmacy is practiced in various member states of the EU influences the perceptions of the practising pharmacists themselves and how well they can influence regulatory bodies and contribute to the wellbeing and wid- ▶



er health of patients through appropriate medicines use. The questions raised in the audience attempted to resolve the tensions and differences between National, European and International priorities and how these can be viewed in the whole.

Professor Alan Lyles from the University of Baltimore in the USA (and Docent at the University of Helsinki in Finland) was the second to speak, addressing the ever present issue of "Business versus public health orientation in pharmacy: lessons learnt from regulatory changes". His presentation provided an overview of the regulations in pharmacy, coupled with emerging drivers of increasing health care costs, increasing drugs and technologies and the need for increased interventions from pharmacy and pharmacists. He highlighted gaps in the system which delay the entry of potentially valuable chemical entities from the immense resources required to the burden of drug and therapeutic committees. The speaker set out examples from the evidence for new initiatives: the impact of pharmacists' consultations on physician geriatric prescribing, where the intervention group had more appropriate pharmacotherapy; the effect of clinical pharmacists to improve inappropriate prescribing in elderly outpatients with polypharmacy and highlighted the decreased inappropriate prescribing scores, increase in prescription drug changes but no changes in reported HRQoL.

> *"if there is no measurable and tangible value to society, why should society pay attention to us?"*

Professor Lyles put forward the question: when does information become evidence? Followed up with evidence of 3.6 billion $USD in cost avoidance as a result of various drug related problems in nursing facilities and another where ADEs were reduced as a result of effective interventions. Questions asked included how medicines reviews are standardised to ensure the evidence is applicable. Professor Lyles replied that different settings had undertaken standardisation in different ways: the key point was to effectively target the big wins. For example, getting pharmacists to target patients with high numbers of drugs, side effects or risks of ADEs is a good way to provide quick wins for policy makers. There is also a need to develop the workforce to meet the needs of the populations – what is the minimum number of pharmacists needed per capita?

Further questions centred on maximising the skill mix of the profession to take account of pharmacy numbers from university through to all sectors of the profession. A further question from the floor was if the US is one of the countries that has done the most to demonstrate the impact of the profession, why has it allowed "drive-thru" pharmacy to happen? Professor Lyles responded by saying too much of the research is "ivory-towered" and does not relate to grass roots service delivery. Too few in our profession speak the language of policy makers, which has allowed the access issue (i.e.: ease of supply of medicines) to dominate and the "drive-thru" to emerge as a feasible business model. From a broad perspective, we need to engage students with the wider vision with strong leadership; with strong leadership comes strong follower-ship.

The third speaker was Professor Alexander Dodoo from the Centre for Tropical Clinical Pharmacology and Therapeutics at the University of Ghana in Africa. The title of his presentation was "How to Convince the Decision Makers about the Value of Pharmacists: A Need for Global Initiatives and Co operation – the African Perspective." He started his presentation with a consideration of the value of pharmacists. The message is clear – if there is no measurable and tangible value to society, why should society pay attention to us? The question was followed by an overview of what pharmacists can do in Africa today: traditional roles include drug supply, industry, pharmacognosy, drug regulation and regulation of the profession. These were contrasted with new and emerging roles: clinical pharmacy, prescribing, medicines use reviews, diagnostic testing and provision of drug information as well as public health roles and patient safety initiatives.

Professor Dodoo then went on to question the low uptake of new roles: different practices in different settings together with different needs from different parts of society all can influence the take up of new roles but this is often in conflict with what African pharmacists are perceived to be doing: making lots of money, shop-owners equated with business men and only dispensing in hospitals. These misperceptions were only further confounded by the fact that all health professionals dislike working in rural or deprived areas where the hours are longer and the work often much harder. Professor Dodoo continued by outlining the effect of the environment on the need for up-skilled health professionals: acute shortages of health professionals, the need for more prescribers, vaccination programmes, and increased push for self management, increasing chronic disease and increasing middle class who may be willing to pay. In order to push pharmacists forward – we need to consider the evidence – both generation and promotion. Some example of evidence he put forward included the benefits of pharmacists in the national health insurance schemes and the risks to healthcare when pharmacists are not present.

Professor Dodoo suggested we need to develop appropriate lobbies, publish and promote the activities of pharmacists (for example, from The Spectator to The Lancet), promote global initiatives and share locally what others are doing nationally. He outlined the lessons in the Crisp Report which provide an incentive for developing coun-

tries to own the solutions to healthcare problems and acknowledged the threats, risks and benefits of full engagement – the benefits to patients must be the biggest drivers for pharmacists to promote what they do best. Questions from the audience included why weren't the policy makers effectively engaging professionals to work in rural areas? Professor Dodoo countered this by saying if he was Minister for Health, he would say there are not enough pharmacists but that it is not the issue: how can pharmacists go where they are not supported? The value in these situations is for pharmacists to make good links with other professionals for the benefit of patients, not simply the profession. If we convince the public of the value of pharmacists, policy will follow. In Ghana there is an initiative to engage pharmacists in all rural areas; the Government supports this and the pharmacists do also. He spoke of the impact of a radio programme which addressed healthcare needs, particularly pharmacy related, that not only meets the patients' needs but raises the profile.

The fourth and final presenter was Dr Kanjanat from the Faculty of Pharmacy, Chang Mai University in Thailand. The presentation was entitled "how to convince the decision makers of the value of pharmacists: a need for global initiatives and co operation – the Asian perspective."

"If we convince the public of the value of pharmacists, policy will follow."

Dr Kanjanat started with an overview of the challenges for pharmacists, the situations in Asia and the strategies that should be used to promote pharmacists in Asia. There is a great move towards providing pharmaceutical care in Asia, following evidence from other countries and the changes in pharmacy education from pharmaceutical science to clinical pharmacy.

Dr Kanjanat went on to describe the various settings in which pharmacists are making a difference and taking on new roles in Thailand, these included: hospital settings, community settings, technology, pharmaceutical marketing and the general emerging goals of pharmacy practice. Issues that need to be considered include the proposed strategies to convince decision makers about the value of pharmacists and to engage these with the goals of healthcare reform. Strategies to increase the value of pharmacists include an integration of professional organisation with regulation, education and society. Despite being the Asian perspective, this was very much in line with other initiatives and developments from the other continents; the similarities of the systems and challenges are very marked and provide further evidence for a body such as FIP to co ordinate and promote the initiatives from the four corners of the world.

Questions following this presentation included the need for good universities to produce good graduates who can take on new roles and adapt to the changing demands society places upon the profession. The speaker agreed that every development required the appropriate education to underpin it – indeed an important issue is one around planning the workforce with the best available evidence and integrating workforce planning with pharmacy education. One comment from the audience stressed that pharmacy can educate the public not only about drugs but also public health, and we need to promote this role to the policy makers. We are not simply drug pushers but also public educators.

Professor Schaeffer drew the session to a close by asking all the speakers to join in a panel discussion with questions from the floor guiding the discussion. The key themes for discussion that summarised the session well were access and applicability to evidence and access to policy makers by active lobbying and increased profiling of the contribution of the profession to patient care through established and ever increasing links. The session concluded on a positive note; whilst each country has different needs and systems for increasing the profile of pharmacy, we can share methods and evidence between countries and hopefully maximise the impact.

FIP should continue to be a vehicle for evidence, communication and access. ■

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ACTION!

Update on the global pharmacy education consultation

FIP-WHO Pharmacy Education Taskforce
Claire Anderson[1], Ian Bates[2], Diane Beck[3], Tina Brock[4], Billy Futter[5], Hugo Mercer[6], Mike Rouse[7], Tana Wuliji[8], Akemi Yonemura[9]

The second FIP Pharmacy Education Consultation was held at the 67th World Congress of Pharmacy and Pharmaceutical Sciences in Beijing, China. The consultation facilitated key stakeholders to reach consensus and shared commitment on an Action Plan to facilitate global developments in pharmacy education. The last issue of the IPJ served as a background document for the consultation and this article aims to update readers with the outcomes from the consultation.

Over 40 representatives and leaders of global, regional and national pharmacy education, pharmacy students and young pharmacists, professional and scientific bodies and FIP convened for the full day consultation. Representatives of the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO) also participated in the consultation and brought wider perspectives relating to education and workforce development in the other health professions as well as other disciplines. Participants were grouped into working groups facilitated by a member of the Pharmacy Education Taskforce committee to ensure rich discussion and incorporation of perspectives from all regions.

Dr Kamal Midha, FIP President, welcomed participants to the consultation. Stressing the importance of pharmacy education on the FIP agenda, he called for comprehensive action to explore how to strengthen and increase the capacity of training institutions to produce competent pharmacists and pharmaceutical scientists.

Chaired by Prof. Claire Anderson, the consultation commenced with brief presentations from Taskforce members and invited guests on many key issues: trends in higher education development; the domains for action identified in the previous consultation; matching educational initiatives and scaling up the workforce.

Dr Muungo, Head of the Department of Pharmacy, University of Zambia, gave a country-level perspective to highlight the real-life challenges of establishing the first pharmacist training institution in the country and building a pharmacy workforce in a developing country context. Zambia, with a population of 11 million people, has some 100 pharmacists in total and graduated its first local cohort of pharmacists in 2004.

The consultation working groups built on discussions from the 2006 roundtable on pharmacy education, reviewed and validated domains for global action, identified priorities and developed a framework for an Action Plan (1;2). The afternoon focused on how to move the global pharmacy education agenda forward and included brief presentations on the Action Plan and role of the taskforce, competency frameworks, quality assurance of education, engaging students for education development, and educational development for both pharmaceutical scientists and pharmacists. The rapporteurs – Prof Anthony Smith, Dr Tina Brock and Dr Jennifer Marriot – gave an overview of the discussions and lead the prioritisation and consensus building process towards an agreed action plan.

In general, all groups felt that the domains for action were appropriate with some slight finessing of terminology to promote inclusiveness for both pharmaceutical scientists and pharmacists. As part of this discussion, it was recognised that a "one size fits all" educational system was neither practical nor desirable and thus education development should be geared towards local needs. The focus of the consultation was to build consensus on an action plan that would seek to facilitate comprehensive pharmacy education development and progress, rather than to examine the educational systems and curricula within different countries. Furthermore, it was agreed that the development of optimal educational systems should progress through a cycle that first seeks to assess and understand local needs. Upon determining local needs, the services (broadly speaking) required to meet those needs can be defined – such as research and development, production, distribution, patient care, public health. The competencies of the workforce should be aligned such to enable optimal

quality in the delivery of these services. Thus education should be geared towards preparing a workforce that is competent. It was emphasised that this process was best represented as an on-going cycle rather than a linear progression.

During the prioritisation process, domains relating to preparing pharmacists, developing a vision and framework for pharmacy education, and quality assurance for pharmacy education were voted as the most important areas for attention. It was recognised that in many countries, the ability to scale up the pharmacist workforce and further develop pharmacy education is directly related to the capacity of the training institution and academic workforce. Finally, the groups addressed the role of the Pharmacy Education Taskforce, determining that it should identify resources, set milestones, facilitate and provide assistance for country studies, and serve as the connection and conduit amongst stakeholders. Stakeholders also urged for continued and greater involvement of UNESCO within the Action Plan and the taskforce.

ACTION PLAN

The three year Action Plan encompasses initiatives to target the priority domains of developing competencies frameworks; tools for the assessment of education needs; guidance in the quality assurance of education; academic/teacher workforce and training capacity; and creating a vision and framework for education development. This Action Plan will be accompanied by process measures that seek to build awareness, advocacy and momentum on the development of pharmacy education; provide a platform for multi-stakeholder exchange and collaboration; and facilitate progress by developing guidelines, tools, resources and evidence.

The Taskforce is working towards finalising the Action Plan, further developing partnerships with WHO and UNESCO for its implementation, seeking resources and developing a platform for ongoing dialogue with stakeholders. The Taskforce will organise a third consultation to report on progress and gather input for the implementation of the Action Plan at the 68th World Congress of Pharmacy and Pharmaceutical Sciences in Basel, Switzerland in September 2008.

