Situational analysis of Medicines Management in Health Care

[Insert country name and dates]

Team Members

- WHO/SEARO: *Insert names*
- Government Departments / Units / Authorities
  - Drug Supply: *Insert names*
  - Drug selection and use: *Insert names*
  - Drug regulation: *Insert names*
  - Drug policy: *Insert names*
- Other institutions represented in the team e.g.
  - National insurance: *Insert names*
  - Academic institution: *Insert names*
Instructions

• This slide set provides a template for a power point presentation for use in a national workshop and should be deleted from the final presentation for any country.
• The presentation should be adapted according to the individual country’s findings.
• The number of slides in this set provides guidance only to the length of presentation and level of detail needed.
• Do not use less than 20 font in any slide, but with poor projection a minimum of 28 font may be needed. Please check that all slides can be read by participants at the back of the room.
• Please provide participants with a print-out of the presentation.
Background information

- Include any relevant information concerning:
  - Past situational analysis with dates
  - Particular problems mentioned by government concerning medicines management (past situational analysis & now)
  - Why medicines management is important and how a situational analysis can help identify problems and solutions
  - Other information on universal health coverage, insurance, organisation of the pharmaceutical system, human resource policy, etc. relevant to the country
Terms of Reference

• To conduct a rapid assessment of medicines in health care delivery covering drug supply, selection, use, regulation and policy,
  – In liaison with national counterparts nominated by the MOH;
  – Taking into account progress made since the last situational analysis done in [insert date]

• To report on the findings and develop an action plan in a workshop of government officials and other stakeholders.
Objectives of the workshop

• Review the situational analysis findings

• Identify the main priority problems to be addressed, in 5 areas:
  – Drug supply,
  – Drug selection,
  – Drug use,
  – Drug regulation,
  – Drug policy

• Formulate recommendations to resolve / address the priority problems in each area.
Agenda of the workshop – example

09.00 – 09.30 am: Opening session with senior government official

09.30 – 10.30 am: Presentation of findings and possible solution by situational analysis team

10.30 – 11.00 am: Tea break

11.00 – 13.00 pm: Group work (5 groups) to develop recommendations for future action on drug supply, selection, use, regulation and policy & coordination

13.00 – 14.00 pm: Lunch

14.00 – 15.30 pm: Presentation by groups 1, 2 and 3 on drug supply, selection and use, with finalization of recommendations

15.30 – 16.00 pm: Tea break

16.00 – 17.00 pm: Presentation by groups 4 and 5 on regulation and policy & coordination, with finalization of recommendations

17.00 – 17.30 pm: Closing session with senior government official
Mission: week 1 [insert dates]

• **Day 1:** orientation of the government team, meeting senior officials

• **Day 2:**

• **Day 3:**

• **Day 4:**

• **Day 5:**

• **Day 6:**
Mission week 2 [insert dates]

• Day 7:

• Day 8:

• Day 9:

• Day 10:

• Day 11: preparation for the workshop

• Day 12: national workshop
Methods

- 2-week data collection using WHO/SEARO situational analysis tool
- Interviews with concerned government officials & stakeholders & document review
- Visits to public health facilities & private pharmacies in 2-3 provinces/regions [insert names]
  - Stock-check for availability of 40 selected essential drugs (selected by the team), stock-out, expired drugs, storage conditions, quality-failed stock, etc.
  - OPD prescription survey for WHO indicators
  - In-patient drug management
  - Drug consumption and management
  - Health system & health care factors
General findings

• General statement
  – e.g. extensive health care system, with substantial infrastructure, trained hardworking health care personnel +/- good health indicators

• Some/much progress since last situational analysis
  – state the main areas of progress

• Some problems remain in drug management
  – state the main areas where problems remain
  – state the major areas that can be addressed by existing resources and capacity and the major areas needing more resources and capacity.
Drug Supply

• Describe the overall system briefly
  – Pull or push system?
  – Central and/or decentralised procurement?
  – Funds for purchase received from government / insurance / other funds?
  – Pooled procurement by provinces?
  – Government departments involved?

• Describe any changes since the last situational analysis
Selected 40 key essential medicines to measure drug availability

Primary health care centres (state the number of medicines selected e.g. 30 medicines or whatever number is chosen)

• List the medicines for use in primary care

Referral hospitals (state the extra number drugs selected e.g. 10 drugs)

• List the extra medicines for use in hospitals only.
Drug Availability

• This Situational analysis [insert date]
  – Availability of key EML drugs: ? % (40 drugs) in hospitals and ? % (30 drugs) in primary care centres
  – Stock-outs: ? % in hospitals; ? % in primary care centres
  – Reasons for non-availability e.g. non-use, poor estimation
  – Overall average number of drugs prescribed per patient and % of prescribed drugs dispensed from the facility

