

***Inaugural Address***

***by***

***Dr Samlee Plianbangchang  
Regional Director, WHO South-East Asia***

***at the***

***Expert Committee Consultation to Develop Fast Track  
Mechanism for the Licensing of vaccines procured through  
UN Agencies***

***WHO/SEARO, New Delhi, India  
13 September 2005***

**Expert Committee Consultation to Develop a Fast Track  
Mechanism for the Licensing of Vaccines procured through UN  
Agencies**

**13 September 2005  
WHO/SEARO, New Delhi, India**

**INAUGURAL ADDRESS BY**

**DR SAMLEE PLIANBANGCHANG  
REGIONAL DIRECTOR, WHO SOUTH-EAST ASIA**

Colleagues;

Ladies and gentlemen;

- I am pleased to attend the opening of this important Consultation.
- I welcome you all to the WHO Regional Office for South-East Asia.
- Immunization has long been recognized as an essential public health intervention to save lives of our children.
- One of WHO's roles is to ensure that all children are protected against vaccine-preventable diseases.
- In order to play this role effectively, we must make sure that all immunization programmes use vaccines of highest quality.
- This Consultation is an important step to ensure that vaccine quality control is effectively carried out in the Region.
- As we are aware, the National Regulatory Authority is ultimately responsible for ensuring vaccine quality in each country.
- South-East Asia is the first WHO Region to have assessed the work of all NRAs, and established plans for strengthening their capacity, in particular cases.
- The requirements for recognition of NRA depend on sources of the vaccines for use in the respective countries.

- However, all NRAs must have capacity to undertake the licensing of vaccines.
- Licensing indicates a process aimed at assessing quality, safety and efficacy of vaccines, before they are allowed to be in the national market.
- For countries that produce their own vaccines, licensing is a straightforward process based on the work of National Control Laboratories.
- In the South-East Asia Region, six countries procure EPI vaccines through UNICEF.
- Though the licensing procedure remains mandatory, these countries may not need to maintain the same level of testing.
- However, the fundamental requirements for licensing must be developed for the individual countries.
- Therefore, this Consultation will address two important issues for these six countries:
  1. Identification of the current or potential regulatory constraints in procuring vaccines through UN agencies, and
  2. Determining approaches to overcome these constraints, in order to meet national and international standards for vaccine licensing.

Ladies and gentlemen;

- Addressing these issues is becoming more challenging due to several factors.
- The number of vaccines and their technical complexity involved are increasing.
- In addition to the basic EPI antigens, many new vaccines may be added to national immunization programmes in the near future.

- Vaccines, such as those for Japanese encephalitis, the DTP-hepatitis B combination, and even the Rota virus are supposed to improve effectiveness and efficiency of the immunization programmes.
- Furthermore, newer ones, such as chimeric vaccines are on the horizon.
- And the older, such as measles vaccines, may now be available in new forms for administration, such as aerosolized spray.
- While these new technologies in vaccine development promise additional improvement in public health interventions, they also offer new challenges for NRA to ensure quality control.
- Another major challenge for licensing of vaccines is the implication of new international trade agreements.
- This topic was discussed at the most recent meeting of Health Ministers of countries of WHO's South-East Asia Region.
- The Ministers recognized the urgent need for strengthening country capacity in this important area and requested for support from WHO.
- The Trade Related Intellectual Property Rights or TRIPS, not only directly affects patents for vaccines, but also has an important implication on the work of NRA.
- The Doha Declaration clearly states that the TRIPS agreement should be implemented in the way that public health interest is protected.
- Vaccines which are already pre-qualified by WHO, and procured through UNICEF may be in a special category for local licensing.
- However, cases such as this needs careful consideration of various implications.

Ladies and gentlemen;

- All in all, we have to develop licensing mechanisms to ensure vaccine quality.

- At the same time, the use of these mechanisms must not be beyond the capacity of the regulatory systems in our respective countries.
- The ultimate goal in this endeavour is to deliver really safe and effective vaccines to all children in need.
- Our task now is to develop a “fast track” system, which satisfactorily addresses both these issues of quality and efficacy.
- This is a formidable challenge, as far as this Expert Committee is concerned, but it should not be beyond our capacity to do.
- In addition to concerned officials from Member States in the Region, representatives from the Developing Countries Vaccine Manufacturers Network and International Federation of Pharmaceutical Manufacturers have also been invited to participate in the Consultation.
- Concerned staff members of WHO from both Headquarters and the Regional Office are here to facilitate the deliberations.
- I am confident that this Consultation will be concluded with a successful outcome.
- I wish the meeting all success.
- Thank you.