Implementing national medicines policy
– Where are we now?

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Problems of access to essential medicines

- Most major causes of morbidity and mortality in developing countries can be prevented or treated with existing essential medicines.

- However, millions of people in developing countries still face the problems of access to the needed essential medicines
  - The medicines are often not available or affordable.
  - Low quality and fake products
  - Inappropriately used

- If the needed essential medicines for infectious diseases, maternal, perinatal and paediatric diseases, respiratory infections, cardiovascular diseases and cancers, can be made available and accessible, 10.5 millions lives can be saved annually (Commission of Macroeconomics in Health, WHO, 2001).
The right to health international agreements

- The Universal Declaration of Human Rights 1948
  Everyone has the rights to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services.

- WHO Constitution, 1946
  The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic and social condition.

- International Covenant and Economic, Social and Cultural Rights,1966
  States parties recognize the right of every one to the enjoyment of the highest physical and mental health.

Health for all – how can it be achieved?

- Alma Ata declaration 1978 – Health for All through primary health care

- Renewed primary health care (WHO, 2008)
  - Universal coverage reforms
  - Service delivery reforms
  - Leadership reforms
  - Public policy reforms.

Primary health care is the key to attaining the target of universal coverage
National medicines policy & universal coverage

- WHO advocates and supports the development, implementation and monitoring of National Medicines Policy.

- National medicines policy is an integral part of health policy, to help achieve universal access to the needed essential medicines within a functioning health system.

Objectives national medicines policy
- **Access:** equitable availability and affordability of essential medicines
- **Quality:** quality, safety and efficacy of all medicines
- **Rational use:** Therapeutically sound and cost-effective use of medicines by health professionals and consumers

Where are we now?
- Existence of NMP
- Existence of EML
- Availability and affordability of the needed essential medicines
- Medicines financing & out of pocket payment
Existence of National Medicines Policies

Figure 1. Progress in the development and/or revision of National Medicine Policy in the Western Pacific Region, 2003–2007

- Existence of National Medicines Policy (official or draft)
- National Medicines Policy official document
- Implementation plan updated in last five years
- National Medicines Policy integrated in National Health Plan

EML as a basis for public procurement or insurance reimbursement

- At least 80% of countries only procure medicines in the EML & at least in 60% of countries some medicines are covered by public insurance.
- How the needs quantified and planned?
- How reliable is the supply system to ensure continuous availability?
- What percentage of population is covered by public insurance?

Countries limiting public sector procurement to EML

Countries with medicines covered by public health insurance

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- How the needs quantified and planned?
- How reliable is the supply system to ensure continuous availability?
- What percentage of population is covered by public insurance?
Access, availability & affordability – the inconvenient truth

- The needed essential medicines are often not available to patients in need.
- The price of medicines are often not affordable to patients and health system.

Availability of essential medicines in public and private health facilities
(UN Millennium Development Goal 2008)
Average availability of generic medicines for chronic and acute diseases in 40 low and middle income countries (Cameron et al., 2011).

<table>
<thead>
<tr>
<th>Selected 15 medicines for acute diseases</th>
<th>Public</th>
<th>Private</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic diseases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti ulcers</td>
<td>51.7%</td>
<td>82.9%</td>
</tr>
<tr>
<td>Anti diabetics</td>
<td>49.5%</td>
<td>65.0%</td>
</tr>
<tr>
<td>Anti-hypertensives</td>
<td>34.7%</td>
<td>57.1%</td>
</tr>
<tr>
<td>Anti-asthmatics</td>
<td>30.1%</td>
<td>43.1%</td>
</tr>
<tr>
<td>Anti-epileptics</td>
<td>29.4%</td>
<td>40.3%</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>27.8%</td>
<td>45.1%</td>
</tr>
</tbody>
</table>

Availability of the first line anti hypertensive hydrochlorothiazide is always low (0 – 10%) (Mendis et al., 2006)

Ratio of consumer prices to international reference prices for selected generic medicines in public and private health facilities (UN Millennium Development Goal, 2008)
Treatment affordability for diabetes with concomitant hypertension
(The World Medicines Situation, 2011)

Affordability measured as the number of days salary the lowest-paid government worker needs to pay for 1-month supply of generic medicines from the private sector.

Welcome to PIE

Welcome to the Price Information Exchange (PIE) for selected medicines in the Western Pacific Region of the World Health Organization.

We have established this source of price information exchange as recommended in the Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005-2010). The aim of the website is to provide comparative information on procurement prices for selected medicines across the Western Pacific Region that countries can use to influence actions to make medicines more affordable and in negotiating with suppliers.

This website lists procurement prices in the private sector for selected medicines in participating countries in the Western Pacific Region. The first set of data was collected from 18 participating countries between May and June 2009. The information was processed by the WHO Western Pacific Regional Office in collaboration with the University of the Philippines Manila – Telehealth Center.

www.piemeds.com
Out of pocket expenditure on medicines

- Out of pocket consumers expenditures on medicines account predominantly for total health expenditures.

- Out of pocket health expenditures drives lower income segment below the poverty line.

