Meeting on Quality-Assured Drugs for Better Public Health: Strengthening and Harmonizing the Regulation of TB Medicines in the Western Pacific Region

12–14 March 2014
Manila, Philippines
REPORT

Meeting on Quality-Assured Drugs for Better Public Health: Strengthening and Harmonizing the Regulation of TB Medicines in the Western Pacific Region

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NOTE

The views expressed in this report are those of the participants of meeting on quality-assured drugs for better public health: strengthening and harmonizing the regulation of TB medicines in the western pacific region and do not necessarily reflect the policies of the Organization.

Keywords:

Antitubercular agents - standards / Pharmacovigilance / Tuberculosis - prevention and control

This report has been printed by the World Health Organization Regional Office for the Western Pacific for governments of Member States in the Region and for those who participated in the Meeting on Quality-Assured Drugs for Better Public Health: Strengthening and Harmonizing the Regulation of TB Medicines in the Western Pacific Region, which was held in Manila, Philippines from 12 to 14 March 2014.
The quality of drugs is paramount for better treatment outcomes and for preventing drug resistance. An uninterrupted and sustained supply of quality-assured tuberculosis (TB) drugs is fundamental to TB control and one of the fundamental pillars of WHO’s recommended approach to TB care and control, the Stop TB Strategy.

The WHO Regional Office for the Western Pacific Stop TB unit and Essential Medicine and Health Technology unit organized a consultation workshop with national TB programmes (NTPs), national medicine regulatory authorities (NMRAs), technical partners and other key stakeholders on strengthening and harmonizing the regulation of medicine in the Region using the example of the tuberculosis programme from 12 to 14 March 2014. The objectives of the meeting were:

1. to establish priorities and design strategies for strengthening and harmonizing the regulation of medicines using the example of TB in the Western Pacific Region;
2. to design strategies for strengthening pharmacovigilance systems to monitor and ensure the safe use of medicines using the example of TB; and
3. to design and discuss mechanisms of improved communication and collaboration among regulatory authorities.

The meeting was attended by 57 participants. There were 31 participants from seven countries in the Region being nominated by the governments. The target audience for this meeting was national TB programme manager, drug procurement focal person, focal points for registration, quality control and pharmacovigilance of the national drug regulatory authorities from Member States (i.e. Cambodia, China, the Lao People’s Democratic Republic, Mongolia, Papua New guinea, the Philippines and Viet Nam).

This meeting served as an example for other disease specific programmes to strengthen collaboration with NMRAs and an entry point for overall strengthening and harmonization of regulations for all medicines in the Western Pacific Region.
The meeting developed a list of priority actions as follows:

1)  Registration
   • assessment of regulatory capacity/ function;
   • fast track registration including collaborative registration and harmonization of technical dossier requirements;
   • legal framework for compassionate use of drugs; and
   • capacity building of product quality evaluators.

2)  Quality assurance and control
   • quality survey of TB drugs (national or regional);
   • reviewing national quality criteria/specification of TB medicine;
   • advocacy with potential manufacturers for pre-qualification of TB medicines;
   • capacity building of inspectors; and
   • strengthening laboratory capacity and increasing availability of reference standard for SLDs.

3)  Rational use
   • establishing/strengthening bold actions to regulation on availability of TB medicines in the private sector (and other sector like animal industry);
   • strengthening public-private mix activities (inclusion of all private sectors) eg. involving pharmacy association and other professional organizations to reduce over the counter sale;
   • inclusion of quality indicators and improve licensing scheme of establishment and insurance scheme;
   • strengthen pharmacy inspection programme in collaboration with other programme (eg. Malaria control programme); and
   • raise awareness among general population (using anti-microbial resistance (AMR) platform).

4)  Pharmacovigilance (PV)
   • strengthening PV system as a component of health system strengthening (reporting, engaging all providers, inclusion of active surveillance, and analytical capacity);
• strengthening coordination (pursuing synergies with other programmes such as adverse effect following immunization (AEFI) system for expanded programme on immunization (EPI));

• strengthening capacity of analysis of data and informing policy changes;

• raising awareness among patients and providers; and

• creating regional centres of excellence of PV

5) Platform for better communication

• considering to set up a regional coordination mechanism.
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1. INTRODUCTION

The regulation of medicines is part of the essential functions of public health. A functioning national medicine regulatory authority (NMRA) is critical to ensure the existence and enforcement of strict regulations for the manufacture, sale and distribution of effective, safe and quality-assured medicine in order to protect public health. Intensification of international commerce and increasing technological complexity of manufacturing and product specifications has created additional challenges for national regulatory authorities, particularly in developing countries. This requires that national regulatory capacity be regularly assessed, areas of weakness identified and appropriate, necessary corrective measures taken.

As is the case with all other health programmes, NMRA is an important stakeholder for national TB programmes (NTP) to ensure the availability of quality-assured TB medicines both in the public and private sectors. Coordination between the NTP and NMRA needs strengthening in many countries in the Western Pacific Region. An uninterrupted and sustained supply of quality-assured anti-TB drugs is fundamental to TB control. The quality of drugs is paramount for better treatment outcomes and for preventing drug resistance. The 66th World Health Assembly resolution (WHA 62.15) urged all Member States to ensure an uninterrupted supply of first and second-line medicines for tuberculosis treatment, which meets WHO prequalification standards or strict national regulatory authority standards. It also urged Member States to strengthen mechanisms to ensure that tuberculosis medicines are sold by prescription only and prescribed and dispensed by accredited public and private providers.

The NMRA plays a key role by ensuring adherence to quality standards for the manufacturing, distribution and sale of anti-TB medicines. There is variation in the capacity of NRAs to enforce national quality standards in the Region’s seven high TB burden countries: Cambodia, China, the Lao People’s Democratic Republic, Mongolia, Papua New Guinea, the Philippines and Viet Nam. Some countries procure TB medicines through international mechanisms such as the Global Drug Facility (GDF), which facilitates the procurement of quality assured anti-TB medicines as per stringent international quality standards (WHO prequalification or registration by stringent national regulatory authority). However, some countries procure drugs locally following the national standards that are not aligned with internationally-accepted quality standards. Therefore, there can be a wide variation in the quality of drugs with the possible risk of substandard products being supplied to national TB programmes.

Regulation of appropriate trade and use of medicine is an important component of national medicine policy which is a public policy that restricts private-sector activities in order to attain social goals set by the State. Cambodia provides a good example of government action to regulate the market. Cambodia banned the sale of TB drugs in the private sector to restrict the distribution of quality-assured TB medicines to the public sector in order to achieve better treatment outcomes and reduce risks from the use of poor quality products or irrational use in the private sector. Enforcement of such regulation is the key.

TB patients frequently suffer from adverse drug reactions. In some cases TB drug side effects are life-threatening. Pharmacovigilance is highly relevant for TB treatment as scaling up of treatment among populations with varied demographic profiles, nutritional status, genetic background, and comorbidity (eg, HIV-TB, diabetes, alcohol use) may influence the form, severity, and frequency of adverse drug reactions. The prospect of having new TB drugs in the
near future means more systematic attention needs to be given to pharmacovigilence to monitor the safety of new anti-TB drugs.

Therefore, the WHO Regional Office for the Western Pacific Stop TB unit and Essential Medicine and Health Technology unit organized a consultation workshop on strengthening and harmonizing the regulation of medicine in the Region using the example of the tuberculosis programme from 12 to 14 March 2014 with financial support from the Government of Japan.

1.1 Objectives

The objectives of the meeting were:

(1) to establish priorities and design strategies for strengthening and harmonizing the regulation of medicines using the example of TB in the Western Pacific Region;

(2) to design strategies for strengthening pharmacovigilance systems to monitor and ensure the safe use of medicines using the example of TB; and

(3) to design and discuss mechanisms of improved communication and collaboration among regulatory authorities.

1.2 Meeting participants

The meeting was attended by fifty seven participants.

The government from seven countries in the Region nominated 31 participants. The target audience for this meeting was national TB programme manager, drug procurement focal person, focal points for registration, quality control and pharmacovigilance of the national drug regulatory authorities from Member States, i.e. Cambodia, China, Lao People's Democratic Republic, Mongolia, Viet Nam, Papua New Guinea and Philippines.

The temporary adviser of this meeting was Dr Souly Phanouvong, Technical Advisor, Drug Quality Control, Unite State Pharmacopeia (USP), Washington DC, USA.

The observers included representatives from Global Drug Facility and Management Science of Health.

The secretariat was composed of representatives from WHO headquarters, WHO Regional Office of the Western Pacific, and WHO country offices (Cambodia, China, Lao People's Democratic Republic, Mongolia, Papua New Guinea, Philippines and Viet Nam).

The full list of participants is in Annex 4.

1.3 Methods of the meeting

The meeting agenda was organized around seven areas: (1) situation assessment; (2) registration; (3) quality assurance; (4) post-marketing monitoring; (5) rational use; (6) pharmacovigilance; and (7) improved communication. Short presentation, group work and plenary discussion were used in the meeting. During group work participants discussed and identified major issues and priority actions.
2. PROCEEDINGS

2.1 Overview

Chair: Dr Ma. Theresa G. Vera, Philippines
Vice Chair: Mr Graham Wavimbukie, Papua New Guinea

2.1.1 Opening

The meeting was opened by Dr Mark Jacobs, Director, Division of Communicable Disease, Western Pacific Regional Office of WHO, followed by the welcome remarks and objectives of the meeting delivered by Dr Nobuyuki Nishikiori, Team Leader, Stop TB and Leprosy Elimination, Western Pacific Regional Office of WHO.

2.2 Plenary presentations

2.2.1 Post 2015 TB strategy: Role of regulation of TB medicine

Dr Nobuyuki Nishikiori, Team Leader, Stop TB and Leprosy Elimination, Western Pacific Regional Office of WHO presented post 2015 TB strategy and role of regulation of TB medicine.

The vision for the post-2015 TB strategy is “a world free of TB”; also expressed as “zero deaths, disease and suffering due to TB”. The goal is to end the global TB epidemic. A set of ambitious targets is proposed: achieving a 95% decline in deaths due to TB compared with 2015, and reaching a 90% reduction in the TB incidence rate from a projected 110 cases/100 000 in 2015 to 10 cases/100 000 by 2035. To ascertain progress of universal health coverage and social protection, an additional target, “by 2020, no TB-affected person or family should face catastrophic costs due to TB care” is proposed. The strategy consists of the following three pillars: (1) integrated, patient-centred care and prevention; (2) bold policies and supportive systems; and (3) intensified research and innovation. The second pillar encompasses strategic actions by and beyond national TB programmes from across ministries and departments, not only to address medical and non-medical needs of patients but also to help prevent TB. Drug quality and rational use of medicine is important component of this pillar.

Dr Nishikiori emphasized that strengthening regulation of TB medicine needs to be seen as a contribution to health system strengthening. This workshop should be seen as an entry point for overall strengthening and harmonization of regulations for all medicines in the Western Pacific Region.

2.2.2 Strengthening national regulatory authorities and their essential regulatory functions

Ms Stephanie Croft, Technical Officer, WHO prequalification team presented the WHO view on global strengthening of regulatory authorities and essential regulatory functions.

Universal health coverage cannot be achieved without functioning health system and drug regulation is an integral part of these systems. Good governance in the public sector, applicable modern laws, enabling legal systems, harmonization and convergence of technical requirements, good regulatory and decision making practices are the key components of regulatory systems. In the current regulatory landscape, several issues exist, such as a weak enforcement of laws in some cases, gaps for product groups or different practices, as well as different standards applied to imported vs. locally manufactured products. There is no alternative for regulatory
convergence and harmonization especially in the case of smaller scale regulatory authorities; however priorities may vary in some countries and regions. The future will require effective sub-regional, regional and global regulatory networks based on collaboration and work sharing.

