

## ASIA PACIFIC CONFERENCE ON NATIONAL MEDICINES POLICIES

Better Health Through National Medicines Policies

Conference  
Report



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This supplement reports on the proceedings of the Asia Pacific Conference on National Medicines Policies, held in Sydney, Australia, on 26–29 May 2012.

It was prepared by Dr Jane Robertson, Chair of the Scientific Program Committee, and does not necessarily represent the views of NPS, WHO, University of Newcastle or the Australian Government Department of Health and Ageing.

The Conference report is published as a supplement to *Australian Prescriber* at [www.australianprescriber.com/supplement/36/1/1/56](http://www.australianprescriber.com/supplement/36/1/1/56)

More detailed summaries of the symposia, workshop discussions and presentations in the plenary sessions are available on the Conference website at [www.apcnmp2012.com.au](http://www.apcnmp2012.com.au)

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## Foreword

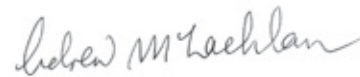
The Organising Committee, the Scientific Program Committee and the International Reference Panel are pleased to present this report of the Asia Pacific Conference on National Medicines Policies 2012.

In offering their support for this conference, the Australian Government and the World Health Organization demonstrated their commitment to national medicines policies in the region and confirmed the importance of robust and effective national medicines policies if the objectives of universal access to needed medicines and rational use of medicines are to be achieved.

The enthusiasm of the delegates and their willingness to openly share their views and experiences of implementing national medicines policies was testament to the commitment of those many

individuals working in the region to deliver on the promises and potential for improved health care embodied in universal access to medicines.

We hope that the open and frank discussions of the barriers and enablers to policy implementation, and the emphasis on next steps and strategies that can be applied to overcome these barriers, provide guidance and direction for national efforts to extend policy implementation in the Asia Pacific region.



**Professor Andrew McLachlan**  
**Chair**  
**Organising Committee**  
**Sydney, August 2013**

## Acknowledgements

The Organising Committee would like to thank:

- AusAID for the support of overseas delegates to this conference
- Therapeutic Guidelines Limited, the Australian Medicines Handbook, and the Pharmaceutical Society of Australia for financial support for delegates

- the international organising committee of the 2011 International Conference on Improving Use of Medicines (ICIUM) for their support and advice in the development of the conference materials and website.

The Scientific Program Committee would like to thank Emeritus Professor Andy Gilbert and Dr John Primrose for their contributions to the development of the scientific program.

## Conference sponsors

The Asia Pacific Conference on National Medicines Policies 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
- the World Health Organization (Western Pacific and South East Asian Regional Offices).



## Preface

The Asia Pacific Conference on National Medicines Policies, held in Sydney, Australia on 26–29 May 2012, was a follow-up conference to the very successful International Conference on National Medicinal Drug Policies held in Manly, Australia in 1995.

The 1995 conference brought together 300 people from almost 50 countries and focused on four key themes of national medicines policies, namely equity of access to medicines, rational use, the quality of medicines, and the role of the pharmaceutical industry.

The Manly conference produced a number of general recommendations along with specific recommendations relating to the four themes of the conference. The proceedings of the conference were reported in a supplement to *Australian Prescriber* (Aust Prescr 1997;20 Suppl 1).

The conference provided the impetus for policy work in the region, seeded a seminar on national medicines policies for 14 Pacific nations in 1996, promoted educational interventions in rational drug use and ethical promotion, and underpinned discussions on rational drug use that continued at the International Conference on Improving Use of Medicines held in Thailand in 1997.

Some 17 years after the Manly conference, 233 delegates from 46 countries participated in the Asia Pacific Conference on National Medicines Policies. The impetus for this conference was the recognition that while many countries in the Asia Pacific region reported having a national medicines policy, progress

on the implementation of these policies had been inconsistent. In addition, it was recognised that robust and effective national medicines policies are an important tool in achieving the objectives of universal access to needed medicines and their rational use.

The conference provided the opportunity for countries in the Asia Pacific region to come together and share their knowledge, skills and experiences as they have moved to implement the various elements of their national medicines policies.

This report provides a record of selected presentations and discussions that occurred at the conference. However, it only provides a relatively small window on the work of the conference, the richness of the discussions, and the generous sharing of experiences in the successes, difficulties and ongoing challenges in implementing national medicines policies in the region.

In keeping with the conference theme of promoting and supporting further implementation of national medicines policies, there is particular emphasis in this report on identifying the key barriers and key enablers to policy implementation, steps to address these barriers and enablers, and how to monitor progress.

Important outcomes of this conference are the continued commitment to further implementation of national medicines policies within the Asia Pacific region. There is enthusiasm for ongoing discussion between countries and the development of regional collaborations, groups and networks to support this important policy work.

### Structure of this supplement

After the Executive summary with Action items is Plenary 1, the opening session of the conference. Plenary sessions 2–10 were mostly chaired sessions with a range of speakers and topics. Plenary 10 was the conference closing session. A special session covered reproductive health services. The four symposia and nine workshops follow.

Outcomes of the discussions are presented as dot point summaries addressing the key issues of

the session, the barriers and enablers for policy implementation, steps to address these, and methods to monitor progress in implementation. For details, see the conference program in Appendix 1.

More detailed summaries of the symposia and workshop discussions and presentations in the plenary sessions are available at [www.apcnmp2012.com.au](http://www.apcnmp2012.com.au)

## Executive summary

### Introduction

According to the World Health Organization (WHO), a national medicines policy defines a framework for setting and monitoring medium- to long-term objectives in the public and private pharmaceutical sectors.<sup>1</sup> The objectives of national medicines policies have not changed substantially over time, namely within the scope of a national health policy to ensure equitable access to and the rational use of safe and effective medicines of good quality and at a price both individuals and society can afford.

Despite the commitment to a national medicines policy in many countries, progress on the implementation of these policies has been inconsistent. In reality, most of the major causes of human morbidity and mortality in developing countries can be prevented or treated with existing essential medicines. For millions of people in these developing countries, problems of access to essential medicines remain. Medicines are often not available or affordable. They may be low quality or fraudulent products and they may be inappropriately used in practice. Consumer out-of-pocket expenses on medicines account for a substantial proportion of total healthcare expenditures in developing countries, and for many people on lower incomes, these out-of-pocket expenses push them below the poverty line with major health consequences.

Australia is unusual among developed countries in having had a functioning national medicines policy since 2000. The policy has the health outcomes of Australians as its objective and is usually described in terms of four arms or pillars:

- equitable access to necessary medicines
- medicines of high quality, efficacy and safety
- quality use of medicines
- a viable and responsible medicines industry.

During the opening session of the conference, Emeritus Professor Lloyd Sansom described the Australian policy as providing an ethos or framework for action. It is a set of broad high-level principles

shared by all stakeholders, upon which processes, systems, resources and behavioural change can be developed and evaluated.

Given the importance of medicines to health care and overwhelming evidence of problems with medicines' access and affordability in the Asia Pacific region, the overall aim of this conference was to advocate action to implement national medicines policies. This will promote universal access to needed medicines of assured safety, efficacy and high quality, and their rational use, by integrating national medicines policies into the healthcare systems of the participating countries. Important outcomes of the conference were agreed priorities and strategies to enable further implementation of national medicines policies across the region.

### Conference objectives

- To share knowledge, skills and experiences delegates have gained as they have moved to implement elements of their national medicines policies.
- To understand the major enablers and barriers to policy implementation.
- To determine the current priority elements of national medicines policies for implementation in participating countries.
- To consider an evaluation framework to monitor implementation of national medicines policies for the region.
- To strengthen networks and collaboration across the region to effectively implement national medicines policies.

### Participants

Conference participants included policy makers, those working in government, health professionals, researchers and academics, representatives of consumers and civil society, non-government organisations, the pharmaceutical industry and those involved in quality use of medicines activities.

Countries from the Asia Pacific region officially represented at the conference were Afghanistan, American Samoa, Australia, Bangladesh, Bhutan, Brunei Darussalam, Cambodia, China, Cook Islands, Fiji, India, Indonesia, Japan, Kiribati, Laos, Malaysia, Marshall Islands, Federated States of Micronesia, Mongolia, Myanmar, Nauru, Nepal, New Zealand, Niue,

<sup>1</sup> How to develop and implement a national drug policy. WHO Policy Perspectives on Medicines. Geneva: World Health Organization; 2003. <http://apps.who.int/medicinedocs/pdf/s4869e/s4869e.pdf> [cited 2013 Jul 16]

Northern Mariana Islands, Pakistan, Palau, Papua New Guinea, Philippines, Samoa, Singapore, Solomon Islands, South Korea, Sri Lanka, Taiwan, Thailand, Timor Leste, Tonga, Tuvalu, Vanuatu, Vietnam and Western Samoa. In addition, the conference attracted delegates from the USA, France, Netherlands, South Africa, Switzerland and the UK.

### The conference program

The emphasis of the conference was on sharing experiences. To this end, the conference included a number of plenary sessions with invited country presentations:

- National medicines policies and universal access to medicines (presentations from WHO Western Pacific Regional Office, South East Asia Regional Office, Australia, and the UK).
- Access to medicines, national medicines policies and healthcare reform (presentations from China, Japan, South Korea, and India).
- Experiences of implementation of national medicines policies (presentations from Indonesia, Malaysia, Thailand, Laos and the Pacific Islands).
- Challenges to implementation of national medicines policies: solutions and unresolved problems (presentations from Bangladesh, Sri Lanka, Vietnam, and the Philippines).

The conference program included four symposia focusing on important topics in the Asia Pacific region:

- Legislation to ensure the sustainability of national medicines policies
- Monitoring medicines use
- Consumer education and health literacy
- Access to and use of opioid medicines.

In addition, there was a special session presented by the United Nations Population Fund titled 'Universal access to reproductive health services and commodities: Opportunities for national medicines policies/universal access to medicines collaboration'.

A key feature of the conference was a series of nine workshops focusing on different components and challenges associated with the implementation of national medicines policies. The workshop topics were:

- Medicines selection and essential medicines lists
- Medicines financing and health insurance initiatives
- Ensuring quality of medicines
- Medicines supply and distribution

- Generic medicines policies
- Antimicrobial resistance and rational use of antibiotics
- Medicines safety
- Advertising and promotion of medicines
- Rational use of medicines.

### Exploring the issues

This report provides summaries of the conference presentations and workshops. Given the importance of the symposia and workshops as forums for the exchange of ideas and the development of strategies for further implementation of national medicines policies, there is relatively more emphasis on these discussions than on the plenaries in this report. The output of each symposium and workshop was a structured dot point summary of key observations relating to the topic, comments on the key barriers to, and enablers of policy implementation, practical steps to address the barriers and enablers and comments on how to monitor progress in the implementation of that aspect of a national medicines policy.

The conference report is published as a supplement to *Australian Prescriber* at [www.australianprescriber.com/supplement/36/1/1/56](http://www.australianprescriber.com/supplement/36/1/1/56). More detailed summaries of the sessions are available at [www.apcnmp2012.com.au](http://www.apcnmp2012.com.au).

### Key observations

Many of the recommendations of the 1995 conference remain important for participants in the 2012 conference:

- Recognising health as a human right.
- Embedding a national medicines policy within a health systems policy framework.
- The importance of political will to introduce appropriate legislation and to support policy implementation.
- The need to provide adequate human and financial resources for national medicines policy activities.
- Enforcing legislation and regulations to ensure affordable access to high quality, safe and effective medicines.

However, in 2012 the emphasis has changed. In 1995 the conference focused on establishing national medicines policies and convincing decision makers of their value. The focus of the 2012 conference was the successful implementation of national medicines policies, using experiences across many countries to propose strategies to enhance policy implementation and sustain national medicines policy activities into the future.

### ***Health as a human right***

This right is embodied in the WHO Constitution:

the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being...<sup>2</sup>

Improving health has many dimensions including adequate shelter, sanitation, improving nutrition, and education along with the provision of appropriate and affordable health care for the prevention and treatment of disease. Medicines will be competing with other programs for scarce resources. However, health is being increasingly viewed as a major issue in, perhaps even an indicator of, economic growth and development particularly in low and middle income countries. Medicines and their judicious selection, availability and use are important in effective health care.

### ***Political commitment to policy and processes***

In a number of countries, the early gains in national medicines policy implementation have been lost due to a lack of ongoing political commitment and loss of policy champions. Governments need to recognise the importance of a strong legislative framework and a commitment to enforcing the law. Existing systems need to be strengthened and financial resources mobilised to address regional problems in providing access to medicines of appropriate quality, safety and efficacy. National medicines policies and activities to support them need to be presented as a compelling business case for governments to support and resource.

### ***National medicines policies need to be embedded in health policies and health systems***

National medicines policies should not exist in isolation. They need to be considered as part of the delivery of high quality health services. The policy milieu extends beyond health systems policy, given that national medicines policies have substantial financial implications and will be affected by financial policy and trade considerations, international treaty obligations, industry policies, education policies and the legislative and regulatory framework of the country. The policy landscape increasingly includes public-private partnerships. These need to be negotiated, monitored and evaluated for their impact on health service delivery.

