

MANUAL ON  
MANAGEMENT OF DRUGS

SECOND REVISION  
2008

MINISTRY OF HEALTH CARE & NUTRITION  
GOVERNMENT OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI  
LANKA.  
385, DEANS ROAD, COLOMBO 10, SRI LANKA

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## **MESSAGE BY THE HON. MINISTER OF HEALTHCARE & NUTRITION**

It is with great pleasure that I am releasing this message which is to be published in the 3<sup>rd</sup> Edition of the “Manual of management of Drugs.”

Sri Lanka is one of the few countries that provides health care free of charge to whole of its population. His Excellency Mahinda Rajapaksha believes that by investing in free healthcare, we can produce a healthy work force that can contribute positively towards the development of the country. As a major proportion of health expenditure is on drugs, the contents of this publication are extremely important.

The latest edition of this publication includes the revisions made to accommodate the changes due to the setting up of provincial councils and devolution of authorities to provincial health ministries and I hope that it will significantly contribute towards the better management of drugs in the institutions under the Ministry of Healthcare & Nutrition and Provincial council.

I would like to thank to the officials of my Ministry for their hand work in publishing this revised edition and especially wish to appreciate the efforts of the Director of the Medical Supplies Division and the Director of the Medical Technology &Supplies.

Hon. Nimal Siripala de Silva  
Minister of Healthcare & Nutrition.

## **MESSAGE BY THE SECRETARY/ MINISTRY OF HEALTHCARE & NUTRITION**

I am pleased to release this message for the 3<sup>rd</sup> edition of the “Manual of Management of Drugs”.

Sri Lanka has based its healthcare system on the Primary Healthcare approach and one of the key areas in this approach is the supply of pharmaceuticals which take up a sizable portion of the health budget. In order to achieve the maximum benefit from this sizable investment, it is necessary to ensure proper management of drugs. Hence this publication is very important in this context.

The first 2 editions of this book have been widely used by healthcare professionals and administrators not only from Sri Lanka but from numerous regions in the world. I anticipate that this edition too, which has taken into account the numerous changes that have taken place especially with the devolution of management of Health Services to the provinces will be well received.

I also wish to thank all the officials from the Ministry of Healthcare & Nutrition especially the Director of the Medical Supplies Division and the Director of the Medical Technology & Supplies for their valuable contribution in publishing this book.

Dr.H.A.P. Kahadaliyanage  
Secretary/Ministry of Healthcare & Nutrition

## **PREFACE**

It is with pleasure that I write this preface to the 3<sup>rd</sup> edition of the “Manual on Management of Drugs.”

This Manual, first published in May 1987 and revised in June 1993, was well received both nationally and internationally. It is widely known and used by those involved in the drug supply system in Sri Lanka.

Over the fifteen years the contents of the manual were discussed at various workshops and meetings and the views expressed noted. Far reaching changes also took place in the drug management system, with the setting up of the Regional MSD in provincial councils. There was thus a need for a revision of the manual, and this second revision is the result.

I am thankful to all those who were involved in revising this edition. Special mention must be made of Director, MSD and his staff, Director, MT & S and his staff, and all the contributors who actively participated and contributed much towards this revision.

It is my hope that this manual will contribute positively towards the ready availability and efficient management of essential drugs in the health care institutions in Sri Lanka.

Dr. U. A. Mendis  
Director General of Health Services  
Ministry of Healthcare & Nutrition

## **ACKNOWLEDGEMENT**

It is a great pleasure for me to have contributed to the 2<sup>nd</sup> Revision of the Manual on Management of Drugs. The manual is the standard reference for those who are involved in the management of pharmaceuticals at different institutions with different responsibilities in the public sector, for example health care institutions of different levels, MSD, RMSD, Offices of RDHS, SPC, etc.

The cost of pharmaceuticals to the Ministry of Health has been increasing over the years due to multiple reasons such as opening up of new units, expansion of health care delivery system, epidemiological transition from communicable disease to non communicable, and the invention of new drugs which are costlier. Though the budgetary allocation has been increasing every year, there is always a gap between the cost of estimated requirements and available funds. Therefore efficient management of available resources in the pharmaceutical supply chain by all stakeholders at each level is very important. In this context, the Manual on Management of Drugs would be of immense use.

In working to this end, I have been fortunate in having the assistance of a group of distinguish contributors. I am very grateful to the contributors who have endeavored to this manual as up to date and comprehensive as possible in spite of the heavy involvement in their routine work.

I owe a special word of thanks to Prof.R.L.Jayakody for his valuable suggestions and guidance in completing this manuscript.

The financial assistance of WHO towards this publication is acknowledged with thanks.

At last, but not least the encouragement support extended by Dr U.A. Mendis, DGHS is very much appreciated.

Dr. B.V.S.H. Beneragama  
Director Medical Supplies Division

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## ABBREVIATIONS

AD	: Assistant Director
CP	: Chief pharmacist
CDD	: Cosmetics, Devices and Drugs
CDDA	: Cosmetics, Devices and Drugs Authority
D(F)	: Director (Finance)
DC	: Dental Clinic
DCP	: Director Campaign
DDG	: Deputy Director General
DDS	: Divisional Drug Store
DHC	: Divisional Health Center
DHO	: Divisional Health Officer
DP	: Divisional Pharmacist
DRMP	: Divisional Registered Medical Practitioner
DTCO	: District Tuberculosis Control Officer
D/PHVS	: Director/ Public Health Veterinary Service
DD	: Deputy Director
DDG (LS)	: Deputy Director General (Laboratory Services)
DESC	: Drug Evaluation Sub Committee
DGHS	: Director General of Health Services
DHS	: Department of Health Services
DRA	: Drug Regulatory Authority
FR	: Financial Regulations
GMP	: Good Manufacturing Practices
HSCO	: Head Stock Control Officer
ID	: Infectious Diseases
IDD	: In-Door Dispensary
MCH	: Maternal and Child Health
MOH	: Medical Officer of Health
MSD	: Medical Supplies Division
MT & S	: Medical Technology & Supplies
NDQAL	: National Drug Quality Assurance Laboratory
NORAD	: Norwegian Agency for Development Co-operation
OIC	: Officer in charge
ORS	: Oral Rehydration Salts
OT	: Operating Theater

ODD	: Out-Door Dispensary
OPD	: Out Patient Department
PDHS	: Provincial Director of Health Services
PPA	: Programme planning Assistant
RDHS	: Regional Director of Health Services
RMSD	: Regional Medical Supplies Divisions
SDHC	: Sub Divisional Health Services
SMO	: Senior Medical Officer
STV	: Stock Transfer Voucher
SV	: Stock Verification
SH	: Secretary Health
SK	: Store Keeper
SLSI	: Sri Lanka Standards Institute
SPC	: State Pharmaceuticals Corporation
TAC	: Technical Advisory Committee
TB	: Tuberculosis
WHO	: World Health Organization

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## CHAPTER 1

### INTRODUCTION

1.Ensuring an adequate supply of safe and effective drugs of acceptable quality is an integral part of the health policy of Sri Lanka. Appropriate legislation and regulations are provided to implement such a policy. Provision of Essential Medicines is one of the elements in the primary health care package.

Pharmaceuticals play a crucial role in preventive and curative healthcare. Drugs are a vital and an expensive component in the provision of health services .A fair proportion of the health budget (11%) is invested in pharmaceuticals. To ensure maximum benefit from such investment, it is essential that the drug requirements should be based on realistic estimates. Rational prescribing and efficient drug management with a sense of cost and quality consciousness are equally important.

2.The Ministry of Health spent Rs.5.34 billion in 2007 on the drugs required for the health institutions in the state sector. The drug budget was Rs. 2.81 Billion in 2000. The present drug budget is around 10% of the total health expenditure and that amounts to Rs.3000 (Approx.30US \$) per person annually.

The expenditure on drugs (state sector) in Sri Lanka from 2000 to 2007 is illustrated in Figure 1.

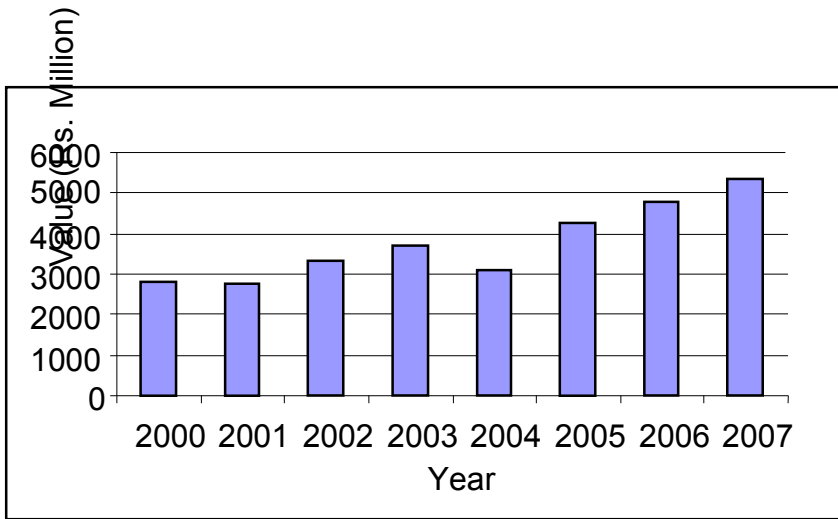


Figure1. The expenditure on drugs in Sri Lanka (2000-2007)

Table1 presents the amounts spent on pharmaceuticals for different provinces/special institutions in Sri Lanka (2007)

Name of province / institution	Total in Rs. Million
Central	197.489302
North Central	154.054582
North Eastern	278.554384
North Western	236.804810
Sabaragamuwa	146.339028
Southern	137.386175
Uva	175.964453
Western	344.807785
National Hospital of Sri Lanka	613.494117
Other Teaching Hospitals Except NHSL & Sri Jayawardenepura Hospital)	1603.656660
Institutions belonging to other Ministries (Armed forces, Police, Local Government Institutions, Prison, Estate Hospitals etc	71.688140
Semi Government Institutions(Sri Jayawardenepura Hospital & Vijaya Kumarathunga Hospital)	46.998660
Private Customers including private healthcare institutions	17.143790



Source – Medical Supplies Division

Table 1: The amounts spent on pharmaceuticals for different provinces/special institutions

Sri Lanka does not practice a strict referral system for patient care. A patient has free access to any hospital. Bypassing smaller medical institutions with limited facilities does occur and is encouraged by the high literacy rate in the country. The patients are aware that they will receive a higher quality of care in the larger institutions. Thus, underutilization of the smaller institutions and overcrowding and over-utilization of major health institutions is common. Provincial boundaries are often crossed. These facts are needed to be considered in interpreting the amounts spent for different provinces / institutions.

The Provincial and Regional Directors decide on the respective allocations to the institutions under their purview, on the recommendations of the Provincial Drug Review Committees.

3.The expenditure on drugs has been increasing each year because of the increased demand for better services, escalating unit cost on drugs, changing pattern of morbidity (heart diseases, cancer, diabetes) and the like. At the same time the efficient use of the available drugs is seen to receive some setbacks. Some of the reasons are over-prescribing, pilferage and wastage.

4.While the Government is committed to the provision of drugs free to all the clientele, there is an urgent need on the part of all officials in the health system responsible for procuring, distributing, storing, prescribing and dispensing whether at national, provincial, regional or institutional level, to imbibe a sense of economy and effectiveness to the management of drugs.

5.In this context this manual describes certain processes and procedures to be strictly adhered to by all concerned, to preserve the quality and ensure the efficacy and safety of the drugs used in order to enable the patients to receive a greater benefit at a given cost. In developing this manual all the existing rules, regulations and procedures with regard to management of drugs issued from time to time as departmental circulars, guidelines etc. have been reviewed, revised and simplified. In addition an educational approach is used with a view to ensuring that the contents are well understood and easily amenable to practice by all the staff involved in the drug management system.

## **CHAPTER 2**

### **POLICY FRAMEWORK**

1. The Government of the Democratic Socialist Republic of Sri Lanka undertakes to provide free health care services to every citizen in the country. Primary Health Care is the key approach to attaining this goal. The supply of essential drugs is a major element in this approach.

#### 2. (i) Cosmetics Devices and Drugs (CDD) Act

The Cosmetic, Devices and Drugs Act No. 27 of 1980 (as amended by Act No. 38 of 1984, No. 25 of 1987 and No 12. of 1993) provides the legislative framework to control the use of cosmetics, medical devices and medicinal drugs in the country. The regulations under the CDD Act were published in Gazette Extraordinary No. 378/3 of 02/12/1985 and further amendments were made from time to time.

The Act controls:

- (a) Registration
- (b) Manufacture
- (c) Importation
- (d) Transportation
- (e) Sale ( Retail and Wholesale )
- (f) Labelling

- (g) Advertising
- (h) Distribution of drug samples
- (i) Testing
- (j) Disposal of outdated or spoilt drugs

Steps are being taken to amend the existing Act to strengthen the areas such as clinical trials, nutraceuticals, dietary supplements and functional foods.

(ii) Poisons, Opium and Dangerous Drugs (Amended) Act.

Poisons, opium and dangerous drugs ordinance (Chapter 218) as amended by Act No 13 of 1984 regulates,

- (a) Importation
- (b) Storage
- (c) Distribution and
- (d) Use

of poisons, opium, and dangerous drugs.

3. The main provisions of the CDD Act with regard to the drugs are :

- (i) Only drugs which are registered with the Authority can be manufactured, imported, offered for sale or used in the country;
- (ii) Licenses are required for importation, manufacture, wholesale trade/retail trade, and transportation of drugs.
- (iii) All drugs registered with the Cosmetics, Devices and Drugs Authority (CDDA) should conform to specified standards.
- (iv) Labelling on the packs and advertisements regarding drugs should conform to the relevant regulations.