2.2.3 Pharmaceutical situation assessment: TB drug regulation in the Region

Dr Tauhid Islam, Medical Officer, Stop TB and Leprosy elimination, Western Pacific Regional Office of WHO presented TB medicine regulation situation in Western Pacific Region.

Among the countries participated the meeting were Cambodia, Lao People's Democratic Republic, Mongolia, Papua New Guinea, procure first line and second line TB drugs through GDF. China, Philippines and Viet Nam procure only second line TB drugs through GDF. The quality of drugs procured from other sources is not well known, but various studies showed that sub-standard TB medicines are available in the open market. The registration, quality assurance, distribution and pharmacovigilance practises vary widely among countries. The private market plays a substantial role in some countries.

<table>
<thead>
<tr>
<th>Country</th>
<th>Registration GDF drugs registered</th>
<th>Waiver Import clearance needed</th>
<th>Fast track registration possible</th>
<th>Batch certificate</th>
<th>inspection</th>
<th>Sample test upon receipt</th>
<th>Sample test from distribution chain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodia</td>
<td>No</td>
<td>-</td>
<td>-</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Fiji</td>
<td>No</td>
<td>-</td>
<td>-</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Laos</td>
<td>Under evaluation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Mongolia</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>No</td>
<td>Under revision</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>-</td>
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<tr>
<td>PNG</td>
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<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

2.2.4 Country presentations

All seven countries presented their regulatory policies and procurement situations. Country presentations are attached as annex 2.

2.3 Registration

Chair: Dr Jin Song, China
Vice Chair: Mr Hiem Sokhem, Cambodia

2.3.1 Registration of TB drugs

Ms Stephanie Croft presented the role of WHO Prequalification in enhancing regulatory capacity at national and regional levels for the registration of TB drugs and other medicines. WHO sets norms and standards to help both manufacturers and regulators. The WHO also provides assistance through facilitating information exchange and cooperation; promoting and facilitating harmonization; helping implementation of norms and standards through capacity building and training; prequalifying essential TB medicines and other products including
vaccines and diagnostics and testing of medicines on the market through a network of prequalified quality control laboratories.

2.3.2 Quality assurance as part of the essential regulatory function

Ms Croft also presented the importance of quality assurance. Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. With regard to pharmaceuticals, quality assurance can be divided into major areas: development, quality control, production, distribution, and inspections. Poor quality medicines can be ineffective and lack of effectiveness can lead to increased negative health effects and even death from the disease as well as resistance.

Quality needs to be built into the product as it cannot be assessed, tested or inspected into the product. Essential regulatory functions for medicines includes:

- Licensing of the manufacture, import, export, distribution, promotion and advertising of medicines
- Assessing the safety, efficacy and quality of medicines, and issuing marketing authorization for individual products
- Inspecting and surveillance of manufacturers, importers, wholesalers and dispensers of medicines
- Controlling and monitoring the quality of medicines on the market
- Controlling promotion and advertising of medicines
- Monitoring safety of marketed medicines including collecting and analysing adverse reaction reports
- Providing independent information on medicines to professionals and the public

There are several challenges for TB medicine regarding quality assurance. There are few manufacturers for TB medicines. Many anti-TB active pharmaceutical ingredients (APIs) are older chemicals having low commercial value thereby limiting manufacturer interest world-wide. A large proportion of APIs are derived from fermentation which makes purification more complex and can often to a higher level of impurities in the product. Quality standards, and in particular good manufacturing practice (GMP) standards, present a challenge to many potential manufacturers.

2.3.3 Compassionate use of drugs

Dr Ernesto Jaramillo, Medical Officer, Global TB Programme, WHO-HQ presented the ways of accessing drugs under development for the management of MDR-TB. Compassionate and expanded use processes are used to access drugs of pre-approval period. Humanitarian importation is used for drugs in interim period between reference approval and country specific approval. Some drugs are used off-label, that is, use of drug to treat a disease different to the one for which it was registered. As the treatment alternatives in extensively drug resistant TB (XDR-TB) are very limited, use of drugs under development and off-label becomes very important. The WHO STAG-TB has recommended the development of capacity in countries to implement compassionate use and expanded access programmes. Essential steps to follow for introducing pre-approval drugs in MDR-TB management are as below:

- Ensure that capacity to apply the basic international standards for patient treatment and care are in place (Programmatic Management of Drug Resistant TB - PMDT, pharmacovigilance, ethics)
2.3.4 Facilitated registration and collaborative procedures

Ms Croft initiated the discussion on the issues of drug registration. Re-assessment and re-inspections of medicines can place significant demands on national medicines authorities (NMRAs). A lot of duplication in efforts in assessing and inspecting a product can often take place when the same medicine is submitted for commercialization in all of the countries of a given region. With the current global environment of constrained resources, many NMRAs could likely benefit from facilitated registration and collaborative procedures. Waiver of registration or fast track registration or common assessment and inspections can be used to facilitate the process. All three options are useful practices, and efforts should be made to see how they could be applied in specific country settings.

The WHO Collaborative registration procedure for WHO prequalified products was discussed as an example of a successful initiative. It has enabled the accelerated registration of products through improved information sharing between the WHO Prequalification of Medicines Programme and national medicines authorities. So far, since the pilot phase began in 2012, over 15 NMRAs in 14 countries have decided to participate in the collaborative procedure. This initiative was recognized as providing many benefits to key stakeholders and by ensuring a more timely access to quality assured products to patients.

2.3.5 Group work (1):

The participants were split into two groups and discussed the issues and way forward for drug registration challenges in their country. Two groups then presented their discussion outcome in a plenary session. The following key issues and actions were identified.

<table>
<thead>
<tr>
<th>Major issues:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Not all TB drugs (mainly SLDs) are registered</td>
</tr>
<tr>
<td>2. Registration process and capacity at the country level</td>
</tr>
<tr>
<td>3. Use of drugs development</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Common priority actions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Assessment of regulatory capacity/ function</td>
</tr>
<tr>
<td>2. Fast track registration including collaborative registration and harmonization of technical dossier requirements</td>
</tr>
<tr>
<td>3. Legal framework for compassionate use of drugs</td>
</tr>
<tr>
<td>4. Capacity building of product quality evaluators</td>
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</tbody>
</table>
2.4: Quality assurance

Chair: Dr Phouvang Vangvichit, Lao PDR
Vice chair: Dr Biam badorj Dembereldorj, Mongolia

2.4.1 What is WHO prequalification?

Ms Croft presented WHO Prequalification process. This is a United Nations Programme managed by WHO which started in March 2001 as a pilot project focusing on HIV/AIDS medicines and with support from UNICEF, UNFPA, UNAIDS and the World Bank. The project expanded to include medicines for tuberculosis, malaria, reproductive health, influenza, acute diarrhoea in children and neglected tropical diseases with objectives to make quality priority medicines available for the benefit of those in need. The rationale for WHO prequalification includes amongst others: the need for products where quality is built-in; lack of well-established drug regulatory agencies in some countries, increasing demand for generics, substandard products on the market and consequences of poor quality medicines.

The key outputs are the published list of prequalified medicines used principally by United Nations agencies including UNAIDS and UNICEF and any other agency or organization involved in bulk purchasing of medicines, to guide their procurement decisions. It has been extended to active pharmaceutical ingredients (APIs) and quality control laboratories.

Ms Croft also explained the prequalification process which includes assessment of dossiers and inspection of manufacturing sites. A manufacturer wishing their medicinal products to be included in the prequalified products list must submit extensive information on the product (dossier) to allow qualified assessors to evaluate its quality, safety and efficacy and should be willing to be subjected to on-site inspections of their manufacturing sites for finished products, APIs and of their clinical bioequivalence studies. Assessors and inspectors are from WHO and from a wide variety of stringent regulatory authorities and national medicines regulatory agencies (NMRAs) from recipient countries.

As of 28 February 2014, three hundred eighty generics and innovator products were prequalified of which 72 were TB medicines. A total of 145 finished products were under assessment, including 43 TB medicines, 70% of which were 2nd line TB products. The prequalification list is not a national marketing authorization but some countries may use it for medicines registration purpose. All the details can be found at http://www.who.int/prequal/.

2.4.2 Quality assurance standard: GF and GDF

Ms Nigorsultan Muzafarova, Product Quality Assurance Officer, Global Drug Facility presented Quality Assurance (QA) standards of GDF and Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). She, highlighted GDF mandate and its key achievements, provided detailed information on second line TB drugs (SLDs), the eligible suppliers and the draft estimates, and informed of the key challenges faced by GDF in ensuring access to quality assured drugs.

GDF has well established quality assurance policy for procurement of anti-TB drugs and the most important criteria is that products are i) prequalified by WHO, ii) approved by stringent regulatory authorities for use; and/or iii) authorized by Expert Review Panel (ERP). Drug monitoring programme is in place which includes consignments pre-shipment inspection, certificate of analysis review, randomized sampling and testing and issuance of clean report of findings. GDF and GFATM criteria for procurement are aligned with recipient countries’ policies, medicines listed in WHO or national essential medicines list and clinical guidelines.
The speaker also described challenges and issues such as short shelf life for SLD, limited number of manufacturers of injectable TB drugs, limited availability of quality API, registration status of GDF supplied medicines in recipient countries, availability of quality assured medicines through the whole supply chain due to long delivery and lead time, limited production capacity, and post-marketing surveillance.

2.5 Post marketing monitoring

Chair: Alan Pasumbal, Philippines
Vice Chair: Ms Nguyen Thi Phuong Thao, Vietnam

2.5.1 Post-marketing monitoring of quality of drugs

Dr Socorro Escalante, Technical Officer and Medicine Policy Advisor, WHO, Viet Nam presented “Post-marketing monitoring of quality of drugs”. Post-marketing monitoring includes quality assurance, quality control and pharmacovigilance or post-marketing surveillance. “Uncertain quality” and poor quality substandard and counterfeit TB medicines (1st and 2nd line) are available in several high-burden TB markets. Critical post-marketing quality assurance functions for regulatory authority includes:

1) inspection of manufacturers, premises of wholesaler, distributors, retail outlets
2) screening, sampling and quality control testing
3) formal quality defect reporting system

Procurement agency need to ensure selection of products, prequalification of suppliers, monitoring storage and distribution conditions, quality testing (pre/post shipment and in the supply chain) and monitoring system to detect and report quality defects to the regulatory authority. Pharmacovigilance (PV) is essential to monitor drugs events, drug reactions, quality issues.

2.5.2 Experience of quality assurance

Dr Souly Phanouvong, Manager, Asia Programs, Promoting the Quality of Medicines Program (PQM), U. S. Pharmacopeial Convention (USP) presented the experience on quality assurance of medicines in Asia. The ineffective legislation and regulations, limited qualified human resources, poor compliance, limited awareness and advocacy activities and inadequate border control contribute to quality problem. The weak mechanism in information-sharing, coordination in investigation, cooperation and collaboration between regulators and other law enforcement agencies, result in ineffective enforcement. PQM of USP works in the greater Mekong sub-region with a view to ensure quality of medicine to protect the public health. The strategic approach of PQM includes; strengthening capacity of regulators, monitor medicine quality to support enforcement, strengthen laboratory and manufacturers, educate and raise awareness and conduct operation research.

Failure Rate of TB medicine samples that were tested under quality monitoring program in Mekong Sub-region 2005-2011 was 3.2%. From 2009 to 2013, Food and Drug Administration (FDA) laboratory of the Philippines tested 441 TB drugs of which 2.7% failed and 11.1% had doubtful reports and 86% passed.

