



World Health Professions Conference on Regulation (WHPCR)

Final Report



Hosted by the World Health Professions Alliance in cooperation with
the World Confederation for Physical Therapy.



World Confederation
for Physical Therapy

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First World Health Professions Conference on Regulation

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Chairs, speakers, on- and off-site participants

with the theme

The Role and Future of Health Professions Regulation

held at the International Conference Centre in Geneva on 17 and 18 May 2008.

The first World Health Professions Conference on Regulation was jointly hosted by the World Health Professionals Alliance (WHPA), comprising the International Council of Nurses (ICN), the International Pharmaceutical Federation (FIP), the World Dental Federation (WDF) and the World Medical Association (WMA), and the World Confederation for Physical Therapy (WCPT).

The conference was attended by more than 500 participants and was also presented live via the Internet to health professionals in 12 other countries. This facility permitted those participating at a distance to put questions to the speakers by e-mail.

Copies of the complete PowerPoint presentations given at the conference are available on the WHPA website (www.whpa.org). This report therefore does not include every point made in every presentation, particularly when a slide contained very detailed information.

The objectives of the conference were

- To identify global trends in changes to healthcare professional regulation.
- To explore the role of the regulators in trade in services and their impact on protection of the patient and the public.
- To examine critically the advantages and disadvantages of different modes of regulation of health professionals.
- To establish a network of professional involved in the regulation of health disciplines.



Saturday 17 May

The President of FIP, Dr Kamal Midha, welcomed participants. He defined regulation as “a rule, a law or other order prescribed by authority especially to regulate conduct” or “a prescription, a regulating principle, a governing direction or a precept.” Dr Midha emphasised the need for a patient centred approach on the part of all practitioners in the health field. This would create an awareness of the greater purpose of practitioners. He noted the emerging challenges for healthcare professionals arising from developments such as the diversification of practice settings, patient and professional demographics, globalisation and increase access by people to information on medical conditions and possible therapies.

Dr Midha introduced the keynote speaker, **Dr Carissa Etienne, Assistant Director General – Health Systems and Services, WHO.**

Dr Etienne emphasised that she was not a regulator or an expert in professional regulation. She had worked for many years in management of health systems in developing countries with rather poor healthcare settings. She was a firm believer that good primary healthcare was vital for successful implementation of a healthcare strategy.

The conference was being held just before the World Health Assembly, at a time of increasing demand both globally and at national level for the strengthening of healthcare systems. The demand was for these to be of high quality and safe and satisfactory, consistent with the values of clients rather than healthcare professionals. Regulation was an evolving process, at the threshold of commitment to the values of primary healthcare. Effective regulation meant good governance of the healthcare workforce. Dr Etienne made the point that, historically, as healthcare developed complete self-regulation was increasingly being influenced by legislation. And emerging health professions defined their roles with reference to the established professions.

The history of the WHO was based on the role of regulation. The challenge was to integrate regulation globally through standards, policy and guidance for member states. The regulation of health workers and systems was needed to protect both patients and health workers themselves. In developing countries the great need was for effective and efficient first level care.

There was, however, a critical shortage in healthcare workers in many developing countries as health professionals migrated mainly for economic reasons. This led to an unbalanced workforce which in turn led to task shifting among those in the workforce. In some developed countries the role of nurses was being extended. This was more difficult to achieve in developing countries where the state was weak in its regulatory role and professional associations were barely functional. Yet it was in such situations that there is the greatest need for good governance and effective regulation.

In Malawi a category of community health worker had been created but the medical and nursing professional bodies had not accepted these individuals on the grounds that they had not been properly consulted. Later when there had been effective consultation on prescribing roles, the proposals had been accepted. This demonstrated that in task shifting guidance, there was a need to identify all stakeholders and consult them in advance. The existing regulatory framework could then be appropriately adapted for the changed roles and regulation was very important, especially in developing countries.

A WHO report in 2006 had identified a global shortage of 4 million health workers. It had also been recognised that there was a need for a globally effective code of ethical conduct for recruitment of health workers. The WHO was in the process of developing such a code. ▶

Dr Etienne accepted that the effective regulation of new categories of healthcare workers and possible action on their unequal distribution, while at the same time ensuring proper quality and safety, were undoubtedly major challenges.

A challenge for the conference would be to take into consideration the realities faced by developing countries. There had to be united action in efforts to overcome these realities. The WHO would act as a facilitator. What proposals would the professions make on the best way forward? The evolving regulatory process rests in the principles within the Alma Alta declaration. How can we ensure this happens in reality?

A speaker from the floor agreed that the human resources crisis in healthcare had to be addressed. Ethical recruitment and task shifting were both levers. There should however be better education and training for first contact health workers and there should be a “positive practice environment” approach for retention.

Dr Etienne recognised that the issues leading to migration were consistent with the rights and freedoms of the individual and there was therefore limited scope for regulation in this area. For this reason the WHO was entering into dialogue with developed countries to seek to establish how best they can help developing countries to retain their healthcare professionals.

Dr Midha thanked Dr Etienne for giving so generously of her time, bearing in mind the intensity of workload associated with the imminent WHA. He noted that she had stressed the importance of primary healthcare and the need for close co-operation between the WHO and health professional organisations, which would certainly be forthcoming from the bodies that had convened the conference. ■



Legislative and policy frameworks

In the chair for the first part of the session, **Dr Hiroko Minami, President ICN.**

The first speaker was **Ms Margaret Grant, Chief Executive Officer of the Australian Physiotherapy Council, who spoke on Models of Health Professional Regulation.**

Ms Grant indicated that the basis of her presentation was the outcome of recent research. She emphasised that patient care was at the centre of the regulation of health professionals. A framework was required that was both flexible and protected the safety and interests of the patient.

The subheadings of Ms Grant's presentation were

- what is regulation?
- approaches to regulation
- external drivers of reform
- policy considerations

Ms Grant made the point that regulation encompasses any form of governance that influences or guides behaviour and outcomes and includes both legal and sociological perspectives.

Government regulation was preferred when conduct created a high risk and/or had a significant impact for a community. Compliance was carefully monitored and non-compliance could lead to punitive measures.

Disadvantages included difficulties in covering all possible eventualities in legislation, leaving the chance of exploitation of ambiguities, the high cost of enforcement, the stifling of innovation and the possible slowness of disciplinary action.

Self-regulation offered flexibility to take rapid action to meet new difficulties and where peers established rules of conduct these were more likely to reflect the concerns of the profession and in turn compliance was therefore more likely.

A major disadvantage was that rules could be seen to be serving the interests of the professionals rather than the interests of clients or the wider community. In addition self-regulation could be seen to limit competition, there could be lack of transparency to external scrutiny and enforcement of compliance might be weak in the absence of power granted by legislation.

Ms Grant described as “quasi-legislation” the indirect influencing of professional practice by government action not aimed specifically at a profession by, say, public health legislation or taxation or funding mechanisms.

Co-regulation, where standards of practice and conduct established by a profession were referred to in legislation was, she said, a more contemporary approach. In “meta-regulation”, a profession was responsible for direct regulation but accountable to government, which regulated the regulators through policy and legislative frameworks. There was a matrix of regulation with horizontal and vertical relationships between regulators.

Ms Grant described Teubner's “regulatory trilemma” encompassing effectiveness, responsiveness and coherence with the underlying values of the national legal system.

External drivers of reform included governments, the communities served, funding agencies and a variety of policy initiatives aimed at ensuring safe, effective, efficient and sustainable delivery of health services.

Policy considerations had to cover the identification of the purpose of statutory regulation, the governance structure, adequacy of resources, community engagement plus efficiency, transparency accountability and fairness of procedures and decision-making. ▶

There also had to be consideration of policies on standards, achieving compliance and disciplinary processes including the balance between punitive measures and those designed to assist practitioners to restore competence.

In summary, Ms Grant indicated that

- A variety of regulatory approaches exist and coherence will limit universality of any legislative and policy frameworks
- A process of evolution will continue globally
- Professions must engage with regulatory bodies, governments and policy makers (and vice-versa)
- There must be an effort to identify the elements that could be considered universal within and between jurisdictions and professions
- The core objective – the community interest - must always be borne in mind and so the community served must be involved in the evolutionary and reform processes

The second speaker in this session was **Dr Eliezer B. Blanes, President of the Philippine Dental Association**. He spoke of health professional regulation in the Philippine setting.

