Standard operating procedures

for supply chain management of health products for **neglected tropical diseases** amenable to preventive chemotherapy

World Health Organization

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Cover illustration: WHO/Sam Bradd

Contents

Tables

Figures

Acknowledgements

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Overview

WHO plays a major role in the cycle of supply chain management for donated and/or procured health products for neglected tropical diseases (NTDs) amenable to preventive chemotherapy and individual case management.

This first edition describes the standard operating procedures for health products for NTDs amenable to preventive chemotherapy and the medicines donated to treat them. These include albendazole for lymphatic filariasis and soil-transmitted helminthiases; azithromycin for trachoma and yaws; diethylcarbamazine citrate for lymphatic filariasis; ivermectin for onchocerciasis and lymphatic filariasis; mebendazole for soil-transmitted helminthiases; praziquantel for schistosomiasis; and triclabendazole for foodborne trematodiases.

Standard operating procedures for diseases amenable to case management will be covered in subsequent editions, including the application process for requesting medicines (Chapter 1). In the meantime, the procedures described in the rest of the document apply for both case management and preventive chemotherapy NTD health products.

WHO and the NTD Supply Chain Forum prepared this set of standard operating procedures to reflect key characteristics in the supply chain management of health products including donated medicines for use in mass drug administration (MDA) at the country level. Health ministries and national programmes for NTDs are encouraged to adopt and adapt them to their country context.

The role of the supply chain in MDA

MDA plays a role in the primary prevention of NTDs amenable to preventive chemotherapy by decreasing transmission rates in populations at risk. The effectiveness of the MDA strategy depends on epidemiological coverage, which is defined by WHO-recommended targets for the proportion of the total population ingesting the medicines during MDA.

In order to meet the coverage targets the supply chain must be managed, from planning and quantifying needs, to moving stock from production sites to patients at the service delivery point to communities, schools and hospitals, among others, and to retrieving and accounting for leftover stock, and all steps in between, as outlined in Fig. 1.

Objectives of these standard operating procedures

These standard operating procedures are intended to help strengthen the capacity of health ministries and national NTD programmes to mainstream and institutionalize efficient management of the supply chain for NTD medicines. They outline supply chain tasks and responsibilities before, during and after MDA. They also present key considerations for optimizing planning and implementation of supply chain activities in the country.

These procedures support the realization of the goal set in the WHO 2030 road map for NTDs: an effective supply chain that ensures timely access to and availability of quality-assured medicines, products and pharmaceutical supplies at all levels and avoiding, e.g. stockout, wastage, loss of tablets *(1)*.

Target audience

The procedures are intended for use as a reference document by responsible persons and key stakeholders of the NTD supply chain, as illustrated below.

Responsible persons and key stakeholders include both organizations and individuals.

Organizations

Health ministries, national NTD programmes, central medical stores, national procurement and logistics agencies, regional and district medical stores, frontline health facilities, schools and national educational institutions.

Individuals

National NTD programme staff and stakeholders, medical stores staff at all levels – pharmacists and warehouse managers, NTD focal persons and MDA supervisors, community health workers and community drug distributors.

Fig. 1. Key supply chain focus areas
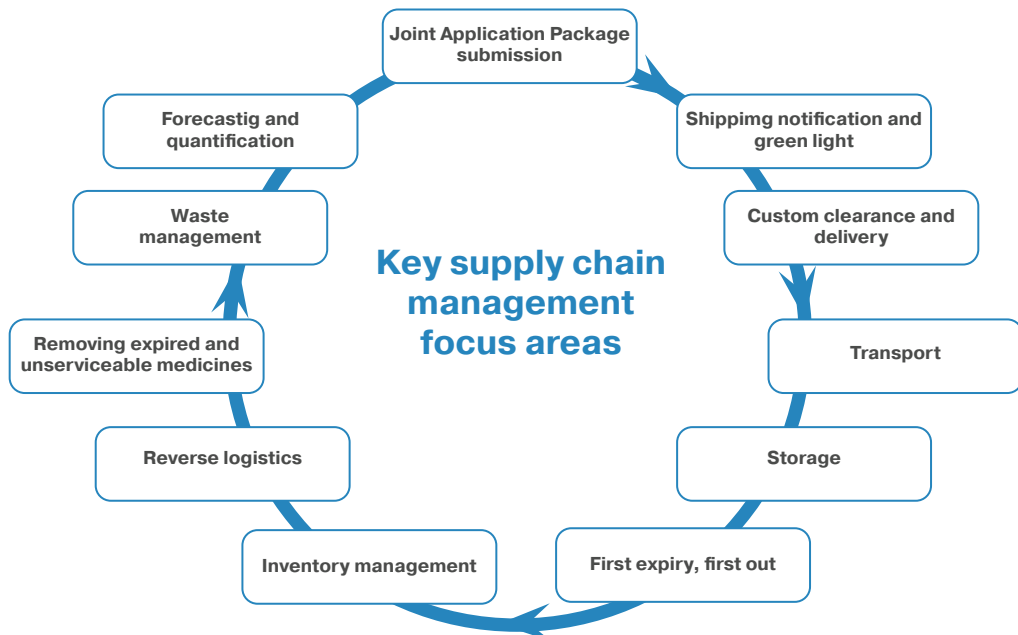
Standard operating procedure by number and MDA timeline

The 11 procedures are shown in **Fig. 2** in their relevant order before, during and after MDA.

Template for standard operating procedures

For each of the 11 procedures the following template is used.

Task	Instruction	Responsibility	References
The timeframe specific for the tasks in this part of the process	Main job role(s) of those responsible for the specific tasks in this part of the process	Key points for the specific tasks in this part of process	Key instructions in this part of the process, in order of activity and/or as listed in the table

The positions and roles identified under responsibility and the instruction for each task are illustrative and should be adjusted according to the local context. Chapter numbers for related procedures and other relevant guidance are listed under references. A glossary of terms is provided as **Annex 1**. Sample template forms and document examples are included as **Annexes 2–12**. If support is needed to develop templates, please contact WHO for assistance (PC_JointForms@who.int).

Fig. 2. Standard operating procedures by number and MDA timeline
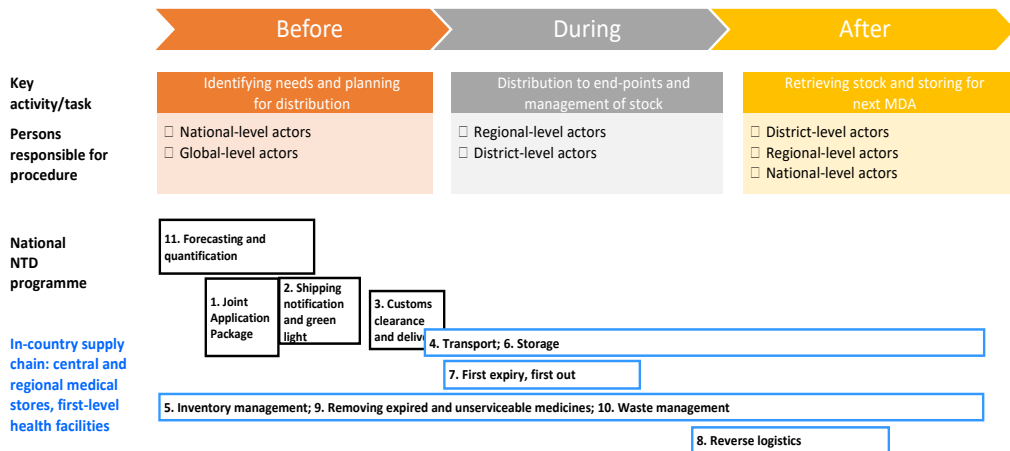
Task	Instruction	Responsibility	References
1	Instruction described in one sentence 1.1. Detailed steps required to fulfil the instruction 1.2. 1.3.	Main job role(s) responsible for the specific instruction	Relevant chapters for related procedures, guidance and annexes

Dissemination and implementation

These standard operating procedures may be used to inform or supplement existing national procedures for supply chain management of health commodities. Where such procedures do not exist or do not address NTD medicines, the current procedures can be adapted to the country context and the national programme. WHO will add additional procedures as needed based on country feedback. For information and assistance, please contact WHO (PC_JointForms@who.int).

References

1. Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021–2030. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/338565, accessed 18 March 2022).

Illustration: WHO/Sam Bradd

Introduction

Preventive chemotherapy and individual case management are core strategies to control, eliminate or eradicate NTDs. Health products (medicines, diagnostics and other supplies) donated for this purpose underpin the success of NTD programmes. Global coordination by WHO safeguards access to medicines for countries in which NTDs are endemic to ensure rational use and reporting, monitoring, evaluation and accountability. Global coordination also contributes to the achievement of outcome 1.3 of WHO's Thirteenth General Programme of Work 2019–2023 (Improved access to essential medicines, vaccines, diagnostics and devices for primary health care), the NTD road map targets for 2030 *(1)* and target 3.8 of the Sustainable Development Goals (Achieve universal health coverage, including access to safe, effective, quality and affordable essential medicines and vaccines for all).

WHO manages most of the health products for NTDs that are either donated by pharmaceutical companies or procured by WHO for use by Member States. The main roles of WHO are to coordinate with and liaise among endemic countries and pharmaceutical donors and ensure that quantities of requested medicines are appropriate and effectively and rationally distributed.

WHO plays a major role in the cycle of supply chain management for donated health products for NTDs amenable to preventive chemotherapy and case management. It facilitates quantification and forecasting as well as timely review and processing of requests for medicines. WHO also coordinates logistic arrangements with pharmaceutical companies and global freight forwarders to ensure that safe, quality-assured health products are made available easily and equitably and are readily accessible to populations in need free of charge. Technical assistance is provided to Member States in managing and monitoring stock balances, minimizing wastage and avoiding expiry of medicines. Overall, WHO works to improve access to universal health coverage for those affected by NTDs and supports the global NTD community in the smooth running of the supply chain management cycle.

The global NTD community, like many other health sectors, faces several challenges and hindrances in the supply chain management cycle. These include selection of

health products, quantification and forecasting, supply planning and procurement to final delivery and consumption, reporting from primary health care units to national levels, and compliance with accountability and transparency requirements as a guarantee of the sustainability of the supply chain for donated health products. As in many areas of health, most of the issues are related to capacity, financial resources, infrastructure, human resources and a lack of tools and awareness related to management of essential health products.

The campaign nature of NTD programmes puts particular stress on supply chain management systems in countries where NTDs are endemic by requiring large boluses of medicines, diagnostics and other medical products to be delivered in relatively narrow timeframes for the purposes of MDA, surveys or other campaign-style events.

Following a consultative assessment exercise with Member States, 11 key supply chain areas were identified and prioritized and a set of specific standard operating procedures were developed by members of the NTD Supply Chain Forum.

The procedures are intended to help strengthen the capacity of health ministries and NTD programmes in mainstreaming and institutionalizing efficient supply chain management for NTD health products including donated medicines. They outline supply chain tasks and responsibilities before, during and after MDA and present key considerations for planning and implementing related activities within countries. They are intended to serve as templates for countries to adapt to their unique contexts, from national to primary health care unit levels. The intention is to help health workers improve their skills in handling, delivering and managing NTD commodities and provide an entry point for managing essential health products for communicable and noncommunicable disease health programmes.

References

1.   Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021–2030. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/338565, accessed 18 March 2022)

1. Joint Application Package

WHO NTD programmes coordinate the donation or/and procurement of health products for diseases amenable to both preventive chemotherapy and case management. This chapter describes the procedures for requesting medicines for the preventive chemotherapy diseases. Most of the requests are consolidated and submitted through the Joint Application Package; separate forms are used to request medicines for foodborne trematodiases, taeniasis and cysticercosis, trachoma and yaws. Most of these forms will be included in the Joint Application Package in due course (see **Table 1.1** for details). The case management diseases have also their own individual medicine request forms and donation management processes, which are beyond the scope of this chapter. Eventually, all requests for medicines will be integrated and reflected in subsequent editions of this document.

1.1   Purpose and scope of this standard operating procedure

This procedure provides technical guidance to national NTD programmes and implementing partners on preparing and submitting the Joint Application Package to request medicines for preventive chemotherapy.

The Joint Application Package is a set of four forms:

■   the Joint Request for selected medicines;

■   the Joint Reporting Form;

■   the Epidemiological Reporting Form; and

■   the Annual Workplan (optional).

Table 1.1. Preventive chemotherapy medicines request forms and management details

Medicine	Disease	Medicine request form	Review process	Donation coordinator
Diethylcarbamazine citrate (100 mg tablets)	Lymphatic filariasis	JRSM	RPRG	WHO
Mebendazole (500 mg tablets)	Soil-transmitted helminthiases[1]	JRSM	RPRG	WHO
Albendazole (400 mg tablets)	Lymphatic filariasis	JRSM	RPRG	WHO
	Soil-transmitted helminthiases	JRSM	RPRG	WHO
Praziquantel (600 mg tablets)	Schistosomiasis	JRSM	RPRG	WHO
Ivermectin (3 mg tablets)	Onchocerciasis	JRSM	MEC	Mectizan® Donation Program
	Lymphatic filariasis in co-endemic countries	JRSM	MEC	Mectizan® Donation Program
	Lymphatic filariasis for triple therapy MDA	JRSM	MEC	Mectizan® Donation Program
Azithromycin (250 mg tablets or 1200 mg in 30 mL (200 mg/5 mL) powder for oral suspension)	Trachoma	TEMF	TEC	International Trachoma Initiative
Azithromycin (500 mg tablets)	Yaws	Standalone request form	WHO	WHO
Triclabendazole (250 mg tablets)	Foodborne trematodiases	Standalone request form	WHO	WHO
Praziquantel (600 mg tablets) or niclosamide (400 mg tablets)	Taeniasis and cysticercosis	Standalone request form	WHO	WHO

JRSM: Joint Request for Selected Medicines; MDA: mass drug administration; MEC: Mectizan Expert Committee; RPRG: Regional Programme Review Group; TEC: Trachoma Expert Committee; TEMF: trachoma elimination monitoring form.

The Joint Request for selected medicines and the Annual Workplan should be submitted at least 10 months before the planned date of MDA. The Joint Reporting Form should be submitted no later than 3 months after completion of the last implementation round in a reporting year. This early stage of planning for MDA is a required step for countries to receive their allocations of medicines.

WHO facilitates the supply of many donated medicines for preventive chemotherapy as part of global efforts to accelerate the expansion of control and elimination of lymphatic filariasis, onchocerciasis, schistosomiasis and soil-transmitted helminthiases. The medicines are (in alphabetical order):

■ albendazole for lymphatic filariasis and soil-transmitted helminthiases;

■ azithromycin for yaws;

■ diethylcarbamazine citrate for lymphatic filariasis;

■ ivermectin for onchocerciasis and lymphatic filariasis;

■ mebendazole for soil-transmitted helminthiases;

■ niclosamide or praziquantel for taeniasis and cysticercosis;

■ praziquantel for schistosomiasis; and

■ triclabendazole for foodborne trematodiases;

A joint mechanism and a set of forms facilitate the application process and improve coordination and integration among NTD programmes. This Excel-based tool is designed to assist countries in quantifying the number of tablets of each medicine required to reach the planned target population and districts for the year of request. The output is a joint request for preventive chemotherapy medicines, which can be printed, signed and submitted to WHO.

(The donation process for azithromycin for the elimination of trachoma as a public health problem is similar to that used for the preventive chemotherapy medicines; the separate application process and timeline are described in section 1.5.1. Further details of the medicines donated by pharmaceutical companies for preventive chemotherapy are shown in **Table 1.2**).

1.1.1   Planning the submission process

■ The set of four forms facilitates the process of applying for the medicines, reporting on their use and planning for their distribution during MDA.

■ The forms are "joint" because they can be used to apply for, report on and plan for the distribution of five preventive chemotherapy medicines donated through WHO; they constitute a Joint Application Package and should be submitted together (**Fig. 1.1**).

■ To ensure the medicines are delivered on time, the request for preventive chemotherapy medicines should be submitted 10 months before the planned date(s) of MDA, regardless of when it is planned.

    ■ Countries can and should submit their application any time during the year.

        – For example, if a country plans to conduct MDA in October 2021, it should submit the Joint Application Package by January 2021 and without waiting any deadline.

Table 1.2. Medicines donated for preventive chemotherapy, by pharmaceutical company

Company (location)	Medicine	Quantity donated	Disease	Commitment	Donation coordinator
Eisai (Japan)	Diethylcarba-mazine citrate (100 mg)	2 200 000 000 tablets total	Lymphatic filariasis	Until elimination	WHO
Johnson & Johnson (United States)	Mebendazole (500 mg)	200 000 000 tablets annually	Soil-transmitted helminthiases[1]	Until 2025	WHO
GlaxoSmithKline (United Kingdom)	Albendazole (400 mg tablets)	600 000 000 tablets annually	Lymphatic filariasis	Until elimination	WHO
		400 000 000 tablets annually	Soil-transmitted helminthiases[1]	Until elimination	WHO
Merck KGaA (Germany)	Praziquantel (600 mg)	250 000 000 tablets annually	Schistosomiasis[1]	Unlimited	WHO
Merck, Sharpe and Dorne (United States)	Ivermectin (3 mg)	Unlimited	Onchocerciasis	Until elimination	Mectizan® Donation Program
		Unlimited	Lymphatic filariasis in co-endemic countries	Until elimination[2]	Mectizan® Donation Program
		Up to 100 000 000 treatments annually	Lymphatic filariasis for triple therapy MDA	Until 2025	Mectizan® Donation Program
Pfizer (United States)	Azithromycin (250 mg tablets or 1200 mg in 30 mL (200 mg/5 mL) powder for oral suspension)	Unlimited	Trachoma	1998–2025	International Trachoma Initiative
Bayer (Germany)	Niclosamide (400 mg)	Up to a total of 2 800 000 tablets	Taeniasis and cysticercosis	2020–2024	WHO
	Praziquantel (600 mg)	Up to a total of 1 339 000 tablets			
EMS SA Pharma (Brazil)	Azithromycin (500 mg)	153 million tablets	Yaws	2019–2023	WHO

Source: adapted from **Fig. 11** of reference *(2)*.

[1] For treatment of school-aged children.

[2] In Yemen and African countries where lymphatic filariasis and onchocerciasis are co-endemic.

– Countries are responsible for planning their joint application packages to ensure the medicines arrive in time for MDA; WHO and the pharmaceutical companies also need significant lead time to ensure the accuracy of applications, to manufacture and ship the medicines, and then for the medicines to clear customs in the country. This is why it is essential to submit the application 10 months before the MDA.

■ When submitting in 2021, for example, the application should include information on planned activities and a request for medicines to be used in year x+1 (i.e. 2022), together with the report on preventive chemotherapy interventions conducted in year x-1 (i.e. 2020).

The four forms and their uses are explained below.

■ **Joint Request for selected preventive chemotherapy medicines** (version 3.1). This form should be used to request albendazole, diethylcarbamazine citrate, ivermectin, mebendazole and praziquantel for use in the year after the year of application.

■ For ivermectin, WHO also shares a copy of this form with the Mectizan® Donation Program, using the JRSM form (see Table 1.1).

■ For triple therapy with ivermectin, diethylcarbamazine citrate and albendazole (IDA), a separate Joint Request and Joint Reporting Form are not needed. However, additional documentation for ivermectin donations is needed by the Mectizan® Donation Program. The application process is summarized in section 1.3.2.

Fig. 1.1. Joint Application Package submission process

Submission	Joint review	Placing order	Manufacture and shipment
• Joint Reporting Form for the previous year • Joint Request for selected PC medicines for the following year • PC Epidemiological Data Reporting Form	• Review and approval of the request	• Discussion and consultation among WHO, manufacturer and country • WHO places order to manufacturers	• 6–8 months for manufacturing and shipping

If forms need to be revised

Submission of the Joint Application Package → 2 weeks → 2 weeks → 6–8 months

Submit any time **before 15 August** of the current year for delivery of medicines during the following year

- Countries co-endemic for loaiasis should use a specific version of the Joint Request for selected medicines to request albendazole for interventions against lymphatic filariasis in non-onchocerciasis endemic areas endemic for loaiasis.

  Exception: The Joint Request form cannot be used to apply for azithromycin for trachoma or triclabendazole for fascioliasis and paragonimiasis; a separate application process is used (see section 1.5.1).

- **Joint Reporting Form**. This form is designed to assist countries in reporting annual progress on integrated and coordinated distribution of medicines across diseases in the reporting year in a standardized format.

  - Countries co-endemic with *Loa Loa* should use a specific version of the Joint Reporting Form to report on interventions against lymphatic filariasis in non-onchocerciasis endemic areas endemic for loaiasis.

- **Epidemiological Reporting Form**. This form is designed to standardize national reporting of epidemiological data on lymphatic filariasis, onchocerciasis, schistosomiasis and soil-transmitted helminthiases. National authorities are encouraged to complete this form and submit it to WHO annually, together with the Joint Reporting Form.

- **Annual Workplan**. This form provides information on the key preventive chemotherapy and collateral activities planned by health ministries for lymphatic filariasis, onchocerciasis, schistosomiasis and soil-transmitted helminthiases in the year of use of the requested medicines.

Further details of preventive chemotherapy and the Joint Application Package, including downloads to the latest multilingual versions of the forms, are available on the WHO website *(1)*.

1.1.2   Completing the forms

The Ministry of Health and its designated officer are responsible for completing the forms, which should be officially signed by a designated authority to request medicine in the country and submitted to the WHO country office of the respective country. Typically, national NTD coordinators, in collaboration with the responsible authority managing medicine procurements, are the most appropriate people to compile all the required information for the Joint Application Package. In their absence, programme managers for each of the targeted diseases should coordinate their respective parts for the joint forms with the assistance, if available, of the national pharmacy or medical stores, to ensure inclusion of existing stock in the country. Technical assistance from implementing partners supporting national programmes is also readily available and is encouraged to assist with preparing the Joint Application Package.

1.1.3   Approval process

Regional Programme Review Group process

After submission to WHO, the WHO secretariat validates the data, reviews them jointly with WHO regional offices and headquarters, and provides feedback to countries for correction. This is one of the most time-consuming periods of the entire process, mainly because it involves feedback from countries. Once in good order, the completed Joint Application Package is submitted by WHO to the Regional Programme Review Group for review and approval. This technical and advisory group of independent experts provides overall strategic and operational review of national and regional NTD programmes with the objective of accelerating the control and elimination of targeted NTDs. One of its mandates is to review applications for medicines submitted by countries to WHO, including for the following preventive chemotherapy medicines: albendazole, diethylcarbamazine

citrate, ivermectin, mebendazole and praziquantel. The group meets once annually to review applications and virtually on an ad hoc basis. The recommendations of the group are considered in the donation process. For requests for ivermectin for treatment of onchocerciasis and lymphatic filariasis using triple medicine (IDA) therapy, the review and approval process is through the Mectizan® Expert Committee outside WHO.