The programme observed some key progresses in enforcement. A network of quality controlled laboratory 'the Network of Official Medicines Control Laboratories for Asia’ (NOMCOL) was set to harmonize methodologies to facilitate acceptance/recognition among countries and regions, enhance performance and technical skills of lab staff through proficiency
testing and training and promote south-south collaboration in quality control (QC). The regulators from across the Greater Mekong sub-region collaborated and set up a mechanism called BREMERE (building regional expertise in medicines regulation, information sharing, joint investigation and enforcement) to strengthen regional cooperation and collaboration in monitoring quality of medicines and addressing counterfeit and substandard medicine products to support control of resistance of malaria, tuberculosis, and other infectious diseases.

2.5.3 Role of laboratory testing and laboratory network

Ms Stephanie Croft presented: “Quality control testing, monitoring and network of WHO prequalified Laboratories”.

Laboratory testing, using well-established and validated analytical procedures, using qualified and calibrated equipment, pharmacopoeial and/or suitably standardized reference standards and performed by adequately trained staff, and performed following suitable processes in compliance with good laboratory practice, is key to verifying the quality of TB medicines on the market as well as prior to batch release by manufacturers. However, the effectiveness of this testing depends strongly on type of test done, reliability of the test and the method. The use of portable qualitative or semi-quantitative tests (e.g. GPHF-Minilabs) has a great value to obtain an indication as to whether a product could be counterfeit or substandard in a rural setting, but in order to make a meaningful conclusion, samples should always be submitted to full quantitative testing by routine/full laboratory testing.

The WHO network of prequalified quality controlled laboratories (QCLs) was established in 2004 to increase the access to services of QCLs that meet recommended standards for testing of medicines, and is committed to test medicines for UN agencies and contribute to capacity building in developing countries. The participation of a QC laboratory is voluntary and currently, any laboratory (private or governmental) can participate. Prequalification is based on evaluation of information submitted by the laboratory, on-site inspection and monitoring of performance of prequalified laboratory. Currently 30 laboratories are WHO prequalified and 37 are under evaluation.

The WHO prequalification (PQ) quality monitoring project monitors the quality of medicines procured by UN agencies. The monitoring has been done mostly focusing on TB, AIDS and malaria medicines. A study on the quality of TB medicine was conducted in 6 ex-Soviet Union countries. A total of 291 samples were tested which included products from 33 manufacturers taken at 84 sampling sites. The total failure rate was 11.3% and none of the failures were for prequalified medicines.

2.6 Rational use

Chair: Liu Haito, China
Vice Chair: Soulivanh Keokinnaly, Lao People's Democratic Republic

2.6.1 Country experience of rational drug use

Cambodia, Philippines, China and Mongolia shared their experience on the rational use of TB drugs restriction of the TB drugs in the market and enforcement of regulation.

Cambodia: Dr Dr Khun Kim Eam, National Centre for TB and Leprosy Control (CENAT), Cambodia presented the experience of regulating TB Drugs in the private Sector. Cambodia banned importation and sales of TB drugs in 2011 through an order by Health Minister. The administrative order was distributed nationwide. Samples and raw materials of TB
drugs were confiscated and collected materials were destroyed. Monitoring was conducted by Regulation Bureau in DDF. The ban on selling TB drugs was recommended by WHO and GDF and was made possible due to the strong political commitment. The successful experience of banning oral artemisinin-based monotherapies for malaria in 2008 also helped to take such bold decision. Collaboration of pharmacy association and expansion of public private mix strategy played an important role to minimize the size of the private market. A study in 2012 revealed that the enforcement of the order is still an issue as four out 18 pharmacies were still selling TB drugs and unaware of the ban. Adequate human resource and financial constrain for monitoring and communication are identified as major challenges to enforce the regulation. The meeting participants suggested incorporating monitoring funds in future requests for (GF) funding.

Philippines: Dr Anna Melissa Guerreo presented the comprehensive national antimicrobial resistance (AMR) plan in the Philippines following the Executive order by Philippine President for combating antimicrobial resistance. An interagency committee and 22 surveillance sites contribute to look at anti-microbial resistance as part of the Antimicrobial Resistance Programme (ARSP). The Philippines has high burden of MDR with a significant impact on the cost of curing patients. The main drivers of AMR are the prescribers using broad spectrum antibiotics and prophylaxis treatments, many antimicrobials are used without prescriptions, pharmacists act as prescribers and many drugstores operate without pharmacist. In response, the Department of Health has issued laws on prescribing and dispensing drugs and is promoting the use of the Philippines National Drug Formulary. An administrative order on the implementation of rational use of medicines is drafted where the AMR program is an integral component. There are no restrictions on use of TB drugs both first and second line. FLDs and some SLDs are available in private sector with unknown impact.

China: Dr Zhai Tiewei Center for Certification of Drugs, China FDA, presented the execution of laws for TB medicines in China. The drug inspection in China covers the whole life-cycle of drugs from development to product discontinuation. Good Manufacturing Practice for Drugs (2010 Revision) was issued in 2010. A deadline to comply with GMP for blood products, vaccine, injection and the other sterile products manufacturer was set as 2013 and for other products such as oral tablets and capsule is set as 2015. The guideline on GMP inspection of fixed dose combination TB medicines was issued in 2012.

Mongolia: Dr S.Oyuntsetseg, supervisor NCCD, TB department presented the experience of Mongolia. In Mongolia, tuberculosis morbidity is decreasing every year by 4.3% between 2006 and 2012. TB drugs are provided only by the public sector and no TB drugs are produced in the country. Currently the Government budget covers 90% of the first line TB drugs while second line TB drugs are procured through GF. Drugs are procured through GDF. NTP benefits from GDF including competitive price, drugs from ”prequalified” manufacturers, user-friendly packages, patient kits, children’s dosages and technical assistance.

2.6.2 Framework for new drug introduction

Dr Ernesto Jaramillo, Global TB Programme, WHO - Geneva presented “The WHO framework for the introduction of new TB drugs”.

Shorter and simpler therapies are needed for both susceptible and resistant tuberculosis. Four repurposed drugs, six new drugs and three new classes of drugs are currently in the global TB drug pipeline. Among those pipeline drugs, Bedaquiline (TMC-207) and Delamanid (OPC-67683) are recently approved by some regulatory authorities. Challenges for TB control programmes include determining optimal new regimens, defining patients’ eligibility, evaluating programmatic feasibility and cost-effectiveness; ensuring pharmacovigilance, and responsible use and preventing off-label use and emergence of resistance.
WHO developed strategic plan for rational introduction of new TB drugs and regimens to assist countries. Approaches for the introduction and delivery of new drugs and new drug regimens depend on the type of new drug/regimen. Market introduction requires mapping-out the detailed expertise, identifying appropriate stakeholders, evaluating market shortcomings and commodity access issues, identifying potential obstacles and working with stakeholders to optimize market introduction.

WHO considers of most importance to:

- Engage with, and support national authorities and stakeholders early in the preparation of policies for introduction of new TB drugs/regimens at programmatic level;
- Ensure that new TB drugs/regimens are introduced in an optimal way to protect patients from misuse and prevent emergence of resistance; and
- Ensure that introduction of new drugs follows policy recommendations and that appropriate plans are made to ensure feasibility and inform policy-making.

China: Dr Huo Xiumin, Centre for Drug Evaluation, China Food and Drug Administration China presented the drug registration legislation in China. MDR-TB drug applications have been listed in fast track evaluation procedure. Technical review for Bedaquiline (TMC207) has been finished for final approval. Delamanid (OPC-67683) are already on clinical trial in China.

Viet Nam: Dr Cornelia Hennig presented the “Introduction of new TB drugs in Vietnam”, on behalf of NTP Viet Nam. The MoH Viet Nam reaffirmed its commitment to protect the emergence of drug resistance to existing and newly developed anti TB drugs through an official letter to WHO in 2012. In response, WHO committed to support the Ministry of Health to increase access to diagnosis and treatment of multi-drug resistant tuberculosis and develop a regulatory package that will prevent further emergence of drug resistance and can serve as a model for other countries in this Region. A national implementation plan for introduction of Bedaquiline following WHO interim policy guidance have been developed. Three pilot sites with a planned cohort of 100 patients/year have been identified. The plan includes updating of MDR-TB guidelines, strengthening clinical review committees, updating informed consent form & patient information, forms, recording–reporting system and pharmacovigilance.

2.6.3 Group work (2):

The participants were split into two groups and discussed the issues and way forward for quality assurance and rational use of TB drugs in their country. Two groups then presented their discussion outcome in a plenary session. The following key issues and actions were identified.
### Quality assurance:

**Major issues:**
1. No systemic data on availability of substandard TB drugs in the Region
2. Lack of post marketing quality survey (PMS)
3. Variable quality standards (GMP etc)
4. Limited qualified human resources
5. Poorly equipped QC labs

**Common priority actions:**
1. Quality survey of TB drugs (national or regional)
2. Reviewing national quality criteria/specification of TB medicine
3. Advocacy with potential manufacturers for pre-qualification of TB medicines
4. Capacity building of inspectors
5. Strengthening laboratory capacity and increasing availability of reference standard for SLDs

### Rational use:

**Major issues:**
1. Unregulated private sector
2. Non adherence to national guidelines
3. Lack of enforcement of existing laws
4. Use of drugs in animal industry
5. Informal market

**Common priority actions:**
1. Establishing/strengthening bold actions to regulation on availability of TB medicines in the private sector (and other sector like animal industry)
2. Strengthening public-private mix activities (inclusion of all private sectors) eg. involving pharmacy association and other professional organizations to reduce over the counter sale
3. Inclusion of quality indicators and improve licensing scheme of establishment and insurance scheme
4. Strengthen pharmacy inspection programme in collaboration with other programme (eg. Malaria control programme)
5. Raise awareness among general population (using anti-microbial resistance (AMR) platform)

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2.7 Pharmacovigilance

Chair: Dr Paul Aia, Papua New Guinea  
Vice Chair: Dr Huot Chan Yuda, Cambodia

2.7.1 Situation assessment: pharmacovigilance (PV) in Asia

Mr Michael Gabra, Systems for Improved Access to Pharmaceuticals and Services Program (SIAPS), Management Science for Health (MSH) presented the topic. Improved access to medicines has increased the burden on countries to monitor those products in the market and ensure they are safe and of good quality for the population. Adverse events due to poor product quality and medication errors may limit the achievement of the full benefits of current treatments.
and new medicines. Few low and middle-income countries have the functional systems or resources to support pharmacovigilance medicine safety surveillance activities.

In 2012, SIAPS/MSH conducted a comparative analysis of pharmacovigilance systems in five Asian countries. All countries assessed have national medicinal laws in place that include legal provisions for medicines; however, PV regulatory requirements vary greatly. Main recommendations and policy options were formulated to strengthen pharmacovigilance systems on national, programme and health facility levels. He presented PV capacity building model as below:

2.7.2 WHO policy on PV of medicines used in TB treatment

Dr Ernesto Jaramillo, WHO Global TB programme, Geneva provided the rationale for pharmacovigilance for medicines used to treat TB. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. PV is an essential element for patient centred care and proper clinical management; to minimize risk and expenses, and to maintain public confidence in public health programs. He provided specific examples involving TB drugs and MDR-TB treatment like the evaluation of the 9 month short MDR-TB regimen, the compassionate and off-label use (clofazimine), new TB drugs in pre-approval stage (bedaquiline). Reference was also made to the recent WHO publication: A practical handbook on the pharmacovigilance of medicines used in the treatment of tuberculosis.

2.7.3 Country experience of Pharmacovigilance

Lao People's Democratic Republic, the Philippines and Viet Nam presented their country experience.