Dr Blanes indicated that the purposes of regulation were to

- Protect the citizen from abuse and neglect
- Provide the benchmark for quality of service
- Minimise if not eradicate the ill-effects of malpractice and illegal practice (Illegal activities in the Philippines included the practice of dentistry under fake professional licences, by under board dental graduates, by dental technicians and hygienists. There was also professional misrepresentation)

Dr Blanes then described the legislative and policy framework under the relevant section of the Philippine Constitution. He noted that under the relevant Article “The practice of all professions in the Philippines shall be limited to Filipino citizens, save in cases prescribed by law.” He went on to describe in detail the historical evolution of legal regulation of the profession of dentistry in the Philippines culminating in the Dental Act of 2007. This was described as “An Act that provides for the regulation, control and supervision of the practice of dentistry, dental hygienist and dental technologist” The broader powers and functions of the Professional Regulatory Board of Dentistry are set out. These include the creation of Speciality Boards in Dentistry, the supervision and regulation of the practice of dental technologists and dental hygienists, the prescribing of a Code of Ethics and Code of Dental Practice and full implementation of continuing professional education. Under the legislation, dentists, dental hygienists and dental technologists are integrated into one national organisation. The legislation also provides for strict implementation of codes of ethics and practice for the three entities and higher penalties than previously for the illegal practice of dentistry.

Dr Blanes then set out the standard criteria in the new law for dental professional regulation. He went on to say that the problem is not now the quality of service provided by dental professionals but rather the exodus of dental professionals to another profession and the dwindling population of dental students. The exodus is to the nursing profession. In January 2008, 314 individuals had passed the Dental Board’s requirements. The comparative figure for the Nursing Board was 28,924.

The government’s planned interventions were to require nurses to undertake two years service in rural areas, for employment abroad a requirement for two years clinical experience and for dentists transferring to nursing, a requirement to take the full curriculum instead of the abbreviated one permitted previously.

Dr Blanes described the serious posi-

tion relating to very low enrolment at dental schools and indicated the measures planned by the government intended to improve the situation.

These included “ladderised dental education” with steps for dental assistant, dental technologist, dental hygienist and full dental degree respectively.

He indicated that the Philippine Dental Association was an accredited professional organisation which recommended mandatory continuing dental education and the Professional Regulations Commission had endorsed amendments to guidelines for the implementation of continuing professional education. He also provided details of the full educational framework applicable to dentists.

Finally, Dr Blanes touched upon “Borderless Practice”, indicating that the Philippines is a member of the Association of South East Asian Nations (ASEAN). It recognises the ASEAN Framework Agreement on Services (AFAS). However, this is not currently implemented because of differences in legislation, religion and cultural practices of each member country. ■



Discussion
During the discussion of these two presentations, the following points were made:

- Regulation by legislation provided an increase capacity to ensure (enforce) compliance and the public saw the structure to be independent of the profession itself. These could be seen as advantages of this type of regulation. On the other hand this type of regulation could be seen as stifling innovations in practice that could be beneficial to patients.
- Self-regulation by, say, physiotherapists or occupational therapists could enable these professions to control themselves. The alternative could be control by another profession and that would eventually be considered to be unacceptable.
- However, there had to be a “critical mass” i.e. an appropriate number of practitioners before a regulatory regime could be implemented for an individual profession. The starting point had to be co-operation with the regulatory body of another profession by taking a seat at the table and seeing developments in the desired direction.
- A Federal/State structure could cause difficulties in ensuring consistency throughout a country. A solution could be to have a model agreed at federal level but implemented at state level.
- Experience had shown that there would be tension in balancing considerations relating to the workforce with ensuring the safety of those for whom services were provided. A very high barrier for safety might be too high to ensure that there was a workforce of adequate size to meet the need.
- Task delegation and task shifting had to be tightly controlled for high-risk procedures or for patients at high risk. The individual to whom a task was delegated or switched must be fully trained to undertake the task. The shortage of health care workers in various locations, meant that there had to be task delegation or switching within these parameters, if an adequate service was to be provided.

In the chair for the second part of the session, **Dr Burton Conrod, President of the FDI.**

The first speaker was **Mr David C. Benton, a registered nurse, currently leading the work of the ICN on regulation, licensure and educational matters.** Mr Benton spoke on the theme “Current and future scenarios in licensure, registration, revalidation and accreditation.”

Mr Benton set the context in which his presentation was set. Developments including the pace of change, demographic factors, expectations of the public and migration and health tourism meant that regulators were faced by new and greater challenges. There were also a number of paradoxes that raised the question of whether the demands placed on regulators were being made clear. There was a clear need for effective primary care as a priority and yet investment tended to be skewed towards acute hospitals. There was generalist education and yet specialist delivery. There was enthusiasm for freedom of movement for both health professionals and patients against a background of insistence on protecting the safety of patients as a priority. Education and training was based on input models whereas the need was to ensure competency. And paradoxically, the availability of a surplus of information could lead to confusion and the individual being less well informed in practice. This was a complex scenario for regulators to address.

The UK’s independent Better Regulation Task Force had defined regulation as “any government measure or intervention that seeks to change the behaviour of individuals or groups.” The ICN definition was “all of those legitimate and appropriate means governmental, professional, private and individual, whereby order, identity, consistency and control are brought to the profession.”

However, currently there seemed to be a loss of trust in regulators on the part of the public due to perceptions of failure to take action and procedures that were slow and inflexible. In addition self-regulation was perceived to serve self-interest. Professions that self-regulated needed to address these and some other concerns.

There were then some detailed slides looking at the past and present scenarios and suggesting possible future developments. What were the purposes of ensuring continuing competence? As well as protecting the public there was promotion of life-long learning and support for innovation. After demonstrating a professional competence curve, Mr Benton asked whether the policy of regulators should be to search for bad apples or to shift the curve? There was also a need to establish whether competency should be related to the right to be a registered practitioner or the right to work in a particular post and setting.

Mr Benton then set out a list of possible tools that could be used to assess competence and said the challenge was to decide which of these either alone or in combination were most likely to ensure continuing competence. Next, he set out, on a detailed slide, the determinants of the performance of the providers of healthcare services. The regulator was but one part of a co-ordinated solution. And the solution had to be seen from more than one perspective. **Promoting continuing competence had to be seen from the view of**

- the individual practitioner
- the regulatory body
- professional organisations
- employers
- educational institutions
- the government
- the patient and the public
- the media



To strengthen self-regulation professions needed to have a coherent vision of how licensure, registration, revalidation and accreditation would

- maintain public confidence in the system
- ensure proper public input to self-regulatory processes
- maintain standards at times of cost containment
- deal with changing and emerging roles
- demonstrate the accountability of practitioners and regulatory bodies
- ensure transparency in policy and practice
- ensure ongoing competence
- be seen as a significant contribution to ensuring quality and facilitating access to care

Aspects that had to be addressed included lack of evidence, lack of vision, transparency, accountability, performance, co-ordination and trust.

Regulation certainly had a future but perhaps not in its present form.

The second speaker was **Professor Peter Noyce, in his capacity as Director, the Workforce Academy, University of Manchester, UK** who took as his theme “Ensuring fitness to practise: the modernisation of health professional regulation.”

He referred to a government policy paper on health professional regulation, adding that this was particularly challenging for pharmacists because a completely new regulatory body was to be established.

The raison d’être of regulation was patient safety and a regulatory system had to be designed to prevent as many failings as possible and set minimum standards compatible with patient safety.

Regulation was not about professional aspiration although the two were complementary.

Professor Noyce set the practice setting, involving educator, practitioner, regulator, and employer. The regulator was responsible for standards of education and practice. The educator had prime responsibility in the provision of learning to achieve initial fitness to practise. The employer was responsible for ensuring that the health professionals employed maintained their fitness to practise. Finally, the professional body was responsible for setting core values, establishing professional aspirations and supported the regulatory process, for example by accreditation procedures.

The issues in ensuring fitness to practise initially were, first, regulatory requirements and secondly key perspectives and practicalities.

Options for the former included

- national vocational qualification
- academic qualification
- supervised practice
- professional qualification
- competency framework

Professor Noyce made the point that so far as professional qualifications were concerned, the move in the UK was towards advanced practice, with Royal Colleges for various specialities

The key practicalities to be addressed were

- who provides training?
- who accredits learning provision and teaching institutions?
- who assesses competency and how?

Professor Noyce dealt next with issues relating to maintaining fitness to practise. Here the commitment in the UK was towards ensuring a professional maintained fitness to practise throughout a career. The public assumed, wrongly in many cases, that such arrangements were already in place. ▶

Possible approaches included

- annual appraisal
- absence of complaints or concerns relating to performance. Conduct or health
- summative assessment of competence

Individual practitioners, employers, professional bodies and regulators all had a part to play in the process. And mechanisms had to be in place to support or retrain or rehabilitate practitioners who failed to maintain fitness to practise.