1.1.4   Advantages of the joint forms for national programmes

The Joint Request for selected medicines assists countries to quantify the number of tablets of the relevant medicines required to reach the planned target populations and districts in a coordinated and integrated manner against multiple diseases for the year of request. The output of the tool is a 2-page summary worksheet, which can be printed, signed, scanned and submitted to WHO together with the full version of the form in order to apply for the medicines. To expedite the application process, the worksheet should be submitted to WHO together with soft copies of the Joint Reporting Form and the Epidemiological Reporting Form. The application process is shown in **Fig. 1.2**.

Any changes to this process will be communicated and the standard operating procedure updated accordingly.

case management diseases have also their own individual medicine request forms and donation management processes, which are beyond the scope of this chapter. Eventually, all requests for medicines will be integrated and reflected in subsequent editions of this document.

Fig. 1.2. Application process for donated preventive chemotherapy medicines

ALB: albendazole; DEC: diethylcarbamazine citrate; GSK: GlaxoSmithKline; IVM: ivermectin; J&J: Johnson & Johnson; MBD: mebendazole; MDP: Mectizan© Donation Program; PC: preventive chemotherapy; PZQ: praziquantel

1.2   Key considerations

The requirements for the Joint Request for selected preventive chemotherapy medicines are:

■   submission of the completed Joint Report with latest available treatment data for a calendar year;

■   in-country available inventory of preventive chemotherapy medicines;

■   funding sources availability; and

■   completion with up-to-date status of endemicity for each of the diseases based on latest available prevalence data submitted through the Epidemiological Data Reporting Form, if surveys were conducted.

The data collected during this process allow the donation programme to determine the long-term needs for medicines in a particular country and to evaluate progress towards elimination. Delays in submitting the annual applications and not adhering to the timelines can impact the availability of medicines to meet in-country requirements.

1.3   Standard operating procedure

The positions identified, their roles and the steps to be taken in this procedure are illustrative and should be adjusted according to the prevailing context in each country.

1.3.1   Preparing and submitting the Joint Application Package (for albendazole, diethylcarbamazine citrate, ivermectin, mebendazole and praziquantel)

When	Who	What	How
The application to request preventive chemotherapy medicines should be prepared, filled in and submitted for review and approval at least 10 months before the planned date of MDA. Given the amount of documentation and data needed to prepare the application and the time required to identify and gather it, it is recommended to begin preparation at least 2 months before submission to ensure timely submission to and approval by WHO.	■ National NTD programme manager/national NTD programme coordinator ■ Implementing partners ■ Monitoring and evaluation manager ■ Supply chain manager/NTD pharmacist or logistician ■ NTD pharmacist and/or logistician	■ Updating mapping and country information on NTDs (e.g. population requiring preventive chemotherapy. This is calculated automatically, but countries should provide population data for the entire country by implementation unit, status of endemicity, number of treatment rounds planned and implemented, MDA dates, treatment data, stock inventory balance, funding availability, assessment reports (e.g. transmission assessment survey, Epidemiological Data Reporting Form)). ■ Completing the four forms. ■ Final review and submission of the filled in forms.	1. Fill in the four forms with accurate and complete information as noted at left. 2. Cross-check the quantification outputs and adjust them based on the current available balance stock. 3. Verify other funding sources of supply in the country.

Task	Instruction	Responsibility	References
1	Meet with stakeholders to identify and gather needed documentation and data (at least 2 months before submission). 1.1. Review previous year pre-approval feedback to determine causes for persistent approval delays. 1.2. Develop solutions to prevent repeat delays. 1.3. Discuss and assign responsibilities for gathering components. 1.4. Schedule a preparatory meeting to serve as the deadline for gathering the required documentation.	■ NTD programme manager ■ Implementing partners ■ Monitoring and evaluation manager ■ Supply chain manager/NTD pharmacist or logistician	*(1)* Refer to previous year's Joint Application Package and WHO feedback See Chapter 8: Reverse logistics See Chapter 11: Forecasting and quantification
2	Complete the Joint Reporting Form for the previous year (no later than 3 months after the last implementation round completed in a reporting year). The epidemiological data should be submitted in the Epidemiological Reporting Form whenever a country conducted epidemiological surveys and results are completed. 2.1. Convene a meeting with stakeholders to gather all the treatment data from the field. 2.2. Generate the Joint Reporting Form using the data received from the field and other available sources.. 2.3. Review the final Joint Reporting Form and submit it for approval.	■ NTD programme manager ■ Implementing partners ■ Monitoring and evaluation manager	*(1)*
3	Complete the Joint Request for selected medicines (at least 10 months before the planned MDA). 3.1. Convene a meeting with stakeholders to present all the required country NTD information necessary to complete the request. 3.2. Complete the request using the accurate information compliant with the local NTD context and status. 3.3. Review the completed request and submit it to WHO country and regional offices for regional review and clearance. If requesting medicines for IDA, verify eligibility guidelines.	■ NTD programme manager ■ Implementing partners ■ Monitoring and evaluation manager ■ Supply chain manager/NTD pharmacist or logistician	See Chapter 5: Inventory management See Chapter 6: Storage See Chapter 8: Reverse logistics *(3)* See section 3.1.2 Supplementary application process for ivermectin for triple (IDA) therapy
4	Complete the Annual Workplan (at least 10 months before the planned MDA). 4.1. Download the Annual Workplan from the ESPEN Portal or the WHO website. 4.2. Fill in the workplan and share it for review.	■ NTD programme manager ■ Implementing partners ■ Monitoring and evaluation manager	*(1, 4)*

1.3.2 Supplementary application process for ivermectin for triple (IDA) therapy

Countries should use the Joint Request for selected medicines form to apply for ivermectin *(1)*.

Within the time limits recommended by WHO, the application should be submitted to:

■ the NTD department of the WHO regional office together with the supporting documents; and

- the Mectizan® Donation Program together with:

  - the revised master plan with IDA adopted by the health ministry as a strategy to eliminate lymphatic filariasis;

  - the Annual Workplan including districts targeted for IDA and the strategy for implementing IDA with effective coverage and post-intervention monitoring and evaluation;

  - the epidemiological evidence of eligibility for IDA for each district; and

  - the signed agreement with the Program to receive and distribute ivermectin.

Applications for ivermectin follow the WHO review mechanism for the Joint Application Package as described above. However, the final decision regarding the number of implementation units to be approved is made by the Mectizan® Expert Committee based on the 280 million tablets allocated annually for IDA up until 2025. Members of the Committee submit recommendations to the Program. Since the expanded donation for IDA is a special provision to facilitate access to ivermectin and accelerate elimination, all applications, either initial or re-applications, are discussed among Committee members who decide whether or not to provide the medicines.

Re-applications for ivermectin to perform a second round of IDA are prioritized. A third round is conditional upon:

- successful implementation of the previous donations with high coverage; and

- data on monitoring and evaluation that justify the need to implement additional MDAs with IDA.

Full details of the application process for ivermectin for IDA are available in the *Guide for donations of Mectizan® to accelerate the elimination of lymphatic filariasis in countries where onchocerciasis is not co-endemic (4*).

1.4   Application process for azithromycin

Azithromycin is made available for the elimination of trachoma as a public health problem through donation from a pharmaceutical company, as for the other medicines in this procedure. Pfizer, through its partner the International Trachoma Initiative (ITI), has a separate annual application process for all countries applying for azithromycin, with distinct requirements and timelines.

ITI provides information on the applicant country's trachoma elimination efforts to the Trachoma Expert Committee, an independent body of internationally recognized experts that meets twice a year to review country applications and make evidence-based, consistent and transparent allocations of the medicine. WHO's Medical Officer for Trachoma has an ex officio observer role at meetings of the Trachoma Expert Committee.

The azithromycin application requests information on programme details, including:

- updated data on district-level trachoma prevalence;

- current population estimates by district;

- treatment distribution data from the previous programme year;

- the country's commitment to full implementation of the SAFE strategy *(5, 6)*; and

- confirmed funding and implementation partners for each district for which azithromycin is requested.

The application forms a part of the WHO Alliance for GET2020 Trachoma Elimination Monitoring Form, which facilitates simultaneous reporting to both WHO and ITI on the previous year's activities (e.g. the form in 2021 is for activities in 2020). For districts for which azithromycin is still indicated, the form includes a tab to request azithromycin for the upcoming year (e.g. application submitted in 2021 is for azithromycin needed in 2022).

Examples of the forms and processes are provided in the Zithromax® management guide (2).

1.4.1   Key considerations

- Countries must submit a request each year in their application for every district in which they plan to treat.

- Each district where a donation is requested must satisfy the donation criteria during every application cycle.

- Applications should be prepared by the national programme manager in close collaboration with the National Trachoma Task Force. ITI assigns each country a programme liaison and a supply chain liaison, who work closely with the national programme to ensure that its needs are addressed.

- With the information that the national programme provides, the programme liaison advocates for the country at meetings of the Trachoma Expert Committee.

- The Trachoma Elimination Monitoring Form (which includes the Zithromax® application) is pre-populated by ITI with projected district population figures and sent out by WHO. The national programme should review and make any corrections to the form, which will update the application tab. Instructions are included in the application package to make the Zithromax® application process easier.

1.4.2   Approval process

The Trachoma Expert Committee makes district-level recommendations to ITI based on the data presented for each district, namely:

- trachoma prevalence;

- population;

- number of rounds of MDA already conducted;

- coverage achieved for each round;

- schedule for population-based prevalence surveys (baseline, impact and surveillance); and

- availability of financial and implementation support for MDA.

Depending on the data presented for each district, the Committee applies one of three decisions to each district request in the Zithromax® application (**Table 1.3**). Once the Committee has reviewed the application for the upcoming year, ITI communicates the decision to the health ministry and its partners.

1.4.3   Memorandum of understanding

A memorandum of understanding is created to outline the legal obligations of the health ministry and ITI regarding the donation and management of azithromycin.

The memorandum contains three components:

- the main agreement detailing the legal obligations to which both ITI and the national health ministry commit to regarding the donation and management of azithromycin;

- an addendum detailing the decisions on allocating azithromycin for the upcoming year; and

- an addendum detailing what should be reported to Pfizer regarding azithromycin product quality concerns, at-risk scenarios and adverse events, and how to report them.

Table 1.3. Trachoma Expert Committee decisions on Zithromax®

1	Approve Zithromax® to be allocated for the upcoming year
2	Approve Zithromax® with contingency:
	A. Pending confirmation of available funding, and/or
	B. Pending results from population-based prevalence surveys, and/or
	C. Pending resolution of a special situation, either:
	a. Outside the control of the national programme
	b. Requiring intervention by the national programme
3	Does not meet criteria

A memorandum of understanding is signed by ITI and the health ministry for a period of 3 years. In subsequent years an addendum to the existing 3-year memorandum is sent to the health ministry detailing the allocation of the medicine for that year.

Once the treatment for any year has been allocated, ITI takes the necessary steps to ensure the medicine arrives in the country before the scheduled MDA.

Failure to comply with the terms set forth in the memorandum of understanding may result in the suspension of the azithromycin donation.

The timeline for the Zithromax® application is shown by month and activity in **Table 1.4**.

Although the Trachoma Expert Committee reviews applications on a set timeline twice per year (in June and November), under certain circumstances ITI and the Trachoma Expert Committee accept requests throughout the year as new data or funding become available.

Full details of the application forms and process are available in the *Zithromax® management guide (2)*.

Table 1.4. Zithromax® application timeline

Month	Activity
January	WHO sends Zithromax® application to national trachoma programme (or national NTD programme trachoma focal point for integrated programmes) for the upcoming year
March	National trachoma programme submits the application to WHO and ITI
June to November	Trachoma Expert Committee decides on allocation of Zithromax®
	ITI sends notification to the health ministry of the Committee's decisions (see **Table 1.3**) and either enters into a new memorandum of understanding or updates the current 3-year memorandum with an addendum
1–2 months before MDA	ITI ships Zithromax® to countries (timing of shipment depends on country's MDA schedule)
March (following year)	Country reports to WHO and ITI on treatments distributed during the past year in the Trachoma Elimination Monitoring Form, which includes the Zithromax® application
Before shipment	Countries report to ITI on remaining inventory from the previous year

1.5   Standard operating procedure

The positions identified, their roles and the steps to be taken in this procedure are illustrative and should be adjusted according to the prevailing context in each country.

Task	Instruction	Responsibility	References
1	January: receive the Zithromax® application. 1.1. WHO sends the pre-populated Zithromax® application to the national trachoma programme manager (or NTD programme trachoma focal point in an integrated programme) for the upcoming year.	▪ ITI programme liaison and WHO	*(7)*

2	March: National trachoma programme manager/ NTD programme trachoma focal point submits the Zithromax® application.
	
	2.1. NTPM/NPM updates trachoma prevalence data.
	  - Steps updated with people or department responsible for completing the process.
	
	2.2. National trachoma programme manager/ NTD programme trachoma focal point obtains current population estimates by district.
	  - Steps updated with people or department responsible for completing the process.
	
	2.3. National trachoma programme manager/ NTD programme trachoma focal point submits Trachoma Elimination Monitoring Form with the treatment distribution data from the previous year.
	  - Steps updated with people or department responsible for completing the process.
	
	2.4. Verify the country's commitment to full implementation of the SAFE strategy.
	  - Steps updated with people or department responsible for completing the process.
	
	2.5. Confirmed funding and implementation partners for each district receiving azithromycin
	  - Steps updated with people or department responsible for completing the process.
		▪ National trachoma programme manager/NTD programme trachoma focal point
		
		▪ Implementing partners
		
		▪ ITI programme liaison
		
		▪ Implementing partners	

3	June to November: receive azithromycin allocation decisions from the Trachoma Expert Committee. 3.1. National trachoma programme manager/NTD programme trachoma focal point receives Zithromax® allocation approval. 3.2. National trachoma programme manager/NTD programme trachoma focal point signs the 3-year memorandum of understanding with ITI or an addendum to the existing memorandum that details the allocation of the medicine for the upcoming year - Steps updated with people or department responsible for completing the process.	▪ National trachoma programme manager/NTD programme trachoma focal point ▪ Implementing partners	

References

1. Joint Application Package – planning, requesting medicines and reporting. In: WHO/Neglected tropical diseases [website]. Geneva: World Health Organization; 2021 (https://www.who.int/teams/control-of-neglected-tropical-diseases/preventive-chemotherapy/joint-application-package, accessed 18 March 2022).

2. Zithromax® management guide. Decatur (GA): International Trachoma Initiative; 2019 (https://www.trachoma.org/zithromax-management-guide, accessed 18 March 2022).

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4. Guide for donations of Mectizan to accelerate the elimination of lymphatic filariasis in countries where onchocerciasis is not co-endemic [version 1]. Decatur (GA): Mectizan® Donation Program; 2017 (https://mectizan.org/wp-content/uploads/2018/07/Guide-Mectizan-Application-for-IDA-countries_V1.pdf, accessed 18 March 2022).

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7. Expanded Special Project for Elimination of Neglected Tropical Diseases. In: WHO/ESPEN [web portal]. Brazzaville: WHO Regional Office for Africa; 2021 (https://espen.afro.who.int/, accessed 18 March 2022).

2. Shipping notification and green light

2.1   Purpose and scope of this standard operating procedure

The shipping notification and green light procedure, together with the list of key contacts, is the first step in the country receiving the donated medicines and is a critical aspect of supply chain management.

This procedure describes the process pertaining to notification by the donor of the shipment of medicines into the country, from the donor's production plant or warehouse to the country's port of entry or central medical store/warehouse. It outlines the contact list required for all shipping documents and the "green light approval" for shipping the medicines, which is only required by some countries. An example of a green light country is one that requires an import permit, container inspection or additional lead-time to prepare for the shipment. For an example flow chart of the process, see **Fig. 2.1**.

2.2   Key considerations

Preparation before a shipment arrives reduces the time for delivering the medicines to the central medical store/warehouse. The availability of the in-country cleared document(s) when the shipment arrives facilitates customs clearance; space and personnel to offload the shipment are also essential for timely receipt of the medicines at the central medical store/warehouse. See Chapter 3 for additional information.

This procedure should be followed in order to:

■   streamline the timeline for transportation by delivering medicines to the country's port of entry or central medical store/warehouse to ensure timely distribution of medicines for MDA;

■   prevent overstock at the central medical store/warehouse;

■   prevent delay due to insufficient staff availability for offloading medicines arriving at the central medical store/warehouse;

■   decrease cost due to delays for both the donor and the country (see glossary (**Annex 1**) for definition of terms):

- ocean freight – demurrage shipping line/port storage and demurrage charges/ detention shipping line/detention inland carrier (using sea freight versus ocean freight).

- air freight – airport storage charges/detention inland carrier.
  (*Example for donor cost due to delays for both ocean and air (storage charges before departure*).

The positions identified, their roles and the steps to be taken in this procedure are illustrative and should be adjusted according to the prevailing context in each country.

Planning. A successful green light process for shipping donated medicines to recipient countries includes the following factors.

Distribution plan

- A distribution plan defines the timing for the donor to start the shipping process, according to the planned month of MDA. The national programme coordinator or WHO must communicate the expected time for delivery of medicines in the country, taking into account the time it takes to clear and transport medicines to communities.

Budget

- Funding to clear shipments from customs and secure truck rental for transportation to the central medical store and any fees associated with the freight, if not already accessible, through existing WHO or government medical supply systems.

  - Example: Funding must be allocated for clearing, transporting and storing donated azithromycin, which does not fall under the WHO supply chain mechanism.

Fig. 2.1. Flow chart of the process
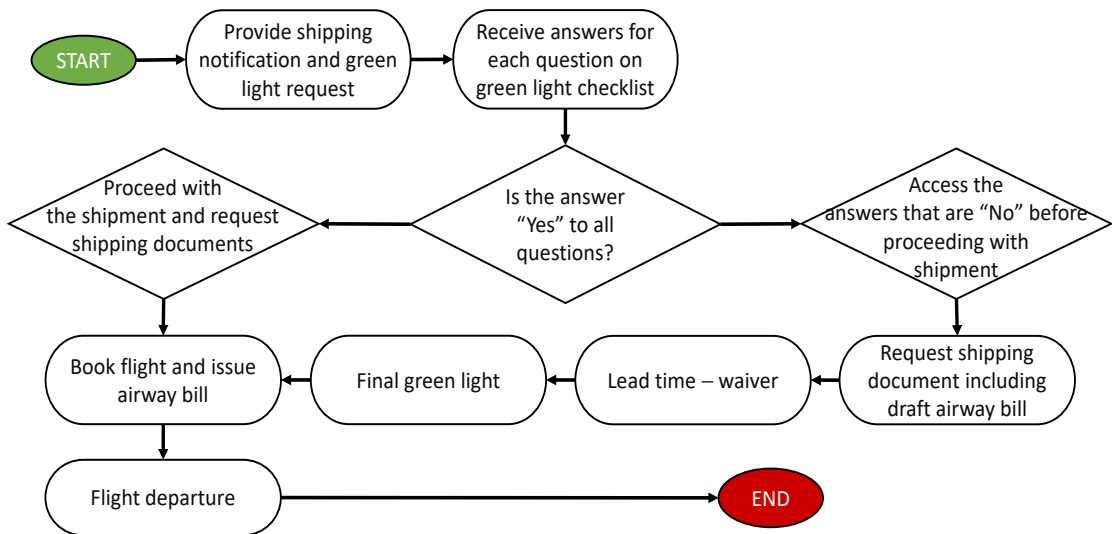
Source: International Trachoma Initiative

2.3   Standard operating procedure

2.3.1   Shipping notification

When	Who	What	How
▪ Prompted by order receipt; may include multiple shipments per year. ▪ Takes into consideration planned MDA dates, lead-time, transit, customs clearance, in-country transportation and time for dispatching medicines to last miles.	▪ National NTD programme, donor, WHO, national programme coordinator, supply chain manager of central medical store/ warehouse. ▪ Donor initiates the shipping notification to countries including NTD programme of health ministry, donor, WHO, national programme coordinator and supply chain manager of central medical store/warehouse.	▪ Notification of shipment transportation and steps taken to streamline its receipt. ▪ Allows countries to prepare for receipt of medicines in-country. ▪ Donor initiates process by email to the Consignee stating that the shipment is packed. ▪ Consignee must confirm that the shipment can proceed to booking.	1. Donor provides shipping notification to WHO/national programme. coordinator and Consignee. 2. WHO/national programme coordinator confirms contact list. 3. WHO/national programme coordinator provides green light to proceed with booking.

Task	Instruction	Responsibility	References
2	Provide shipping notification to countries. 2.1. Provide the shipping notification in the timeline indicated by the NTD programme of health ministry.	▪ Donors send email notification to recipient countries, health ministry, WHO/national programme coordinator to inform them about the upcoming shipment of medicines.	▪ Refer to country contact list (health ministry, national programme coordinator/WHO) Refer to country application for donated medicines for: - lymphatic filariasis, schistosomiasis, soil-transmitted helminthiases and onchocerciasis *(1)*; - trachoma *(2)*

Task	Instruction	Responsibility	References
3	Prepare for shipment departure from production sites/logistics centre. 3.1. Prepare the shipment. 3.2. Plan and execute the booking.	▪ Donor emails national programme coordinator/WHO informing them of the impending shipment in the shipping notification email with detailed information on quantities.	Provide shipping notification to countries. ▪ Pre-alert/final documents - Limited shipping documents available and shipment booked or in the process of being booked. ▪ Shipping notification - Limited shipping documents available and shipment in the process of being booked. ▪ Shipping advice - All shipping documents provided, and shipment booked.. ▪ Other - Refer to shipping documents provided by donor, which may include: 1. Invoices 2. Bill of lading or airway bill (if available) 3. Bill of lading (available after ship sails from the port of origin 4. Packing list 5. Certificate of origin 6. Certificate of analysis 7. Certificate for exemption of customs duties (WHO) 8. Certificate of donation
4	Prepare for shipment arrival.	▪ WHO/national programme coordinator ▪ Supply chain manager of the central medical store/warehouse	▪ WHO/national programme coordinator to verify with donor if timelines are appropriate for both ocean and air shipments. ▪ WHO/national programme coordinator to ensure paperwork is ready to receive and clear the shipment from customs. ▪ Supply chain manager to ensure central medical store has planned the arrival of the shipment and made all resources available: trucks, labour to unload trucks, storage space.