More information will soon be made available on the FIP website. Comments, questions, and expressions of interest are welcome and can be sent to Tana Wuliji, FIP Project Coordinator at tana@fip.org. ■

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Clinical development can be a lengthy and costly process. Reducing development time and expenditure while maintaining the quality of data is a constant challenge for drug developers. With its large population, improving economic conditions and growing ambition to be a bigger player on the world stage, China is surfacing as an increasingly attractive location for conducting clinical trial research.

Made in China

China emerges as the most attractive, low-cost, global location to hold clinical trials

Emilii Malmi

Fewer costs, many patients

Low expenses and ease of access to patients are the main incentives for clinical trial outsourcing. This is the key that is opening the door to the East, with costs of clinical trials for a new drug in China tallying to half of a comparable trial in the United States or Western Europe. This is directly owing to lower labour and infrastructure scales.

As a significant portion of clinical trial budgets are spent on payment to participating medical doctors and hospitals for *each* patient studied, it is easy to understand that low labour cost contributes to low clinical development cost. But it is questionable if such low payment to physicians will continue in the future. In China, clinical investigators take responsibility for the management and results of the trials. Physicians are considered leaders and highly respected in their own field. Therefore, it is very important for foreign companies to respect Chinese physicians in the same manner as they do their Western counterparts.

Clinical trials in China also reveal lower hidden costs, such as fewer costly days needed to recruit patients. Availability of patients for trials is hearty – from a population of 1.3 billion it is relatively easy to find suitable individuals. Furthermore, it has been shown that a considerable number of patients in China are willing to enter clinical trials for the free Western medicine (this poses ethical dilemmas, however, as at the end of a trial many Chinese patients are unable to the medicine necessary to continue treatment).

Other major advantages of conducting clinical trials in China are:

1) Rival drug makers are not competing so fiercely to obtain patients for similar trials;
2) patients in China are less likely to be taking other medicines that could interact with the drug being studied;
3) the numbers of clinical trial sites are increasing with the involvement of a growing number of qualified centres.

However, several hurdles face companies looking to locate their trials in China, including poor data standardization, delays in gaining trial authorization from regulators and questionable ethical standards. The new trials approval process of China's State Food and Drug Administration (SFDA) can take up to one year. SFDA was created in 2003, and one of the agency's first steps was to overhaul China's clinical practices, conducting audits and creating a database of physicians certified to do such research.

To maintain the high quality of clinical trials with international standards, foreign partners must help Chinese colleagues to build solid infrastructures of clinical trials and human resources. To improve evaluation of outcomes, it is important to build a proper information system and to establish standard operating procedures.

The Chinese Register joins WHO – a critical step

In many trials in China, the drugs being tested have been approved in the West. Chinese authorities, however, want trials conducted in their own country before allowing the drugs to be sold locally.

The Chinese government controls one very important part of the clinical trial process – it licenses the physicians who decide how the trial is conducted and how data are gathered, and who hire fellow doctors to lead trials and recruit patients. Drug companies fund the trials, provide the medicine and offer input on the goals of the trials.

The Chinese Clinical Trial Register was established in 2005 and met the criteria to submit its trial registry data to WHO's web search portal in July 2007. By participating as a primary register in WHO's International Clinical Trials Registry Platform, the Chinese Register will ensure that researchers, whether in the public or private sector in their respective countries, will be more accountable to the people who consent to participate in trials and to those who may benefit from research results.

Visit the WHO web search portal at http://www.who.int/trialsearch to get a global picture of planned, ongoing and completed clinical trials. ■

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Experiential Learning

The evidence is mounting

Zhining Goh

Experiential Learning. This concept has come to infer numerous expectations and professional training responsibilities for students, educators, practitioners and professional affiliations. The inherent value in both the theoretical notion and practical institution of Experiential Learning is gaining professional recognition on a global level. In response to this, Experiential Learning was the topic of a session jointly organised by the FIP Academic Pharmacy Section and the International Pharmaceutical Students' Federation (IPSF) at the 67th FIP Congress in Beijing. A seamless series of presentations by speakers from the UK, IPSF, Australia and US led the nearly-full room of participants in exploring the concept and value of this form of education in pharmacy curricula, as well as surrounding issues and challenges.

Professor Ian Bates, Head of Education Development at the School of Pharmacy, University of London spoke on experiential learning as a way to overcome curriculum limitations that are indirectly extinguishing the drive for better and more cost-effective healthcare delivery, and the need for a shift from evaluating theoretical knowledge to assessing competency-based performance in pharmacy practitioners. Experiential education that brings relevant experience to theory and reinforces primary learning is needed to move learning towards developing competence – a complex educational construct that encompasses knowledge, skills, values, attitudes and behaviours.

In the United Kingdom, the pre-registration year has shown to double pharmaceutical care competency scores from 30% to 60% as measured using the Objective Structured Clinical Examination (OSCE). This was deemed insufficient and the government-funded Joint Programmes Board (JPB), a working collaboration between the higher education sector and the National Health Service (NHS) in England, was established to reform post-registration development for pharmacists. The JPB offers a three-year Postgraduate Diploma in General Pharmacy Practice that aims to equip practitioners with skills and competences in accordance to a General Level Framework to ensure safe and effective pharmaceutical care practice.

Professor Bates emphasised that in order to distinguish the special role pharmacists play in healthcare and the unique knowledge pharmacists can offer to their healthcare colleagues, it is essential that the pharmaceutical sciences be the foundation of pharmacy education, with pedagogy that integrates scientists as practitioners and inculcates self-directed life-long learning. He introduced a learning modality model which illustrated the ideal progress of learning modes with time and career pathway to develop and maintain competence – as one progresses from undergraduate to advanced post-registration practice, there is an increasing shift from predominantly face-to-face cohort learning on-site in higher education institutions to independent, career-driven experiential and distance learning off-site.

competence:
a complex educational construct that encompasses knowledge, skills, values, attitudes and behaviours

Ms Zhining Goh, Immediate-Past IPSF Chairperson of Education and Practice, reported on the discussion and recommendations from a forum on experiential learning conducted at the 53rd IPSF Congress in August 2007. Forty pharmacy students from 12 countries attended the session. There was unanimous agreement amongst the participants that experiential learning should be an essential and compulsory component of undergraduate pharmacy education as it has great impact on students' vision of their future profession.

The forum attendees saw the need to balance theory with experience in pharmacy curricula, but reported a general insufficiency in experiential education internationally. They expected their courses to provide them with opportunities of exposure to various sectors of the profession but recognised the lack of training places, lengthy administrative procedures, time commitment required and attitudes of students and preceptors as some of the barriers to quality experiential learning. There is a need for well-trained preceptors willing to teach students, and for universities, employers and regulators to work together to ensure adequate training places and assure quality of learning.

In addition, the students discerned that the most effective way to garner sufficient training spots and to change the attitudes of unwilling pharmacy employers and healthcare administrators was to increase the recognition of pharmacists in society. This would allow pharmacy education to go the

way of medical education where the public recognises the need for physicians to learn and train in actual practical settings, and to make it a norm. There is thus a need for all sectors of the profession to actively promote and advocate for pharmacy.

Dr Jennifer Marriott, Senior Lecturer in Pharmacy Practice at the Victorian College of Pharmacy, Monash University, Australia highlighted the need for well-prepared preceptors in experiential education. A preceptor, according to Morrow's 1984 definition, is one *"who teaches, counsels, inspires, serves as a role model, and supports the growth and development of an individual … for a fixed and limited amount of time with the specific purpose of socialising the novice into the new role."* Citing the World Health Organization's definition of the role of a pharmacist in the healthcare system, she pointed out that providing education and training to student and junior pharmacists is a professional obligation that also yields benefits for the practitioner. Being a preceptor allows for gain in new knowledge, fine-tuning of existing skills, increases job satisfaction and renews enthusiasm for the profession.

However, while good preceptors have been acknowledged to be fundamental to an optimal learning experience for student and junior pharmacists, pharmacists in clinical settings may be competent expert practitioners but poor teachers as they lack teaching expertise which requires formal education and training to develop. Formal training programmes not only increase preceptors' confidence and motivation, they equip them with teaching and learning theory to better prepare them for the student. Preceptor courses have evolved from the traditional face-to-face workshops or lectures that required significant investment of time, travel and cost, to contemporary flexible, web-based delivery which offers advantages for time-restricted or isolated pharmacists as they can be undertaken at a time that best fits the schedule of the learner, and has no mandatory time requirement to fulfil.

Dr Mariott presented the Australian Preceptor Education Programme developed by the Australian Consortium for the Education of Preceptors (ACEP) as an example. The well-received programme was originally developed for pharmacy, nursing, physiotherapy and speech pathology but has now been redeveloped for general allied health purposes. This interactive online course, which takes approximately 24 hours to complete, focuses on learning and teaching theory in relation to experiential education and builds on a constructivist approach that makes the curriculum suitable for all levels of preceptorship. Moderated discussion groups allow for reflection, sharing of experiences, peer mentoring and programme-based support. The course structure is divided into six comprehensive modules – Exploring Clinical Education (theory and practice), Focus on Learning, Focus on Being a Clinical Educator, The Relationship between the Learner and Clinical Educator, Learning in the Workplace and Mentoring.

Mr Mike Rouse, Assistant Executive Director of the Accreditation Council for Pharmacy Education (ACPE) described the US model of experiential education and the principles driving quality assurance. The Doctor of Pharmacy (PharmD) programme is the only accredited professional degree that requires a minimum six years of study. Pharmacy practice experiences are incorporated into the later four professional years of the programme, with the final year exclusive to advanced experiences.

Mr Rouse explained that quality assurance of education is not about having identical curricula designed and delivered in identical ways. Instead, identifying criteria and establishing standards to define quality, putting general standardisation procedures in place and ensuring consistency across the board should serve as quality assurance fundamentals to allow for institution-driven, mission-related quality advancement characterised by innovation and individuality. 12 out of 30 ACPE accreditation standards address in-practice experiential education.

The responsibility of the pharmacy school in assuring quality of experiential programmes was stressed. Duties of the school included but are not limited to goal-setting and compliance to standards, selecting and securing training sites, providing preceptor training and support, as well as maintaining sufficient resources to manage and co-ordinate an effective programme efficiently. Assessment as an essential component for quality was another focal point of the presentation. Individual and collective evaluation of achievements of desired outcomes by students needed to be mapped to professional competences using specific and valid measures and standard procedures and instruments. The process should be transparent and results should be used in a cyclical overall evaluation system of the school to bring about continuous quality improvement. ■

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Chicken or Egg?

Health system financing and expanding pharmacy practice

Boyan Todorov

The issues of revenue collection and governance, or simply how healthcare is financed, were topics of the Educational Forum hosted by the FIP Young Pharmacists Group (YPG) during the 67th FIP Congress in Beijing. The forum provided young pharmacists and other participants alike the opportunity to learn more about health care funding and to highlight the fact that the way health systems are designed, managed and financed affects the profession. The overall notion was this: change health systems; impact the profession; affect healthcare.

Dr Gisselle Gallego from the Centre for Health Economics Research and Evaluation in Sydney opened the forum providing some cross country comparisons of health care financing and delivery, describing them in terms of health care expenditure and outcomes. "Are our health care dollars achieving what they are supposed to achieve?" she wondered, providing examples from countries implementing different funding alternatives.