4. The Director General of Health Services (DGHS) is the CDDA. A Technical Advisory Committee (TAC) has been set-up under this Act to advise the Hon. Minister of Health on matters pertaining to the implementation of the Act

Composition of the Technical Advisory Committee:

- Director General of Health Services - Chairman
- Deputy Director General of Health (Laboratory Services)
- Director, Medical Technology & Supplies - Secretary
- Director, Medical Supplies Division
- Director, National Drug Quality Assurance Laboratory

- Professor of Pharmacology of the University of Colombo
- Pharmacologist of the Medical Research Institute
- Chairman of the State Pharmaceuticals Corporation
- Government Analyst
- Consultant Physician nominated by the Minister of Health
- Consultant Surgeon nominated by the Minister of Health
- a Consultant Physician nominated by the College of Physicians
- a representative of the Pharmaceutical Manufacturers' Association nominated by that Association
- a representative of the Sri Lanka Standards Institution, nominated by the Minister in charge of the subject of Industries
- a representative of the Pharmaceutical Society of Sri Lanka nominated by that Society
- a representative of the Sri Lanka Medical Association nominated by that Association
- a representative of the Independent Medical Practitioner's Association nominated by that Association
- a representative of the College of General Practitioners of Sri Lanka nominated by that College
- a representative of the Sri Lanka College of Obstetricians and Gynaecologists nominated by that College
- a representative of the Sri Lanka Dental Association, nominated by that Association
- a representative of the Pharmaceutical Traders Association (at present known as Sri Lanka Chamber of Pharmaceutical Industry), nominated by that chamber.

The DGHS is the Chairman of the TAC and the Director Medical Technology and Supplies (DMT&S) is the Secretary. Based on the powers delegated by the DGHS, the DMT&S functions as the CDDA.

5. Four Sub Committees have been set up by the TAC, namely:

- (a) Drugs Evaluation Sub-Committee(DESC) to review and make recommendations on drugs submitted for registration ;
- (b) Cosmetics Evaluation Sub-Committee to review and make recommendations on cosmetics submitted for registration ;

- (c) Devices Evaluation Sub-Committee to review and make recommendations on medical devices submitted for registration ;
  - (d) Advertisements Sub-Committee to screen advertisements of drugs and to make recommendations on the information given in the advertisements.
6. To implement the CDD Act and the Regulations therein, Authorized Officers have been appointed by the Hon. Minister of Health from the following categories of government officers.
- Provincial Directors\* and Regional Directors of Health Services\*,
  - Medical Officers of Health
  - Divisional Pharmacists
  - Food & Drugs Inspectors
  - Public Health Inspectors
7. All correspondence regarding matters pertaining to the regulation of Cosmetics, Devices and Drugs should be addressed to the Director (Medical Technology & Supplies) No 120, Norris Canal Road, Colombo 10. (Tel: 011-2695173, 011-2687743, 011-2687744, Fax: 011-2 2689704, [Email: cdda@health.gov.lk](mailto:cdda@health.gov.lk)).
8. Registration of Drugs
- Registration of drugs is one of the main functions of the CDDA. The first step of drug registration procedure is the evaluation of the manufacturer for compliance to Good Manufacturing Practices (GMP) standards. Applications for registration of drugs are accepted only if the production facilities of the relevant manufacturer conform to required standards of GMP. Evaluation of foreign manufactures is done by evaluating their company profiles while local manufactures are inspected by a team of officers attached to the Office of MT&S and the National Drug Quality Assurance Laboratory (NDQAL) for GMP compliance. Every foreign manufacture has to appoint an agent in Sri Lanka who is responsible for registration and other activities related to their products in Sri Lanka.

The manufacturer should submit registration applications to the Office of D/MT&S through the local agent along with samples for quality testing. The DESC comprises of specialists in medical and pharmaceutical fields and, administrative sector of the Ministry of Health makes recommendations on registration of drugs. Quality, safety and efficacy are

considered as the main criteria for registration. The DESC makes use of the WHO GMP certification scheme on the quality of pharmaceutical products moving in international commerce to assess GMP standards and registration status of the product in the country of manufacture. Approval of the product for registration or refusal of the same by the D/MT&S is based on the recommendations of the DESC. The registered drugs are entered in a register maintained at the D/MT&S office and periodically published through government gazette notifications. Work pertaining to drug registration is carried out at the office of the D/MT&S with the assistance of the NDQAL.

9. The operational policies adopted by the government to ensure adequate supply of essential medicines to all patients seeking care at government institutions are:
  - a) Procurement of drugs which are registered with the CDDA based on their generic names, wherever generic names are available;
  - b) To encourage local manufacturers to produce essential Medicines within the country in a phased manner subject to their techno-economic feasibility and granting a duty free concession for all raw material used in their pharmaceutical formulations and 20% rebate for locally manufactured products;
  - c) Development and periodical revision of a List of Essential medicines for Sri Lanka with separate lists for different levels of health care institutions depending on the services provided and facilities available.

## **CHAPTER 3**

### **ORGANIZATIONAL STRUCTURE AND FUNCTIONING OF THE STATE SECTOR DRUG MANAGEMENT SYSTEM**

1. In order to ensure that all drugs required by the institutions are available in required quantities at all times to serve the needs of the patients, Medical Supplies Division (MSD) of the Ministry of Health follows a management cycle, the major activities of which are depicted in Figure 2.

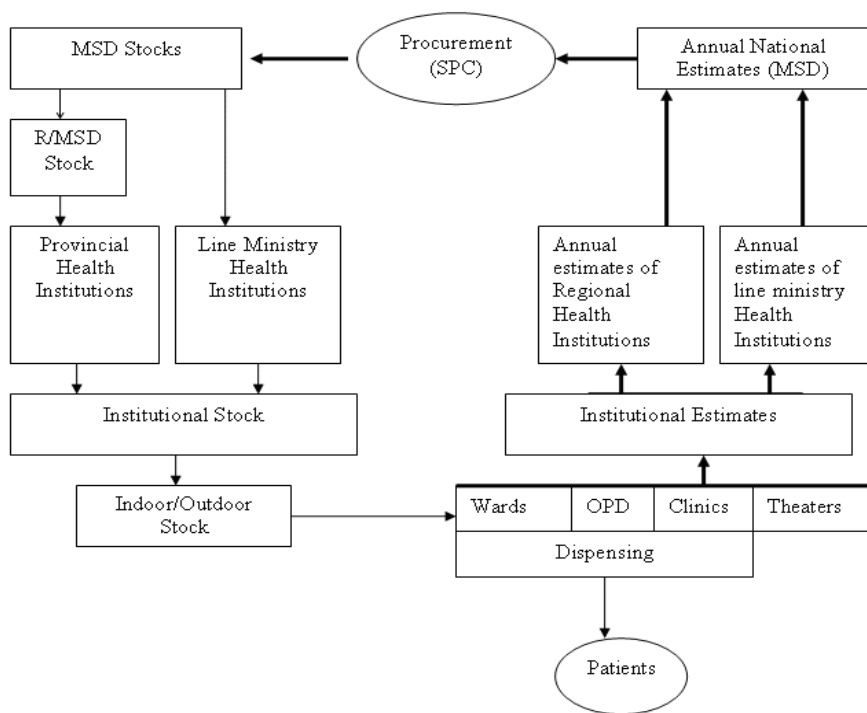


Figure 2: Management cycle of pharmaceuticals

2. To support implementation of these activities, an organizational framework exists within the Ministry of Health, that comprises of the,
  - a) CDDA (Office of D/MT&S) for registration of drugs.  
The main functions of the MT &S are detailed in Annexure 1.
  - b) The Medical Supplies Division at the central level for estimation, storage, distribution and monitoring of drugs.  
The main functions of the MSD are detailed in Annexure II.
  - c) NDQAL for quality assurance of drugs.
  - d) The State Pharmaceuticals Corporation (SPC) for procurement
  - e) Regional Medical Supplies Divisions (RMSD) at regional level (26 in number) for storage and distribution for provincial council institutions.
  - f) A drug store in each health care institution.

The organization chart of the same is depicted in Figure 3



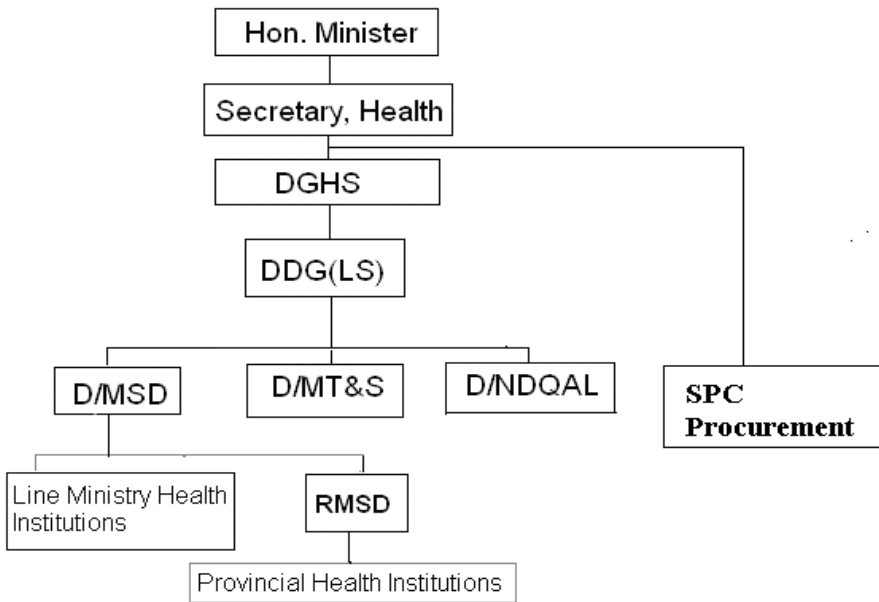


Figure 3: Organization chart of drug management

3. (a) The MSD of the Ministry of Health is responsible for the consolidation of annual requirements of drugs for the institutions under the Central Ministry and the Provincial Councils. National indents so developed are passed on to the SPC for procurement. The drugs so procured are sent to the MSD by the SPC for storage and distribution to all the institutions.

(b) The management cycle begins in August of the current year (year 1) with the preparation of institutional estimates for the next year (year 2). Institutions should send their estimates by October of current year (year 1) to MSD. The MSD consolidates the estimates, forecasts the annual requirements and places the orders with the SPC before the expiry of January of next year (year 2). These orders are scheduled to be supplied during year 3.

As mentioned above, institutional estimates for year 2 are cumulated during the period from November (year 1) to January (year 2) to form the national requirement of drugs which would lead to;

- Forecasting and placing orders with SPC for year 3.
- Identification of additional requirement for year 2 and place supplementary orders with SPC.

- Distribution of year 2 requirements of the institutions.

In addition to the above functions, MSD also orders and supplies the annual requirements of surgical dressings, radio pharmaceuticals, X-ray films and chemicals, surgical consumables, surgical non-consumables, laboratory chemicals & glassware, dental consumables and dental non-consumables on indents through the SPC. Medical gases are purchased by institutions directly from medical gas suppliers.

Printed forms and counterfoil books are also distributed by the MSD. The supplier is the Government Printing Department.

Director, MSD and his staff periodically visit and monitor the activities in relation to drug management in the respective provinces / institutions.

4. Drug Therapeutic Committees (Drug Review Committees) form a very useful forum for the monitoring of efficient management of drugs. The forum allows for decision-making by consensus among representatives of different units involved in the management of drugs. It is, therefore essential that Drug Therapeutic Committees at:

- a) National Level
- b) Provincial Level
- c) Regional Level and
- d) Institutional level

are established and that they functions regularly.

(a)National Drug Therapeutic Committee (Drug Review Committee)

A National Drug Therapeutic Committee should be established at the Office of DGHS.

The recommended membership for this committee is:

- Director General of Health Service- Chairman.
- Deputy Director General (Laboratory Services)
- Deputy Director General (Finance)
- Director Medical Supplies Division (MSD)- Secretary
- D/MT&S
- D/NDQAL
- All the Provincial Directors of Health Services
- Chairman –SPC
- Directors of all Teaching Hospitals
- Directors of Specialized Campaigns

This committee should meet quarterly. The functions of the committee would be to monitor supply, distribution and consumption of drugs at national, provincial, and institutional levels.

(b) Provincial Drug Therapeutic Review Committee (Drug Review Committee)

The Provincial Drug Therapeutic Committee should be established at the Office of the Provincial Director of Health Services, the recommended membership for this committee is;

- Provincial Director of Health Services (PDHS) – Chairman
- Regional Director of Health Services of the District
- Medical Superintendents of Provincial /District General/Base Hospitals in the Province
- Consultants from Provincial / District General/ Base Hospitals
- Accountant/PDHS. Office
- Provincial /Divisional Pharmacists (Secretary)
- Regional Epidemiologists/MOO – M.C.H.
- Officer in Charge – R-MSDD
- Chief Pharmacists of the Provincial / District General / Base Hospitals
- Co-opted members decided by the Chairman

This committee should meet quarterly. The functions of the committee would be to monitor supply, distribution and consumption of drugs at provincial, regional, and institutional levels.

(C) Regional Drug Therapeutic Committee (Drug Review Committee)

A Regional Drug Review Committee should be established at the Office of the Regional Director of Health Services (RDHS). The recommended membership of this committee is:

- RDHS – Chairman
- Regional Epidemiologist(RE)
- Medical Officer (Maternal and Child Health)
- Regional Dental Surgeon (RDS)
- Accountant/RDHS Office

- Medical Officers in charge of specialized campaigns
- Officer in charge (O i/c) of Regional Medical Supplies Division (RMSD)
- Divisional Pharmacist (Secretary)
- Divisional Registered Medical Practitioner (RMP)
- All Officers in charge of institutions in the Region
- Regional Food & Drug Inspector
- Chief Pharmacists of Provincial /District General/ Base Hospitals
- Superintendent MLTT of the Region

This committee should meet once in two months. A copy of the minutes should be sent to the Director/MSD. The functions of the committee would be to monitor supply, distribution and consumption of drugs at regional and institutional levels.