There was also a need for coherence in the regulation of health professionals. Intra-disciplinary regulation should achieve efficient skill-mix. And there was a need to regulate specialists and “paraprofessionals” within the discipline concerned. Inter-disciplinary regulation was needed to harmonise standards where a member of more than one profession was permitted to undertake a task that was controlled such as prescribing prescription-only medicines. An integrated system of regulation was needed, for example, to reduce the number of adverse events from medicines. In the USA, the cost incurred in dealing with adverse effects of treatments was equal to the total sum spent on the treatment of cancer.

Reducing the number of adverse events required safe products, safe systems and safe professionals. Professor Noyce concluded by stating how this could be achieved through the right combination of governance and regulation. ■

Discussion

The first comment related to how rules governing state-funded health systems could inhibit the ability of a professional to perform a task an individual was qualified to perform. In Victoria, Australia a nurse practitioner in a rural area with legal authority to supply a medicine could not do so because he or she did not have the necessary authorisation number under the pharmaceutical benefits scheme to secure reimbursement. A prescription had to be written to take to a pharmacy. It was suggested that patient organisations should be lobbied to secure support for the necessary changes to be made.

When a participant from the USA suggested that in line with provisions that ensured fitness for purpose of medicines, there should be provisions on fitness of process for practitioners, Professor Noyce responded that this would need careful thought, bearing in mind the different settings in which a process might be carried out.



The final two speakers for the day covered the theme “When things go wrong.”

The first speaker was **Dr Robert Schaefer, Chief Medical Officer, Chamber of Physicians, North Rhine, Germany.** Medical Ethics, Regulation and Professional Conduct are included in the topics on which Dr Schaefer concentrates.

He set the scene by indicating that while the Federal Republic had 300,000 physicians and a population of 82 million, the corresponding figures for North Rhine were 50,000 and 10 million.

The responsibilities of the Chamber, which was a corporation under public law, covered the whole area of professional regulation for medical doctors, including postgraduate training, continuous medical education and issuing the health professional card for physicians. The Chamber also undertook the role of prosecutor when that was necessary and had responsibility for organising the emergency medical services. The Chamber was financially independent with no tax revenue. It undertook “governmental functions”, with legal supervision by the appropriate government ministry. It had responsibility, in North Rhine, for the implementation of the legislation arising from EU directive 2005/36 on the recognition of professional qualifications of physicians from other Member States.

The Chamber accepted the principles that medicine must be safe and patient centred. He suggested that in the past, self-complacency might have led to inhibition of self-criticism. It was a swell to remember that “Murphy’s Law” – if something can go wrong it will – applies to healthcare. Spontaneous handling was no longer appropriate. Risk management systems must now be in place. Following any adverse incident, the patient was the priority. How could harm be minimised? How best could improvement be sought? What is the right course of action in the circumstances?

An adverse event was defined as something that was caused by medical management rather than the patient’s medical condition. A medical or serious error may be systematic but be seen as a personal event. Minor errors, “near misses” and preventable adverse events all had to be reviewed. However, it had also to be recognised that an incident might not have been preventable.

The best policy was openness and honesty. If there was a possibility that an error had been made, that should be admitted and an apology given. The patient often felt that the trust placed in the practitioner had been undermined but still wanted to know about every error.

Experience had shown that failure to acknowledge an error was likely to lead to litigation. An apology was an essential element in restoring trust. The patient was also anxious to ensure that the same error would not happen again. Someone the patient could rely upon should explain measures taken towards that end, to the patient. This required appropriate training for communication in such circumstances. Indeed communication skills should be taught at medical schools. In addition, caregivers should be trained in how to deal with such circumstances. They required support and suitable arrangements for that to be provided should always be in place.

The elements of an appropriate institutional policy, said Dr Schaefer, in summary were

- a commitment to communicate
- the provision of guidance to care-givers
- the education of care-givers to communicate well
- empathy and honesty
- emotional support for both patient and family
- good public communication
- proper documentation and reporting.

In brief, a completely professional approach is needed when things go wrong. ▶

The second speaker in this session was **Dr Peter Swiss, Chairman of the Ethics and Dental Legislation Working Group of the FDI**. Dr Swiss has, for more than 20 years, advised dentists facing complaints, claims or professional disciplinary action.

Dr Swiss asked those present to see the situation from the patient's perspective. Why do things go wrong?

- Lack of clinical competence or overconfidence in ability and failure to refer to a more experienced colleague
- Complications may occur and failure to recognise their importance may lead to a serious incident
- Negligent treatment – the patient may not be able to distinguish between this and complications
- Malpractice such as falsification of records or false claim of expertise
- Interference by non-professionals- managers may have a different ethos and may overstep the mark

When things go wrong nothing may happen. Alternatively, there could be an incident report for the employing authority or the patient could submit a formal complaint. **Why do patients complain?**

- they consider their treatment to be substandard
- they may have had unrealistic expectations
- they feel they were not given proper care, respect or courtesy
- they feel reasonable requests were ignored or refused
- the proposed treatment was not fully explained
- they were discharged before they were fully fit
- they are chronic complainers – these are few and far between

Complaints may be made direct to the clinician, to his or her employing authority, through the courts, to the clinician's professional or regulatory body or via the media. The choice of route to make the complaint will be influenced by the perceived seriousness of the incident, how speedily and effectively the mishap was treated, the nature and duration of the necessary remedial treatment and the final outcome following that treatment. Another important factor was the pre-existing relationship between that patient and the practitioner. The outcome following very similar mishaps could be very different, depending upon that relationship.

How best can complaints be resolved? The best scenario is resolution by informal discussion with the patient. A formal written explanation may be necessary. An apology may be appropriate. Sometimes, the refund of any fees paid by the patient and meeting the cost of any necessary remedial treatment can resolve the situation. However more formal procedures may be instituted through the employing authority or the courts or the clinician's regulatory body. In the courts or disciplinary proceedings the public and the media would normally be permitted to attend.

There was multiple jeopardy.

- loss of professional reputation
- censure or dismissal by employer
- legal action and possible court appearance
- restriction of future practice by regulatory body.

There was increasing involvement of governments and more lay input to disciplinary procedures.

Clinical risk management was vital to avoid the avoidable and to manage the mishaps. Risk management was a team effort involving everyone from receptionist to clinician to specialist. Dr Swiss said that it was important to bear in mind that by and large people still



trusted health professionals. That was shown in consumer surveys with pharmacists topping the list in the most recent. So at the start the patient was at one with the health professional. However, trust takes a long time to gain and very little time to lose. Poor communication was at the root of 85 to 90 percent of all complaints.

In closing, Dr Swiss said that performance reviews by employing authorities were very important and continuing professional education (CPE) should be mandatory. Before it was made mandatory for dentists, 25 per cent of those practising did not undertake any CPE. ■

Discussion

A pharmacist from the USA made the point that it had been said that a professional should learn from an error so that it would not be repeated but professionals were punished following errors. Could any process overcome this difficulty? Dr Schaefer responded that complaints had to be dealt with under the process that was in existence. Dr Swiss added that it was only in the last resort that a practitioner would be barred from practising. The protection of the public must be the first priority and retraining facilities should be in place to bring errant practitioners up to standard.

A participant asked Dr Swiss if he agreed with Dr Schaefer that someone trained in communication skills, rather than the practitioner, should speak with the patient when something went wrong. The response was that one size does not fit all. In a general dental practice, it may be the dentist himself or a senior clinician within the practice who dealt with the matter. It was best, in Dr Swiss's view if the matter could be handled informally when there was good rapport between patient and practitioner. However, in a hospital setting, there was less likelihood of such close rapport and the matter would then have to be dealt with under institutional policy, which might involve someone trained to communicate.

The same participant made the point that many practitioners were responsible for a large number of people yet Dr Schaefer had indicated that the pre-existing relationship between practitioner and patient could affect outcome in the case of very similar mishaps. Dr Schaefer accepted the point but said that the style of delivery of care was a vital element. If a patient knew that a clinician had done everything possible in a given set of circumstances, that patient was likely to be more forgiving.

A physician agreed that an appropriate apology was important when something went wrong but how could doctors be convinced to admit an error rather than stating that the event was an accident. Dr Swiss said that it was sometimes difficult to distinguish between error and accident – not, of course, if the wrong tooth was extracted or the wrong limb amputated. ▶

In other cases, there could be ways of apologising, without admission of liability. For example, one could apologise that a procedure had been more painful than expected. Dr Schaefer added that sometimes a patient did not fully understand the complications associated with a procedure and there needed to be a full explanation in advance. ■

Discussion with full panel of six speakers and Dr Conrod in the chair.

A remote participant (New York) asked if there were any studies listing the reasons for incidents, such as malpractice, lack of clinical competence etc.

