Access to medicines and high-quality therapeutics: global responsibilities for clinical pharmacology

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A major theme of the 2004 World Congress of Clinical Pharmacology and Therapeutics was worldwide equity of access to medicines

The 8th World Congress of Clinical Pharmacology and Therapeutics was held in Brisbane in August 2004. There were 940 participants from 60 countries, with Japan, Germany, Korea, South Asia and the United Kingdom well represented. The Congress featured three themes: Medicines and Society; Therapeutic Horizons; and Drug Discovery, Development and Disposition. Our report focuses on the Medicines and Society theme, which was strongly emphasised at the 8th Congress, differentiating it from previous Congresses. The prominence of this theme was to encourage the participation of clinical pharmacologists from South Asia and the Pacific regions, where access to lifesaving medicines and confidence in their quality are matters of everyday importance. The Congress also sought to encourage clinical pharmacologists from the developed world to engage with the serious global inequities in access to medicines for the major infectious diseases in the developing world, such as tuberculosis, malaria and HIV/AIDs, as well as the emerging developed-world lifestyle disorders, notably cardiovascular disease.

Equity of access to medicines

Several plenary lectures focused on access to medicines in developing countries. Suwit Wibulpolprasert (Senior Advisor on Health Economics, Ministry of Public Health, Thailand) gave an inspirational and challenging presentation *Philanthropy for the few — equity of access for the many?*, tackling the difficult issue of donated medicines. He exposed the increasing gap between rich and poor in both developed and developing countries, and the many interacting social, political and financial influences that conspire to take resources away from the people who most need medicines. He concluded with practical steps that clinical pharmacologists could take to alleviate problems of access to medicines, such as promoting the use of the World Health Organization (WHO) model list of essential drugs in their own countries.[1] This theme was reinforced by Sri Suryawati (Head of the Department of Clinical Pharmacology, Gadjah Mada University, Yogyakarta, Indonesia) who challenged all clinical pharmacologists to become involved in achieving the three "As" of medicine use in their own countries: access, affordability and appropriate use.

An important and contentious recent issue has been access to cheap, generic versions of fixed-dose combinations of antiretroviral drugs to deal with the HIV epidemic in Africa. Lembit Rago (Director of the WHO Division of Quality and Safety of Drugs, Geneva, Switzerland) discussed the difficult progress towards international acceptance of WHO guidance regarding registration of these products.

Attention was also given to the rapidly expanding complementary medicines sector. Charlie Xue (Program Leader, Division of Chinese Medicine, RMIT University, Melbourne, Vic) outlined the WHO's perspective on traditional medicine, and provided examples of the role of complementary medicine as a mainstay of public health systems in South-East Asia and the Pacific regions. Chu Quoc Truong (Director of The National Hospital of Traditional Medicine, Hanoi, Vietnam) related that the Vietnamese government has formally integrated traditional medicine with Western conventional medicine, with apparent good effect, notably wide acceptance of both traditions, allowing selection of cost-effective options from each.

Tony Smith (Emeritus Professor of Clinical Pharmacology, University of Newcastle, NSW) summed up the unfinished business for clinical pharmacology and world health. He reminded Congress participants that clinical pharmacology arose as a discipline largely in developed countries and continues to be vital to the stellar advances in drug discovery, providing guidance to early-phase human studies, interpretation of pharmacokinetic, clinical and adverse-effects profiles, and development of product information for virtually every significant new chemical entity entering clinical practice. However, many of the needs of developing countries remain unmet, partly because of the limited numbers of clinical pharmacologists. He highlighted the vital tasks of these "few":

- political advocacy for appropriate drug use;
- elaboration and implementation of national medicines policies; and
- specific "bread and butter" tasks, such as the collaborative development of standard treatment guidelines and essential medicines lists, and the promotion of rational prescribing, especially through training programs in medical schools.

All the plenary speakers uniformly encouraged the international umbrella organisation for clinical pharmacology, the International

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Union of Basic and Clinical Pharmacology (IUPHAR), to continue to become more proactive in these areas, particularly through strong collaborations with WHO and similar organisations. This paradigm shift was strongly endorsed at the IUPHAR council meeting held during the Congress.

