

# Asia Pacific Conference on National Medicines Policies

## Jane Robertson

Senior Lecturer<sup>1</sup>

## Budiono Santoso

Former Team Leader<sup>2</sup>

## Kathleen Anne Holloway

Regional Advisor

Essential Drugs and Other Medicines

World Health Organization

Regional Office for South-

East Asia

New Delhi

India

## Jonathan Dartnell

Executive Manager

Innovation and Evaluation

NPS MedicineWise

## Klara Tisocki

Senior Technical Officer<sup>2</sup>

## Andrew McLachlan

Professor of Pharmacy

(Aged Care)

Faculty of Pharmacy and

Centre for Education and

Research on Ageing

The University of Sydney

## Anthony Smith

Professor Emeritus<sup>1</sup>

<sup>1</sup> School of Medicine

and Public Health

University of Newcastle

New South Wales

<sup>2</sup> Essential Medicines and

Health Technologies

World Health Organization

Western Pacific Regional

Office

Manila

Philippines

## Key words

drug industry, drug

regulation, drug utilisation

*Aust Prescr* 2012;35:190–3

## SUMMARY

Medicines have an important role in providing health for all people. National medicines policies can help to achieve this goal.

Delegates from the Asia Pacific region have met to discuss how to actively implement national medicines policies. Although the countries are diverse, they have common challenges such as access to medicines, antibiotic resistance and the rational use of medicines.

Health insurance schemes can improve access to medicines. The pharmaceutical industry also needs to be involved in achieving universal access and rational use.

Consumer groups have an important role in ensuring policies are implemented. They can also be involved in promoting health literacy.

There is a need to build the capacity of drug regulatory agencies in the region. Regional cooperation will be needed to tackle problems of medicines quality, safety and rational use.

## Introduction

Universal health coverage is the most powerful component of public health.<sup>1</sup> An important element of this commitment is universal access to essential medicines.<sup>2</sup> Robust and effective national medicines policies are an important tool in achieving the objectives of universal access. Good policies appropriately implemented can help achieve health objectives within budgetary constraints.<sup>3</sup> While many countries in the Asia Pacific region say they have a policy, implementation has been inconsistent and in some cases early momentum has been lost. The consequence is that access to essential medicines remains compromised.<sup>4</sup>

Australia is unusual among developed nations in having an integrated national medicines policy. This is not the situation in many of the countries in the region. There are problems with access and affordability, and high out-of-pocket expenses can impoverish people on low incomes.

## The Sydney conference

A conference was held in Sydney on 26–29 May 2012 (see [www.apcnmp2012.com.au](http://www.apcnmp2012.com.au)) to emphasise the importance of actively implementing a national medicines policy to promote universal access to, and rational use of, essential medicines of assured safety, efficacy and quality. The 230 conference participants, a mix of policy makers, health professionals, regulators, academics, consumers and representatives of pharmaceutical industry, came from 45 countries. The diversity of the countries is reflected in their populations – small Pacific islands with populations of less than 25 000 inhabitants (Nauru, Tuvalu, Palau) compared to China and India with a combined population over 2.5 billion. Around half of the participating countries were low to low-middle income countries, but there were also high income countries like Australia, Brunei Darussalam, Japan, the Republic of Korea and Singapore.

The conference was a follow-up to the successful International Conference on National Medicinal Drug Policies held in Sydney in 1995.<sup>5</sup> Discussions at the 1995 conference endorsed the role and importance of having a national medicines policy and focused on four selected themes:

- the quality of medicines
- equity of access to medicines
- rational use of medicines
- the role of the pharmaceutical industry

These themes are reflected in the four pillars of the Australian National Medicines Policy.<sup>6</sup>

- safe and efficacious medicines of appropriate quality (functions managed by the Therapeutic Goods Administration (TGA))
- affordable access (through the PBS)
- the quality (or rational) use of medicines (a key role of NPS MedicineWise)
- a viable and responsible pharmaceutical industry (supported through a range of taxation, trade and financial incentives, government policy and codes of practice).

For a policy to be effective, activities need to be integrated within a functioning health system. At the time of the 1995 conference, elements of the Australian National Medicines Policy were in place, however an integrated policy was not launched until December 1999.

## 17 years on ... what's different?

The 2012 conference focused on the importance of an effective, enacted national medicines policy in ensuring access to good quality medicines and their rational use. The range of countries, their sizes and economic diversity mean that the challenges of policy implementation differ. Some countries have substantial local manufacturing and export medicines, others are completely reliant on imports. While some countries have embraced information technology using data for real-time analysis of medicines use, others have few data for monitoring performance and informing policy development. The policy themes of 1995 remain largely unchanged in 2012, however there are new challenges in each of the policy areas.

### *Safe, effective, good quality medicines*

While international attention focuses on fraudulent or counterfeit medicines,<sup>7,8</sup> a big concern is poor quality (substandard) medicines. A study of 1437 samples of five classes of antimalarial drugs purchased in South East Asia between 1999 and 2010 found that 35% failed chemical analysis, 46% of 919 failed packaging analysis, and 36% of 1260 were classified as falsified (counterfeit).<sup>9</sup> In 2008, a heparin produced with contaminated raw material procured from Asia caused deaths in the USA.<sup>10</sup> Unregulated companies and poor adherence to good manufacturing practice and international regulatory standards threaten medicine users worldwide, particularly in countries which are reliant on imports but lack their own regulatory framework or laboratory testing capacity.