In addition this committee should decide on the annual financial allocation for drugs for each institution. For the purpose of approval of annual estimates of drugs for each institution, a sub-committee will be appointed consisting of the following Officers:

- (i) RDHS. - Chairman
- (ii) Divisional Pharmacist/a nominee of RDHS - Secretary
- (iii) Two Consultants of the main hospitals in the region
- (iv) Officer in charge of the institution whose annual estimate is to be considered
- (v) Accountant / RDHS Office
- (vi) Senior Medical Laboratory Technologist (MLT) of the institution

The sub-committee will scrutinize the annual estimates carefully and recommend alternations, where necessary.

(d) The Institutional Drug Therapeutic Committee (Drug Review Committee)

An institutional Drug Therapeutic Committee should be established in all Teaching, Provincial, Specialized hospitals, District General, Base and Divisional Hospitals.

The recommended membership of the committee is:

- Director/Medical Superintendent/Medical Officer in Charge - (Chairman)
- All Consultants – (if so staffed)
- Senior Medical Officer OPD
- Chief Pharmacist of the institution – (Secretary)
- Accountant - (if so staffed)
- Special Grade Nursing Officer (Matron) or Senior Nursing Officer

and in the case of small institutions, all prescribing officers.

It is recommended that RDHS together with one or more of his staff namely Oic (R/MSD), Divisional Pharmacist, Divisional RMP should attend the meetings of the Drug Therapeutic Committee of the major institutions. At least one officer from amongst the above should attend all meetings. Officer in charge, R/MSD should compulsorily attend all Drug Review Committee meetings of Provincial and Base Hospitals.

In the case of MOH division, the forum will be the monthly conference of the Medical Officer of Health with the field staff.

The Committee should meet monthly. A copy of the minutes should be sent to the RDHS for necessary action. In the case of Provincial / District General and Base Hospitals, a copy of the minutes should in addition, be sent to the Director MSD.

Its functions are:

- (i) Preparation of annual estimates of drugs
- (ii) Monitoring of supply and use of drugs in the institution.
  - (iii) Monitoring of local purchases and use of special drugs in the institutions.
- (iv) Ensure economy in the use of drugs
- (v) Ensure adequate supply of critical/essential medicines in institutions
- (vi) Ensure consumption of drugs within the financial allocation
- (vii) Any other functions assigned to it by the RDHS./Head of the Institution.

## 5. Specialized Institutions and campaigns

Specialized campaigns[e.g. Anti Malaria, Anti Filariasis, Anti-Leprosy, Respiratory Diseases Control Programme and National Sexually transmitted Diseases & AIDS Control Programme (NSACP)] obtain their requirements of drugs from the Medical Supplies Division and distribute same to their

respective regional or local level institutions. These specialized campaigns should also establish Drug Review Committee at the national level, Specialized Campaigns coming under Provinces should obtain their supplies through the R/MSD.

## **CHAPTER 4**

### **ESTIMATION OF ANNUAL REQUIREMENTS OF DRUGS**

1. The estimation of the quantity of each drug required for the following year is a vital activity in the management of drugs. Over estimation leads to excess stocks (and therefore wastage and pilferage). Underestimation results in shortages.

2. Estimation of the annual requirement of drugs is primarily the responsibility of:
  - a) The Head of the institution at the institutional level
  - b) The Regional Director of Health Services at the regional level
  - c) Provincial Director of Health Services at the provincial level

However, management of drugs is a collective responsibility as many officers are involved at different levels.

Sub-committee of the Drug Review Committee is an appropriate forum for making decisions in this regard at the Provincial/Regional Level.

In Teaching, Provincial, District General / Base and Divisional Hospitals\*, the Institutional Drug Review Committee is the forum. In the smaller institutions, it is best that all prescribing staff under the direction of the Medical Officer in Charge of the institution should get involved in this activity (refer Chapter-3).

3. There are two methodologies available for estimation of drug requirement of an institution namely morbidity pattern and standard treatment method which is the more realistic method of estimating drug requirement of specific drugs. For estimation of requirement of other drugs, the average adjusted consumption method is the most appropriate.

However due to non-availability of accurate and sufficient data on morbidity pattern, Standard Treatment method is not followed and Adjusted Consumption Method is practiced in estimation of requirement of drugs.

**Step 1**

Forecasting monthly consumption for the year - 1.

Prepare a statement showing the quantity available and quantity consumed of each drug monthly for the previous 12 months.

Table 2: Model chart of quantity available

Month	Stock	Consumption/units
July 2006	2,800	2,800
August 2006	5,000	3,000
September 2006	2,000	2,000
October 2006	-	-
November 2006	10,000	3,100
December 2006	6,900	3,000

January	2007	3,900	3,300
February	2007	10,300	3,200
March	2007	7,100	3,150
April	2007	3,950	3,100
May	2007	7,850	3,350
June	2007	4,500	3,250

\* Divisional hospitals are categorised as type A, type B, type C

Select minimum of 9 months data of consumption when sufficient stocks are available. Identify the mean of the 9 months consumption and examine the trend of use in consumption with usage of alternative drugs, drugs of different strengths (if applicable dosage forms). Calculate the average monthly requirement based on these data.

**Suppose we do this exercise for one drug:**

The non-consumption for this drug in October 2006 is due to drug being out of stock in the institution. The low consumption in July and September 2006 may be due to low availability of the drug. Therefore the consumption in August 2006, November 2006, December 2006 and January 2007 to June 2007, may count to calculate average monthly consumption.

$$\begin{aligned} \text{Therefore Average monthly consumption} \\ &= \frac{3,000 + 3,100 + 3,000 + 3,300 + 3,200 + 3,150 + 3,100 + 3,350 + 3,250}{9} \\ &= 3,161 \end{aligned}$$

As per data given in the above chart monthly consumption is showing an increasing trend. Hence suggest forecasting monthly consumption for the year – 1 as **3,300**.

**Step 2**

Identify the stock available as at the date of preparation of estimates. Determine the availability in months based on the above forecasted monthly requirement.



### Step 3

Based on stock availability duration in months determined as above, identify the delivery of 1<sup>st</sup> quarter/1<sup>st</sup> lot of year - 2

#### Condition:

Acceptance of stock during the period from the date of stock considered and end year should be only to build two months buffer stock as at January of the following year (year - 2)

### Step 4

Estimation for the said year (Year - 2)

#### Condition:

Quantity estimated to build a two months buffer stock as at January of year - 3 based on forecasted monthly requirement.

### Step 5

#### **Illustrated by an example for estimating year – 2 requirement**

The anticipated stock duration as at January of year - 2 is 1

The number of months from January Year –2 to February – Year –3 is 14

Then request is for  $14 - 1 = 13$ .

Hence the estimate for year - 02 is 13 x the Forecasted Monthly Requirement (FMR) ,

Hence the estimate for year – 02 is  $13 \times 3,300 = 42,900$ units

## CHAPTER 5

### RECEIPTS, ISSUES AND STOCKS CONTROL

General

1. The objective of Stock Control is to ensure that appropriate quantities of drugs of specified quality are available in stock to meet the estimated demand.

The quantity in stock of any item depends upon receipts and issues. The areas of

- (a) Indenting (receipts)
- (b) Issues
- (c) Maintaining a specified buffer stock

at drug stores at the central , regional and institutional levels are dealt with in this Chapter.

2. To have an effective control on stocks, it is essential to maintain a specified buffer stock depending on the level of the institution (e.g. at MSD stock of 3 months).

The duration recommended for other institutions is 1 to 2 months.

In addition, the following information should be available.

- (i) Quantity in stock, its shelf life and batch numbers ;
- (ii) Estimated quantity for a specified period ;
- (iii)Quantity on order and its expected time of delivery (e.g Limited application of EOQ principles under periodic order review (midyear) ;
- (iv) Actual consumption and its trends ;
- (v) Lead time and stock levels - Re-order Level (ROL), Safety Stock Level(SSL),Maximum Stock Level (MSL), Minimum Stock Level (MSL), Economic Order Quantity (EOQ)(Annexure III) .
- (vi)Unusable quantities in stock (obsolete, expired, spoilt, quality failed etc.

3. All medical institutions under the provincial administration should forward a quarterly return of the stocks available to Officer in-charge (O i/c) of the Regional Medical Supplies Division RMSD.The O i/c RMSD in turn should forward the quarterly return to the MSD.

In the case of institutions under the Central Ministry, such a return should be forwarded to the Director, MSD with the following information.

Stores Reference	Name of Drug	Annual estimat	Receipts up to	Balance in stock	Amount of drug
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(SR) Number		e	date	with expiry dates	required for next quarter

Table 3: Quarterly return of availability of stocks

4. Dates of quarterly returns from institutions to MSD/ R/MSD are given below:

Quarter –(Period)	From Institutions to RMSD/Line Ministry to MSD	From RMSD to MSD
	Due Date	
1 <sup>st</sup> – (January – March)	1 <sup>st</sup> week of January	2 <sup>nd</sup> week of January
2 <sup>nd</sup> – (April – June)	1 <sup>st</sup> week April	2 <sup>nd</sup> week of April
3 <sup>rd</sup> – (July – September)	1 <sup>st</sup> week July	2 <sup>nd</sup> week of July
4 <sup>th</sup> - (October – December)	1 <sup>st</sup> week October	2 <sup>nd</sup> week of October

Table 4: Schedule to supply items to institute

All institutions which do not send the quarterly returns prior to the above due dates will have to bear the full responsibility for not getting the required stocks at the correct time in correct quantities.

Stock control procedures at Institutional drug stores

5. Based on the quarterly return and the annual estimate, the RMSD or MSD (for centrally managed institutions) shall supply the quantity of drugs required by the institution.
6. (a) However, under special circumstances of emergency or short supply situations the institution should make an urgent request and the same will be issued by RMSD or MSD. Similarly if the MSD has excessive stocks of certain items which can be used by the institutions, the MSD may distribute such items irrespective of the estimate, to the institutions with their consent, in order to prevent wastage.

(b) Stock control and distribution of cold store items

Supply of Anti Rabies Vaccine and Anti Rabies Serum should strictly be done on monthly returns and request forms (see Annexure - IV) and copy of the same should be sent to Director/ Public Health Veterinary Service (D/PHVS), O i/c, Vaccine Monitoring Centre, Medical Research Institute and the Epidemiologist.

Officer requesting cold stores items should ensure that adequate cold storage space and cold chain transport facilities are available to transport and store the quantity requested.

A Pharmacist or Oi/c RMSD should personally take over the stock from issuing stores of MSD. Officer collecting such cold storage stock is fully responsible for continued maintenance of the cold chain and prevention of exposure of stocks to inappropriate storage conditions.

7. With regard to indenting of narcotics and medical gases the guidelines in Chapter 7 are applicable.

8. When drugs are received,

(a) at the MSD, the stocks are checked for compliance with the indent with regard to specifications, quantity, conditions for supply and other information against the supplier's invoice.

(b) at the RMSD or Line Ministry Institutions, the

(i) SR number and item

(ii) Quantity

(iii) Expiry date

(iv) Batch number

are checked against the Stock Transfer Voucher (STV). If there are any damages, shortages or any other discrepancies detected, it should be brought to the notice of the Head of the Institution through Chief Pharmacist in case of hospitals and to the RDHS in case of RMSD, within 24 hours. The RDHS/Head of the Institution should take action to check the entire consignment by a board appointed by him and a report should be submitted to the D/MSD within 3 days.

(c) at the Hospitals coming under the Provincial administration the

(i) SR number and Item

(ii) Quantity

(ii) Expiry date

(iii) Batch number

are checked against the invoice. If there are any damages, shortages or any other discrepancies detected it should be brought to the notice of Head of the Institution through Chief Pharmacist within 24 hours. The Head of the Institution should take action to check the entire consignment by the Divisional Pharmacist and a report should be submitted to the RDHS within 3 days with copy to RMSD.

9. In the case of institutions, the entries in the registers should be rechecked along with the Stock Transfer Voucher (STV)/invoices by the Chief Pharmacist regularly and by the Head of the Institution on a random basis. The STV/Invoice certified by the Chief Pharmacist or the Head of the Institution should be forwarded to DMSD/ RDHS respectively, within 3 days of the receipt of the drugs.

10. When requests for issues are received from sub-stores of an institutions [in-door dispensary (IDD), out-door dispensary (ODD) and wards etc.], the issuing pharmacist should check the drug ordering register (Form H 37) as to whether the entries are correct and the books have been balanced correctly. If not, it should be indicated in the register in red colour with signature and date. He should also check the balance stock available at the sub-stores periodically, at least once a month.

11. The Chief Pharmacist or the supervising officer of the hospital drug stores and the hospital dispensaries (IDD or ODD) should carry out test checks on the stocks of drugs at sub-stores, wards and all units in the institution periodically and report to the Head of the Institutions via T127 form. Head of the Institution or his deputies should also test check the hospital drug stores at random.

12. Maintaining a minimum emergency stocks of life saving vaccines, sera and antidotes (up to 20% of annual estimate) or as decided by the Head of the institution, is mandatory for all levels of drug stores. Accordingly, officers concerned will not be held responsible for expiry of these life saving items up to their emergency stock limit, if it is not specifically owing to their negligence. However any short shelf life stocks should be reported as required in the redistribution process

Stock Control Procedures at the Indoor Dispensary (IDD)

13. As soon as the drugs are received from the main drug stores of the institution by the IDD, the quantity of drugs received should be checked with the amounts noted as “issued” in the drug register and verified as correct.

14. Only a week’s supply of drugs should be issued to the units/wards, in addition to a buffer stock of one week supply which should always be available in the unit/ward. Availability of excess quantities of drugs in the units/wards will cause pilferage and should be avoided.

15. The pharmacists issuing drugs to the respective units (wards, operating theatres etc.) in the institution should ensure that;

- (a) the requests received from the respective units for the issue of drugs are in order, reasonable and the books are balanced properly ;
- (b) the balanced stocks of drugs in the respective units conform to guidelines issued on minimum stocks to be kept ;
- (c) the balances stated in the request books are correct ; and
- (d) the issue of drugs has been authorized by the Head of the Institution.

16. At the time of re-ordering, the empty containers/vials/spools of fast moving expensive items should be returned to the issuing officer when requesting for new stocks. These are classified as follows:

(a) Drugs with abuse potential.

