Module 5. Medicines for Preventive Chemotherapy: Planning, Applying, Managing, Reporting

Sessions 1 & 2. Joint Application Package (JAP) and Drug Supply Chain (DSC) Management
PART 1. JOINT APPLICATION PACKAGE (JAP)
How many forms does the JAP include?
Joint Application Package

- A tool designed to facilitate integrated planning, implementation, M&E, and reporting of preventive chemotherapy interventions. It includes:
  - Joint Request for Selected PC Medicines (ALB, MEB, PZQ, DEC)
  - Joint Reporting Form (ALB, MEB, PZQ, DEC)
  - Annual Work Plan (activities, timeline, costs...)
  - PC Epidemiological Data Reporting Form
FRANÇAIS: http://www.who.int/neglected_diseases/preventive_chemotherapy/reporting/fr/index.html
ESPÁÑOL: http://www.who.int/neglected_diseases/preventive_chemotherapy/reporting/es/index.html
Joint PC Process at Global Level

WHO

Independent review group e.g. RPRG

Joint Request + Joint Report + Annual work plan + EPIRF

ORDER

GSK Eisai J&J Merck KGaA

ALB DEC MBD PZQ

SHIPMENT

AZI ITI

Joint PC

Process at Global Level

National Programme/s
Joint Application Package

- MoHs are invited to submit the JAP electronically, once a year, via WHO CO, WHO RO and WHO HQ.
  - Deadline for submission is **15 August**
  - Request for the following year and Report for the previous year. (e.g. now Request for 2016 and Report on 2014 treatment)

- Applications are reviewed by independent bodies, coordinated by the RO with support from WHO HQ.
### Requesting Medicines – JRSM

#### Joint request for selected PC medicines

The World Health Organization (WHO) manages the supply of albendazole 400 mg tablets (Ethos) to national lymphatic filariasis elimination programmes and national soil-transmitted helminths control programmes. Albendazole 400 mg tablets (Etham) for national lymphatic filariasis elimination programmes, oxamniquine (750 mg per tablet) for national soil-transmitted helminths control programmes, and praziquantel 1.5 mg tablets (Mebendate) for schistosomiasis control programmes. WHO also collaborates to supply isoniazid 3 mg tablets (Mebrafor) for tuberculosis and lymphatic filariasis elimination programmes.

This form constitutes an official government request to WHO for the supply of the above medicines. It can be submitted any time before 15th August of the current year for delivery of medicines during the following year. For example, if preventive chemotherapy is planned between 1 January 2024 and 31 December 2024, this request should be submitted before 15 August 2023.

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
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<tbody>
<tr>
<td></td>
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</tbody>
</table>

#### Number of tablets

Please select the medicine required:

<table>
<thead>
<tr>
<th>Number of tablets</th>
<th>Number of tablets</th>
<th>Total number of tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requested</td>
<td>In stock</td>
<td>In pipeline</td>
</tr>
</tbody>
</table>

#### Number of people to be treated with treated medicines

Please select drug:

<table>
<thead>
<tr>
<th>Number of people treated</th>
<th>Number of people treated</th>
<th>(Round 1)</th>
<th>(Round 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requested</td>
<td>(Round 1)</td>
<td>(Round 2)</td>
<td></td>
</tr>
</tbody>
</table>

### Information to be filled in the form

- **Title:**
- **Name:**
- **Address:**
- **Fax:**
- **Email:**
- **Date:**

**NOTE:**

- Who should fill in the form?
  - National NTD coordinator should complete all required information needed to complete the request form. If the absence of such a coordinator, specific programme managers should coordinate their respective part. The final single request must be approved by the Ministry of Health.