### ***Ethical questions and challenges***

In an environment of resource constraints and competing demands for limited financial resources, there will be difficult ethical questions to confront. If it is not possible to provide for all people, how can governments allocate resources to maximise the benefits of policy interventions? Decisions need to be supported by high quality evidence and take account of societal values, recognising that equity is an important goal of universal access. Transparent decision-making frameworks along with active monitoring and evaluation of policy activities are required to ensure that systems are effective, efficient and sustainable.

### ***Health literacy and engagement of civil society***

Civil society has an important role in maintaining pressure on governments and decision makers to continue to value and to deliver on health care. The dialogue on resource allocation must engage all levels of civil society, especially the consumers of health care. Greater awareness and understanding of health issues and active community engagement will need to be underpinned by improvements in health literacy. In many settings there is an abundance of information and promotional activity from the pharmaceutical industry, but a relative lack of health literacy and objective information meeting consumer needs. Furthermore, it is essential that governments and societies continue to place a high value on health literacy as a long-term investment in the health of each nation's people.

### ***Sufficient financial and human resources***

Capacity building to fulfil the functions of a national medicines policy was a recurring theme of the conference. Adequate staffing and task-specific training are essential to implement national medicines policies, along with adequate financial resources to retain and develop high quality staff. Through strategic collaboration, international and regional experts can help to train local staff in areas such as the law, quality assurance, regulatory control, medicines procurement and the design, development, delivery and evaluation of programs for the rational use of medicines.

### ***Monitoring and appropriate use of health and medicines data***

Routine collection of relevant health and medicines data is required to monitor the effectiveness and efficiency of existing systems and to assess progress in national medicines policy implementation. Data collection and analysis need to be timely. Information needs to be provided to decision makers and

<sup>2</sup> Constitution of the World Health Organization. <http://apps.who.int/gb/bd/pdf/bd47/en/constitution-en.pdf> [cited 2013 Jul 16]



stakeholders in ways that are easy to understand and provide a platform for action. There is an urgent need for training staff in data collection, analysis and interpretation of health and medicines information. IT systems offer the promise for cost-efficient data collection but need to be designed to support monitoring and evaluation. Data are needed to demonstrate the value of implementing national medicines policies.

### **Collaboration and relationship building**

Regional partnerships and networks may help overcome capacity constraints. Recognising medicines evaluations and quality assurance activities conducted by other drug regulatory authorities provides an opportunity to minimise the duplication of effort. Sharing experiences, challenges, resources and solutions will support further activities to implement national medicines policies.

### **Advocacy**

An important missing link in implementing national medicines policies is the voice of the consumer. This reflects the failure of the national medicines policy movement to engage effectively with communities and to socialise and politicise the issues of medicines access and affordability. The consumer viewpoint must be heard and community values and priorities incorporated in policy development and decision making. Effective civil society action will require

champions to energise the debate and advocate for change on behalf of those who will benefit most from effective national medicines policies.

## **Conclusion and next steps**

An overwhelming view of the conference was of the value and importance of regional collaboration and networks, to share experiences, information and expertise. The conference provided an important platform for starting to build these collaborations and networks. The conference discussions gave rise to a number of important action items that can help stimulate further implementation of national medicines policies in the Asia Pacific region.

The next steps involve dissemination of the conference outcomes to policy makers and those actively involved in the medicines-related activities. In addition, follow-up activity will involve developing a small number of regional projects that foster relationship building and information exchange, and that encourage data collection and reporting both within and between countries.

Delegates gave overwhelming support to a future conference on national medicines policies in three to five years to continue the dialogue and reflect on progress towards universal access to needed medicines of assured safety, efficacy and quality, and their rational use.



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World Health Organization

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The Cook Islands, Niue, Samoa, Tokelau and Tonga are also part of the WHO Western Pacific Region but are not shown in this map projection.

## Action items

The plenary sessions, workshops and symposia identified important medicines-related activity where action is required. A number of actions were common to multiple aspects of a national medicines policy:

- the need for capacity building
- the importance of data collection and analysis for monitoring progress in implementing national medicines policies
- opportunities for regional collaboration and information sharing.

### 1. Capacity building and information sharing

- Regional collaboration to build capacity for evaluation of medicines for inclusion on a national essential medicines list.
- Sharing expertise for the design, development, delivery and evaluation of rational use of medicines and medicines safety programs led by regional experts.
- Sharing of health and medicines-related data on:
  - medicines prices in the public and private sectors
  - medicines regulation and quality assurance activities
  - successes and failures with rational use of medicines activities.

**Action:** Maintain a register of regional expertise to enable countries to quickly identify resources to assist with medicines safety problems.

**Action:** Create and maintain networks of interested healthcare professionals and policy makers for specific areas of policy activity – for example antimicrobial resistance – to facilitate discussion, information sharing, problem solving and capacity development.

### 2. Data collection and analysis for monitoring policy implementation

Regular monitoring and reporting on:

- Drug regulatory authority staffing and functions, and outcomes of regulatory activities including inspections and product testing.
- Procurement, access and use of opioid medicines within each country.
- The performance of medicines supply systems.
- Reproductive health program-specific indicators.
- Medicines availability, use and affordability (including out-of-pocket expenses).
- Monitoring of prices, use and quality of generic medicines.
- Antimicrobial resistance, prescribing practices, ease of antimicrobial availability and consumer use of antibiotics.
- Outcomes following identification and analysis of medicines safety problems.
- Indicators relating to regulation, advertising and rational use of medicines.

**Action:** Examine routinely collected medicines-related data within country to assess usefulness for monitoring and reporting activities. When this does not exist, establish minimum data sets and standardised methods to provide useful data to inform and monitor program delivery.

**Action:** Develop limited sets of validated indicators relevant to each national medicines policy activity to be used for within-country monitoring and to facilitate between-country comparisons.

**Action:** Use examples of data collection and analysis to advocate for human and financial resources to support national medicines policy activities and to sustain ongoing monitoring.

### 3. Legislation to ensure sustainability of national medicines policies

**Action:** Promote dissemination and sharing of best practice legislation, regulations, codes and standards.

**Action:** Promote greater collaboration between the legal and health sectors regarding laws related to medicines and national medicines policies through engagement in topic-specific projects.

**Action:** Develop country level programs to train medicines inspectors on the evidence required to pursue successful prosecutions in the court system.

**Action:** Conduct country level reviews of penalties, sanctions and successful prosecutions for breaches of medicines laws.

### 4. Health insurance and health care financing

**Action:** Develop a regional database on insurance medicines benefits policies and situations. The health insurance surveys of the Medicines and Insurance Coverage initiative (see Appendix 4) could be a useful initial tool to collect country information.

### 5. Access to and use of opioid analgesic medicines

**Action:** Develop policies and guidelines on prescribing and availability of opioid medicines within a country.

### 6. Medicines industry

The conference provided an important opportunity to engage in discussions on industry roles and responsibilities with national medicines policies. Both multinational and local manufacturers of branded and generic medicines need to participate in discussions on mechanisms to increase medicines access, ensure quality products are available and maintain the security of the supply chain, improve policies and practices around promotion, and address needs for antimicrobials and medicines for neglected diseases. There is a need to explore new business models that recognise the need to balance profits with affordable and universal access to medicines, particularly in low and middle income countries.

**Action:** Engage stakeholders (industry, regulatory authorities, consumers, health professionals, academia) to examine paths to progress affordable and universal access to medicines in low and middle income countries. Tools such as the Access to Medicine Index (see Appendix 4) may provide a mechanism for monitoring industry activity and progress towards universal access objectives.

### 7. Reproductive health services and commodities

**Action:** Explore the possibilities for collaboration between procurement and supply of essential medicines and the provision of reproductive health services and commodities.

## Conference opening

### Plenary 1

The conference began with a 'welcome to country' ceremony from Mr Michael West, a cultural representative of the Metropolitan Local Aboriginal Land Council who are the traditional custodians of the land, air, water and culture within their boundaries.

Dr Suzanne Hill, the Chair of the Australian Pharmaceutical Benefits Advisory Committee, formally opened the conference, speaking on behalf of the Australian Minister for Health, the Hon Tanya Plibersek.

Dr Henk Bekedam from the Western Pacific Regional Office of the World Health Organization (WHO) welcomed conference delegates on behalf of the WHO.

Professor Andrew McLachlan, the Chair of the Organising Committee for the conference, welcomed delegates on behalf of the Australian organisers.

## Opening address

**The Hon Tanya Plibersek MP**  
Australian Minister for Health  
Speech delivered by

**Dr Suzanne Hill**  
Chair  
Pharmaceutical Benefits  
Advisory Committee

I would like to begin by acknowledging the traditional custodians of the land on which we meet, and pay my respects to their elders, both past and present.

It is a great pleasure to be with you today on behalf of the Australian Minister for Health, Tanya Plibersek.

Australia is pleased to again host an international conference on national medicines policies – an opportunity for constructive sharing of knowledge, skills and experiences on this vital aspect of health care.

I am delighted to see so many countries from across the South East Asia and Western Pacific regions represented here today, along with visitors from countries further afield including the United States, the United Kingdom and Europe.

Australia led the way with our National Medicines Policy. Established in December 1999, it continues to evolve to meet the changing needs and circumstances of government, consumers, health professionals and industry.

Of course there are initiatives in other countries which will be of great interest to Australians and could help to make a good system even better – which is what the exchange at this conference is all about.

Similarly the Australian approach can be of interest even though it may not be directly transferable to some countries.

Different countries in our region are at different stages in their development and implementation of health system and medicines policies.

They will need to ensure their own medicines policies are developed to best serve their people and their health systems.

We are all here to learn.

In this afternoon's plenary session, Professor Lloyd Sansom will provide a more detailed account of Australia's experience in implementing our National Medicines Policy.

For now, I would like to highlight the partnership approach which has underpinned that implementation.

The policy framework is based on partnerships between:

- governments (Commonwealth, States and Territories)
- health educators
- health practitioners and other healthcare providers
- the medicines industry
- patients and their carers.

All of these partners work together to promote the four central objectives of the policy.

These are:

- timely access to medicines that Australians need at a cost individuals and the community can afford
- ensuring that all medicines meet appropriate standards of quality, safety and efficacy
- quality use of medicines by consumers and health professionals
- maintaining a responsible and viable medicines industry.

First, timely access to affordable medicines.

The Pharmaceutical Benefits Scheme (PBS) is the primary means through which the medicines policy is implemented to ensure reliable, timely and affordable access to a wide range of medicines for all Australians.

The inclusion of medicines on the PBS is done on advice of an independent statutory authority, the Pharmaceutical Benefits Advisory Committee. The Committee considers not only the clinical effectiveness of a medicine but also its cost-effectiveness before recommending it to Government. It is this process that has helped Australia achieve highly competitive prices for new and innovative medicines.

The Government currently subsidises over 4,000 medicines through the PBS, making it one of the most accessible and affordable medicine subsidy schemes in the world.

Some of the subsidies provided by the PBS – on rare and expensive medicines – are very large.

The overall cost of the PBS represents a large portion of the health budget. In 2005–06 the PBS represented 12.8% of all Commonwealth Health expenditure. In 2010–11 that percentage had grown to 14%.

In fact, the PBS is expected to cost the Australian Government around \$9.4 billion in 2011–12, which is an increase of 6.1% on 2010–11.

This investment is a direct reflection of the commitment the Australian Government has to the PBS because, just as it has done since 1948, it provides all Australians with affordable access to the medicines they need. And in combination with providing funding and support to around 5,000 pharmacies it also ensures these medicines can be accessed in a timely fashion, wherever in Australia you are.

Ensuring the ongoing sustainability of this system is of the utmost importance to the Government. This is why consecutive governments have introduced various reforms to ensure the correct balance between taxpayer-funded PBS subsidies, contributions from consumers and an environment that encourages industry to bring new medicines to Australia.

I am sure that you will be hearing more about the PBS and the approvals process during the course of the conference.

The second priority of the National Medicines Policy is that medicines meet appropriate standards of quality, safety and efficacy.

One of the major mechanisms for this is the Therapeutic Goods Administration (TGA). The TGA is responsible for ensuring that therapeutic goods available for sale and supply in Australia are safe and fit for their intended purpose.

Before a prescription medicine can be marketed in Australia it must be included in the Australian Register of Therapeutic Goods. In order to register a new medicine in Australia, a sponsor must submit an application together with supporting data to the TGA. The TGA evaluates the data to establish the quality, safety and effectiveness of the product when used as intended.

The TGA also usually seeks advice from two independent, expert advisory committees, before deciding to approve or reject a new product.

The third objective of the medicines policy is quality use of medicines.

It means –

- selecting management options wisely
- choosing suitable medicines, if medicine is needed
- using those medicines safely and effectively.

The National Prescribing Service (NPS) is the Australian Government's implementation body for quality use of medicines under the medicines policy.

The NPS provides independent advice to prescribers, pharmacists and consumers to support decisions about medicines, and raise awareness about the quality use of medicines.

The work of the NPS covers all prescription, non-prescription and complementary medicines and many of its programs are targeted directly towards areas of specified need.

One of these is antibiotic resistance – a key challenge currently facing Australia and many of the countries represented here today, and the focus of Workshop 6.

Last February, the NPS launched a five-year program to address antibiotic resistance within the Australian community, initially targeting health professionals, with a consumer component launched in April 2012.

A new government program to support quality use of medicines involves monitoring the use of medicines after they have been listed on the PBS. Postmarket monitoring of the way medicines are used in clinical practice will improve medication safety, evidence development, quality use, effectiveness and cost-effectiveness.