2 http://www.who.int/medicines/publications/Pharmaco_TB_web_v3.pdf
Lao People's Democratic Republic: The management and coordinating committee for Pharmacovigilance for anti-retro viral drugs was established by the Ministry of Health in May 2012. The project focused on targeted Spontaneous Reporting of adverse drug reaction for specific toxicities of Zidovudine to monitor anaemia and Nevirapine to monitor rash/Steven’s Johnson syndrome and hepatotoxicity. The Lao People's Democratic Republic has become an associate member of the WHO Uppsala Monitoring Centre drug monitoring center in 2013. The plan is to expand the service and establish proper system.

Philippines: Philippines initiated the Adverse Drug Reaction Monitoring Programme in 1994, and became the 42nd member of the WHO Collaborating Center for International Drug Monitoring now known as the WHO Uppsala Monitoring Centre in 1995. In 2012 and 2013, around 4000 adverse drug reaction reports were received. The plan is to strengthen the surveillance system; encourage active surveillance and integrate of all public health programmes with PV.

VietNam: Viet Nam has two pharmacovigilance centres, at Hanoi University of Pharmacy and Cho Ray Hospital in Ho Chi Minh City. The online reporting system started in 2013. There were 2407 and 3024 spontaneous reports received in 2011 and 2012. Viet Nam has established technical working group for new TB drugs and planned for cohort event monitoring for Bedaquiline.

Countries in this Region are at different stages; the discussion confirmed the need for looking at PV from a system approach, the need to raise awareness among care providers, the importance of providing feedback to ADR reporters, the potential benefit of mentoring/twinning programs involving NMRA’s of countries at different stages of development.

2.7.4 Group work (3)

Like previous group work sessions, the participants were split into two groups and discussed the issues and way forward for strengthening pharmacovigilance system in their country. Two groups then presented their discussion outcome in a plenary session. The following key issues and actions were identified.
Major issues:

1. Lack of system strengthening approach
2. Limited collaboration between national PV system and disease specific programmes
3. Lack of feedback mechanism and analysis of information for action
4. Lack of awareness at all levels

Common priority actions:

1. Strengthening PV system as a component of health system strengthening (reporting, engaging all providers, inclusion of active surveillance, and analytical capacity).
2. Strengthening coordination (pursuing synergies with other programmes such as adverse effect following immunization (AEFI) system for expanded programme on immunization (EPI))
3. Strengthening capacity of analysis of data and informing policy changes
4. Raising awareness among patients and providers
5. Creating regional centres of excellence of PV

2.8 Communication platform

Chair: Dr Otgonbaatar Dondonkhuu, Mongolia
Vice Chair: Mr Du Hoang Son, Viet Nam

2.8.1 Experience and expectation: Expanded Programme on Immunization

Dr Jinho Shin, Medical Officer, Expanded Programme on Immunization (EPI) presented the experience of EPI programme. Ensuring equitable access to quality-assured vaccines is vital to the programmatic success for EPI to fight off vaccine preventable diseases. The WHO’s goal for Vaccine Quality Assurance is to ensure that “100%” of vaccines used in all National Immunization Programmes are of assured quality. The National Regulatory Authority (NRA) for vaccines independently controls the quality of vaccines in accordance with six critical functions including marketing, licensing, pharmacovigilance, lot release, laboratory, regulatory inspection and regulatory oversight. The WHO assist to strengthen and sustain functional NRA and ensure quality of vaccines through development of assessment tools and processes, conducting assessment, developing institutional development plan, providing technical assistance and training, monitoring and evaluation.

In response to the request of Member States in 2011, a regional alliance was established to support establishing / strengthening vaccine regulatory system and functions in the Western Pacific Region. Expedite registration and review of vaccines; regulatory harmonization and laboratory collaboration are priorities of the regional alliance. The harmonization of WHO-NRA assessment process and tools for medical products and convergence of regional NRA platform for communication and collaboration are significant to achieve success in disease control and in improvement of health outcomes.

2.8.2 A platform for better communication for strengthening and harmonizing the regulation of medicines (KT/EMT)

Dr Klara Tisocki, Team Leader, Essential Medicines and Health Technologies introduced audience on idea of a platform for better communication for strengthening and harmonizing the regulation of medicines.
Having effective food and drug regulations prevent the public from health risks and support growth, investment and innovation. The National Regulatory Authorities (NRA) aimed to ensure that all medical products marketed in a country are of assured quality, safety and efficacy and are accompanied by appropriate information to promote their rational use. However, capacity of NRAs varies widely and challenges in regulatory processes are still remaining. Substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFC) still remains a serious problem in Asian markets. The lack of regulatory capacity was observed in many countries. Pharmacovigilance is developing but still not functional in some countries. The WHO continue to provide support for regulatory agencies including developing evidence through assessments, provide technical support, stimulating collaboration between regulators from various countries and promoting harmonization.

In a broad sense, harmonization means harmonization of technical requirements for medicines regulation, i.e., legislations, guidelines, procedures, etc. It requires effective communication and collaboration aimed at building capacity and trust (e.g., information sharing, recognition and joint working). There are several existing initiatives for collaboration.

- ASEAN: pharmaceutical and cosmetic harmonisation
- APEC Life Sciences Innovation Forum - Regulatory Harmonization Steering Committee (LSIF-RHSC)
- Mekong: BREMERE, NOMCOL (USAID)
- ICH: USA, Japan
- PICS: Australia, Malaysia, Singapore, USA
- WHO: WPR Regional Alliance for NRAs for Vaccines
- WHO: ICDRA, prequalification of medicine quality control laboratory, PQP medicines, diagnostics, vaccines (only limited countries participating from Asia)

However, there is a need for connecting regulators better across Asia to widen information sharing and collaboration. The use of modern information technologies and technology platforms can facilitate regulatory exchange, in secure environments, between regulators on key issues facilitates convergence. Thus a regional platform may assist to build trust and effective mechanisms to minimize duplicative efforts and develop more cooperation, collaboration and information sharing mechanisms. However this needs further brainstorming to identify key goals/priorities of such a regional platform.

2.8.3 Group work (4)

Participants discussed on the possibility to set up a regional platform for regulatory authorities. It was agreed by all that there is an absence of a platform to share experiences and good practices in the Region. However, it will need a broader discussion at the country and the Regional level to identify common objectives to set up a Regional platform. It was also discussed that the scope and organogram of the Regional alliance for vaccine quality can be broadened to use as a platform for strengthening quality of medicine in priority public health area. It was decided that countries will discuss internally and inform the way forward through their country specific action plan.

Major issues:
Absence of a platform to share experiences and good practises

Way forward:
Considering to set up a regional coordination mechanism
3. CONCLUSIONS AND RECOMMENDATIONS

Recommendations derived from all group works were combined and reviewed in a plenary session at the end of the workshop. Based on this consensus, the following priority action areas were identified. It was decided that all countries would review the priority areas and develop their action plan through in-country consultation.

Priority areas:

1) Registration
   - assessment of regulatory capacity/ function;
   - fast track registration including collaborative registration and harmonization of technical dossier requirements;
   - legal framework for compassionate use of drugs; and
   - capacity building of product quality evaluators;

2) Quality assurance and control
   - quality survey of TB drugs (national or regional);
   - reviewing national quality criteria/specification of TB medicine;
   - advocacy with potential manufacturers for pre-qualification of TB medicines;
   - capacity building of inspectors; and
   - strengthening laboratory capacity and increasing availability of reference standard for SLDs.

3) Rational use
   - establishing/strengthening bold actions to regulation on availability of TB medicines in the private sector (and other sector like animal industry);
   - strengthening public-private mix activities (inclusion of all private sectors) eg. involving pharmacy association and other professional organizations to reduce over the counter sale;
   - inclusion of quality indicators and improve licensing scheme of establishment and insurance scheme;
   - strengthen pharmacy inspection programme in collaboration with other programme (eg. Malaria control programme); and
   - raise awareness among general population (using anti-microbial resistance (AMR) platform)
4) Pharmacovigilance (PV)

- strengthening PV system as a component of health system strengthening (reporting, engaging all providers, inclusion of active surveillance, and analytical capacity);
- strengthening coordination (pursuing synergies with other programmes such as adverse effect following immunization (AEFI) system for expanded programme on immunization (EPI));
- strengthening capacity of analysis of data and informing policy changes;
- raising awareness among patients and providers; and
- creating regional centres of excellence of PV

5) Platform for better communication

- considering to set up a regional coordination mechanism.
ANNEX I

PROVISIONAL ACTION PLANS

Cambodia

1. **Topic: Registration**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish/strengthen coordination mechanism (NTP-NMRA) including other</td>
<td></td>
</tr>
<tr>
<td>stakeholders</td>
<td>✓</td>
</tr>
<tr>
<td>Organizing assessment mission with WHO</td>
<td>✓</td>
</tr>
<tr>
<td>Regional collaboration between NRAs</td>
<td>✓</td>
</tr>
<tr>
<td>Implementation of fast track registration mechanism and provide assistance</td>
<td>✓</td>
</tr>
<tr>
<td>to update technical documents</td>
<td></td>
</tr>
<tr>
<td>Capacity strengthening on the use of registration software (covered by the</td>
<td>✓</td>
</tr>
<tr>
<td>action above)</td>
<td></td>
</tr>
<tr>
<td>Actively participate and utilize ongoing regional harmonization initiatives</td>
<td>✓</td>
</tr>
<tr>
<td>(initiatives including ASEAN)</td>
<td></td>
</tr>
<tr>
<td>Exchange of best practices, knowledge among countries of the Region</td>
<td>✓</td>
</tr>
<tr>
<td>through study tours or other modalities</td>
<td></td>
</tr>
<tr>
<td>Continue dialogue on necessity and modality of legal framework for</td>
<td>✓</td>
</tr>
<tr>
<td>compassionate use</td>
<td></td>
</tr>
<tr>
<td>Implementation of Expedited registration based on WHO PQ</td>
<td>✓</td>
</tr>
</tbody>
</table>

2. **Topic: Quality assurance and control**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan and implement a survey on TB drug quality in collaboration with</td>
<td>✓</td>
</tr>
<tr>
<td>partners</td>
<td></td>
</tr>
<tr>
<td>Procurement policy review including QA policy of public procurement agency</td>
<td>✓</td>
</tr>
<tr>
<td>with looking the possibility of review &amp; alignment with global QA standards (GDF, GFATM) for procurement</td>
<td></td>
</tr>
<tr>
<td>Training of inspectors in NRA</td>
<td>✓</td>
</tr>
<tr>
<td>Training of procurement specialist</td>
<td>✓</td>
</tr>
<tr>
<td>Mapping availability/cost of TB drugs</td>
<td>✓</td>
</tr>
</tbody>
</table>

3. **Topic: Rational use**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review of current regulations and practices on availability of TB medicines (regulation, licensing scheme, insurance scheme?)</td>
<td>✓</td>
</tr>
<tr>
<td>Strengthening PPM activities (inclusion of all private sectors) with increased focus on rational use eg. Involving pharmacy association and other professional organizations</td>
<td>✓</td>
</tr>
<tr>
<td>Strengthen pharmacy inspection programme in collaboration with other programmes (e.g. malaria)</td>
<td>✓</td>
</tr>
<tr>
<td>Raise awareness among general population (using AMR platform)</td>
<td>✓</td>
</tr>
</tbody>
</table>
4. **Topic: Pharmacovigilance**

