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EXAMINATION OF THE DATA ON NATIONAL MEDICINE POLICIES (NMP) AND DRUG USE IN SOUTHEAST ASIA

National Medicine Policy plays an important role to bring together all the government policies, private and public sectors, and all the health resources available to the country under a common framework to best address the complicated and interdependent problems like lack of essential medicine, poor quality and irrational use of drugs and various new challenges and persistent problems. Often unplanned and piecemeal approaches result in failure to solve problems and may further result in contradicting policies. In SEA Region where countries are looking forward towards Universal Health Coverage in near future, it is extremely important for the countries to have a comprehensive, effective and up-to-date NMP. Thus a lot of importance is being given to NMP by both WHO and FIP.

FIP conducted a workshop during Centennial Congress in 2012 on National Medicine Policy (NMP) which was attended by participants from 14 countries along with representatives from SEARPharm Forum. In the workshop participants deliberated on the status of NMP in the world and made us sensitive towards the subject. After further research it was found that not all countries in the SEAR have NMP. Also they are not all at par even with the world average in terms of various standards necessary for implementing NMP successfully like number of pharmacist etc. It was thus realized that a great amount of work can be done on understanding and implementing NMP and establishing the role of Pharmacist in its implementation in the SEA Region. Thereafter a proposal for a survey to conduct situational analysis in the SEA Region to assess the status of the NMP in the region was made. Thus in Sept 2013 the Secretariat of the SEARPharm Forum undertook the study on “Assessment of the Implementation of National Medicine Policies in South East Asian Region of WHO.”
To gather the data for the study, the Secretariat designed a questionnaire on an electronic format as well as a hardcopy for National Pharmaceutical Associations in South East Asian Region and sought their response. The National Pharmaceutical Associations or their representatives from Indonesia, Thailand, India, Sri Lanka, Bhutan and Nepal participated in the survey. The survey brought out the status of

- Country Demographics
- National Medicine Policy
- Selection of Drugs
- National Formulary
- Supply (Including Procurement and Production Issues) Inventory Control/ Re-order Level
- Standard treatment Guidelines (STGs)
- Rational Drug Use

The information obtained was collated, analysed and presented in the SEARPharm Forum Regional Conference in Colombo, Sri Lanka on 29th June, 2013.
DESIGN AND VALIDATION OF A PICTOGRAM BASED HIV-TB INFORMATION LEAFLET/POSTER TO SUPPORT THE ROLE OF COMMUNITY PHARMACISTS IN INDIA

This multi-step project aims at developing and validating an easy to use pictogram-based information leaflet or poster for HIV-TB treatment to support the role of community pharmacists as part of the Revised National Tuberculosis Control Program (RNTCP) in India.

The study objectives are:

(a) To identify which pictograms communicate the intended key counseling points best towards all population including low literacy individuals; and

(b) To obtain feedback on how to improve the pictograms to make it easier to convey the intended message

Status of the Project:

- **PHASE 1**
  (Information gathering) & 2 (Semilogy Analysis)

Status: **Completed**

- **PHASE 3& 4**

Leaflet Evaluation and pictogram validation (For guessability and translucency)

**Status:**

1. Redesign of pictograms using Graphic artist with Indian background for validation in India is **completed**.

2. The partnership with Revised National TB Control Program (RNTCP) of India for validation of pictograms in HIV-TB co-infected patients at its various **centers is confirmed**.

3. To undertake the process of testing the pictogram in Indian population, protocol is received which **requires Ethics Committee approvals** from CHEO, Canada and RNTCP, India.

4. Draft Protocol for Submission to Ethics Committee (Approved by RNTCP with investigators and co-investigator names from their side and translation of Consent forms (Vernacular: Hindi)- **Completed**
5. While Ethic Committee approval by CHEO, Canada is completed, there has been substantial delay by RNTCP in getting approval by Govt. Ethics Committee in India. On persistent follow up, RNTCP has informed that Govt. Ethics Committee meeting is scheduled on 16th August, 2014, at Bangalore, India in which this agenda item will be put up.