This conference is also looking at some postmarket monitoring of medicines. In particular those used in the management of pain. This will be another area where the discussions at this conference offer a valuable learning opportunity for all.

Objective four of the National Medicines Policy is maintaining a responsible and viable medicines industry.

The Government and the peak body representing the majority of suppliers to the PBS, signed a four-year Memorandum of Understanding (MOU) – to promote the efficiency and sustainability of the PBS, and support a viable and responsible medicines industry in Australia.

This MOU provides for a period of stable pricing policy and improved listing timetables for all suppliers, in exchange for more competitive prices for generic medicines on the PBS. This agreement is delivering over \$1.9 billion in savings to the PBS over five years.

In the past two years, the Government has also introduced measures to make it easier for companies to list new and innovative medicines on the PBS and new tax incentives to support research and development. This is coupled with its fifth agreement with Australia's community pharmacies which not only ensures that medicines are available when they

are needed, but has also recently contributed over \$1 billion in savings over five years to support the sustainability of these services.

In all of these ways, partnerships are continuing to help the Australian Government to deliver medicines to Australians who need them.

There will be a further opportunity for partnership with consumers from 1 July 2012 when the Personally Controlled Electronic Health Record becomes available.

This e-health innovation has the potential to improve the efficiency and safety of health care, including use of medicines, by reducing transcription errors and duplication.

Medicines are essential to the health of any person and any nation. Medicines policy is of great importance, which is why the Australian Government has supported this conference through the NPS, the Department of Health and Ageing and AusAID.

It is another example of a valuable partnership. The Government thanks the NPS, the University of Newcastle and the World Health Organization for their hard work in bringing this conference to fruition.

I have great pleasure in declaring the conference open.

# National medicines policies and universal access to medicines

## Plenary 2

**Dr Budiono Santoso** highlighted that since the conference on national medicines policies held in 1995, most countries of the Asia Pacific region have developed national medicines policies that embrace the key elements of medicines access, safety, efficacy and rational use. However, in many countries these policies are not fully implemented. A key issue was the availability and affordability of essential medicines.

A critical barrier for access to medicines is significant out-of-pocket expenses, particularly in the private healthcare sector. Out-of-pocket medicine expenses account for most health expenditure and these costs can drive low-income earners below the poverty line. The procurement cost of medicines is a key issue. One solution that has been implemented is a Price Information Exchange website ([piemeds.com](http://piemeds.com)) to voluntarily share the prices of medicines procured in the public sector in an attempt to achieve transparency.

The quality and safety of medicines remain concerns in the Asia Pacific and around the world as a result of a lack of rigorous regulatory control. For example, the contamination of glycerine (used in liquid dose forms) with di-ethylene glycol has led to numerous deaths across many countries over the last three decades.

Dr Santoso reinforced the key issues in successfully implementing national medicines policies to improve health outcomes for people in the Asia Pacific region. These include:

- Political commitment to policy and processes.
- A focus on the health services delivery system (including appropriate funding and staffing and an efficient medicines delivery system).
- The need for monitoring progress in policy implementation.
- Information exchange, sharing of experiences and consultation.

Successful implementation of a national medicine policy requires a functioning health system.

**Dr Kathleen Holloway** addressed the question of the evidence of benefit from the successful implementation of national medicines policies. She highlighted some challenges in policy implementation including the prevalence of unsafe practices (for example pulverising and mixing medicines), inappropriate medicines promotional activities and the lack of policies in place to encourage the rational use of medicines.

Central to this presentation was an analysis of data to investigate whether public sector medicine use is better in those countries with pharmaceutical policies compared to those countries without such policies. This study drew on medicines policy data from questionnaires sent to ministries of health in 2003 and 2007 and quantitative data on public sector medicine use in 58 countries for 2002–08 from the WHO databases of medicines use indicators. Although the comparability of the data was problematic, the study found that a number of policies intended to improve rational medicines use and medication safety were correlated with better medicine use. Furthermore, it was found that the more policies that were implemented, relating to rational use of medicines, the better the overall use.

The implication is that implementing policies is critical to improving medicines use and that the most significant effects are observed when a number of policies are implemented together. Dr Holloway concluded that an integrated coordinated package of strategies and policies is needed to improve medicines use.

**Emeritus Professor Lloyd Sansom** presented the Australian experience on implementing national medicines policy. His presentation provided a historical perspective on the emergence and maturity of the Australian National Medicines Policy including the key role that consumers played. In particular, he highlighted that many of the key structures that facilitated the objectives of the policy, such as a strong medicines regulatory body and a scheme supporting subsidised access to medicines, were well established before the Australian policy was accepted and approved by all arms of government. Central to the success of the implementation of the Australian National Medicines Policy has been the focus on

### Session chairs

Madeleine de Rosas-Valera  
Philippines  
Andrew McLachlan  
Australia

### Speakers

Budiono Santoso  
Western Pacific  
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Kathleen Holloway  
South East Asia  
Regional Office  
WHO  
India  
Lloyd Sansom  
Australia  
Michael Rawlins  
United Kingdom

health outcomes for Australian consumers and the partnership approach.

The presentation mapped the course of policy development and implementation in Australia including the roles of expert committees, the availability of resources (for example Therapeutic Guidelines, Australian Medicines Handbook), engagement of stakeholders and key action organisations (such as NPS MedicineWise).

Professor Sansom said that the need for a national medicines policy was led by Australian consumers and the primacy of the consumer was central to strategies to implement the policy and the quality use of medicines. He concluded that although Australia's policy is not perfect, it provides a focus and structure to deal with future health demands for the benefit of all stakeholders. Lastly, Professor Sansom encouraged delegates to reflect on the progress to date and to see that significant change and improvement in this sector is possible.

**Sir Michael Rawlins**, chairman of the UK National Institute for Health and Clinical Excellence, provided an international perspective on the implementation of medicines policy with a focus on health technology assessment. He highlighted the need for comprehensive assessment processes to investigate comparative effectiveness and the resource implications for decision making in the context of national medicines policies. The presentation considered the limitations of the hierarchy of evidence (including the lack of empirical evidence) and the need to consider the context in allocating limited health resources. Central to the presentation was the concept of 'distributive justice', meaning the socially just allocation of resources.



# Access to medicines, national medicines policies and health care reform

## Plenary 3

### China: Health care reform and the essential medicines system to ensure universal access – experiences of China

**Dr Sun Jing** described the nationwide comprehensive and systematic health care reform that has been carried out since 2009 in China. A framework of universal access to basic health care has been established, national coverage of basic health insurance has increased, and the benefit package available to citizens has been continuously improved with the aim of decreasing individual out-of-pocket health expenditure. The basic public health services have been strengthened by secured government funding. Primary care in both urban and rural areas has been reinforced. The essential medicines system commits to equal physical and financial access to quality medicines and their rational use.

The Chinese Government is committed to further reforms to improve the universal basic health insurance system, to consolidate the essential medicines system and broaden implementation of the zero mark-up policy, and to enhance the operation of primary care. However, a fully secured system of universal access to safe, efficient, convenient and affordable basic health care will not be achieved until 2020.

### Japan: Experiences in implementing a policy on universal coverage of health insurance

**Professor Kazuko Kimura** noted that Japan celebrates 50 years of implementation of universal coverage of health insurance. The origins of the system can be traced to 1905 and the Kanebo Company and Yawata steel enterprise which established Mutual Aid Associations for employees to provide comprehensive benefits including health care. The Health Insurance Act of 1922 covered workers from factories, mines and transport – around 3% of the population. The National Health Insurance Act followed in 1938, and since 1961 all citizens have been covered.

Improved access to medicines has been followed by improvements in health outcomes. Child mortality rates for infectious diseases and vaccine preventable diseases dropped sharply between 1950 and

1965, and high adult mortality from tuberculosis rapidly declined between 1950 and 1977. Access to antihypertensive drugs and reduced dietary salt intake contributed to the lowering of average blood pressures in the 1960s. Healthy lifestyle, compulsory education, established healthcare systems, good water supply systems, maternal health as well as strong government stewardship, and universal access to medicines and medical care contribute to Japanese life expectancy being the longest in the world.

### South Korea: Pharmaceutical policy in Korea: Role of health insurance in pricing, reimbursement and monitoring

**Professor Soonman Kwon** described the Korean national health insurance system that provides universal coverage of the population. Health insurance benefits for medicines are based on a positive listing system that includes formal economic evaluation. Prices of originator medicines are negotiated between the insurer and the pharmaceutical manufacturer. The prices of generic medicines are fixed as a percentage of the originator drug.

Measures are in place to monitor the behaviour of prescribers and to contain pharmaceutical expenditure, including monitoring and prescriber feedback in the areas of expenditure, polypharmacy, and the use of generics and antibiotics. There are financial incentives to prescribers for savings in costs. The real-time drug utilisation review checks precautions for age and pregnancy, duplications, and adverse interactions. These programs use information technology, and information on provider performance on medicines use is also disclosed on the website of the insurer.

Pharmaceutical expenditure accounts for a large share of health expenditure. Payment system reforms for healthcare providers have been proposed, but not implemented due to strong opposition.

### India: Working towards universal health coverage in India

**Dr Amit Sengupta** described the situation in India as a paradox. While India is the third largest producer of medicines (by volume) in the world, it also has the largest number of people (more than 650 million)

#### Session chairs

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Philippines  
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#### Speakers

Sun Jing  
China  
Kazuko Kimura  
Japan  
Soonman Kwon  
South Korea  
Amit Sengupta  
India

without secured access to essential medicines. A key barrier to access in India is extremely high out-of-pocket expenses for health care as public expenditure on health is low (around 25% of total health care expenditure). More than 75% of out-of-pocket healthcare expenses relate to medicine purchases. Retail sales account for more than 80% of the total value of medicines consumed.

Challenges for the health system in India are the need for significantly enhanced coverage by the public health system (requiring increased procurement and distribution of medicines) and the need for price controls for essential medicines. An additional challenge relates to changes in global and domestic policy environments, including implications of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. The acquisition of Indian generic manufacturing companies by transnational corporations points to the vulnerability of generic drug production in India, with consequent impacts on access to affordable medicines.

### General points

The experiences of these countries highlight that assuring universal access to medicines is most often a step-wise process. Importantly there is some evidence to support the argument that better access to medicines leads to better health outcomes at the population level. The challenges differ according to setting, however progress towards universal access to medicines requires government commitment to policy implementation through effective legislation, and financial resources to sustain and expand systems.

Ongoing monitoring activities are important at both system and healthcare professional level. Information technology can support these activities.

The contents of benefit packages need to be reviewed to ensure the sustainability of health insurance systems and their relevance to a country's healthcare needs. Progress towards cost containment, affordable medicines and universal access will sometimes be impeded by industry and health care professionals with vested interests. In all of the countries represented in this plenary session, universal access to medicines remains a work in progress.

# Experiences of implementation of national medicines policies

## Plenary 4

### Indonesia: Implementing medicines policies in the decentralised environment

**Dr Lucky S Slamet** described the introduction of a revised Indonesian National Medicines Policy in 2006 in response to new challenges posed by a global medicines industry and a decentralised medicines management system in Indonesia. An important strategy of the policy is the revitalisation and implementation of the national essential medicine concept and a focus on a robust quality assurance system. Decentralised supply requires efficient planning, financing, procurement, and distribution systems. All public health facilities are obliged to procure generic essential medicines.

Data monitoring since the introduction of the revised policy suggests some improvements in the availability of essential medicines in public health centres, although this falls far short of ideal and results vary between hospital and district health facilities.

The quality assurance system remains a centralised function (National Agency of Drug and Food Control), with regulations, standards, and enforcement activities imposed by the national government. While decentralisation and effective quality assurance have been key factors in maintaining the accessibility and affordability of good quality medicines in Indonesia, there are ongoing challenges in balancing functions in a decentralised environment.

### Malaysia: Pharmacy transformation planning; reform for universal access to medicines

**Dr Salmah Bahri** outlined strategies for pharmacy transformation in Malaysia consequent to the 2006 Malaysian National Medicines Policy. A number of strategies were introduced to support the objectives of the policy including:

- Improving the legislation and regulation of medicines and pharmaceutical quality assurance activities.
- Strengthening the supply of medicines through effective delivery services of medicines.
- Ensuring the affordability of medicines through effective monitoring of drug price, generic policies and drug financing.

- Improving the quality use of medicines by enhancing clinical pharmacy services, providing training and education to healthcare providers and the general public.

Effective strategies to address medicine affordability are a particular challenge. Good governance for medicines is inculcated in best pharmacy practices and the management of the entire pharmaceutical sector. A new pharmacy bill, pharmacy liberalisation, benchmarking and accreditation of pharmacy facilities will soon be introduced. At the central level, the Pharmaceutical Services Division will be responsible for the ongoing implementation of strategies to achieve the medium- and long-term goals of the policy.

### Laos: Implementing national medicines policies in resource constrained environments

**Dr Lamphone Syhakhong** described revisions to the Lao National Drug Policy in 2000. In addition to a focus on essential medicines, the policy also promotes the use of traditional medicines.