In her talk, she introduced key concepts such as equity and responsiveness as a measurement of health care. "How we raise money and how the providers are paid presents challenges for pharmacists" she said, giving Australia as a case study. The Australian health care system is characterized by a blend of public and private sectors, in both funding and provision of health care services. Like other developed countries, Australia's pharmaceutical use is increasing forcing new policies, including mandatory cost-effectiveness analysis, reference pricing and fixed patient co-payments as part of the Pharmaceutical Benefits Scheme (PBS). She outlined the leading example of Australia in granting the Pharmaceutical Benefits Pricing Authority a monopolistic purchaser position in an attempt to secure low prices. Nevertheless, expense projections were presented showing that pharmaceuticals remain the fastest growing component of the healthcare expenditure,

> *"Are our health care dollars achieving what they are supposed to achieve?"*

prompting further action. The cost containment trend since the early 1990s prompted actions with different impacts on the profession, as some see the pharmacy sector as a potential area to reduce government expenditure.

Dr Janet Sylvester, president of the American Society of Health-Systems Pharmacists, discussed the complexities of the USA health care system. She began by outlining crucial differences, including the significant number of uninsured individuals and their impact on the health care system. Key measures in evaluation of the health performance were introduced including quality (accreditation), safety and outcome measures, focusing on the health status of Americans. It was noted the relatively large voluntary private contributions could act as a strong incentive for outcome-based funding in health care, including pharmacy.

Dr Sylvester went on to briefly discussed the mix of federal, state and private plans, underlining the weak governmental intervention in health markets. Nevertheless, she pointed out that about half of the total expenditure in USA is due to government funded programs such as Medicare and Medicaid, providing limited options for public regulation. "Variations and diversity are key elements of the American health system" she said, pointing out that "this gives rise to competing, discrete market forces that adversely affect the efficiency". Further she focused on the concept of managed care and the experience of pharmacists working with managed care organisations (MCO). She described how the introduction of managed care in US temporarily contained the increase of heath costs; nevertheless the inflation of health related costs in the US has continued at twice the rate of national consumer price index. The reason for that might be that care is still managed on level of individual insurers, instead of being implemented system-wide. Finally she discussed pharmacy benefit plans, such as the Medicare part D and examples of employer based programs. Such planning has improved the utilization and has encouraged patients to take active interest in their therapies.

The issue of decentralization and equity was addressed by Mr. Reijo Kärkkäinen, a health lawyer and the CEO of the Association of Finnish Pharmacies. He defined the main objectives of health policy in Finland as universal coverage, quality of life, equity in access and financial solidarity. He went on to note that the responsibility for organising healthcare is placed with the municipalities, which independently or jointly provide healthcare, or could purchase it from the private sector. Finnish healthcare is primarily financed from tax revenue, with the total health expenditure accounting for about 7.6 % of GDP. Notably, 16% of these expenses are spent on medication from community pharmacies.

> *"Health care reform seeks to advance the role of community pharmacies, especially with regards to self-medication, and reaffirms the role of the pharmacy as a basic unit of the health care system"*

Mr. Kärkkäinen discussed newly implemented government policies in Finland, aimed at increasing responsiveness in the healthcare system. He went on to explain plans to reinforce primary care in Finland, including pharmacy practice. Measures included an overhaul of the reimbursement system to control rising costs and implementing strict cost effectiveness analyses for new medicines. In his closing remarks, Mr. Kärkkäinen stressed the potential negative effect of decentralization in health care on equity, unless counteracted by equalization mechanisms for sharing the burden of very high-cost patients.

Mr. Ulrich Dietz from the Federal Ministry of Health in Germany spoke of planned reforms outlining an important role for the pharmacy profession in healthcare management. He described the major marks of the Bismarckian healthcare financing model, including the statuary duty of all residents to insure against health risks in competing public, non-for-profit organisations. He projected on the expected changes with the introduction of the Federal Health Care Funds in 2009 and the introduction of man-

aged care tariffs by the providers. The different base for the allocation of resources for pharmaceuticals in hospital and community pharmacies was another interesting point he made. In the hospital practice, medication costs are allocated prospectively according to the Diagnostic Related Groups (DRGs).

With regards to community practice, Mr. Dietz saw opportunities for the community pharmacists to act as health managers, sharing responsibility for treatment outcomes of their patients. He stated that pharmacists are in a prime position to influence the utilisation and costs of drugs. Under the new plans, pharmacies could join managed-care tariffs and offer "integrated care" in networks of professionals of in- and outpatient care. "Health care reform seeks to advance the role of community pharmacies, especially with regards to self-medication, and reaffirms the role of the pharmacy as a basic unit of the health care system", he said. In the future, Mr. Dietz envisages a greater role for insurance companies in the medicines supply, allowing pharmacies to function as healthcare professional institutions. "Pharmacists have an important role in administering the health services in the community, ensuring quality and efficacy of care" he concluded.

The representative from the Pharmaceutical Services Negotiating Committee (PSNC) in England, Ms Lindsay McClure, introduced the National Health Service (NHS) and explained its consequence for the pharmacy profession. She noted the role of the PSNC as representative of community pharmacy on NHS matters, speaking on behalf of about 10.500 pharmacies in England & Wales. Detailing on the role of the committee, Ms. McClure focused on the ongoing negotiation of funding and the terms and conditions of national pharmacy contract there. The new conditions required new type of pharmacy service, expanding essential services like dispensing to include medicines use review and targeted pharmaceutical interventions. As the contract developed, it incorporated additional nationally commissioned duties for diagnostic testing, substance misuse services, supplementary prescribing, minor ailments treatment and full clinical medication review, reported Ms McClure.

The closing discussions examined key differences between the German and British healthcare systems. Although the principles of solidarity, equity and efficiency are shared between the two, the participants recognised there are country specifics that should be taken into account. "Health system funding reflects national policy and economics", noted the forum host, Mr. Boyan Todorov. "Nevertheless it has a significant impact on pharmacy practice", he added. Advancements in pharmacy practice could be understood only in view of the health system in question. Thus to develop as influential partners in health systems cost analysis, pharmacists need to learn to think more and more like health system managers. ■

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Developing Evidence

International medication review service models

Katja Hakkarainen

The worldwide philosophical shift in pharmacy practice from product supply towards patient-centred delivery of cognitive services, with the goal of quality use of medicines, has led to the implementation of pharmaceutical services. This was stated by Dr Tim Chen from the University of Sydney during the session entitled *"Medication reviews – from medication counselling towards service delivery"***, a joint FIP Congress initiative of the FIP Pharmacy Information Section and the International Pharmaceutical Students Federation (IPSF).**

The concept of medication review and the implementation of medication review services are timely, especially considering the aforementioned philosophical shift, changes in legislation and regulation either as a precursor or result of that shift, and growing autonomy yet increased responsibility on both patients and their multidisciplinary care givers.

As an example of a current programme, Dr Chen introduced the Australian Home Medicines Review (HMR) service, a comprehensive clinical review of a patient's medicines involving a home visit by an accredited pharmacist. The successful delivery of the service requires tight collaboration with physicians, highlighted Dr Chen, who also noted that the increasing age demographics of the population would require medication reviews as an essential part of overall patient care.

In addition to the Australian HMR, other types of medication review services have been introduced in other countries, which were brought to the table by Ms Katja Hakkarainen from Finland. Since the renewed community pharmacy contract in 2005, English and Welsh community pharmacists have provided Medicines Use Reviews (MUR). While MUR is not a full clinical review, clinical medication review services are organised and provided at local levels in England and Wales. In the US, targeted beneficiaries have been entitled to receive Medication Therapy Management (MTM) services since 2006, but the service model is not nationally regulated. Because these and other services are often referred as "medication review" even thought the services are very different, it is important to distinguish them and understand the existing models when developing future services.

Prof Charlie Benrimoj from Australia argued that there has been a lack of change management when professional pharmaceutical services have been integrated into health care in different countries. All levels of the profession, from individual pharmacists to external stakeholders, should be considered, he stated. Prof Benrimoj continued that taking a holistic approach to the overall service model and considering the professional and business environment is crucial in achieving a sustainable foundation for professional pharmaceutical services.

In Finland, the development of a comprehensive medication review service started by establishing a long-term continuing education course in 2005, described Mrs Lea Tuomainen. The 18-month course involves five modules, including courses on rational pharmacotherapy, clinical pharmacy, tools for conducting medication reviews and multidisciplinary collaboration. By the end of 2007, 120 pharmacists will be specialised to deliver comprehensive medication reviews in hospitals and ambulatory care. A national model for a pharmacist-conducted medication review service is expected to be launched in the near future.

Prof Alan Lyles from the University of Baltimore discussed the evidence for medication review services, stating that the evidence strongly suggests that drug related morbidity and mortality results in major costs in the society, and these costs could be avoided if consultant pharmacists were better utilised. While some studies exploring medication review services have shown positive economic, clinical and humanistic outcomes, the evidence is still controversial. Thus, more and higher quality pharmacoeconomical research on medication review services is needed.

The role of pharmacists conducting medication review services is seemingly one of the many that are becoming standard within the expanding pharmacist's portfolio. But the success of such actions, measured in both increased patient health and decreased healthcare costs, is much more: it is invaluable evidence of the inherent value of pharmaceutical services, and a push for the re-evaluation of regulations and professional ethics to support such provisions. ■

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Their Right to Choose

Strengthening the responsible self care of patients

Emilii Malmi

The concept of "patient self care" spans numerous autonomous activities and methods of gathering information. As a concept, patient self-care is widely practiced in both developed and developing countries, which brings a new sense of independence for patients, but also new challenges for health care providers in ensuring patients are making educated, safe choices.

Self-medication is increasing

Responsible self-medication can help to prevent and treat symptoms and ailments that do not require medical consultation, reducing the increasing pressure on medical services especially where financial and human resources are limited. This has the potential to create a more efficient health care environment, increasing the availability of health care to such populations as those living in rural or remote areas where access to medical advice may be difficult.

It has been proposed that self-medication has increased because patient responsibility in self-care and personal health has not only been promoted, but demanded by the growing health workforce shortage. Enforcing this notion is the fact that more and more prescription drugs are being deregulated to over-the-counter (OTC) sales, negating the need for both pharmacist and doctor intervention. There has also been an increase in competitive promotion of self-medication products and cross-border sale via the Internet.

The take home message, so to speak, for both patients and healthcare providers is that self-medication increases access to drugs, which in turn can contribute to improving public health. What are imperative to this process however are joint efforts by industry and regulators guaranteeing that self-medication products meet the expectations of consumers: products must be safe, effective and accompanied by good information.

Transparency to processes

The standard process is that medicines are approved as being acceptable for self-medication by national drug regulatory authorities, but there are still countries in which classification is either not done or not implemented. Such medicines are normally used for the prevention or treatment of minor ailments or symptoms that do not justify medical consultation. In some chronic or recurring illnesses, self-medication is possible after initial diagnosis and prescription.

Drugs authorized for self-medication will vary from one country to another – depending on the existing health-

care system and social and economic factors. Criteria for selection are common to all and should be based on demonstrable efficacy and evidence of a wide margin of safety. The criteria and process of selection should also be fully transparent.

Germany was the first country to switch a triptan from prescription only to an OTC-medicine. Triptans are highly specific towards alleviating migraine pain and they have a high-level of safety. During the process many authorities protested that migraine symptoms can not correctly be diagnosed by OTC patients. However, the German Expert Committee for Prescription and German Government jointly disagreed, stating that patients with re-occurring migraine are able to manage their attack (stipulating that patients with first migraine symptoms need to be diagnosed by a doctor).

Since the switch in April 2006, there have been no reports of serious side effects, accidents or abuse. Germany is preparing to switch a second triptan to OTC status soon, setting important precedents for other countries.

Patient Safety through more and better information – the ultimate goal

Self-medication drugs should be provided with labels and instructions that are accurate, legible and clearly understandable. They should include complete information on the drug content, indications for use and for stopping use, recommended dosages, warnings against unsafe use or storage and warnings against drug interactions. Every attempt should be made to ensure the appropriate use of self-medication and to guard against any unacceptable risks it may entail.

Various types of information are needed by consumers to ensure the safe, effective and rational use of drugs in self-medication. The advice to the patient should present the use of the product without medical supervision and the circumstances when referral for medical advice is necessary.

High ethical standards should be applied for providing information as well as for promotion and advertising. The content and quality of information as well as information communication remain the key issues.