The point was made that many regulators prepared annual reports of complaints received and outcomes, in some cases indicating the reasons for the occurrence. Efforts were then made to guard against similar incidents in the future. This could result in improvements in education. Dr Schaefer confirmed that he looked at complaints received annually. Figures for various types of incident varied from year to year. It was important to feed this information back to doctors to help them to avoid adverse events of the same kind. Later, the point was made that the constitution of a country could define the process of disclosure. This could mean that in some countries, relevant information could not be disclosed publicly. Dr Blanes added that when the media picked up an alleged error, the reputation of a professional could be tarnished before the regulatory body ever investigated the matter. In his view this was unreasonable. The professional body should first be given an opportunity to examine the facts and refer the matter to the regulatory body if appropriate. The procedure and possible outcomes should be made clear at the outset.

A participant from Norway commented on migration. People were travelling from one country to another to obtain treatment at a lower cost than would be charged in their own country. On the other hand nurses were moving from the Philippines to Norway for economic reasons. Dr Blanes responded that, in his country, dentists were moving to nursing mainly for political reasons.



Professionals had lost confidence in the government. And more wanted to work abroad, especially those in the public service who were poorly paid. In the USA, on the other hand, nurses were well paid. When doctors and dentists could become registered nurses in one year the incentive was great, particularly as the whole family could move for a better life. One result was an increase in illegal dental practice in rural areas in the Philippines. In his presentation, Dr Blanes had outlined the preventative measures the government had now taken.

The participant from Norway also put it to the panel that the mantra seemed to be "It's all the fault of the system." Surely if there were doctors with mental or physical illness and/or patients were being abused, this was a matter for an individual to be dealt with rather than the system.

The response was that whether the fault lay with individuals or the system, knowledge had to be gained from the incident and used to avoid the same or a similar event in the future. Reference was also made to the airline industry where there was blame-free disclosure i.e. one could report about an adverse incident or near miss involving self or another, with a guarantee of no legal or disciplinary action being taken. Was not a similar arrangement necessary for healthcare, so that disciplinary action would not follow a report given voluntarily?

Ms Grant reiterated that for both clinicians and institutions, the goal should be to learn from an incident. It was possible to write a report on an incident without identifying individuals. She considered that if an individual identified himself or herself as possibly being at fault, this should not lead to blame or shame. Professor Noyce made the point that everything should be done to ensure that a system encouraged the reporting of adverse incidents and near misses, so that lessons could be learned. A speaker from the floor emphasised, however, that regulators had a duty to deal firmly with incidents that disclosed very poor practice by a health professional. The interests of the patient must be paramount.

Mr Benton indicated that a recent change of policy led to reasons being given for decisions of a tribunal. On some occasions professionals were in denial about their practice methods and giving reasons could help such practitioners to take the necessary remedial action.

A participant from Portugal spoke in favour of a blame-free culture but firmly against anonymity. Ms Grant said that her earlier comment related to a mistake rather than incompetence on the part of a practitioner. In the case of preventable errors, there may be no need to identify an individual or individuals, where the reasons for the error were set out.

A nurse participant from Canada said that there was a move to a just culture where people feel free to report adverse incidents. There needed to be a multidisciplinary approach because it was seldom that only one practitioner was involved. Dr Swiss mentioned the need for regular meetings at group practice level to discuss any adverse event and how to avoid a similar incident in future. At that stage there might also be agreement on the terms of a letter to be sent to the patient to explain the circumstances and the action taken. Mr Benton confirmed the value of such meetings – a culturally good idea. Any procedure for investigation could be at a higher level.

A participant asked if where a licensing authority was a government body and a professional body was responsible for specialist education, should the regulatory or the professional body have responsibility for discipline, or should that be the function of a separate third body. Professor Noyce repeated the point that where there was self-regulation, there was often the perception that the professional body tended to favour practitioners rather than those to whom they provided services. On the other hand regulation of health professionals was not seen to be for politicians. Thus there should be a body independent of both to regulate a health profession.

A remote participant from Ethiopia asked for advice on the approach that should be adopted in a developing country that did not have an adequate regulatory system. Mr Benton ▶

responded that advice would be available from the appropriate WHO Regional Office. The best solution would vary from country to country depending on the specific situation. Ms Grant added that effectiveness and coherence of a system had to be considered. Both the cultural background and the legal system would determine the system that would be most appropriate. Ethical guidelines from other countries could be used as a starting point.

A nurse regulator from Ireland stressed that clinical risk management was very important for patients. The process should normally be blame-free, although this may not be possible in all incidents.

Most cases, in her experience, arose from events other than clinical incidents. If an incident was the result of the ill health, or misconduct on the part of a practitioner, the individual must be identified once all the facts had been established and there had been a finding that a complaint had been justified. She also asked for better sharing of information between regulatory authorities to prevent an individual whose practice had been restricted from resuming unrestricted practice in another country.

Dr Swiss said that regulatory authorities had to be realistic. There were bound to be a few "bad apples" in any profession and they had to be dealt with firmly in the interests of the public and to uphold the reputation of the regulatory body concerned. Where there was serious misconduct or persistent clinical failure, "whistle blowing" may be vital in the interests of patients.

The session of 17 May was then concluded, with the Chair thanking all the speakers and those who had participated in the discussions. ■



Sunday 18 May

First Session Governance of regulatory bodies and accountability

The chair was taken by **Dr Marilyn Moffat, President WCPT.**

The first speaker was **Dr Terje Vigen, Medical Association, Norway**, who described the Norwegian model. There was one medical association with voluntary membership and about 25,000 members – approximately 97% of the total. The Association had been founded in 1886 and in 1913 the first 13 specialisms had been established. There were now 44. The Association had special administrative structure for each of these, with a specialism council and course committees.

Legislation in 1982 had placed formal responsibility for regulating physicians on the Ministry of Health but this had been delegated to the NMA. The same had happened in 1999 in relation to health services personnel.

Each hospital was assessed for the quality of the specialist education it offered. The NMA reported annually to the relevant government authorities on specialist education.

Experience over the years had confirmed that if responsibility was taken seriously and the task of regulation was discharged well, government was content to delegate. (N.B. In EU terms this would be described as co-regulation).

The system worked well because of the direct involvement of a large number of NMA members. Doctors worked closely with patients. This was seen to be important in the

establishment of specialisms and their subsequent development. Participation in the development of medical education was an integral part of the profession's activity. Members had proved to be much more interested in the activities of the NMA in the field of education than in its "trade union" functions.

In general, society and health authorities seemed to accept that the job is done well under the current system, although some in universities would prefer the educational institutions to take over the responsibility.

The second speaker was **Ms Laura Skidmore Rhodes, Vice-President, Board of Directors, National Council of State Boards of Nursing, USA.**

Ms Rhodes explained that, in general, the structure for regulation of nursing was the same as that for other major health professions in the USA. The overall mission was the protection of the public. This could be secured by many paths via umbrella and single boards respectively. Individual boards for nursing, pharmacy, physiotherapy etc, operated under the umbrella of Health Care Licensing Boards, which in turn were under Boards of Health.

The individual boards shared resources for investigations and processing of licence applications. However, staff were allocated to individual boards, with sufficient flexibility to ensure that high workloads in any could be dealt with efficiently. This umbrella structure, in effect centralising the work, was considered to be best in economic terms. Nonetheless, a board that collected a large sum in fees often felt frustrated that this money was not made available to fund the activities of that particular board. The major funding consisted of fees within an annual budget approved by the relevant legislature.

The membership of a board included representatives of the public, educational establishments, practitioners, stakeholders and ►

the medical profession. There were requirements for board members relating to age, educational standards, residency and experience. All members had voting rights and a board had responsibilities to the public, to the relevant authorities and to licensees. There was a commitment to ongoing regulatory excellence (CORE) with the ultimate goal of protection of the public, achieved by various means.

In response to questions it was established

- In the USA, appointments to boards were made by government authorities
- In Norway, there did not appear to be any serious allegation that self-regulation was “softer” than the regulation would have been under state control. The system was seen to work well and efficiently, at no cost to the taxpayer.
- In Norway, an appeal by an individual whose application had been rejected lay to a state body. But there were only 3 to 4 such appeals per annum. In the USA, appeals lay to the courts.
- There was much more state involvement in regulation of health professionals in Denmark and Sweden as compared with Norway. ■

Second Session Setting standards and codes of conduct

The chair was taken by **Dr Henri R. Manasse, Professional Secretary FIP.**

The first speaker was **Dr Konstanty Radcevell, President of the Polish Chamber of Pharmacists and Vice-President of the EU Standing Committee of Doctors (CPME).**

Dr Radcevell said that the Polish Chamber of Physicians and Dentists incorporated 130,000 physicians and about 35,000 dentists in a country with a population of 40 million. The professions were self-governing. Membership of the Chamber was compulsory for those who wished to practise. There were 24 Regional chambers and one Central Chamber.