Eg: All narcotic injectable preparation such as morphine, pethidine, fentanyl

(b) High value items.

Eg: Certain anaesthetic drugs such as isoflurine, halothane, thiopentone sodium, bupivacaine, lidocaine and injectable antibiotics such as cephalosporins, ampicillin, cloxacillin, benzylpenicillin.

(c) Empty cans over 2 liter volume and bottles over 500 ml volume.

Head of the Institution may add any other items into the above list.

Items so received should be taken into a register and disposed of periodically with the approval of Head of the Institution.

In the case of dressings, especially in Teaching, Provincial, District General/Base and Divisional Hospitals , a central distribution system should be adopted.

17. When authorizing issue of drugs on the register, the Head of the Institution should ensure that the issues are monitored and controlled to avoid overstocking at the user level.

18. Drugs should be issued to the respective units weekly according to a roster prepared in consultation with the units concerned. However drugs shall also be issued on emergency requests as and when necessary, to avoid shortages.

19. All the normal procedures recommended for indenting, accounting etc. of drugs should be adhered to, to the extent applicable.

#### Stock Control Procedures at Out Door Dispensary

20. As drugs are issued to the OPD patients and the clinic patients from the outdoor dispensary, in addition to the procedures regarding the receipt of drugs from the drug stores as given in under 1-4 paragraphs the following procedures should be followed.

21. A list of specimen signatures of all authorized prescribing officers authenticated by the Head of the Institution should be available with the officers dispensing drugs at the OPD and clinics. These officers should make sure, before issuing drugs to the patients, that the prescriptions have been signed by the authorized prescribing officers only. The Chief Pharmacist will do a random check of about 30 prescriptions fortnightly to verify the genuineness of the prescriptions.

22. OPD patients shall be issued drugs sufficient for not more than three days but in the case of antibiotics, the full prescribed course should be issued.

23. If further prescription is given at the next visit of the patient, it should be elicited from the patient that the drugs dispensed earlier had been fully consumed.

24. No clinic patient shall have a prescription re-dispensed at the next visit unless all drugs are re-prescribed item by item.

25. Before re-issuing any drugs, it should be ensured that the patient has in fact taken regularly the drugs prescribed earlier.

26. Drugs should not be issued to patients for a period of over four weeks.

27. For patients discharged from indoor, drugs should be prescribed only for three days or to last till the next clinic date. In any event the issue should not be in excess of two weeks.

Other Stock Control Procedures (applicable to both indoor and out door dispensaries)

28. All OPD and Clinic prescriptions should carry the name, age and the full postal address of the patient. The address should be with sufficient detail so that the patient could be located in the community.

29. The dispensing officers should indicate the number of units of each drug issued on the prescription. If any drug is out of stock, this should be indicated in the prescription and signed by the officer dispensing the drug.

30. The dispensing officer should give clear instructions (both written and verbal) to the patients with regard to the use of drugs dispensed by them. In addition, name of the drug should be written on the label of each drug dispensed.

31. List of non available and low stock drugs as well as the drugs that are found to be in excess/slow moving at the institution or at RMSD/MSD (if such information is available), should be brought to the notice of all prescribing officers at weekly intervals. Such information is to be displayed at appropriate places for easy attention of all prescribing officers. With regard to non-available drugs and those in low stock, suitable alternatives/ substitutes available should also be brought to the notice of prescribing officers so that suitable substitutes can be prescribed. The responsibility to see that these are done lies with the Chief Pharmacist.

1. The following formulations should be accounted for in detail, daily at points of use.

- i. Tablets and capsules costing Rs. 5.00 or more per unit.
- ii. Injections costing Rs. 25.00 or more per vial or ampoule
- iii. Intravenous fluids costing Rs. 30.00 or more per bottle.
- iv. External preparation costing Rs. 30.00 or more per bottle of 60ml or less, tube or vial.
- vi. All steroidal preparations
- vii. All antibiotics



## Local Purchase of Drugs

32. Consultant may use the facility of local purchase of drugs for individual indoor patients and such purchases should only be done at the request of the consultant in writing. The Head of the Institution, after verifying that the drug in question is not available in the RMSD and MSD may approve such purchase. Such information is provided to the institutions by MSD via e-mail weekly. In addition, it is published through the Ministry of Health website ([www.health.gov.lk](http://www.health.gov.lk)).

33. Under the above scheme, consultants may request for local purchase of special items which are not included in the Sri Lanka Hospital Formulary or in the annual drug estimate but registered for use in the country.

All requests for local purchases have to be made by the generic names only. (Circular No. 02-30/2003 of 19<sup>th</sup> May 2003.)

34. For this purpose, the Regional Director of Health Services will make an allocation at the beginning of the year to Provincial, District General /Base Hospitals with consultants, who are only allowed this facility. In the case of centrally managed institutions, the allocation will be given by the Ministry of Health

- i. National Hospital - 10% of value of annual drug estimate
- ii. Teaching Hospitals - 10% of value of annual drug estimate
- iii. Provincial Hospitals – 5% of value of annual drug estimate
- iv. District General Hospitals - 5% of value of annual drug estimate
- v. Base Hospitals- 2.5% of value of annual drug estimate

35. Quotations for local purchase should be opened in the presence of the Procurement Committee (refer National Procurement Agency guidelines).

36. All purchases should be reported to the Director/MSD monthly as per format in the following table by the O i/c of the institution.

Name of the Drug	Date of Purchase	Quantity Purchased	Unit Price (Rs.)	Total Cost (Rs.)	Source of Purchase	Folio of Drug Register

Table 5: Format for local purchase report to D/MSD

36. In the case of institutions managed by the Provincial Councils, reports should be sent to PDHS, RDHS in addition to DMSD.

37. Information regarding local purchases made by each consultant should be circulated among all consultants of the institutions monthly.

38. A review of the expenditure on local purchase by each unit should also be made available at the monthly drug review committee meeting and comparison of the same with respect to expenditure on hospital formulary items and its variation over the month should also be discussed.

#### Procedure of indenting drugs by the MSD.

39. All institutional and regional drug estimates are consolidated to arrive at the national requirement. In addition, the actual consumption of each item during the last three years and its trend are also taken into account in this exercise.

40. To determine the indenting quantity, it is necessary to consider the expected stocks on orders which have been already placed.

41. Order lists are prepared indicating detailed specifications for each item.

42. Delivery schedules are planned based on storage capacity at MSD for different types of items (eg. cold storage).

43. Order lists are then forwarded to the SPC.

44. A mid year review of the supply position is done in order to make adjustments to the existing orders or to place additional orders if necessary.

## Procurement Procedure of the SPC

45. The SPC has been designated as the sole procurement agency for pharmaceuticals and surgical consumables items required by the government health institutions.

These items are imported or locally purchased and supplied to the MSD of the Department of Health Services from where they are distributed to government health institutions.

46. The SPC follows the “Government Tender Procedure – Revised Edition August 1997” to procure such medical supplies.

Worldwide tenders are invited, giving approximately six weeks for suppliers to submit tenders. A tender box is opened for each such tender where quotations are deposited. Tenders are opened in the presence of foreign suppliers and / or their local agents.

47. After tenders are opened, the tenders are scheduled in ascending order of prices quoted. Scheduling of offers is handled by the Imports Department of the SPC and submitted for technical evaluation.

48. After technical evaluation, the files are submitted to the relevant Tender Boards depending on the value of the recommended offer.

The Tender Boards are as follows:-

	<u>Limits of Authority</u>
1. Minor Tender Board	up to Rs. 5 million
2. Departmental Tender Board	up to Rs. 25 million
3. Ministry Tender Board	up to Rs. 100 million
4. Cabinet Appointed Tender Board	above Rs. 100 million

49. After a tender award, an indent is sent to the supplier, who is asked to submit a Performance Bond if the value is above Rs. 5 million. Where the value is above Rs. 10 million, a contract is signed between the supplier and the SPC.

Letters of Credit are opened instalment-wise for the requirements.

50. Indents and Letters of Credit are sent by the SPC specifying the documents required to be submitted such as Invoice, Packing List, Certificate of Analysis/Quality and Bill of Lading.

51. Bank guarantees are obtained if the documents are in order, and Customs Entries are framed and passed through the Import Control Department and Customs Department before clearance of cargo.

Re-distribution of excess / short dated stocks of drugs

52. The RDHS. should decide whether the excess drugs could be transferred to another institution in his region, or to the RMSD.

53. If this is not possible, the RDHS will arrange with PDHS for re-distribution within the province. In the event such use is not possible, PDHS to communicate with RDHSS/PDHSS of other provinces, for re-distribution among institutions in other regions and with Director/ MSD for re-distribution among Central Government Institutions.

55. In respect of institutions coming under the central ministry, the Head of the Institution should circularize a list of excess / short dated stocks among all central government hospitals, with copy to director /MSD for re-distribution.

56. In all these re-distribution processes, institutions should ensure that all excess/short dated stocks with minimum of 6 month shelf life are intimated using the format in Annexure–V and prompt action is taken regarding the replies received therein.

## **CHAPTER 6**

### **CARE IN PRESCRIBING DRUGS**

1. Drugs should be prescribed considering safety, quality and cost.
2. All drugs should be prescribed by their generic names.

3. The prescriptions should contain the diagnosis/indication for use of drugs, correct dosage, frequency with which the drug should be taken and amounts to be issued. The prescription should carry the name of the patient, age, sex, date, be legibly written and signed by the prescribing officer.
4. The recommended standard schedules of treatments (eg. circular on post exposure prophylaxis of rabies) should be adhered to as far as possible. This should be strictly complied by primary care institutions, divisional hospitals and OPD of other categories of institutions.
5. All patients attending OPD should be prescribed drugs for the minimum period possible and should not exceed 3 days of treatment except antibiotics, which may be prescribed for 5 days. Discretion lies with the medical officer examining the patient whether drugs should be prescribed or not.

Intern medical officers should prescribe drugs only for in-patients and patients attending specialist out-patient clinics.

6. Patients attending specialist out-patient clinics can be prescribed drugs for a maximum period of 4 weeks. If the drugs have to be continued, each and every drug has to be written separately with the dosage.
7. The prescribing officer should ensure that:
  - a. the patient is prescribed the minimum drugs that are essential for the treatment.
  - b. cost of drugs be taken into consideration when drugs are prescribed.
  - c. the patient clearly understands as to how the drugs prescribed are to be taken;
  - d. the patient is educated about the common and significant side effects of the drugs.
8. The dispensing officers should,

- a. dispense the exact amounts of drugs prescribed
- b. educate the patients on how to use the drugs and their possible side effects.
- c. advise the patient to take the full course of drugs prescribed.
- d. educate the patient regarding the safe (eg. keep out of reach of children) and proper storage of the drugs.

9. All prescribing officers should exercise utmost care in prescribing expensive drugs. Whenever possible, prescribing officers should refrain from issuing prescriptions for tonics etc. even on request, to be purchased outside, since it brings disrepute to the institutions and causes hardships to the patient.

Where a drug or a substitute is available in the institution, prescriptions should not be issued for purchase outside.

10. In the wards, repeating drugs should not be complied with at the end of the fifth day if number of days has not been specified at the time of prescribing or the drugs are reordered by name, dosage and frequency.
11. The Chief Pharmacist of the institution should bring to the notice of all authorized prescribing officers the cost of antibiotics as well as the other expensive, frequently used drugs so that the Head of the Institution can encourage them to be cost-conscious.
12. The poster "Do you know the cost?" should be displayed prominently at the clinics. OPD and wards, so as to inspire a sense of cost consciousness among the prescribes.
13. All drugs prescribed for over 3 days and antibiotics over 5 days for OPD patients should be authorized by the head of the institution or the officer delegated for that purpose.

## **CHAPTER 7**

### **DISTRIBUTION AND LOGISTICS**

1. The MSD receives and stores all the medical supplies (drugs, dressings, X ray films, surgical consumables and non-consumables, dental consumables and non-consumables, laboratory chemicals and glass ware and radio active material) for the state sector medical institutions.

MSD is the sole supplier to both public and private sectors in the case of narcotics. The supply of printed materials is also the responsibility of MSD. These items are then distributed among the 26 RMSDD and the line ministry institutions.

2. At the end of every quarter, the MSD prepares an advance programme for distribution of drugs to the RMSDD and line ministry healthcare institutions during the succeeding quarter and communicates the same to Regional Directors of Health Services/Head of the line ministry institutions and Officer in-charge (Oi/c) of RMSD. The date of dispatch and the mode of dispatch of the drugs are also indicated in this document.
3. Independent of the communications in (2) above, each RMSD is required to inform the MSD at the beginning of the quarter (table 4) through a quarterly return (Table 3) the quantity of drugs required for the next quarter. If the quarterly returns are not received as scheduled in Table 4(chapter 5), action will be taken to distribute estimated quarterly requirements according to the quarterly distribution programme of the MSD. Availability of stocks and variations in consumptions at institutions may not be considered in such situations. The cost of transportation should be born by the respective RDHS/Head of Line Ministry Institution.

Requisitions will be not accepted from the institutions which do not provide the quarterly returns at the beginning of the respective quarter.

As such, to ensure the continuous availability of drugs, it is the responsibility of the RDHS, Head of the Institution, Chief Pharmacist and Oi/c/RMSD to submit the quarterly return to Director/MSD without fail.

4. If the Provincial and Regional Directors request the Director/MSD to dispatch the medical supplies to their Provinces/Divisions, the expenditure incurred on fuel and labour should be reimbursed by respective the Provincial Councils. MSD will take every attempt to distribute drugs by railway wherever that facility is available and the respective institutions should settle the bills at the receiving end. Also if the Provincial/Regional Directors desire to get their medical supplies by Railway they may do so, having informed the Director/MSD well in advance and settle the transport charges accordingly. If the Provincial



and Regional Directors are able to provide their own transport they may do so, having informed the Director/MSD.

Cold chain has to be maintained for all thermo labile drugs during transport. Cold storage items will not be issued to any officer other than the pharmacist/storekeeper of the relevant institute/RMSD. Also sufficient number of cold boxes and cooling elements should be brought.