Patient safety should be at the top of the agenda for pharmacists and multi-disciplinary health care partners. As such, it is clear that more efforts are needed to educate consumers about responsible self-medication in parallel with the ongoing development of pharmacists' skills necessary to support patients' self-care and self-medication. ■

Critical issues in self-medication:

- Safe use of drugs
- Avoidance of delay in diagnosis and treatment
- Appropriate consumer information
- Avoiding interactions
- Promotion practices in media
- Excessive and non-medical use
- Drug dependence/reliability
- Assurance of rational use of drugs.

Reference: WHO

The following list is a sample that should be adjusted to meet the needs and abilities of the consumer:

1. International Non-proprietary Name (INN) of each substance in the product.

2. A brief and simple description of pharmacological effects and mechanism of action.

3. Clinical information:
   a) Indications: whenever appropriate, simple diagnostic criteria should be provided.
   b) Dosage regimen:
      - average and range for adults and children
      - dosing interval
      - average duration of treatment
      - special situations, e.g. renal, hepatic, cardiac, or nutritional insufficiencies that require either increased or decreased dosage or special precautions
   c) Contraindications for use
   d) Precautions and warnings (reference to pregnancy, lactation, etc.)
   e) Adverse effects (quantify by category, if possible)
   f) Drug interactions, including the effects of alcohol use

4. Pharmaceutical information
   a) Dosage forms
   b) Strength of dosage form
   c) Excipients, including substances causing allergic reactions
   d) Storage conditions and shelf-life (expiry date)
   e) Pack sizes

Reference: WHO

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Stopping the Most Avoidable Risk

Curbing the tobacco pandemic

The evolving, imperative role of the pharmacist

Tina Brock, Tana Wuliji, David Taylor

The early stages of the global tobacco pandemic were associated with the beginnings of greater wealth and a rapid spread of the smoking habit in relatively advantaged communities. Its end stages are seeing tobacco use increasingly concentrated in relatively poor, less educated and more vulnerable populations. Tobacco use remains the single greatest avoidable threat to public health worldwide. Without more effective action to control tobacco use and support quit services, smoking will kill in the order of a billion people in the 21st century. Research shows that community pharmacy-based smoking cessation services can be cost-effective and reach uniquely into communities, in particular in those with limited access to other health services. The value of pharmacy-based smoking cessation services has been demonstrated in North America, Australasia and the European Union. Nations such as China, India and Malaysia are also beginning to test the impact of such efforts. But all nations need to develop further their approaches to support citizens' efforts to stop smoking, and through the provision of quit medicines and behavioural counselling the profession of pharmacy is positioned to be able to contribute immensely.

To highlight these opportunities, The University of London School of Pharmacy and the International Pharmaceutical Federation (FIP) launched a joint report entitled "Curbing the Tobacco Pandemic: The Global Role for Pharmacy" and hosted an associated discussion session during the 68th International Congress of FIP. The report, authored by Dr Tina Brock, Ms Tana Wuliji and Professor David Taylor, includes case studies from a global survey of tobacco use cessation activities coordinated by pharmacists worldwide and is available electronically for download from http://www.fip.org.

The final recommendations of this report include the following:

- Governments and other stakeholders in better public health should work globally to ensure that due emphasis is placed on tobacco cessation service provision;
- all health professionals should recognise the importance of tobacco use as worldwide threat to health, partnering with public and private groups to promote tobacco cessation;
- pharmacy leaders should encourage appropriate investments in professional training to allow pharmacists to play a full and confident role in ending the global pandemic of tobacco-related harm and
- members of the public seeking to take a responsible approach to community-wide public health should support the provision of universally available quit products and services.

The Congress session included experts from around the world discussing cultural constructs of tobacco use, challenges in harm reduction in developing countries, strategies for training the pharmacy workforce to provide cessation services and implementation of the WHO Framework Convention on Tobacco Control (FCTC), the world's first public health treaty. After an overview of FIP's involvement in pharmacy-based smoking cessation activities (by Ms. Wuliji), Professor Taylor summarised the report findings, challenging the audience to resolve any professional uncertainties about the safety and overall value of nicotine replacement therapy (NRT) and other stop-smoking medicines that may serve as a barrier to improving the quantity and quality of quit services provided globally. Following this, Dr Jiang Yuan from the National Tobacco Control Office in Beijing discussed data suggesting that the personal smoking patterns of Chinese health professionals influences their attitudes and behaviours towards provision of quit services for their patients. China is the world's largest tobacco producing and consuming country, accounting for more than a third of the global total on both counts and Dr Jiang acknowledged that improved access to quit medications and pharmacy-based cessation services could complement recent control efforts such as the impending ban on tobacco advertising.

> *"Tobacco use remains the single greatest avoidable threat to public health worldwide"*

Dr Terry Maguire, from PharmacyHealthLink, then discussed cessation results from a nationally funded program established in the United Kingdom, specifically targeting practices that might be transferrable to the developing world. Using this model, more than 70% of pharmacies in Northern Ireland currently offer quit services and during the first three months of 2007, more than 5000 weeks of NRT had been provided to patients within the pharmacy scheme.

Following this, Dr M Haniki Nik Mohamed from the International Islamic University in Pahang, Malyasia discussed how the Malyasian Pharmaceutical Society had trained about one-third of community pharmacists in the country with the knowledge and skills to help smokers quit. Their three-step Certified Smoking Cessation Provider program represents a successful example of collaborative health promotion among the NGOs, health professionals, government and the private sector. This was complemented by Dr Karen Hudmon's presentation of the seven-year impact of the federally-funded Rx for Change

program which used a comprehensive 'train the trainers' system for pharmacy faculty to target professional students across the US. Dr Hudmon, of the Purdue University School of Pharmacy in Indiana (USA), says that nearly 25,000 pharmacy students have now completed the training and invites international schools to review and adapt the evidence-based materials available for download at http://rxforchange.ucsf.edu.

Mr M V Siva Prasad Reddy, Executive Secretary SEARPharm Forum, discussed the fact that tobacco use is entwined closely with Indian culture, with more than 5 million child smokers in the country. Mr Reddy also suggested that because around 86% of tobacco sales in India consist of chewing tobacco, beedi and gutkha, counselling patients regarding cessation often requires pharmacists to use different strategies as compared to those for conventional cigarettes. Despite these challenges, however, Mr Reddy highlighted the successes from several pharmacy-based cessation initiatives in India.

Following a series of interactive questions posed from the audience and facilitated by Dr Brock, Ms Lynne Elliott of the International Non Governmental Coalition Against Tobacco explained the development and the implications of the FCTC as well as specific opportunities for the profession of pharmacy to contribute to enhanced tobacco control policy and quit services around the world.

In the final analysis, the speakers all acknowledged that when considering how best to proceed with global tobacco cessation efforts, each nation's immediate developmental priorities must be respected. Still, the evidence is overwhelming that in virtually all but the poorest of the modern world's nations, tobacco smoking is the biggest single avoidable risk to health and tobacco cessation support is one of the most cost-effective of health investments. In this way, helping individuals to stop smoking represents a bridgehead to extending pharmaceutical care in other emerging 21st century problem areas, such as obesity, diabetes and cardiovascular diseases, in developed and developing economies alike. ■

For information about getting more involved with pharmacy-based tobacco cessation efforts, see http://www.fip.org/projectsfip//pharmacistsagainsttobacco/

Do You Know Anecdote From Evidence?

The quality of online health information

Ellen Diedrichsen

It is undeniable: the internet is a widely used resource for health information. This health information available exists in many forms, from journal articles to consumer blogs, health care associate sites to online pharmacy stores; the quality of the information available is as varied as the medium of the internet allows. But how do consumers use the internet and how are we as health care workers influenced by the internet? Can we tell the difference between good and bad drug information available online? These are the questions the FIP Pharmacy Information Section and the Young Pharmacists Group sought to answer during the FIP Congress in Beijing.

Eighty percent of consumers use the internet for health information, with 95% of physicians using the web for information about diseases. Over half consumers and over 90% of health care providers use Google as their primary search engine. In two paediatric studies, as presented by Gerald McEvoy, USA, searches regarding the management of fever and diarrhoea/dehydration were conducted. The search results yielded a variety of information and misinformation. In both studies, misinformation was commonly identified, while appropriate management was buried within the searches, not easily identified. These two cases highlight the need for quality assurance. But what is the best approach?

The drive to quality assurance for medical information began in the mid to late 1990's. The initial effort for quality monitoring was to assess the quality of individual web-

pages looking at authors, sponsors, source of content, confidentiality clauses and content updates. However, of the various accreditation organisations that started, only the Health on the Net Foundation (HON) out of Switzerland remains. The HON code focuses on authoritative, stated purpose that complements but does not replace physician, privacy/confidentiality, content documented, health claims justified, detailed website contact information, financial disclosure and advertising policy. With new websites and information available daily, accrediting each site individually becomes a daunting, if not an insurmountable task.

Instead of focusing on accrediting each site individually, the new focus is on prioritizing results from search engine searches. In this case, when a search is conducted in Google for health information, the most relevant and appropriate information would come to the front. For example, if a search is conducted on management of diarrhoea in infants, management guidelines from the most reliable sources such as the American Academy of Pediatrics, the WHO and WebMD, to name a few, would come to the top of the search results. This would reduce the time required in a search to identify appropriate information and reduce the likelihood of providing misinformation to patients. Regardless of the quality assurance measure adopted, it needs well-established quality criteria, wide-spread adoption/application, an educated, interested and active consumer, credible enforcement and a sustainable model.

Challenges facing the accreditation task apply to both search engines and accreditation groups. Consistent quality definitions, language, terminology, and readability must be agreed upon. Information available must be current and requirements enforced. Health care providers must accept their role as intermediaries of health information quality.

Producers of health information must accept the burden of the responsibility of posting online information. Consumers must accept their role in understanding and interpreting online health information. Implementing programs may be quite costly; the program must be realistic and sustainable, allowing substantial room for growth of internet resources.

With the advent of web 2.0, the internet will explode as a resource. As practitioners, increased communication regarding not only current health information, but also current medical internet technology could be equally beneficial. It is imperative that all pharmacists understand the quality assurance measures that are in place as well as the limitations of these checks to provide appropriate medication information to our patients. ■

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Where Does the Medicine End Up? **The environment tells the story**

Edward O. Amporful

Expectedly focused on the inward effects of pharmaceuticals, their effects, side effects and how pharmacists relay such information to the patient, the FIP Congress this year took a step in a different direction with a Session on Pharmaceuticals in the Environment. Chaired by Astrid Kågedal of Apoteket AB, Sweden and Erich Sturzenegger of Novartis, Switzerland, the Session brought forward somewhat eye-opening revelations on the potential of pharmaceutical waste on the environment; a timely view at pharmacy and the pharmaceutical sciences considering the announcement from the WHO that World Health Day 2008 will focus on health, climate change and the environment.

Presenting on 'Pharmaceuticals and the Environment' Prof. Klaus Kummerer from the Institute of Environmental Medicine and Hospital Epidemiology, raised serious concerns about the environmental effects of pharmaceuticals. About one million tonnes of pharmaceuticals are used annually in the world today. This comprises substances/agents of varying pharmaceutical classes such as anti-inflammatory agents, lipid lowering agents, pain killers, antibiotics, anti-depressants, anti-neoplastics, etc. There is potential contamination of the air, water and soil through volatile compounds and agents used as human or veterinary medicines. Detection of these contaminants could be through periodic assaying of air, water sources/bodies (hospital effluent, waste water, rivers, ground water, drinking water).

Pharmaceuticals are special agents designed for bioactivity and stability. They are complex molecules with several different functional groups and consequently can be harmful to the ecosystem – bacteria, algae, fish, daphnids,

etc. This calls for risk assessment in the design of new pharmaceuticals, measuring the ratio of predicted expected concentrations (PEC) to predicted no-effect concentrations (PNEC) in the environment.