Quality assurance systems have been strengthened through the development of law and regulations, and there have been improvements in drug selection, registration, licensing and procurement procedures. Inspections of public and private pharmacies, pharmaceutical companies and factories have been carried out. Good pharmacy practice, good wholesaling practice and good manufacturing practice have been promoted.

The rational use of medicines has been improved through training for health staff and education of the general public. In addition, standard treatment guidelines have been developed, and drug and therapeutics committees have been formed. Village revolving drug funds have enhanced access to essential medicines. However, many challenges remain, particularly in building the capacity of the drug regulatory authority in law and regulations enforcement, strengthening the quality assurance system, improving the rational use of medicines and ensuring the sustainability of revolving drug funds.

### Session chairs

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Western Pacific  
Regional Office  
WHO  
Philippines  
Anthony Smith  
Australia

### Speakers

Lucky S Slamet  
Indonesia  
Salmah Bahri  
Malaysia  
Lamphone Syhakhong  
Laos  
Melenaita Mahe  
Tonga

### **Pacific Island countries: Implementing national medicines policies in small island states**

**Ms Melenaite Mahe** noted that the recommendations of key meetings of ministers and directors of health in 1995, 1997, 1999 and 2009 have translated into the construction or drafting of national medicines policies in 14 Pacific Island countries. This has occurred with the assistance of technical and financial support from development partners and other stakeholders. A priority has been ensuring access to essential medicines. Policy implementation has generally been carried out by pharmacy departments. Information and knowledge acquired is shared with all the Pacific Island countries.

The specific example of Tonga was mentioned. Priority activities implemented since the endorsement of the Tongan National Medicines Policy in 2000 include:

- Development and enactment of key pharmaceutical legislation.
- Development of standard treatment guidelines and essential medicines lists.
- Strengthening the procurement and inventory management systems.
- Public awareness programs on rational use of medicines.
- Establishment of a national drug and therapeutics committee.

Common challenges in the Pacific Island countries are a lack of political will and commitment to policy implementation, lack of qualified personnel and high staff turnover, lack of cooperation with other ministries, inadequate funding for pharmaceutical activities and delays in the endorsement of legislation. Medicines policies should be aligned with and linked to broader health policies and plans. Inter-country collaboration in some areas has proved to be essential.

### **General points**

These country examples highlight the challenges of implementing the many aspects of a national medicines policy. While the specific issues may differ according to setting, common themes are the need for government commitment to policy implementation, the availability of adequate human and financial resources to support medicines related activities, and the importance of a medicines policy being seen as part of the broader healthcare system. As issues regarding quality assurance and medicines selection are addressed and more efficient supply systems are put in place, attention is turning to the rational use of medicines. Training of healthcare professionals and education of the general public about appropriate use of medicines are key strategies to improve medicines use in practice.

# The pharmaceutical industry and national medicines policies – panel discussion

## Plenary 5

The industry plenary session focused on the approaches and attitudes of the pharmaceutical industry towards national medicines policies in the Asia Pacific region. The panel considered a number of specific questions:

- What are the effects of public-private partnerships on access to medicines in the Asia Pacific region? Is there a role for differential pricing in improving access to needed medicines?
- Is there a role for pharmacoeconomic analysis in low and middle income countries?
- What are key issues in the security of the pharmaceutical supply chain?

### The role of public-private partnerships

The panel recognised the importance of engaging with the pharmaceutical industry to discuss strategies to improve medicines access and use in low and middle income countries. In doing so, generic manufacturers are as relevant as originator companies as stakeholders in the discussions concerning access to medicines. Industry initiatives and partnerships to improve access should be guided by corporate responsibility principles and will be judged by how well they 'fit' the national medicines policy model. Effective models for improving medicines access in the region may include market segmentation and differential pricing, voluntary licensing, comprehensive patient access programs, and long-term philanthropic donations. The panel noted that the voice of the consumer is central to a properly constituted and functioning policy.

Discussions on new business models for industry have been prompted by concerns about the increasing prevalence of market failures. Examples include increasing antimicrobial resistance and the urgent need for discovery and development of new antibiotics, and the need for new treatments for neglected diseases. Options that have been identified to address these issues include pre-competitive research and development funding mechanisms and product development partnerships.

The marketing of pharmaceuticals in the region received attention. Patchy policies and practices that are clearly not aligned with the principles of

the rational use of medicines are a substantial issue for the region. Low and middle income countries generally have less effective regulations about promotion, although it was acknowledged that this was a problem in all countries and regions.

The panel discussed the Access to Medicine Index. This index aims to competitively rank the activities of pharmaceutical companies in promoting access to medicines in low and middle income countries.

The purpose is to try to quantify the range of pharmaceutical company practices with respect to access to medicines according to the principles of rational use. Performances are ranked from poor to excellent as a mechanism to promote stakeholder ownership, dialogue and action. The idea of showcasing best practice as a competitive stimulus as well as being attractive to an enlightened industry was of interest to the panel.

### The role of pharmacoeconomic analysis in low and middle income countries

The panel noted that there was considerable expertise in pharmacoeconomic analysis in the region that could be helpful to these countries. It was suggested that a resource listing the various agencies and academic institutions involved in this work would be helpful for low and middle income countries in the region. The policy would assist in having all stakeholders involved in setting goals, roles and responsibilities to achieve affordable access, continued supply and quality use.

### Security of the pharmaceutical supply chain

There was support for transparency among manufacturers and wholesalers when difficulties in supply are foreshadowed. This engagement would be promoted by a robust medicines policy. The panel acknowledged that supply chain integrity is a complex issue. Inadequate cold storage facilities at local pharmacies and distribution centres are a particular concern.

A surprising proportion of generic drugs in the region are of poor quality. These problems are often overshadowed by discussions and concerns over counterfeit or fraudulent drugs, but substandard medicines are a much greater issue. Stronger

#### Panel members

Eugene Salole  
Australia  
Dennis Ross-Degnan  
USA  
Reiner Gloor  
Philippines  
Sivalal Sadasivan  
Malaysia

#### Facilitators

Will DeLaat  
Australia  
Ric Day  
Australia

**PLENARY 5**

regulatory agencies could be encouraged by cooperative arrangements with developed countries and agencies in order to enhance standards, training, and procedures. Problems with good manufacturing practice throughout the region could also be addressed by these measures. In addition, there are opportunities for sharing the results of quality assurance activities between countries in the region. There has been a substantial shift in thinking over time. Where once it was broadly perceived that industry had no place in discussions about improving access and use of medicines in low and middle income countries, the current view is that

the pharmaceutical industry should be engaged. The comprehensive nature of a developed and appropriately implemented national medicines policy provides a framework, for example, for developing the Access to Medicine Index, product development partnerships, pooling research and development funding, and antibiotic development. The pharmaceutical industry is involved in the distribution of pharmaceuticals and the responsible promotion of medicines, and has legitimate interests in reasonable pricing for medicines and transparency around pricing decisions.

# Challenges to implementation of national medicines policies: solutions and unresolved problems

## Plenary 6

### Bangladesh: A long history of national medicines policy: where are we now?

**Dr Zafrullah Chowdhury** reflected on the pioneering work on national medicines policies with the introduction of the National Drug Policy in Bangladesh in 1982. Activities at that time included the import of raw materials on international competitive tender, price fixation of all essential medicines by government and a ban on the manufacture of antacids and oral vitamins by foreign companies. Over 1700 harmful or unnecessary medicines were deregistered and destroyed. Most drug prices dropped by 50–75% in two years. Drug registration procedures and the quality of medicines improved. Since then, Bangladesh has achieved near self-reliance in the manufacture of quality essential medicines. However, some of the early gains have been lost.

While the prices of some essential medicines are reasonable, others are not. The government introduced the Indicative Price System, violating procedures in the drug policy. Under these revised processes, the prices of 117 drugs and vaccines are fixed by the Drug Regulatory Authority and the rest by manufacturers. In the absence of continuing education for practising physicians, irrational prescribing is common. Pharmaceutical company representatives have taken the role of teachers for doctors. An excellent drug policy will fail to protect patients without ongoing support and commitment of politicians and bureaucrats to rigorous and transparent processes and regular, high quality continuing education for medical practitioners.

### Sri Lanka: A long history of national medicines policy: where are we now?

**Dr Palitha Abeykoon** traced the history of attempts to provide efficacious, affordable and safe medicines to the Sri Lankan population, from the visionary pioneering initiatives of Professor Senaka Bibile nearly five decades ago to the adoption of a comprehensive national medicines policy in 2005. In addition to assessment of the efficacy, safety, and quality of medicines and the promotion of their rational use,

the national medicines policy includes considerations of need and cost-effectiveness as criteria in the registration of medicines. While the policy objectives are clear there have been political, social and technical difficulties encountered in enacting the legislation necessary to effectively implement the national medicines policy.

The key issue in Sri Lanka is the implementation gap. Without political commitment, support and leadership implementation efforts will founder and the activities of interested lobby groups and opponents can slow progress. The difficulties of change management cannot be underestimated. Acceptance of change by healthcare professionals and re-education of consumers and other stakeholders is not easy. If not managed carefully, comprehensive reform can end up as piecemeal exercises, and in isolation, only some of the changes may be positive. It is important to recognise that 'medicines are politics' and to 'seize the moment' to garner the necessary political support and commitment for change.

### Vietnam: Balancing industry development and public health

#### Dr Socorro Escalante, presenting on behalf of

**Dr Truong Quoc Cuong**, described activities undertaken by the government of Vietnam in recent years towards strengthening the local production of pharmaceuticals. In doing so, the challenge has been to balance economic and industry goals with public health goals. The government aims to meet 70–90% of Vietnam's needs for medicines through local production by 2030, using the production standards of developed countries.

Local pharmaceutical production can be beneficial to Vietnam if it can respond to the most pressing public health needs, which are access to medicines, especially for diseases of high public health importance, that are affordable, safe, effective and quality assured. Currently however, the local industry produces more vitamins and medicines for symptomatic treatment rather than products for the most pressing illnesses such as non-communicable diseases, HIV/AIDS and tuberculosis, and life-saving

#### Session chairs

Krisantha Weerasuriya  
WHO  
Switzerland  
Janette Randall  
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#### Speakers

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Bangladesh  
Palitha Abeykoon  
Sri Lanka  
Socorro Escalante  
Vietnam  
Madeleine de Rosas-Valera  
Philippines

medicines for mothers and children. Creating the balance means shifting the paradigm of the local production agenda from trade to public health, and moving indicators of success from market share and per capita consumption to measures of quality, availability and affordability of key medicines.

### **Philippines: From commitment to action: ensuring access to essential medicines in the Philippines**

**Dr Madeleine de Rosas-Valera** described the Philippines 1988 Generics Act as the source of the guiding principles of people empowerment, quality assurance, rational drug use, self-reliance, and tailored procurement for subsequent government programs related to drug policy. The Philippine national drug formulary was developed to support the Generics Act, and provides the basis for drug procurement. Amendments in the National Health Insurance Act followed and included the Drug Price Reference Index as the basis for the reimbursement of drugs and medicines, and the creation of the Food and Drug Administration to assure the safety and quality of medicines. The Cheaper Medicines Act was introduced to encourage competition in the pharmaceutical sector and provide power to the State to regulate

drug prices. Successive interventions have been designed to encourage safety and quality, access and availability, accountability through reliable supply systems, and a strengthened health system that is supported by efforts towards good governance, transparency and public-private partnerships in health. Monitoring and evaluation occurs through the Essential Drug Price Monitoring System. However, problems remain with limited market competition for crucial essential medicines, irrational drug prescribing, dispensing and use, and the limited capacity of the Food and Drug Administration to monitor and regulate drug establishments.

### **General points**

These countries highlight the importance of legislation for managing medicines issues. However, legislation alone is not sufficient – there must be political will, commitment and support for the policy and leadership for policy change. Without recognition of the political dimension to medicines policies and the importance of political support, implementation efforts will fail, the views of opponents and lobby groups may prevail, and important measures to address access and availability of essential medicines will be thwarted.



# National medicines policies: where will we be in 2030?

## Plenary 7

**Sir Michael Rawlins**, chairman of the UK National Institute for Health and Clinical Excellence, said the next 20 years will see the demand for health services increase and the prevalence of disease alter as social and economic development and population demographics change. There will be a shift in many countries from a dominance of acute life-threatening illnesses to a greater emphasis on disease prevention and the management of chronic disease. The incidence of cancer will increase as the population ages and many cancers will probably become a 'chronic illness' with multiple lines of therapy following a pattern of disease progression and remission. At the same time, we will see a greater understanding of molecular pathogenesis with a growing number of targeted, but expensive, new drugs and the development of therapeutic vaccines. Science will continue to provide new advances in therapeutics. New challenges will emerge. Examples include pandemics because of a more mobile global population, changes in disease patterns in regions influenced by climate change and multiresistant organisms.

The demands and costs of health services will increase and the capacity of nations to provide

equitable access will continue to be a challenge. More and more nations will address the 'value for money' of new technologies across competing demands for health resources. Governments and instrumentalities will need to make deliberative choices of resource allocation and look at ways to improve the use of medicines by their populations. There will need to be a global perspective of health and a greater acknowledgement of health as a major issue in economic growth and development, particularly in low and middle income countries.