The Chamber played the part of trade union but was also responsible for supervision of the professions and setting the principles of ethics and deontology. It also acted as the regulatory authority for licensing providers of CPD. The Chamber was also represented on the legislative authority for any legislation on healthcare.

In setting standards the Chamber took into account the sciences concerned, aspects of medical practice, financial and political factors. It was also aware of social factors.

Dr Radcevell was strongly of the opinion that the more influence exercised by medical doctors in the provision of healthcare and the least by politician, and those who were responsible for funding healthcare, the better for patients.



In discussions on ethics, the influences in decision making included philosophy, religion, culture and tradition, medical science and medical technology, social awareness and politics. Bodies with a contribution to make in the setting of ethical standards were medical associations, chambers and the authorities. The speaker traced, briefly, the history of ethical codes from the Hippocratic Oath to modern national codes. He also showed slides relating to a pronouncement of the Polish Constitutional Tribunal dated 7 October 1992, which should, ideally, be read alongside this report.

Dr Radcevell also commented briefly on the result of a study undertaken by the CPME in 2004 and 2005. This indicated, he said, that it was better to leave regulation in the hands of the profession. Self-regulation was good in that it ensured high quality and the acceptance of responsibility as well as contributing significantly to building civil society.

The second speaker in this session was **Dr Paul van Ostenberg, Executive Director since November 2007 of the Department of Standards Development and Interpretation of Joint Commission International (JCI).** He addressed the topic of the role of accreditation of the standard of setting within which healthcare services are provided.

The speaker made the point that JCI was a non-governmental, private sector, voluntary, not-for-profit organisation.

He touched on distributed accountability within the regulatory framework and integrated accountability in public-private partnerships.

Distributed accountability embraced competent practitioners which meant education to ensure core competencies and the involvement of professional associations. It also involved ensuring that health care organisations

were capable and this included factors such as licensing and adequate payment sources. Safe clinical processes were also incorporated. This covered professional practice standards, effective risk management and retrospective examination of any adverse incidents. All of this required the use of good science and research. There was also a need for quality data on everything from infection rates to payment schemes. The key element of this model (distributed accountability) was patient safety.

Integrated accountability required external quality evaluation. Many countries, said Dr van Ostenberg, were exploring the relationship between governmental regulatory bodies and private sector evaluation agencies. He suggested that these public-private sector partnerships held great promise for augmenting governmental regulation of health professionals with the accreditation of practice settings. The JCI model included a rigorous process to evaluate the credentials of health practitioners with data from primary sources and the limiting of practice by practitioners to areas of documented competencies.

There were JCI standards for capable organisation, for supporting the incorporation of the latest science into practice and for quality data. The standards also supported ongoing review of professional practice. Thus, accreditation standards shaped the functions and processes that supported good professional practice in the context of improvement of both quality and performance.

The standards promoted patient-safe professional behaviour. There was engagement with the health professions as major stakeholders in every aspect of the process.

However, since external accreditation was a voluntary option, there was limited impact nationally if penetration was limited. The impact was then not national but limited to those organisations that had voluntarily gone through the accreditation process. (Again for those with a particular interest, Dr van Ostenberg's slide on the key elements of the integrated accountability model, will be helpful). ▶

In a very brief question and answer session the following emerged

- In Poland, although the Chamber had authority for “policing” many activities of doctors, the final decision was taken by a court when necessary.
- JCI was working internationally with governments to strengthen accreditation. The cost was met by the organisation going through the accreditation process. ■

Third Session Assuring quality accreditation of education and practice

The chair was again taken by **Dr Henri Manasse**

The first speaker was **Dr Hugo Mercer**, currently **Deputy Editor, WHO Human Resources for Health Online Journal**.

Dr Mercer reminded the conference that in 2006, the World Health Assembly had called for a rapid “scaling up” of numbers in the healthcare workforce (HWF). In many countries there was inadequate capacity to train sufficient members of the HCW and insufficient financial resources to correct this position. Member States had been urged to promote training in accredited institutions of the full spectrum of high quality health professionals and also to train community health workers. There was a critical shortage of healthcare workforce in many African countries and in India and Pakistan among other countries. In some of these countries these were high incidences of HIV/AIDs and malaria and very low numbers of healthcare workers.

The challenge was how to substantially increase the production of healthcare workers without losing quality, safety and the trust of populations. Factors to be considered included regulation, retention, working conditions, education and training, recruitment procedures, remuneration incentives, investment, the overall labour market and skill mix.

A social system cannot function without regulation and healthcare is a social system. Different models of regulation could be used. One incorporated targeted rules and regulatory agencies. A second utilised all modes of



state intervention including competition and a third utilised all mechanisms of social control by whomsoever exercised.

Two types of regulation were directly related to human resources. One affected educational institutions and encompassed the establishment of educational standards, licensing, recognition and accreditation of specific schools. A second related to the way in which healthcare workers performed their activities, their practice and applied their knowledge and skills. The 2006 World Health Report had highlighted the fact that regulation was closely linked to the trust needed for the healthcare system to be respected by society (providers, users, authorities etc.)

Observatories in Latin America, Asia-Pacific and Africa were producing a global directory of educational institutions for health professionals and developing standards for quality assurance. There was also a research body on the governance of health professionals. A 2006 survey of medical regulatory agencies had found that a smaller number than expected were involved with education and CPD.

The WHO was eager to exercise its “convenor role” to define changes to regulatory systems

The second speaker was **Ms Elizabeth Oywer, Registrar/CEO, Nursing Council of Kenya**.

Ms Oywer said she would attempt to explain the role of accreditation as a quality assurance process, to describe the process of accreditation and to discuss the parameters assessed during that process. She defined accreditation as a “formal process by which a recognised body assesses an institution and educational programme as meeting predetermined standards.” Establishing standards for, and accrediting, training institutions, educational and training programmes, curricula and those who train health care professionals was the key to assuring continuing quality and appropriateness of basic and post basic training. Stan-

dards were developed by experts in the field and assessments carried out by individuals (peer groups) with the necessary expertise.

The purposes and benefits were to ensure professional and public confidence, to improve the quality of care and to demonstrate accountability in terms of public safety.

Regulatory bodies, through legislation, had the legal authority, mandate and responsibility to protect the public by setting parameters for the scope of practice and standards of education.

In Africa, ECSACON and the East African Community Medical Council had started the process of harmonisation of core competencies and joint inspections respectively. This was seen to be important for cross-border mobility, comparability and equivalence. There was also some discussion on the same topic at international level.

Ms Oywer explained the accreditation process. The standards approach to quality was used with the parameters being separated into the three dimensions of input, process and outcome. At the end of the process, the result could be full accreditation, provisional accreditation, a decision not to accredit or to withdraw accreditation previously granted.

On inputs/structure, the focus was on physical facilities (e.g. wards and lecture theatres), human resources, transport/infrastructure/equipment/supplies, bed capacity and occupancy, financial management and the ratio of staff to patients. Other factors might also be taken into account.

There was then consideration of processes such as procedures carried out, infection protection practice etc.

Outcomes were then considered, including the performance of staff, morbidity and mortality, plus the satisfaction level of the staff and the community served. Publishes research papers were also taken into account. An example of a verification report from a hospital was shown. ▶

Ms Owyer was convinced that accreditation, through the application of a rigorous process, ensured quality. She closed with a quotation from Henry Ford "Quality is really doing the right thing when no-one is looking."

There then followed a question, comment and answer session involving all the speakers who had given presentations in the Sunday morning programme.

A question was raised on whether the influence of third party payers could adversely affect quality. Dr Radcevell suggested that third party payer involvement was legitimate and did affect regulation. This could not be avoided because these third parties would seek quality and economy i.e. value for the expenditure involved.

Dr van Ostenberg added that a cost of care increased, payers would seek to identify high quality care and pay those providers more than institutions providing poorer care. Thus sound data was needed and had to be provided. He also said that when a private body was acting in an accrediting role, there had to be an open and transparent discussion on e.g. aspects of patient safety.

On the question of how one dealt with a third party which, in practice, was depriving people of high quality care, Dr Radcevell suggested that it was important not to be seen to be defending bad practice. Both sides of the situation had to be looked at. If too much emphasis was placed on negotiating better terms and conditions, the profession would lose the confidence of the public and politicians.