• Last Situational analysis [insert date]
  – Brief statements comparing the findings of the last situational analysis with the findings given above from this situational analysis
Insurance system

- Describe any national insurance system if any
Procurement

- **Describe the procurement system**
  - Who does it?
  - Procurement rules?
  - 1 or 2-envelope tendering system?
  - Technical criteria?
  - Lead time?
  - Where do most drugs come from – government manufacturer, locally-based private manufacturers, foreign imports?
Stock Management

• Describe stock management
  – State of the drug stores?
  – Documentation concerning drug supplies?
  – Electronic logistic management information system?
  – Management of expired drugs? use of First-expired, First-out (FEFO) system?
  – Quantification process? Availability of consumption data?
  – Redistribution?
  – Presence and role of pharmacists in store management and distribution of medicines?
Drug Supply: summary

• List the good practices and the major problems, and any progress made since the last situational analysis
Drug Supply: suggested solutions

• List some major solutions/recommendations to the problems as identified by the team
National Essential Medicines List (NEML)

• Summarise the main features of the NEML
  – Date of last revision
  – On the web? [Give website address]
  – Number of active ingredients? and number of formulations?
  – Categorisation by prescriber facility type? [List the categorisation types]
  – Process of revision
Selection process

• Describe the selection process
  – Who made the first draft?
  – What committees and sub-committees were involved and how often did they meet?
  – Number and type of experts involved?
Implementation of NEML

• Describe actions taken to implement the NEML
  – Use in government procurement
  – Use in pre-service training (undergraduate) and in-service training (postgraduate training and continuing medical education)
  – Distribution of the NEML
  – Monitoring compliance

• Describe EML compliance in the public and private sectors as found in the OPD prescribing survey
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<th>No</th>
<th>Drug name</th>
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% total budget (not just top 20) spent on EML drugs ?, antibiotics ?, vitamins ?

Indicate in different colored (red) font which drugs are not on the EML
Top 20 drugs by value in a referral hospital

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% total budget (not just top 20) spent on EML drugs ?, antibiotics ?, vitamins ?

Indicate in different colored (red) font which drugs are not on the EML
Drug selection: summary

• List the good practices and the major problems, and any progress made since the last situational analysis
Drug selection: suggested solutions

• List some major solutions/recommendations to the problems as identified by the team
Drug use: survey methods

• Describe the prescribing survey methods used for outpatients
  – Different sources of data in public facilities and private pharmacies / shops
  – Number of prescriptions reviewed / patients observed / sales conducted per facility
  – Indicators used

• Describe how dispensing was reviewed
  – Observing dispensing in public sector facility outpatients and private pharmacies
  – Reviewing inpatient drug management and administration
<table>
<thead>
<tr>
<th>Drug use indicator</th>
<th>Referral hospital n=</th>
<th>District hospital n=</th>
<th>Health Centre n=</th>
<th>Retail pharmacy n=</th>
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<tbody>
<tr>
<td>Av. no. drugs / patient</td>
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<td>% patients with Antibiotic</td>
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<td>% patients with Vitamins</td>
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<td>% patients with Trad. Med.</td>
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<td>% URTI cases with antibiotic</td>
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<td>% prescribed generic drugs</td>
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<td>% prescribed NEML drugs</td>
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<td>Av. drug cost / prescription</td>
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Prescribing and dispensing: results

• **Comment on the results:**
  – Prescribing survey in the public and private sectors
  – How the prescribing survey compares with the previous situational analysis
  – Dispensing practices in outpatients and private pharmacies
  – Inpatient drug management and dispensing practices
Policies impacting on drug use (1)

• Monitoring of drug prescribing and dispensing
  – What is done?
  – Is it done regularly, occasionally or never?

• Health System factors
  – Patient crowding and referral systems
  – Prescriber and dispenser types (e.g. doctors, nurses, pharmacists, paramedical workers?)
  – Workload (e.g. number of patients per doctor per day e.g. number of patients per dispenser per day)
  – Do doctors work in both the public and private sectors
  – Do prescribers earn income from drug sales?
Policies impacting on drug use (2)

• **Standard Treatment Guidelines (STGs)**
  – Describe what is available and whether it is used
  – Have doctors received training on the STGs?

• **Hospital Drug & Therapeutic Committees (DTC)**
  – Describe whether these exist in most hospitals, what they do, and whether monitor medicines (incl. antibiotic) use
  – Are the DTCs active in antibiotic (AB) stewardship?
Policies impacting on drug use (3)

• Undergraduate education
  • Describe what kind of training undergraduates get on general rational prescribing, NEML, STGs, AB use

• Continuing Medical Education
  – Describe what kind of CME exists and whether it includes anything general rational prescribing, NEML, STGs, AB use
Policies impacting on drug use (4)

• Community / public education
  – Describe any nationwide public education campaigns on safe use of medicines (incl. antibiotics, injections) that have been done?
  – Were village health volunteers used to spread messages on safe & prudent medicines/AB use?
  – Was public education been done via the media?