**Name and signature of NTD coordinator or Ministry of Health representative:**

**Date:**
Requesting Medicines - JRSM

• Countries are invited to express their 2016 national needs for the following medicines:
  – **LF**: DEC and ALB
  – **SCH**: PZQ
  – **STH**: ALB or MEB

• Countries should express their needs even if they already secured drug supply from sources other than WHO.
  – This is to improve coordination among all other donors/partners
Requesting Medicines – JRSM

Additional note on PZQ

• PZQ is currently donated only for SAC.
• However, countries that are willing to include adults in the target population of preventive chemotherapy interventions against schistosomiasis, are invited to express the relevant drug needs in the PZQ tab of the JRSM.
• Such request will not appear in the Summary tab, however it will help estimate global drug needs in view of the increased availability of PZQ from 2016 onwards.
Reporting on Treatment - JRF

- The JRF should be used to report on any preventive chemotherapy intervention implemented in 2014.
  - including the use of DEC, ALB, MEB or PZQ
  - Including treatment data whatever the source of the medicines is (WHO or other partners or direct purchasing)
  - data by sub-national level (e.g. district) for the ENTIRE COUNTRY

- Only treatment data should be included in JRF.
  - M&E data e.g. mapping SS/SC, morbidity data and TAS results should be included in EPIRF
Annual Work Plan (AWP)

- **AWP** (Excel table) should indicate the **planned schedule and funding situation** of key PC activities during the year for which drugs are requested.

### Annual Work Plan Matrix and Timeline

<table>
<thead>
<tr>
<th>Activities - Sub-Activities</th>
<th>Timeline for implementation</th>
<th>Estimated cost</th>
<th>Funding</th>
<th>Gap</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Jan</td>
<td>Feb</td>
<td>Mar</td>
<td>Apr</td>
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<tr>
<td></td>
<td>LCU</td>
<td>LCU</td>
<td>LCU</td>
<td>LCU</td>
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<tr>
<td>Strategic planning</td>
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<tr>
<td>- Social mobilisation</td>
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<tr>
<td>- Development of IEC materials</td>
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<tr>
<td>- Dissemination of IEC materials and messages</td>
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<tr>
<td>- MDA training</td>
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<tr>
<td>- Training of supervisors</td>
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<tr>
<td>- Training of health workers</td>
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<td></td>
</tr>
<tr>
<td>- Registration</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>- MDA drug distribution</td>
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<tr>
<td>- Trachoma MDA</td>
<td></td>
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</tr>
<tr>
<td>- IT and SC MDA</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>- Malaria control and support</td>
<td></td>
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<tr>
<td>- Trachoma surgery</td>
<td></td>
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<tr>
<td>- TB and SC Malaria control and support</td>
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<td></td>
</tr>
<tr>
<td>- TB and SC Malaria treatment</td>
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<td></td>
</tr>
<tr>
<td>- Office Running Costs</td>
<td></td>
<td></td>
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<tr>
<td>- Others</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Estimated cost**:
- LCU (Local Currency Units)
- Funding
- Gap (LCU)
Epidemiological Data Reporting Form (EPIRF)

- **Epidemiological Data Reporting Form (EPIRF)** should indicate:
  - new mapping data completed recently
  - M&E data (e.g. SS/SC survey results)
  - TAS results
  - >>> used to revise the estimates of population requiring PC
  - morbidity-related data

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**Module 5: Medicines for Preventive Chemotherapy**

**Sessions 1 & 2: Joint Application Package (JAP) and Drug Supply Chain (DSC) Management**
Where Can I Find the Forms?

- All forms are available in English: [http://www.who.int/neglected_diseases/preventive_chemotherapy/reporting/en/](http://www.who.int/neglected_diseases/preventive_chemotherapy/reporting/en/)
- ... in French: [http://www.who.int/neglected_diseases/preventive_chemotherapy/reporting/fr/](http://www.who.int/neglected_diseases/preventive_chemotherapy/reporting/fr/)
- ... and in Spanish: [http://www.who.int/neglected_diseases/preventive_chemotherapy/reporting/es/](http://www.who.int/neglected_diseases/preventive_chemotherapy/reporting/es/)
- A **userguide** on how to fill the forms is available (English only, currently being translated into Fr and Sp): [http://apps.who.int/iris/bitstream/10665/83962/1/9789241505499_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/83962/1/9789241505499_eng.pdf?ua=1)
- **Video tutorials** are also available
Managing Drug Flow is Almost Managing the Whole Programme