Proper use of medicines

Another theme running strongly through the meeting, and prominent in the Medicines and Society stream, was the concept of QUM (quality use of medicines), which was developed in Australia in the early 1990s. The Congress was an important opportunity for Australia to showcase our progress in QUM, through the gathering of evidence about what actually works, followed by implementation of effective strategies through networks, products and services. The major sponsorship of the Congress by our own National Prescribing Service — itself a prominent outcome of the QUM movement — effectively emphasised the importance of the movement in Australia and its potential for other parts of the world.

Tom MacDonald (Professor of Clinical Pharmacology, Ninewells Hospital and Medical School, Dundee, UK) delivered an entertaining contribution with the important message that large returns in population health outcomes would accrue if we could better implement evidence-based guidelines and improve patients' adherence to therapy. For the prevalent cardiovascular disorders, lowering blood pressure is the intervention with the best evidence. Despite its proven benefits, blood-pressure control is poor worldwide. There are good arguments to support a more aggressive approach to blood-pressure management and treatment of younger individuals, but long-term compliance is a problem.

Drug safety

An increasing concern echoed in the Congress is the safety of medicines in older people, who are likely to have multiple comorbidities and increasing exposure to multiple, potent medicines. The future conduct of pharmacovigilance for new drugs is being shaped by interesting therapeutic risk management initiatives across the world, some of which were presented in a lively symposium entitled *Medication safety and pharmacovigilance*. These initiatives seek to better identify, evaluate and minimise the impact of adverse reactions, and to communicate evolving safety risks throughout the life cycle of a drug. Susana Perez-Gutthann (Senior Director, Global Epidemiology, Safety and Risk Management, Pfizer Worldwide Development, Barcelona, Spain) emphasised the need for this process to be proactive. The techniques of pharmacoepidemiology and use of advanced information technology to "mine" large automated health databases have revolutionised pharmacovigilance.

The problem of the "therapeutic orphan" status of children was examined in depth by speakers from Europe, the United States and Australia. Incentives to pharmaceutical companies to evaluate already marketed medicines in children, along with mandatory studies for new medicines in this age group (provided they are potentially useful) has been a successful strategy in the US since the mid-1990s and is now having a positive impact in Europe. A paediatric working party has advised Australian Health Ministers via their Advisory Council on steps to improve access to prescription drugs registered for use in children and the quality use of these medicines. However, the Congress heard that political pressure still needs to be maintained to overcome this problem for children in all countries.

Advertising medicines

A symposium on the controversial topic of direct-to-consumer advertising of prescription pharmaceuticals drew great interest, as the situations in Canada, the US, Europe, Thailand, New Zealand and Australia were compared. This advertising is legal only in the US and New Zealand. There were two main themes: first, that regulation is difficult; and secondly, as presented most forcibly by Barbara Mintzes (Postdoctoral Fellow, Centre for Health Services and Policy Research, University of British Columbia, Vancouver, Canada), that there are many, and increasing, instances of advertisements that skirt the boundaries of existing laws and regulations in jurisdictions where this advertising is illegal.

In developing countries, Krisantha Weerasuriya (Regional Adviser, Essential Drugs and Medicines Policy, WHO Regional Office for South-East Asia, New Delhi, India) pointed out that there is, in reality, often no distinction between supposed prescription and over-the-counter medicines in terms of access. It is very difficult to control direct-to-consumer advertising of so-called prescription drugs when prescription-only status is not upheld at law — the case in most countries in South-East Asia. However, in countries where direct-to-consumer advertising is currently illegal, there appears little appetite for its introduction because of concerns about quality use of advertised medicines, consumer demand leading to distortion beyond the "reasonable" need for medicines, and finally, morbidity and mortality from the adverse effects of medicines whose use was unnecessary. However, it was emphasised that there is continuous and considerable pressure from industry and advertising interests to reverse this attitude.

We have concentrated on the theme Medicines and Society, not because the other core themes of the Congress were less important, but because the urgency of addressing inequities in access to essential medicines around the globe is overwhelming. We were delighted that there was strong support to build on this focus at the 9th World Conference of Clinical Pharmacology and Therapeutics, which will be held in Montreal, Canada, in 2008 (http://www.cpt2008.com/).

Competing interests

None identified.

References

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