• Independent drug information
  – Describe what Drug Information Centre services and independent drug information are available

• Drug promotion
  – Do pharmaceutical representatives visit doctors & pharmacists in both public & private sectors?
Projects to promote rational use

- Describe any other projects or programmes (if any) to promote rational use of medicines (incl. antibiotics)
Drug use: summary

- List the good practices and the major problems, and any progress made since the last situational analysis
Drug use: suggested solutions

• List some major solutions/recommendations to the problems as identified by the team
Drug regulation (1)

- **National Medicines Regulatory Authority (NMRA):**
  - Name: mention the name of the NMRA and if it is under the MOH
  - Legislation: mention the Drug Acts

- **Pharmaceutical sector:**
  - Number medicine products: allopathic - ?; TRM - ?; veterinary - ?
  - Number manufacturing plants: allopathic - ?; TRM - ?
  - Number wholesale/retail outlets: allopathic - ?; TRM - ?; veterinary - ?

- **NMRA staffing**
  - Number of staff: all staff ?; technical ?; pharmacists
  - Collaboration with provinces/regions/districts

- **SOPs/Checklists**
  - Do SOPs exist for most procedures? What significant gaps are there?

- **Regulation & enforcement in the last one year**
  - Number of manufacturer inspections: ?
  - Number of retail and wholesale outlet inspections: ?
  - Number of prosecutions ? and value of fines for offences: ?
Drug regulation (2)

• **Drug Quality Assurance**
  – National drug testing lab and peripheral labs
  – Number of samples tested in the last one year ?; and % failure ?
  – Whether results of testing are published

• **Drug Schedules**
  – Describe the drug schedules
  – Over-the-counter, prescription-only, narcotic & controlled drugs?

• **Drug Price Controls**
  – Describe what price controls exist
  – What monitoring is done
Drug Regulation (3)

• Drug Registration
  – Describe the process for assessing (1) new products for old molecules; (2) new molecules
  – Mention the registration life and fees
  – Describe the capacity to evaluate dossiers and do GMP inspections
  – Discuss registration approval and conflict of interest?

• Drug promotion
  – Pre-approval: number of labels, package inserts, adverts pre-approved in the last one year?
  – Post-approval: number of adverts reviewed in the last one year and number of adverts found to be misleading?
  – Fines for misleading adverts?

• Adverse Drug Reaction (ADR) Monitoring
  – Number of ADRs reported in the last one year?
  – Member of WHO Upsala global monitoring centre?
Drug regulation: summary

• List the good practices and the major problems, and any progress made since the last situational analysis
Drug regulation: suggested solutions

• List some major solutions/recommendations to the problems as identified by the team
National Medicines Policy

• National Medicines (Drug) Policy (NMP)
  – Insert the name and date of the latest NMP document
• Vision
  – Describe the vision statement
• Objectives & Strategies:
  – Describe the objectives and strategies - do they cover
    • Access to medicines
    • Essential Medicines List
    • Rational use of medicines
    • Domestic pharmaceutical industry
    • Regulatory system
• Implementation plan and monitoring
  – Describe the plan and what monitoring has been done
Government Structures

• **Describe the MOH structure**
  – Highlight the major departments concerned with drug management
  – Identify medicines management functions that are not covered by a MOH department (e.g. monitoring use)

• **Describe other Ministries with a role &/or influence in medicines management and policy formation**
  – E.g. Ministries of Education, Trade and Industry, Finance

• **Describe other bodies with a role &/or influence in medicines management and policy formation**
  – E.g. Insurance companies, Accreditation bodies, Professional councils
Coordination and Committees

• Describe how coordination is managed between the different government structures?
  – Is there a high-level mandated committee to advise the Minister of Health on pharmaceutical issues and to coordinate pharmaceutical policy?
  – Is there an executive body in the MOH to carry out the wishes of the high-level mandated committee?

• Identify examples of conflicting policy or policy gaps
  – E.g. conflicting interests between Ministry of Trade and Industry and Ministry of Health over quality, prices, etc.
Drug policy & coordination: summary

• List the good practices and the major problems, and any progress made since the last situational analysis
Drug policy & coordination: suggested solutions

• List some major solutions/recommendations to the problems as identified by the team
Group work

- Each group to draft 3-5 recommendations with practical steps including
  - What will you do?
  - Who will do it?
  - In what time line?
- Groups (maximum 5 slides/group, 20 font minimum)
  - Drug supply
  - Drug selection
  - Promoting rational drug use
  - Drug regulation
  - National medicines (drug) policy and coordination