Task	Instruction	Responsibility	References
5	Request of the tax-and-duty-free waivers. WHO/national programme coordinator requesting additional unessential documents can delay receipt of the shipment. Documents outside of the standard shipping package may need 3 months to generate. Providing the donor with the information on the country-specific requirements and their timeline in advance can help them better coordinate the shipment arriving after the receipt of the in-country clearance document(s). Preventing the shipment from being delayed in clearance is vital for timely delivery. 5.1. WHO/national programme coordinator request the creation of the tax-and-duty-free waivers from the finance ministry or other appropriate government body. 5.2. [This section should clearly list below the country's documentation requirement(s) for the clearance of the medicines through customs and the process for obtaining them.] Examples may include: - Approval from the finance ministry. - Health ministry stamped copies of original shipping documents provided by the donor: - invoices - packing list - certificate of origin - certificate of donation - certificate of analysis	▪ WHO/national programme coordinator ▪ [Country to outline prerequisites for obtaining all administrative documents for clearing the shipment.] ▪ Health ministry/national programme coordinator/WHO to determine the timeline for obtaining each document and resources to be allocated.	
6	Notify supply chain manager Include in the notification: ▪ amount of treatments; ▪ shipment size (volume, number of pallets and boxes); ▪ anticipated date of shipment in the port; and ▪ expected date and time of delivery to the central medical store.	▪ NTD logistics officer ▪ WHO/national programme coordinator ▪ Central medical store supply chain experts can be vital in identifying bottlenecks within the donation supply chain. Use of their knowledge is key when updating this standard operating procedure.	

Task	Instruction	Responsibility	References
7	Prepare central medical store/warehouse: 7.1. Verify storage capacity. 7.2. Coordinate personnel for reception of shipment.	▪ Supply chain manager to prepare central medical store/warehouse for the receipt of the medicines. ▪ Steps for verifying space will be available for the shipment when it arrives. ▪ Steps for coordinating personnel to offload shipment. Paid labourers or current staff, rented equipment of offloading, other.	▪ See Chapter 5: Inventory Management ▪ See Chapter 6: Storage ▪ Substantial charges from the inland carrier can occur if space is not available for the medicines when they arrive. ▪ Tracking is available for selected medicines: - Country summary online view *(3)* - Country page subscription form *(4)* - Country Zithromax® tracking *(5)*

2.3.2   Contact list

When	Who	What	How
Prompted by order receipt; may include multiple shipments per year. Updated contact list to be provided by health ministry/national programme coordinator/WHO to donor before shipment is packed.	▪ NTD programme of health ministry ▪ Donor ▪ WHO, national programme coordinator ▪ Supply chain manager of the central medical store/warehouse.	The contact list is the first step in getting things set up with the donor's shipping service and getting the pro forma invoice. ▪ Donor provides NTD programme of health ministry, WHO, national programme coordinator with a draft list of contacts based on the previous delivery to which they are invited to make changes or make additions, if necessary. ▪ This process allows the recipient country to provide the list of people to be informed about the evolution or the routing of the shipment. ▪ WHO/national programme coordinator provides the up-to-date contact list to ship the medicines.	Before each shipment, donor will request updated contact information. ▪ Donor sends the first draft of the contact list to the recipient country for updates. ▪ National programme coordinators use the draft contact list to update the list of people to be informed about the upcoming shipment. ▪ Clear correspondence on the date of feedback is essential to prevent the need for constant email request for updates. See Chapter 3: Customs clearance and delivery

Task	Instruction	Responsibility	References
1	**Donor sends first draft of contact list for updating.** 1.1. In the initial email announcing the shipment, donor requests WHO/national programme coordinator to update the contact list	▪ WHO/national programme coordinator to update contact list and return updated file to donor to initiate the order. ▪ This process allows the recipient country to provide the list of people to be informed about the evolution or the routing of the shipment.	▪ Initial contact list is drafted based on the contact list from previous shipments (see template in **Annex 2**)
2	**WHO/national programme coordinator receives and updates the contact list.**	▪ WHO/national programme coordinator to ensure all stakeholder contacts are included and up to-date. ▪ WHO/national programme coordinator receives the contact list of the impending shipment and takes the appropriate actions to provide the approval.	▪ WHO/national programme coordinator to use the contact list received from the donor for updates.
3	**WHO/national programme coordinator responds to the contact list request.** 3.1. WHO/national programme coordinator emails the updated contact list back to the donor..	▪ WHO/national programme coordinator to ensure the accuracy of the contact information before submitting to the donor. ▪ WHO/national programme coordinator to respond to the contact list request within 2 weeks of its receipt. ▪ If for some reason WHO/ national programme coordinator cannot return the updated contact list, they will explain the reasons for the delay and provide anticipated date of approval.	▪ WHO/national programme coordinator to contact all stakeholders to update contacts that should be informed about the shipment. ▪ The contact list may include the following: 1. Donee of record 2. Consignee (organization or person to whom the product is officially sent or delivered) 3. Consign to/delivery to 4. National programme coordinator 5. Importer of record 6. Routing/notify

Task	Instruction	Responsibility	References
			7. Point of contact at the "deliver to" address (physical address to which the shipment should be delivered)
			8. Person responsible for customs clearance
			9. Anyone else who should be notified of the upcoming shipment

2.3.3   Green light

When	Who	What	How
Prompted by order receipt; may include multiple shipments per year. The green light checklist may be sent to the Consignee/WHO/national programme coordinator by donor before starting the order process and before booking freight. The green light request may be requested by the donor at the same time as sending the shipping notification, and the contact list request. National programme coordinator/WHO to provide green light before donor proceeds booking freight.	▪ NTD programme of health ministry, donor, WHO, national programme coordinator, supply chain manager of the central medical store/ warehouse. ▪ Donor requests green light from Consignee, NTD programme of health ministry, or WHO/ national programme coordinator.	▪ Consignee, WHO/ national programme coordinator provides the approval to ship the medicines to the donor, called a "green light".	▪ This process allows the recipient country to provide the required documents, inspection or other action to receive the medicines in the country.

Task	Instruction	Responsibility	References
4	**Assess the green light requirement.** 4.1. NTD drug application programmes assess the requirement of a green light based on their programme guidelines. 4.2. National programme coordinators should email the Director of the Mectizan® Donation Program (ysodahlon@taskforce.org) to request additional information of the requirements of a green light for their country.	■ NTD drug application programmes, WHO/national programme coordinator.	■ For lymphatic filariasis, schistosomiasis and soil-transmitted helminthiases, contact WHO: PC_JointForms@who.int ■ For onchocerciasis, contact the Mectizan® Donation Program Director (currently Dr Yao Sodahlon: ysodahlon@taskforce.org) or mectizan@mectizan.org ■ For trachoma, contact the International Trachoma Initiative: www.trachoma.org/contact-us
5	**Green light request.** 5.1. Donor emails the green light request to WHO/national programme coordinator. The notification can include the following documents: 1. Invoices 2. Draft airway bill* (if available) 3. Packing list 4. Certificate of origin 5. Certificate of analysis 6. Certificate for exemption of customs duties (WHO) 7. Certificate of donation * The bill of lading is not available until after the ship leaves the port of origin.	■ NTD drug application programmes, WHO/national programme coordinator ■ A green light is a confirmation message from the national programme coordinator/WHO to the donor stating that the country is ready to receive the shipment of medicines. WHO or the national programme coordinator must confirm the needed preparations have been completed before sending a green light note. ■ Health ministry/national programme coordinator/WHO to assign staff responsible for assessing each of the five questions on the green light checklist.	■ See action items and greenlight checklist in **Annex 3**: the national programme coordinator/WHO/ consignee must answer "YES" to all questions before giving green light.

Task	Instruction	Responsibility	References
6	**Freight booking.** 6.1. Donor books shipment and places it on a transport (air or sea). 6.2. Issuing shipping documents. 6.3. Donor couriers shipping documents to national programme coordinator/WHO.		

References

1.   Joint Application Package – planning, requesting medicines and reporting. In: WHO/Neglected tropical diseases [website]. Geneva: World Health Organization; 2021 (https://www.who.int/teams/control-of-neglected-tropical-diseases/preventive-chemotherapy/joint-application-package, accessed 18 March 2022).

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5.   Country Zithromax® tracking. In: GET2020 [online database]. Decatur (GA): International Trachoma Initiative; 2021 (https://www.trachomadata.org/supply-chain/subscription, accessed 18 March 2022).

3. Customs clearance and delivery

3.1 Purpose and scope of this standard operating procedure

Customs clearance and delivery are the final steps in receiving medicines into the country. This procedure outlines the key processes for the donors and recipients of the medicines.

Customs clearance is the first process. It involves releasing the medicines from the point of entry to the recipient.

Delivery is the second process. It involves moving the medicines from the point (after their release) to the central medical store/warehouse. This procedure should be followed in order to:

- streamline the transport of medicines, from the donor's factory or production warehouse to the country's central medical store, to enable timely MDA;

- avoid delays due to lack of staff availability for offloading medicines delivered to the central medical store; and

- reduce costs to the donor and the recipient country, including:

  - sea freight costs: shipping company container rental, port storage and demurrage charges as well as the costs of holding by the shipping company or by the continental carrier, and

  - air freight costs: airport storage and detention costs by the continental carrier.

3.2 Key considerations

- The positions identified, their roles and the steps to be taken in this procedure are illustrative and should be adjusted according to the prevailing context in each country.

- For landlocked countries, maritime cargoes may require clearance at both the seaport and the land border. Factor in the additional time required for multiple clearance.

3.3 Standard operating procedure

3.3.1 Shipping notification

When	Who	What	How
Before the shipment of medicines arrives at the port/border; typically as soon as the pharmaceutical donor has initiated the shipment (weeks to months ahead of arrival, depending on shipment mode).	▪ WHO ▪ National programme coordinator ▪ Donor freight forwarder or WHO/national programme coordinator freight forwarder (the "forwarder") ▪ Supply chain manager of the central medical store or warehouse	▪ WHO/national programme coordinator provides the country-required documentation[a] to the donor's or WHO's forwarder for the clearance of the medicines [a] The procedure for obtaining the required documentation for clearance of medicines in a country is described in Chapter 2 Shipping notification and green light.	1. WHO/national programme coordinator should initiate the process of obtaining the required documentation as soon all the documents necessary for the shipment from the pharmaceutical donor are received and should identify and gather the required documents, signatures and approvals in the country.

Task	Instruction	Responsibility	References

1	WHO/national programme coordinator provides the required country documentation* to the donor's or WHO's forwarder for the clearance of the medicines.
	1.1. Identify the document requirements for your country, which may include:
	  - tax exemption waiver
	  - import permits
	  - medicine distribution plan
	  - marketing authorization
	  - approval from the federal finance ministry
	  - Health ministry stamped copies of documents such as invoice, packing list, shipping slip, certificate of origin, certificate of donation or certificate of analysis.
	1.2. Forwarder may also approach customs services to confirm required documentation and enquire about additional requirements or process changes in the country.
	  - tax exemption waiver
	  - import permits.
		▪ WHO
		▪ National programme coordinator
		▪ Forwarder
			See Chapter 2: Shipping notification and green light

2	Documents, in particular tax exemption waivers and import permits, may be required from different channels, depending on the contents and value of the cargo. It is important to know the appropriate channel(s) for your country ahead of time to avoid clearance delays while pursuing approvals.		

3.3.2   When the cargo arrives at the point of entry or border

When	Who	What	How
Upon arrival, and within 2 days to 2 weeks after arrival	▪ WHO ▪ National programme coordinator ▪ Forwarder ▪ Supply chain manager or designee	▪ Customs clearance is carried out	1. Inform all relevant parties 2. Set timetable 3. Submit required signed/sealed documents

Task	Instruction	Responsibility	References
1	**Forwarder informs the relevant parties of the shipment's arrival.** 1.1. Forwarder informs WHO/national programme coordinator of the shipment's arrival and provides a forecast timetable for customs clearance and delivery to the central medical store by email or telephone. 1.2. WHO/national programme coordinator provides the above information to the supply chain manager, central medical store operations manager or NTD programme pharmacist, as designated in the country.	▪ Forwarder ▪ WHO ▪ National programme coordinator	See Chapter 2: Shipping notification and green light
2	**Forwarder completes customs clearance.** 2.1. Forwarder ensures all required documents are submitted, with appropriate signatures/seals as required by the customs regulations. 2.2. Forwarder communicates the arrival time at the central medical store to WHO/national programme coordinator and supply chain manager or designee. 2.3. Supply chain manager or designee verifies to the NTD programme pharmacist, and WHO/national programme coordinator, that the necessary space is available at the central medical store and that staff will be available to offload the cargo upon arrival.	▪ Forwarder ▪ Supply chain manager or designee	See Chapter 5: Inventory management

3.3.3   After customs clearance: delivery to the central medical store/warehouse

When	Who	What	How
After the cargo clears customs	■ Forwarder ■ Supply chain manager or designee	■ The medicines are delivered to the central depot or warehouse and received	1. Provide clear guidelines for the delivery of medicines to the central medical store/warehouse. 2. Ensure clear processes are in place for the receipt and confirmation of the medicines.

Task	Instruction	Responsibility	References
1	**Supply chain manager or designee provides clear instructions for the delivery of the medicines to the central medical store/warehouse** 1.1. Forwarder clears the cargo and informs WHO and national programme coordinator of the planned arrival time at the central medical store/warehouse. 1.2. Supply chain manager or designee provides the forwarder with the central medical store/warehouse details, including the exact route and instructions on the offloading process: - Forwarder transports the cargo to the central medical store/warehouse. - Central medical store/warehouse manager receives the medicines and supervises the offloading. - Central medical store/warehouse manager oversees the transfer of the medicines to facility pallets and shelves. - This section should contain the complete process of offloading each medicine; solid, chewable, powder or liquid formulations may require different processes.	■ Forwarder ■ Supply chain manager or designee ■ Central medical store/warehouse manager	See Chapter 4: Transport
2	**Supply chain manager or designee prepares the depot or warehouse to receive the medicines.** 2.1. Central medical store/warehouse manager confirms there is sufficient space for the new cargo and personnel to handle the offloading and storage.	■ Supply chain manager or designee ■ Central medical store/warehouse manager	See Chapter 5: Inventory Management See Chapter 6: Storage See Chapter 7: First expiry first out
3	**Medicines are delivered to the central medical store/warehouse** 3.1. Forwarder transports the cargo to the central medical store/warehouse in its original container. 3.2. Supply chain manager or designee provides personnel to offload trucks into the central medical store/warehouse.	■ Forwarder ■ Supply chain manager or designee ■ National programme coordinator	See Chapter 4: Transport

Task	Instruction	Responsibility	References
	3.3. Supply chain manager or designee checks to verify that the seal on the container is not broken. If the seal is broken: - ask the driver to write down the broken seal on the delivery voucher; and - when possible, take a picture of the broken seal so that there is a time stamp and to create visual proof. - A broken seal may indicate that some medicines have been removed from the cargo.		

4	**Delivery is received and confirmed.**
	
	4.1. Supply chain manager or designee conducts a physical inventory of all the medicines received and confirms that all pallets and boxes are present and in good condition, in accordance with the shipping documents. If medicines are not in good condition, or if they are missing, complete the following:
	
	- If pallets are damaged, open all damaged boxes on the pallet and verify medicines are in good condition. Good condition would include that the bottles are not damaged, and seals on bottles not broken.
	
	   - Report on the delivery note any unusable medicines due to damage and keep a copy of the record.
	
	   - If possible, take pictures of all damaged goods so that there is a time stamp and visual proof of the damage.
	
	- If pallets are missing, have the driver note any missing pallets and the batch or lot number of medicine(s) associated with that pallet on the proof of delivery form..
	
	   - The shipping slip (packing list) and invoice contain the lot or batch number.
	
	   • If possible, take pictures of each received pallet to help confirm the missing pallet(s).
	
	   • Report the damaged or missing medicines to the forwarder and request that they file a formal report.
	
	4.2. The national programme coordinator is responsible for requesting replacement medicines per the requirements of the NTD drug application.
	
	4.3. The central medical store manager prepares and submits official reports to the supplier within 10 days.
	
	4.4. Supply chain manager or designee signs the delivery order from the forwarder and ensures that the driver signs the central medical store supervisor's copy of the delivery order.
	
	4.5. The copy of the proof of delivery form provided to the supply chain manager must be clear and readable. A legible copy of this document will allow the country to receive a replacement cargo for missing or damaged medicines.
	
	4.6. Forwarder provides the delivery to the donor and WHO/national programme coordinator.
		■ Forwarder
		
		■ Supply chain manager or designee
		
		■ National programme coordinator	

3.4   Supplementary information

The NTD Supply Chain Forum developed NTDeliver (www.ntdeliver.com), an online supply chain information portal which centralizes information from a variety of sources to improve the monitoring and evaluation of the supply chain for donated medicines. The goal of NTDeliver is to increase the visibility of the NTD supply chain from the issuance of orders to the delivery of shipments. With this knowledge, countries and partners can better coordinate their internal supply chains.

To enhance timely access to information, recipient countries can track available shipments through:

■   country summaries *(1)*, which allow tracking of many of NTD medicines shipments in real-time and is accessible on a computer, smartphone or tablet; and

■   a country page subscription form *(2)*, which allows subscribers to select a country that they would like to receive email notifications. Also, NTDeliver provides a weekly update to the subscriber.

Shipments available for tracking include those for:

■   lymphatic filariasis

    ■   albendazole donated by GlaxoSmithKline through WHO

    ■   diethylcarbamazine citrate donated by Eisai through WHO

■   schistosomiasis

    ■   praziquantel donated by Merck KGaA through WHO

■   soil-transmitted helminthiases

    ■   albendazole donated by GlaxoSmithKline through WHO

    ■   mebendazole donated by Johnson & Johnson through WHO

■   trachoma

    ■   azithromycin donated by Pfizer through the International Trachoma Initiative.

Ivermectin is not tracked through NTDeliver. Please refer to the Mectizan® Donation Program (https://mectizan.org/).

References

1.   Country summary [online view]. In: NTDeliver Supply Chain Information System [website]. (https://www.ntdeliver.com/country, accessed 18 March 2022).
2.   Country page subscription form. In: NTDeliver Supply Chain Information System [website]. (https://www.ntdeliver.com/subscribers/new, accessed 18 March 2022).

4. Transport

4.1   Purpose and scope of this standard operating procedure

This standard operating procedure covers the transport of medicines from central medical stores to regions/states/provinces, or from regions to district-level distribution points. The key steps are illustrated in Fig. 4.1.

Transporting medicines from customs clearance to distribution points involves many steps and time, usually by road, but in some countries also by plane. Ensuring that the correct medicines in their correct quantities reach each post requires careful planning and processes; recovering excess medicines from one location to meet the needs in another location, perhaps across the country, can be very costly and significantly delay scheduling of MDA. It is essential to know ahead of time where the medicines are needed, and how much are needed and when they are needed, well ahead of the date of transport.

4.2   Key considerations

Planning. Successful transfer of medicines includes the following significant factors.

Distribution plan

■   A distribution plan that defines the circuit and stages of distribution from the central to district level.

Budget

■   Funding to secure truck rental, drivers' per diems or security, if not already accessible, through existing government medical supply systems.

   ■   Example: The national NTD control programme allocates funding to the national supply pharmacy for medicines at regional supply pharmacies. At the regional level, a transport line is allocated to districts for removal and routing at service delivery points.

Responsible authority

■ Identify who decides which regions or districts receive which medicines, especially when they will be arriving in-country at different times. Verify that the noted authority has the power to prioritize.

■ Identify the signature authority at the receiving end.

Security

■ Some medicines have a high value for other needs (livestock, other target audiences); ensuring that they can be safely transported without damage or theft is crucial to conducting MDA with good coverage and achieving elimination and control goals. Safety of medicines must be ensured at all levels, from receipt into the country to the community.

Documentation

■ Tracking of electronic stock-keeping units is highly valuable for supply chain management from central to district levels; however, paper-based systems are adequate if managed appropriately with detailed processes and signed forms returned to their origin for filing (closing the loop).

■ Ensure the country has appropriate forms to document the transport process.

■ Ensure systems are in place to monitor stocks at every step; correctly filled out documents should accompany the delivery at every stage.

Environmental conditions

■ Medicines travelling in unpredictable weather (e.g. warm or dry season versus wet season) or on bad roads can be easily damaged. It is essential to ensure that the transport mechanisms used are adequate to preserve stocks from damage or deterioration and to ensure their arrival in a condition that is considered intact or undamaged. For further information, see Chapter 9 for clarification.

Fig 4.1. Key steps transporting medicines
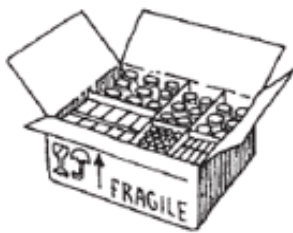
Fill voids in cartons with packing material	Prevent breakages
Load vehicles carefully and systematically first-in/last-out	Save time when unloading / Prevent physical damage
Secure vehicle doors	Prevent losses or theft
Protect supplies from sun or rain / Stay near the vehicle	Minimize deterioration of pharmaceuticals during transit / Guard against theft
Start early in the day and drive with care, especially on hazardous roads	Avoid nightime driving
Ensure safe and timely delivery	Prevent accidents
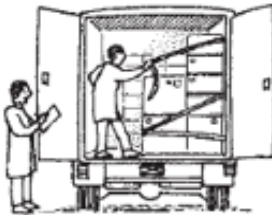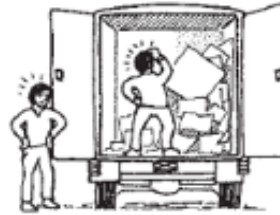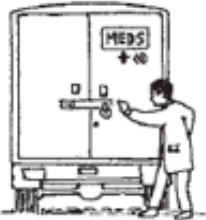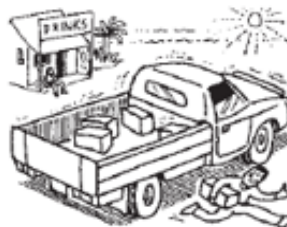
Source: reproduced with permission from Management Sciences for Health [Figure 25-3: Transporting pharmaceuticals safely. In: MDS3: Managing access to medicines and health technologies. Arlington (VA): Management Sciences for Health; 2012 (https://www.msh.org/resources/mds-3-managing-access-to-medicines-and-health-technologies)].

4.3 Standard operating procedure

The procedure has two stages: transport from central level to regions/states/provinces (3.4.1) and transport from regions to districts (3.4.2). Use of these steps for development of standard operating procedures can be independent or combined depending on the supply chain's specific need. The timeframe for transport planning is usually 2–4 weeks before the MDA. An example transportation flow diagram is provided in **Fig. 4.2**. The positions identified, their roles and the steps to be taken in this procedure are illustrative and should be adjusted according to the prevailing context in each country.