The issues facing health systems in the next 20 years will be a mixture of the new and old challenges. What will not change is the need for a framework in which these challenges can be addressed. While individual countries will have different health systems and competing demands, the principles of product quality, access (including affordability), relevant and appropriate best practice guidelines, rational or quality use of medicines and health advocacy will always be present. National medicines policies will continue to assist in improving the quality of health care for the next 20 years and beyond. They may evolve in their appearance, but the principles are timeless.

### Session chair

Lloyd Sansom  
Australia

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### Speaker

Michael Rawlins  
United Kingdom

# Feedback on workshop and symposium discussions

## Plenary 8

### Session chairs

Kumud Kafle

Nepal

Jane Robertson

Australia

Reports from four symposia, nine workshops and a special session on reproductive health commodities were presented to delegates. The overarching themes in the reports were the importance of political commitment to national medicines policies and their implementation, and the recognition that adequate financial and human resources were required to sustain and expand national medicines policies activities. Other important themes were identified.

### **National medicines policies need to be embedded in health policies and health systems**

Policy activities need to be considered as part of the delivery of high quality health services.

### **Infrastructure and the need for strengthening existing systems**

While national medicines policies exist in many settings, implementation is inconsistent and the infrastructure to support implementation is missing. In some settings, early gains have been lost due to a lack of ongoing political commitment and loss of policy champions.

### **The importance of a strong legislative framework and a commitment to enforcement of the law**

Laws provide the framework and commitment to national medicines policies. Regulations, standards, codes, and guidelines can be used to support policy implementation and provide greater flexibility as they are easier to change than legislation. Successful prosecutions will reinforce the message that there are consequences for illegal activity and breaches of codes of practice.

### **Capacity building across all domains of policy activity**

Adequate staffing and task-specific training are essential. International and regional experts can help to train local staff in areas including the law, quality assurance and procurement.

### **The need to prioritise activities**

Given the limitations in financial and human resources available, choices will have to be made. Decisions need to be supported by good evidence and take account of societal values, recognising that equity is an important goal of universal access. Defining minimum benefits insurance packages for medicines will involve trade-offs between costs and the scope of coverage.

### **The importance of measuring and monitoring**

The routine collection of relevant and informative data is essential. Without data, it is not possible to assess improvements or worsening of performance against agreed standards or benchmarks over time. There is a need for skilled staff who are able to analyse and interpret data at both local and national levels.

### **Using tools and resources that have already been developed**

Given capacity constraints, countries should use best practice models and existing tools for legal frameworks, drug selection, quality assurance, procurement and distribution of medicines.

### **Collaboration and relationship building**

Regional partnerships and networks may help overcome capacity constraints. Recognising medicines evaluations and quality assurance activities conducted by other drug regulatory authorities will minimise the duplication of effort. Sharing experiences, challenges and solutions will support further policy implementation.

# Advocacy for implementing national medicines policies: what will make a difference?

## Plenary 9

The session chairs confronted the conference with several challenges:

- The national medicines policy movement had not, until now, effectively socialised or politicised the issue.
- The policy primarily served citizens who did not understand its importance in their lives.
- Forming and engaging champions for national medicines policies beyond technical contexts is needed.

Speakers drew on various experiences and contexts to reflect on these challenges.

**Carol Bennett** outlined the history of the Consumers Health Forum (CHF) of Australia since 1985 when the government of the day provided the mechanism for the consumer voice in health policy development. The CHF agenda has widened beyond medicines policy to include the shaping of the health system:

- Achieving better outcomes for the health consumers who pay for and use the health system.
- Improving the quality, accessibility and accountability of the health system and making it more responsive to health consumers' needs.
- Driving reform in work practices, information sharing and consumer engagement.

Consumers were partners in the development and implementation of the National Medicines Policy from the outset. The consumer voice was not limited to one CHF representative, but included those of the aged, multicultural, Aboriginal and veteran communities. CHF's work continues to provide value in policy debates, basing its policy on the views of the consumers it represents.

**Dr Amit Sengupta** from India reflected on the 'silos' inadvertently created between the two movements of access to medicines and rational use of medicines. Early activists including Salvador Allende (Chile) and Seneka Bibile (Sri Lanka) focused on essential drug programs and ensuring access to medicines in resource poor settings. In the 1990s, reforms to trade and intellectual property rights changed the balance, with increasing power and influence

divested to pharmaceutical companies. With the HIV/AIDS epidemic ravaging Africa, it seemed that chief executive officers of large corporations decided on access to medicines, effectively determining who would live and who would die. Since then there have been successes with the Medicines Access Campaign in a number of countries – court cases in South Africa, the Doha Declaration, and the production and supply (by Cipla) of generic HIV medicines for poor countries. This activism, while narrowly focused on HIV, had visibility and impact, and resulted in better access to critical medicines. Progressing affordable access and rational use requires cooperative rather than separate advocacy efforts in order to deliver good health outcomes for consumers and society. Both access and rational use need to be part of an advocacy for health that addresses the collective ills in society, so that improved health is an outcome of development.

**Dr Sun Jing** described the process of healthcare reform in China. It has been a mixed top-down and bottom-up process in which the government set the direction of the reform policy, based on academic and consultant input, and amended it after wide online input and rounds of consultation hosted by the Premier. The top-down approach consists of structural change at all levels to support the change of direction with clear mandates, annual work plans and quantitative targets for focal agencies. Local governments have full rights to implement innovative strategies towards achieving the agreed goals. Bottom-up approaches work by ensuring that the evidence obtained from pilot programs undertaken locally lead to changes in the central policy. Policy can also be adjusted through the People's Representative Conference and the Political Consultation Conference. Hence the process is a practice-learn cycle that secures orderly transition to a predetermined goal.

Dr Sun reflected on the increasing visibility of social organisations in China. There is increasing donor funding to these organisations. They have increasing roles in policy development for treatment and care and their increased lobbying power is helping secure patient access to affordable life-saving medicines.

### Session chairs

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WHO  
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Mary Murray  
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### Speakers

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Australia  
Amit Sengupta  
India  
Sun Jing  
China  
Niyada Kiatying-Angsulee  
Thailand  
Michael Chai  
Malaysia

**Dr Niyada Kiatying-Angsulee** from Thailand reflected on the importance of people's engagement and ownership of policies that affect their lives. Change is often complex and difficult, and involves small steps. Thailand has evolved a framework for change in social and health issues that links the creation of relevant knowledge, social movement and political involvement. Change requires all three dimensions, and collaboration between many interest groups with commitment and shared vision. There have been examples of joint action for a national medicines policy in Thailand:

- Patient and consumer groups (HIV, renal failure, family network and Thai Drug Users Network)
- Local and international non-government organisations (Health and Development Foundation, FTA watch, Raks Thai, Médecins Sans Frontières, Oxfam)
- Academia and professionals (law, social pharmacy, drug system monitoring and development program)
- Government and Civil Society e.g. the Governing Board of the Thai Health Promotion Foundation is chaired by the Prime Minister, with half the Board members from independent social organisations.

**Dr Michael Chai** from Malaysia spoke of the importance of involving the community of stakeholders if a policy is to be relevant, understood, sustainably implemented and its course regularly reviewed and corrected. It may seem appropriate to adopt successful policies from elsewhere, however context is important. While resource constraints are often cited as a difficulty in policy development and implementation, it may be that weak institutions, poor human rights, disregard for the rule of law and democratic processes, corruption, and ethnic and religious tensions are limiting progress.

Vested interests may hijack policy agendas and disenfranchise some groups. It is often difficult to have effective consumer advocacy within countries and there is an emerging role for networking across borders to increase the consumer profile and visibility, and to plan strategies to engage with policy-makers. This is the strategy behind the ReAct process in South East Asia for multisector action on antibiotic resistance. National policy platforms are built by connecting people across borders. Collaboration is essential for increasing consumer advocacy within the region.

### General points

The consumer voice must be heard. People need to be engaged at all levels of society, and different contexts must be taken into account in the shaping of health policy. Viewing policy implementation outcomes from local perspectives is essential in understanding the impacts on people. However, few countries have effective mechanisms for consumer, citizen, community or local engagement. These processes have different meanings in different settings. The success of people's advocacy will depend on effective mobilisation of resources and collaboration with existing social advocacy groups, academics and other health professional advocates. There are roles for policy champions, peer educators and peer-to-peer movements to engage people. It takes time and resources to establish an effective framework and processes to develop and influence policy. The contribution to national medicines policies of people for whom policy is designed is important. The objectives and goals of national medicines policies are framed around affordable access to safe and effective medicines in order to improve health outcomes for all patients and communities. Advocacy at global and regional levels must support this.

# Conference closing

## Plenary 10

### What progress has been made?

#### Emeritus Professor Lloyd Sansom

This conference on national medicines policies has been the first regional meeting for a number of years. At our first meeting in Sydney in 1995, the topic was about the establishment of national policies and what we needed to do to convince decision makers to commit to the creation of a framework in which key issues of quality, access and rational use could be discussed. It also recognised for the first time that our core focus was to improve the health of the consumer and to encourage advocacy by and on their behalf. The topic of this meeting has been not about the creation of national medicines policies but their implementation. For those of us fortunate enough to be present at the two meetings, it has been outstanding to see the enormous development in the practical application of the key principles that underpin the elements of a national medicines policy. That is not to say that we have solved all the problems or that we have prevented new issues emerging that threaten to undermine those principles. However, what we have seen is that the presence of an active national medicines policy and the networking that flows from the policy has enabled us to be in a position, both as individual countries and as a networked region, to address the issues and to propose and advocate solutions.

Sometimes the process of behavioural change can be extremely slow and frustrating and we may doubt the advantage of having a national medicines policy. However, what this meeting has absolutely confirmed is that, on reflection, very significant advances have been made. We sometimes forget what it was like before and reflections on the past can be extremely informative and affirming. However, it must be remembered that the only thing that we can change is the future and without a national medicines policy to guide us, the approach to medicines policy will be fragmented and lack focus and direction.

The conference has renewed our commitment to continue to advocate on behalf of consumers and all

other partners involved in promoting and improving health through medicines use as a component of a health system, and for the continuing and further development of the health outcomes that emerge from having a national medicines policy. The road is long, but this conference has reaffirmed our direction and re-energised us to continue on the journey, a journey that will sometimes be hard and will require us to detour for a while or even to retrace our path. The goal is still clear and our friends and colleagues from the region will also be there to help if we ask, because they also have the same goal although their pathways may be different.

### Closing comments

#### Dr Budiono Santoso

This conference highlighted many practical aspects in the implementation of national medicines policies. It did not confine discussions to how to develop policies, but how to implement them to ensure that the needed medicines are available and accessible, and that they are of assured quality and rationally used for the health of the people. Significant progress has occurred since the first conference in 1995. Relevant indicators are now available to measure such progress and to monitor different elements of national medicines policies, enabling us to know where we are and where we need to go. Obviously, there are still many challenges ahead. Despite commitment from national governments and stakeholders, policy implementation involves a complex political process, and furthermore, it is often hindered by weak regulatory and health system environments. Hence, we should not be locked up in lengthy and complex political debates, neither can we be complacent only looking at the statistics on indicators. We need to move beyond them, to improve the health system and to make the needed medicines accessible for the people. After all, national medicines policies are about people and how to improve their health. The policies and indicators are not the goal, but only a means to better serve the people.

#### Session chair

Kathleen Holloway  
South East Asia Regional  
Office  
WHO  
India

#### Speakers

Lloyd Sansom  
Australia  
Dennis Ross-Degnan  
USA  
Budiono Santoso  
Western Pacific Regional  
Office  
WHO  
Philippines

# Legislation to ensure sustainability of national medicines policies

## Symposium 1

### Convenor

Michele Forzley  
USA

### Rapporteurs

David Newby  
Australia  
Jane Robertson  
Australia

### Summary of key issues

- Law is hierarchical. International law and national legislation are important, but administrative regulations, codes and standards are useful instruments to manage the pharmaceutical sector.
- Wording of the law is important. There is a need to mandate what governments are obliged to do.
- Political will is needed to enforce the rule of law.
- High profile legal action can serve as an effective deterrent to infringements of medicine-related law.
- There is a need to address the mismatch between breaches and penalties. Penalties are needed to deter others.
- Drug regulatory authority inspectors need adequate powers as well as training and support to successfully implement laws and regulations related to medicines.

### Key barriers

- Lack of political will to maintain the expertise and adequate numbers of qualified staff.
- Limited data on how laws are implemented, their effects and impact, and how the law is broken.
- Corruption in some sectors has the potential to undermine regulatory and enforcement efforts.

### Key enablers

- Respect for the rule of law. A comprehensive body of law should support drug regulatory agency functions. There should be effective enforcement of laws and regulations.
- Training and support for medicines inspectors to gather the evidence required to facilitate prosecution in the courts.

### Steps to address barriers and enablers

- Better dissemination and sharing of best practice regulations, codes and standards. This may be facilitated by sharing digitised versions of laws and regulations.
- Greater collaboration between the legal and health sectors regarding medicines law.
- Consider development of a regional taskforce to review national laws relating to access to medicines.
- Provide a forum to learn about sanctions that have been successful in the pharmaceutical sector.

### How to monitor progress in implementation

- There should be routine monitoring and reporting on the staffing and functions of drug regulatory agencies, and the outcomes of regulatory activities including inspections.

