Report from the Western Pacific to the 13th International Conference of Drug Regulatory Authorities (Berne, 2008)

Budiono Santoso
Pharmaceuticals Program
WHO Western Pacific Region
<table>
<thead>
<tr>
<th>Member States in the Western Pacific</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Big countries with sizable industry</strong></td>
</tr>
<tr>
<td>Australia</td>
</tr>
<tr>
<td>China</td>
</tr>
<tr>
<td>Japan</td>
</tr>
<tr>
<td>Malaysia</td>
</tr>
<tr>
<td>S Korea</td>
</tr>
<tr>
<td>Philippines</td>
</tr>
<tr>
<td>Singapore</td>
</tr>
<tr>
<td>Viet Nam</td>
</tr>
<tr>
<td><strong>ASEAN</strong></td>
</tr>
<tr>
<td>Brunei, Cambodia, Laos, Malaysia, Philippines, Singapore, Viet Nam, Indonesia, Thailand</td>
</tr>
<tr>
<td><strong>Mekong</strong></td>
</tr>
<tr>
<td>Cambodia, Laos, Viet Nam, China, Myanmar and Thailand</td>
</tr>
<tr>
<td><strong>Pacific Island countries</strong></td>
</tr>
<tr>
<td>Cook Island, Fiji, French Polynesia, Kiribati, Marshall Islands, Micronesia, Nauru, New Caledonia, New Zealand, Niue, Northern Mariana, Palau, PNG, Pitcairn Islands, Samoa, Solomon Islands, Tokelau, Tonga, Tuvalu, Vanuatu</td>
</tr>
</tbody>
</table>
Mekong: counterfeit
ASEAN: harmonization
Pacific: Harmonization, quality assurance, human resource
WHO Program relevant to ICDRA recommendations

- Pharmaceuticals program
- Traditional medicines
- Blood safety and health technologies

Improving access, quality and use of medical products and technologies
Pharmaceuticals program:
 highlights of countries collaboration
 2006 -2007

- National medicines policies
- Access to essential medicines
- Medicines regulation and quality assurance
- Rational use of medicines
Six countries reviewed, revised or developed policies and strategic plan & assess pharmaceutical sector.

Continued support for 14 Pacific countries through WHO EC PIC partnerships on pharmaceutical policies.

Annual consultation/workshop on Pharmaceutical Policies and Access to Essential Medicines for Pacific island countries.
Pharmaceuticals program: access to essential medicines

- Two regional and 5 national consultations on public health, innovation and intellectual property
- Review of medicines financing in (5 PIC countries)
- Review of patent legislation (3 countries)
- Regional consultation on medicines financing (9 countries) & on affordable essential medicines (11 countries)
- Medicine price monitoring in 3 countries (MAA, PHL and VTN)
- Medicines information management system (5 countries)
- Review of national medicines supply system (3 countries)
- Supervision and monitoring of medicines management (4 countries)
- Inter-country consultation on access and human rights (4 countries)
- Improving medicines supply & decentralization (2 countries)
- Feasibility on pooled procurement for PICs
- Support for Medicines Transparency Alliance (META) (1 country)
- Advocacy campaign for generics (1 country, PHL)
Pharmaceuticals program:
medicines regulation & quality assurance

- Expansion of rapid alert system (RAS). Intensified surveillance, inspection and advocacy (4 countries) to combat counterfeit
- Medicines regulatory assessment (6 countries)
- GMP, good distribution & inspection (6 countries)
- Regional workshop on medicines surveillance & regulatory functions (13 countries)
- Medicines legislation (2 PIC countries)
- Computerized medicines registration (2 countries)
- Pilot project on involving consumers in medicines surveillance (2 countries)
- GGM (good governance in medicines) project (6 countries)
- Medicines quality seal program in PHL & decentralization
- Regulatory assessment & strengthening for vaccines production and quality assurance (2 countries) and investigation of ADR following immunization
- Workshop on production, control and regulation of anti venom
- Regional training on pharmaco-vigilance
Counterfeit anti-malarial artesunate in Greater Mekong countries

- Newton et al 2001
  38 % without active ingredients

- Dondorp et al 2004
  53 % without active ingredients

Production and distribution channel are not yet disrupted
Combating counterfeit medicines in Greater Mekong countries

- Focused on anti malarials and antibiotics
- Involving national regulatory authorities and law enforcement agencies, international agencies
- Leading to criminal investigation and enforcement
Good governance in medicines

- To promote transparency and ethical practices and minimize vulnerability to corruption in medicines registration, selection and procurement through system approach in medicines sector

- Laos, Cambodia, Indonesia, Malaysia, Mongolia, Philippines, PNG, Thailand
Pharmaceuticals program: rational use of medicines

- MTP (monitoring training and planning) interventions for rational use (5 countries)
- Drugs therapeutics committee, rational use of antimicrobials & containment of AMR (CHN, PHL, Solomon)
- ASEAN training workshop on rational use
- Revision of essential medicines list & treatment guidelines (4 countries)
- National training workshop on pharmaco-economics (Malaysia) on RDU (5 countries)
- Problem based pharmacotherapy teaching (2 countries)
- Public education campaign on RDU & antibiotic use (2 countries). Active small group community learning for RDU (CBIA) (3 countries)
- Using pocket computer for formulary information
Harmonization & collaborative mechanism for Pacific island countries

- Feasibility study of pooled procurement mechanism of medicines in Pacific island countries
- Non economic benefits
- Harmonization
  - List of essential medicines & formularies
  - Therapeutic guidelines
  - Prequalification of suppliers
  - Collaborative quality testing arrangement
  - Exchange of information
Traditional medicines

- Support a number of research activities on herbal medicines conducted by selected countries such as China, Mongolia, Viet Nam, Republic of Korea. WHO collaborating centres on traditional medicine, as part of their terms of reference, regularly conduct clinical trials/studies on efficacy of traditional medicine.

- WPRO continued "observer" role in the Regional Forum on Harmonization of Herbal Medicines (FHH), which consists of representatives from relevant regulatory authorities, related research and academic institutions, and invited relevant industry associations from FHH members. WPRO participated in FHH's annual standing committee.
Summary

- Strengthening medicines regulation, quality assurance & regulatory functions is an important priority.
- Transparency, efficiency, ethical practice and good governance in medicines regulations
- Collaborative approach for small countries
- Implementing regulation in private market
- Combating counterfeit and sub standard medicines