Fig 4.2. Example transportation flow diagram
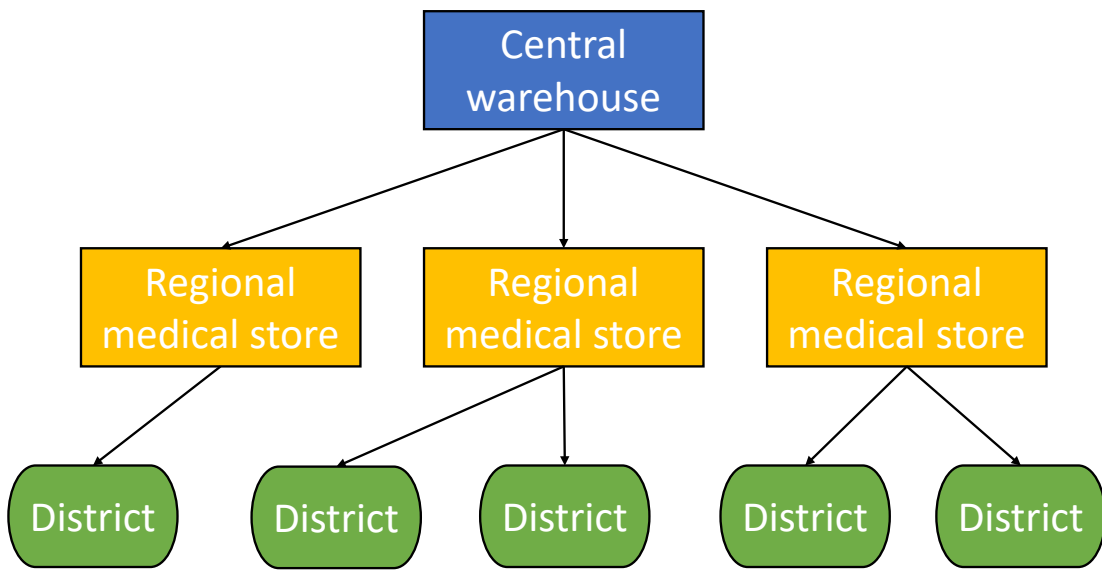
Note: If no regional medical store exists the flow would go directly to the districts.

4.3.1 Transport from central level to regions/states/provinces(or to districts if no regional facility)

When	Who	What	How
Upon request of regional level (usually 2–4 weeks ahead of MDA) After MDA if stocks are returned to central level	▪ WHO/Consignee ▪ NTD programme ▪ Implementing partners (if supporting costs) ▪ Central pharmacy ▪ Central medical stores ▪ State medical store ▪ Regional medical stores ▪ Drivers ▪ Truck loaders/unloaders Level of authority required ▪ Signature authority to assign specific quantities of medicines to regions ▪ Signature authority to remove medicines, either to release them to field sites or for destruction	▪ To transport donated/procured drug materials from central to regional sites ▪ To allocate and disseminate correct amounts of medicines to regional/district level distribution points	1. Prepare for transport shipment from central level 2. Assemble cartons/boxes for each regional medical store 3. Prepare issue/receiving voucher for each regional medical store and waybills for total cartons for each destination 4. Inspect/count sealed/complete cartons and count the number of bottles in the open cartons 5. Load trucks 6. Unload trucks 7. Regional medical store receipt of shipment(s) and documentation 8. Delivery confirmation.

Task	Instruction	Responsibility	References

1	**Prepare for shipment transport from central level.**
	1.1. Liaise with the NTD programme and regularly check when medicines are due at regional level(s) is accurate with the drug distribution schedule.
	    1.1.1. Have consignee and regional focal points' contact information on hand.
	1.2. Confirm regional repository is aware of the planned delivery and that space is available.
	    1.2.1. Identify calendar restrictions for delivery (e.g. deliveries not accepted on weekends).
	1.3. Create a quantity and distribution schedule in coordination with the NTDP to ensure safe, efficient transport; share with the regional medical store.
	    1.3.1. This should include approximate travel times for each regional medical store delivery, factoring in appropriate rest stops, avoidance of night driving and poor road conditions.
		▪ Central medical store's point of contact in coordination with:
		  ▪ NTD programme
		  ▪ WHO/consignee
		  ▪ Implementing partners
		  ▪ District health office's point of contact
		  ▪ Regional medical store's point of contact
		  ▪ Drivers
		  ▪ Truck loaders/unloaders
			See Chapter 6: Storage
			
			See Chapter 11: Forecasting and quantification

Task	Instruction	Responsibility	References
	1.4. Obtain necessary approval from the district NTD coordinator or district health office for the distribution plan, transportation budget and secure funding.		
	1.4.1. Consider providing drivers with mobile airtime for reporting incidents en route; if drivers do not have mobile phones, consider providing a temporary phone with camera.		
	1.4.2. Ensure driver is paid to return signed forms to central medical store or state medical store for confirmation of delivery.		
	1.5. Ensure transport vehicles meet acceptable standards for transfer of medicines (e.g. working condition, appropriate cover from weather).		
	1.6. Determine the total number of cartons/boxes to be delivered to each regional medical store and prepare waybills.		
	1.7. Ensure vouchers are prepared for each regional medical store designee.		
	1.8. Ensure that transport to regional medical store is arranged for the necessary date(s). E.g., if trucks are not available for use by central medical , how will transport be provided?		
	1.9. Central medical store to notify regional medical store that the truck is being prepared for transport in advance.		
	1.9.1. Ensure staff are available to load/unload truck(s).		
	1.10. Prepare for transport security from theft, weather or other risks.		
	1.11. Identify/confirm who will have access to the stock during transport (if locked in truck)		
2	**Assemble cartons/boxes for each regional medical store.** 2.1. Reassemble cartons with stock based on quantity needs identified in distribution schedule. 2.2. Fill voids in cartons with packing material to avoid damage. 2.3. If feasible, label each carton by destination of regional medical store for secondary verification. 2.4. Ensure oldest and previously opened stock is included first (per the "FEFO" method). 2.5. Any damaged/expired stock should be documented and removed.	▪ Central medical store's point of contact in coordination with: ▪ Regional medical store's point of contact ▪ District health office's point of contact	See Chapter 7: First expiry first out See Chapter 10: Waste management
3	**Prepare issue/receiving voucher for each regional medical store and waybills for total cartons for each destination.** 3.1. Mark clearly how many bottles of each medicine type are going to each regional medical store. If possible, also include the distribution posts earmarked by each carton.	▪ Regional medical store's point of contact in coordination with: ▪ Central medical store's point of contact ▪ Driver	

Task	Instruction	Responsibility	References
4	**Inspect/count sealed/complete cartons and count the number of bottles in the open cartons.** 4.1. Ensure tally sheets or other appropriate inventory management forms are in place before loading onto trucks. 4.2. Central medical store and driver confirm against prepared vouchers and waybills and sign both.	▪ Regional medical store in coordination with: ▪ Central medical store's point of contact ▪ Drivers	See Chapter 5: Inventory management
5	**Load trucks.** 5.1. Load trucks systematically, using "first in, last out" procedure. 5.2. Use loading straps to prevent physical damage. 5.3. Secure vehicle doors against theft and weather. Confirm who has access. 5.4. Ensure routing provides sufficient time for rest, safety (avoid driving at night, bad roads). 5.5. Any shipment delivery longer than 1 day should be secured and visually inspected at every overnight stop and each morning, with appropriate documentation.	▪ Regional medical store's point of contact in coordination with: ▪ Drivers ▪ Truck loaders	
6	**Unload trucks.** 6.1. Upon arrival, unload per the distribution schedule and first in last out policy. 6.2. Driver to present voucher and waybill to recipient at each regional medical store driver, including title, name, signature and date (dd/mm/yyyy). 6.3. Regional medical store point of contact to inspect/count sealed and unsealed cartons and sign prepared voucher and waybill. 6.4. Any damaged/expired stock should be documented and removed.	▪ Regional medical store in coordination with: ▪ Drivers ▪ Truck Unload	See Chapter 6: Storage See Chapter 10: Waste management
7	**Regional medical store receipt of shipment(s) and documentation.** 7.1. If documentation is incomplete or missing, the regional medical store should not accept the shipment; contact the central medical store point of contact for guidance. 7.2. If documentation does not match quantities received: 7.2.1. Accept delivery and prepare a supply discrepancy report to record the shortage or excess received. Give a copy to the driver to submit to the central medical store point of contact. 7.3. In case of excess supply, return the excess goods and invoice to driver, and request a new invoice for quantity accepted. 7.4. Notify NTD programme point of contact and district health office that quantities were received. 7.5. Any damaged/expired stock should be documented and removed.	▪ Regional medical store's point of contact in coordination with: ▪ Central medical store's point of contact ▪ Drivers	See Chapter 10: Waste management

Task	Instruction	Responsibility	References

8	Delivery confirmation.
	
	8.1. Driver to receive and file with central medical store a copy of the signed receiving as a record of delivery and date (dd/mm/yyyy)..
		▪ Regional medical store in coordination with:
		
		  ▪ NTD programme
		
		  ▪ WHO/consignee
		
		  ▪ Regional medical store's point of contact
		
		  ▪ Drivers	

4.3.2 Transport from regions to districts

(Including transport from districts after MDA to regional/central level for final storage or destruction)

When	Who	What	How
Upon request of district level (usually 2–4 weeks ahead of MDA) After MDA or after disease-specific assessment if stocks are returned to central/regional level or for destruction	▪ WHO/consignee ▪ NTD programme ▪ District health office ▪ Implementing partners (if supporting costs) ▪ Regional medical store ▪ Drivers ▪ Truck loaders/unloaders Level of authority required ▪ Signature authority to assign specific quantities of medicines to districts/distribution points ▪ Signature authority to remove medicines, either to release medicines to field sites or for destruction	▪ To transport donated/procured medicines and/or diagnostic materials ▪ To allocate and disseminate correct amounts of medicines and/or diagnostics to district level distribution points	4. Prepare for shipment transport from regional or district level, or after MDA to long-term storage and/or waste destruction 5. Assemble cartons/boxes for each distribution point 6. Prepare issue/receiving voucher for each regional medical store for total cartons for each destination 7. Inspect and count sealed cartons/count the number of bottles in the open cartons 8. Load trucks/unload trucks 9. Temporary storage or destruction 10. District receipt of shipment(s) and documentation 11. Delivery confirmation.

Task	Instruction	Responsibility	References
1	**Planning/coordination district to prepare for the district depot.** 1.1. 5 days before the start of the MDA, the district health office must ensure the medicines are implemented at the district level. 1.2. The NTD programme must ensure that the district depot manager is informed of the planned delivery and that the depot has storage space. 1.3. The NTD programme must build on the MDA's micro-planning to develop a district distribution plan. 1.4. The NTD programme must share the distribution plan with the district depot manager and inform them about the timing of the transition. 1.5. Depot manager must establish the bill of lading by district 1.5.1. This plan should include approximate travel times for each district-level delivery, taking into account appropriate downtime to rest, the need to avoid night driving and the use of the usual taxiways. 1.5.2. Obtain the necessary NTD programme approval for the distribution plan and transportation budget	▪ Regional medical store/district health office's point of contact coordinate with: ▪ NTD community programme ▪ Implementing partners ▪ Drivers ▪ Truck loaders/ unloaders	See Chapter 6: Storage
2	**Assemble cartons/boxes for each distribution point.** 2.1. Reassemble cartons with stock based on each district's quantity needs, identified in the distribution schedule. 2.2. Fill voids in cartons with packing material to avoid damage. 2.3. If feasible, label each carton by district destination for secondary verification. 2.4. Ensure oldest and previously opened stock is included first. 2.5. Any damaged/expired stock should be documented and removed.	▪ Regional medical store/district health office's point of contact coordinate with: : ▪ NTD community programme	See Chapter 7: First expiry first out See Chapter 10: Waste management
3	**Prepare issue/receiving voucher for each regional medical store for total cartons for each destination.** 3.1. Clearly mark how many bottles of each medicine type are going to each district.	▪ Regional medical store/district health office's point of contact coordinate with: ▪ NTD community programme ▪ Drivers	
4	**Inspect/count sealed cartons and count the number of bottles in the open cartons.** 4.1. Ensure tally sheets or other appropriate inventory management forms are in place before loading onto trucks. 4.2. Regional medical store and driver confirm against prepared vouchers and waybills and sign both.	▪ Regional medical store/district health office's point of contact coordinate with: : ▪ NTD community programme ▪ Drivers	See Chapter 5: Inventory management

Task	Instruction	Responsibility	References
5	Load trucks. 5.1. Load trucks systematically, using "first in, last out". 5.2. Using loading straps to prevent physical damage. 5.3. Secure vehicle doors against theft and weather. Confirm who has access. 5.4. Ensure routing provides sufficient time for rest, safety (avoid driving at night, bad roads). 5.5. Any shipment delivery taking longer than 1 day should be secured and visually inspected at every overnight stop and morning, with appropriate documentation.	■ Regional medical store/district health office's point of contact coordinate with: ■ NTD community programme ■ Drivers ■ Truck loaders	
6	Unload trucks and temporarily store or destroy. 6.1. Upon arrival, unload per the distribution schedule and follow the first expiry, first out approach. 6.2. Driver to present voucher and waybill to recipient at each district level, including title, name, signature and date (dd/mm/yyyy). 6.3. District point of contact to inspect/count sealed and unsealed cartons and sign prepared voucher. 6.4. District level should have designated storage for medicines until MDA. 6.5. Any damaged/expired stock should be documented and removed.	■ District point of contact in coordination with: ■ Regional medical store's point of contact ■ Drivers ■ Truck unloaders	See Chapter 6: Storage See Chapter 7: First expiry first out See Chapter 10: Waste management
7	District receipt of shipment(s) and documentation. 7.1. If documentation is incomplete or missing, district level should not accept the shipment; contact regional medical store point of contact for assistance. 7.2. If documentation does not match quantities received: 7.2.1. Accept delivery and prepare a supply discrepancy report to record the shortage or excess received. Give a copy to the driver to submit to the regional medical store point of contact. 7.3. In case of excess supply, return the excess goods and invoice to driver, and request a new invoice for quantity accepted. 7.4. Notify NTD community programme point of contact and district health office that quantities were received at district level.	■ District point of contact in coordination with: ■ Regional medical store's point of contact ■ Drivers	
8	Delivery confirmation. 8.1. Driver to receive and file with regional medical store a copy of the signed receiving as a record of delivery and date (dd/mm/yyyy).	■ District point of contact in coordination with: ■ Regional medical store's point of contact ■ NTD community programme ■ Drivers	

4.3.3 Transport from districts to care delivery points

(Including transport from districts after MDA to regional/central level for final storage or destruction)

When	Who	What	How
Upon request of district level (usually 2–4 weeks ahead of MDA) After MDA or after disease-specific assessment if stocks are returned to central/regional level or for destruction	▪ WHO/consignee ▪ NTD community programme ▪ District health office ▪ Implementing partners (if supporting costs) ▪ Regional medical store ▪ Drivers ▪ Truck loaders/unloaders Level of authority required ▪ Signature authority to assign specific quantities of medicines to districts/distribution points ▪ Signature authority to remove medicines, either to release them to field sites or for destruction	▪ To transport donated/procured medicines and/or diagnostic materials ▪ To allocate and disseminate correct amounts of medicines and/or diagnostics to district level distribution points	1. Prepare for shipment transport from regional or district level, or after MDA to long-term storage and/or waste destruction 2. Assemble cartons/boxes for each distribution point 3. Prepare issue/receiving voucher for each regional medical store for total cartons for each destination 4. Inspect and count sealed cartons/count the number of bottles in the open cartons 5. Load trucks/unload trucks 6. Temporary storage or destruction 7. District receipt of shipment(s) and documentation 8. Delivery confirmation .

Task	Instruction	Responsibility	References
1	Prepare for shipment transport from regional or district level, or after MDA for long-term storage and/or waste destruction. 1.1. Have NTD community programme distribution point of contact and implementers' (if required) contacts information on hand. 1.2. Liaise with the NTD community programme and regularly check when medicines are due to distribution points level(s). 1.3. Confirm district repository is aware of the planned delivery and that space is available. 1.4. Create a quantity and distribution schedule in coordination with the NTD community programme to ensure safe, efficient transport; share with the regional medical store and the district-level point of contact. 1.4.1. This should include approximate travel times for each district level delivery, factoring in appropriate rest stops, avoidance of night driving and poor road conditions.	▪ Regional medical store/district health office's point of contact coordinate with: ▪ NTD community programme ▪ Implementing partners ▪ Drivers ▪ Truck loaders/unloaders	See Chapter 6: Storage See Chapter 11: Forecasting and quantification

Task	Instruction	Responsibility	References
	1.5. Obtain necessary approval from the district NTD coordinator or district health office for the distribution plan and transportation budget.		
	1.5.1. Consider providing drivers with mobile airtime for reporting incidents in route; if drivers do not have mobile phones, consider providing a temporary phone with camera.		
	1.5.2. Ensure driver is paid to return signed forms to regional medical store or state medical store confirmation of delivery.		
	1.6. Ensure transport vehicles meet acceptable standards for transfer of medicines (e.g. working condition, appropriate cover from weather).		
	1.7. Determine the total number of cartons/boxes to be delivered to each distribution point.		
	1.8. Ensure vouchers are prepared for each district level designee.		
	1.9. Ensure that transport to districts is arranged for the necessary date(s). If trucks are not available for use by regional medical store, how will transport be provided?		
	1.10.Ensure staff are available to load/unload truck(s).		
	1.11.Prepare for transport security from theft, weather or other risks.		
	1.12.Identify/confirm who will have access to the stock during transport (if locked in truck).		
2	**Assemble cartons/boxes for each distribution point.** 2.1. Reassemble cartons with stock based on each district's quantity needs, identified in the distribution schedule. 2.2. Fill voids in cartons with packing material to avoid damage. 2.3. If feasible, label each carton by district destination for secondary verification. 2.4. Ensure oldest and previously opened stock is included first. 2.5. Any damaged/expired stock should be documented and removed.	▪ Regional medical store/district health office's point of contact coordinate with:: ▪ NTD community programme	See Chapter 7: First expiry first out See Chapter 10: Waste management
3	**Prepare issue/receiving voucher for each regional medical store for total cartons for each destination.** 3.1. Mark clearly how many bottles of each medicine type are going to each district..	▪ Regional medical store/district health office's point of contact coordinate with: ▪ NTD community programme ▪ Drivers	
4	**Inspect/count sealed cartons and count the number of bottles in the open cartons** 4.1. Ensure tally sheets or other appropriate inventory management forms are in place before loading onto trucks. 4.2. Regional medical store and driver confirm against prepared vouchers and waybills and sign both.	▪ Regional medical store/district health office's point of contact coordinate with: : ▪ NTD community programme ▪ Drivers	See Chapter 5: Inventory management

Task	Instruction	Responsibility	References

5	Load trucks.
	
	5.1. Load trucks systematically, using first in, last out approach.
	
	5.2. Using loading straps to prevent physical damage.
	
	5.3. Secure vehicle doors against theft and weather. Confirm who has access.
	
	5.4. Ensure routing provides sufficient time for rest, safety (avoid driving at night, bad roads).
	
	5.5. Any shipment delivery taking greater than 1 day should be secured and visually inspected at every overnight stop and morning, with appropriate documentation.
		▪ Regional medical store/district health office's point of contact to coordinate with::
		
		  ▪ NTD community programme
		
		  ▪ Drivers
		
		  ▪ Truck loaders	

6	Unload trucks and temporary storage or destruction
	
	6.1. Upon arrival, unload per the distribution schedule and follow the first in, first out approach.
	
	6.2. Driver to present voucher and waybill to recipient at each district level, including title, name, signature and date (dd/mm/yyyy).
	
	6.3. District POC to inspect/count sealed and unsealed cartons and sign prepared voucher.
	
	6.4. District level should have designated storage for drugs until MDA.
	
	6.5. Any damaged/expired stock should be documented and removed
		▪ District point of contact in coordination with:
		
		  ▪ Regional medical store's point of contact
		
		  ▪ Drivers
		
		  ▪ Truck unloaders
			See Chapter 6: Storage
			
			See Chapter 7: First expiry first out
			
			See Chapter 10: Waste management

7	District receipt of shipment(s) and documentation.
	
	7.1. If documentation is incomplete or missing, district level should not accept the shipment; contact regional medical store point of contact for assistance.
	
	7.2. If documentation does not match quantities received:
	
	  7.2.1. Accept delivery and prepare a supply discrepancy report to record the shortage or excess received. Give a copy to the driver to submit to the regional medical store point of contact.
	
	7.3. In case of excess supply, return the excess goods and invoice to driver, and request a new invoice for quantity accepted.
	
	7.4. Notify NTD community programme point of contact and district health office that quantities were received at district level.
		▪ District point of contact in coordination with:
		
		  ▪ Regional medical store's point of contact
		
		  ▪ Drivers	

8	Delivery confirmation.
	
	8.1. Driver to receive and file with regional medical store a copy of the signed receiving as a record of delivery and date (dd/mm/yyyy).
		▪ District point of contact in coordination with:
		
		  ▪ Regional medical store's point of contact
		
		  ▪ NTD community programme
		
		  ▪ Drivers	

5. Inventory management

5.1 Purpose and scope of this standard operating procedure

The purpose of managing inventories of donated NTD medicines is to:.

- minimize the total cost of inventory by balancing the costs of carrying and ordering stock;

- ensure that information on stock levels in the health system is readily available in all locations;

- facilitate adequate inventory for distribution to affected populations;

- avoid stockouts;

- ensure proper record-keeping;

- minimize losses, damage and misuse; and

- ensure accountability to pharmaceutical donors.

Inventory management is performed whenever stock is received, stored, transferred, near expiration or disposed of. It involves physical inspection, counting and maintaining records of stock.

5.2 Key considerations

The tasks and responsibilities in this procedure are relevant for:

- the national NTD programme;

- the supply chain, warehouse/stores and pharmacy staff at all levels of the health system; and

- NTD focal persons and supervisors of school and community drug distributors. The positions identified, their roles and the steps to be taken in this procedure are illustrative and should be adjusted according to the prevailing context in each country.

The national NTD programme should:

- regularly contact all sites where donated medicines are stored for inventory updates;

- encourage sites to conduct their own regular inventories of donated medicines alongside other health commodities and to create alert systems for expiring stock; and

- report the results of physical inventory to all stakeholders including implementing partners, national supply chain department, WHO, pharmaceutical donors or any other actor involved in MDA.