# Access to, and rational use of, opioid medicines

## Symposium 2

### Summary of key issues

- Patients in pain require effective analgesia, however outcomes with opioid medicines depend on how they are used by consumers and health professionals within health systems.
- There are cultural differences in attitudes to pain and its treatment.
- Some countries have low, sometimes suboptimal, use of opioids, while others have very high use, especially in chronic non-cancer pain.
- There is a lack of evidence for the effectiveness of opioids in some forms of chronic pain. Rising opioid use is associated with increased harm including death, but inadequate treatment of pain is also harmful.
- Legal requirements for prescribing opioids vary widely between countries.
- There is a lack of policy and guidelines on prescribing opioids in some countries, especially for chronic non-cancer pain.

### Key barriers

- Some health professionals are unduly fearful of prescribing opioids.
- Lack of access to opioids or effective alternatives. This may be due to narcotic laws limiting availability. In other cases supply chain issues affect availability.

### Key enablers

- Development and dissemination of evidence-based treatment guidelines and education of health professionals regarding the rational and safe use of opioids.
- Access to effective adjunctive or alternative treatments for pain, including non-pharmacological options.
- Policies, standards and regulations to enable access, supply and appropriate use of opioids.

### Steps to address barriers and enablers

- Access to evidence-based treatment guidelines and health professional training in opioid use.
- Further research to provide evidence to support the use of opioids for pain in different settings.

### How to monitor progress in implementation

- There should be regular monitoring and reporting of opioid procurement, access and use within country.
- National initiatives involving opioids need to link with international surveillance activities carried out by the International Narcotics Control Board.

### Convenors

Anthony Smith  
Australia  
Krisantha Weerasuriya  
WHO  
Switzerland

### Rapporteurs

Siutaka Siua  
Tonga  
John Dowden  
Australia

# Monitoring medicines use

## Symposium 3

### Convenors

Kathleen Holloway  
India

Libby Roughead  
Australia

### Rapporteurs

Isidro Sia  
Philippines

Sallie Pearson  
Australia

### Summary of key issues

- Medicines-related data are powerful and should be relevant to need. There should be local level ownership and understanding of data. Start with simple efficient systems and build on successes.
- Collecting and managing data requires a skill base. There is a need for capacity building for data collection, analysis, interpretation and presentation of results in formats suitable for feedback to decision makers and other stakeholders.
- Medicines monitoring can be used to improve drug selection and procurement, measure availability and affordability, and (with increasing sophistication of data sources and information technology) link to health outcomes of therapy.
- Efficient and effective methods for monitoring are required with clear and concise formats, agreed frequency of reporting, timeliness for decision making, and feedback to stakeholders to facilitate the quality use of medicines.

### Key barriers

- Limited political and financial commitment to monitoring and a lack of awareness of its value. There are few incentives to collect medicines-related data.
- Limited workforce to undertake monitoring, data analysis and interpretation, and limited budgets for training.
- Validity, relevance and usefulness of the data – timeliness of data provision and analysis, lack of understanding of data limitations including the representativeness of reports.

### Key enablers

- Governments and other stakeholders need to 'own' the processes of medicines monitoring, with clearly defined roles, responsibilities and reporting cycles.
- Improved data quality with validated indicators is needed to assess medicines affordability, availability and rational use. Reports and presentations of key messages should be in simple formats for dissemination to all stakeholders.

### Steps to address barriers and enablers

- Establish appropriate reporting cycles for health sectors based on available resources.

### How to monitor progress in implementation

- Regular, routine use of medicines monitoring data derived from standardised methods is needed to inform key stakeholders for clinical practice, research, and to drive policy change.
- There needs to be regional sharing of medicines monitoring information based on minimum data sets.



# Consumer education and health literacy

## Symposium 4

### Summary of key issues

- Patients are dependent on others (family, community, professionals, media) for getting correct diagnosis and unbiased information.
- Health care should empower consumers to become health literate and move beyond the paternalistic approach which has characterised consumer–health professional interactions in the past.
- Self-help can work – consumers can learn to understand medicine labels and other basic concepts of over-the-counter medicines, in group sessions with responsible media or peer-educators.
- The poor and older people are at special risk, but are more difficult to reach with interventions and programs to develop health literacy.
- Social media and the internet are powerful channels of health and medicines information and are widely accessible. They can be helpful, but also risky because much of the information is not independently scrutinised for accuracy and relevance.

### Key barriers

- Abundance of biased health and medicines information and promotion, and relative lack of objective, understandable information on medicines and their appropriate use.
- Vested interests and system inertia have limited progress to date.

### Key enablers

- Community-based organisations promoting appropriate use of medicines and empowered, health literate consumers asking 'WHY?', and actively seeking information on medicines.
- Access to unbiased information on medicines and health. Understanding needs more than just good information – messages must be clear, simple, objective and motivate for appropriate action.

### Steps to address barriers and enablers

- Government valuing health literacy as a national priority that provides long-term health benefits for the nation.
- Consumer education programs to improve health literacy – health education begins in schools.
- Community organisations and peer networks can support appropriate use of medicines.

### How to monitor progress in implementation

- Develop and evaluate tools to measure steps towards health literacy.

### Convenors

Anthony Smith  
Australia  
Carol Bennett  
Australia

### Rapporteurs

Wilbert Bannenberg  
Netherlands  
David Sless  
Australia

# Universal access to reproductive health services and commodities: Opportunities for national medicines policy/universal access to medicines collaboration

## Special session

### Convenor

Peter Zinck  
Fiji

### Rapporteurs

David Lee  
USA

Mary Hemming  
Australia

### Summary of key issues

- Maternal mortality rate remains alarmingly high in many developing countries.
- Family planning is still an unfinished agenda.
- Reproductive health supplies are commonly out of stock at service delivery points.

### Key barriers

- Lack of policies and adequate funding to support reproductive health programs.
- Weak bureaucracies limit the implementation of agreed policies in some countries.
- Complex systems of funding, multiple procurement agencies, logistics operators, and reproductive health service providers hamper efficient service delivery.
- 'Silo' approaches and fragmented systems contribute to duplication and inefficiency.

### Key enablers

- Improved information and supply management systems.
- Collaboration in providing reproductive health services and commodities, and essential medicines, through national medicines policies.
- A regional policy framework needs to be developed and requires commitment and implementation.

### Steps to address barriers and enablers

- Political will and action are needed to align reproductive health activities with national medicines policies and to build partnerships and collaboration.
- Reproductive health commodity supply management systems need strengthening and integration to ensure security of supply and avoid stock-outs.
- Human resource development to support, implement and maintain programs.

### How to monitor progress in implementation

- Regular monitoring and reporting on reproductive health program specific indicators.
- Regional sharing of monitoring information based on comparable minimum data sets.

# Medicines selection and essential medicines lists

## Workshop 1

### Summary of key issues

- Countries may start with either standard treatment guidelines or an essential medicines list – evolves over time, as capacity increases within the country.
- Need evidence to support the review of either an essential medicines list or standard treatment guidelines and expertise to review and interpret the evidence – capacity issues exist in many countries.
- Evidence should be used to both add **and** remove medicines from the essential medicines list.
- Essential medicines list strategies need to plan for balancing the needs for acute and chronic health conditions.
- Dealing with patients that are on medications not included in the essential medicines list adds to costs.
- Levels of standard or specialised treatment guidelines may be developed according to country-specific needs.

### Key barriers

- Lack of expertise to evaluate the evidence on medicines for inclusion in essential medicines lists.
- Conflict between vertical program treatment guidelines and national treatment guidelines.
- No established processes for removing medicines from the essential medicines list once they are included.

### Key enablers

- Official approval and endorsement of the essential medicines list (by national departments of health/WHO).
- Stakeholder involvement in the process from the outset creates ownership of the essential medicines list.

### Steps to address barriers and enablers

- Countries with limited capacity may start with the WHO Essential Medicines List.
- National therapeutic committees need to play a role in the development and approval of all guidelines and medicines lists that are to be implemented in the country.
- Training in essential medicines lists and standard treatment guidelines should be included in undergraduate health sciences programs.
- Regional collaboration in capacity development may accelerate progress.

### How to monitor progress in implementation

- Regular reporting on updating and revisions to essential medicines list.
- Assess dissemination strategies for essential medicines lists and standard treatment guidelines.
- Review links between standard treatment guidelines, medicines procurement, distribution and use of medicines in practice.

### Convenors

Suzanne Hill  
Australia  
Krisantha Weerasuriya  
Switzerland

### Rapporteurs

Vanchinsuren Lkhagvadorj  
Fiji  
Fatima Suleman  
South Africa

# Financing and health insurance initiatives

## Workshop 2

### Convenors/Rapporteurs

Anita Wagner  
USA

Madeleine de Rosas-Valera  
Philippines

### Moderator

Dennis Ross-Degnan  
USA

### Summary of key issues

- The scope and coverage of a minimum benefits plan must be defined – prioritising of activities may be required. Constraints (financial, workforce, other) raise ethical questions that must be addressed.
- Benefits decisions based on previous care practices may not be appropriate as existing practices may not reflect quality care.
- Products covered should match standard treatment guidelines – coverage should be based on cost-effective products (generics or branded medicines).
- There are substantial data needs for developing a minimum benefits plan relating to disease epidemiology, standard treatment guidelines, capacity of the healthcare system to deliver care, availability and costs of medicines.
- Need to consider health seeking behaviour, patient satisfaction with care, as well as unmet need for care and medicines for those currently unable to access health care systems.

### Key barriers

- Inadequately functioning healthcare delivery systems.
- Lack of valid, reliable, routinely collected relevant data to inform minimum benefits plan decisions.

### Key enablers

- Data systems that allow monitoring of medicines utilisation by diagnoses – claims data alone are insufficient.
- Public education on the value of health insurance to reduce out-of-pocket expenses.

### Steps to address barriers and enablers

- Sharing data (including prices, utilisation) between public and private sectors within countries – sharing experiences between countries.

### Next steps/monitoring progress

- Proposal for a regional network to focus on medicines benefits in health insurance schemes.
- WHO might facilitate development of a regional database on insurance medicines benefit policies and situations. The Medicines and Insurance Coverage (MedIC) health insurance surveys could be a useful initial tool to collect country information.

# Ensuring quality of medicines

## Workshop 3

### Summary of key issues

- Workshop focused on unintentional poor quality medicines.
- Quality medicines are an essential component of a national medicines policy – industry needs to have an active role in ensuring quality products are manufactured.
- Existing WHO pre-qualification processes are limited in scope – there is a role for inter-country cooperation and collaboration to share manufacturing quality information with the possibility of harmonisation of standards.
- Capacity of individual countries is different, making a simple solution difficult.
- Regulators require the financial and human resources to follow up and enforce standards.

### Key barriers

- With so many products in the market, regulatory authorities have limited capacity to assure quality.
- Mistrust between manufacturers and regulators (policing not partnership role).

### Key enablers

- Strengthen regulatory authorities and where appropriate make use of existing quality assurance schemes, policies, standards, and share experiences between countries.
- Develop stronger relationships between responsible manufacturers and regulators.

### Steps to address barriers and enablers

- Member states should work with WHO to initiate regional discussions on regulatory collaborations.
- Individual governments should encourage inter-agency and industry collaboration to assess needs and develop capacity.

### How to monitor progress in implementation

- Regular country level monitoring and reporting on results of regulatory activities including inspections and product testing.
- Regional sharing of information on quality assurance activities.

### Convenors

Susan Walters  
Australia  
Bhupendra Thapa  
Nepal

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### Rapporteurs

Andrew Brown  
Australia  
Manuj Weerasinghe  
Sri Lanka

# Medicine supply and distribution

## Workshop 4

### Convenors

Bev Snell  
Australia

Klara Tisocki  
Philippines

### Rapporteurs

William Mfuko  
Cambodia

Apolosi Vosanibola  
Fiji

### Summary of key issues

- Quantification and forecasting
  - Lack of reliable, good quality data
  - Lack of oversight by dedicated staff or committee
  - Staff often not proficient in quantification methods (consumption and morbidity methods)
  - Often poor coordination between central departments and peripheral units.
- Inventory management systems
  - Varying accuracy
  - Manual operations do not provide real-time data capture
  - Computer systems require staff training
  - It takes time to develop proficiency with the systems
  - Often there are no alternative systems for managing when computer systems are down
  - Poor data recording leads to inaccurate and unreliable data
  - Donor and vertical disease programs (for HIV, tuberculosis and malaria) often use separate reporting systems
  - Often poor linkage between stock management, essential medicines lists and standard treatment guidelines.
- Issues in supply chain infrastructure
  - Often inadequate human and financial resources to run programs, along with poor quality buildings, limited storage and poor storage conditions
  - May be no effective donation policies or guidelines in place or where these exist they are not enforced
  - Diversion from public to private sector occurs in some settings.

### Key barriers

- Inadequate, untrained and inexperienced workforce and limited financial resources.
- Lack of clearly articulated guidelines on ordering and supply management along with fragmented supply and distribution systems.

### Key enablers

- Essential medicines lists and standard treatment guidelines to guide the management of the supply and distribution system.
- Adequate financial and human resources and strengthening of existing supply systems.

### Steps to address barriers and enablers

- Develop and use consensus-based supply chain management guidelines and standard operating procedures for every step of the supply and distribution chain.
- Integrate and harmonise supply and distribution systems – recognise the importance of resilient supply chain systems as part of a functioning healthcare system.