Proposed activities:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developing PV strengthening detailed plan (road map) with all stakeholders for building sustainable PV system</td>
<td>✓</td>
</tr>
<tr>
<td>Establish coordination mechanism (TB programme- PV centres, inclusion of patient representative and professional association in the coordination mechanism)</td>
<td>✓</td>
</tr>
<tr>
<td>Strengthening human resource capacity</td>
<td>✓</td>
</tr>
<tr>
<td>Regional workshop followed by national activities</td>
<td>✓</td>
</tr>
<tr>
<td>Inclusion of PV training on pre – post training of health providers (nurses, pharmacist, doctors) at all level</td>
<td>✓</td>
</tr>
<tr>
<td>Advocacy and awareness raising about medicines safety issues for patients</td>
<td>✓</td>
</tr>
<tr>
<td>Exchange missions/mentorship programme (south-south partnership)</td>
<td>✓</td>
</tr>
<tr>
<td>Regional collaboration, harmonization of standards like ASEAN initiative</td>
<td>✓</td>
</tr>
<tr>
<td>Inclusion of PV related budget in GF proposal</td>
<td>✓</td>
</tr>
</tbody>
</table>

5. **Topic: Platform for better communication**

Set up a regional coordination mechanism

<table>
<thead>
<tr>
<th>Key goals/priorities of such a regional platform</th>
<th>Benefits of a regional platform</th>
</tr>
</thead>
<tbody>
<tr>
<td>• share and exchange information and knowledge on medicines related issues (quality and safety of medicines)</td>
<td></td>
</tr>
<tr>
<td>• share experiences</td>
<td>• Exchange of reliable, up-to-date information</td>
</tr>
<tr>
<td>• Exchange of reliable, up-to-date information</td>
<td>• Networking</td>
</tr>
</tbody>
</table>

interested to expand the TOR of existing Regional Alliance of NRA for Vaccines to start with Medicines

<table>
<thead>
<tr>
<th>Other product area need for such regional collaboration</th>
<th>Potential key barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Malaria</td>
<td>• Human resource capacity</td>
</tr>
<tr>
<td>• HIV/AIDS</td>
<td>• Infrastructure (equipment, internet, phone…)</td>
</tr>
<tr>
<td>• Antibiotics</td>
<td>• Possible reluctance from Government</td>
</tr>
<tr>
<td>• Vaccines and biological products</td>
<td></td>
</tr>
</tbody>
</table>
China

1. **Topic: Registration**

<table>
<thead>
<tr>
<th>Activity</th>
<th>✔️</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish/strengthen coordination mechanism (NTP-NMRA) including other stakeholders</td>
<td></td>
</tr>
<tr>
<td>Organizing assessment mission with WHO and through regional collaboration between NRAs</td>
<td>✔️</td>
</tr>
<tr>
<td>Exchange of best practices, knowledge among countries of the Region through study tours or other modalities</td>
<td>✔️</td>
</tr>
<tr>
<td>Expedited registration based on WHO PQ</td>
<td>✔️</td>
</tr>
</tbody>
</table>

2. **Topic: Quality assurance and control**

<table>
<thead>
<tr>
<th>Activity</th>
<th>✔️</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan and implement a survey on TB drug quality in collaboration with partners</td>
<td></td>
</tr>
<tr>
<td>Information and technical assistance to potential manufacturers to improve GMP and possibly enter into WHO PQ</td>
<td>✔️</td>
</tr>
<tr>
<td>Training of inspectors in NRA</td>
<td>✔️</td>
</tr>
<tr>
<td>Training of procurement specialist</td>
<td>✔️</td>
</tr>
<tr>
<td>Development of communication material targeted to</td>
<td>✔️</td>
</tr>
</tbody>
</table>

3. **Topic: Rational use**

<table>
<thead>
<tr>
<th>Activity</th>
<th>✔️</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strengthen pharmacy inspection programme in collaboration with other programmes (e.g. malaria)</td>
<td></td>
</tr>
<tr>
<td>Raise awareness among general population (using AMR platform)</td>
<td>✔️</td>
</tr>
<tr>
<td>Establishing/strengthening bold actions for regulation of quality of TB medicines in the private sector (and other sector like animal industry)</td>
<td>✔️</td>
</tr>
</tbody>
</table>

4. **Topic: Pharmacovigilance**

<table>
<thead>
<tr>
<th>Activity</th>
<th>✔️</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review current PV situation</td>
<td></td>
</tr>
<tr>
<td>Developing PV strengthening detailed plan (road map) with all stakeholders for building sustainable PV system</td>
<td>✔️</td>
</tr>
<tr>
<td>Strengthening human resource capacity</td>
<td>✔️</td>
</tr>
<tr>
<td>Regional workshop followed by national activities</td>
<td>✔️</td>
</tr>
<tr>
<td>Inclusion of PV training on pre – post training of health providers (nurses, pharmacist, doctors) at all level</td>
<td>✔️</td>
</tr>
<tr>
<td>Advocacy and awareness raising about medicines safety issues for patients</td>
<td>✔️</td>
</tr>
<tr>
<td>Inclusion of PV related budget in GF proposal</td>
<td>✔️</td>
</tr>
</tbody>
</table>
### 5. Topic: Platform for better communication

Set up a regional coordination mechanism

<table>
<thead>
<tr>
<th>key goals/priorities of such a regional platform</th>
<th>To establish a platform to share information on MA/GMP in TB medicines producing, which will inform WHO and all countries in the Region on the current situation of TB medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>the most important benefits of a regional platform</td>
<td>To the administration and management organization, the most important benefit is to get to know the dynamic situation of TB medicines in the current market.</td>
</tr>
<tr>
<td>interested to expand the TOR of existing Regional Alliance of NRA for Vaccines to start with Medicines</td>
<td>Yes</td>
</tr>
<tr>
<td>other product area need for such regional collaboration</td>
<td>Medicines on list of the WHO PQ project.</td>
</tr>
<tr>
<td>potential key barriers</td>
<td>Language barrier while sharing information.</td>
</tr>
</tbody>
</table>
**Laos**

**1. Topic: Registration**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish/strengthen coordination mechanism (NTP-NMRA) including other</td>
<td>✓</td>
</tr>
<tr>
<td>stakeholders</td>
<td></td>
</tr>
<tr>
<td>Organizing assessment mission with WHO and through regional collaboration</td>
<td>✓</td>
</tr>
<tr>
<td>between NRAs</td>
<td></td>
</tr>
<tr>
<td>Implementation of fast track registration mechanism and provide assistance</td>
<td>✓</td>
</tr>
<tr>
<td>to update</td>
<td></td>
</tr>
<tr>
<td>Capacity strengthening on the registration process including introduction</td>
<td>✓</td>
</tr>
<tr>
<td>of appropriate software and review of technical dossiers</td>
<td></td>
</tr>
<tr>
<td>Actively participate and utilize ongoing regional harmonization initiatives( initiatives including ASEAN)</td>
<td>✓</td>
</tr>
<tr>
<td>Exchange of best practises, knowledge among countries of the Region</td>
<td>✓</td>
</tr>
<tr>
<td>through study tours or other modalities</td>
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</tr>
<tr>
<td>Continue dialogue on necessity and modality of legal framework for</td>
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</tr>
<tr>
<td>compassionate use</td>
<td></td>
</tr>
<tr>
<td>Expedited registration based on WHO PQ</td>
<td>✓</td>
</tr>
</tbody>
</table>

**2. Topic: Quality assurance and control**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan and implement a survey on TB drug quality in collaboration with</td>
<td>✓</td>
</tr>
<tr>
<td>partners</td>
<td></td>
</tr>
<tr>
<td>Procurement policy review including QA policy of public procurement</td>
<td>✓</td>
</tr>
<tr>
<td>agency with looking the possibility of review &amp; alignment with global QA</td>
<td></td>
</tr>
<tr>
<td>standards (GDF, GFATM) for procurement</td>
<td></td>
</tr>
<tr>
<td>Information and technical assistance to potential manufacturers to</td>
<td>✓</td>
</tr>
<tr>
<td>improve GMP and possibly enter into WHO PQ</td>
<td></td>
</tr>
<tr>
<td>Training of inspectors in NRA</td>
<td>✓</td>
</tr>
<tr>
<td>Training of procurement specialist</td>
<td>✓</td>
</tr>
<tr>
<td>Development of communication material targeted to</td>
<td>✓</td>
</tr>
<tr>
<td>Include post marketing quality monitoring in GF proposal</td>
<td>✓</td>
</tr>
<tr>
<td>Mapping availability/cost of TB drugs</td>
<td>✓</td>
</tr>
</tbody>
</table>

**3. Topic: Rational use**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review of current regulations and practices on availability of TB</td>
<td>✓</td>
</tr>
<tr>
<td>medicines (regulation, licensing scheme, insurance scheme?)</td>
<td></td>
</tr>
<tr>
<td>Strengthening PPM activities (inclusion of all private sectors) with</td>
<td>✓</td>
</tr>
<tr>
<td>increased focus on rational use eg. Involving pharmacy association and</td>
<td></td>
</tr>
<tr>
<td>other professional organizations</td>
<td></td>
</tr>
<tr>
<td>Inclusion of quality indicators into the insurance scheme</td>
<td>✓</td>
</tr>
<tr>
<td>Strengthen pharmacy inspection programme in collaboration with other</td>
<td>✓</td>
</tr>
<tr>
<td>programmes (e.g. malaria)</td>
<td></td>
</tr>
</tbody>
</table>
### 4. Topic: Pharmacovigilance

<table>
<thead>
<tr>
<th>Action</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raise awareness among general population (using AMR platform)</td>
<td>✓</td>
</tr>
<tr>
<td>Establishing/strengthening bold actions for regulation of quality of TB medicines in the private sector (and other sector like animal industry)</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Review current PV situation**

**Developing PV strengthening detailed plan (road map) with all stakeholders for building sustainable PV system**

**Establish coordination mechanism (TB programme- PV centres, inclusion of patient representative and professional association in the coordination mechanism)**

**Strengthening human resource capacity**

**Regional workshop followed by national activities**

**Inclusion of PV training on pre – post training of health providers (nurses, pharmacist, doctors) at all level**

**Advocacy and awareness raising about medicines safety issues for patients**

**E-health tools for patient reporting of adverse events & product quality problem**

**Exchange missions/mentorship programme (south-south partnership)**

**Regional collaboration, harmonization of standards like ASEAN initiative**

**Inclusion of PV related budget in GF proposal**

### 5. Topic: Platform for better communication

Set up a regional coordination mechanism

<table>
<thead>
<tr>
<th>Key goals/priorities of such a regional platform</th>
<th>Key goal: Strengthening regulatory system through efficient, effective cooperation, collaboration mechanisms and building trust across the region with the ultimate goal of improving access to quality assured drugs for better public health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key priorities:</td>
<td>• Regulatory capacity building for NRAs to be competent in regulatory function (Pre-marketing and Post-marketing)</td>
</tr>
<tr>
<td>• Promote exchange information and data in order to facilitate decision-making</td>
<td></td>
</tr>
<tr>
<td>• Reduce duplicated efforts and cost savings</td>
<td></td>
</tr>
<tr>
<td>• Review existing regulatory initiatives</td>
<td></td>
</tr>
<tr>
<td>the most important benefits of a regional platform</td>
<td>in Asia</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>• Resource saving</td>
<td></td>
</tr>
<tr>
<td>• Technical expertise and information sharing</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>interested to expand the TOR of existing Regional Alliance of NRA for Vaccines to start with Medicines</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>other product area need for such regional collaboration</td>
<td>• Medical devices, Traditional medicines and Biologicals</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>potential key barriers</th>
<th>- Insufficient capacity for NRAs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Weak IT capacity</td>
</tr>
<tr>
<td></td>
<td>- Limited funding for strengthening regulatory system</td>
</tr>
<tr>
<td></td>
<td>- Weak enforcement of legislations/regulation</td>
</tr>
</tbody>
</table>
### Mongolia