In case the head of the institution decides to send an officer other than a pharmacist/storekeeper, he may do so by taking full responsibility of maintaining the cold chain during transport and such delegation should be communicated to the Director/MSD in writing.

5. If the drugs by any chance do not reach the RMSD and other health institutions as per the advance programme of the MSD, or if sufficient quantities of the drugs ordered are not received, the Oi/c/RMSD or the responsible officer should immediately contact the assistant director in charge of the relevant section and ascertain the status. Where necessary he should in consultation with RDHS and D/MSD, make alternate arrangements to collect the drugs from the MSD. For this purpose any mode of transport mentioned in paragraph 4 above could be utilized.

6. Narcotics.

As regards to narcotic drugs, each institution should submit periodical indents through the respective RDHS to Director/MSD as and when the institutional stocks reach a low level (one month requirement). The Director/MSD will then issue the narcotic drugs to the authorized person or to an identified representative of the authorized person as stipulated in the Poison, Opium and Dangerous Drugs Act.

7. Medical Gases.

As regards to medical gases, each medical institution will be supplied a specified number of cylinders. This will meet the requirements for buffer stock as well. An inventory of cylinders should be maintained at the institution. Records of the inventory should be updated when new cylinders are obtained from the surgical stores of MSD and the unusable cylinders are disposed. An inventory should be maintained for regularly used cylinders as well as for buffer stocks. Line ministry hospitals are authorized to deal directly with gas suppliers. Institutions coming under the provincial councils could obtain medical gases from

the supplier through RMSDD. The cost of same should be reimbursed by MSD.

8. The RMSD shall distribute the quarterly requirement of drugs, dressings, X'Ray films, surgical consumables, surgical non-consumables, laboratory items, narcotic drugs and oxygen cylinders to each institution in the area. For this purpose Oi/c/RMSD shall prepare an advance programme for distribution of quarterly requirements and send the same to each institution after obtaining the approval from the RDHS. Whenever necessary the stock receiving institution should provide necessary transportation facilities to supply drugs. They should strictly follow the instructions given in the quarterly distribution programme with respect to mode of dispatch.
9. If the drugs, by any chance, do not reach the institution as per the advance programme, the Head of the Institution or the responsible officer of the health institution shall immediately inform the RDHS and O i/c RMSD for appropriate action.
10. If certain drugs are required urgently the Oi/c of the institutional drug stores should make arrangements to collect same from the RMSD. For this purpose the ambulance may be used as far as possible during transport of patients. Such urgent indents should be limited to small quantities, which could be conveniently transported by the ambulance. Under no circumstances should heavy containers of drugs be kept on the stretcher/seats of the ambulance. In case of institutions belonging to the provincial councils, for all vital and essential items, if not available at the institution as well as at the RMSD, the institution should obtain an endorsement from the Oi/c/RMSD to that effect before going to MSD to obtain these items. Any direct issue from the MSD to an institution in a province should be intimated to the O i/c RMSD of that province within a week by the head of the receiving institutions.
11. With respect to vaccines, requests should be forwarded to the Epidemiologist of the Ministry of Health in case of EPI vaccines. Items listed below are the EPI vaccines currently used in the national immunization programme
  - BCG vaccine

- Oral polio vaccine
- DPT vaccine
- Hepatitis B vaccine (HBV)
- DT vaccine
- Adult Tetanus and diphtheria vaccine
- TT vaccine
- Rubella vaccine
- Measles vaccine
- Measles Rubella vaccine
- DPT-HBV- Hib vaccine
- Inactivated Japanese Encephalitis vaccine
- Live Japanese Encephalitis vaccine

For vaccines handled by the MSD, the requests should be forwarded to the Director/MSD. Cold chain should be maintained for all vaccines during transport from the MSD or Epidemiology Unit to RMSD/line ministry institutions and from RMSD to peripheral institutions using cold chain boxes.

12. With respect to family planning supplies, the request should be submitted to the Director/Family Health Bureau(FHB)

The following items are supplied by the FHB.

- Oral contraceptive pills,
- Depot Medroxyprogesterone injection,
- Intrauterine device CuT 380A,
- Implanon implants,
- Condoms,
- Iron folate tablets,
- Calcium lactate,
- Vitamin C,
- Vitamin A mega dose,
- Emergency contraceptive pills,

13. If there are any external signs of damage to the packages and/or tampering or difference in weight noticed on receipt of package at RMSD or institutional stores, the o/i C. of the RMSD/institution shall record the details thereof in a register of losses/damages/breakages in the presence of the officer from the MSD/RMSD and shall open the packages in their presence and check the entire contents of the consignment with the copy of the STV enclosed in the package.

14. In case of line ministry institutions it should be directly reported to the Director/MSD.
15. The Oi/c of RMSD or the institution shall make a written preliminary report to the Regional Director of Health Services. In the case of RMSD, a copy of the report shall be sent to the D/MSD on the same day the discrepancy is detected.
16. The Oi/c of RMSD/Institute shall thereafter make a detailed report within three days to RDHS in the case of RMSD; the same will be done on form CF 55 in triplicate to the D/MSD through RDHS.
17. The RDHS will on receipt of the preliminary report cause if necessary an inquiry to be held and the statements of the parties concerned may be recorded in order to fix responsibility for the damage, breakage, loss on transit etc. The RDHS will make his own observation on the findings of such an inquiry and inform PDHS accordingly.
18. Where the RDHS after his investigation and inquiry, finds that the officers of the RMSD are not responsible for loss or damage or he will make his observations on form CF 55 and forward his report in duplicate to D/MSD, with copy to PDHS.
19. Director/MSD on receipt of the preliminary report, cause an investigation to be carried out at the MSD and take action as follows
  - a. Where the value of loss, damage or breakages does not exceed Rs. 25,000/= the Director/MSD will authorize (pending treasury approval) to write off, provided no fault can be attributed to the officers at the Medical Supplies Division. PD Level
  - b. Where the responsibilities for the loss, damage or breakage is fixed on the officers at the MSD the Director/MSD shall take action to recover the value thereof from the officers responsible.
  - c. Where the value of the loss, damage or breakage exceeds Rs. 25,000/= up to Rs.1, 000,000/= he shall have the case

investigated and forward a copy of CF 55 with his own recommendation to the Secretary /Health.

20 On receipt of the Form CF 55 the Director/MSD Secretary/Health shall then grant the necessary authority for the write off the losses / breakages / damages on the authority granted by Director/MSD, Secretary/Health.DPDHS should arrange to dispose such breakages/damages in the presence of responsible officer and ensure that items are actually written off the books by the Oi/c.

<b>SR No.</b>	<b>Name of the Drug</b>	<b>Amount Received during the quarter</b>	<b>Amount used during the quarter</b>	<b>Balance available at the end of the current quarter</b>	<b>Amount required during the next quarter</b>

Table 6: Indenting Format

Note: Requisitions for drugs are not necessary from the institutions that provide the quarterly return at the beginning of the quarter concerned.

## CHAPTER 8

## QUALITY ASSURANCE OF DRUGS

1. It is necessary to develop and maintain a drug quality assurance system as an integral part of the national drug management system, designed to prevent the production, import and distribution of ineffective, harmful or low quality drugs.

2. Quality assurance of drugs is the total sum of the organized activities performed with the object of ensuring that pharmaceutical products are of required quality for their intended use. It comprises of GMP as well as factors like product design, development, safety, efficacy, product testing, appropriate transportation, proper storage and dispensing, correct use and the like.

3. The CDD Act No. 27 of 1980, amended by Act No. 38 of 1984, Act No. 25 of 1987 and Act No. 12 of 1993 form the legal base for the national drug quality assurance system.

4. The principal institutions responsible for implementing the activities of the national drug quality assurance system are:

1) Office of Director Medical Technology & Supplies

a) Registration & Licensing Division

b) Enforcement Division

(MT & S organizational structure – see Annexure VI)

2) National Drug Quality Assurance Laboratory (NDQAL)

(NDQAL organizational structure – see Annexure VII)

4.1 The office of Director Medical Technology & Supplies

a)Registration and Licensing

Every drug has to be registered with the CDDA, before it is imported or manufactured locally. Issuing of certificates of registration of the drugs and licenses to import, distribute, sell and manufacture drugs under the regulations of the Act, are implemented by the Director/MT&S as delegated by the DGHS as the CDDA.

b) Enforcement

The main function of the Enforcement Division of the CDDA is to assist in the enforcement of the Act, by verifying that all elements within the pharmaceutical supply system comply with the regulations of the Act. Verification by inspection includes assessment of manufacturing, distributing organizations, wholesale and retail outlets.

Those duties are performed by the authorised officers (PDHS, RDHS, MOH, Food & Drugs Inspectors/F&DI, Divisional Pharmacists and Public Health Inspectors\*). Chief F&DI at the Enforcement Division coordinates these activities with the authorized officers in the provinces/regions. This division too comes under the Director/MT&S whose office is at 120, Norris Canal Road, Colombo 10.

\* Public Health Inspectors have not been appointed as authorized officers yet

#### 4.2 National Drug Quality Assurance Laboratory (NDQAL)

National Drug Quality Assurance Laboratory was first established in 1971 as Drug Quality Control Laboratory at the General Hospital Colombo premises, with its facilities limited to chemical analysis of pharmaceuticals. A modern well-equipped laboratory with facilities for chemical, microbiological and biological analysis of pharmaceuticals was established in 1990 with the support from NORAD. This laboratory is situated at 120, Norris Canal Road, Colombo 10. Director/NDQAL has been appointed as an additional approved analyst under the provisions made by the Act

The primary function of the NDQAL is to conduct laboratory tests necessary for determining compliance with product safety and quality requirements. Quality testing of drug products is carried out on samples collected on random basis at different points of the distribution; namely at pre-marketing and post-marketing stages, and issue reports/recommendations based on the analyses/evaluations.

Quality of a drug product is assessed by measuring its degree of conformity to its claimed standards. The quality standards may be prescribed according to pharmacopoeial (BP, USP, IP, Int. P, etc.) or non-pharmacopoeial (manufacturer's) specifications.

In the assessment of quality, the important characteristics of a drug product to consider are its appearance, identity, purity, potency, uniformity and bioavailability. Further, in appraising quality of products, their packaging and labeling are examined to ascertain if they are adequate.

#### a) Pre-marketing stage

At this stage, samples of drug products submitted by:

- Director/MT&S during the drug registration process
- Chairman/SPC - tender samples or pre-consignment samples
- Director/MSD-pre-consignment samples are assessed for their conformity to specifications claimed.

#### b) Post-marketing stage

At the post-marketing stage, random samples are collected from both government institutions and private sector pharmacies.

Particular attention is accorded to products,

1. that are commonly used
2. potentially dangerous
3. unstable under local conditions of storage
4. difficult to formulate properly
5. known to be associated with bioavailability problems.

Post-marketing quality surveillance in the government sector has been expanded to testing of drugs available at RMSDs, Teaching hospitals, Provincial Hospitals, District General Hospitals, Base Hospitals and Divisional Hospitals as part of a regular quality assurance programme. Officers of the NDQAL will also visit these health institutions periodically and collect samples for testing under this quality-testing programme. Authorised officers also may collect samples from government health institutions for analysis when necessary.

Post marketing quality surveillance in the private sector has been expanded to testing of drugs in the pharmacies and other organizations. Collection of such samples is usually done by Authorised officers and submitted for analysis.

Prescriber's complaints on product quality and adverse reactions are also investigated at the NDQAL. State sector institutions may send any suspected product directly to NDQAL.

Prescribers are requested to submit such samples to:

**Director, National Drug Quality Assurance Laboratory,**



**120, Norris Canal Road, Colombo 10. (Tele: 011-2687741, 011-2687743/4;  
Fax: 011-2687742; E-mail: [govndq@sltnet.lk](mailto:govndq@sltnet.lk))**

The method of collection and dispatch of such samples has been communicated to the Provincial Directors, Regional Directors and other Heads of Institutions by the Director General of Health Services by his letter LAC/60/89 of 08.08.1990. (annexure VIII)

Complaints from private sector prescribers should be routed through the Director /MT&S

An authorized officer who collects samples of drug products under section 22(1) (a) of the CDD Act for test, examination, and analysis should strictly adhere to the procedure specified under Part-XI of the regulations of the Act. (Annexure IX )

Following procedure shall be adopted in submitting samples of drug products to NDQAL

### **Collection and submission of samples**

In collecting a sample for quality testing from bulk packs, an intact (unopened pack) is preferred. However, if this practice is not possible, the minimum required amount of dosage units indicated in the Table 7 should be packed in a sealed plastic bag and this bag should then be placed in a suitable rigid airtight container and sent for quality testing.

The label on such container must indicate the following. When practical, attach an original label to the container. If the label is hand written, following information should be provided.

- i. Name of the product (Generic / Brand)
- ii. Specifications (state whether B.P., U.S.P., I.P, N.F., etc.)
- iii. Strength of the product (i.e. amount of active ingredients)
- iv. Batch number / Lot number
- v. Date of manufacture (if any)
- vi. Date of expiry
- vii. Manufacturer's name and address.
- viii. Quantity submitted.
- ix. Storage requirements stated on the label.
- x. Details of any preservative added if indicated on the label.
- xi. Any other remarks

In the case of liquid or semisolid preparations (mixtures, elixirs, solutions, applications, creams etc.), only intact (unopened) packs should be sent.

A separate report will be issued for every sample of the drug product submitted, based on an evaluation of the same through laboratory analysis and other relevant scientific evidence, considering the batch/lot number. Hence the samples from different batches should be submitted in separate containers. Where there are complaints as to the potency and the toxic effects of a particular drug product, it is always advisable to submit the samples from the same container used for issuing the drug to the patients along with another unopened (intact) pack of the same drug product of the same batch from the stores.

Whenever a sample is submitted with the complaint of microbial contamination or discolouration in bulk packs, in addition to the packs with the observed defect, at least two intact (unopened) packs of the same batch/lot should be sent.