**Step 1**
- Annual work planning
- Drug forecast
- Drug request (including treatment planning)
- Drug supply

**Step 2**
- Drug distribution (PC) &
- Its related work (survey, M&E)

**Step 3**
- Treatment reporting
Who should fill the JAP?
JAP: Take Home Message

• Submission deadline is 15 August 2015 (at latest).
  – Requests can be accepted all year round but the earlier submitted the better (i.e. more timely delivery of medicines)
  – It will take at least 6 months between submission of the request and delivery
• The forms do not necessarily need to be submitted all together. You can submit whichever form as soon as they are completed.
• A bottom-up approach is recommended: MoHs fill the forms in coordination with partners, with the support of WHO COs/Ros.
  – Submission is by email: pc_jointforms@who.int
PART 2. DRUG SUPPLY CHAIN (DSC) MANAGEMENT
Objectives of Drug SCM System

- To provide the correct **quantity** of PC drugs.
- To provide the correct **quality** of PC drugs.
- To the correct **location** (where needed and most strategic).
- At the correct **time** (in time for treatment, no stock outs or overstocks).
- At the lowest possible **cost**.
## Preparing for Shipment

<table>
<thead>
<tr>
<th>Green Light Check List</th>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>Are the customs agents aware of the shipment and the quantities of the shipment?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Customs Clearance Waiver</td>
<td>Has the customs clearance duty waiver been prepared?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Customs Duty</td>
<td>Is the money ready to pay for duty for the inbound shipment?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Warehouse Space</td>
<td>Does the central medical store have space to receive the shipment?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Distribution</td>
<td>Is the program prepared to distribute the drugs?</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

Receipt and Inspection

• Inspect the shipment and give feedback to suppliers and the donation programme on compliance to contract or donation specifications.
  – Quantity-damaged or short landed items included
  – Drug Type
  – Presentation
  – Packaging and labeling

**Note some countries require pre-inspection before shipment.**
Port Clearance: Shipping Documents

- **Certificate of Donation** - Confirms source, authenticity, sent by donation program.
- **Pro Forma Invoice** - confirms quantities, source of products shipped, sent by supplier/donation program prior to shipment, used for application for duty waivers, ex and taxes exemptions. It can also be used for Drug Regulatory Authority approvals.
- **Invoice** - final document provided by the shipper stating costs, freight, insurance.
- **Certification of Analysis** - it is usual practice for a buyer to insist on certification. Usually NTD programs are WHO pre-qualified.
- **Certificate of Origin** - documents stating that the products were produced by the manufacturer stated.
- **Airway Bill, Packing List, Bill of Laden** - issued by the shipper, indicates which vessel (by air or by sea), date of departure and arrival. Originals accompany goods, but copies are scanned and sent to NTDPs prior to arrival of goods to be used to alert clearing agent of Expected Date of Arrival (EDA).
Examples of Poor Storage

- Inadequate storage space and organization for drugs and laboratory products.

Photos provided by Management Sciences for Health
Examples of Poor Storage

- Poor storage conditions for pharmaceutical and laboratory products.

*Photos provided by Management Sciences for Health*
Examples of Good Storage

- Inventory management can be conducted with ease and bin cards can be affixed to the shelves.

*Photos provided by Management Sciences for Health*
Distribution Plan

- Should be based on schedule of drug distribution at the district level.
- Communications with storage facilities to ensure adequate capacity & supply.
- All districts must receive full supply at least 2-3 weeks before distribution begins.

### Shelf Life

<table>
<thead>
<tr>
<th>Medication</th>
<th>Shelf Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALB, MBD</td>
<td>60 months</td>
</tr>
<tr>
<td>IVM, DEC</td>
<td>36 months</td>
</tr>
<tr>
<td>PZQ</td>
<td>24 months</td>
</tr>
<tr>
<td>AZM tablets</td>
<td>48 months</td>
</tr>
<tr>
<td>AZM pediatric oral suspension (before reconstitution)</td>
<td>36 months</td>
</tr>
<tr>
<td>AZM pediatric oral suspension (after reconstitution)</td>
<td>10 days</td>
</tr>
</tbody>
</table>
Why do drugs sometimes expire at the national, subnational or district levels?