Out-of-pocket expenditure on health as a percentage of total expenditure on health (measured in US$), 2010
Effect of out of pocket payment on poverty estimates in 11 countries in Asia
(Doorsloer et al., 2006)

<table>
<thead>
<tr>
<th>Country</th>
<th>Prepayment normalised gap</th>
<th>Postpayment normalised gap</th>
<th>Percentage point change</th>
<th>Percentage change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>22.8%</td>
<td>30.5%</td>
<td>2.6%</td>
<td>9.4%</td>
</tr>
<tr>
<td>China</td>
<td>17.0%</td>
<td>18.2%</td>
<td>1.2%</td>
<td>7.1%</td>
</tr>
<tr>
<td>India</td>
<td>33.9%</td>
<td>35.9%</td>
<td>2.0%</td>
<td>6.0%</td>
</tr>
<tr>
<td>Indonesia</td>
<td>17.3%</td>
<td>18.1%</td>
<td>0.8%</td>
<td>4.7%</td>
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<tr>
<td>Kyrgyz Republic</td>
<td>7.4%</td>
<td>8.0%</td>
<td>0.6%</td>
<td>8.0%</td>
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<td>Malaysia</td>
<td>2.8%</td>
<td>2.9%</td>
<td>0.1%</td>
<td>3.0%</td>
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<tr>
<td>Nepal</td>
<td>37.4%</td>
<td>38.7%</td>
<td>1.3%</td>
<td>3.4%</td>
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<tr>
<td>Philippines</td>
<td>19.3%</td>
<td>19.8%</td>
<td>0.5%</td>
<td>2.8%</td>
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<tr>
<td>Sri Lanka</td>
<td>10.1%</td>
<td>10.6%</td>
<td>0.5%</td>
<td>5.3%</td>
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<tr>
<td>Thailand</td>
<td>6.1%</td>
<td>6.4%</td>
<td>0.3%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Vietnam</td>
<td>9.3%</td>
<td>11.0%</td>
<td>1.7%</td>
<td>18.3%</td>
</tr>
<tr>
<td>TOTAL$</td>
<td>23.0%</td>
<td>24.5%</td>
<td>1.5%</td>
<td>6.7%</td>
</tr>
</tbody>
</table>

Quality assurance and regulatory system

- Quality assurance measures are needed not only in the manufacturing phase or retail phase but also in the distribution chains.
- Most countries have legal provisions for regulation and inspection of premises \( \rightarrow \) BUT very limited capacity for strong enforcement.
- Risk based approaches needed to efficiently use available capacity and resources.

Countries with medicines regulatory system

<table>
<thead>
<tr>
<th>Country</th>
<th>Present</th>
<th>Absent</th>
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<tbody>
<tr>
<td>Asia</td>
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<tr>
<td>Australia</td>
<td>2/7</td>
<td>5/7</td>
</tr>
<tr>
<td>European Medicines</td>
<td>1/3</td>
<td>2/3</td>
</tr>
<tr>
<td>Europe</td>
<td>1/6</td>
<td>5/6</td>
</tr>
<tr>
<td>South East Asia</td>
<td>1/5</td>
<td>4/5</td>
</tr>
<tr>
<td>Western Pacific</td>
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Countries with legal provision for inspection

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<tr>
<td>Western Pacific</td>
<td>1/5</td>
<td>4/5</td>
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Unsafe sub standard and fake products

- The distribution and sales of unsafe sub standard and even fake products often penetrate the supply chain of medicines in many countries due to weak enforcement of medicines regulation.

Medicines safety catastrophes

- In January 2012, over 100 heart disease patient died due to contamination of a common cardiac medicine with an antimalarial agent (pyrimethamine)

- Lack of existence NMRA as a result of constitutional de-centralisation of the public health sector contributed to the crisis.

- On 6 February, taking note of this regulatory Failure the Pakistan's Supreme Court directed the federal government to re-establish a central Drug Regulatory Authority (DRA)

- Five countries had banned drug imports from Pakistani following the tragedy.
Di-ethylene glycol poisoning -
deadly recurring catastrophe
due to contaminated cough mixtures

- Recurring events – where and when the next?
  - USA (1937) → over 100 deaths
  - India (1986) → 14 deaths
  - Argentina (1992) → 23 deaths
  - Nigeria (1990) → 47 deaths
  - Bangladesh (1992) → 236 deaths
  - Haiti (1995) → 89 deaths
  - India (1998) → 30 deaths
  - China (2006) → 20 deaths
  - Panama (2006) → 100 deaths
  - Nigeria (2010) → 84 deaths

- Distribution of the genuine glycerin is easily intercepted by the counterfeiter.

The existing surveillance fail to detect at early stage

Lessons learnt – past and present

- Political commitment
  - Policy process & negotiation
  - Policy implementation & action

- Health services delivery system
  - Underfunded & understaffed
  - Inefficient medicines delivery system
  - Reform agenda (KOR, CHN, MAA, TH, PHL, INA, VTN etc)

- Monitoring of progress

- Information exchange, experiences sharing & consultation
Ten leading causes of inefficiency in health systems (WHO, 2010)

1. Medicines - underuse of generics
2. Medicines - use of sub standard and counterfeits
3. Medicines – inappropriate and ineffective use
4. Health care products & services – overuse
5. Health workers – inappropriate or costly staff mix
6. Health care services – inappropriate hospital admissions and length of stay
7. Health care services – inappropriate hospital size
8. Health care services – medical errors and suboptimal quality of care
9. Health system leakages – waste, corruption & fraud
10. Health interventions – inefficient mix/inappropriate strategies

WHO Regional framework for action on access to medicines

- Guides for WHO in collaborating with Member countries
- Traffic light indicators
The way forward

- Advocacy, consultation, commitment & translate into action → improved access and health outcome
- Reviving the medicines system as part of reform agenda
- Focus also on priority issues with impact on health outcome
  - Infectious diseases
  - Maternal and child health
  - Non communicable diseases
- Periodic monitoring of medicines sector
  - What gets measured, gets done.
- Collaborating network of academics & researchers to provide feedback to policy makers
  - Critical analysis
  - Which strategies work & do not work
  - Impacts on access & health outcome