5.3   Standard operating procedure

5.3.1   Before and during MDA

When	Who	What	How
- Whenever stock is received, stored, issued or transferred, near expiration or disposed of. - Before MDA.	Responsible persons for stores management at each level of the health system, including: - supply chain manager - pharmacist - pharmacist technician - warehouse or stores supervisor - NTD programme staff - transporter - NTD programme coordinator - Health ministry	Physical inspection, counting and maintenance of stock records.	- Inspect and count stock received - Store donated medicines separately - Follow procedure in Chapter 7 First expiry first out - Use transfer forms to record stock movements (see Annex 4 for template)

Task	Instruction	Responsibility	References
1	Receiving donated medicines. 1.1. Before receiving stock, ensure that there is sufficient storage space and consider shelving. 1.2. Ensure that the area is clean, clear and prepared for receiving and storing stock. 1.3. Inspect and count stock received, updating the stock card and eLMIS system (where such a system is in use) accordingly. 1.4. Inspect stock for any damage and check expiry dates. 1.5. If required, follow the appropriate procedure for damaged and/or expired stock. 1.6. Complete a transfer form upon receipt of stock at each level. This form should be signed, dated, and a copy returned to the origin location.	- Supply chain manager - Pharmacist or technician - Warehouse or stores' supervisor - NTD programme coordinator - Transporter (driver)	See Chapter 3: Customs clearance See Chapter 4: Transport See Chapter 6: Storage See Chapter 7: First expiry first out See Chapter 8: Reverse logistics See Chapter 9: Removing expired and unserviceable medicines See Chapter 10: Waste management
2	Storing. 2.1. Physically separate the donated medicines from the nationally procured medicines. 2.2. Create a unique stock card and a unique stock code in the eLMIS (where such system is in use) to ensure that donated medicines are distinguishable from nationally procured medicines. 2.3. Attach a separate stock card to each stack of medicines in the warehouse/stores.	- Supply chain manager - Pharmacist or technician - Warehouse or stores' supervisor	See Chapter 6: Storage See Chapter 7: First expiry first out See Chapter 8: Reverse Logistics

Task	Instruction	Responsibility	References
3	**Issuing.** 3.1 Follow the first expiry, first out policy at all levels. 3.2. Only open one carton at a time to issue bottles at the community level. 3.3. Do not break cartons into single bottles except when issuing to school and community drug distributors. 3.4. Update the stock card immediately after issuing medicines (i.e. record keeping).	■ Supply chain manager ■ Pharmacist or technician ■ Warehouse or stores supervisor ■ Transporter (driver) ■ NTD programme coordinator	See Chapter 4: Transport See Chapter 7: First expiry first out
4	**Transferring.** 4.1. The transfer form should be used when issuing donated medicines, from one storage facility to another or to school or community drug distribution teams. 4.2. If there is no eLMIS system, two copies of the form should be used to record each transaction: ■ one copy goes to the destination with the carrier (i.e. the person responsible for transportation); and ■ one copy is kept in the location of origin for record-keeping. ■ Both copies of the form should have the same serial number. 4.3. The first part of the form records the origin, destination and name of the person transporting the shipment along with the quantity issued. 4.4. This part should be filled in at the origin location and signed by both the carrier and the issuer. 4.5. The second part of the form should be filled in at the destination and signed for by the carrier and the receiver. 4.6. Any damaged quantity in the shipment should be recorded on the form and the relevant staff informed, including NTD programme staff. 4.7. Follow relevant procedures for removing expired and unserviceable medicines (Chapter 9) and waste management (Chapter 10). 4.8. All levels of the health system, including school and community drug distribution teams, should use the same form when receiving medicines. 4.9. Transfer forms should be kept safely on file for the length of time mandated by the health ministry/donor	■ Supply chain manager ■ Warehouse or stores supervisor ■ Transporter (driver) ■ NTD programme coordinator ■ School or distribution centre point of contact ■ District health officer	See Chapter 4: Transport See Chapter 7: First expiry first out Annex 4: Stock transfer form template See Chapter 8: Reverse logistics See Chapter 9: Removing expired and unserviceable medicines See Chapter 10: Waste management

5.3.2 After MDA

When	Who	What	How
■ After each MDA ■ Before applying for and requesting a new consignment. For example, immediately before submitting the annual Joint Application Package/ Trachoma Elimination Monitoring Form ■ Whenever a regular physical inventory of other health commodities is conducted. ■ Any time when alerted to damage, loss and/ or theft. ■ When requested by the donor.	Responsible persons for stores management at each level of the health system, including: ■ supply chain manager, ■ pharmacist, ■ pharmacist technician, ■ warehouse or stores supervisor, ■ NTD programme staff, ■ transporter	1. Plan 2. Organize 3. Count 4. Reorganize 5. Update 6. Action	■ Check actual physical stock against the stock card balances. ■ Identify quantities of usable stock for distribution. ■ Detect and separate damaged and/or expired stock.

Task	Instruction	Responsibility	References
1	**Plan physical inventory.** 1.1. Set specific dates and times to conduct physical inventories. At a minimum, before and after each MDA, and whenever a regular physical inventory of other health commodities at the storage site is conducted. 1.2. Avoid busy times, as receiving and issuing stock must be paused for the duration of the counting process. 1.3. Identify at least two people (wherever possible) to conduct the count and reconciliation. 1.4. Ensure that there are no conflicts of interest. For example, the person in charge of the inventory should not participate but should be available on site to show the inventories	■ Supply chain manager ■ Warehouse or stores supervisor	See Chapter 6: Storage See Chapter 7: First expiry first out See Chapter 8: Reverse logistics
2	**Organize stock.** 2.1. Group bottles according to their expiry date. 2.2. Arrange the medicines by expiry date, older medicines at the front and newer at the back. 2.3. Opened bottles should be kept separate from closed bottles. ■ Any reconstituted oral solutions (e.g. pediatric oral solution of azithromycin) should not be saved in the inventory but disposed of immediately ■ Any chewable tablets (i.e. mebendazole) once opened have a shelf life of only 1-2 months, so should not be stored for the next MDA. 2.4. Separate damaged and/or expired medicines from usable stock. Follow the procedures for removing expired and unserviceable medicines (Chapter 9) and waste management (Chapter 10)	■ Supply chain manager ■ Warehouse or store supervisor	See Chapter 6: Storage See Chapter 7: First expiry first out See Chapter 8: Reverse logistics See Chapter 9: Removing expired and unserviceable medicines See Chapter 10: Waste management

Task	Instruction	Responsibility	References
3	**Count stock.** 3.1. One person should count while the other person records. 3.2. Use a different coloured pen to highlight the physical inventory quantities on the stock card. 3.3. Count one location at a time and record separately by expiry date group. 3.4. Count the number of bottles per expiry date group. 3.5. Mark the expiry date clearly, in large, dark numbers on the front of each carton. Separate any damaged or expired medicines, recording the amount in the losses/adjustments column on the stock card and provide a brief explanation for the expiry or damage. 3.6. Count the number of sealed/complete cartons first, then multiply this by the number of bottles in a carton; this will give you the total number of bottles. 3.7. Count the number of unopened bottles in open cartons. 3.8. Count the number of open bottles and divide the total count of by two; this will give you the estimated equivalent number of the full bottles. 3.9. Do not mix or consolidate open bottles into a single bottle. 3.10. On the physical inventory form (from the donor) record: - quantity of opened bottles - quantity of unopened bottles - expired and/or damaged product 3.11. Record quantities in the lowest unit denomination, and not by bottles. 3.12. Obtain sign-off on the final physical inventory report by the pharmacist/pharmacist technician or other relevant member of staff. 3.13. Set up an alert system for expiry dates of stock-on-hand; this should include alerts at 6 months, 3 months and 30 days. 3.14. Notify the NTD programme manager via SMS of any stock expiry alerts, providing medicine and quantities expiring.	▪ Supply chain manager ▪ Warehouse or stores supervisor ▪ NTD programme manager	See Chapter 6: Storage See Chapter 7: First expiry first out See Chapter 9: Removing expired and unserviceable medicines
4	**Reorganize stock.** 4.1. Reorganize the stock according to the expiration dates and complying with the first expiry first out (FEFO) policy. 4.2. If open stock is allowed for use, ensure that it is issued first during the next MDA campaign. 4.3. Complete the process as quickly as possible to allow normal operations to resume.	▪ Supply chain manager ▪ Warehouse or stores supervisor	See Chapter 6: Storage See Chapter 7: First expiry first out

Task	Instruction	Responsibility	References
5	Update stock card. 5.1. Once counting is finished, reconcile the total number of bottles counted with the quantities recorded on the stock card. 5.2. Use a different coloured pen to highlight the physical inventory stock quantity on the stock card. 5.3. If there are any differences, add or subtract the number of bottles on the stock card under the loss/adjustment column. Clearly record the date, quantity difference and write "Physical inventory". 5.4. Keep records of all stock cards for donated medicines. 5.5. Transfer stock cards that are older than 2 years to the national NTD programme.	▪ Supply chain manager ▪ Warehouse or stores supervisor	Annex 5 Stock card template Annex 6 Physical inventory count form template See Chapter 9: Removing expired and unserviceable medicines
6	Action. 6.1. Share physical inventory reports on donated medicines with the national NTD programme and national supply chain department where relevant. If the physical inventory differs from the stock card balance, report the reasons for the discrepancy. 6.2. Include actions resulting from physical inventory in budget planning. This may cover reverse logistics and waste management.	▪ Supply chain manager ▪ Warehouse or stores supervisor ▪ NTD programme manager	See Chapter 8: Reverse logistics See Chapter 9: Removing expired and unserviceable medicines See Chapter 10: Waste management

6. Storage

6.1   Purpose and scope of this standard operating procedure

Proper storage ensures the safety and high quality of medicines until their distribution to populations at risk through MDA. The procedure for proper storage conditions including monitoring storage ambient conditions must be observed to maintain the quality of the medicines until they exit the storage or warehouse. The main objectives of proper storage are to:

■   receive donated/procured medicines and/or diagnostic shipments;

■   safely store medicines and/or diagnostics until required by field distribution teams;

■   allocate and disseminate correct amounts of medicines and/or diagnostics to distribution points; and

■   receive and serve as a repository for remaining usable medicines and/or diagnostics after MDA or for disease-specific assessment.

6.2   Key considerations

A strong central or regional medical storage relationship with the NTD programme should be in place for management, operations, documentation and communication. To guide the amount of space in cubic metres required for different quantities of medicines, please refer to **Table 6.1**.

Management

■   Government-owned or private franchise.

■   Level of the warehouse central, regional, district or subdistrict levels.

■   Access, security and safety conditions of the storage/warehouse.

Table 6.1. Summary of logistic information for medicines donated for preventive chemotherapy

Medicine	No. of tablets/ bottle	No. of tablets/ shipper per case (carton box)	No. of shippers/ pallet	No. of tablets/ pallet	Size of pallet width/ length (cm)	Height of pallet (cm)	Net weight of pallet (kg)	Gross weight of pallet (kg)
Albendazole (400 mg tablets)	200	200 x 30 bottles (6000 tablets)	52	312 000	120 x 100	120	392	410
Mebendazole (500 mg tablets)	150	150 x 20 bottles (3000 tablets)	135	405 000	120 x 80	115		381
Praziquantel (600 mg tablets)	1000	1000 x 9 bottles (9000 tablets)	30	270 000	121 x 81	122	426	429
Diethylcarba- mazine citrate (100 mg tablets)	1000	1000 x 12 bottles (12 000 tablets)[a]	84	1 008 000	Min. 110 x 110 Max 120 x 120	127	322	340-350
Ivermectin (3 mg tablets)	500	500 x 96 bottles for full shippers	25[b]	1 195 000[c]	120 x100	115	127.9	153
Triclabendazol (250 mg tablets)	4	1200 tablets (320 paper boxes; 4 tablets/box)	18	21 600	120 x 80	89	88	~ 121
Azithromycin (500 mg tablets) for yaws	3	3 tablets x 60 packs	132	23 760	120 x 80	160	138	144
Praziquantel (600 mg tablets) from Bayer	1000	(1000 x 10)/ carton box	21	210 000	120 x 80	103	~ 400	
Niclosamide (400 mg tablets)	4	720 tablets/ shipper (4 x 15 x 180)	32	23 040	120 x 80	985	75	90
Azithromycin (250 mg tablets) for trachoma	500	500 x 24 (12 000 tablets)	54	648 000	120 x 100	80	359	379

[a] Shipping carton box (containing 1000 tablets/bottle x 12 bottles) of size 32 (L) x 25 (W) x 16 (W) cm and weight of 3.36 kg.

[b] 25 cartons (normally 24 full cartons with 96 bottles each; the last carton could be uncompleted, in this case, 86 bottles).

[c] Assuming 2390 units = 1 195 000 tablets is the largest pallet.

Operations

- Adequate storage procedure and system.

- Visual inspection and physical inventory frequency.

- Lot quality assurance sampling implementation and frequency, where available.

- Adequate storage conditions, observation and monitoring, including:

  - a cooling system;

  - power maintenance;

  - a storage structure; and

  - a daily log of conditions.

- Management/storage of other NTD supplies.

- Storage operation protocol including:

  - first expiry first out; and

  - waste/damage prevention and management.

Documentation and communications

- Forms and logbooks adapted to needs and properly used.

- Documentation processes for receipt/removal.

- Proper protocol for documentation.

- Electronic logistics information management system (eLMIS) and communication procedure.

6.3 Standard operating procedure

The positions identified, their roles and the steps to be taken in this procedure are illustrative and should be adjusted according to the prevailing context in each country.

6.3.1 Central storage of medicines before MDA

When	Who	What	How
▪ Central level → When providing green light to ship medicines to the country until 1 month before MDA	▪ Central NTD supply chain manager ▪ National NTD programme manager ▪ Consignee/forward clearing agent	▪ To receive and store NTD medicines initially arriving in country until needed for MDA ▪ To accurately allocate appropriate medicines and quantities to regions for distribution	▪ Prepare sufficient space and confirm arrival date to ensure access to storage ▪ Receive shipment(s) and documentation ▪ Stack new inventory ▪ Monitor storage ambient conditions

Task	Instruction	Responsibility	References
1	**Prepare sufficient space and confirm arrival date to ensure access to storage.** 1.1. Prepare storage space and proper conditions for shipment arrival. 1.2. Ensure necessary tools, including registers and stock cards are on hand. 1.3. Ensure tally sheets or other appropriate inventory management forms are in place. 1.4. Have consignee contact information on hand (with consignee previously designated) 1.5. Liaise with the NTD programme and regularly check delivery status and when medicines are due. 1.6. Ensure that transport to central medial store is arranged for the necessary date(s). 1.7. Ensure staff are available to unload the truck(s) and store stock. 1.8. Identify/confirm who will have access to the stock.	▪ Central NTD supply chain manager ▪ NTD programme manager ▪ Consignee/forward clearing agent	See Chapter 3: Customs clearance See Chapter 4: Transport See Chapter 5: Inventory management and Chapter 7 First expiry first out

2	**Inspect/count sealed/complete cartons received.**
	2.1. Receive shipment(s) and documentation.
	2.2. Verify and identify the quantity of each product received against documentation.
	2.3. Visual inspection and physical count of ... sealed/complete cartons:
	   ▪ physically count sealed/complete cartons; and
	   ▪ physically count the number of bottles in the open cartons.
	2.4. Document and remove any damaged, expired stock upon arrival
	2.5. Do not combine open bottle stocks into one bottle; keep them in separate bottles and label the carton accordingly regarding expiry date(s).
	2.6. Create a delivery confirmation note and send it to the NTD programme/central medical store manager.
		▪ Central NTD supply chain manager	See Chapter 3: Customs clearance
			
			See Chapter 5: Inventory management
			
			See Chapter 10: Waste management

Task	Instruction	Responsibility	References

3	Receive shipment(s) and documentation.
	
	3.1. Sign voucher and waybill, returning a copy to the clearing agent.
	
	3.2. If documentation is incomplete or missing, do not accept the shipment; contact the consignee for assistance.
	
	3.3. If documentation does not match quantities received:
	
	  ■ accept the delivery and prepare a supply discrepancy report to record the shortage or excess received; give a copy to the driver to submit to the supplier/shipper.
	
	  ■ In case of excess supply, return the excess goods and invoice to the driver, and request a new invoice for the quantity accepted.
	
	3.4. Notify consignee
		■ Central NTD supply chain manager
		
		■ Transporter
		
		■ NTD programme manager
		
		■ Consignee/ forward clearing agent
			See Chapter 3: Customs clearance
			
			See Chapter 4: Transport
			
			See Chapter 5: Inventory management

4	Create a delivery confirmation note and send to the NTD programme. 4.1. Document quantities received (e.g. pharmacy log; transfer forms/signed acknowledgment of receipt or report of the transaction by delivering and receiving parties). 4.2. Ensure NTD programme is notified if stock quantities do not match documentation (whether too much or too little).	■ Central NTD supply chain manager ■ Transporter ■ NTD programme manager ■ Consignee/ forward clearing agent	See Chapter 3: Customs clearance See Chapter 4: Transport See Chapter 5: Inventory management
5	Implement lot quality assurance protocol, if applicable 5.1. Ensure protocol is in place for lot testing if country pharmacovigilance policy and personnel are in place. 5.2. Document quality assurance activities and prepare report for WHO and/or national NTD programme.	■ Central NTD supply chain manager	
6	Stack new inventory (see Fig. 6.1). 6.1. Sort according to national policy, then by batch and expiry date, moving older drugs already in stock to the front of storage rack. 6.1. 1. If storing open cartons (leftover from previous MDA), reorganize the cartons to ensure oldest stock is at the front. 6.2. Mark the date received, expiry date and initials of the person making the notation clearly in large, dark numbers on the front of each carton/box and ensure markings all face forward. 6.3. Ensure as much as possible that NTD medicines are kept cool, dry, away from direct light and at an appropriate height for access and avoiding damage. 6.4. Fill in stock and bin cards.	■ Central NTD supply chain manager	See Chapter 5: Inventory management See Chapter 7: First expiry first out
7	Monitoring storage ambient condition 7.1. Daily monitoring should be conducted to maintain temperature control, security and to ensure boxes remain appropriately stacked. 7.2. Log monitoring results on an appropriate form	■ Central NTD supply chain manager	See Chapter 5: Inventory management

Fig. 6.1. Appropriate carton storage, with description, batch numbers and expiry dates facing forward "Keep temperature at 0–25 °C and relative humidity at 45–75% (personnel to measure twice weekly)" "Medicines stacked a minimum of …" "Stack height no more than 2.5 metres"

Source: Illustration by Cassandra Holloway

6.3.2 Central storage of medicines after MDA (2 weeks to 1 month after MDA)

When	Who	What	How
▪ Central level --> 1 month after MDA ▪ Regional/district level --> 2 weeks to 1 month after MDA ▪ Peripheral health facility --> 2 weeks to 1 month after MDA	▪ Central NTD supply chain manager ▪ Regional/district/ peripheral health facility NTD drug manager ▪ National NTD manager	▪ To receive and store leftover NTD medicines after MDA until needed for next MDA	▪ Prepare sufficient space and confirm arrival date to ensure access to storage ▪ Receive shipment(s) and documentation ▪ Stack new inventory ▪ Monitor storage ambient conditions

Task	Instruction	Responsibility	References
1	Prepare sufficient space and confirm arrival date from the regional/district level to ensure access to storage. 1.1. Prepare appropriate storage space and proper conditions for shipment arrival (see **Fig. 6.1**). 1.2. Ensure transport to central medical store is arranged with national NTD programme manager and regional/district supply chain manager. 1.3. Prepare a receiving voucher from each regional/district medical store for total cartons from each destination.	▪ Central NTD supply chain manager ▪ NTD programme manager ▪ Regional/district supply chain manager	See Chapter 4: Transport See Chapter 5: Inventory management See Chapter 6: Storage and **Table 6.1**
2	Receive shipment(s) and documentation and stack received inventory. 2.1. Receives shipment(s) and documentation. 2.2. Inspect/count the number of sealed cartons (after MDA) and the number of sealed bottles in open cartons (after MDA)/number of open bottles in open cartons (after MDA). 2.2.1. Any leftover bottles should be marked "opened dd/mm/yyyy" with initials. 2.3. Verify and identify the quantity of each product received against the receiving voucher from the regional/district medical store. 2.4. If the documentation does not match the quantities received from the regional/district medical store ▪ Accept the delivery and prepare a supply discrepancy report to record the shortage or excess received to the NTD programme and regional/district medical store as applicable. 2.5. Document and remove any damaged, expired stock upon arrival. 2.6. Reorganize and stack cartons/boxes. 2.7. Create a delivery confirmation note for the NTD programme, including all quantities by category (sealed, opened, damaged, expired). 2.8. Submit the delivery confirmation note and the supply discrepancy report (as needed) to the NTD programme	▪ Central NTD supply chain manager ▪ Transporter ▪ NTD programme manager	See Chapter 4: Transport See Chapter 5: Inventory management See Chapter 7: First expiry first out See Chapter 8: Reverse logistics See Chapter 9: Removing expired and unserviceable medicines See Chapter 10: Waste management See Chapter 6: Storage

Task	Instruction	Responsibility	References
3	Storage condition maintenance and monitoring. 3.1. Daily monitoring of storage temperature, security, and proper storage of stacked boxes. 3.2. Log monitoring results on an appropriate form.	▪ Central NTD supply chain manager	See Chapter 6: Storage

6.3.3   Regional/district/peripheral health facility storage before MDA

When	Who	What	How
1 month to 2 weeks from MDA date, upon receipt of new medicines	▪ Regional/district/peripheral health facility level programme coordinator or designee 　▪ Regional/district/peripheral health facility supply chain manager/logistician 　▪ Regional/district/peripheral health facility pharmacist ▪ Central national NTD supply chain manager ▪ National NTD manager	▪ To receive and store NTD medicines initially arriving at regional/district/peripheral health facilities before MDA ▪ To accurately allocate appropriate medicines and quantities to distribution points	▪ Prepare sufficient space and confirm arrival date to ensure access to storage ▪ Receive shipment(s) and documentation ▪ Stack new inventory ▪ Monitor storage ambient conditions

Task	Instruction	Responsibility	References
1	Prepare sufficient space and confirm arrival date to ensure access to storage. 1.1. Prepare for shipment arrival (from central level or field level as applicable) and ensure proper conditions for shipment arrival are in place. See **Fig. 6.1**. 1.2. Ensure appropriate space and pallets are available and necessary tools and registers/stock cards are on hand. 1.3. Ensure tally sheets or other appropriate inventory management forms are in place. 1.4. Have NTD country programme contact information on hand. 1.5. Liaise with the NTD programme and regularly check delivery status. 1.6. Ensure that transport to the regional medical store is coordinated with the district health office or NTD community programme. 1.7. Ensure staff are available to unload the truck(s) and store stock. 1.8. Identify/confirm who will have access to the stock. 1.9. Prepare receiving voucher for each regional/district medical store for total cartons from each destination.	▪ Regional/district/peripheral health facility NTD supply chain manager or designee ▪ NTD programme manager ▪ Central NTD supply chain manager	Section 6.3.4 Regional/district/peripheral health facility level storage See Chapter 4: Transport See Chapter 5: Inventory management Section 3.1 Central storage before MDA

Task	Instruction	Responsibility	References

2	**Receive shipment(s) and documentation and stack received inventory.**
	
	2.1. Receives shipment(s) and documentation.
	
	2.2. Visual inspection and physical count of sealed/complete cartons.
	
	   ■ Physically count sealed/complete cartons.
	
	   ■ Physically count the number of bottles in the open cartons.
	