It was suggested the evaluation of settings seemed to be a very expensive operation and the question was asked as to whether there was clear evidence that this really resulted in improvements for those receiving care. Ms Owyer accepted that ensuring provision of quality care was expensive but suggested the expenditure was well worthwhile. There was a need for continuous appraisal to promote improvement. The objective reports of the expert assessors should give advice on how to achieve improvements.

Dr Radcevell added that it was important not to over-regulate because any additional expenditure if that were done could not be justified objectively. And although participation in CPD should be a professional obligation, the requirements should not be too prescriptive.

Dr van Ostenberg was asked if there were any differences in the assessment criteria applied to public and private hospitals respectively and if a hospital was closed as a result of the process, how would the care needs of the community concerned be met. The reply was that the same criteria were applied to both sectors and made the point that both large and small facilities were accredited. He also made the point that a private sector accreditation body would not be in a position to close a facility. The relevant regulatory body would make such a decision.

Responses to a question on the numbers of lay members on Councils or Boards disclosed variations from country to country.

In response to a comment about regulation in Britain of an activity, in whichever setting the practice was carried out, Dr van Ostenberg said that he knew something of the commissioning process in the national health service. There seemed to him to be very little on quality. He added that the danger was to begin to define quality in too many ways. Also differences were seen in different parts of a country, especially if there was a system devolved to regions. There should be a national system that defined what people should expect.

On sustainability of self-funded bodies in large countries such as India, Dr Mercer said that the main problems occurred in countries with generally weak governance. Capacity was fragmented in India but the question to be asked was whether the procedures and rules worked in practice. Each country should decide the best regulatory system to meet the needs of its people.

On the question of regulating individuals such as traditional healers etc in India, Dr Radcevell said this should be avoided because statutory regulation of a non-legitimate activity could

be seen to legitimise that practice. A participant from Australia challenged that view, making the point that adverse events had been seen for the practice of traditional Chinese medicine. The government of the state of Victoria had decided to regulate these practitioners to protect the public. In Kenya, many people use the services of traditional healers and herbalists etc. The government was seeking to regulate but had not found it possible to do so to date. She agreed that if people were using these services, the practitioners should be regulated to protect the public. Who were these practitioners? How are they trained? Perhaps a new type of regulation would be needed for country-specific situations. Dr Radcevell suggested that one had to decide if a practice was "real medicine" Non-traditional practitioners who presented dangers should be looked at by the police rather than a regulatory body! If dangerous, the practice should be stopped. If it was, like astrology, not dangerous it should be allowed to continue.

A key question was raised by a representative of medical regulators, on whether if skill-shifting continued at the current rate, the current regulatory system for healthcare professionals could continue to be effective. Differing views were expressed. Dr Mercer considered that regulation was for the benefit of human beings globally. More involvement of the public would be seen and increased blurring of boundaries of practice between various health professionals. Regulation had changed historically and would continue to evolve to meet changing circumstances. Dr Vigen, on the other hand, asked if we wanted skill-shifting to continue if these were indeed a risk of lowering quality.

On reciprocal arrangements for recognition of accreditation, Dr van Ostenberg said the EU situation was worthy of study. There one set of standards was sought. People were moving from one EU Member State to another, seeking high quality/low cost healthcare. When an insurer or government had to pay for a procedure carried out in another country, it is to be expected that that data will be requested on the competence of the practitioners involved etc. There would be international norms but regulation at national level.

Ms Owyer indicated that there were reciprocal arrangements within the five countries of East Africa for accreditation of academic institutions.

A comment was made that professional bodies should be seen to have some regulatory activities and a question was raised on the implications of accreditation of educational programmes. Dr Vigen made it clear that although the Association in Norway contributed to all aspects of medical education, its delegated authority related only to specialist training and education. At undergraduate level, the involvement was limited to giving advice.

Dr Henri Manasse, in closing the session, made the following points:

- A fundamental question raised was whether a profession should self-regulate or should this be done by government?
- The Federal/State situation had also to be considered.
- Also to be considered was the role of the market in governing practice.
- In the USA, the chain drug stores dictated practice, in his view. The target appeared to be volume and numbers rather than care models.
- The global problem of shortage of health care workers had been highlighted and the question had been raised of how this impacted on regulation.
- Were the skills of all healthcare professionals being used to the maximum or is the use being made too narrow?
- What were the implications for regulation in the long term, if any, of skill-shifting?
- Should all care settings submit themselves for accreditation? For example in the USA, hospital pharmacies were subject to accreditation procedures but application to community pharmacies had been vigorously resisted by that sector.

Thus, there was no shortage of topics for in-depth discussion at a future conference. ■



Sunday 18 May

Fourth Session GATS and domestic regulation – two sides of the same coin or strained bedfellows?

The chair for this session was taken by **Mr Edward Hill, Chairman of the Council of WMA.**

The first speaker was **Mr Dale Honeck, WTO Trade in Services Division.**

Mr Honeck opened by listing the functions of the WTO as a:

- Forum for trade negotiations
- Administrator of trade agreements
- A settler of disputes
- A reviewer of trade policies
- A promoter of technical co-operation and training

Further information is available at www.wto.org

The General Agreement on Trade in Services (GATS) is a framework text that includes:

- Schedules of commitments (an important part of the document, entries were flexible – could be one page or 100 pages)
- Core principles (transparency, most favoured nation, Article 4 the increasing place of developing countries in world trade etc)
- Article XIX – progressive liberalisation, flexibility.

The preamble to the GATS recognised the right of member states to regulate and to introduce new regulations on the supply of services within their territories to meet national policy objectives and the particular need of developing countries to exercise this right.

The WTO and the GATS have no direct role either in promoting the creation of domestic regulations or in specifying their content. WTO is not a standard setting organisation. The GATS objective is to ensure that regulations do not create unnecessary barriers to trade. Flexibility and predictability were equally important.

Referring to trade barriers and domestic regulation, Mr Honeck made the point that Article XVI dealt with market access including quantitative restrictions and Article XVII with national treatment and discriminatory measures. Domestic regulation as covered by Article VI made it clear that Members had regulatory autonomy, subject to GATS rules aimed at minimising trade restrictive effects. A regulation did not have to be in the schedules if it was within the terms of this rule.

Mr Honeck explained that there were few GATS commitments in the health sector and the same was true of education. Looking at new offers health services were again near the foot of the list. Developed countries were unwilling to make commitments in this field.

Returning to Article VI Mr Honeck explained that in sectors where commitments were made, VI.1 made it clear that there had to be reasonable, objective and impartial administration of measures of general application, VI.3 required decisions on applications to be made within a reasonable time-scale and VI.6 set out procedures to verify competence.

VI.2 set out procedures for the review of administrative decisions affecting trade in services in all sectors, with or without commitments.

Under VI.4, regulatory disciplines would be developed by the Service Council to ensure that measures relating to qualification require-



ments and procedures, technical standards and licensing requirements did not constitute unnecessary barriers to trade. These disciplines would aim to ensure that such measures were based on objective and transparent criteria, were not more burdensome than necessary and, in the case of licensing procedures, were not in themselves a restriction on supply.

In tracing progress to date, Mr Honeck mentioned the ministerial Decision of April 1995 by which a Working Party on Professional Services had been established. This required the immediate implementation of Article VI.4, with priority being given to the accountancy sector. Subsequently in May 1997 the WTO Council for Trade in Services had adopted voluntary guidelines for Mutual Recognition Agreements (MRA) in the Accountancy Sector. Among other things, these include recommendations on the form and content of MRAs in accountancy.

Mr Honeck then went on to give more details of developments in the accountancy field, including a workshop on domestic regulation held on 29 and 30 March 2004. **Topics covered had included**

- The GATS and domestic regulation
- Concepts related to the development of disciplines in domestic regulation
- The wider application of the accountancy disciplines
- The views of regulators and those regulated

In brief the accountancy disciplines cover

Transparency

- Information on competent authorities
- Information on activities regulated, licensing requirements and procedures, qualification requirements and procedures; and technical standards
- Information on the rationale behind measures relating to legitimate objectives (this supplied on request)
- The need to endeavour to provide an opportunity for prior comment before adoption of new measures

The WTO Working Party on domestic Regulation was established in April 1999 and replaced the Working Party on Professional Services. The emphasis is on the development of disciplines applicable generally to all services sectors. **The issues under consideration include**

- The necessity test – the obligation not to create “unnecessary barriers to trade”/policy objectives/least trade restrictive measures/reasonable available alternative means
- Transparency – clarification of existing GATS transparency provisions
- Equivalence – consideration of education, professional experience etc obtained abroad
- International standards (IS) – role as a benchmark?/presumption in favour of regulation based on IS/requirement to base regulation on IS

Mr Honeck then gave details of domestic regulation in the new round of discussions and the Hong Kong Ministerial Declaration adopted on 18 December 2005. The wording was “members shall develop disciplines on domestic regulation pursuant to the mandate under Article VI.4 of the GATS before the end of the current round of negotiations. We call upon Members to develop texts for adoption. In doing so, Members shall consider proposals and the illustrative list of elements for Article VI.4 disciplines.”