When submitting samples of drug products which require special storage conditions (controlled temperature such as 2-8 °C etc), it is important that all necessary arrangements are made to ensure the maintenance of cold chain until the sample is received at NDQAL.

Further information, if necessary should be obtained from the Director, NDQAL.

(Specimen request form is in annexure X)

### **Handling of quality failure of drug products**

Considering the NDQAL recommendations, D/MT&S will inform D/MSD to issue circulars explaining the action to be taken on a batch/batches/product detected with non-conformity to their claimed specifications for state sector institutions. In the case of private sector Director/MT & S himself will issue a circular.

Recommended action could be:

1. To withhold the batch/batches/product as a preliminary precaution
2. To withdraw the batch/batches / product
3. Discontinue to use the containers which shows the defect

Upon the issue of such recommendations, the officials at the health institutions are expected to take following actions.

(Recall procedure- see annexure XI)

In keeping with the recall procedure, the following procedure should be adopted

**(a) To withhold the batch/batches/product as a preliminary precaution**

➤ Procedures to be followed by the MSD

- To inform to all institutions, the details of the item by a circular based on the decision by the Director/MT&S in keeping with the NDQAL recommendations (Report).
- To coordinate with the NDQAL to expedite the final decision on the withheld item/items.

➤ Procedures to be followed by the Institution

- Store the available stocks of withheld batch/batches/product separately under proper storage conditions.
- To inform the quantity withheld from use to the Director/MSD on or before the specified date.
- To inform details of all available batches of this product to NDQAL to select samples for further testing, with copies to Director/MSD. Samples will be collected/or requested by NDQAL for further analysis and an appropriate recommendation will be made on the batch/batches/products considering the analytical findings.

**(b) To withdraw the batch/batches/product**

➤ Procedures to be followed by the MSD

- To inform immediately to all institutions the details of the item by a circular based on the decision by the Director/MT&S in keeping with the NDQAL recommendations.

- To request institutions to inform the withdrawn quantity to the Director/MSD on or before the specified date.
- To inform SPC, the quantity and the institutions having the withdrawn stocks for replacement or reimbursement of the cost of the same by the supplier.
- To request SPC for reimbursement of the cost of unused quantity of the withdrawn product.
- To deduct the cost of the withdrawn item from the payment due to SPC, if the reimbursement of cost is not completed within five months from the date of request to SPC.

➤ Procedures to be followed by the Institution.

- To inform the quantity withdrawn from use to the Director/MSD on or before the specified date, to enable Director/MSD to obtain replacement or reimbursement of the cost.
- It is the responsibility of the PDHS, RDHS and respective Heads of Institutions to ensure the withdrawn stocks are kept in safe custody to be inspected by SPC, MSD or the supplier.

**(C) Discontinue to use the Containers which show the defect (the defect will be indicated in the circular)**

- Store the containers which show the defect separately.
- Inform Director/MSD, Director/MT&S the quantity available with defects at the institution for further action.

Table 7: Minimum amount of dosage units required (sample size) for issuing a complete report is given below.

DOSAGE FORM	STRENGTH / VOLUME	SAMPLE SIZE
Tablets / Capsules Suppositories / Pessaries	Less than or equal to 5mg	200 Tablets / Capsules suppositories / Pessaries
Tablets / Capsules	More than 5mg	100 Tablets/Capsules

Suppositories / Pessaries		suppositories / Pessaries
Infusions	Less than or equal to 200ml	20 units
Infusions	More than 200ml	15 units
Injections	Less than or equal to 3ml	85 vials/ampoules
Injections	More than 3ml	65 vials/ampoules
Powder for Injection	Less than or equal to 2mg	85 vials
Powder for Injection	More than 2mg	65 vials
Eye / Ear Drops / Nasal Drops	-	45 containers
Mixtures / Elixirs / Oral Suspension / Syrups	-	06 unopened containers
Applications / Tinctures	-	02 containers
Oral Rehydration Salts (ORS)	-	25 packets

**In case of requesting to test for microbial contamination or discolouration in bulk packs, at least two (02) unopened containers should be sent.**

More samples may be requested in addition to the amounts indicated above, when necessary.

## CHAPTER 9

### STORAGE OF DRUGS.

1. Proper storage of drugs is essential to ensure efficacy, safety quality, accountability and availability up to their point of use.

2. Storage areas should be of sufficient capacity, well-ventilated, well lighted, should be clean and dry and maintained within acceptable temperature limits. When special storage conditions are required air-conditioned rooms are appropriate.

3. There should be adequate number of qualified personal to achieve pharmaceutical quality assurance objectives. All personal should receive proper training in relation to good storage practices, regulations, procedures, safety and accountability.

4. On receipt of pharmaceutical preparations it should be verified with the relevant documents against the quantity, expiry date, batch number and labeling instructions etc.

5.

i. Drugs should be stored by sections, according to pharmacological groups and by SR No., within pharmacological groups

ii Storage of drugs should be done in a manner to facilitate to follow, first expiry/first out “FEFO” principle.

iii. Narcotics and other dangerous drugs should be kept under lock and key and in the custody of the designated officer.

iv. Pharmaceutical products as well as substances presenting special risks and pressurized gases should be stored in a demarcated area that is subjected to appropriate additional safety, and precautionary measures.

v. In the wards life saving drugs should as far as possible be kept together in a glass-fronted cupboard for easy visibility.

vi Validity expired, sub-standard, quality suspect (withheld and or withdrawn) drugs should be stored separately in a demarcated area. Such drugs should be identified giving necessary information.

## 6. Cold Storage

Vaccines, sera and all other thermolabile pharmaceuticals should be stored in cool rooms/ refrigerators to maintain the temperatures specified by the manufacturer. Generally the temperature range is +2°C to + 8°C, unopened oral polio vaccine which should be stored below 0°C

For proper storage of vaccines /sera etc. it is important to follow the following guidelines.

- i. Selection of suitable refrigerators.
- ii. Avoid small, poorly ventilated rooms for refrigerators/freezers as they produce heat.
- iii. Space units away from walls to provide good ventilation. Refrigerators/freezers should be spaced at least 20cm away from walls and 30cm away from other equipment and they should be mounted about 10cm above floor level.
- iv. To ensure stable electricity supply, plugs and switches should be taped permanently with adhesive tape to wall outlets, and power supply should be connected to the generator supply power line.
- v. Performance of the generator should be checked periodically.
- vi. A temperature chart should be maintained for each refrigerator/freezer daily at 9.30am and 3.30pm (specimen form annexed can be used for this purpose).
- vii. Refrigerator thermometer should be placed in the middle part of the main chamber and the accuracy of the thermometer should be checked periodically.
- viii. Defrosting of refrigerator/freezers should be done at least once a week on a specific day and/or whenever necessary. (Maintaining and signing of such records are very important).
- ix. It is very necessary to check, record and sign the indicators of vaccine vial monitors and cold chain monitors when receiving supplies.( a register should be maintained for this purpose and these records should be kept in a separate file.)
- x. Ordering of stocks should be done based on the availability of storage space. It is advisable to provide 25% storage space for air circulation.
- xi. Storage of vaccine in the refrigerator should be started from 1<sup>st</sup> shelf below the freezer and then to the lower shelves. Vaccines should never be stored in the refrigerator door.

- xii. Water bottles may be kept in the doors of the refrigerator to maintain the temperature during power failures. (Preferably they should be added with some coloring agent or salt to prevent being used for other purpose).
- xiii. Withheld stocks should be identified and kept separately in the refrigerator to prevent use by mistake.
- xiv. Do not open the refrigerator unnecessarily. Display a label pasted on the door  
 “STOP DO YOU HAVE TO OPEN THIS REFRIGERATOR”  
 (Sinhala & Tamil)
- xv. During transport of cold storage drugs all precautionary measures should be taken to maintain the cold chain
- xvi. (Cold room monitoring chart- Annexure XII)

7. 7.1 Comprehensive records should be maintained showing all receipts and issues of drugs in the specified registers.

7.2 In addition to the drug registers use of bin/lot cards that indicate information such as stock re-order level re-order quantity, expiry date, batch number etc is recommended  
 (Lot card specimen form- Annexure XIII)

8. 8.1 The Managerial staff should periodically inspect drug stores and test checks should be carried out to ensure that the drugs are stored and accounted properly.

8.2 All discrepancies should be investigated as a check against inadvertent mix-up and /or incorrect issues.

9. The security of the drug stores should be ensured to prevent theft/burglaries/pilferage. Specific instructions should be issued to security personnel/watchmen on continuous vigilance on the security of the drug store.

10. Maintenance of drug stores should be considered a priority. Budgetary provisions for this purpose must be made every year, during annual budget preparation and for in the estimates for maintenance. Repairs to stores buildings and equipment should be attended promptly.

Guidelines for proper storage of drugs



1. Clean storerooms with adequate space proper ventilation and white wash walls.
2. Check roof for water leakages.
3. No direct sunlight on the supplies.
4. Storeroom not subjected to water penetration.
5. Supplies to be stacked at least 4" (10cm) from floor.
6. Supplies to be stacked at least 1ft. (25cm) from walls.
7. Stacks not more than 8ft. (2.5m) High.
8. Identification marks and other markings etc. and other instructions should be followed and practiced.
9. Separate stacks accessible for "FIRST EXPIARY FIRST OUT"(FEFO) and for easy counting and general management.
10. Temperature controlled drugs (vaccines/sera) should be stored according to manufactures instructions on the labels.
11. Proper placement of fire extinguishers. (train staff to handle and test for proper performance)
12. Periodical checks on damages to supplies from pests/rodent and steps to be taken to control them.
13. Insecticides and other chemicals should not be stored with medical supplies.
14. Damaged and condemned supplies to be stored separately in a demarcated place. Disposal of unserviceable items to be carried out according to guidelines given in Chapter 11.
15. Stores keys must be available at all times.
16. Daily cleaning of stores according to a standard operational procedures.

## CHAPTER 10

### MONITORING OF CONSUMPTION OF DRUGS

1. Monitoring is important to ensure continuous availability of drugs in medical institutions.

Monitoring implies

- a) identification of gaps or deficiencies and
- b) taking of timely corrective action.

Continuous monitoring prevents;

- a) out of stock situations of supplies and
- b) accumulation of excess quantities of drugs and obsolete items.

Monitoring should also be aimed at

- a) quality suspected drugs,
- b) drugs causing adverse reactions
- c) drugs which are withheld / withdrawn.

2. The reasons for a drug being “Out of Stock” are many. These include:

- i. non-indenting of the drug.
- ii. under estimation of the requirement of drugs.
- iii. actual consumption has exceeded the estimate.
- iv. withdrawal/withholding of a drug due to quality issues
- v. non-compliance to the delivery schedule with regard to quantity and time by the procurement agency.

3. Possible reasons for non-compliance to the delivery schedule include:

- Inability to find a prospective supplier/manufacturer through normal procurement process due to limited sources in the market or the quantity indented being commercially unattractive.
- Late awarding of the tender
- Administrative or financial problems
- Partial award (eg. 25%) of tenders to suppliers with a history of quality failures/new suppliers, and keeping the balance pending subject to good performance of the product.
- Request for price increases after awarding the tender or inability to provide quality certification required for shipment/customs clearance causing delay in supply.

Substitution of “Out of Stock” drugs with available alternatives increases its consumption beyond estimated requirement, leading to secondary “Out of Stock” situation of the substitute.

2. Some of the reasons for a drug to be in excess of quantities required are: The actual consumption of the drug is substantially less than the estimated requirement due to changes in morbidity pattern,

- i. Change in the pattern of prescribing,
- ii. Changes between forecasted annual national demand and the actual national usage / demand due to long time duration. .
- iii. Calculation errors in estimation at institutional/regional/provincial /national level.
- iv. Under consumption of items with short expiry due to non-acceptance by the institutions.
- v. Sharp drop in demand of an item when a new alternative drug is introduced.

While carrying of excess stock of any drug is uneconomical “out of stock situation ” would cause difficulties to patients. The only way to minimize both is through careful monitoring of the following periodically.

- a) Quantity Available: Monitoring index is the stock duration within the shelf life of the product based on current ( $SD_c$ ) and estimated ( $SD_e$ ) monthly requirement and stock level monitoring (MSL,ROL,SSL,etc)
- b) Quantity Consumed: Monitoring indexes are average monthly consumption ( $AM_c$ ) worked out as per Chapter 4.3 and duration of the total stock transferred out ( $SD_t$ )
- c) Quantity Indented: Monitoring indexes are balance due on order and its stock duration based on estimated requirement ( $SD_o$ )
- d) Quantity Received : Monitoring index is total expected availability duration (TEAD)
- e) Primary Quality Requirements: Monitoring indexes are age analysis of the stock annual percentage obsolescence and screening the batches for basic physical Q.A tests before accepting stocks.
- f) Supplier Performance: Monitoring index is supply defaulting index for compliance to quality standards and delivery schedules.

3. Tools which can be used for monitoring of consumption of drugs.

- i. ABC analysis ( See annexure XIV )
- ii. VEN analysis ( See annexure XV )

6. Monitoring is an important task in the management of drugs at different levels such as;

1. National level -DGHS, DDGLS, Chairman/SPC, D/MSD,D/MT&S,D/NDQAL
2. Provincial level -PDHS ,Provincial Pharmacist
3. Regional level -RDHS,Divisional Pharmacist,OIC/ RMSD
4. Institutional level -Head of the institution, Chief pharmacist, Officers in charge of main drug store/indoor pharmacy/out door pharmacy -Nursing officer in charge of wards/units

7. For this purpose

a)The head of the institution should hold a monthly drug review committee\* meeting with the officers concerned and discuss the problems/difficulties in indenting, receipt, storage, accounting, consumption, etc, vide (Chapter 3), and take immediate corrective action.. A copy of the minutes of such meetings should be submitted to the RDHS, in the case of provincial institutions and to the D/MSD in case of line ministry institutions.

a) Similarly RDHS should hold a quarterly meeting at the regional level and send a copy of the minutes to PDHS and Director (MSD)

b) At these meetings special attention should be paid to quantity consumed in relation to –

- estimated consumption (amount allowed);
- previous month's consumption;
- consumption during the same month of last year;
- consumption of locally purchased items;
- prescribing pattern in the O.P.D. and clinics.
- Any significant variations should be investigated and corrective action be taken.

c) Financial aspects of estimated requirement, consumption and supply has to be monitored with respect to funds appropriated for the medical supplies at institutional level, regional level, provincial level and at national level.