There are various strategies (short, medium, long terms) to reduce the risk of PEC on the environment.

Short-term risk management strategies include efficient treatment of effluents; medium term risk management strategies include information dissemination, training and education, holding of small stocks, reduction of product diversity, use of alternatives, avoidance of dumping unused medicines in drains, rational drug use, national and international surveillance and new approaches to drug development (drug targeting, drug delivery on site, etc). Long term risk management strategies focus on the design of readily degradable molecules.

Throughout the Session, in an exposition on "Drug residues in the environment: Levels and risks" Ake Wennmalm gave an over-view of pharmacokinetics of drugs - absorption, distribution, biotransformation and excretion. Several non-metabolized pharmaceuticals entered the aquatic environment via Sewage Treatment Plants (STP). Currently, many STPs lack specific processes to eliminate drug residues and other biologically active chemicals as shown by data from India, USA and several European countries. Drugs analysed included pain killers, psychotropics, NSAIDs, beta-blockers, calcium channel blockers and anti-microbials.

Such substances pose harm to fish and other aquatic organisms through impaired reproduction and changed behaviour; bioaccumulating drugs may reach humans via consumption of fish, shellfish, and other aquatic organisms; drug residues and metabolites may reach humans via drinking water; unknown effects of prolonged exposure to low concentrations of drugs; lack of methods to evaluate possible existence of such effects.

It was stressed that in studying the effects of pharmaceutical residues on the environment it is better to abide by the precautionary principle of being proactive than reactive. Risk assessment was based on the ratio of predicted environmental concentration (PEC) to predicted no effect concentration (PNEC). PEC:PNEC less than one (1) was generally good while PEC:PNEC greater than one (1) was not. Another risk assessment tool was based on the Stockholm County Council system which measured the Persistence (P), Bioaccumulation (B) and Toxicity (T) of the drug: PBT.

In presenting on "Environmental classification of drugs", Bo Gunnarson from Apoteket AB, Sweden, recounted the various players contributing to the issue of pharmaceuticals in the environment – scientists, drug producers, approval authorities, reimbursement authorities, prescribers, purchasing health care sector and patients/consumers. Reference was made to two approaches in environmental classification of drugs;

i) **Hazard classification** (Stockholm model) which was linked to the chemical, physical and toxicological properties of the drug in terms of its persistence (P), bioaccumulation (B) and toxicity (T) and

ii) **Risk classification** (Swedish model) which was linked to the ratio of predicted environmental concentration (PEC) to predicted no effect concentration (PNEC). This model defined risk under three levels- patient, prescriber and specialist:

Patient level risk made the ensuing considerations;

- **PEC/PNEC <0.1**
  meant use of medicine resulted in insignificant environmental risk
- **0.1 < PEC/PNEC <1**
  meant use of medicine resulted in low environmental risk
- **1 < PEC/PNEC <10**
  meant use of medicine resulted in moderate environmental risk
- **PEC/PNEC >10**
  meant use of medicine resulted in high environmental risk

Prescriber level risk combines all the considerations in patient level risks in addition to the following factors:

- Details of the PBT classification for the active substance of the drug.
- If there was insufficient data to characterize the potential for degradation or bioaccumulation, information given was that the potential for persistence or bioaccumulation could not be excluded due to lack of data.

Specialist level risk referred to detailed environmental data on the product such as results from ecotoxicological tests; results from degradation tests; results of CMT test (carcinogens, mutagens, teratogens), together with details of the potential for endocrinal disturbance; pharmacological activity of the metabolites; total quantity (kg) of sales in Sweden of the active substance (to include all products with the same active substance); and calculation of risk assessment.

Anne Niquille from the Swiss Association of Pharmacists traced the causes of left-over medicines. These included patient's death, change in the prescription, poor medication adherence, poor packaging and repeated medication without checks on home stock(s). More than 50% of such unwanted medicines were disposed of through the trash cans followed by flushing down sewage systems. In various pharmacy return programs, two-thirds were found to be prescription medicines, under-scoring the issue of waste in the health care delivery system.

The community pharmacy and pharmacists could be of immense help in programs geared towards collection of unwanted medicines, providing patient information, preventing wastage.

Representing the pharmaceutical industry, David Taylor from Astra-Zeneca explained the approaches being employed to curb the detrimental environmental effects of drug production and waste. Such measures include control of emissions from manufacturing plants, comprehensive programs for collection of unused medicines (compulsory in the European Union) and environmental risk assessment of all new molecules using a blend of proactive and reactive approaches.

There is close collaboration with other players in the pharmaceutical industry to better understand how drugs are removed in waste-water treatment; prediction of the fate of drugs in the environment; how the ecotoxicity of drugs could be inferred by data from mammalian studies; and prediction of the chronic impact of 'atypical' drugs.

The ultimate goal is towards attaining 'greener pharmacy' where the needs of patients coincide with that of the environment, characterized by 100% oral absorption (lower emissions from patients), disease receptor specific (no impact on healthy receptors), no effects other than ther-

apeutic (no non-target effects), metabolized in patient to inert substances (release of only inert residues), and effectiveness in all patients treated (produces lower overall drug usage).

The issue of pharmaceuticals in the environment is one which is increasingly engaging the attention of governments, policy makers and as evident from the WHO, international institutions. While efforts are being made to develop safe and environmentally friendly products it is imperative that measures are taken to safeguard the environment from the harmful effects of available pharmaceuticals. Good pharmacy practices such as rational drug use, patient medication reviews and patients counseling and pharmacy-led initiatives through return drugs programs and public education of proper drug disposal, are all critical in ensuring a safe environment. ■

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Validating the Anecdotes

WHO/FIP workshop on herbal medicines

Edward O. Amporful

The FIP Congress in Beijing, and its accompanying theme, From Anecdote to Evidence, helping patients make the best use of medicines was an invitation to examine not only current and future pharmacy practices and their stock of medicines, but also an open door to discuss the thousands of years of medicines history that have laid the foundation for contemporary treatments and services. As such, FIP, in collaboration with the World Health Organization, held a joint workshop on traditional herbal medicines, with the goal of better practitioner understanding of products that are still today hugely impacting global medicines markets and patient care.

In chair for this important workshop was Dr Zhang Xiaorui, the coordinator for Traditional Medicines Department of Essential Drugs of the World Health Organization (WHO). She was ably supported in this duty by Prof. Charlie Xue from the WHO collaborating centre for Traditional Medicine in Australia.

Presenting on 'WHO global survey on national policy on traditional medicines(TM) and regulation of herbal medicines' she gave an overview of the global traditional medicines market with special emphasis on China. The Chinese herbal market is reputed to be over $14 billion, accounting for about 24% of the entire global market of traditional medicines. The export component of this market is about $830 million.

The market is also growing in USA and Japan as well as in Europe, particularly in France and Germany. In developing countries such as Africa herbal medicines constitute a key component of health care for people. Considering many herbal medicines are available as over-the-counter (OTCs) preparations, this justifies the need for education and training of pharmacy practitioners.

The WHO has been trying to coordinate global policies on herbal medicines, but this has been fraught with challenges such as lack of research data, lack of appropriate central mechanisms, lack of education and training, lack of expertise, wide diversity of flora and varied cultures of herbal medicine practitioners and users. As such, there was the need for member countries to share information on regulatory issues, safety and guidelines on herbal medicines.

The WHO strategies on herbal medicines include policy development, guidelines on safety, efficacy, quality and access and promotion of rational herbal medicines use. This has resulted in the formation of International Regulatory Cooperation for Herbal Medicines (IRCH) with its first meeting being held in Beijing, China October 2006, with Ghana proposing to host the next IRCH meeting. The IRCH is currently made up of eighteen member countries and nine observer countries covering five regional/sub-regional groups.

The WHO views the preparation of monographs on medicinal plants as critical in its quest to ensuring the safety, efficacy and quality of herbal medicines. But so far it has been able to prepare monographs for only one hundred and twenty (120) medicinal plants, and is therefore encouraging individual countries to develop their own monographs.

Also brought to the table during the workshop was the introduction of new anti-malarial drug policies owing to increasing resistance of plasmodium to monotherapy drugs. The new policies emphasize artemisinine combination therapy (ACT); China is the main source of this medicinal plant and efforts are underway to cultivate it on a large scale in developing countries (especially Africa) in a bid to increase access to the drug.

As agreed by Dr Zhang Xiaorui, in Ghana in spite of the WHO recommendation for artemisinine combination therapy as first line in the treatment of malaria, Cryptolepis sanguinolenta based decoctions were widely used for malaria treatment. This had been shown to be highly effective in clearing the plasmodium parasites. With adequate research funding it should be possible to develop appropriate dosage forms for all sections of society, especially children under five who carry the heaviest malaria burden.

Dr Zhang stressed the need for education and training and a shift from folklore so as to bring herbal medicine in sync with other medical practices. Countries such as China, which has formalized the education and training of herbal medicine practitioners, are reaping tremendous benefits. Training is critical in removing the barriers and suspicions in the practice of herbal medicine. It is important to direct the educational and training programs towards diagnosis, prescription, dispensing and distribution of herbal medicines, as it is only through training that consumers could be guaranteed the safety, efficacy, quality and appropriate information on the use of herbal medicines.

Supporting these notions, Prof. Zhang Bing from the University of Beijing, China went on to present on 'Educating pharmacists and the public on safe use of Chinese Herbal Medicines'. She defined Chinese medicines as *drugs that prevent and treat diseases*. Within the traditional realm of explanation, Chinese medicines have components and in the main dwell on restoring the balance between the 'yin' and 'yang' of the body, so as to reach a new state of harmony. Consequently, Chinese medicines are used to improve sub-health states, in addition to treating diseases of the immune system and other chronic conditions.

The success or acceptability of Chinese medicines in China and beyond could be due to its low cost, efficacy, convenience and ready availability. The problems associated with use of Chinese medicines normally stem from use which deviated from the fundamentals of Chinese medicines.

This demonstrated the importance of education on safe use of Chinese medicines in both forms, public and professional. Public education requires general health education and 'over the counter' use of Chinese medicines. Professional education itself was also of two forms, one leading to licensure of pharmacists (Diploma training) and the other being a continuing education program. There are thirty-two universities and colleges offering undergraduate training in Chinese medicines. Of approximately 144,000 pharmacists in China, one third are experts in Chinese medicines and two-thirds experts in Western medicines. The pharmacy training in China allows close collaboration between Western and Chinese medical practices.

Presenting on 'Chinese material medica education in Singapore', Mr. Lee Tiong Sa from the Traditional Chinese Medicine (TCM) College, Singapore, explained the basis for the establishment of the institute, not the least of which was the fact that out of the 4 million population of Singapore about 77% were Chinese and used Traditional Chinese medicine (TCM).

It is therefore important to have a formal system of training professionals to prescribe, dispense and use these preparations in Singapore. The Singapore TCM Organizing committee (STOC) was formed in 1995 with the CMM Professional Training Study group being established in 2001.

The Chinese Material Medica (CMM) college of Singapore works in close collaboration with the Beijing University of Chinese Medicine. There is currently a student enrolment of one thousand with three hundred at the intermediate levels and one twenty en route for their professional diplomas.

In presenting on 'Herbal medicine practice: regulation, education and safety', Prof. Charlie Xue, from the WHO Collaborating Centre for Traditional Medicine, Australia drew on the experiences from Safe Access to Raw Herbs in the state of Victoria, Australia. Factors contributing to safety could be found in standardised education, practitioner registration, herbal scheduling and means of dealing with complaints. It is therefore necessary to institute structures to govern and control herbal medicines as has been done for Western medicines.

It is hoped that with these measures a growing comprehension of traditional medicines as well a fuller understanding of their use, effectiveness and safety profiles can be achieved by both practitioners and patients. ■

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Borne out of necessity in the recognition of increasing patient use of complementary and alternative medicines together with those that are considered in the realm of "Western" practice, the FIP Congress in Beijing hosted a timely forum on the concurrent use of both, with the aim of informing and helping pharmacists best manage such patient medication profiles.