Details of the illustrative list of elements were then given as well as information on proposals made by Member States in the current round.

Outstanding issues in the Working Party were qualification requirements, where there was a wide divergence in the substantive requirements of Members and technical standards. In the case of the latter, some Members were unsure about the relevance of technical standards in services and about the impact of disciplines in this area. ▶

Possible legal forms for disciplines in domestic regulation included

- An annex to the GATS this would require a consensus and an amendment to the GATS
- Reference paper(s) – this would not require consensus or an amendment to the GATS
- Other forms for example additional commitments under Article XVIII, negotiated through requests and offers.

The next stages would be the circulation of an issues paper by the Chairman, the conversion by Members of their proposals into legal texts, the giving of a mandate to the Chairman to produce a first comprehensive draft and then text-based negotiations on the draft prepared by the Chairman.

The second speaker was **Dr Jens Gobrecht, Federal Association of German Associations of Pharmacists (ABDA)**, who entitled his presentation “Steering and Regulating Health Systems”.

Dr Gobrecht asked why health systems required steering? **This, he said was necessary because the goals were**

- To ensure universal access
- To ensure health services were of high quality
- To ensure equality
- To provide solidarity within society

Health systems were not “free markets”. There was information asymmetry between providers and those for whom services are provided. Social health systems subsidise the ill and the poor to ensure equal access to health services of high quality. Patients do not have free choice.

What are the implications of the GATS for health systems?

The objectives of the GATS were

- To ease trade in services
- To reduce trade barriers
- To promote liberalisation of trade in services

Possible effects of liberalisation of services according to the WTO were

- More competition
- Improved efficiency
- Improved quality of services
- Higher productivity
- More choice for consumers
- Lower prices
- Faster innovation
- Higher employment
- Technical transfer
- Greater transfer and predictability

The modes of trade in health services within the GATS were

- Mode 1- cross border trade. This included the shipment of lab samples; electronic and tele-health; clinical consultations; surveillance pathology; tele-education for health professionals; insurance.
- Mode 2 – consumption abroad. This included movement of patients for medical and dental services, health promotion and health tourism.
- Mode 3 – commercial presence abroad. This included provision of hospitals, clinics, nursing homes etc as well as training. There may be joint ventures and/or alliances.
- Mode 4 – movement of health professionals, trainers and managers

Services excluded are those supplied in the exercise of government authority i.e. any service supplied neither on a commercial basis, nor in competition with one or more service suppliers. Also under the Annex on



financial services, activities forming part of a statutory system of social security or public retirement plans are excluded.

After repeating the general obligations under the GATS, Mr Gobrecht dealt with the health exceptions in Article XIV. **This Article**

- Authorises Member states to take measures to restrict services and service suppliers for the protection of human, animal and plant life or health
- Gives Members the right to determine the level of health protection they deem appropriate
- Confirms that the WHO has recognised human health as being important in the highest degree
- Makes it clear that Article XVI measures override other obligations

However, the relevance of any measures taken has to be proven scientifically and are required to be no more trade-restrictive than necessary – although “no more trade-restrictive than necessary” had been defined.

Health-related sectors include medical and dental services, services provided by nurses and midwives, hospital services and life and health insurance. Community pharmacy services are not included.

Turning to specific commitments, the speaker made the point that each Member State is free either to make, or to decline to make, commitments and to choose both the number of sectors and the quality of their commitments (none, partial or full). If a Member State makes a commitment, it relates to all other Member States, regardless of whether an other Member State makes the same commitment or not. Specific commitments can be made on market access and/or national treatment.

Article XVI limits the measures that can be adopted or maintained if a Member State undertakes market access commitments. These all apply to health services and all are used.

Mr Gobrecht emphasised his conclusion that health systems are not free markets. Regulation is necessary if the goals of universal access, quality and solidarity are to be achieved. Liberalisation of trade in health services has to be in accordance with regulation to gain the benefits and mitigate the risks. He argued that a health service is in serious trouble if liberalisation makes regulation impossible by blocking key “steering tools”. Countries had to agree which steering tools have to be at their disposal if they are to be in a position to exercise their responsibilities for the organisation, financing and delivery of health services and medical care. This political agreement had then to be respected in trade negotiations as a “sovereign political decision” of the Member States. Countries had to be very careful in deciding which tools they were prepared to give away. **They must**

- Know about the effects of the “market access” tools for a health system
- Know about the “side effects” of not having steering tools any more
- Try to achieve a policy coherence between trade and health policies

Most of all, they had to realise that once steering tools were gone, they were gone for good. ■

Fifth session

Modes of supply and regulatory changes

The chair was again taken by **Dr Edward Hill**.

The first speaker was **Dr Alexandra Sidorenko, Australian National University**. She spoke of the globalisation of health services. This resulted from global connectivity and mobility, changing demography, new international players, improvement of healthcare provision in many developing countries and liberalisation of trade in services.

This presented both challenges and opportunities. She asked, "What makes health services special"? **The answers were**

- These services were directly related to well-being
- Equity of access is a key issue in public financing (large public financing needed to ensure access by the poor)
- Aspects of opening up health services to global competition including the impact on public services, the "crowding out" of nationals, internal or external brain drain and possible regional inequalities.

Regulation was necessary to prevent market failure and to achieve goals in terms of distribution of services. The speaker repeated the information about the four modes of trade in health services and made the point that although health services were "carved out" of the GATS, the dispensing of prescriptions was not included and this had led to e-pharmacies offering this service.

Problems in cross-border provision of health services included legal difficulties, privacy

protocols, setting of technical standards, regulatory issues on qualifications etc, ensuring professional indemnity cover and limits to benefits payable for a tele-consultation.

When patients travelled to access treatment in another country, there were problems for the country of origin in portability of the national health insurance benefits package and in consumer protection when something went wrong. The home country's healthcare system could have to bear the cost of remedial work. Some countries sought to attract fee paying "health tourists". This could lead to doctors leaving the public sector. In addition there were public health risks in some cases. Immigration and foreign exchange controls could have an impact in some cases.

Where international providers sought to establish hospitals or clinics, questions about the investment climate, tax policies and limitations on the number and/or form of establishments and applicable standards arose.

When health professionals moved, the following arose

- Registration and licensing requirements
- Recognition of education and experience in practice
- Variation in standards and/or clinical practices
- Limitations on type of employment permitted
- Limitations on geographical mobility within the host country
- The social impact of increased mobility including access to healthcare and regional distribution
- Under-utilisation of skills in the host country and shortages of health professionals in the home country
- Language and cultural barriers
- Social vulnerability of migrants

Dr Sidorenko then gave details of an ASEAN Mode IV study. The motivation had been to increase mobility of health professionals



internationally, including within the ASEAN region. Healthcare services were one of the priority sectors for ASEAN economic integration. There were potential benefits from increased temporary movement of health professionals within the region, with excess demand in some countries and excess supply in others.

However, there were barriers both explicit and implicit to mobility. Explicit barriers included visa regimes, quotas on foreign providers and minimum wage requirements. Implicit barriers included qualification and licensing requirements and procedures. The implicit barriers were said to be for consumer protection but in practice they significantly restricted movement when such matters as citizenship and residency requirements were specified.

The speaker then outlined regional initiatives that had been taken with a view to facilitating movement including

- ASEAN Mutual Recognition Arrangement on Nursing Services of 2006
- An ongoing project on "Skills standardisation for the nursing profession
- Western Pacific and South East Asian Region Common Competencies for the Nursing Profession (2006). This related to 27 countries.

Lessons to be learned from the ASEAN experience included

- Movement was impeded by regulatory measures such as qualification and licensing procedures, some of which would fail the "minimum necessary" test had it been applied.
- Regional agreements were in the lead in facilitating mode IV trade in health services.
- Liberalisation was more advanced in nursing than in medical services.
- More work was required on professional standards
- Much better data were required.

In concluding, Dr Sidorenko made the point that regulatory challenges existed in all modes of supply. Liberalisation of the private health sector had been "cautious" under the WTO/GATS and there was a need for regulatory and professional bodies to co-operate internationally to ensure the quality of health services and consumer protection in a cross-jurisdictional setting.