### How to monitor progress in implementation

- Core indicators of supply chain management should be used to measure performance of the system at regular intervals.

# Generic medicines policies

## Workshop 5

### Summary of key issues

- Generic medicines are usually well established with respect to efficacy and safety and are a key strategy used by governments to contain medicines costs and improve affordable access to medicines.
- With the expiry of patents of many 'blockbuster' medicines there is an important opportunity to save money by using generic medicines and to improve medicines access.

### Key barriers

- Mistrust in the quality of generic medicine products – bioequivalence may not be assessed.
- Lack of appropriately skilled inspectors and monitoring to ensure the quality of generic medicine products.
- Poor acceptance by consumers and health professionals due to quality concerns and misconceptions.
- Mismatch between public (generic prescribing) and private (brand name prescribing) sectors.
- Failure to fully implement generic substitution policies and guidelines.
- Interplay between innovator and generic medicines sponsors, governments and healthcare professionals creates potential for conflicts of interest and opportunities for corruption.

### Key enablers – the four Cs

- **Coordinate** the implementation of generic medicines policies including procurement, reimbursement, retail price controls, and reference pricing to support the uptake of generic medicines.
- **Communication** – regulators to make clear statements about the procedures involved in approving generic medicines and promote trust in the quality of generics to the community.
- **Commitment** to procedures and infrastructure to demonstrate, evaluate and promote bioequivalence and maintain product quality to build confidence in generic medicines.
- **Community trust** – educate public/consumers and health professionals to support understanding and confidence in generic medicines, and allow informed choices by consumers.

### Steps to address barriers and enablers

- Integrate generic medicines policies within the broader framework of national medicines policies and make active efforts to promote confidence in their quality and use.

### How to monitor progress in implementation

- Regular reporting on monitoring for the quality, price and use of generic medicines.
- Assess changes in consumer and healthcare professional attitudes to generic medicines.

### Convenors

Azmi Hassali  
Malaysia  
Tuan Nguyen  
Australia

### Rapporteurs

Andrew McLachlan  
Australia  
Vandana Roy  
India

# Antimicrobial resistance and rational use of antibiotics

## Workshop 6

### Convenors

Mary Murray  
Australia

Niyada Kiatying-Angsulee  
Thailand

### Rapporteurs

Michael Chai  
Malaysia

Debra Rowett  
Australia

### Summary of key issues

- Antibiotic resistance is a growing but 'invisible' problem and, with few new antibiotics being developed and poor present use, it is a global issue requiring immediate action.
- Contributors to antimicrobial resistance include:
  - Lack of access to affordable health care, leading to self-medication with antibiotics, combined with truncated courses of treatment due to poor knowledge and costs.
  - Poor use of antimicrobials based on patient demand not clinical need.
  - Poor use of up-to-date treatment guidelines, which are lacking altogether in some countries.
  - Inappropriate availability of antibiotics and use of sub-standard products.
  - Widespread use in animals for food production.
  - Global trade and travel that facilitate cross-border transfer of resistance.

### Key barriers

- Complexity – the dynamics of resistance, lack of knowledge and surveillance, misguided expectations, economic incentives in health systems and unregulated access in many settings.
- Overcrowding in hospitals, poor infection control practices, the lack of reliable diagnostic tools and laboratory facilities mean infections may not be correctly identified and treated.
- Time pressures when it is easier to prescribe an antibiotic than explain why it is not needed – powerful flow-on effects where pharmacists and drug sellers copy doctors' prescribing.

### Key enablers

- Government recognition of antibiotic 'crisis' and commitment to action and resources including regulation of all actors in the supply chain including quality assurance and sanctions.
- A prescriber ethos: 'my individual behaviour impacts groups and systems around me'.
- Communication material and processes that engage people emotionally in the issue.
- Restricting access and therefore use of antibiotics by making them prescription-only medicines.

### Steps to address barriers and enablers

- Build partnerships and strengthen collaboration to make antibiotic resistance visible, and connect the enablers in a resourced national antibiotics policy platform to the national medicines policy.
- Training in antimicrobial resistance in undergraduate and continuing health professional education programs to promote rational prescribing and dispensing of antibiotics – link research projects and training.

### How to monitor progress in implementation

- Policy platform for monitoring, evaluation (outcomes and impacts) and course corrections.



# Medicines safety

## Workshop 7

### Summary of key issues

- Diversity in the region in country size, population, delivery and supply of medicines, and dependence on public and private sectors.
- Need for country-specific national medicine safety programs embedded within a national medicines policy.
- Medicines safety is more than adverse drug reaction monitoring and includes appropriate medicines, appropriate sources of supply, availability of unbiased information, as well as mechanisms to identify problems with medicines and processes to deal with them.
- There needs to be unbiased information for the safe use of medicines available to doctors, pharmacists, nurses and consumers.
- Stringent regulatory framework must exist for efficacy, quality and safety of medicines.
- Proper vision and an ethos for setting up and working for safety of medicines is required.
- There are challenges in access to expert clinical advice and prompt laboratory testing in some resource-poor settings.

### Key barriers

- Poor access to unbiased information, poor consumer health literacy and language barriers.
- Lack of proper vision and framework to support a medicines safety program.

### Key enablers

- Experiences of countries that have good medicines safety programs.
- WHO expertise on the implementation of medicines safety.

### Steps to address barriers and enablers

- Medicines safety activities should be embedded within the national medicines policy.
- A network of Asia Pacific countries to share experiences and expertise for medicines safety program implementation.

### How to monitor progress in implementation

- Monitoring the outcomes following identification and analysis of signals of problems.

### Convenors

John McEwen  
Australia  
Socorro Escalante  
Vietnam

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### Rapporteurs

Anita Kotwani  
India  
Judith Mackson  
Australia

# Advertising and promotion

## Workshop 8

### Convenors

Ken Harvey  
Australia  
Shila Kaur  
Malaysia

### Rapporteurs

Jared Hyams  
Australia  
Edelina Dela Paz  
Philippines

### Summary of key issues

- WHO ethical criteria are still relevant – the challenge is to embed an ethical ethos into the behaviours of pharmaceutical industry and health professionals ('it takes two to tango').
- Country regulations (based on WHO code) need to be enforced, breaches of codes and standards need to be appropriately penalised and publicised to facilitate deterrence.
- The unregulated internet marketing of medicines poses challenges for regulators and law enforcement – consumer education should discourage online purchase of medicines.
- The boundaries of medicines advertising need to be well defined (that is, information versus promotion) and the limitations of pre-clearance of advertising material recognised.
- Promote transparency of medicines industry payments to health professionals (monetary and in-kind gifts, funding of continuing medical education) and consumer groups – for example, the US Sunshine Act.

### Key barriers

- Increasing outlets for medicines advertising (TV, online).
- Monitoring advertising is a large and difficult task, especially for monitoring evidence for claims made – regulations are difficult to enforce and penalties need to be easily applied.
- Industry opposition to regulation of advertising and promotion of medicines.

### Key enablers

- Develop ethical frameworks and monitoring of medicine advertising compliance.
- Work with regulators and law enforcement agencies (Interpol for internet activities).
- Use regulations rather than legislation – inform the public about violations and sanctions.

### Steps to address barriers and enablers

- Strengthen pre-approval process for medicine advertising – increase powers to enforce laws and regulations.
- Provide independent, objective information to health professionals and consumers.

### How to monitor progress in implementation

- Monitor medicines industry-sponsored activities including continuing medical education, advocate for independent education arrangements, and track complaints and sanctions applied.
- Development and regular reporting on indicators relating to regulation and advertising.
- Monitor the processes of self-regulation to ensure standards are adequate and appropriate independent mechanisms are in place to manage breaches.

# Rational use of medicines

## Workshop 9

### Summary of key issues

- Implementing the rational use of medicines is often forgotten or considered too hard.
- Needs to be aligned with all other elements of a national medicines policy to be effective.
- Less than 50% of countries are implementing policies based on WHO recommendations for rational use of medicines.
- It is critical to define the problem to prioritise actions and design interventions.
- Political will is needed and can be engendered by data and supported by activism.
- Sustainability should be included in planning for rational use of medicines.
- There should be official endorsement of a body responsible for rational use of medicines within each country.

### Key barriers

- Workforce – rational use of medicines requires a broad skill base in program design, knowledge translation, educational strategies, behaviour change, communication, project management and evaluation.
- Absence of data to clearly define problems with medicine use.
- Misalignment of incentives, training, recognition and reward systems in the health sector.

### Key enablers

- Supportive and enforceable regulatory framework for rational use of medicines.
- Solutions that are relevant to culture and setting – these will be supported by appropriate evidence.
- Accountability and transparency for everyone engaged in the rational use of medicines.

### Steps to address barriers and enablers

- Twelve key interventions advocated by WHO offer a comprehensive approach to the rational use of medicines.
- Support and resource drugs and therapeutics committees and rational use of medicines champions.
- Information sharing across the region on successes and failures of rational use of medicines activities.

### How to monitor progress in implementation

- Evaluate specific interventions and programs – this requires data and skills in analysis.
- Use existing networks, such as the International Network for the Rational Use of Drugs and the International Society of Drug Bulletins, and social media to communicate and engage with consumers and healthcare professionals and to evaluate impact.

### Convenors

Lynn Weekes  
Australia  
Kumud Kafle  
Nepal

### Rapporteurs

Nimmi Athuraliya  
Australia  
Michael Nunan  
Australia

# Appendix 1

## Conference program

Saturday, 26 May 2012

12:00 noon	Registration open, Level 2, Sheraton on the Park
<b>Plenary 1</b> Hyde Park Room 2:00pm-3:30pm	<b>PLENARY SESSION</b> <b>Welcome to country</b> <b>Welcome and introduction</b> - Prof Andrew McLachlan, Chair, Organising Committee <b>Formal opening of the conference</b> - Minister for Health or delegate <b>Thanks to the Minister for Health or delegate</b> - Prof Andrew McLachlan <b>Message from WHO, WPRO and SEARO</b> - Dr Henk Bekedam (WPRO) <b>Introduction of participating countries and dignitaries</b> - Prof Andrew McLachlan
3:30pm-4:00pm	<b>AFTERNOON TEA</b>
<b>Plenary 2</b> Hyde Park Room 4:00pm-6:00pm	<b>PLENARY SESSION National medicines policies and universal access to medicines</b> <b>Where are we now? A review of the state of implementation of NMPs globally and in the Asia Pacific region</b> - Dr Budiono Santoso, WPRO <b>Does having a NMP matter?</b> - Dr Kathy Holloway, SEARO <b>Implementation of NMP: the Australian experience</b> - Prof Lloyd Sansom <b>International perspectives</b> - Sir Michael Rawlins
6:00pm-7:30pm	<b>WELCOME RECEPTION</b> Sheraton on the Park

Sunday, 27 May 2012

8:00am	Access for presenters to put up their poster				
<b>Plenary 3</b> Ballroom 1 8:30am-10:15am	<b>PLENARY SESSION Access to medicines, national medicines policies and health care reform</b> <b>China:</b> Health care reform and the essential medicines system to ensure universal access - Dr Sun Jing <b>Japan:</b> Experiences in implementing a policy on universal coverage of health insurance - Prof Kazuko Kimura <b>South Korea:</b> A uniform national system for insurance reimbursement and the role of effective IT support for monitoring - Prof Soonman Kwon <b>India:</b> Working towards universal health coverage in India - Dr Amit Sen Gupta				
10:15am-10:45am	<b>MORNING TEA</b>				
10:45am-12:30pm	<table border="1"> <tr> <td><b>WORKSHOP 1</b> Medicine selection and Essential Medicines Lists (EMLs) Hyde Park Room</td> <td><b>WORKSHOP 2</b> Financing and health insurance initiatives Ballroom 2</td> <td><b>WORKSHOP 3</b> Ensuring quality of medicines Philip Rooms 1 &amp; 2</td> <td><b>SYMPOSIUM 1</b> Legislation to ensure sustainability of NMPs Ballroom 1</td> </tr> </table>	<b>WORKSHOP 1</b> Medicine selection and Essential Medicines Lists (EMLs) Hyde Park Room	<b>WORKSHOP 2</b> Financing and health insurance initiatives Ballroom 2	<b>WORKSHOP 3</b> Ensuring quality of medicines Philip Rooms 1 & 2	<b>SYMPOSIUM 1</b> Legislation to ensure sustainability of NMPs Ballroom 1
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12:30pm-1:30pm	<b>LUNCH</b>				
1:30pm-2:00pm	<b>RESPONSES TO WORKSHOPS AND SYMPOSIUM</b>				
<b>Plenary 4</b> Ballroom 1 2:00pm-4:00pm	<b>PLENARY SESSION Experiences of implementation of national medicines policies</b> <b>Indonesia:</b> Implementing national medicines policies in a decentralised environment - Dr Lucky Slamet <b>Malaysia:</b> Pharmacy transformation planning - Dr Salmah Bahri <b>Thailand:</b> Implementing NMP to achieve universal access to essential medicines in Thailand - Dr Sauwakon Ratanawijitrasin <b>Laos:</b> Implementing national medicines policies in resource constrained environments - Dr Lamphone Syhakhang <b>Pacific island countries:</b> Implementing national medicines policies in small island states - Ms Melenaita Mahe				
4:00pm-4:30pm	<b>AFTERNOON TEA</b>				
<b>Plenary 5</b> Ballroom 1 4:30pm-5:30pm	<b>PLENARY SESSION The pharmaceutical industry and national medicines policies</b> Panel members: Assoc Prof Dennis Ross-Degnan, Dr Eugene Salole, Dr Sivalal Sadasivan, Mr Reiner Gloor Moderators : Mr Will Delaat and Prof Ric Day				
<b>Plenary</b> Ballroom 1 6:30pm-8:00pm	<b>SYMPOSIUM 2 – Access to, and rational use of opioid medicines</b>				