A Comprehensive Future

With conventional, complementary and alternative medicines practice

Edward O. Amporful

Chaired by Robert DeChristoforo (USA), the session welcomed insights from invited speakers on how such treatment choices are posing new challenges to pharmacists in ensuring that both safety and efficacy of both types of medicines are upheld. Furthermore, these scenarios are demanding that pharmacists attain a much broader comprehension of a "medicines set" that may not be thoroughly taught in many pharmacy curricula.

Presenting on "How can complementary and alternative medicines co-exist with conventional medicines?' Dr Laura Shane-McWorther from the University of Utah, USA, defined conventional medicine as "western, allopathic, scientific or modern medicine". Complementary and alternative medicine is the broad set of health care practices that are not part of a country's own tradition and not integrated into the dominant health care system. It is also generally referred to as *natural* or *holistic* medicine.

Currently, the most popular complementary and alternative medicines (CAM) in the USA are Echinacea, Ginseng, Ginkgo Biloba, Garlic, Glucosamine ± chondroitin, St. John's Wort, Peppermint, Fish oil/omega fatty acids, Ginger and Soy.

According to WHO, approximately 80% of the world's population relies on herbal therapies. Dr Shane-McWorther commented that the only way to derive desired synergy from the co-existence of Conventional and CAM is through ▸

responsible integration. In reference to those medicines derived directly from plant sources, it was noted that there should be an increased drive towards evaluating all known plant species and substances in use as CAM and that it is important to apply the standards used in the development and use of allopathic medicines to CAM. This will guarantee their safety, efficacy and appropriate usage as well shed light onto CAM-drug interactions and CAM-disease interactions. The choice of CAM for a patient also depends on clinical conditions and specific patient factors (ie weight, age, renal function, hepatic function, etc).

Serious and significant interactions between St. Johns Wort and warfarin, statins, digoxin, cyclosporine and ethinyl oestradiol. **Antagonistic interactions** between Kava and Parkinson's disease.

Health systems must also be resourced to train health care providers on CAM, as education is critical to both health care providers and consumers. To this end formularies on CAM should be established to guide its use by all stakeholders. In turn, regulatory agencies must be strengthened to specify guidelines on GMP, safety, efficacy and quality of CAM. Quality issues which need to be noted include contamination/adulteration, misidentification, mislabeling and counterfeiting. The time of harvest also has implications on product content.

The increasing use of CAM has led to the emergence of a new health care system called Complimentary and Integrative Medicine. Presenting on "Who will pay for complementary and alternative medicines?', Dr Jeff Poston from the Canadian Pharmacists Association, Canada, noted that CAM was either used **with** conventional medicines (complementary) or **in place of** conventional medicines (alternative). Some types of CAMs in use were Whole Medical systems (homeopathy, naturopathy, Traditional Chinese medicine), Mind-Body medicine (meditation), Biologically-based practices (use of natural products, herbs, etc), Manipulative & Body-based practices (chiropractic, massage therapy) and Energy medicine (gi gong Reiki).

Dr Poston revealed the prevalence of use in developed health systems (36%, 20% and 10% in the USA, Canada and the UK respectively) yet stressed that in spite of these statistics there are still no provisions/claims made for CAM under the various health insurance systems.

The contending issues are centred on both health and cost benefits, namely measuring the clinical effectiveness of CAM, assigning the appropriate economic value to CAM and the level of funding (or claims) that should be allocated to a CAM product.

Measuring clinical effectiveness requires an evidence-based approach with requisite funding of such research, as is done with conventional medicines. Evidence-based medicine (EBM), the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients, is crucial in treatment and funding decisions.

A true integration of CAM products into conventional health settings requires funding under health insurance systems, which itself requires consideration of individual cash, income tax credit, private insurers and public health insurance systems. Ultimately, re-imbursements for CAM under health insurance would be based on the increasing use of CAM, practitioners' advocacy, better evaluation and established economic value of CAM.

Dr Zuguang Ye from the Chinese Academy of Traditional Chinese Medicines (TCM), China, showed the extensive work done by the academy to evaluate and define the various TCMs through scientific methods. He referred to the

monographs on TCM and the applications of these agents in clinical practice. Education and training of health care providers had been very critical to the safe use of TCMs.

Presenting on the 'Social, economic and public policy issues and the future use of complementary and alternative medicines', Dr Torkel Falkenberg stressed that traditional medicines (TM), and CAM were widely and increasingly being used in all regions of the world. The global market

> *"the **process** of health care is equally as important as the **outcome**"*

for these was about $60 billion with growth rate of between 5-15% per year. In the USA, spending on CAM stood at approximately $30 billion per year; more than out-of-pocket expenses on conventional treatments by primary care physicians. Out of China's $41 billion pharmaceutical market, 26% is represented by Traditional Chinese Medicines (TCMs) alone.

Dr Falkenberg highlighted inherent challenges to CAM use, including lack of or inadequate sound scientific evidence, research efficacy, proper use, organised networks, training and licensing of practitioners and lack of cover by various health insurance policies. Common risks associated with CAM are the prevalence of unqualified practitioners, missed or delayed diagnosis, stoppage or refusal of effective conventional treatment, waste of funds on ineffective treatments and adverse effects and interactions from treatments. These challenges need to be addressed in line with evidence-based health care considering the high and increasing patronage of CAM across the globe.

He noted that the world was now in the era of post modern medicine where social concerns and trends impact on health care practices and the process of health care is equally as important as the outcome. The upsurge in the use of CAM should therefore be seen as a consequence societal demands. What needs to be done, however, is to harness the synergies between modern and CAMs through integration.

China remains one of the only four countries recognised by the WHO as having a fully integrated, conventional and complementary and alternative medicines health care system.

The USA currently has over four hundred programmes for integrative medicine. Some basic yet imperative principles of Integrative Medicine (I.M.) are partnership between patient and practitioner; consideration of all factors that influence health, wellness, and disease including body, mind and spirit; a philosophy that neither rejects conventional medicine nor accepts alternative medicine uncritically; and recognition that good medicine should be based on good science, inquiry driven and open to new paradigms.

It is key for the rest of the world to draw lessons from the Chinese model to facilitate social, economic and public policies for the fusion of conventional and complementary and alternative medicines. It is clear that provisions need to be made in currently available health systems for CAM, and that Western health care providers, including pharmacists, need to embrace evidence-based CAM in their health care systems in other to derive the desired synergy for the optimum health of the patient. ■

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The Future of Pharmacy

Will current priorities ultimately bear success?

Ema Paulino

Community pharmacists face a number of new challenges and opportunities. No matter where in the world community pharmacists are practicing, issues such as collaborative practice (or prescribing pharmacist in UK), deregulation of the pharmacy sector, leadership and succession, and the role of the pharmacist are being discussed.

With the goal of diving into these issues and surfacing with tangible conclusions, the FIP Community Pharmacy Section, the Young Pharmacists Group and the International Pharmaceutical Students' Federation hosted a symposium at the FIP Congress Beijing. Brought together were policymakers, practicing pharmacists as well as future professionals in an open debate about the future of the profession.

Collaborative Practice

With the right to prescribe initial therapy and/or to adjust ongoing therapy, pharmacists in some countries have recently seen their role critically extended. There are challenging opportunities ahead, which will certainly have an impact not only on pharmacists' work, but also on public and policymakers' perception of pharmacists.

David Pruce, director of practice and quality improvement at the Royal Pharmaceutical Society in the UK, and co-chair of the FIP Working Group on Collaborative Practice, initiated his presentation by taking us through the two different types of pharmacist prescribing. While collaborative or supplementary prescribing incorporates restrictions on the prescribing activity, as determined via protocols or formularies, independent prescribing does not imply a written agreement. However, this does not mean that decisions are completely autonomous. Rather, they are usually part of collaboration with other healthcare professionals and patients themselves.

Dr Pruce challenged participants to reflect on what this advanced clinical role for the pharmacist may implicate. Will it become routine? And furthermore, does this mean that pharmacists will have to give up on other activities? Many of these questions remain unanswered, as this new function slowly matures in the profession. Importantly, at the outset, issues such as education and training for pharmacists, as well as ethical implications to the profession have to been considered. Ensuring the profession is technically and ethically capacitated to take on new responsibilities is crucial and helps in facing important barriers, namely reactions from other stakeholders. Dr Pruce exemplified with the initial reaction from doctors in the UK, who claimed that giving pharmacists the right to prescribe was irresponsible and dangerous. However, six months later the British Medical Association said it had relaxed its "opposition" because of the "stringent" lines of accountability and training being introduced by regulators.

> *"What do patients want? Should pharmacists place patient needs above their own needs and wants? Have the risks and benefits of regulation been clearly defined and understood?"*

To face this new challenge, pharmacists will not only have to possess extensive knowledge of medicines and medicines use, but also have a good understanding of clinical processes involved in diagnosis and assessment of patients, as well as interpretation of test results. Furthermore and of the utmost importance, pharmacists have to be in a collaborative relationship with the other members of the healthcare team, initiating and maintaining effective channels of communication.

Further challenges remain ahead, such as access to medical records, the possibility of undertaking or ordering tests, and also finding the time and appropriate facilities to undertake patient counselling. Dr Pruce concluded saying that "Prescribing is not a goal in itself. It is just a tool used by clinicians".

Deregulation of Pharmacy

Patrick Reid, from the Pharmacy Guild of Australia, dealt with this challenging second topic. In the past few years, many countries have seen liberalisation of community pharmacy ownership and establishment. Some countries have introduced regulations, while in others such regula-

tions have never existed. How does regulation/deregulation of community pharmacies affect the profession and the way young pharmacists and students perceive their future as community pharmacists were the objects of his presentation.

Mr. Reid started by defining deregulation as "the reduction or elimination of government power in a particular industry, usually done to create more competition within the industry". Several purposes for different types of deregulation have been pointed out, such as improving patient choice and convenience, improving access, reducing demand on doctors and hospitals, improving quality assurance, reducing health inequality and introducing economic reforms such as drug cost containment and patient cost containment measures.

During his presentation he pointed out the different issues that have to be considered in deregulation. These cover areas related to ownership as well as economic, accessibility and professional issues. He left three main questions for the audience to reflect upon. What do patients want? Should pharmacists place patient needs above their own needs and wants? Have the risks and benefits of regulation been clearly defined and understood? And finally, is deregulation more than just an economic, emotional or professional argument? The speaker concluded his presentation stating that patient outcomes should be the focus of pharmacists' activities. Governments will no doubt continue to attempt to reduce drug budget costs and in the process pharmacists may be 'priced out'. Therefore the profession has to prove it has the ability to service patients as well as contribute to the development and sustainability of healthcare systems.

Leadership and succession

The third topic posed the question whether we are actively preparing the next generation of community pharmacists. Tana Wuliji, Project Coordinator at FIP, and a young pharmacist herself, believes that young pharmacists and pharmacy students should be recognised as professionals rather than viewed as an unavoidable future. She introduced a series of concepts significant to the topic at hand: sustainable leadership, social entrepreneurship, and social networks.

The 2006 FIP Global Pharmacy Workforce and Migration Report enlightens global shortages of pharmacists, particularly due to workforce distribution imbalances between rural and urban areas, and between public and private practice. It shows there is an increasing migration within and between countries, partially due to poor skills utilisation and recognition, and it foresees a leadership gap in 5 to 10 years.

> *"is deregulation more than just an economic, emotional or professional argument?"*

Ms Wuliji believes that leadership is about putting qualities into practice: experience, competence, social networks, mentoring, space, self-reflection, openness and honesty, opportunities, strategic vision, drive, and decision making. But it is also about developing leadership by learning from challenges, learning from relationships, training, and assigning jobs.