	2.3. Verify and identify the quantity of each product received against the transport documentation.
	
	2.4. Document and remove any damaged, expired stock upon arrival.
	
	2.5. Do not combine open bottle stocks into one bottle; keep them in separate bottles and label the carton accordingly regarding expiry date(s).
		■ Regional/district/ peripheral health facility NTD supply chain manager	See Chapter 5: Inventory management
			
			See Chapter 10: Waste management
			
			See Chapter 6: Storage before MDA

3	**Receive shipment(s) and documentation.**
	
	3.1 Sign the receiving voucher and return a copy to the central medical store (confirm the transporter is contracted to do this).
	
	   ■ If the documentation is incomplete or missing, contact the field logistician, district health office or NTD community programme point of contact for assistance.
	
	   ■ If the documentation does not match the quantities received:
	
	     - Accept delivery and prepare a supply discrepancy report to record the revised totals.
	
	3.2. SMS the NTD programme manager with final counts received to ensure quick confirmation in case medicines can be used in other locations within the same MDA period.
	
	3.3. Create a delivery confirmation note and send to the NTD Programme.
		■ Regional/district/ peripheral health facility NTD supply chain manager
		
		■ Transporter
		
		■ NTD programme manager
			See Chapter 4: Transport
			
			See Chapter 5: Inventory management
			
			See Chapter 6: Storage before MDA

4	**Stack new inventory (see Fig. 6.1).**
	
	4.1. Sort according to type of medicine, then batch and expiry date, moving older bottles already in stock to the front of the storage rack.
	
	   ■ If storing open bottles leftover from MDA, ensure they are marked "opened dd/mmm/yyyy" with initials.
	
	   ■ Ensure that open bottles are issued first for upcoming MDA.
	
	4.2. If not already marked, mark the expiry date clearly, with large, dark numbers on the front of each carton/box and ensure markings all face forward.
	
	4.3. Ensure (as much as possible) medicines are kept cool, dry, away from direct sunlight and at an appropriate height for access and avoiding damage.
	
	4.4. Fill in stock and bin cards as applicable.
		■ Regional/district/ peripheral health facility NTD supply chain manager	See Chapter 5: Inventory management
			
			See Chapter 7: First expiry first out
			
			See Chapter 6: Storage before MDA

Task	Instruction	Responsibility	References
5	Storage conditions maintenance and monitoring. 5.1. Daily monitoring of storage temperature, security, and proper storage of stacked boxes. 5.2. Monitoring of temperature on an appropriate form. Recorded temperature monitoring data should be available for review. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. Equipment used for monitoring should also be calibrated at defined intervals.	▪ Regional/district/ peripheral health facility NTD supply chain manager	See Chapter 5: Inventory management See Chapter 6: Storage before MDA

6.3.4 Regional/district/peripheral health facility level storage after MDA (1 month – 2 weeks after MDA)

When	Who	What	How
2 weeks to 1 month after MDA date	▪ Regional/district/ peripheral health facility level programme coordinator or designee ▪ Regional/district/ peripheral health facility supply chain manager/logistician ▪ Regional/district/ peripheral health facility pharmacist ▪ Central national NTD supply chain manager	▪ To receive and store NTD medicines leftover after MDA until needed for next MDA	▪ Prepare sufficient space and confirm arrival date to ensure access to storage ▪ Receive shipment(s) and documentation ▪ Stack new inventory ▪ Monitor storage ambient conditions

Task	Instruction	Responsibility	References
1	Prepare sufficient space and confirm arrival date to ensure access to storage. 1.1. Prepare for shipment arrival (from field level as applicable) and ensure proper conditions are in place. 1.2. Ensure necessary tools, including registers, stock cards, tally sheets or other appropriate inventory management forms, are in place. 1.3. Liaise with the NTD programme and regularly check delivery status and when medicines are due. 1.4. Ensure that transport to central medical store is arranged for the necessary date(s). 1.5. Ensure staff are available to unload the truck(s) and store stock. 1.6. Identify/confirm who will have access to the stock. 1.7. (if regional medical store) Prepare receiving voucher from each district medical store for total cartons from each destination.	▪ Regional/district/ peripheral health facility NTD supply chain manager or designee ▪ NTD programme manager	Section 6.3.3: Regional/ district/ peripheral health facility level storage before MDA See Chapter 4: Transport See Chapter 5: Inventory management

Task	Instruction	Responsibility	References
2	**Receive shipment(s) and documentation and stack new inventory.** 2.1. Receives shipment(s) and documentation. 2.2. Conduct a visual inspection and physical count of sealed/complete cartons (physically count sealed/complete cartons; physically count the number of bottles in the open cartons). 2.3. Create a delivery confirmation note and send it to the NTD programme/central medical store manager. 2.4. Sort according to type of medicine, then batch and expiry date, moving older bottles already in stock to the front of the storage rack. ▪ If not already marked, mark the expiry date clearly, with large, dark numbers on the front of each carton/box and ensure markings all face forward. ▪ Any leftover bottles should be marked "opened dd/mmm/yyyy" with initials. 2.5. Ensure (as much as possible) medicines are kept cool, dry, away from direct sunlight and at an appropriate height for access and avoiding damage. 2.6. Fill in stock and bin cards as applicable. 2.7. Ensure that the open bottles are issued first during the next round of MDA. 2.8. If medicines will remain in regional/district/peripheral health facility storage until the next MDA, send a final tally with expiry dates to NTD programme point of contact for use in preparing the Joint Reporting Form and the Joint Request for selected medicines. 2.9. If medicines will be transported elsewhere or destroyed, notify the NTD community programme point of contact as soon as possible, with details on drugs and quantities.	▪ Regional/district/peripheral health facility NTD supply chain manager	Section 6.3.3: Regional/district/peripheral health facility level storage before MDA See Chapter 5: Inventory Management See Chapter 7: First expiry first out See Chapter 9: Removing expired and unserviceable medicines See Chapter 10: Waste management
3	**Storage conditions maintenance and monitoring.** 3.1. Daily monitoring of storage temperature, security, and proper storage of stacked boxes. 3.2. Log monitoring results on an appropriate form.	▪ Regional/district/peripheral health facility NTD supply chain manager	6.3.3 Regional/district/peripheral health facility storage before MDA See Chapter 5: Inventory management

7. First expiry, first out

7.1 Purpose and scope of this standard operating procedure

This procedure explains the process of minimizing the risk of wastage due to expiry, by ensuring that stock with the earliest expiry date is used first. Stock is organized according to expiry date; stock that will expire first is issued first, regardless of receipt into the medical stores or health facility. The "E" refers to the expiry date of the product, which is set by the manufacturer. First expiry first out (FEFO) is a best practice for stock management and is part of good storage practice and inventory management.

7.2 Key considerations

Warehouse management systems. Warehouse management systems should be used or introduced where possible to facilitate FEFO, whether electronic or paper-based. On receipt of stock, the batch/lot numbers, expiry dates and shelf/rack location should be captured in such systems and indicated on the shelves/rack where the product is stored. The store pharmacist/supply chain manager should set up an alert system and conduct regular checks to identify stock nearing expiry and to notify relevant stakeholders such as the NTD programme. Bottles and cartons should have their batch/lot number and expiry date clearly marked on each carton (see Fig. 7.1) and stock ledger cards (see Annex 7 for template).

Maximizing labour resources and productivity, and minimizing stock wastage due to expiry. The FEFO method can save labour costs and time, reducing issues related to expiry dates at the time of stock distribution. With such a process in place, the NTD programme can better manage stock levels and avoid wastages through expiry, thereby maximize the acceptable remaining shelf-life of stock-on-hand and increase overall resource productivity and benefits to local target populations. **Physical inventory checks and monitoring of stock expiry dates are still required.**

Stewardship of donated medicines. The FEFO method has the benefit of demonstrating effective programme stewardship of donated NTD medicines, reducing reported numbers of expired and wasted stock on the Joint Reporting Form (see Chapter 1) and decreasing additional stock needs due to more accurate reporting of available stock (see Chapter 11), ensuring greater confidence in the relationship between pharmaceutical donors and recipients.

Fig. 7.1. Writing the expiry date(s) on each carton of medicine received (dd/mm/yyyy)
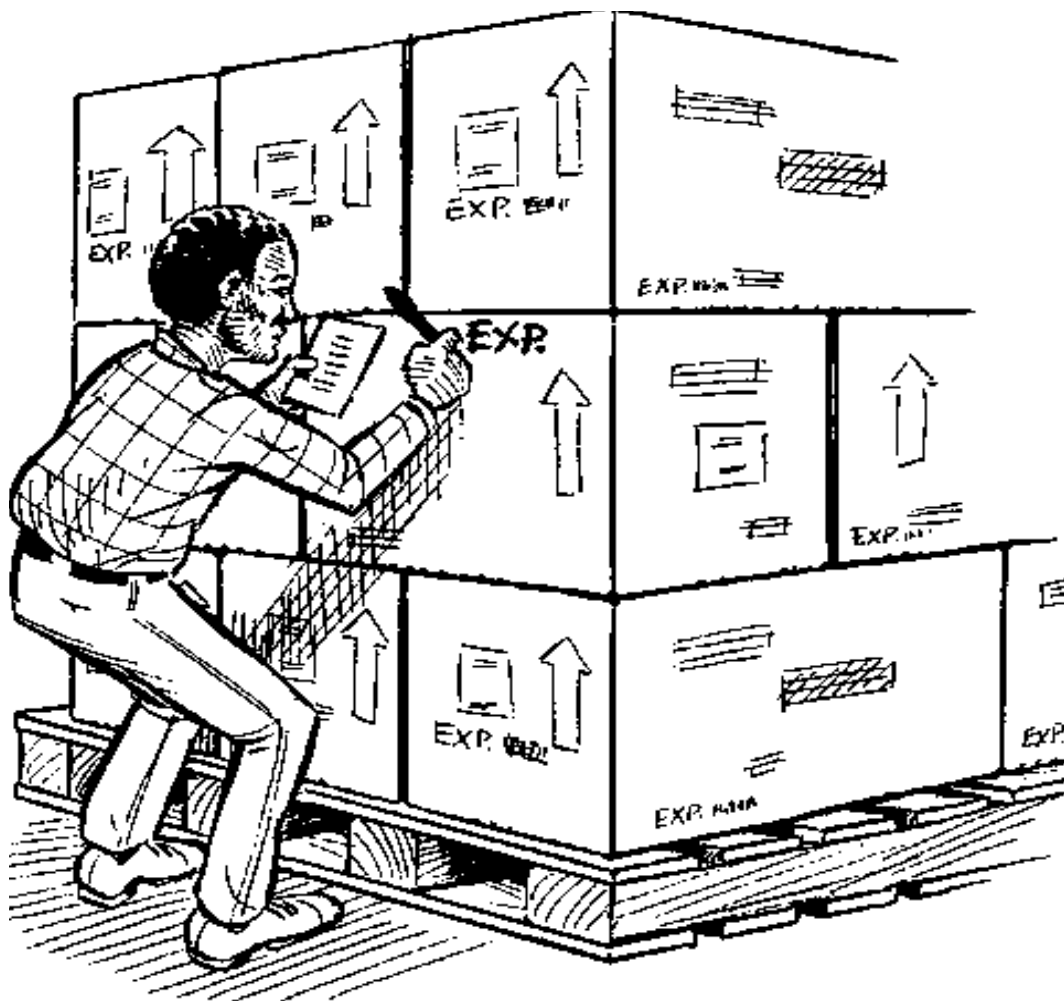
Source: Illustration by Cassandra Holloway

7.3   Standard operating procedure

The positions identified, their roles and the steps to be taken in this procedure are illustrative and should be adjusted according to the prevailing context in each country.

7.3.1   Central storage of medicines before MDA

When	Who	What	How
▪ Whenever medicines are received into the storage facility ▪ Whenever medicines are to be transferred between storage facilities ▪ Before MDA ▪ After MDA and on receipt of leftover stock	▪ Store pharmacist ▪ Pharmacy technician ▪ Medical store supply chain managers at all levels (central, regional, district, point of care)	▪ Prioritize distribution of soon-to-expire medicines ▪ Minimize wastage of medicines due to expire	▪ Clearly mark expiry dates and keep records on inventory ▪ Conduct routine checks and keep stock organized by expiry date ▪ Check remaining shelf-life policies and issue notifications of stock with expiry dates less than 6 months

Task	Instruction	Responsibility	References
1	Clearly mark expiry dates and keep records on inventory (Fig. 7.1) 1.1. On receipt of new or leftover stock, mark expiry dates with a black marker on the outside of each carton, making sure that the dates are visible at a distance. 1.2. In the case of single unopened bottles, write the expiry date in large letters on the bottle. 1.3. Any opened bottles should be marked "opened dd/mm/yyyy" with initials as well as the expiry date in a different colour marker. 1.4. Record inventory details such as batch/lot number, expiry dates and quantities on stock forms and warehouse systems (e.g. stock ledger card, warehouse management system). 1.5. Confirm and document the acceptable remaining shelf-life for medicines. Follow the country policy at the time of receipt of stock.	▪ Store pharmacist ▪ Pharmacy technician ▪ Medical store supply chain managers at all levels (central, regional, district, point of care)	See Chapter 5: Inventory management See Chapter 6: Storage See Chapter 8: Reverse logistics
2	Keep stock organized by expiry date at all times 2.1. Place bottles or cartons of each medicine so that the stock first to expire is stacked in front of or on top of the stock of the same medicine that will expire later. Where several products that have the same expiry date, follow same the principle: place stock that has the earliest expiry date first for picking/issuing. 2.2. Conduct routine checks and reorder each time additional stock is received.	▪ Store pharmacist ▪ Pharmacy technician ▪ Medical store supply chain managers at all levels (central, regional, district, point of care)	Stock ledger card (Annex 7) Warehouse Management System (where available) See Chapter 5: Inventory management See Chapter 6: Storage

Task	Instruction	Responsibility	References
3	**Expiry date notifications and issuing stock.** 3.1. Use the stock ledger card or the warehouse management system where available to routinely check the expiry dates of stock-on-hand and to confirm that the batch/lot number of the stock picked is based on first expiry, first out. 3.2. Routinely share quantities of stock-on-hand and expiry dates with the NTD programme. 3.3. Issue monthly notifications of products with expiry dates of < 6 months. 3.4. Any expired medicine must be documented and transferred for proper disposal as soon as possible per national policy. 3.5. Notify the NTD programme of all expired medicines, by name and quantity.	▪ Store pharmacist ▪ Pharmacy technician ▪ Medical store supply chain managers at all levels (central, regional, district, point of care) NTD programme manager	Stock ledger card (Annex 7) Warehouse management system (where available) See Chapter 6: Storage See Chapter 5: Inventory management See Chapter 9: Removing unserviceable and expired medicines See Chapter 10: Waste management

8. Reverse logistics

8.1   Purpose and scope of this standard operating procedure

This procedure guides countries through the process of reverse logistics for NTD medicines, including return and transfer of medicines from downstream to upstream of the supply chain system. Arranging reverse logistics is as important as distribution planning and should be developed as a part of MDA. This procedure mainly applies to unused NTD diagnostics.

Objectives

■   To ensure integrity of the national supply chain for donated and procured medicines.

■   To prevent theft and commercialization of medicines.

■   To avoid wasting resources in countries by procuring or requesting too much or too little for MDA needs, whether from WHO, procurement agencies or other purveyors.

Expected results

■   No diversion of medicines from designated repositories before or after MDA.

■   No expired medicines.

■   No wasted medicines.

■   Appropriately stored medicines for use in the next round of MDA.

■   Unusable medicines directed for disposal according to national policy.

8.2   Key considerations

To ensure that leftover medicines are properly managed and to prevent loss of stock, the national NTD programme coordinator(s) or assignee(s) should take the following into consideration.

- Ensure adequate budget to support reverse logistics (per diems, transportation, fuel, etc.) as part of MDA planning including:

  - developing strategies to motivate community drug distributors, teachers or health facility workers (as applicable) to round up and consolidate leftover medicines after MDA. These responsible parties are not always compensated for travel when returning medicines, which decreases their motivation to do so.

- Ensure that all unused medicines are returned to the final designated repository <u>no more than one month</u> after completion of MDA campaigns. This entails:

  - planning a specific timeline for each stage of return;

  - identifying people to conduct the inventory at each stage and aggregating the leftover stock at each designated level; at least two people should jointly conduct the inventory; and

  - planning for follow-up of identified gaps in leftover returns so that all medicines are reconciled or reported.

- Develop a plan and identify those responsible for executing, finalizing and submitting reconciliations of open and closed bottles, storage/reuse versus destruction to the central medical store or central pharmacy (see procedures for transport (Chapter 4), inventory management (Chapter 5), Storage (Chapter 6), first expiry first out (Chapter 7) and waste management (Chapter 10) for recommended steps at each stage).

- Report open and closed bottle stocks stored for future use on the Joint Reporting Form after MDA (Chapter 1) and forecasting and quantification (Chapter 11).

  - For azithromycin tablets or pediatric oral solution, also report stocks to the International Trachoma Initiative (ITI).

  - Any reconstituted oral solutions should not be saved in the inventory but disposed of immediately.

  - For chewable tablets (i.e. mebendazole) the shelf-life is only 1–2 months after opening, so they should not be stored for the following year's MDA.

- Sort and dispose of expired and damaged medicines according to government guidelines and document this process (see procedure for waste management in Chapter 10). Share the documentation with the national NTD programme coordinator or assignee to ensure their inclusion in the Joint Reporting Form. The positions identified, their roles and the steps to be taken in this procedure are illustrative and should be adjusted according to the prevailing context in each country.

8.3   Standard operating procedure

The overarching steps in the reverse logistics process may vary by country context. The positions and responsibilities below illustrate typical steps taken at each stage of reverse logistics, from MDA level to central medical storage. It is recognized that some countries may opt to keep leftover medicines at regional or district levels; if so, the subsequent points on the timeline can then be disregarded. This procedure can and should be adapted to the specific context of each country. Sample template forms are included in Annexes 8 and 9. Other forms and documentation needed for effective reverse logistics are **shown in bold in the instructions**. For assistance in developing document templates, please contact WHO.

When	Who	What	How
Immediately after MDA	▪ Community drug distributors/teachers/ health facility staff, as applicable to MDA context ▪ District medical store manager	▪ Returns leftover, damaged and expired medicines to a previously designated facility/district medical store (as applicable in country).	▪ Complete the drug return/transfer form according to the job aid (Annexes 8 and 9)
1–2 weeks after MDA (if medicines are to move to higher level storage facilities)	▪ District NTD coordinator or assignee ▪ Regional/district medical store manager	▪ Confirms total treatment numbers against received medicines. ▪ Notes any discrepancies and/ or missing stock for follow up and sends report to regional or national NTD coordinator (as appropriate in country context). ▪ Takes custody of returned medicines and keeps records of quantities received from each district (and implementation unit if available). ▪ Makes note of data gaps and reports them to national NTD coordinator for follow up.	▪ Complete the drug return/transfer form according to the job aid (Annexes 8 and 9)
1–2 weeks after MDA (if medicines are to move to higher level storage facilities)	▪ District NTD coordinator or assignee ▪ Regional/district medical store manager ▪ Central medical store	▪ Confirms receipt of returned medicines from all districts. ▪ Returns all Stage 2 collected medicines to central storage after consultation with National NTD Coordinator. ▪ Takes custody of returned medicines.	▪ Complete the drug return/transfer form according to the job aid (Annexes 8 and 9)

Task	Instruction	Responsibility	References
1	Stage 1: Collection at designated facility or storage nearest to MDA point (typically district level, but may be subdistrict, depending on number of implementation units in area) 1.1. Plan to complete this task immediately after MDA. 1.2. Damaged, expired or otherwise unusable medicines should be clearly labelled and packaged separately. Batch numbers (located on bottle or packaging) should also be provided if available. 1.3. Collect empty bottles and deface labels (using a dark marker or lighter) for destruction per country waste management policy. 1.4. Count open bottles/containers separately from unopened (sealed) bottle/containers. 1.5. Provide a count of total treatment numbers and **drug stock balance record** or drug return/transfer forms to district NTD coordinator along with the leftover medicines. 1.6. District store or health facility contact keeps temporary custody of returned medicines and keeps **records of quantities received**, including batch numbers. 1.7. If this is a formal storage facility where MDA medicines will remain, updates **stock ledger** and prepares **stock status report** of available quantities, expiry dates, waste for NTD programme. Medicines are then boxed and stored.	■ Community drug distributors/ teachers/health facility staff as applicable to MDA context ■ Transporter (as applicable) ■ District medical store manager ■ District NTD coordinator	Drug return/transfer form (Annex 8) Job aid for completing drug return/transfer form (Annex 9) See Chapter 5: Inventory management See Chapter 6: Storage See Chapter 7: First expiry first out See Chapter 10: Waste management
2	Stage 2: Collection of aggregated bundles from all Stage 1 facilities at regional store (if medicines are to move to higher level storage facilities) 2.1. Plan to complete this task within 1–2 weeks after MDA. 2.2. Confirm total treatment numbers against received medicines. 2.3. Note any discrepancies and/or missing stock for follow-up and send **report** to regional or national NTD coordinator (as appropriate in country context). 2.4. Return all Stage 1 collected medicines to the regional medical store after consultation with the national NTD coordinator. 2.5. Take custody of returned medicines and keep **records of quantities received** from each district (and implementation unit if available). 2.6. Make note of data gaps and report them to the national NTD coordinator for follow up. 2.7. Collate the quantity returned with the batch numbers clearly stated. 2.8. Update the **stock ledger** and also prepare the **stock status report**	■ District medical store manager ■ District NTD coordinator or assignee ■ Regional/ provincial medical store ■ Transporter (as applicable)	Drug return/transfer form (Annex 8) See Chapter 5: Inventory management See Chapter 6: Storage See Chapter 7: First expiry first out

Task	Instruction	Responsibility	References

3	Stage 3: All leftover medicines after MDA returned to central medical store for next MDA
	
	3.1. Plan to complete this task within 1–3 weeks after MDA.
	
	3.2. Confirm **receipt** of returned medicines from all districts.
	
	3.3. Return all Stage 2 collected medicines to the central medical store after consultation with the national NTD coordinator.
	
	3.4. Central medical store takes custody of returned medicines.
	
	3.5. Verify numbers of damaged, expired medicines against reports; separate those for destruction.
	
	3.6. Group opened bottles by medicine type and ensure open bottles are properly labelled as open, marked "opened dd/mm/yyyy" with initials as well as the expiry date in a different colour marker.
	
	    3.6.1. Follow national policies regarding future use of opened bottles.
	
	    3.6.2. Any reconstituted oral solutions should not be saved in the inventory but disposed of immediately.
	
	    3.6.3. For chewable tablets (i.e. mebendazole) the shelf-life is only 1–2 months after opening, so they should not be stored for the next year's MDA.
	