### *Solutions*

Possible responses to these challenges include regional sharing of information about manufacturing quality, strengthening the capacity of drug regulatory authorities for quality assurance activities, enforcement of regulations, and legal prosecutions. Medicines inspectors need to be empowered to act – to seize goods and shut down operations when necessary – and to be trained in the evidential standards needed for successful prosecutions. The plethora of medicine products, inadequate numbers of qualified staff and corruption threaten these regulatory efforts. Agencies like the TGA have an important role in undertaking product testing and supporting capacity building in the region through leadership and sharing information.

### *Safety*

Medicines safety is more than adverse drug reaction reporting. While the World Health Organization (WHO) provides guidelines for establishing pharmacovigilance centres,<sup>11</sup> these centres are not feasible in many smaller countries. In addition, these

centres do not deal with other safety problems related to poor quality medicines (substandard or counterfeit products), or physical problems (for example products degraded by poor storage conditions or a lack of refrigeration).

There is an important role for medication error reporting systems to cover problems related to dispensing, prescribing and administering of medicines. Equally important is the ability to investigate and respond to these problems. This is a particular challenge when implementing national medicines policies with limited resources. These countries will need access to external experts and laboratories to support investigations until they build their own local capacity.

### *Affordable access to medicines*

An emerging challenge is the transition from the treatment of acute disease and infections to the management and prevention of chronic disease.<sup>12</sup> 'Vertical disease' programs, supported by international donors, have had enormous success in delivering both health care and medicines for tuberculosis, malaria and HIV. However, sustained efforts will be required to ensure adequate funding for medicines to treat chronic non-communicable diseases such as diabetes and cardiovascular disease. Without attention to this emerging need, there will be more examples of 'I wish I had AIDS', in response to the relatively poor access to affordable treatment for patients with diabetes compared to HIV in Cambodia.<sup>13</sup>

### *Solutions*

Health insurance schemes have the potential to improve affordable access to medicines in the region. An important consideration is what is included in a minimum benefits insurance package, balancing healthcare needs with financial constraints. Poor medicines coverage policies that do not meet prioritised healthcare needs may threaten the viability of these insurance schemes. The conference posed the difficult ethical question that if it is not possible to provide universal coverage, how can we best allocate the resources available?

Generic medicines have a key role in cost containment and for increasing affordable access to medicines. However, concerns about the quality of generic medicines in some countries create mistrust and poor acceptance by consumers and prescribers. While drug regulatory authorities have an important role in assessing bioequivalence and ensuring manufacturers comply with good manufacturing practice, education strategies are also needed to promote confidence and more widespread acceptance and use of generic medicines.

### ***Rational use of medicines***

It has been suggested that policies relating to the rational use of medicines (called quality use of medicines in Australia) can only be pursued after addressing the problems of medicines regulation, quality, access, pricing, financing, cost containment and generics.<sup>14</sup> In many Asian countries, medicines sales are used as a means for revenue generation to support the delivery of health services, making promotion of rational use extremely difficult. Perhaps it is not surprising that the rational use of medicines is often forgotten or considered too hard, but it needs to be aligned with the rest of a national medicines policy if the policy is to be effective. Key challenges in the region are the absence of data to clearly define the problems and a limited workforce able to design, implement and evaluate interventions to improve medicines use.<sup>15</sup>

### ***Solutions***

The WHO has advocated 12 key interventions to promote more rational use of medicines.<sup>16</sup> While most countries have some policies that support the implementation of these interventions, these need to be addressed comprehensively and systematically. The conference heard that those countries with more comprehensive policies to support the quality use of medicines do seem to achieve increased rational use.<sup>17</sup>

### ***Pharmaceutical industry***

Both multinational and local manufacturers need to be active participants in discussions about increasing access to medicines and ensuring quality products are available through a secure supply chain. They also need to improve policies and practices for medicines promotion, and explore new business models that recognise the need to balance profits with affordable and universal access to medicines. Important economic challenges remain for industry with differential pricing of medicines in low to middle income countries and more widespread use of pharmacoeconomic analyses to inform purchasing decisions by health insurance managers and governments. Already there is evidence, particularly from the multinational companies, of a willingness to be involved in providing affordable, universal access to medicines. The Access to Medicine Index\* provides a method to monitor and evaluate the performance of the pharmaceutical industry in areas such as research and development, equitable pricing, patents and licensing, along with product donations and philanthropic activities.

\* [www.accesstomedicineindex.org/methodology-index-2012](http://www.accesstomedicineindex.org/methodology-index-2012)

### **What's new?**

Several new challenges have emerged since 1995.