Ms. Wuliji presented some examples of models where succession was well taken care of: the distributed leadership at the Hospital Pharmacists Association of Kenya (HOPAK), the mentoring database and the leadership pack of the United Kingdom Clinical Pharmacists Association and the Guild of Healthcare Pharmacists, the 'Train the Trainers' programme launched in 2006 by the International Pharmaceutical Students' Federation, and the Ashoka fellowships for social entrepreneurship.

Community pharmacist – the forgotten healthcare team member?

Karen McGill, a pharmacist from the USA and President of the International Pharmaceutical Students' Federation, expressed her views on what the role of community phar-

macists in multidisciplinary healthcare teams is and can be. Ms. McGill argued that pharmacists do not communicate necessary information about patient care to physicians. Similarly, physicians do not communicate with pharmacists about patient care. Pharmacists must take a more pro-active role in patient care, and the speaker emphasized the fact that action must begin from within our profession.

Evidence shows that physicians and pharmacists working together as a team is helpful to patients. However, collaborative experiences are isolated and not disseminated in everyday community pharmacy. Several barriers are mentioned by pharmacists for not collaborating: the quantity of patients and prescriptions, interruptions, the complexity of problems, inadequate staff and poor teamwork.

Ms McGill continued, acknowledging the fact that physicians tend to be resistant to increased responsibility of the pharmacist, whilst patients don't trust or are not aware of what a pharmacist can do. At the same time, pharmacists seem comfortable with their current practice. To move on, pharmacists have to introduce themselves to local physicians, tell others their goals to increase patient care into your daily practice, and continue to challenge the current system.

Another important aspect is that pharmacists are typically reimbursed for the "product" they "sell" and not the information or education they provide. A change is needed, to move from a product reimbursement model to one that incorporates the pharmacists' time and knowledge into fees. There is also a role for Universities, which must provide quality and complete education regarding drug therapy, ensure a basic standard of knowledge for pharmacists and incorporate social skills into pharmacy curricula.

Finally, there is a need to change the current system and workflow. The use of technology should be intensified to obtain access to electronic medical records. Additionally, the pharmacist has to redesign the pharmacy space to accommodate a consultation area.

Karen McGill finished by presenting the results from a recent Workshop on community pharmacy, held at the IPSF World Congress in August 2007. Participants mentioned the existence of a good relationship with patients, by whom the pharmacist is considered the medication expert. However, a not-so-good relationship with physicians was identified, felt as competition and lack of respect for each others' activities. Students affirmed that they want to be recognized as a valued member of a healthcare team, but for that there is a need to change pre and post-graduate education to increase clinical applications of medication use, foster education with other healthcare professionals, include communication skills and increase availability of non-pharmacy courses such as business, management and psychology.

This Session within the 67th FIP Congress was extremely significant. It emphasised major issues facing current practice conditions and moreover raised crucial questions: Are pharmacists working towards the goals that will truly change practice – and healthcare – for the better? Are we properly re-engineering ourselves for the future? The debate continues. ■

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First World Health Professions Conference on Regulation

‘The Role and Future of Health Professions Regulation’

Geneva, 17th and 18th of May 2008

Self-regulation protects the public, defines our professions and is currently under review by many governments. It is therefore imperative that leaders from the health professions consider key dimensions of regulation and formulate ideas that will shape future legislation.

Join the World Health Professions Alliance and their partners when we bring together leaders in health professions regulation to discuss:

- Different models of health professional regulation
- Regulatory body governance and performance
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in cooperation with the World Confederation for Physical Therapy.

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Changing the Rules

The role and future of health professions regulation

David Benton

Professional self regulation has a long and, for the most part, a successful history. Various professions over time have lobbied governments, arguing that decisive steps are needed to ensure that those who wish to call themselves by a particular professional title measure up to the exacting standards of education and practice as well as behaving in a manner concordant with the code of conduct set by the profession. However, some would argue that professional self regulation is at variance with protecting the public. They argue that professions cannot be trusted to act in the public's best interest; they argue that instead, professional self regulation acts in the interests of the profession and therefore needs to change. High profile failures from around the word have resulted in many governments asking questions about the future of professional regulation. The media has often rightly drawn attention to these failures but have frequently drawn unjustified conclusions. In short, based on a single rogue or malicious act they have concluded that the system is a total failure and that the profession as a whole cannot be trusted.

It is true that professionals are now having to work in very different ways – explicitly as part of teams and also often in a much wider range of settings. Demographics are impacting both on the needs of the public that the professions serve as well as the profile of the practitioners. Globalisation presents increased challenges as migration of practitioners and the phenomenon of health tourism places very different pressures on how our professions need to be regulated in the future.

The various professions serving traditional and evolving healthcare needs recognise these challenges. As a result the World Health Professions Alliance(WHPA), in collaboration with the World Confederation for Physical Therapy, are organising a conference on regulation, bringing together leaders in health professions regulation to discuss issues under three main topics: 'Different models of health professional regulation', 'Regulatory body governance and performance', and 'Trade in services and implications for regulation'. These three themes are critical to the future of regulation and unless the professions actively debate these matters and formulate ideas for the future then governments will, often in response to the latest media report, react at best with short term objectives and at worst in a reactive and overly controlling manner that fails to take advantage of the many benefits that self regulation can bring.

The conference will consider the advantages and disadvantages of various regulatory models and how these can facilitate flexible responses to the demands being placed on the professions by health systems redesign. In addition, it is critical, irrespective of the model of regulation, that the public and other key stakeholders have confidence in the governance of the arrangements and that they deliver the necessary results in an open, transparent and accountable manner. Accordingly, the conference will seek to identify best practices in this regard. Finally, the third theme focuses on the issue of trade agreements and the fact that these are often developed without the benefit of input from the very health professionals that will be affected the most. Accordingly, unforeseen patient safety problems can emerge when individuals or services cross borders. Regulators and the profession have a contribution to make if safe effective and efficient trade agreements are to result.

If you believe that professional self regulation has a new and exciting future then it is imperative that you participate in the debate. It is true that the world has changed since our predecessors lobbied for the original legislation that created those bodies that have protected patients and shaped our practice over the past decades. It is undoubtedly true that further changes will take place in the coming years that will test the way that our professions are regulated. The challenge is to refresh the vision, offer new solutions and lead the debate. Join us at the First World Health Professions Conference on Regulation at the International Conference Centre in Geneva on the 17th and 18th of May 2008 and shape the future. ■

For further information, registration details and to submit an abstract visit http://www.whpa.org/reg/index.htm

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It Will Never Happen To Me. But It Could.

Fighting counterfeit medicines from all sides.

Xuanhao Chan

It has been said that there are two kinds of medicine: quick acting and long lasting – and when in pain we have to decide whether we want to feel better now or later.

But there is a third category of medicine, counterfeit medicine with which at best, it will never make you feel better – not now, not later, and not ever. At worst, it will kill you.

According to the World Health Organization (WHO)[1], a counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source and may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients. A counterfeit medical product is not a medical product. Counterfeiting medical products is a serious crime that threatens the health of all, including that of legislators, ministers, inspectors, health care professionals, patients, judges, enforcers, and custom officers; honest and corrupt alike.

Counterfeit medicines are unsafe and ineffective. They result in wasted resources spent on purchasing, inventory, transport and dispensing with little or no effect and may even cause harm to the patient. Counterfeit medicinal products threaten patient safety by, at best, causing no improvement and at worst causing added burden of disease and even death. They endanger public health by increasing the risk of antimicrobial resistance and decrease patients' trust in health professionals and health systems, who are seen as not being able to provide adequate treatment. Public health and patient safety are being put at risk - now is the time to act.

According to the International Medical Products Anti-Counterfeiting Taskforce (IMPACT)[2], it is reasonable to estimate that the prevalence of counterfeit medicines ranges from less than 1 percent of sales in developed countries to between 10-30 percent in developing countries, depending on the geographical area. Very often, we try to seek definite ▶

1) Available from http://www.who.int/medicines/services/counterfeit/faqs/05/en/index.html

2) Available from http://www.who.int/impact/en/

Industry meets regulatory face to face, working together to combat counterfeiting

1st IMPACT! GLOBAL FORUM

International **M**edical **P**roducts **A**nti-**C**ounterfeiting **T**askforce

Using Technology to Combat Counterfeit Medical Products

Technology developers meet manufacturers and regulators

Singapore, **13-15 February 2008**

The International Medical Products Anti-Counterfeiting Taskforce (**IMPACT**) is a voluntary grouping of governments, organizations, institutions, agencies and associations from developing and developed countries. They will join leaders from the pharmaceutical manufacturing and wholesale industries and the world's best advocates for global healthcare, including the World Health Organization at the 1st IMPACT Global Forum with the purpose of working towards the common goal of fighting counterfeit medical products.

The IMPACT Global Forum offers the only international network of multifaceted stakeholders fostering concerted efforts to **stop** counterfeit medicines.

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IMPACT! International Medical Products Anti-Counterfeiting Taskforce

FIP International Pharmaceutical Federation

World Health Organization

numbers of counterfeit cases knowing that it is very difficult to determine the prevalence or patient "kills" due to counterfeit medicines. The rhetorical question is, do we need to know the exact figures? Quoted from Dr V. Reggi, WHO[3], at the recent 67th FIP Congress in Beijing, a rough indication of different prevalence around the world is enough, because even a single case is not acceptable!

This is why each health professional has an imperative role to play in keeping patients safe from counterfeit medicines. The International Pharmaceutical Federation (FIP) is leading the IMPACT Working Group on Communications and more specifically, in risk communications related to counterfeit medical products. In this work, we define risk communications[4] to refer both to the content of any message concerning a hazard and the means of delivering that message. Risk communication can only be considered effective if it alerts the target audience as to what is hazardous, the extent of the danger and what should be done to protect oneself.

As part of the IMPACT Communication Working Group, FIP aims to raise awareness of counterfeit medical products as a threat to public health worldwide in a safe and coordinated way that leads to action. As Pharmacists, we need to educate patients and the general public on what is a counterfeit medicine and among our colleagues in healthcare, the appropriate and efficient reporting systems available for suspected cases.

Globally, FIP provides a platform that reflects and communicates the objectives and actions of IMPACT and all its working groups. In attempting to provoke actions leading to policy change, we advocate key messages that promote appropriate measures to combat counterfeit. These messages include:

"Only get your medicines from known and reliable sources"

"Counterfeit medicines are a threat to personal and public health worldwide"

"When treatment fails, consider counterfeits as possible suspects"

Health professionals need to consider counterfeit medicines as a reason for non-response or unexpected response in pharmacotherapy in the patients they care for. The necessary vigilance of healthcare professions is paramount as often, in most primary care settings, the pharmacist is the most readily accessed health care provider and as such, need to be able to pick up signs and symptoms of our patients and people we interact at the pharmacy.

Together with our colleagues from the World Health Professions Alliance (WHPA), a toolkit has been developed to identify some key steps – "BE AWARE"[5] – for health professionals to fight such criminal practices of counterfeiters and to be accountable for the safe treatment of patients in their use of medicines. This was launched at the IMPACT meeting in Lisbon[6] on the 10th to 13th December 2007.

All agree, however, that to make true headway in this plight multi-faceted, concerted and concentrated efforts must come forth from those bodies that have the most potential in initiating and fulfilling concrete changes: regulators, industry, governments and international institutions. With this as the foundation, FIP will join the World Health Organization in hosting the 1st IMPACT Global Forum in February of 2008. The 1st IMPACT Global Forum is a visionary, first-of-its kind opportunity, initiated and developed under a unique and innovative strategy: invite the leaders in anti-counterfeiting technology to teach and inform decision makers, regulatory personnel and respected health care institutions – individuals who will comprise the participants of the IMPACT Global Forum.

WHO and FIP are eager to bring together all parties to exchange knowledge and improve collaboration amongst national and regional authorities and other key decision-makers. ▶

3) Valerio R.
IMPACT: A WHO initiative to combat counterfeit medical products:
Proceedings of the 67th FIP World Congress of pharmacy and pharmaceutical sciences held in Beijing, China, 2007

4) Breakwell GM.
Risk communication: factors affecting impact. Br Med Bull 2000; 56(1):110-20.
Available from http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uid =10885109&dopt=Abstract

5) Will be made available from http://www.whpa.org
(This acronym has been developed by the WHPA for the purpose of this toolkit.)