8. A broad list of areas to be monitored by whom and when is presented in Table 8. The Heads of the institutions and the RDHS should decide what should be monitored, over and above what is indicated therein.

Table :8 - Monitoring of Drugs.

	Area	Dimension to be monitored	By whom	Timing
1 (a)	Quarterly issues under Advance Distribution Programme based on annual estimates	- % supplied of the Annual Estimates w.r.t. overall national /regional values	D/MSD/RDHS /DP/OIC/R-MSD	Last month of the quarter
		- % No. of items supplied below the average (<50%), moderately (50-100%) and above the average (>100%), w.r.t. national/regional values.		
		- % No. of items issued below the estimate balance based on proportionate share of the stock for the quarter .		
1 (b)	Issues outside the quarterly distribution programme	- Number and % of drugs issued against the requests by RMSD	D/MSD/RDHS /DP/OIC/R-MSD	Last month of the quarter
		- Number and % of requests not complied in spite of availability of stocks		
		-% Number of items issued below the requested Quantity. and % number of items not complied on requests.		
		- As above	DPDHS/DRM P/DP	First month of the following quarter
2	Stock position at;	Item wise accumulated annual “stock out” duration and percentage of item found in excess w.r.t. numbers & value	OIC RMSD /DP/DPDHS)	Monthly
	(a) RMSD	- Stock duration of each drug, separately listed as out of stock (<2 weeks), very low stock (< 1 month) and low stock (< 3 months)		
	(b) MSD	- As above		

3	Care inprescribing-wards	Compliance with instructions Quantity consumed of each drug	D (MT&S)/DPDHS MO(IC)/DRMP/DP	½ yearly/quarterly Quarterly
4	Inspection of RMSD	As per format prepared by each officer	D(MT&S)/D(MSD)	Six monthly
			AD (MSD)	Quarterly
			DPDHS/DRMP	Monthly
			DP	Weekly
5	Financial Control	- Cumulative percentage of allocation spent		
		a) By Regions	DPDHS	1 <sup>st</sup> month of succeeding quarter
		b) By Institution (DPDHS)		
		c) By MSD	D/MSD	- do -
d) By SPC	Chairman/SPC	- do -		
6	Reports to DDG (L/S)	- Problems regarding area (1) above	D/M T & S	Quarterly
		- Shortage of critical drugs at the centre	D/M.S.D.	Monthly
		- Cumulative % national allocation of medical supplies actually spent	D/M.S.D/ Acct. (F)/MSD	Quarterly
		- A short evaluation regarding supply, consumption and stock outs situation of medical supplies in the regions.	DPDHS/DRMP/DP	Quarterly
		- Same with respect to MSD/SPC	D/MSD/ Acct./MSD	Quarterly
		- A short evaluation on financial aspects of supplies at all levels a) at PDHS Level b) at DPDHS level c) at MSD level d) at SPC level	PDHS / Accountant DPDHS / Accountant D/MSD / Accountant Chairman/SPC	Quarterly

9. Monitoring of quality of drugs;

(i) Drugs supplied by the SPC should be registered at CDDA and conform to international standards as specified in the British Pharmacopoeia, International Pharmacopoeia, United States Pharmacopoeia and Indian Pharmacopoeia etc.

(ii) Nevertheless, quality defects (due to issues relating to efficacy, safety and quality) and adverse drug reactions may be encountered by prescribing officers/other relevant officers.

a) These problems on quality should be communicated to D/MSD, D/MTS and Director / NDQAL as specified in Chapter 8.

b) The format for reporting quality issues is given in Annexure X

Information on Adverse Drug Reactions (ADR)

(iii) All adverse drug reactions should be reported to the ADR-monitoring centre of the Pharmacology Department / University of Colombo, in the form provided in Annexure – XVI

In addition ADRs should be reported to Director/MSD, Director / MTS and Director / NDQAL.

**Quality Assurance of Vaccines**

(1). The quality assurance of vaccines is done by the Medical Research Institute (MRI), Additional Approved Analyst for vaccines and related products Annexure xvii

**Monitoring the quality and usage of vaccines and sera ;**

In respect of all problems of vaccine and sera relating to unsatisfactory clinical responses, adverse reactions and exposure to bad storage conditions has to be reported within 24 hours by telephone and followed up with samples as specified below, with detail report relevant to the product, storage condition, maintenance of the cold chain, reaction caused, dosage used etc. to National Control Lab for Vaccines/MRI (Head/Virology Department, MRI – contact No. 2698660, Res. 2597723)

Sample size for Q.A. Test – i. Single dose vials - 05 vials

ii. Multi dose vials - 03 vials

N.B. To be sent in a vaccine carrier with copies of all relevant documents/certificates of the consignment eg: Lot release certificate, summary lot protocol, suppliers invoice etc.  
(More detail in annexure XVII)

10. Annual survey of Drugs and Surgical Equipment and Laboratory items. In terms of FR756, all stocks of medical supplies held in each institution, RD/PDHS Office, offices of the decentralized units/specialized campaigns / RMSD have to be verified annually commencing from early part of the financial year. With respect to MSD, annual stock verification is done in the last month of the financial year. A Board of Survey is appointed for this purpose.

11. The Board of Survey for verification of stocks at the Medical Supplies Division, Teaching Hospitals, Specialized Hospitals, Institutions of specialized campaigns and other institutions of the central line Ministry of Health will be appointed by the DGHS. This is carried out in terms of Section 3 and 4 of Chapter XI of the Manual of the Department of Health, Part –V (Finance)

12. The Board of Survey for verification of all stores including drugs, surgical equipment and laboratory items at the institutions coming under the provincial administration will be appointed by the PDHS for institutions over 100 beds and by RDHS for those under 100 beds respectively. The Board will comprise two or three officers, with the senior officer functioning as the Chairman of the Board.

13. The verification shall be carried out as detailed below:

(i). The verification should cover all stores except printed forms. The verification should not be confined to the items appearing in the books only but also to items that are in the premises but not entered in the books (In case of MSD, in the computer ledger)

(ii). 100% of receipts and at least 10% of all issues should be checked with the connected consignment notes, invoices, etc. to ensure that all entries made in the books including write-offs and the balances shown have been correctly arrived at.

(iii). In the case of consumable stores, the physical verification of quantities available should be done first. In the case of non-consumable articles the book balance should be checked first. The correct book



balance as per ledger, actual balance on hand, excesses and shortages found should then be entered in form Treasury and Audit – 66.

(iv). Besides reporting of excesses and shortages, the Board should comment in a separate report any unsatisfactory features observed in the accounting of stores, excesses non-moving items, fast moving items, idling equipment, etc.

(v). After completion of the entries in form Treasury and Audit-66, the Board should obtain the signature of the Officer-in-Charge of stores on the forms certifying to the fact that the quantities entered in the forms are correct.

(vi).The excess items found at the verification should be entered in the Stock Book.

(vii). The form Treasury Audit-66 should be prepared in quadruplicate. They should be signed by all the members of the Board of Survey. The forms should then be handed over to the Head of the Decentralized Unit/Specialized Campaign, Officer in Charge of the institution, together with their special report.

(viii).The Head of the Decentralized Unit/Specialized Campaigns should forward the copies of the report as follows;

- a) One copy to the Auditor General
- b) One copy to the Deputy Director General (Finance) of the Ministry;
- c) One copy to the Head of the Institution for reporting the value of shortages and fixing the responsibility on officers responsible for the shortages.

(ix). The Head of the Institution will personally and primarily be responsible for ensuring that the amounts noted in the shortage register are promptly recovered from the officers responsible and the items are written off from the books.

(x). All recoveries in the first instance should be kept in the Miscellaneous deposits of the General Deposit Account for a period of three months. If no appeals are received during this time such amount should be credited to revenue.

14. It shall be the responsibility of all OIC of drugs, surgical equipment and laboratory stores to have their inventory book balanced at the end of each financial year and carry forward the balances to the new year to enable the Board of Survey to commence verification early in the financial year. The Officers should also assist the Board of Survey by providing all information required for the verification and proving the physical existence of the items

## CHAPTER 11

### DISPOSAL OF EXPIRED/SPOILT DRUGS AND MINIMIZING WASTAGE

Past experience has shown that significant percentage of drugs procured for the state health sector has been disposed of due to: -

1. Expiry
2. Spoilage due to improper storage
3. Quality failure.

The proportion of drugs wasted is so high, the financial value amounts to millions of rupees annually. Therefore every attempt should be made to minimize such wastage.

Some important steps are,

1. Preparation of realistic estimates.
2. Creation of cost consciousness among the officers concerned will help to take precautionary measures.
3. Computerization of medical supplies management information system linking all institutions will help to minimize wastage.
4. Adherence to standard treatment protocols,
5. Avoidance of over prescribing and polypharmacy
6. Avoidance of prescription on patient demand
7. Re-distribution of excess and short expiry drugs
8. Taking all possible steps to prevent pilferage
9. Maintenance of proper storage conditions
10. Proper and careful handling of packages

The following guidelines are laid down for efficient disposal of expired/spoilt drugs.

#### **1. Excess drugs: -**

1.1 It shall be the responsibility of the head of the institution and RMSD to furnish lists of excess drugs to RDHS monthly.

1.2 The RDHS should take action to transfer the excess drugs to another institution or to RMSD. If this is not possible RDHS will arrange with the Provincial Director for redistribution within the province. In the event such action is not possible PDHS should communicate with other PDHSS/Director MSD for redistribution among other provinces/regions or institutions coming under the central ministry.

1.3 In case of institutions coming under the central ministry, the head of the institution should communicate with Director/MSD for redistribution.

1.4 Transferring of excess drugs should be on “Issue Order “using form General 141.

1.5 Acceptance will be on “receipt order” using form General 219 at RMSDD and other health institutions. MSD will coordinate/ monitor this activity.

1.6 Past experience has shown that change of consultants has caused accumulation of certain drugs in an institution. In such instances action may be taken to transfer those drugs to the institution where the consultant has been transferred to, in consultation with the head of the institution.

Refer Chapter 5 for the procedure on re-distribution of excess/short dated stocks of drugs

## **2. Short Expiry Drugs**

2.1 Officer in charge of the drug store and head of the institution should give special attention with regard to short expiry drugs.

2.2 Action should be taken to redistribute short expiry drugs at least 6 months prior to the expiry date.

## **3. Disposal of withdrawn, expired and spoilt drugs**

3.1 Disposal of all medical supplies should be done periodically. Officer/ Pharmacist in charge of the stores should submit the unserviceable items list in form G 47 including the value in quadruplicate to the head of the institution as per schedule shown bellow.

Table 9: Periodic disposal of all medical supplies by the institutions

RMSD/TH/PH/DG H	BH	DH/RH/PU/CD/SDC/ MOH
quarterly	½ yearly	yearly

### 3.2 Establishment of Board of Survey

The Board of Survey is establishing for disposal of unusable stocks of equipment, pharmaceuticals and other items, under FR 756. On the recommendation of the Board approval for disposal / sale, is granted by director (stock verification).

The Board consist of 1 to 4 of the following officers and specialty officer as relevant to the item/ items concerned, which comes under 5 to 8 of the following.

1. Head of the Institution –Chairman
2. Accountant- Member
3. Hospital Secretary/ Administrative officer- Member
4. Director (Finance) / Nominee–Member
5. Director Biomedical Engineering /Nominee–Member
6. Director- MSD /Nominee–Member
7. Director Building –Ministry of Health / Nominee–Member

In case of drugs withdrawn due to quality failure the respective head of the institutions/ RMSD should inform the quantity so withdrawn to D/MSD as per instructions given in circular.WMS-02/66/2007 (Annexure xviii)

### **04. Reporting of disposal**

4.1 All drugs disposed of should be reported as indicated below using the quarterly return form (annexure xix) – to

- (a). Directors of TH and other institutions under the line ministry of health should send this return to D/MSD
- (b). All provisional institutions should send this report to respective provincial director.
- (c).Provincial Director should forward a consolidated return to D/M.SD
- (d).D/M.S.D. in turn should submit a consolidated report to DGHS

### **5. Disposal**

5.1 Every possible step should be taken to dispose of the condemned medical supplies to ensure that they cannot be reused or does not cause environmental problems.

5.2. The best way to destroy them is by incineration.

5.3. Tablets, capsules can be buried in a pit, minimum of 5 to10 feet deep from the ground level, minimum of 50 feet away from any water resource,

in a suitable land which does not cause environmental pollution. Vials and Ampoules should be crushed and buried.(Circular No CA/1/2007, date 05/10/2007)

**6. Authority to write off:**

6.1 Write off from books (losses and discarding)

Except in case of irregularities, theft or procedural faults, all other write off authorities are delegated as follows

Table 10: Write off authorities

DGHS	Up To Rs. 25,000/=
Deputy Director(F)/ Assit. Director(F)/ Accountant( subject to Treasury approval )	Up To Rs. 25,000/=
Director Medical Supplies Division ( subject to Treasury approval )	Up To Rs. 25,000/=
Director / Head of Specialized institutions ( subject to Treasury approval )	Up To Rs. 25,000/=
Director (F) Stock verification	Up To Rs. 10,000/=
Secretary Ministry of Health Care & Nutrition ( except in case of theft /forgery etc)	Up To Rs. 1,000,000/=
With relevance to FR 105	Up To Rs. 500,000/=

Except for the above losses, write off of all other have to be referred to Secretary Health. All the institutions should maintain damage/ lost register and report. Annual account of same to be included in the appropriation account

6.2 Where the value of medical supplies condemned exceeds these limits write off authority should be obtained from PDHS/Director (finance) Ministry of Health.