#### ***Health literacy***

National medicines policies have to address the issue of providing quality medicines information to consumers and health professionals, particularly given the importance of adhering to the treatment of chronic illness. While the need for consumers to be informed and health literate seems obvious, strategies for achieving this are not. The conference heard about activities that focus on improving health literacy and consumer knowledge about medicines. People can learn basic concepts of over-the-counter medicines in group sessions from responsible media or peer-educators. By understanding medicine labels and product contents, consumers can make more informed medicines purchases. Some interventions have aimed at women as consumers of healthcare and the source of medicines knowledge within families. A challenge for all of these programs is showing that improved knowledge translates into behavioural change and sustained improvements in medicines use.

#### ***Advocacy and civil society***

The development of the Australian National Medicines Policy was the result of strong consumer (civil society) advocacy and lobbying in the 1990s.<sup>6</sup> While there are examples of consumer activism in other countries (such as India, Thailand and China), a lack of financial support for consumer groups and poor access to policy makers make progress difficult. Some recent advocacy has relied on networking across borders to share evidence and develop strategies for engagement in policy development and reform.

It is critical that civil society organisations are involved in policy discussions about universal access. A key challenge remains engaging civil society to pressure governments to deliver policies which enhance affordable access and guarantee that safe and high quality medicines are available.

#### ***Antimicrobial resistance and antibiotic use***

Antimicrobial resistance is a global problem.<sup>18,19</sup> Contributing factors include high rates of antibiotic prescribing by doctors and non-medical prescribers, inappropriate choices of antibiotics, availability of antibiotics without a prescription, community expectations of a 'quick fix', and widespread and routine use in veterinary and agricultural practice. It is difficult to assess the extent of the problem as there are few reliable data available and it is a challenge to convince policy makers, health professionals and consumers that this is a real or soluble problem.

Regional collaboration and partnerships are essential and this is the strategy behind Action on Antibiotic Resistance.<sup>20</sup> This network has programs in South East Asia which link researchers, advocacy groups, and those engaged in prevention, control and management of antimicrobial resistance at community and hospital levels. Projects include Antibiotic Smart Use (Thailand), Smart Use of Antibiotics (Indonesia) and the Antimicrobial Stewardship Programme (Singapore).

### What's needed?

Further implementation of national medicines policies in the Asia Pacific region requires renewed political will and commitment to medicines policies. There are also important needs for improving healthcare delivery systems including capacity building within countries, information sharing and the collection and analysis of data to monitor performance and progress.

### Building capacity

Capacity building is required in several areas – regulatory activities, evaluation of medicines for inclusion on essential medicine lists and reimbursement programs, monitoring medicines use and the design, delivery and evaluation of programs for rational use and medicines safety. There are opportunities for regional sharing of information on quality assurance, medicine prices and health financing initiatives.

Processes can be adapted from vertical disease programs to improve medicines procurement, supply and distribution.

Regional analyses by the WHO have identified needs for training in clinical pharmacy, clinical pharmacology and pharmaceutical sector management, and also problems of health system fragmentation associated with donor and vertical disease management programs. Much better coordination is required.

### Developing data

Data collection and analysis are needed to support the monitoring of drug regulatory authorities and their activities including inspections and product testing, performance of medicine supply and distribution systems, medicines affordability, availability and use. A first step is examining routinely collected data to assess its usefulness for monitoring and reporting. Where routine data collection does not exist, it will be necessary to identify (and commit to build) minimum data sets to inform and monitor the delivery of a national medicines policy. There is also a role for the development of validated indicators that can be used for within-country monitoring and between-country comparisons.

### What's next?

A significant theme of the conference discussions was the value and importance of regional collaboration and networks, to share experiences, information and expertise. To build on this momentum, a small number of regional projects will be undertaken to foster relationship building and information exchange. Some early successes with these projects will encourage support for further collaboration and promote further country-specific activities.

The successful implementation of national medicines policies is critical to improving the health outcomes of people in our region. This conference addressed many of the practical aspects and solutions that will help facilitate this. There was widespread support from participants for another conference in three to five years to continue the dialogue, and to report on policy developments and on progress towards universal access to medicines. ◀

Details of the program, presentations at the conference and the full conference report will be available at [www.apcnmp2012.com.au](http://www.apcnmp2012.com.au)

#### Conflict of interest:

*Professor McLachlan has received funding for a PhD scholarship from GlaxoSmithKline investigating ethnic differences in drug response, funding for a research assistant for development of a herb-drug interaction database from IMGateway, and an investigator-initiated research grant from Pfizer. Other research funding is provided by NHMRC Project Grants.*

#### Acknowledgements:

*The Organising Committee would like to acknowledge and thank AusAID for the support of overseas delegates to this conference.*

*The Organising Committee is grateful for the financial support for delegates provided by Therapeutic Guidelines Pty Ltd, Australia, the Australian Medicines Handbook Pty Ltd and the Pharmaceutical Society of Australia.*

*The Asia Pacific Conference was made possible through the generous support of its sponsors – NPS MedicineWise, the Australian Government Department of Health and Ageing, the University of Newcastle, Australia and the World Health Organization (Western Pacific and South-East Asian Regional Offices).*

### REFERENCES

References are online with this article at [www.australianprescriber.com/magazine/35/6/190/3](http://www.australianprescriber.com/magazine/35/6/190/3)