#### 1. Topic: Registration

<table>
<thead>
<tr>
<th>Proposal</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish/strengthen coordination mechanism (NTP-NMRA) including other stakeholders</td>
<td>Yes, strengthening coordination mechanism needed</td>
</tr>
<tr>
<td></td>
<td>We have coordination mechanism: NTP, NMRA, Minister of Finance, Boarder agency, General inspection agency. However, cross agency coordination is weak which hinders and slow down registration</td>
</tr>
<tr>
<td>Organizing assessment mission with WHO and through regional collaboration between NRAs</td>
<td>Right now, this is not the priority activity. Such kind of assessment conducted every year or two years but not systematically and the assessment doesn’t give following output</td>
</tr>
<tr>
<td>Implementation of fast track registration mechanism and provide assistance to update</td>
<td>Support to strengthen and update fast tracking mechanism needed. Mongolia has fast tracking registration of medicines but it should be reviewed and updated regularly.</td>
</tr>
<tr>
<td>Capacity strengthening on the registration process including introduction of appropriate software and review of technical dossiers</td>
<td>Yes, capacity strengthening including learning and introduction of appropriate software for registration needed. Right now, we use software which is old, very slow and a lot of mechanic work required to do</td>
</tr>
<tr>
<td>Actively participate and utilize ongoing regional harmonization initiatives (initiatives including ASEAN)</td>
<td>Yes, exchange new information and knowledge, share experience</td>
</tr>
<tr>
<td>Exchange of best practises, knowledge among countries of the Region through study tours or other modalities</td>
<td>Yes, share experience between countries, learn from each other is important.</td>
</tr>
<tr>
<td>Continue dialogue on necessity and modality of legal framework for compassionate use</td>
<td>Yes, even though our government doesn’t allow to register drug which under development and strict on it. However, thinking about TB patients especially XDR-TB we really need convince them and agree for “compassionate use”</td>
</tr>
<tr>
<td>Expedited registration based on WHO PQ</td>
<td>Yes. In the near future, may be even in 2016, we might need transfer procurement of TB drugs from GF to the government budget. In this case, expedited registration based on WHO PQ would really needed</td>
</tr>
</tbody>
</table>
### 2. Topic: Quality assurance and control

<table>
<thead>
<tr>
<th>Plan and implement a survey on TB drug quality in collaboration with partners</th>
<th>Yes, survey is very important otherwise we don’t know whether the drug we use is effective or not even the survey for GDF drug would useful also. We just blindly trust drugs procured through GDF. Also, survey is important for adverse effects of drugs. The survey is important for us when we will transfer TB drug procurement from GF to the government budget. It is important to compare drugs of different companies. Some survey studies included in the national DRA action plan but due to shortage of funding and lack of experience, it wasn’t conducted yet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training of inspectors in NRA</td>
<td>Yes, we need training</td>
</tr>
<tr>
<td>Training of procurement specialist</td>
<td></td>
</tr>
<tr>
<td>Development of communication material targeted to</td>
<td>Yes, communication materials needed</td>
</tr>
<tr>
<td>Include post marketing quality monitoring in GF proposal</td>
<td>Yes, we need. Right now, GF is doing such kind of monitoring but not systematic. When the TB drug procurement will fully under government responsibility, it really would needed</td>
</tr>
<tr>
<td>Mapping availability/cost of TB drugs</td>
<td>Yes, Mapping of TB drug cost is very important</td>
</tr>
</tbody>
</table>

### 3. Topic: Rational use

<table>
<thead>
<tr>
<th>Review of current regulations and practices on availability of TB medicines (regulation, licensing scheme, insurance scheme?)</th>
<th>Yes, because starting from 2016 Mongolia government will need procure TB drugs from government budget line</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strengthening PPM activities (inclusion of all private sectors) with increased focus on rational use eg. Involving pharmacy association and other professional organizations</td>
<td>Yes. This activity only at start stage in Mongolia</td>
</tr>
<tr>
<td>Strengthen pharmacy inspection programme in collaboration with other programmes (e.g. malaria)</td>
<td>Yes. Strengthening pharmacy inspection is very important in Mongolia. Share experience with other countries on this also needed for Mongolia</td>
</tr>
<tr>
<td>Raise awareness among general population (using AMR platform)</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Establishing/strengthening bold actions for regulation of quality of TB medicines in the private sector (and other sector like animal industry) | Yes. There are private clinics operating in Mongolia who prescribe illegally TB drugs to patients who doesn’t wan’t go to public clinic (TB department). Also, patients who interrupted treatment due to adverse effects, they go to private clinics.

### 4. Topic: Pharmacovigilance

<table>
<thead>
<tr>
<th>Activity</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review current PV situation</td>
<td>Yes. PV was established in Mongolia with support from ADB-HSD-4 project. Systematic review of PV situation in Mongolia is important. There is not much study on adverse effects of TB drugs</td>
</tr>
<tr>
<td>Developing PV strengthening detailed plan (road map) with all stakeholders for building sustainable PV system</td>
<td>yes</td>
</tr>
<tr>
<td>Establish coordination mechanism (TB programme- PV centres, inclusion of patient representative and professional association in the coordination mechanism)</td>
<td>yes</td>
</tr>
<tr>
<td>Strengthening human resource capacity</td>
<td>yes</td>
</tr>
<tr>
<td>Regional workshop followed by national activities</td>
<td>yes</td>
</tr>
<tr>
<td>Inclusion of PV training on pre – post training of health providers (nurses, pharmacist, doctors) at all level</td>
<td>Yes. We conduct one time such kind of training among health workers including doctors, nurses, and pharmacist. However, training curriculum and training materials weren’t developed. It was one time training but we need training curriculum for sustainable and periodic training.</td>
</tr>
<tr>
<td>Advocacy and awareness raising about medicines safety issues for patients</td>
<td>Yes</td>
</tr>
<tr>
<td>E-health tools for patient reporting of adverse events &amp; product quality problem</td>
<td>Yes</td>
</tr>
<tr>
<td>Exchange missions/mentorship programme (south-south partnership)</td>
<td>yes</td>
</tr>
<tr>
<td>Inclusion of PV related budget in GF proposal</td>
<td>Yes. GF is doing PV for Mongolia but not systematic. Also, budget for adverse effect drugs is always not sufficient because every year the drug price is increasing and we should shift budget for adverse effect to TB drug procurement.</td>
</tr>
</tbody>
</table>
**Papua New Guinea**

1. **Topic: Registration**

<table>
<thead>
<tr>
<th>Action</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish/strengthen coordination mechanism (NTP-NMRA) including other stakeholders</td>
<td>✓</td>
</tr>
<tr>
<td>Organizing assessment mission with WHO and through regional collaboration between NRAs</td>
<td>✓</td>
</tr>
<tr>
<td>Implementation of fast track registration mechanism and provide assistance to update</td>
<td>✓</td>
</tr>
<tr>
<td>Capacity strengthening on the registration process including introduction of appropriate software and review of technical dossiers</td>
<td>✓</td>
</tr>
<tr>
<td>Actively participate and utilize ongoing regional harmonization initiatives (initiatives including ASEAN)</td>
<td>✓</td>
</tr>
<tr>
<td>Exchange of best practises, knowledge among countries of the Region through study tours or other modalities</td>
<td>✓</td>
</tr>
<tr>
<td>Continue dialogue on necessity and modality of legal framework for compassionate use</td>
<td>✓</td>
</tr>
<tr>
<td>Expedited registration based on WHO PQ</td>
<td>✓</td>
</tr>
</tbody>
</table>

2. **Topic: Quality assurance and control**

<table>
<thead>
<tr>
<th>Action</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan and implement a survey on TB drug quality in collaboration with partners</td>
<td>✓</td>
</tr>
<tr>
<td>Procurement policy review including QA policy of public procurement agency with looking the possibility of review &amp; alignment with global QA standards (GDF, GFATM) for procurement</td>
<td>✓</td>
</tr>
<tr>
<td>Training of inspectors in NRA</td>
<td>✓</td>
</tr>
<tr>
<td>Include post marketing quality monitoring in GF proposal</td>
<td>✓</td>
</tr>
</tbody>
</table>

3. **Topic: Rational use**

<table>
<thead>
<tr>
<th>Action</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strengthening PPM activities (inclusion of all private sectors) with increased focus on rational use eg. Involving pharmacy association and other professional organizations</td>
<td>✓</td>
</tr>
<tr>
<td>Raise awareness among general population (using AMR platform)</td>
<td>✓</td>
</tr>
</tbody>
</table>

4. **Topic: Pharmacovigilance**

<table>
<thead>
<tr>
<th>Action</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review current PV situation</td>
<td>✓</td>
</tr>
<tr>
<td>Developing PV strengthening detailed plan (road map )with all stakeholders for building sustainable PV system</td>
<td>✓</td>
</tr>
<tr>
<td>Strengthening human resource capacity</td>
<td>✓</td>
</tr>
<tr>
<td>Regional workshop followed by national activities</td>
<td>✓</td>
</tr>
<tr>
<td>Inclusion of PV training on pre – post training of health providers (nurses, pharmacist, doctors) at all level</td>
<td>✓</td>
</tr>
</tbody>
</table>
### 5. Topic: Platform for better communication

Set up a regional coordination mechanism

<table>
<thead>
<tr>
<th>key goals/priorities of such a regional platform</th>
<th>the most important benefits of a regional platform</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Improve networking and information exchange between Regional NRAs</td>
<td>• Potential harmonization of technical requirements between member NRAs, for registration etc.</td>
</tr>
<tr>
<td>• Minimize duplication of efforts by Regional NRAs, e.g. in GMP inspections</td>
<td>• Capacity building for member countries with least developed NRA capacity</td>
</tr>
<tr>
<td></td>
<td>• Access to key information (technical and scientific) available through such a platform will promote swifter action</td>
</tr>
<tr>
<td></td>
<td>by Regional NRAs e.g. in registration of new chemical entities</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>interested to expand the TOR of existing Regional Alliance of NRA for Vaccines to start with Medicines</th>
<th>Yes – The Vaccines NRA modal is well structured and adoptable</th>
</tr>
</thead>
<tbody>
<tr>
<td>other product area need for such regional collaboration</td>
<td>• Anti-malarial</td>
</tr>
<tr>
<td></td>
<td>• ARV</td>
</tr>
<tr>
<td></td>
<td>• Anti-microbials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>potential key barriers</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>- National regulations</td>
<td>- Clear understanding of the usefulness and potential of such a regional platform</td>
</tr>
<tr>
<td>- Clear understanding of the usefulness and potential of such a regional platform</td>
<td></td>
</tr>
</tbody>
</table>
## Philippines

### 1. Topic: Registration

<table>
<thead>
<tr>
<th>Activities</th>
<th>Action Plan</th>
<th>Timeline</th>
<th>Agency responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish/strengthen coordination mechanism (NTP-NMRA) including other stakeholders</td>
<td>Include FDA in the DSM sub-technical working group. Assign specific topics related to registration of medicines and introduction of new drugs.</td>
<td>Q2 2014</td>
<td>NTP</td>
</tr>
<tr>
<td>Organizing assessment mission with WHO and through regional collaboration between NRAs</td>
<td>FDA open for assessment by WHO and regional NRAs specific for registration of TB medicines and new drugs.</td>
<td>Q1 2015</td>
<td>WHO</td>
</tr>
<tr>
<td>Implementation of fast track registration mechanism and provide assistance to update</td>
<td>Mechanisms are in place for the fast-tracking of registration.</td>
<td>Ongoing</td>
<td>FDA</td>
</tr>
<tr>
<td>Capacity strengthening on the registration process including introduction of appropriate software and review of technical dossiers</td>
<td>FDA have the capacity to train additional Product Evaluators, but additional computers are needed with appropriate software.</td>
<td>Q2 2014</td>
<td>DOH-FDA (computers) WHO (software)</td>
</tr>
<tr>
<td>Actively participate and utilize ongoing regional harmonization initiatives (initiatives including ASEAN)</td>
<td>FDA is already participating in the ongoing ASEAN regional harmonization initiative.</td>
<td>Ongoing</td>
<td>FDA</td>
</tr>
<tr>
<td>Exchange of best practises, knowledge among countries of the Region through study tours or other modalities</td>
<td>Incorporated with PV activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continue dialogue on necessity and modality of legal framework for compassionate use</td>
<td>Mechanisms are already in place.</td>
<td>Ongoing</td>
<td>FDA</td>
</tr>
<tr>
<td>Expedited registration based on WHO PQ</td>
<td>Mechanisms are already in place for expedited registration</td>
<td>Q2 2014</td>
<td>NTP</td>
</tr>
</tbody>
</table>
of WHO prequalified vaccines and biologics. But there is a need to include WHO pre-qualified anti-TB drugs. Dialogue with FDA and the NTP will be done during the DSM subgroup meetings.