6) Available from http://www.impactglobalforum.org

im•pact [the~] /n. ’ĭmpækt;

[noun]:

1) a forceful consequence; a strong effect;
2) influencing strongly;
3) the force exerted by a new idea, concept, technology, or ideology: *the impact of the industrial revolution*;

Government regulatory authorities from at least 18 countries representing developing, transitional and developed economies, leaders from the pharmaceutical manufacturing and wholesale industries and the world’s best advocates for global healthcare will be present, offering the only international network of multi-disciplinary stakeholders fostering concerted efforts to stop counterfeit medicines.

The 1st IMPACT Global Forum will set a global precedent for action against counterfeit medicines. For more information on how to participate, please visit www.impactglobalforum.com

FIP and its dedicated partners recognise that the imminent, rapid growth of counterfeit medicines will only be stopped through global cooperation among legislators, law enforcement units, health, and industry representatives from major countries of the world. It is also under an essential social imperative that all pharmacists as health professions are urged to fight against counterfeit medical products in our daily practice.

The misnomer of “it will never happen to me” is a dangerous one. ■

For more information about FIP’s activities in combating counterfeit medical products, please contact impact@fip.org

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Expanding the Continuum

The future of hospital pharmacy practice

Lee Vermeulen, Satu Siiskonen *and* **Andy Gray** *on behalf of the Global Conference Steering Committee*

The setting of hospital pharmacy practice is unique. The high acuity of hospitalized patients, the high complexity of care and the use of technology are challenges that face hospital pharmacy practitioners on a daily basis. Globally, hospital pharmacists are "supply focused" assuring that the medicines required by patients are available, and of assured quality. In many parts of the world, hospital pharmacists have also taken a much more active role in assuring that medication use in the hospital is as safe, effective, and economical as possible. Pharmacists are engaged as members of the health care team, providing patient care – overseeing the medication administration process, guiding physician prescribing of medicines, educating patients, and importantly, monitoring the outcomes of medication therapy.

However, significant threats exist that may limit the pharmacist's role within organised health care delivery settings. The ratio of pharmacist staffing to hospital patient load varies immensely among countries, influenced by a number of factors. Such factors include the commonly accepted mission of hospital pharmacy within the country and the resources available for health care, hospital care, and health professional education. The extent to which hospital pharmacists are in a position to influence the overall quality of medication therapy varies among countries and even among types of hospitals within a specific country.

The FIP Hospital Pharmacy Section has recognised the need for a clear and well-supported vision on the preferred future of hospital pharmacy practice that articulates **(1)** typical stages of evolution in the development of hospital pharmacy practice and **(2)** practical guidance on how to foster a country's development of hospital pharmacy practice that is consistent with the country's needs.

The Global Conference on the Future of Hospital Pharmacy

The FIP Hospital Pharmacy Section will host a global conference 30-31 August 2008, in conjunction with the upcoming 68th FIP World Congress of Pharmacy and Pharmaceutical Sciences in Basel, Switzerland. The Global Conference is being organised in collaboration with several national and regional hospital pharmacy organizations, including the European Association of Hospital Pharmacists and the American Society of Health-System Pharmacists.

Framework for the Global Conference

Several general concepts will help guide the consensus development process during the Global Conference. First, it is acknowledged that hospital pharmacy practice varies widely both within and amongst countries. Second, continuum of professional practice exists that is reflective of cultural characteristics of each country, practical differences, and other determinants. It was recognised that if ▶

the practice of hospital pharmacy is to mature globally, it is insufficient to simply identify and describe ideal practice standards. It is also insufficient to articulate minimum practice standards. Instead, the continuum of professional practice must be articulated in a way that illustrates the range of practice standards and practice development, from the basic to the ideal standards and beyond.

A different continuum will exist for each of the five main components of the medication use process in hospital pharmacy including **(1)** procurement of medicines, **(2)** preparation and delivery of medicines, **(3)** prescribing of medicines, **(4)** administration of medicines, and **(5)** monitoring of the outcomes of therapy. Another continuum will deal with human resources and training in hospital pharmacy. The Global Conference will be divided into these six areas, and a facilitator has been assigned to lead a working group for each. Along each continuum, working groups will identify the range of practice standards from minimum, basic standards through ideal practice standards, and beyond.

Official representatives from every UN-recognized country will be invited to represent their country. The conference will also be open to other hospital pharmacists and individuals interested in hospital pharmacy practice. The results of the conference will be disseminated widely to political leaders, hospital leaders, pharmacy educators, and other appropriate individuals around the globe.

Global Survey of Hospital Pharmacy Practice

In order to inform the discussions during the conference, a Global Survey of Hospital Pharmacy Practice is currently being conducted. A FIP Board of Pharmaceutical Practice Special Project, this survey will identify opportunities for global advancement of hospital pharmacy practice relevant to the needs of each participating country.

The Steering Committee for the meeting is now raising funds in order to offer travel scholarships and thus ensure representation from as many countries as possible. Support from hospital pharmacy professional structures is also being sought, not only to identify the most appropriate national delegates, but also to support the Global Conference as a whole.

The conference will truly be a unique opportunity to influence, in a very direct way, the development of hospital pharmacy in all countries of the world, consistent with the critical need for pharmacists' expertise, shared by both patients and healthcare professionals ■

For more information and registration, please visit www.fip.org/globalhosp

With thanks to Cardinal Health for their support

Global Conference on the Future of Hospital Pharmacy

30-31 August 2008, Basel, Switzerland
during the 68th International Congress of FIP

The FIP Hospital Pharmacy Section (HPS) is hosting a Global Conference on the Future of Hospital Pharmacy immediately before the 68th International Congress of the International Pharmaceutical Federation (FIP). The conference will truly be a unique opportunity to influence, in a very direct way, the development of hospital pharmacy in all countries of the world, consistent with the critical need for pharmacists' expertise shared by both patients and healthcare professionals. The findings of an elaborate Global Survey on Hospital Pharmacy will be presented. The FIP Congress itself will provide you with a full Hospital Pharmacy Programme. ***For more information please visit www.fip.org/globalhosp.***

Make plans now to attend both the Global Conference on the Future of Hospital Pharmacy and the 68th International Congress of FIP. We hope to see you in Basel!

PROGRAMME

FRIDAY, 29 AUGUST 2008
Welcome reception

SATURDAY, 30 AUGUST 2008
Welcome Address

Opening Plenary Session
The Future Vision and Challenges for Hospital Pharmacy: The WHO Perspective.
A Global Survey of Hospital Pharmacy Practice: Complete Findings.

Introduction to Working Group topics

Working Group Sessions

1. Medicines procurement

2. Prescribing of medicines

3. Preparation and distribution of medicines

4. Administration of medicines

5. Monitoring of medication therapy

6. Human resources and training in hospital pharmacy

SUNDAY, 31 AUGUST 2008
Reports from each working group and consensus voting

Final Plenary Session
Opportunities for Global Collaboration
Global Conference Conclusions

Closing Remarks and Adjournment

Opening of the 2008 World Congress of Pharmacy and Pharmaceutical Sciences, 68th International Congress of FIP

Hospital pharmacists from around the world belong to the Hospital Pharmacy Section of the International Pharmaceutical Federation (FIP). The Hospital Pharmacy Section, founded in 1957, focuses on education, communication and improving the pharmacy practice in hospitals around the world.

Hosted by the FIP Hospital Pharmacy Section

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Change Demands Change

Re-engineering pharmacy practice in a changing world

FIP BPP Board of Pharmaceutical Practice Programme Committee

Fuelled by changing patient demographics, emerging health epidemics such as obesity and the cost of new health technology, health expenditure is rising at unprecedented rates around the world. It is also an era of unparalleled scientific development, evidenced by the increasing understanding of the human genome and the impact of genetics on disease and the use of medicines. From the 29th August until the 4th September 2008, the 68th FIP Congress will be held in the Swiss city of Basel and will take a timely look at how pharmacy practice can and needs to be re-engineered to meet the challenges of our ever changing world.

As in previous years, the congress programme includes central practice and science symposia supported by a varied range of sessions organised by FIP's sections and special interest groups (SIG).

The Practice symposia will be begin with a session on 'Health Care Systems in Change', designed to set the stage by discussing some of the health care problems we face in the 21st century and how the profession can facilitate the adoption of solutions. The second symposium in the series will focus on 'Pharmacy Practice: it's Present and Future'. Pharmacy practice currently exists as part of a fragmented health care delivery system. The traditional role of pharmacists is preparing and distributing medicines, but increasingly pharmacists believe that more emphasis needs to be placed on the use of medicines to close the gap between efficacy and effectiveness. By looking at current innovations, the symposium will envision what the future of pharmacy practice might look like.

Patients will be the focal point of the third Practice Symposium. A recent U.S. Institute of Medicine report 'Preventing Medication Errors' makes recommendations for consumer actions to enhance the safe, effective, and appropriate use of medications. It suggests that patients should no longer be passive witnesses to the care that they receive, but rather active participants. The patient can be a final check in validating the treatment that they receive and an active participant in monitoring their care long after they have had an encounter with a health care professional. This symposium will consider different models for patients assuming responsibility for their care and discuss how the profession can adapt and respond to 'patients as partners'.

With increased demands on the profession and a clear need for professional roles to evolve, the final practice symposium will consider whether we have a sufficiently skilled and competent workforce to meet the challenges ahead? A particular issue is the acute shortage of pharmacists in developing countries, exacerbated by migration but also in the long-run in developed countries. It is unrealistic to assume that there will be a dramatic increase in the number of pharmacists in the near future and shortages in other health professions may contribute to our workload. This symposium will explore short and long range strategies to meet the public need for a better medication-use system.

Topics in the 2008 cutting-edge science symposia include dissolution testing, vaccines, natural products as therapeutic modulators, targeted drug delivery and biosimilars. Although specially targeted at pharmaceutical scientists, the symposia will also consider translational science, how research can be translated into clinical practice more rapidly.

The FIP sections and special interest groups take responsibility for organising sessions for like-minded colleagues with shared specialist interests. In such a diverse profession ▶

this means that attendees have an extensive range of special interest sessions to choose from – there is always something for everyone. Highlights include sessions on medicines information for patients ICT Showcase with demonstrations of new computer and database technologies, medication reviews, ethical conflicts, pharmacogenetics, paediatric medicines, technology supporting patient adherence, industrial pharmacy education and a day long training event on 'pharmacoeconomics for practitioners', to name just a few.

In advance of the Congress on the 30-31 August 2008, the FIP Hospital Pharmacy Section will host the 'Global Conference on the Future of Hospital Pharmacy'; a real must for hospital pharmacists. The conference aims to build a shared vision of the envisioned future of hospital pharmacy practice with topics under discussion including medicines procurement, prescribing, preparation and distribution, medicines administration, outcome monitoring and human resources.

While country delegates will be designated, observers to this conference are welcome to attend.

As in previous years, the vast majority of sessions during the congress will be accredited and therefore recognised for continuing education purposes in a many countries.

We are looking forward to fruitful, interesting, and inspiring symposia and sessions in Basel 2008.

See you there! ■

More information including details of how to register can be found online at http://www.fip.org/

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29 august – 4 september '08

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There is no better venue to explore and develop your potential than at the FIP Congress. Here you will meet international pharmacists and pharmaceutical scientists to exchange knowledge and experiences within accredited sessions and motivating workshops, delving into the most important current and future issues facing the profession.

This year the city of Basel will ensure a beautiful backdrop to a magnificent social programme.

We welcome you to the 68th FIP World Congress in Basel, Switzerland

68th FIP World Congress of Pharmacy
and Pharmaceutical Sciences
www.fip.org/basel2008

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“**the process** of health care is equally as important as the outcome.”