	3.7. Store remaining, usable medicines for the next MDA.
	
	3.8. Update the **stock ledger**, including batch numbers, and also prepare the stock **status report.**
		▪ Regional NTD coordinator or designee
		▪ Central medical store
		▪ Transporter (as applicable)
			(1)
			
			See Chapter 5: Inventory Management
			
			See Chapter 6: Storage
			
			See Chapter 7: First expiry first out
			
			See Chapter 10: Waste Management

References

1. Zithromax® management guide. Decatur (GA): International Trachoma Initiative; 2019 (https://www.trachoma.org/zithromax-management-guide, accessed 18 March 2022).

9. Removing expired and unserviceable medicines

9.1 Purpose and scope of this standard operating procedure

This procedure covers expired or unserviceable medicines that are stored at any level of the health system. It involves removing stock from the medical stores/health facilities where medicines are stored and updating inventory records for stores/facilities and the national NTD programme. It is part of inventory management of stock in country to assure quality of products used in NTD treatments such as MDA.

Expired medicines include any medicine that has passed the manufacturer's expiry date listed on the label. These medicines are not suitable for distribution to any population requiring treatment.

Unserviceable medicines include:

■ damaged stock (e.g. water damaged, contaminated, broken, exposed to prolonged temperature variations);

■ stock whose shelf-life is considered too short for distribution in the next scheduled MDA, including

  ■ leftover reconstituted paediatric oral solution of azithromycin,

  ■ opened bottles of chewable mebendazole and

  ■ new medicines that will expire during MDA

■ missing medicines (e.g. lost/theft) from the physical inventory; and

■ opened bottles recovered from theft, due to the loss of quality control.

9.2   Key considerations

Generally, stock is managed through periodic inventory management, which may be conducted monthly, quarterly and annually (see related procedure for inventory management in Chapter 5).

For medicines used in preventive chemotherapy, this procedure should help to:

■   confirm inventory for use in MDA;

■   eliminate use of expired medicines during MDA;

■   reduce storage costs; and

■   verify available stock before and after MDA for use in forecasting and quantifying next year's request for medicines.

Appropriate inventory tools and reports include:

■   stock inventory reports/registers as applicable;

■   stock cards; and

■   stock adjustment request forms.

Accurate reporting of stock to the NTD programme is essential to upstream communication to WHO, donors and implementing partners and to properly plan upcoming and subsequent MDAs.

9.3   Standard operating procedure

The positions identified, their roles and the steps to be taken in this procedure are illustrative and should be adjusted according to the prevailing context in each country.

9.3.1   At any time before, during and after MDA

When	Who	What	How
■ At least 30 days (i.e. one calendar month) before MDA ■ Maximum 21 days (i.e. within one calendar month) of MDA ■ Periodically at central, regional and district medical stores and health facilities where medicines are stored	■ Warehouse clerk(s) ■ Storekeeper/ supervisor ■ Distribution pharmacist ■ NTD focal person	■ Identification of expired or unserviceable stock ■ Complete the Stock Adjustment Request Form ■ Reporting to the NTD programme	1. Immediately separate affected stock from usable stock 2. Communicate to NTD programme 3. Update store and stock inventory records e.g. stock card

Task	Instruction	Responsibility	References
1	**Review physical inventory and reports** 1.1. Review the most recent physical stock and inventory records to identify any expired or unserviceable stock and quantities. ▪ If the last inventory record is more than 90 days old, conduct a new physical inventory to update the record. 1.2. Goods in/out processes (e.g. receiving, picking and packing stock) should not happen while conducting a physical inventory	▪ Warehouse clerk ▪ Storekeeper ▪ Pharmacist	See Chapter 5: Inventory Management See Chapter 6: Storage Inventory report/register (Annex 10) Stock adjustment request form (see Annex 11 for template) Stock card (see Annex 5 for template)

2	**Report and separate expired and unserviceable stock**
	
	2.1. Upon identification of expired or unserviceable stock, the warehouse clerk completes a stock adjustment request form and submits it to the distribution pharmacist for endorsement.
	
	2.2. Upon review and approval, the distribution pharmacist completes a stock adjustment.
	
	2.3. The warehouse clerk separates expired or unserviceable stock from usable stock.
	
	2.4. The warehouse clerk removes expired or unserviceable stock to a separate location for storage, pending safe and proper disposal.
	
	    ▪ Where space is limited, expired or unserviceable stock should be clearly labelled and placed inside a clearly labelled, sealed carton to avoid it being distributed during or after MDA.
	
	2.5. The warehouse clerk updates the stock card:
	
	    ▪ Remove approved expired and unserviceable quantities from the appropriate stock card.
	
	    ▪ For expired stock, write "EXP" and the reference number of the stock adjustment request form in the remarks column.
	
	    ▪ For damaged/unserviceable stock write "DAM" and the reference number of the *Stock adjustment request form* and the nature of the damage in the remarks column.
	
	    ▪ For missing stock write "MIS" and the reference number of the stock adjustment Request form in the remark's column.
	
	2.6. Follow national guidelines for waste management of medicines.
		▪ Warehouse clerk
		▪ Storekeeper
		▪ Pharmacist
			See Chapter 5: Inventory Management
			
			See Chapter 10: Waste Management
			
			Annex 11: Stock adjustment request form
			
			Annex 5: Stock card

3	**Report to the NTD programme.** 3.1. Report the quantities of unserviceable medicines with details and rationale for expiry or unserviceability to the NTD programme.	▪ Stores in-charge ▪ Pharmacist ▪ NTD focal person	Refer to NTD programme report

10.   Waste management

10.1   Purpose and scope of this standard operating procedure

This procedure covers the process of disposing of expired and unserviceable medicines as well as guidance on disposal methods for empty bottles. It should be read in conjunction with the procedures for reverse logistics (Chapter 8) and for removing expired and unserviceable medicines (Chapter 9).

Waste management helps prevent dispensing of expired and unserviceable medicines to the communities we serve. It is essential to avoid diversion of unusable medicines for commercialization or illegal markets.

Medicines that have expired or are unserviceable should NOT be administered under any circumstances; they should be destroyed and reported to WHO via the Joint Reporting Form (and to ITI for azithromycin products).

Expired and unserviceable medicines include:

■   all tablets or paediatric oral solutions of medicines that have expired;

■   all damaged bottles of medicines (e.g. punctured or leaking bottle);

■   all open bottles of chewable or reconstituted medicines or paediatric oral solutions that remain after completion of the MDA campaign; and

■   all medicines in bottles without any expiry date or with a label that is illegible.

If donated medicines meet any of the conditions above, the national NTD programme manager and the NTD pharmacist at the relevant storage level should be notified immediately. Identified field personnel should follow the necessary steps in this standard operating procedure for the destruction of medicines under the direction of the national NTD programme manager or their assignee.

MDA campaigns do not produce infectious waste; however, there are two types of waste relevant to NTDs and MDA:

- **ordinary waste**, including empty bottles and packaging materials, gloves, masks, cups and spoons used during MDA; and

- **pharmaceutical waste**, including expired or unserviceable (e.g. damaged, contaminated) medicines. These medicines are termed "unusable drugs" and should be treated in accordance with the country's governmental directives on pharmaceutical waste management.

10.2   Key considerations

10.2.1   Cooperation

Disposal of pharmaceutical waste usually requires cooperation among different departments or agencies, ministries and levels of the government within a country. Depending on the country, the authority in charge of managing pharmaceutical waste may be the Department of Pharmacy within the Ministry of Health, the Drug Regulatory Authority, a regional or local authority, or the Ministry of Environment. The NTD programme should identify the authorized regulatory body and appropriate stakeholders. Once identified, these stakeholders and authorities should identify and implement the correct procedures for safe management of NTD pharmaceutical waste.

Lack of awareness of the consequences of irresponsible waste management for NTD medicines, as well as lack of training for community health workers including MDA supervisors and community drug distributors on the correct procedures, can lead to serious health consequences. Stakeholders should therefore ensure that expired and unserviceable medicines are kept away from unauthorized groups or individuals and returned to a safe location for proper disposal.

Keeping expired and unserviceable NTD medicines in storage facilities, even if separated from usable medicines, can lead to unqualified dispensing of unusable medicines. It also allows expired and unserviceable medicines to occupy vital storage space that could be used for other medicines/commodities.

Secure removal of expired and unserviceable medicines from storage facilities helps the national NTD programme to mitigate the risk of unusable medicines being dispensed to the target population. It also avoids jeopardizing public health and the reputation of the national NTD programme.

10.2.2   Integrated waste management

In many situations, MDAs occur in conjunction with other health interventions such as child health days or vaccination campaigns. In these situations, the management of waste from the respective programmes should be coordinated equally as planning of implementation of the service distribution. This will help to reduce costs and lower risks of waste being improperly disposed of.

10.3   Standard operating procedure

The positions identified, their roles and the steps to be taken in this procedure are illustrative and should be adjusted according to the prevailing context in each country.

10.3.1 Before and after MDA – national level

When	Who	What	How
▪ During the planning stages for MDA ▪ After MDA	▪ National NTD programme manager ▪ MDA supervisors ▪ Central/regional medical stores manager ▪ NTD pharmacist ▪ National health waste management coordinator	▪ Disposal of unusable NTD medicines and packaging at the national level	▪ Planning and training ▪ Disposal of unusable NTD medicines and packaging ▪ Reporting of disposed NTD waste

Task	Instruction	Responsibility	References

1	**Planning and training**
	
	1.1. Review the Joint Application Package for required reporting on leftover, expired and wasted stocks.
	
	1.2. Review the national health waste management policy for requirements.
	    ▪ Determine the policy's applicability to NTD medicines and packaging..
	
	1.3. Develop an NTD waste management plan, including WHO reporting requirements.
	    ▪ Identify persons responsible to execute, finalize and submit reconciliations of open bottle stocks as well as closed bottles, storage/reuse versus destruction to the central medical store or central pharmacy. At least two people should jointly conduct the physical inventory and verify counts.
	    ▪ If NTD waste will be destroyed at regional level, coordinate with regional medical stores to develop and employ the NTD waste management plan.
	
	1.4. Ensure there is an adequate budget to support reverse logistics and waste management (per diems, transportation, fuel, etc.) as part of MDA planning.
	
	1.5. Develop strategies to motivate community drug Distributors, teachers or health facility workers (as applicable) to round up and consolidate leftover as well as unusable drugs after MDA.
	
	1.6. Plan a specific timeline for each stage of return.
	
	1.7. Communicate the NTD waste management plan to NTD coordinators, focal persons, MDA supervisors, pharmacists, medical stores managers and other relevant stakeholders as required.
	
	1.8. Ensure all persons responsible for generating, handling or transporting contaminated waste are trained. Training should occur as a component of the MDA training.
		▪ NTD programme manager/ coordinator
		▪ NTD pharmacist
		▪ Central/regional medical stores manager
			See national health waste management policy
			
			See Chapter 1: Joint Application Package
			
			See Chapter 4: Transport
			
			See Chapter 5: Inventory management
			
			See Chapter 8: Reverse logistics
			
			See Chapter 9: Removing expired and unserviceable medicines

Task	Instruction	Responsibility	References
2	**Disposal of unusable drugs and packaging.** 2.1. Ensure that all unusable drugs are disposed of no more than one month after completion of MDA campaigns. . ■ In some countries, this activity is done through a well-established committee or team composed of different sectors and several representatives from the health sector. In such circumstances, the already existing mechanism should be used, adapted to include the NTD programme or focal points. ■ Employ the developed NTD waste management plan, ensuring each stage is followed as documented. ■ Dispose of expired and damaged medicines according to government guidelines and document the process. 2.2. Any reconstituted oral solutions of a medicine should not be saved in the inventory but disposed of immediately. 2.3. For chewable tablets (i.e. mebendazole), the shelf-life is only 1–2 months after opening, so they should not be stored for the next year's MDA but should be disposed of.	■ NTD programme manager/ coordinator ■ NTD pharmacist ■ Central/regional medical stores manager ■ National health waste management coordinator (where existing)	See Chapter 1: Joint Application Package See Chapter 4: Transport See Chapter 5: Inventory management See Chapter 6: Storage See Chapter 7: First expiry first out See Chapter 8: Reverse logistics See Chapter 9: Removing expired and unserviceable medicines See Chapter 11: Forecasting and quantification
3	**Reporting of disposed NTD waste.** 3.1. Report the disposal of damaged, expired or otherwise unusable stocks on the Joint Reporting Form. 3.2. For azithromycin tablets or paediatric oral solution, also report damaged, expired or otherwise unusable stocks to the International Trachoma Initiative. 3.3. Follow up on any identified gaps in returns of leftover medicine, so all medicines (whether usable or not) are reconciled or reported on the Joint Reporting Form.	■ NTD programme manager/ coordinator	See Chapter 1: Joint Application Package See Chapter 8: Reverse logistics See Chapter 9: Removing expired and unserviceable medicines *(1)*

10.3.2   After MDA – community level

When	Who	What	How
Immediately after MDA	Community drug distributors/teachers/ health facility staff (as applicable to MDA context)	Return waste to designated supervisor, health facility, district medical stores	Return ordinary and pharmaceutical waste

Task	Instruction	Responsibility	References
1	**Return ordinary and pharmaceutical waste.** 1.1. Ordinary and pharmaceutical waste is returned to a previously designated health facility or district medical stores (as applicable in the country): ■ label expired and unserviceable medicines; ■ record information on the quantity returned, batch/lot number, reason for unusable condition, etc.; ■ package expired and unserviceable medicines and store separately from usable leftover stock	■ Community drug distributors ■ Teachers/ health facility staff (as applicable to MDA context)	See Chapter 8: Reverse logistics See Chapter 9: Removing expired and unserviceable medicines National health waste management policy **Fig. 10.1** examples A and B

10.3.3   After MDA – supervisor level

When	Who	What	How
■ Within 2 weeks after MDA	■ MDA supervisor or assignee ■ NTD focal person	■ Collect waste from all MDA implementation units in area of responsibility ■ Prepare for disposal ■ Return to designated level	■ Gather and separate usable leftover stock and unusable stock (waste) ■ Prepare for return and disposal ■ Return all collected waste to designated waste repository

Task	Instruction	Responsibility	References
1	**Gather and separate usable leftover stock and unusable stock (waste).** 1.1. Take possession of ordinary and pharmaceutical waste from all MDA implementation units 1.2. Centralize all waste from distribution sites within their area of responsibility. 1.3. Separate empty bottles and unusable stock from usable leftover stock 1.4. Conduct a physical inventory of this waste	■ MDA supervisor or assignee ■ NTD focal person	See Chapter 5: Inventory Management See Chapter 8: Reverse logistics **Fig. 10.1** examples A and B
2	**Prepare for return and disposal.** 2.1. Oversee defacing of bottles, as per country health waste management policy. If permitted by the policy, empty, defaced bottles may then be preserved at district facility level for personal use with instructions to thoroughly wash inside of bottle with soap and water. 2.2. Aggregate quantities, conditions, and reports of unusable stock for return and disposal. 2.3. Consult with NTD focal person for designated area on the next step. If facilities available and permitted by the policy, dispose at site following authorized methods. 2.4. Send report to the district or regional level (as applicable in the country) for disposal incineration no more than seven days after the MDA is completed in the area of responsibility.	■ MDA supervisor or assignee ■ NTD focal person	See national health waste management policy **Fig. 10.1** example B

Fig. 10.1. Stock destruction

Example A: Destruction options

Example B: Defacing labels

Source: Illustrations and photographs by Cassandra Holloway

Task	Instruction	Responsibility	References
3	Return all collected waste to district or regional medical store or other designated waste repository. 3.1. Steps to be identified per country health waste management policy and NTD waste management plan.	▪ MDA supervisor or assignee	See national health waste management policy See Chapter 8: Reverse logistics

10.3.4   After MDA – district/regional level

When	Who	What	How
Within one month after MDA	▪ District or regional/provincial medical stores or assignee ▪ NTD focal person	Gather all quantities of expired and unserviceable stock returned after MDA and prepare for disposal or transfer	▪ Collate unusable stock from district and subdistrict levels ▪ Return all collected waste to designated waste repository ▪ Record information on standard forms and report to relevant stakeholders

Task	Instruction	Responsibility	References
7	Collate unusable stock from district and sub-district levels. 7.1. Ensure that district-level NTD waste has been collected and brought to the regional level for disposal or transfer to central level (as applicable in the country) as outlined in the NTD waste management plan. 7.2. Record all quantities and batch/lot numbers of each NTD medicine marked for disposal, along with reasons for disposal; verify that all bottles have been appropriately defaced. 7.3. Keep stock for disposal separate from usable stock, and ensure it is clearly marked. 7.4. If the waste is to be destroyed at district level, the regional NTD focal person should receive the report that the MDA waste has been destroyed or defaced and that no further action is needed.	▪ District or regional/provincial medical store or assignee ▪ Regional NTD focal person	Annex 12 document examples Chapter 8: See national health waste management policy See NTD waste management plan Fig. 10.1 example B
8	Prepare for return and disposal. 8.1. Initiate process for disposal as outlined in the NTD waste management plan. 8.2. Follow guidelines on disposal methods and document all quantities destroyed or defaced. 8.3. If waste is to be transferred to central level, document all quantities to be transferred and prepare a report for the national NTD coordinator.	▪ District or regional/provincial medical store or assignee	Section 10.3.1: Handling ordinary and pharmaceutical waste

Task	Instruction	Responsibility	References
9	Record information on standard forms and report to relevant stakeholders. 9.1. If the waste is to be destroyed at regional-level, prepare a report that the MDA waste has been destroyed or defaced and that no further action is needed. 9.2. Submit report to the national NTD programme for recording on the Joint Request Form.	▪ Regional NTD focal person	Annex 12 document examples

10.3.5 Handling ordinary and pharmaceutical waste: guidance on disposal methods

Managing empty bottles. All empty bottles of medicines should be defaced with a permanent marker and washed thoroughly, if the national health waste management policy agrees to let the community keep and reuse empty bottles (**Table 10.1**).

One of the following waste disposal methods should be used to dispose of the damaged/expired medicines, adhering to the national waste management policy (**Table 10.2**).

Table 10.1. Ordinary waste management documentation and destruction

Priority scale	Action	Guidance
First	Disposal	Follow the health ministry and/or national environmental regulations for disposal of pharmaceutical containers where available. This may include incineration in a "burn and bury" pit or incinerator burning at 800–1000 °C (see **Fig. 10.1, example A photographs**). **Incineration with medium-to-high temperature burning disposal method for MDA waste**. This is especially important for NTD medicines that may have health and environmental concerns if not disposed of properly. This option may not be available locally, but it may be possible to return waste to an offsite facility that uses incineration (burning at ⩾ 800–1000 °C). **Incineration at a local cement kiln, if available**. A cement kiln can use small amounts of waste (5%) as fuel. These incinerators reach similar temperature ranges. **Drum or pit-burning low-temperature burning**, while not ideal, can provide some level of proper incineration while reducing the environmental and health hazards of NTD MDA waste products. To use this method, collect trash and put it in a barrel-shaped furnace or pit, and set it on fire. Ensure that it is placed downwind of work and residential areas and away from any water source. The combustible part of the trash will burn (< 400 °C), and the remainder will melt. Generally, low-temperature burning is not recommended for several reasons: plastics and pharmaceuticals release toxic gases when they are burned, releasing contaminants into the air. Therefore, drum or pit burning should be the last option for NTD programme waste. Designated staff should supervise the fire. After the fire is out, cover the ash and remaining material with soil, as described above, to prepare for the next burn and bury. **Never remove or move ash in a burn-and-bury pit**.
Second	Reuse	Preserve the bottles for personal use after they are properly cleaned and defaced using a lighter or permanent marker. The NTD drug label is pressure-sensitive and cannot easily be peeled off (see **Fig. 10.1, example B photographs**).
Third	Recycle	If the bottles are not reused, send them to a recycling facility, where available in the country.

Table 10.2. Pharmaceutical waste management documentation and destruction

Priority scale	Disposal method	Method
First	Disposal	As outlined in **Table 10.1**.
Second	Manufacturer-recommended disposal method	Add water to the product to wet it down to render unusable, then incinerate as described in **Table 10.1** example A.
Third	WHO guideline	For solid tablets, suitable methods are: ■ waste encapsulation in a concrete, non-reactive steel or plastic container and burial; and ■ medium or high temperature incineration (cement kiln incinerator; see **Table 10.1** and **Fig. 10.1** example A) For paediatric oral solution or other liquified medicines: ■ dilute with water, leave to stand for several weeks and then discharge to sewer.

11. Forecasting and quantification

11.1 Purpose and scope of this standard operating procedure

This procedure explains the annual process for accurately estimating the quantities of preventive chemotherapy medicines required to reach the planned target population and coverage in the country, for the year of request. It covers the preventive chemotherapy medicines that are part of WHO's global NTD medicine donation programme for endemic countries.

Quantification is the first step in the forecasting process.

11.2 Key considerations

This exercise should be done by the national NTD programme and submitted to the WHO regional office. The WHO regional office and WHO headquarters then review and finalize the forecast. The forecasted information is communicated by WHO headquarters to the donating pharmaceutical companies to help with their production plans.

Accurate and timely forecasts are critical to the provision of donated medicines for NTDs amenable to preventive chemotherapy. Short-term forecasts are requested by WHO from country programmes to accommodate the planning, production and shipping time for the donating pharmaceutical companies to meet the annual need for production. This forecast is submitted during the annual request for medicines in the Joint Application Package for the following year showing the forecasts for the next 2 years.

It is the responsibility of the NTD programme to:

■ collect and analyse the epidemiological data;

■ secure commitments for government and/or donor funding, resources and implementing partner support;

■ check eligibility for donated medicines and obtain accurate stock-on-hand data, as well as plan to procure medicines where required; and

■ ensure technical and programmatic capacity to distribute the medicine in the country.

The forecast quantification of the number of tablets is determined according to the parameters shown in **Table 11.1**.

11.3　Standard operating procedure

The positions identified, their roles and the steps to be taken in this procedure are illustrative and should be adjusted according to the prevailing context in each country.