### 2. Topic: Quality assurance and control

<table>
<thead>
<tr>
<th>Activity</th>
<th>PHL</th>
<th>Timeline</th>
<th>Agency responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan and implement a survey on TB drug quality in collaboration with partners</td>
<td>With ongoing USAID project on monitoring TB drug quality</td>
<td>Ongoing</td>
<td>USP-PQM</td>
</tr>
<tr>
<td>Procurement policy review including QA policy of public procurement agency with looking the possibility of review &amp; alignment with global QA standards (GDF, GFATM) for procurement</td>
<td>Review and align the current procurement policy. With technical assistance and assessment from SIAPS.</td>
<td>Q2-Q3 2014</td>
<td>MSH/SIAPS</td>
</tr>
<tr>
<td>Information and technical assistance to potential manufacturers to improve GMP and possibly enter into WHO PQ</td>
<td>With ongoing initiatives thru United States Pharmacopoeia – Promoting Quality of Medicines (USP-PQM)</td>
<td>Ongoing</td>
<td>USP-PQM</td>
</tr>
<tr>
<td>Training of inspectors in NRA</td>
<td>Need supplemental training for inspectors for specific topics like Good Storage Practice, Good Distribution Practice.</td>
<td>Q3-Q4 2014</td>
<td>FDA, TA from WHO</td>
</tr>
<tr>
<td>Training of procurement specialist</td>
<td>Will conduct “Comprehensive Training on the Government Procurement Reform Act for the New Procurement</td>
<td>May 7-9, 2014</td>
<td>COBAC</td>
</tr>
<tr>
<td>Practitioners”</td>
<td>Development of communication material targeted to</td>
<td>Development of additional IEC materials on importance of quality drugs</td>
<td>2014-2015</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------------</td>
<td>------------------------------------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Include post marketing quality monitoring in GF proposal</td>
<td>With budget from GF and additional support from SIAPS and USP-PQM</td>
<td>Done</td>
<td>PBSP, SIAPS, USP-PQM</td>
</tr>
<tr>
<td>Mapping availability/cost of TB drugs</td>
<td>With price monitoring care of NCPAM</td>
<td>Ongoing</td>
<td>NCPAM</td>
</tr>
</tbody>
</table>

### 3. Topic: Rational use

| Review of current regulations and practices on availability of TB medicines (regulation, licensing scheme, insurance scheme?) | Will be part of the USAID assessment | Q2-Q3 2014 | MSH/SIAPS |
| Strengthening PPM activities (inclusion of all private sectors) with increased focus on rational use eg. Involving pharmacy association and other professional organizations | Ongoing based on the Philippine Plan of Action to Control Tuberculosis (PhilPACT) | Ongoing | NTP |
| Inclusion of quality indicators into the insurance scheme | Will be discussed during the Thematic meeting for certification and accreditation | Q2 2014 | NTP |
| Strengthen pharmacy inspection programme in collaboration with other programmes (e.g. malaria) | FDA inspection already in place. | Ongoing | FDA |
| Raise awareness among general population (using AMR platform) | Combined with the activity of NCPAM in the development of IEC Materials. | Ongoing | NCPAM |
| Establishing/strengthening bold actions for regulation of quality of TB medicines in the private sector (and other sector like animal industry) | Will review and discuss with partners and FDA on the possibility of restrictions on the availability of TB drugs in the private sector. | Ongoing review | NTP, Health Policy Development Project (HPDP-USAID), NCPAM |
### 4. Topic: Pharmacovigilance

<table>
<thead>
<tr>
<th>Activity</th>
<th>PHL</th>
<th>Timeline</th>
<th>Agency responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review current PV situation</td>
<td>PV assessment already done in 2012.</td>
<td>Done</td>
<td></td>
</tr>
<tr>
<td>Developing PV strengthening detailed plan (road map) with all stakeholders for building sustainable PV system</td>
<td>Developing of PV detailed plan in collaboration with SIAPS</td>
<td>Q2 2014</td>
<td>SIAPS</td>
</tr>
<tr>
<td>Establish coordination mechanism (TB programme- PV centres, inclusion of patient representative and professional association in the coordination mechanism)</td>
<td>Will be part of the PV strengthening detailed plan</td>
<td>Q2 2014</td>
<td>SIAPS</td>
</tr>
<tr>
<td>Strengthening human resource capacity</td>
<td>Will be part of the PV strengthening detailed plan</td>
<td>Q2 2014</td>
<td>SIAPS</td>
</tr>
<tr>
<td>Inclusion of PV training on pre – post training of health providers (nurses, pharmacist, doctors) at all level</td>
<td>Will be part of the PV strengthening detailed plan</td>
<td>Q2 2014</td>
<td>SIAPS</td>
</tr>
<tr>
<td>Advocacy and awareness raising about medicines safety issues for patients</td>
<td>Development of IEC materials specific for safety issues for patients</td>
<td>2014-2015</td>
<td>NCPAM</td>
</tr>
<tr>
<td>E-health tools for patient reporting of adverse events &amp; product quality problem</td>
<td>With existing FDA reporting system</td>
<td>Ongoing</td>
<td>FDA</td>
</tr>
<tr>
<td>Exchange missions/mentorship programme (south-south partnership)</td>
<td>Will be part of the PV strengthening detailed plan.</td>
<td>2014</td>
<td>WHO (?)</td>
</tr>
<tr>
<td>Regional collaboration, harmonization of standards like ASEAN initiative</td>
<td>System already in place (Post Marketing Alert System). Sharing of information regarding PV among ASEAN countries</td>
<td>Ongoing</td>
<td>FDA</td>
</tr>
<tr>
<td>Inclusion of PV related budget in GF proposal</td>
<td>Yes. With additional support from SIAPS</td>
<td>Ongoing</td>
<td>PBSP, SIAPS</td>
</tr>
</tbody>
</table>
### 5. Topic: Platform for better communication

Set up a regional coordination mechanism

<table>
<thead>
<tr>
<th>key goals/priorities of such a regional platform</th>
</tr>
</thead>
<tbody>
<tr>
<td>– <em>Sharing of best practices, technical issues, experiences, knowledge and priorities</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>the most important benefits of a regional platform</th>
</tr>
</thead>
<tbody>
<tr>
<td>- <em>to address technical issues surrounding pharmaceutical management issues and regulations.</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>interested to expand the TOR of existing Regional Alliance of NRA for Vaccines to start with Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>other product area need for such regional collaboration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostics</td>
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<table>
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<tr>
<th>potential key barriers</th>
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<td>Funding</td>
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</table>
Quality assurance drugs for better public health: Strengthening and harmonizing the regulation of TB medicine in the Western Pacific Region
12-14 March, Manila, Philippines

Medicine Policy Regulation & Procurement Situation

Country: Lao PDR

Presented by: Mrs. Soulyvanh Keokinnaly & Dr. Phouvang Vangvichit
Date: 12 March 2014, Manila

Contents

• Medicine Policy regulation:
  - Organization Chart
  - Existing legislation/regulation
  - Registration
  - Quality Control and Assurance
• Procurement Situation
  - Current procurement situation of medicines special for TB medicines
• Challenges

Vision

• To ensure good quality, safety and efficacy of drugs and medical products as well as their rational use for all Lao people

Main Task of Drug Regulatory Authority

• Ensuring quality of medicines
• Pre-marketing quality assessment: marketing authorization, licensing and registration
• Post-marketing surveillance: quality and adverse events, advertising, and promotion control
• Adequate legislation and law enforcement

Law and regulations (1)

• The Law on Drugs and Medicinal Products No. 01/NA, date 13 August 2003, revised in 2012
• The regulation on private Pharmacy, No. 482/ MOH, dated 19 April 2002.
• The regulation on the import and export of drugs, No. 1442/ MOH, dated 13 August 2003
**Law and regulations (2)**
- The regulation governing drug registration in Lao PDR, No: 1441/ MOH, dated 13 August, 2003
- The regulation on drug manufacturing in 1989
- The regulation on GMP, No.1021/ MOH, dated 11 August 1999.
- The regulation on banned drugs, No. 738 / MOH, dated 29 May, 2003
- The regulation on drug advertisements, in 1997
- The regulation on drug procurement, in 1998
- The regulation on drug donation, in 2002.

**Quality Assurance System**
- All drugs to be placed on the market in Laos must be evaluated and registered by the FDD of the Ministry of Health
- Number of registered products:
  - Up to July 2013: 1,586 registered products (276 locally produced and 1310 imported, about 55.6% (882) were Essential Medicines with generic name)
- Licensing of private pharmacies, pharmaceutical companies and factories every two years
- Drug selection: EML updated every two years, about 300 items of medicines in generic name

**Quality Assurance System (cont)**
- Monitoring and inspection of private pharmacies, pharmaceutical companies and factories by using GPP, GWP and GMP indicators and checklist, sample collection and testing
- Food and Drug Quality Control Centre, GLP, ISO/IEC 17025: 2005

**Quality of Medicines**
- Data source: Annual report of FDD inspection

**ASEAN Harmonization**
- Standard, Quality, Conformity Assessment
- Requirement for Drug Registration
  - Regulation No 1441/MoH, 13/08/2003
  - ASEAN Common Technical Dossier/ASEAN Common Technical Requirement since January 2009
  (Part I: Administrative, Part II: Quality
  Part III: Non-Clinical, Part IV: Clinical)
  - Time line: approximately 6 months upon receiving of all supporting documents

**Procurement of TB drugs**
- WHO prequalified TB drugs are procured by direct procurement mechanism from Global Drug Facility (GDF, Stop TB Partnership, Geneva ) with Global Fund (GF) funding
- Procurement process follows GF principles:
  - NTC develops an annual procurement (AP) plan
  - Joint Quantification and of TB drugs (first line and second line ) by NTC and GDF monitoring mission, based on AP plan and usable stock in central warehouse
  - Request for TB drugs is verified by PR procurement team and send to GDF for quotation and placement of order after payment GF
  - Shipment authorization given after MoH approval and custom clearance
  - All TB drugs are stored in central warehouse
  - Distribution ensured by NTC
**Ongoing Challenges**

- Capacity building of staff for both regulators and industries to implement ACTD/ACTR and all ASEAN guidelines
- Enhancement of drug control system based on regional and international standards
- Strengthening Quality Assurance system (Pre market and Post market Control, Pharmacovigilance)
- Combating counterfeit, substandard and unregistered medicines in the market
- Ensuring that local pharmaceutical factories follow GMP standard
- Need more international exchange and cooperation
- Limited budget for post-marketing QC
Drug regulation in Mongolia

OTGONSUKH SODNOM,
MINISTRY OF HEALTH

Strengthening and harmonizing the regulation of TB medicines, 12-14 March 2014

Overview

• Drug regulation policy
• Procurement situation

Country profile

- Total area - 1.6 million square kilometres
- Population - 2.7 million
- Density - 1.7 persons per square kilometres
- 38.6% of the population were residing in rural areas
- Cities population - 61.4% of overall

Government policy on medicines

Vision
To create the conditions to consume highly effective, safe, quality assured medicines, biologically active products (hereinafter referred to as “medicines”), to provide continuous, equal and sufficient supply of necessary drugs for hospitals, veterinary organizations and people, to form their rational use.