The next speaker was **Dr Suwit Wibulpolprasert, Senior Adviser in Disease Control at the Ministry of Public Health in Thailand**. He opened by making it clear that policy makers in developing countries, fearful of losing scarce health-care workers, were naturally resistant to measures that would facilitate an out-flow.

Those in developed countries wanted agreements that would assist them to obtain less expensive labour that would encourage more competition and produce higher profits. Thus an analysis of Mutual Recognition Arrangements (MRAs) under the ASEAN Framework Agreement on Services (AFAS) of 2001 insofar as they applied to health professionals, demonstrated that they did not facilitate more movement. In fact, they may create more hurdles to movement of health professionals. The recognition of degrees and licenses to practise still depended on the national regulatory systems of each country, without any mutual recognition. For example, within the MRA on Nursing Services, there is an added requirement for at least three years of practice after graduation before an application can be submitted for recognition. There was no such requirement in the local regulations of each country. For medical doctors and dentists, this requirement increased to five years. These conditions make it much more difficult to migrate.

These non-facilitating MRAs may be due to concerns about the unequal standards of education, professional recognition and health

services in the various countries. On the other hand they may stem from the conservative nature of most health profession regulatory bodies. Political decisions may not always be based on good rationale. It would be many more years before there were equal standards of education, professional regulation, training and practice, before real mutual recognition could be in place. On the other hand, the negotiations had created better understanding among the regulatory bodies for health professionals in the various countries. Eventually, a regional collaborative mechanism between national regulatory bodies for individual professions would be established. This would then facilitate joint development towards harmonisation of educational standards and licensing processes. In turn, this would be conducive to real mutual recognition.

At present, Dr Wibulpolprasert said, every country in the region was negotiating in its own interests. The feeling was that if one committed to the GATS, one lost control. If one did not commit, the door could be opened if advantages became apparent. He gave eight examples of current barriers to effective MRAs, illustrating the way in which a profession “protects itself” in its own country. ■

Sixth session Equivalence and global standards

Ms Judith Oulton was in the chair.

The speaker was Ms Jan Robinson, currently Registrar and CEO of the College of Physiotherapists in Ontario, Canada. In the time available, she said only a perspective could be offered.

A profession in various countries was different in terms of models of practice, education, the health system within which one operated, regulation (if it existed) and, of course, language and culture. On the other hand there were similarities in the interest in public safety and quality of care. Everyone faced resource challenges and, where there were regulators, they formed part of the country's economy.

There were new rules in the global market place, the drivers being the trade in services movement, the movement towards uniform standards and that towards accreditation. On trade in services, the conversations were global and regional and they concerned standards, performance and mutual recognition. Health was seen as a “global human right”.

After giving the ISO/IEC 17000/024 definition of a standard, Ms Robinson said the purpose of standards was to

- make the development and supply of services more efficient and safer
- facilitate trade between countries and make it fairer
- provide governments with a technical base for health and safety legislation and conformity assessment
- share advances and good practice



- disseminate innovation
- safeguard consumers
- make life simple by providing solutions to common problems

For services the push for standards was from governments

For conformity assessment, the principles to be applied (modified from Standards Council of Canada 2004) were

- contributes to safeguarding public health, the environment and public safety
- based on international standards and protocols without undue national bias
- avoids creating unnecessary obstacles to trade
- accessible, equitable and fair in treatment of all users
- in accordance with an accepted code of ethics
- results made publicly available.

There had, she said, been a prolific growth in international standards in recent decades – from a few dozen in the 1960s to 17,000 in 2007. And there were about 1100 new ISO standards per annum nowadays. There was an increasing link between standards and regulation. Questions were bound to be asked about the effect this had on economic efficiency and when voluntary standards had the effect of creating barriers to trade.

The “Washington Accord” indicated that accreditation comprised a systematic review of an academic education programme against set and agreed criteria to confer (or not confer) a status of achievement by a recognised legitimate review body. The benefits were generally improved quality of programmes and the creation of a basis for mutual recognition agreements. There was still only limited effect.

Ms Robinson expressed the view that accreditation should be regional rather than global and expressed doubts on whether, in practice, global standards could be achieved. Usually regionally, “equivalence” was qualified by

the word “substantial” and there was a link to achievement of about 80 per cent of competencies. Globally one could capture between 40 and 60 per cent of baseline competencies. Thus the “global professional” does not exist in practice. Also factors such as language, technology, ethics the practice environment and funding models had to be taken into account.

Professionals must, however, be part of the global dialogue and must “think and act global” in setting local standards. International principles must be developed on key elements for movement of professionals and partnerships developed across the health sector. There had to be links with leaders discussing standards and conformity and best practices must be shared. Common approaches and processes to fill gaps must be developed. If the imperative is public health and safety globally and locally, the only answer to the “global question” in Ms Robinson's view was to participate in building the solutions.

Panel discussion

All afternoon speakers took part. The following comments were made and answers given:

- There was no single structure for the dialogue suggested by Ms Robinson. Regional consultations were, or should be, in progress. The models seen at the conference should be used with a “bottom up” approach.
- In discussions on deregulation, professional and regulatory bodies could play an important role - not directly in WTO negotiations, only government representatives could do that, because they have power to implement agreements. These bodies should, however, influence government policies by advocacy. Professional bodies should also seek to ensure that health ministries representatives were present, alongside trade officials, during negotiations.
- There were positive examples of providing access to high quality health professionals in countries unable to produce their own. ▶

On the other hand, there were negative situations where countries suffered serious loss of healthcare workers, who migrated for economic reasons. They could also be an important source of foreign currency.

- The accountancy profession had worked for five years within the GATS but had been disappointed by the outcome, which had been “too soft” and was not yet legally in force. Considerable resources had been expended in the efforts. However, accountants still represented a possible springboard since a reasonable starting place had been established.
- One speaker suggested that in both mobility and skill mix changes, the rich tended to benefit and the poor gained very little. There was a need to gain the trust of the people because that brought power with it. If the public saw health professionals as “profit makers”, the professions lose the trust of the people and thus authority. Another speaker took a contrary view, suggesting that it was possible for both partners to gain.
- Would the health professions be able to set out the objectives they would wish to achieve within the GATS? The answer was probably “Yes”. If so, the information should be made publicly available. Regulators should be asked questions on why they impose specific controls such as those covering language skills. They should be reminded of the “no more burdensome than necessary” principle.
- If it were possible to agree global minima for educational standards and competencies for, say, medical doctors, mobility would be much easier to accomplish. In poorer countries, the worries were not at this level but rather at the level of having sufficient community health workers.
- National health systems differed from country to country for historical and cultural reasons. There should therefore be no attempt to “harmonise”.
- All the speakers shared some concerns about the likely effects of “free trade” in health professionals. The approach should be how to deliver good quality healthcare to poor people. There were benefits from good standards when the

same physicians were treating all patients in a public hospital.

- Rural areas presented a difficult problem.
- The EU was a good model for the gradual process towards providing a good standard of healthcare provision throughout the 27 Member States.
- Where commitments have been made in the GATS, one had to go to domestic legislation to determine what disciplines were needed. There was no automatic gain or loss from liberalisation. There were risks and opportunities.
- “Tourism for medical services” is occurring in South Africa and some regulation is necessary. Care to the local population can suffer. In addition, litigation has implications for liability cover for local providers. They deal in local currency but can be sued by a patient from a country with a stronger currency. This leads to increases in premiums for cover for local providers which, in turn, causes them to push up fees. This makes access more difficult for local poorer people. This situation also applies in Thailand. How could the situation be balanced? One possibility is to have a special tax for foreign patients and to use this to assist the local poor. The argument used against this approach is that it would make Thailand non-competitive and it would then lose out to other countries. In Thailand the current situation is leading to the best specialists and medical academics moving to private facilities for greater financial rewards. The challenge was to strike the right balance. Dr Sidorenko suggested that the best doctors moving to the private sector would not have been serving the poor before they moved. It was for governments to tackle the problem of movement from the public to the private sector by incentives.



In closing the conference, Dr Snaedel (WMA) thanked the organisers and everyone who had contributed to the undoubted success of the event. Individuals from the five participating organisations had carried out most of the work. The CEO of the ICN had suggested the overall topic of regulation. Thanks were also extended to the speakers, those who had displayed posters and the sponsors.

The shortage of healthcare workers was leading to task moving. This had always happened to some extent but with the support of health professionals. However, this was now being done without consultation with health professional bodies. The situation had to be closely monitored. The view had been from the top down. What was needed was a bottom up approach i.e. from the point of view of the health professions. It had been found that many health professionals considered that some regulation was a hindrance rather than a help towards the provision of effective and efficient healthcare services, although this had not been the intention. A balance had to be achieved.

The conference had identified topics that should be debated in more detail at subsequent similar events. ■