11.3.1　Complete the Joint Request for selected medicines: not less than 12 months before MDA

When	Who	What	How
Not less than 12 months before MDA	■ NTD programme manager ■ Disease-specific managers ■ Logistics manager	■ Data collection and analysis ■ Forecasting and quantification ■ Submission of accurate, complete Joint Request signed by health ministry	1. Contact relevant stakeholders to provide data for analysis 2. Download and complete the requirements of the Joint Request 3. Sign and submit the Joint Request to WHO headquarters and the WHO regional office

Task	Instruction	Responsibility	References
1	Gather all the data needed to enter into the Joint Request, as outlined in Table 11.1. 1.1. Request required data from all disease-specific program managers and implementing partners. Data to include (but not necessarily limited to): 　■ Current endemicity level of the implementation units using results of recent epidemiological survey (e.g. mapping surveys, transmission assessment survey results, impact assessment survey) 　■ Number of rounds of MDA required for each disease for control/elimination targets, according to disease-specific epidemiology 　■ Target population and dosage needs by age 1.2. Request stock-on-hand data from the central medical stores and all other subnational medical stores where NTD preventive chemotherapy medicines are stored. Inventory data of medicines remaining should be recorded in the (e)LMIS and/or obtained from all levels from NTD focal points 1.3. Call a meeting with relevant stakeholders to review data	■ NTD programme manager ■ Logistics manager ■ NTD implementing partners ■ Disease-specific managers ■ WHO national programme coordinator	See Demographic information Disease mapping data National (e)LMIS (or equivalent system which records the inventory of NTD preventive chemotherapy medicines in country) Other drug sources, if available in country Contact information for WHO regional office See Chapter 1: Joint Application Package See Chapter 5: Inventory management See Chapter 8: Reverse logistics

Table 11.1. Parameters for forecasting quantification of donated medicines for preventive chemotherapy

Parameter	Source(s)	Use
1. Current endemicity level of the implementation units using results of recent epidemiological survey (e.g. mapping surveys, transmission assessment survey results, impact assessment survey)	Country report using Epidemiological Reporting Form Formal and informal publications and survey reports or presentations	This epidemiological information may indicate that part of the country would interrupt or expand MDA in the following year. Estimate the number of people eligible for MDA based on up-to-date population data and disease prevalence by district or implementation unit.
2. Check if there is a plan to procure or receive medicine donations from other sources	Other donor information or government procurement plan	Subtract the committed amount from the forecast or indicate the amount and source so that it will not be considered in the donor's pharmaceutical donation plan.
3. Information on commitment from the funding or implementing partners in support of the country	Amount of committed funding (domestic or donor support) Country agreement with donor Official memorandum of understanding or informal donor information on predicted funding for the next 2 years	Information on commitment indicates that part of the country would continue, expand or interrupt MDA in the following year.
4. Information on the country's capacity to distribute the medicine (technically and/or financially)	Data from previous implementation Availability of human resources and infrastructure of the country (e.g. NTD programme, implementing partner support)	Information on capacity indicates that part of the country would continue, expand or interrupt MDA in the following year.
5. Number of rounds of MDA required for each disease for control or elimination according to disease-specific epidemiology	Guidelines on preventive chemotherapy and transmission control	According to disease prevalence, the frequency of yearly MDA and the total number of rounds of MDA may differ (e.g. schistosomiasis, soil-transmitted helminthiases, trachoma).
6. Consider the target population and estimate needs based on the dosage needs by age	Guidelines on preventive chemotherapy and transmission control	The average amount of medicine must be calculated to quantify the total requirement. For example, the average amount of medicine for diethylcarbamazine citrate is 2.5 tablets and for albendazole and mebendazole is 1 tablet.
7. Total number of tablets estimated to be needed in the country	Population requiring preventive chemotherapy based on above multiplied by the number of tablets in an average dose. Demographic data (population numbers and growth, demographic trends) at the implementation unit level	This will provide the upper limit of a donation. If it is discordant from the country request, the country should request an update in the WHO PCT databank.

Task	Instruction	Responsibility	References
2	**Complete annual forecasting and quantification for country demand.** 2.1. Download appropriate Joint Request form (Microsoft Excel template) from the WHO website that corresponds to your local language and NTD endemicity 2.2. Fill in the form with recent epidemiological and up-to-date stock data for the country 2.3. Produce the annual forecast of the quantity of medicine needed for each disease, in collaboration with the disease focal points at the WHO regional office 2.4. Complete the consignee information on the shipment tab 2.5. Obtain signature from appropriate health ministry representative and date the form	▪ NTD programme manager ▪ Logistics manager	See quantification result/report See Chapter 1: Joint Application Package
3	**Submit the completed, signed form to WHO headquarters, the WHO regional office and cc the WHO country representative.** 3.1. Ensure the Joint Request includes the Joint Reporting Form and the Epidemiological Data Reporting Form 3.2. Ensure the Consignee and the central medical store are aware of the submission and prepared to receive the medicines when they arrive.	▪ NTD programme manager ▪ WHO national programme coordinator	See Chapter 1: Joint Application Package See Chapter 6: Storage
4	**Maintain and update records for future submissions.** 4.1. Store the (2–3 year) forecasts locally and update annually as part of the Joint Application Package submission process	▪ NTD programme manager	See Chapter 1: Joint Application Package

Annex 1. Glossary of key terms and abbreviations

This glossary provides brief definitions of terms and abbreviations used in the document; they may have different meanings in other contexts.

annual workplan

Form that provides information on key preventive chemotherapy and collateral activities by health ministries for planning purposes (see Joint Application Package).

batch number, control number or lot number

Any distinctive combination of letters, numbers or symbols, or any combination of them, from which the complete history of production, processing, packaging, handling and distribution of a batch or lot of medical product or other material can be determined *(1)*. This number is available on the packing list, invoice and pallet.

DAM ("damaged medicines")

Example notation for recording damaged or unserviceable stock on the stock card.

delivery confirmation note

Document that accompanies a shipment of goods and provides a list of the products and quantity of the goods included in the delivery.

demurrage

Daily fees assessed on containers inside a port until the consignment is cleared through customs and received by the consignee. The shipment has a limited amount of free time, calculated in days, before these fees are imposed. This free time depends on the shipping company and the port of entry (in the United States, for example, there is a 4-day fee exemption for dry containers and 2 free days for refrigerated containers).

detention inland carrier

Hourly fee assessed on the amount of time a driver has to wait for unloading of cargo at a warehouse. The shipment has a limited amount of free time in hours before assessment of charges. Free time depends on the shipping line and the port of entry.

detention shipping line

Daily fees assessed on containers outside a port until the inland carrier returns the container to the shipping line. The shipment has a limited amount of free time in days before assessment of charges. Free time depends on the shipping line and the port of entry.

drug aggregation

Process of gathering leftover medicines from the same level (e.g. from multiple distribution points for mass drug administration), bundling them together with an aggregated count and then transferring that bundle to the next stage in the process of the returning medicines.

drug distribution schedule

Schedule containing the plan for transporting medicines based on the quantities required by region and district.

drug return process

Movement of medicines from the distribution point (lowest level) to the long-term storage or destruction point (highest level).

drug transfer

Movement of medicines between facilities at the same level (e.g. between distribution points during mass drug administration).

eLMIS

Electronic logistics management information system used to manage government supply chain systems in a country.

Epidemiological Reporting Form

Form to assist countries in reporting epidemiological information including coordinated distribution of medicines (see Joint Application Package).

EXP ("expired medicines")

Example notation for recording expired stock on the stock card.

first expiry, first out

Method used to organize stock including medicines by expiry date and issue stock with the earliest expiry date regardless of the date of receipt. This process differs from first in, first out because leftover medicines may be returned from the field and stored for future mass drug administration; they may have newer expiry dates than recently received or transferred stock. Expiry date is the driving factor, not the date of receipt.

first in, first out

Method used to ensure stock that enters medical stores or pharmacies first is also sold first. It does not take into account the age of the product or how long it has been in a country. For neglected tropical diseases, first expiry, first out is the standard approach.

> Example: if a storage facility (at any level) receives a shipment of albendazole on 1 April with an expiry date of September 2023, that stock should be stored BEHIND the leftover albendazole that arrived from the field on 30 June and expires in September 2022. The 30 June stock arrived later but expires earlier. The later-expiring stock should ALWAYS be stored in front of the earlier-expiring stock of the same product.

first in, last out

Procedure whereby the last order is loaded first, the second to last loaded next and so on, with the first to be delivered now being located at the back of the truck.

inventory management

Process of ordering, storing and using inventory, as well as warehousing and processing of such items.

invoice

Time-stamped commercial document that itemizes and records a transaction.

Joint Application Package

WHO-led system through which countries request medicines donated by pharmaceutical companies for treatment of neglected tropical diseases amenable to preventive chemotherapy. It is a set of four forms: the Joint Request for selected medicines, the Joint Reporting Form, the Epidemiological Reporting Form, and the Annual Workplan.

Joint Reporting Form

Form to assist countries in reporting annual progress on integrated and coordinated distribution of medicines across diseases in the reporting year in a standardized format (see Joint Application Package).

Joint Request for Selected Medicines

Form to assist countries in applying for albendazole, diethylcarbamazine citrate, mebendazole, ivermectin and praziquantel for use in the year after the year of application (see Joint Application Package).

mass drug administration (MDA)

Distribution of medicines to the entire population of a given administrative setting (for instance, state, region, province, district, subdistrict or village). In this document, the terms mass drug administration and preventive chemotherapy are used interchangeably.

MIS ("missing medicines")

Example notation for recording medicines missing from stock.

neglected tropical diseases (NTDs)

A diverse set of 20 diseases and disease groups that disproportionately affect populations living in poverty, predominantly in tropical and subtropical areas. They impose a devastating human, social and economic burden on more than 1 billion people worldwide. They include Buruli ulcer; Chagas disease; dengue and chikungunya; dracunculiasis; echinococcosis; foodborne trematodiases; human African trypanosomiasis; leishmaniasis; leprosy; lymphatic filariasis; mycetoma, chromoblastomycosis and other deep mycoses; onchocerciasis; rabies; scabies and other ectoparasitoses; schistosomiasis; snakebite envenoming; soil-transmitted helminthiases; taeniasis and cysticercosis; trachoma; and yaws.

open bottles

Contents of bottles that have not been fully used at the end of mass drug administration. Each medicine will have a different shelf-life once opened and should be considered on a case-by-case basis following the manufacturer's recommendations and the opening date clearly marked on the bottle/container.

periodic inventory

Monthly, quarterly, biannual or annual inventory stock counts as may be the standard practice at specific warehouse levels in the country.

physical inventory

Process of counting stock and reconciling records of stock.

physical inventory form

Form to record results of stock count reconciliation, discrepancies in quantities and reasons.

preventive chemotherapy

Large-scale use of medicines, either alone or in combination, in public health interventions. Mass drug administration is one form of preventive chemotherapy; other forms could be limited to specific population groups such as school-aged children and women of childbearing age. In this document, the terms preventive chemotherapy and mass drug administration are used interchangeably.

proof of delivery

Document signed by the recipient to confirm that the shipment was delivered in good condition.

receiving voucher

Transactional document that provides a permanent record of medicines received from central or regional medical stores.

record-keeping

Physical inventory is accounted for on two important forms: stock cards and transfer forms. Storage facilities should use both forms to record current stock and the history of all transactions or adjustments (i.e. receiving, issuing, distributing and physical inventory reconciliation).

reverse logistics

Process of returning usable surplus supplies including medicines and/or expired or damaged supplies from lower levels to the next level within the supply chain to facilitate redistribution to places where medicines are needed or need to be disposed of if damaged and/or expired.

SAFE strategy

Surgery, antibiotics, facial cleanliness and environmental improvement to eliminate trachoma as a public health problem.

shelf-life

Length of time for which a material may be stored while retaining its properties of use.

stock card

Card to specifically record receipts, issues and adjustments for medicines stored in a particular location and generally to keep track of inventories of medicines while in storage.

stock ledger card

Also known as a "bin card", a card to keep a record all receipts and issues of stocks from the pharmacy stock/store department.

supply discrepancy report

Tool to report shipping or packaging discrepancies attributable to the responsibility of the shipper (including US Government sources and contractors/manufacturers/vendors) and to provide appropriate responses and resolution, including financial action when appropriate. The purpose of the supply discrepancy report exchange is to determine the cause of such discrepancies, effect corrective action and prevent recurrence.

Trachoma Elimination Monitoring Form

Form designed by the International Trachoma Initiative to assist countries in applying for azithromycin (Zithromax®) and for monitoring progress towards elimination of trachoma as a public health problem.

transfer form

Form to record the details of stock movements from one location to another.

transmission assessment survey

Survey designed to measure whether evaluation units have lowered the prevalence of filarial infection to a level where recrudescence is unlikely to occur, even in the absence of mass drug administration interventions.

waybill

Document prepared by the carrier of a shipment of goods that contains details of the shipment, route and charges.

References

1. Code of Federal Regulations, Title 21. Washington (DC): United States Food & Drug Administration; 2018 (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3, accessed 17 May 2021).

Annex 2. Contact list template

[Medicine name] contact sheet

Pharmaceutical contacts for shipment:

Add appropriate names as relevant. Confirm contacts with WHO.

Proforma information:

Add appropriate names as relevant. Confirm contacts with WHO.

Contact/delivery information:

Consign to/deliver to:

Importer of record:

Routing/notify:

Annex 3. Action items and greenlight checklist

Action	Responsible
1. Review contact list for accuracy and completeness.	
2. Confirm that shipping documentation requirements are correct.	
3. Review green light checklist items A, B and C. Answer "Yes" when ready.	

Medicine shipment green light checklist		Responsible	Yes/No
A. Communication	Are the customs agents aware of the shipment and its quantity?		
B. Customs duty waiver	Has the customs duty waiver been prepared?		
C. Customs clearance and handling costs	Are funds available to pay customs clearance and handling costs for the inbound shipment?		
D. Warehouse space	Does the central medical store have space to receive the shipment?		
E. Distribution	Is the country prepared to distribute the medicines?		

Annex 4. Stock transfer form template

STOCK TRANSFER FORM

Form Serial No. _____
Date: _____

Origin:
Destination: _____

Name and address of the carrier/person responsible:

_____

_____

Transfer Item list: (to be filled at the origin)

Item	# of cartons	# of bottles	Total quantity shipped in good condition (in # of bottles)
(INSERT NAME OF DRUG)			
(INSERT NAME OF DRUG)			

Issuer: _____   Carrier: _____

(The following section should be filled out at the destination)

List of quantity received in good condition:

Item	# of cartons	# of bottles	Total quantity shipped in good condition (in bottles)	Damaged/loss (in bottles)	Total quantity received in good condition (in bottles)
(INSERT NAME OF DRUG)					
(INSERT NAME OF DRUG)					

Note for damaged /lost quantity (if any):

Issuer: _____   Carrier: _____

Annex 5. Stock card template

NAME OF MEDICINE: **STOCK CARD**

Storage location: **Storage unit:**

Date (dd/mm/yyyy)	Transfer form serial no.	Origin/destina-tion	Quantity received (bottles)	Quantity issued (bottles)	Losses/adjust-ments (bottles)	Quantity on hand (bottles)	Remarks	Signature of the store in-charge

Annex 6. Physical inventory count form template

SAMPLE PHYSICAL INVENTORY COUNT FORM

SAMPLE PHYSICAL INVENTORY COUNT FORM

Sheet No.		Date	
Performed by		Department	

Inventory No.	Item description	Purchase price	Quantity	Location

Signature	
Your signature	

Annex 7. Stock ledger card template

Item:		Unit/pack size:			Card no.	
Strength/size:					Code no.	
Maximum level:		Reserve stock level:			Lead time:	
Minimum level:		Order quantity:				
Date	**Received from/ Issued to**	**No. received**	**No. issued**	**New balance**	**Remarks**	**Signature**

Source:Procurement and management of supplies and equipment. In: Kaur M, Hall S. Medical supplies and equipment for primary health care. Surrey (UK): ECHO International Health Services Ltd; 2001: 13–28 (https://www.who.int/management/resources/procurement/MedicalSuppliesforPHC(2)Procurement&Management.pdf, accessed 18 March 2022).

Annex 8. Drug return/transfer form template

Text in red is illustrative.

Step	Responsible	Data point
1.	State/region/district where transfer originates	
2.	District/MDA distribution point where transfer originates	
3.	Receiving facility: Write the name of the facility where the medicines are to be returned/transferred at this stage.	Receiving facility: FLHF/LGA/State central medical store
4.	Medicines returning/transferring facility: Write the name of the facility that is returning or transferring the medicines.	Medicines returning/transferring facility: e.g. public health center Ibeto, Kontagora District store or central medical store
For each medicine being returned or transferred:		
5.	Item description, strength and dosage form Write the name and description of the medicine	Item description and dosage form: Zithromax tablet 250 mg
6.	Unit: Write the smallest unit of measurement for the medicine.	Unit: Tablet, cap, bottle, tube, etc.
7.	Batch no: Write the batch number of the medicines being returned/transferred.	Batch no: EPA22221
8.	Expiry date: Write the expiry date of the medicines being returned/transferred.	Expiry date: December 2024 or 12/2024

Step	Responsible	Data point
9.	**Quantity returned/transferred:** Write the quantity of medicines being returned/transferred.	**Quantity returned/transferred:** 600 tabs, caps, tubes or bottles
10.	**Reason for return/transfer:** Write the reason why the product is being returned.	**Reason for return/transfer:** Damaged, expired, unused or redistribution
11.	**Items return/transfer officer:** The person who is returning/transferring the medicines writes his/her name and signature, mobile number and date.	**Items return/transfer officer:** Mohammad Amin, MA, 080xxxxxxxxxxx, 16/11/2019
12.	**Items return/transfer approving officer:** The person who approves the return/transfer writes his/her name, signature, mobile number and date.	**Items return/transfer approving officer:** Moses Jacob, MJ, 083xxxxxxxxxxxx, 16/11/2019
13.	**Transporter:** The driver transporting the medicines writes his/her name, signature, mobile number, date and vehicle registration number.	**Transporter:** Nathan Yao, NY, 060xxxxxxxxxxx, 16/11/15, BDG 114 XY
14.	**Receiving facility:** The person who receives the returned/transferred medicines writes his/her name, signature, mobile number and date.	**Receiving facility:** Amy Ido, AI, 090xxxxxxxxxxx, 17/11/15
15.	**Receiving witness:** The person who witnesses receipt of the returned/transferred medicines writes his/her name, signature, mobile number and date.	**Receiving witness:** Jasmin Riota, JR, 089xxxxxxxxxxx, 19/11/15
16.	**Remarks:** Written by the receiving officer to acknowledge the quantity and condition of the returned medicines.	**Remarks:** e.g. complete, incomplete, unlabelled, improperly packaged

Annex 9. Job aid for completing the drug return/transfer form

This job aid can be used to complete the form for returning or transferring NTD medicines from one level to another.

The form is a transaction record that should be completed in quadruplicate (four copies). Once this activity is completed, the copies are distributed as follows:

■ white copy to the receiving facility;

■ yellow copy to the returning/transferring facility;

■ green copy to the transporter; and

■ blue copy to remain at the returning/transferring facility.

Job aid
Task: Completing the NTD medicines return/transfer form.

Completed by:

■ the officer at the community/MDA distribution level who is returning or transferring the medicines;

■ the officer approving the return or transfer of the medicines;

■ the person responsible for transporting the medicines;

■ the person receiving the medicines; and

■ the person witnessing the transaction.

Purpose:
To track the return or transfer of NTD medicines.

When to perform:
Each time NTD medicines are returned or transferred from any level.

Materials/tools needed:
Blank NTD medicines return/transfer form, calculator, metre ruler and pen.

This task is completed when:

- the names of the state, district or health facility to which the medicines were sent and the facility returning or transferring the medicines have been completed;

- the returned or transferred medicine is fully described by batch number, expiry date, the quantity returned/transferred recorded and the reason(s) for the transaction stated;

- the person returning or transferring the medicines signs the form;

- the transporter signs the form;

- the approving officer signs the form;

- the witness to the transaction signs the form;

- the receiving officer signs the form; and

- a signed copy of the form is sent back to the facility that returned or transferred the medicines.

Annex 10. Inventory report/register

Date of inventory:	Service/section:		
In-charge name:	Title:	Signature:	
Witness name:	Title:	Signature:	

Item description	Record		Remarks (e.g. action required, action taken)
	Functional	**Non-functional**	

Source: Procurement and management of supplies and equipment. In: Kaur M, Hall S. Medical supplies and equipment for primary health care. Surrey (UK): ECHO International Health Services Ltd; 2001:13–28 (https://www.who.int/management/resources/procurement/MedicalSuppliesforPHC(2)Procurement&Management.pdf, accessed 18 March 2022).

Annex 11. Stock adjustment request form template

Form serial no. _____

Date (dd/mm/yyyy): _____

Origin: _____

Destination: _____

Name and address of the person responsible:

Stock adjustment list:

No	Stock code	Type of stock	Original quantity	Reduced quantity	Remarks
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

Department: _____

Requested by: _____   Approved by: _____

Signature: _____   *Signature*: _____

Name: _____   Name: _____

Date (dd/mm/yyyy): _____   Date (dd/mm/yyyy): _____

Annex 12. Pharmaceutical waste and destruction document examples

A12.1. Pharmaceutical waste for disposal or destruction – community drug distributor register

(To accompany waste materials collected for disposal or destruction)

MDA site		Waste storage type (e.g. plastic bag)	
Name of community drug distributor/health worker		Receipt by health post focal point signature and date (dd/mm/yyyy)	
Date (dd/mm/yyyy)			

Item name	Packaging type	Expiry date	No./qty returned	Comment
(Example): 500 tablet albendazole bottle	Bottle	21/12/2020	5	Bottles cleaned according to proper guidelines and kept by community health workers

A12.2. Pharmaceutical waste for disposal/destruction – health post register

Health post site		Waste storage type (e.g. plastic bag)	
Name of focal point		Receipt by district post focal point signature and date (dd/mm/yyyy)	
Date (dd/mm/yyyy)			

Item name	Packaging type	Expiry date	No./qty returned	Comment
(Example) Spoiled albendazole tablet	Bottle	21/12/2020	215 tablets	

A12.3. Pharmaceutical waste for disposal or destruction – district health facility register

District health facility		Waste storage type (e.g. plastic bag)	
Name of focal point		Receipt by regional health facility signature and date (dd/mm/yyyy)	
Date (dd/mm/yyyy)			

Item name	Packaging type	Expiry date	No./qty returned	Format and date disposed of (dd/mm/ yyyy)	Comment
(Example) Spoiled albendazole tablet	Bottle	21/12/2020	215 tablets		Sent to regional health facility

A12.4. Pharmaceutical waste for disposal or destruction – regional health facility register

Regional health facility		Waste storage type (e.g. plastic bag)	
Name of focal point		Receipt by national health facility signature and date (dd/mm/yyyy)	
Date (dd/mm/yyyy)		Pharmacist supervising destruction of waste	

Item name	Packaging type	Expiry date (dd/mm/ yyyy)	No./qty returned	Format and date disposed of (dd/mm/ yyyy)	Comment
(Example) Spoiled albendazole tablet	bottle	21/12/2020	215 tablets	Incinerated (21/1/2021)	Incinerated at XXXX cement factory furnace

A12.5. Pharmaceutical waste for disposal or destruction – national health facility register

National health facility		Waste Storage Type (e.g. plastic bag)	
Name of focal point		Receipt by National Health Facility Signature and Date	
Date (dd/mm/yyyy)		Pharmacist supervising destruction of waste:	

District	Item name	Packaging type	Expiry date (dd/mm/yyyy)	No./qty returned	Format and date disposed of (dd/mm/yyyy)	Comment
	(Example) Expired albendazole tablet	Bottle	21/12/2020	170 tablets	Incinerated (12/01/2021)	