Strategy goal
Measures of state regulation on the manufacture, import, export, sale, distribution and control of drugs, medical devices, biologically active products.

Regulatory and inspection

Ministry of Health
Division of Pharmaceuticals and Medical Devices
To organize and coordinate policy implementation for the supply of medicines

General Agency for Specialized Inspection
Division of Health Inspection, Drug Control Laboratory
Quality control of medicines

Division of Pharmaceuticals and Medical Devices

- To organize and coordinate policy implementation for the manufacturing and supply of medicines
- To organize and coordinate policy implementation for the quality and safety of pharmaceuticals and medical devices
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Policy documents on drug regulation

• National Policy on Medicines, 2002-2012 (updated 2013-2014)/
• Pharmaceuticals and medical device’s law 1998 (updated 2010)/
• Medicine and biological active preparation’s registration rule (updated 2012)/
• National pharmacopeia, 2011 (Included 153 monographs of raw material of herbal medicines)/
• National GMP /Good Manufacturing Practice/, GPP /Good Prescription Practice, GDP /Good Distribution Practice/ approved as Mongolian national standards

Medicine registry and procurement

According to the Pharmaceuticals and medical device’s law in Mongolia:

• Medicines manufactured, retailed and imported must be registered in national medicine registration list
• Mongolia began to registered medicines since 1994

Medicine registry and procurement (cont.)

According to the Medicine and biological active preparation’s registration rule:

• The medicine which is registered in Mongolia must be marketed /registered/ in country of origin more than 3 years.
• The medicine which is registered as a rapid registration must be essential and emergency medicine.

Inspection

To approved as Mongolian national standards:

- Drug prescription and prescribing MNS 5376-2011
- General principles for drug wholesalers MNS 5530-2009
- General principles for drug manufacturing MNS 5524:2011
- General principles for pharmacy MNS 5260-2011

Vaccines supply

• Government of Mongolia purchases all routine vaccine through UNICEF which were prequalified
• Also we purchase non routine vaccine from various local suppliers.
Thank you for your attention
TB Burden in PNG

- Notifiable cases 2013
  - All forms: 26,662 reported cases
  - Pulmonary: 16,757 cases
  - New smear positive (NS+): 3,164 (12% of cases smear tested)
  - Smear not done: 7,015 (29% of cases notified)

- Treatment outcome 2012 cohort (NS+)
  - Treatment success: 68%
  - Cure rate: 58%
  - Treatment completed: 18%

- TB/HIV 2011
  - All TB tested for HIV: 5,412
  - % tested for HIV: 24%
  - No tested vs. HIV: 822
  - HIV prevalence (all TB) 14%

- MDR/XDR TB
  - 174 (9% of) patients put on treatment since 2011

Source: PNG DoH

NMRA – NDoH (1)

- Pharmaceutical Service Standards (PSS) Branch
  - Registrar of medicines and other health products for the NDoH
  - Branch established in 2010
  - 22 staff, 19 technical staff, mostly pharmacists and chemist(s)
  - Responsible for administering the Medicines and Cosmetic Act 1999
  - Medicines Policy 2013, has been developed by the Branch

What the branch does.

- Product Registration
  - Product registration has stalled for so long
  - With technical assistance from WHO, provisional registration has commenced in 2013, full registration planned for 2016
  - Target is to register products supplied through NDoH procurements

- Licensing
  - Importers, wholesalers, retailers and personnel
  - Inspection for Good Storage and Good Distribution Practices
  - N/GMP inspection

NMRA – NDoH (2)

- Pharmacovigilance
  - Adverse product reaction monitoring
  - Roll of Medicines Therapeutic Committee (MTC) to public hospitals
  - Registration to Uppsala (Sweden) for reporting adverse events

- Drug Information and promotion
  - to health professionals and the public
  - A drug information unit is planned to be established
  - Reference materials supplied by WHO and a hotline is being organized
  - Control of adverts and promotions for medicines

- Laboratory Quality control
  - Sampling and testing of medicines (Chemistry testing)
  - NEL testing as yet, samples sent to Therapeutic Goods Administration (TGA), Aus
  - A pilot facility is being established with the University of PNG
  - 2 HPLC units have been procured with other lab wares and consumables on the way

Regulatory controls for TB products

- TB medicines subject to registration (provisionally)
- The National Medicines Policy 2013 allows for fast tracking and waiver for essential medicines and those on clinical trials
- The policy also allows for sourcing from only WHO prequalified manufacturers
- Laboratory testing for TB medicines, collaboration in 2013 and onwards
- Adverse event monitoring – a workshop is planned between the PSSB and vertical programs for adverse event monitoring
The National TB Program

- NTP is part of the Public Health Division
- Staffed by the NTP Manager and 3 Regional Medical Officers
- 1 specialized TB Clinic at the Port Moresby General Hospital
- TB Programs run by the 20 Provincial Health Offices and hospitals
- Multiple development partners assisting program expansion

TB Supply Chain coordination

<table>
<thead>
<tr>
<th>Activity</th>
<th>National TB Program (NTP)</th>
<th>Procurement Branch (MSPD)</th>
<th>Regulating Branch (PSSB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection</td>
<td>X</td>
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<tr>
<td>Quantification</td>
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<tr>
<td>Policy</td>
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Procuring Quality assured TB Medicines

- GFATM TB grant procurements all through GDF since 2008
- GFATM Round 6 TB Grant closure Aug 2014
- Gov’t to meet 100% costs for TB medicines from 2014
- Procuring through GDF and local suppliers
- Quality assurance measures

Challenges

- Government to procure 100% from 2014 onwards as GFATM grant winds down and the long processes of tendering and funds transfer
- Supply chain integration
- Information collection for both cases and drugs
- Reliable forecasting and quantification
- Sourcing only from WHO prequalified manufacturers or through WHO recommended procurement agencies
- Quality testing for TB medicines
- Adverse events monitoring
- Resistance to 1st line treatment and high cost of 2nd line treatment
- Funding support for the NTP following GFATM grant closure

THANKYOU...

Dr Paul Aia – NTP Manager
Mary Kuirih – T/A Product Registration
Klepa Wila-Fabi – T/A Medical Stores & Distribution
Graham Wavimbukie – T/A Quality Control
**PROMISSONAL TIMETABLE**

Meeting on Quality-Assured Drugs for Better Public Health: Strengthening and Harmonizing the Regulation of TB Medicines in the Western Pacific Region, 12-14 March 2014, Manila, Philippines

<table>
<thead>
<tr>
<th>Wednesday, 12 March</th>
<th>Thursday, 13 March</th>
<th>Friday, 14 March</th>
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<tbody>
<tr>
<td><strong>08:30</strong></td>
<td><strong>Summary of Day 1</strong></td>
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<tr>
<td>Registration</td>
<td>Session 3: Quality Assurance</td>
<td><strong>08:15</strong></td>
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<tr>
<td><strong>09:00</strong></td>
<td>Objective: To raise awareness on quality assurance policy</td>
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<tr>
<td>Opening ceremony</td>
<td>(1) What is WHO prequalification? (SC/EMT-HQ)</td>
<td><strong>08:30</strong></td>
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<tr>
<td>- Welcome remarks: Dr Shin Young-soo Regional Director</td>
<td>(12) Quality assurance standard: GF and GDF (NM/GDF-HQ)</td>
<td><strong>08:50</strong></td>
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<tr>
<td>(2) Meeting objectives (NN)</td>
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<td><strong>09:10</strong></td>
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<td>- Introduction of participants and observers</td>
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<td><strong>10:00</strong></td>
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<td>- Administrative Announcements</td>
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<td><strong>12:30</strong></td>
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<tr>
<td><strong>10:00</strong></td>
<td>Lunch Break</td>
<td><strong>15:00</strong></td>
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<td>Group Photo – Coffee/Tea Break</td>
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<td><strong>15:00</strong></td>
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**Session 1: Overview**

Objective: Situation assessment

- Post 2015 and TB strategy: Role of regulation of TB medicine (NN/STB)
- Strengthening the national regulatory authorities and the essential regulatory function: Focus on TB medicine (SC/EMT-HQ)
- Pharmaceutical situation assessment: TB drug regulation in the Region (TI/STB)
- Country Presentations (7 countries)
  - Regulatory policy
  - Procurement situation

**Session 2: Registration**

Objective: Identifying priority activities to strengthen registration system

- Registration of TB drugs (SC/EMT-HQ)
- Quality assurance as part of the essential regulatory function (SC/EMT-HQ)
- Compassionate use of drugs (EJ/GTB-HQ)

**Session 3: Quality Assurance**

Objective: To raise awareness on quality assurance policy

- What is WHO prequalification? (SC/EMT-HQ)
- Quality assurance standard: GF and GDF (NM/GDF-HQ)
- Group work followed by plenary discussion: Identifying Priority on strengthening quality assurance practice

**Session 4: Post-marketing monitoring**

Objective: Identifying priority activities to strengthen post-marketing monitoring

- Post-marketing monitoring of quality of drugs (Good Distribution Practice and Good Storage Practice) (SE/EMT-VNM)
- Experience of quality assurance (SP/USP)
- Role of laboratory testing and laboratory network (SC/EMT-HQ)
- Group work followed by plenary discussion: Identifying priority activities for strengthening post marketing monitoring

**Session 5: Rational use**

Objective: To share good experiences, inform on the new drug introduction, identifying priority activities

- Country experience of restriction of drug availability (Cambodia/Philippines)
- Enforcement of regulation (China/Mongolia)

**Session 6: Pharmacovigilance (PV)**

Objective: Situation assessment and identifying priority activities to strengthen PV system

- Situation assessment: PV in the Western Pacific Region (MG/SAP+MSH)
- WHO policy on PV of medicine used in TB treatment (EJ/GTB-HQ)

**Session 7: Improved communication and collaboration**

Objective: Explore option of a single regional regulatory platform for better communication

- Expanded Programme on Immunization (JS/EPI)
- Malaria Programme (LV/MVP)
- A platform for better communication for strengthening and harmonizing the regulation of medicines (KT/EMT)

**Session 8: Conclusion and Recommendations**

Recommendations: Compiled Road Map (STB/EMT)

EJ: Ernesto Jaramillo; JS: Jinho Shin; KT: Kaira Tiscoki; LV: Lasse Vestergaard; MG: Michael Gabra; NM: Nigor Muzaffarova; NN: Nobuyuki Nishikiori; SC: Stephanie Croft; SE: Soorco Escalante; SP: Souly Phanouvong; TI: Tauhidul Islam
MEETING ON QUALITY ASSURED
DRUGS FOR BETTER PUBLIC HEALTH:
STRENGTHENING AND HARMONIZING THE
REGULATION OF TB MEDICINES IN THE
WESTERN PACIFIC REGION

Manila, Philippines
12-14 March 2014

INFORMATION BULLETIN NO. 2

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