How can we avoid this?
MDA and Village Health Volunteers (VHV)s
Scenario A

Community-based distribution

- Drugs have arrived (when and where)
- Distributors are trained and ready
- Communities are informed and come for treatment
- MDA takes place
What are the key concerns regarding the PC drugs at this point, for you as a NTDP Manager?
Drug SCM and Logistics

• What stock transfer strategies could be employed?
• Are there alert systems that can be put in place?
• How do you retrieve and account for unused stock after the MDA?
• Are there logistics concerns for other supplies needed for the MDA?
What information needs to be collected as part of the treatment intervention – specific to drug SCM?
Record Keeping and Information Reporting

- Should include:
  - # drugs at the beginning of the treatment
  - # drugs used for treatment
  - # drugs wasted
  - # drugs expired
  - # drugs remaining at the end of the treatment
Who is responsible for this information collection and how does it return to you as a Programme Manager?
Drug SCM at the Point of Distribution

• Key concerns:
  – Drug is given in correct dose to persons in need
  – Exclusion criteria are understood by CDDs and communities

• Who is responsible?
• CDDs must give the right information.
• CDDs must do the right thing so as to ↓ the chances of AE/SAEs.
• CDDs should be able to recognize and give appropriate initial management/referral for SAEs.
• Children are not forced to swallow tablets and risk choking.
• Children are not taking tablets when hungry or dehydrated.
## Dosage and Exclusion Criteria

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
</table>
| **IVM** | 150-200 μg/kg using tablet pole • 1 tablet • 2 tablets • 3 tablets • 4 tablets | • <5 years of age • Pregnant women • Severely ill • <1 week postpartum mothers  
IVM where Loa loa is endemic, assessed by RAPLOA is justified only when oncho prevalence is >40% |
| | • 90-120 cm (35-47”) • 120-141 cm (47-55”) • 141-159 cm (55-63”) • >159 cm (>63”) | |
| **DEC** | 6 mg/kg or by age • 100 mg • 200 mg • 300 mg | • Sick individuals • <2 years of age • Pregnant women • DEC is contraindicated in areas where oncho and loiasis might co-exist |
| | • 2-5 years of age • 6-15 years of age • >15 years of age | |
## Dosage and Exclusion Criteria

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
</table>
| ALB  | One 400 mg tablet per person | < 2 years of age  
Pregnant women in 1st trimester |
| MBD  | One 500 mg tablet per person | <1 year of age  
Pregnant women in 1st trimester |
| PZQ  | 40 mg/kg using pole  
600 mg tablets  
•1 tablet  
•1 1/2 tablets  
•2 tablets  
•2 1/2 tablets  
•3 tablets  
•4 tablets  
•5 tablets |  
• 94-110cm (37-43”)  
• 110-125cm (43-49”)  
• 125-138cm (49-54“)  
• 138-150cm(54-59“)  
• 150-160cm(59-63“)  
• 160-178cm(63-70“)  
• >178cm(70“)  
<4 years of age |
| AZM  | 20mg/kg using dose pole  
250 mg tablets | <6 months of age |
Tools for the Drug Distributor

- Standardized Height-Based Treatment Schedule for azithromycin POS and tablets for Trachoma.

![Graph showing standardized height-based treatment schedule for children aged 5 to 15 years and 6 months to 5 years, with dosages for different height ranges.](image)
Looking at all the components of the distribution cycle, what are the areas where monitoring and supervision is most critical?
What are the key messages from this session?
Key Messages

• By understanding SCM and issues that can delay or interrupt it, NTD PMs can better plan and implement effective MDA.

• A detailed Distribution and Transportation Plan is an essential part of SCM.

• As the last point of drug SCM and the primary point of contact with the community, CDDs play a critical role in distribution and reporting.

• Effective CDD training, job aids, support, and supervision should be provided.

• Respect the season of availability of CDDs and communities to participate in MDA.
Thank you