## Monday, 28 May 2012

<b>Hyde Park Room</b> 7:00am-8:15am	<b>EARLY MORNING SESSION</b> <b>Universal access to reproductive health services and commodities: Opportunities for NMP/universal access to medicines collaboration</b> Convenors: Peter Zinck (UNFPA), Ray Skinner (Australia)			
8:30am-10:15am	<b>WORKSHOP 4</b> <b>Medicine supply and distribution</b> <b>Ballroom 2</b>	<b>WORKSHOP 5</b> <b>Generic medicines policies</b> <b>Philip Rooms 1 &amp; 2</b>	<b>WORKSHOP 6</b> <b>Antimicrobial resistance and rational use of antibiotics</b> <b>Hyde Park Room</b>	<b>SYMPOSIUM 3</b> <b>Monitoring medicines use</b> <b>Ballroom 1</b>
10:15am-11:00am	<b>MORNING TEA AND POSTER VIEWING</b> <b>RESPONSES TO WORKSHOPS AND SYMPOSIA</b>			
<b>Plenary 6</b> <b>Ballroom 1</b> 11:00am-12:30pm	<b>PLENARY SESSION Challenges to implementation of national medicines policies: solutions and unresolved problems</b> <b>Bangladesh:</b> A long history of NMP: where are we now? - Dr Zafrullah Chowdhury <b>Sri Lanka:</b> A long history of NMP: where are we now? - Dr Palitha Abeykoon <b>Vietnam:</b> Balancing industry development and public health - Dr Truong Quoc Cuong <b>The Philippines:</b> From commitment to action - Dr Madeleine de Rosas-Valera			
12:30pm-1:30pm	<b>LUNCH</b>			
1:30pm-2:00pm	<b>ATTENDED POSTER SESSION</b>			
2:00pm-3:45pm	<b>WORKSHOP 7</b> <b>Medicines safety</b> <b>Hyde Park Room</b>	<b>WORKSHOP 8</b> <b>Advertising and promotion</b> <b>Philip Rooms 1 &amp; 2</b>	<b>WORKSHOP 9</b> <b>Rational use of medicines</b> <b>Ballroom 2</b>	<b>SYMPOSIUM 4</b> <b>Consumer education and health literacy</b> <b>Ballroom 1</b>
3:45pm-4:30pm	<b>AFTERNOON TEA AND POSTER VIEWING</b> <b>RESPONSES TO WORKSHOPS AND SYMPOSIA</b>			
<b>Plenary 7</b> <b>Ballroom 1</b> 4:30pm-5:30pm	<b>PLENARY SESSION National medicines policies: where will we be in 2030?</b> Sir Michael Rawlins			
7:00pm-10:30pm	<b>CONFERENCE DINNER</b> Sydney Harbour Cruise			

## Tuesday, 29 May 2012

<b>Plenary 8</b> <b>Ballroom 1</b> 8:30am-10:30am	<b>PLENARY SESSION Feedback session</b> Feedback from all symposia and workshops			
10:30am-11:00am	<b>MORNING TEA AND POSTER VIEWING</b>			
<b>Plenary 9</b> <b>Ballroom 1</b> 11:00am-1:00pm	<b>PLENARY SESSION Advocacy for implementing national medicines policies: what will make a difference?</b> Consumers achieving change in national medicines policy: the Australian experience - Ms Carol Bennett Civil society advocacy on access to medicines: time to break the silos - Dr Amit Sen Gupta Advocacy for medicines policy options in Thailand: mobilising stakeholders and strengthening the network for drug system monitoring - Dr Niyada Kiatying-Angsulee Public health matters: what has worked, what has not - examples from the Asia Pacific with lessons for NMP - Dr Michael Chai Institutionalization and socialization of the medicines sector reform policies in China - Dr Sun Jing			
1:00pm-2:00pm	<b>LUNCH AND POSTER VIEWING</b>			
<b>Plenary 10</b> <b>Ballroom 1</b> 2:00pm-3:00pm	<b>PLENARY SESSION</b> <b>Overview and summary of conference</b> - Assoc Prof Dennis Ross-Degnan, Emeritus Prof Lloyd Sansom <b>Closing comments from WHO</b> - Dr Budiono Santoso			
3:00pm	<b>FORMAL CLOSE OF CONFERENCE</b>			

## Appendix 2

### Official representatives and committees

#### Organising committee

Professor Andrew McLachlan, University of Sydney, Australia (Chair)

Dr Henk Bekedam, Western Pacific Regional Office, World Health Organization, Philippines

Dr Jonathan Dartnell, NPS MedicineWise, Australia

Associate Professor David Newby, University of Newcastle, Australia

Dr Jane Robertson, University of Newcastle, Australia

Dr Budiono Santoso, Western Pacific Regional Office, World Health Organization, Philippines

Emeritus Professor Tony Smith, University of Newcastle, Australia

Representatives from the Australian Government Department of Health and Ageing

Lidia Dalton, Expert Events, Australia

#### Scientific program committee

Dr Jane Robertson, University of Newcastle, Australia (Chair)

Emeritus Professor Lloyd Sansom, University of South Australia (Co-Chair), Former Chair of Pharmaceutical Benefits Advisory Committee, Australia

Dr Henk Bekedam, Western Pacific Regional Office, World Health Organization, Philippines

Dr Jonathan Dartnell, NPS MedicineWise, Australia

Professor Ric Day, University of New South Wales, Australia

Dr Ken Harvey, La Trobe University, Australia

Dr Kathleen Holloway, South East Asia Regional Office, World Health Organization, India

Dr Richard Laing, World Health Organization, Switzerland

Dr Mary Murray, International consultant on national medicines policies, and ReAct – Action on Antibiotic Resistance

Dr Budiono Santoso, Western Pacific Regional Office, World Health Organization, Philippines

Emeritus Professor Tony Smith, University of Newcastle, Australia

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Professor Kumud Kafle, TU Teaching Hospital, Kathmandu, Nepal

Professor Kazuko Kimura, Kanazawa University, Japan

Professor Soonman Kwon, Seoul National University, South Korea

Dr Hélène Moller, UNICEF, Denmark

Dr Dennis Ross-Degnan, Harvard University, USA

Dr Amit Sengupta, People's Health Movement, India

Dr Lucky Slamet, National Agency of Drug and Food Control, Indonesia

Dr Beverley Snell, Burnet Institute, Australia

Dr Göran Tomson, Karolinska Institute, Sweden

Dr Anita Wagner, Harvard Medical School, and Yong Loo Lin School of Medicine, Singapore

Dr Brenda Waning, UNITAID, Switzerland

Dr Peter Zinck, United Nations Population Fund, Fiji

#### Pharmaceutical industry reference panel

Professor Ric Day (Chair), University of New South Wales, Australia

Dr Alex Condoleon, Sanofi Australia and New Zealand

Mr Will Delaat, Australia, Former Chair of Medicines Australia, Former Chief Executive Officer of Merck Sharp and Dohme Australia

Dr David Grainger, Eli Lilly, Australia

Dr Eugene Salole, Pfizer Australia

Dr Brendan Shaw, Medicines Australia

Dr Edmund Tsuei, Asia Pacific Medicine Development Consulting, Australia

## Appendix 3

### Conference participant list

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Bankar	Mangesh	Government Medical College	INDIA
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Choong	Chih Tzer	Health Sciences Authority	SINGAPORE
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## Appendix 4

### Resources

#### Access to Medicine Index

[www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

The Access to Medicine Index provides a method to monitor and evaluate the performance of the pharmaceutical industry by assessing the output and outcomes of access-to-medicine initiatives. Some of the indicators in this index may be relevant for longitudinal or trend analysis.

The Index includes a range of measures and indicators that assess industry commitment, transparency, performance and innovation (the four strategic pillars) in relation to:

- general access to medicines management
- public policy and market influence
- research and development
- equitable pricing, manufacturing and distribution
- patents and licensing
- capability advancement in product development and distribution
- product donations and philanthropic activities.

#### Medicines and Insurance Coverage (MedIC) initiative

[www.whocpp.org/research/medic.asp](http://www.whocpp.org/research/medic.asp)

The Medicines and Insurance Coverage (MedIC) initiative aims to improve the health of populations by supporting the design, implementation, evaluation, and routine monitoring of evidence-based medicines coverage policies for vulnerable populations across the world. MedIC's goal is to improve the health and economic well-being of people in low and middle income countries by improving availability, affordability, and appropriate use of medicines through health insurance schemes.

#### WHO Resources

[www.who.int](http://www.who.int)

The WHO has a vast library of resources available which can be accessed in a variety of ways. Access the WHO Bookshop and WHO Library database from the Publications tab.

#### *Institutional Repository for Information Sharing (IRIS)*

[apps.who.int/iris](http://apps.who.int/iris)

#### *Medicines Publications and Documentation*

[apps.who.int/medicinedocs](http://apps.who.int/medicinedocs)

This site allows searching by title, topic, author, region or country. The public sub-collection tab links to a collection of articles on all aspects of national medicines policies. You can also create your own sub-collection of articles of interest.

#### *Essential Medicines and Health Products Department*

[www.who.int/medicines](http://www.who.int/medicines)

This page, with multiple links, identifies the range of work activities undertaken. The medicines topics tab links to an alphabetical index of topics.

#### *Guidelines on the pharmacological treatment of persisting pain in children with medical illnesses*

[www.who.int/medicines/areas/quality\\_safety/guide\\_perspainchild](http://www.who.int/medicines/areas/quality_safety/guide_perspainchild)

This package consists of four online publications: the WHO guidelines on treating persisting pain in children and three brochures with highlights from the guidelines selected for:

- physicians and nurses
- pharmacists
- policy-makers and medicines regulatory authorities, hospital managers and health insurance managers.

#### *Western Pacific Regional Office*

[www.wpro.who.int](http://www.wpro.who.int)

#### *South East Asian Regional Office*

[www.searo.who.int](http://www.searo.who.int)

## International Narcotics Control Board

[www.incb.org](http://www.incb.org)

The International Narcotics Control Board is the independent and quasi-judicial monitoring body for the implementation of the United Nations international drug control conventions. It was established in 1968 in accordance with the Single Convention on Narcotic Drugs, 1961. It had predecessors under the former drug control treaties as far back as the time of the League of Nations. The functions of the Board are laid down in the following treaties:

- the Single Convention on Narcotic Drugs, 1961
- the Convention on Psychotropic Substances of 1971
- the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988.

In the discharge of its responsibilities, the Board:

- administers a system of estimates for narcotic drugs and a voluntary assessment system for psychotropic substances and monitors licit activities involving drugs through a statistical returns system, with a view to assisting governments in achieving, inter alia, a balance between supply and demand
- monitors and promotes measures taken by governments to prevent the diversion of substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances and assesses such substances to determine whether there is a need for changes in the scope of control of Tables I and II of the 1988 Convention
- analyses information provided by governments, United Nations bodies, specialised agencies or other competent international organisations, with a view to ensuring that the provisions of the international drug control treaties are adequately carried out by governments, and recommends remedial measures
- maintains a permanent dialogue with governments to assist them in complying with their obligations under the international drug control treaties and, to that end, recommends, where appropriate, technical or financial assistance to be provided.

## Regional journals

### ***Southern Medical Review***

[www.fmhs.auckland.ac.nz/sop/smr](http://www.fmhs.auckland.ac.nz/sop/smr)

The Southern Medical Review is published twice a year. It is an open access peer reviewed journal focusing on Pharmaceutical Policy Research. The journal provides a platform for the dissemination of commentary and empirical research findings with a view to improving rational use of and access to essential medicines.

In June 2013, this journal was re-launched as the ***Journal of Pharmaceutical Policy and Practice (JoPPP)***, as part of BioMedCentral and is an open access publication. It is relevant to research and practice in low and middle income countries.

[www.joppp.org](http://www.joppp.org)

### ***The WHO South East Asia Journal of Public Health (WHO SEAJPH)***

[www.searo.who.int/publications/journals/seajph/en/index.html](http://www.searo.who.int/publications/journals/seajph/en/index.html)

This is a peer-reviewed, indexed, open access quarterly publication of the World Health Organization Regional Office for South East Asia. The Journal aims to provide an avenue to scientists for publication of original research work so as to facilitate use of research for public health action.

### ***Australian Prescriber***

[www.australianprescriber.com](http://www.australianprescriber.com)

*Australian Prescriber* is Australia's national independent journal of drugs and therapeutics. Its purpose is to help health professionals make informed choices when prescribing, including whether to prescribe a drug or not. *Australian Prescriber* provides independent, reliable and accessible information about drugs and therapeutics. As well as publishing short didactic reviews, it facilitates debate about complex, controversial or uncertain therapeutic areas.

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