6. In the mean time, the Bill & Melinda Gates Foundation (BMGF), India are very willing to undertake the Ethics Committee approval and complete the process of testing the pictogram in Indian population. However, their patient population is predominantly TB infected and among them HIV co-infected patients are only 10%. Since, the FIP Pictogram Project approval is based on HIV-TB treatment, this would have been challenging and hence the matter was not taken up further.
### Example: Data Collection Tool

#### Data Collection Tool 1

<table>
<thead>
<tr>
<th>Number</th>
<th>Pictogram: (circle the chosen pictogram)</th>
<th>Guessability: As stated by subject</th>
<th>C= CORRECT, X= INCORRECT, PC= PARTIALLY CORRECT (as per independent readers)</th>
<th>Translucency: Indicate numeric score from 1 to 7 (1= no relationship, 2 to 6= some relationship, 7= very strong relationship)</th>
<th>Qualitative input: (free text)</th>
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<tr>
<td>1</td>
<td><img src="image1.png" alt="Pictogram 1" /></td>
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<td><img src="translucency_scale.png" alt="Translucency Scale" /></td>
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<tr>
<td>2</td>
<td><img src="image2.png" alt="Pictogram 2" /></td>
<td></td>
<td></td>
<td><img src="translucency_scale.png" alt="Translucency Scale" /></td>
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<td>Example: Data Collection Tool</td>
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An Update
DATABASE ON THE INCIDENTS OF COUNTERFEIT MEDICINES IN THE
WHO-SEA REGION

Background

Definition of counterfeit medicines:

In its 2003, FIP Statement on Counterfeit Medicines, FIP adopted the 1992
WHO definition of a counterfeit medicine, that is to say: “the deliberate and
fraudulent mislabeling with respect to the identity, composition and/or source
of a finished medicinal product, or ingredient for the preparation of a medicinal
product. Counterfeiting can apply to both branded and generic products and
to traditional remedies. Counterfeit products may include products with the
correct ingredients, wrong ingredients, without active ingredients, with
insufficient quantity of active ingredient or with false or misleading packing;
they may also contain different, or different quantities of, impurities both
harmless and toxic.”

This WHO definition was officially endorsed in a meeting, convened in
Geneva, 1-3 April 1992, which gathered experts from governmental
institutions of WHO member states, INTERPOL, World Customs Organization
(at the time known as Customs Cooperation Council), International Narcotics
Control Board, IFPMA, International Organization of Consumer Unions, and
the International Pharmaceutical Federation (FIP).

One of the SEARPharm Forum's objectives is to encourage and support a
dialogue and collaboration among national and regional pharmaceutical
associations in the South-East Asia Region of WHO by supporting WHO-
policies and goals and combating the production and distribution of counterfeit
medicine and sale of medicine by people who are not qualified. The print and
electronic media has been widely reporting the problem. The open source
media reports continue to provide coverage on the various permutations that
encompass the act of pharmaceutical counterfeiting and substandard drugs
like identical copies, look-alikes, rejected and relabeled.

Identical copies: These are made with the same ingredients, formulation and
packaging as the originals. As high priced prescription medications, they are
irresistible to counterfeiters.

Look-alike: the packaging and appearance are high quality, but there may be
little or no active ingredient. Some look-alikes may even contain harmful
substances such as chalk, boric acid, glass or fungus etc.

Rejects and relabeled: Drugs that have been rejected by the manufacturer
for quality reasons are illegally obtained by counterfeiters or authentic drugs
that have expired are relabeled with the longer shelflife and sold.
However, the shortcoming of the open source media reporting is that the same data at times get published by different agencies compound the information and show the problem in a much larger magnitude.

Nevertheless, in the absence of any authentic data, we depend upon news items being published in credible leading newspapers and journals. These reports mainly deal with situation in India, Nepal, Bangladesh, Thailand, Sri Lanka and Indonesia.

The Secretariat has been regularly updating such data since 2001. It is now submitting the updates on the incidents of counterfeit medicines for the year 2012-2013. This list does not reference every media report published, nor does it contain any confidential information.

**Pradeep Mishra**  
Professional Secretary  
SEARPharm Forum Secretariat
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