6.3 DGHS circulars will notify any revisions of values vested.

## **ANNEXURE**

### **ANNEXURE 1:**

#### **The main functions of the Office Director MT&S**

1. Registration of cosmetics, devices and drugs
2. Licensing imports and manufacturing of cosmetics, devices and drugs
3. Inspection and licensing of retailers and wholesalers of cosmetics, devices and drugs
4. Convening meetings of the
  - a. Technical Advisory Committee
  - b. Drug Evaluation Sub Committee
  - c. Cosmetics Sub Committee
  - d. Devices Sub Committee
  - e. Advertisements Sub Committee
5. Participating in control activities of narcotics, psychotropic and precursors
6. Carry out GMP inspections of local manufacturers of cosmetics, devices and drugs
7. Issue of personal user licenses for drugs and devices.
8. Screening of drug advertisements.
9. Collection and reporting adverse drug reactions
10. Conducting educational training programmes for health sector and the public
11. Training of authorized officers
12. Keeping product records.

13. Liaison with companies dealing in cosmetics, devices and drugs

## **ANNEXURE I1:**

### **Main functions of Medical Supplies Division**

1. Receiving and consolidating of annual estimates to analyse and forecast national annual requirements of drugs, surgical items and laboratory items (medical supplies).
2. Preparing indents for requirements of medical supplies and forwarding same to SPC for procurement and supply.
3. Monitoring process of orders placed with SPC in order to ensure proper delivery .
4. Receiving consignments of items ordered from SPC and storing of same.
5. Distribution of medical supplies to RMSD/ Institutions according to a programme.
6. Analysing periodically stock availability and performance of supply and distribution of medical supplies.
7. Collecting, consolidating and analyzing the information received from the institutions relevant to medical supplies, locally purchased at the institutional level.
8. Revision of annual estimate books of medical supplies with assistance of Collages/Association of medical consultants and other relevant experts.
9. Functions relevant to quality assurance activities
10. Correspondence with institutions regarding complaints, reports, performance, and re-distribution of excess/short shelf life items.
11. Maintenance of an efficient medical supplies management system with computerized facilities.



12. Coordinating and conducting in-service training for the staff.
13. Visiting institutions/Divisions to monitor and co-ordinate/participate at Drug Review meeting activities relating to medical supplies management in respective institutions/divisions.
14. Support, review, revise and disseminate rules, regulations and procedures to ensure scientific management of drugs.

## ANNEXURE – III

### Lead Time:

Normal lead time of procurement by SPC

Approximate lead time required by SPC for normal imports under MSD orders are;

- a) Department Tender Board - 11 months
- b) Ministry Tender Board - 11 - 12 months
- c) Cabinet Appointed Tender Board (CATB) -14 - 15 months

However orders coming under the purview of the Ministry Tender Board and CATB some times require a much longer lead time than above.

Composition of lead time of imports by SPC

	<u>Duration in weeks</u>
1. Preparing specifications and obtaining D/MSD approval	04
2. preparing tender document	02
3. Time for suppliers to quote	06
4. Scheduling of offers	02
5. Evaluation of offers	05
6. Tender Board decision	02
7. Opening letters of credit	02
8. Obtaining raw material	08
9. Manufacturing time with DHS markings	10
10. Quantity control	02
11. Packing and obtaining shipping space	03
12. Shipment time	01
13. Clearance time	<u>01</u>
 Total Number of Weeks	 48 (11 months)

### Re-Order Level (ROL):

Usage in the lead time of supply

### Economic Order Quantity (EOQ):

Specially for bulk items

$$EOQ = \sqrt{2AB / CI}$$

A- Annual requirement for usage

B- Marginal cost of ordering an item

C- Purchase unit price

I - Annual stock holding cost as a proportionate of stock value

**Safety Stock Level (SSL):**

Usage in a fixed duration determined based on ABC category (1-3 months) for items with consistent demand and for items with less consistent demand, standard deviation of the difference of demand [forecasted or estimated and actual demand x selected safety factor (25%-40%)]

Minimum Stock Level (MSL):

$$\text{MSL} = \text{Re-Order Level} + \text{Usage in the review period}$$

Maximum Stock Level (MSL):

$$\text{MSL} = [\text{Minimum stock level} + \text{EOQ} - (\text{The usage in review period}/2)]$$

## ANNEXURE – IV

### Monthly Return and Request for Vaccine /Serum

- (a).Period of the Monthly return ; From..... To.....  
 (b). Name of the Institution : .....  
 ( c ). Institution Code : .....  
 (d)Year/Month .....

For the Month ( a )  
above

SR No	Items	Estimate Balance	Opening Stock of the month ( Vial at hand at beginning of month)	( during the month ) Stocks received	Consumption ( Vials used during the month )	Stock as at end of the month ( Balance in hand at end of the month	Quantity . requested for the month ahead
060026	Anti Rabies cell culture vaccine. (ARV)						
060042	Anti Rabies Serum (ERIG) 1000 IU/5ml						
065131	Anti rabies human Immunoglobulin (HRIG) (300 IU/vial)						
065343	Anti rabies human Immunoglobulin (HRIG) (750 IU/vial)						

**Note:-** I assure that , required cold storage and transportation facilities are available at this institution to maintain the cold chain of the stocks requested above.

Please hand over the above Vaccine and Serum requested above to bearer, whose specimen signature is appended below.

Specimen Signature .....  
 Name : .....  
 Designation : .....  
 National Identity Card No : .....

Requesting Officer  
 (Head of the Institution )  
 Date : .....

**Anti Rabies cell culture vaccine. (ARV)**

Schedule	No of Patients	No of Vials Used
Intra muscular		
Intra dermal		
Total		

Note: The above information should be send monthly to the following officers

- Cc     01. Director / Public Health Veterinary Services f.i.  
        02. Epidemiologist f.i.  
        03. Dr. Omala Wimalaratne, Consultant Virologist, MRI f.i.

**Protocol for anti rabies post exposure therapy (PET)**

**1.0 Management of a patient following an animal bite**

- 1.1 Wounds should be washed immediately with soap and water for 3-5 minutes.
- 1.2 Wounds should be cleaned thoroughly at the hospital with 70% alcohol or povidone iodine.
- 1.3 Anti tetanus immunization should be inoculated when necessary.
- 1.4 Antimicrobials should be prescribed if necessary to control bacterial infection.

It is essential to screen the patient and the animal before the decision is made regarding PET.

**2.0 Screening the patient - Categorization of the exposure**

**2.1 Major exposures:**

- a. Single or multiple bites with bleeding on head, neck, face, chest, upper arms, palms, tips of fingers and toes and genitalia.

- b. Multiple scratches with bleeding on the head, neck and face.
- c. Single or multiple deep bites on any part of the body.
- d. Contamination of mucous membranes with saliva.
- e. Bites of wild animals with bleeding.

## **2.2 Minor exposure:**

- a. Single, superficial bite or scratch on the lower limbs (excluding tips of toes) upper limbs (excluding upper arms, palms and tips of fingers) abdomen and back.
- b. Nibbling of uncovered skin.
- c. Contamination of open wounds with saliva.
- d. Drinking raw milk of rabid cow or goat.

## **3.0 Screening the animal**

### **3.1 In case of major exposures to dogs and cats:**

3.1.1 If the animal is apparently healthy, observable and has had a minimum of 2 rabies vaccinations, with the last vaccination given within 1 year of the incident PET can be delayed while observing the animal for 14 days.

3.1.2 When the animal is suspicious or sick, but observable initiate PET while observing the animal. Discontinue treatment if the animal is apparently healthy after 14 days.

3.1.3 If the animal is having rabies (confirmed by laboratory diagnosis) or unobservable (animal dead, killed, missing or stray animal) initiate PET and continue the full course.

### **3.2. In case of minor exposures to dogs and cats:**

3.2.1 If the animal is apparently healthy, observable and has had a minimum of 1 rabies vaccination.

- within 1 year of the incident.
- at an age above 3 months.
- incident occurring at least 1 month after the vaccination.

PET can be delayed while observing the animal for 14 days.

3.2.2 When the animal is suspicious or sick, but observable, initiate PET while observing the animal. Discontinue PET if the animal is healthy after 14 days.

3.2.3 If the animal is having rabies (confirmed by laboratory diagnosis) or unobservable (animal dead, killed, missing or stray animal) initiate PET and continue the full course.

The patient must be clearly advised that the animal should be put in a cage or leashed\_during the observation period. If the animal dies, becomes sick or develop any abnormal behaviour, the patient should be advised to report to the hospital immediately. In case of death of the animal patient should be encouraged to send the head of the animal for laboratory confirmation of rabies.

The following are not considered\_as exposures:

- a. Contamination of intact skin with saliva of a suspected animal.
- b. Petting, bathing or coming in contact with utensils of a suspected rabid animal.

#### **4.0 Anti Rabies PET: When indicated:**

4.1 All patients in the major category should be given rabies immunoglobulin (Equine or Human) followed by a course of anti rabies vaccine (ARV).

4.2 Patients in the minor category should be given only a course of ARV

#### **5.0 Rabies Immunoglobulins(RIG)**

5.1 RIG available in Sri Lanka at present:

- a. Equine rabies immunoglobulin (ERIG)
- b. Human rabies immunoglobulin(HRIG)

Administration of RIG should be considered as an emergency. Rabies immunoglobulin should\_be given immediately after the incident.\_However if the patient reports late, RIG could be given up to 3 months after exposure, if the patient has not taken the anti rabies vaccine.

It is essential to test for sensitivity before administering ERIG, Method of sensitivity testing (ST) for ERIG is given in annexure IV. HRIG does not require sensitivity testing prior to its administration.

If a patient with a major exposure is ST positive for all available products of Equine-RIG, Human RIG should be considered.

However, in a situation where HRIG is not available in the country:

a. If the animal is apparently healthy and observable, the 8 site ID - ARV schedule could be considered.

b. If the animal is suspicious of having rabies or unobservable, WHO recommended method of using ERIG under adrenaline and antihistamine cover in an ICU should be considered.

Please note: In a patient with a major exposure, 8 site ID-ARV should not be considered as equivalent for RIG and a course of ARV.

In case of major exposure where 8 site 1D-ARV was administered in place of HRIG and the patient reports that the animal is dead, missing, sick or having abnormal behaviour within 07 days of initiation of ARV, WHO recommended method of using ERIG under adrenalin and antihistamine cover should be administered in an ICU. This should be followed up with a fresh course of 2 site 1D-ARV.

a. If the patient reports after 7 days of initiation of ARV, continue and complete the 8 site ID-ARV schedule. Rabies immunoglobulin is not indicated. In such situations it is advised to seek expert opinion.

## **5.2 Dosage of RIG**

a. Equine rabies immunoglobulin (ERIG) 40 IUI kg body weight.

b. Human rabies immunoglobulin (HRIG) 20 IUI kg body weight.  
RIG should be infiltrated in and around all wounds. After infiltration of the wounds if there is any remaining RIG, it should be given 1M on the thighs. Deltoids should be spared for ARV when giving RIG. Vaccines should be administered preferably on the same day after RIG, but at a different site.

## **6.0 Anti Rabies Vaccines (ARV)**

Following anti rabies vaccines are available in Sri Lanka at present:

a. Purified chick embryo cell culture vaccine (PCEC)



b. Purified Vero cell rabies vaccine (PVRV)

6.1 Intramuscular (1M) schedules of ARV\_

This schedule is used in hospitals where less than 5 patients following animal bites are treated per day.

6.1.1 For major exposures: 5 dose regimen with RIG IM-ARV one dose\* each on D0, D3, D7, D14 & D30.

6.1.2 For minor exposures: 4 dose (2-1-1) regimen

2 doses\* of IM-ARV one on each deltoid on D0 followed by 1 dose\* each on D7 & D21.

\* 1 dose = PCEC 1 ml (1 vial) / PVRV 0.5 ml (1 vial)

IM injections should be given into the deltoid muscle or in small children into the anterolateral thigh muscle.

6.2 Intradermal (1D) schedules of ARV\_

These schedules are administered in Teaching Hospitals, General Hospitals, Base Hospitals and some District Hospitals where more than 5 patients following animal bites are treated per day. WHO has recommended the use of ID schedules in developing countries, where cost of vaccines is a major limiting factor.\_

Intradermal schedules of ARV is not recommended for immunocompromised patients (patients on cytotoxic drugs, on long term steroids, positive for HIV/AIDS, on anti-malarials etc.)

They should be administered IM-ARV schedule after expert consultation.

The recommended ID dose is 0.1ml per site for both PCEC and PVRV

6.2.1 The 2 site ID Schedule (2-2-2-0-1-1 schedule)

The standard schedule used in the government hospitals: one dose each (0.1ml) is given at 2sites, on both arms (over deltoids) on D0,D3,D7 and one dose (0.1ml) is given at 1 site each on D30 & D90

6.2.2 The 8 site ID Schedule (8-0-4-0-1-1 schedule)

The dose(0.1ml)given at 8 sites on day D0 ( deltoids, lateral thighs, supra scapular regions lower quadrants of abdomen), one dose(0.1ml)given at 4 sites on day D7(deltoids, lateral thighs)and one dose (0.1ml)given at 1 site over the deltoid on days d30 & D90.

### 6.3 Precautions that should be taken when using ID-ARV Schedules

All injections should be administered only by trained staff under supervision of a medical officer. Once the vaccine is reconstituted the contents should be used as soon as possible ( preferably within 8 hours, stored at 2-8<sup>0</sup>C) separate disposable syringes and needles should be used for each patient.

## 7.0 Anti rabies pre-exposure therapy

This form of therapy is indicated for persons who are at higher risk of exposure to rabies virus ie laboratory staff handling live rabies virus, veterinarians, rabies control staff( vaccinators) wild life officers, employees in animal quarantine premises and zoological establishments.

The recommended schedule is IM-ARV- 1dose each on D0,D7& D28 A booster dose is given 1 year after the 1<sup>st</sup> dose. Additional booster doses are given once every 5 years.

Administration of RIG is contraindicated in persons on pre-exposure therapy They should be given additional doses of IM-ARV 1 dose each on D0& D3 as boosters even in a case of a major exposure.

## 8.0 Important points to be noted

- Suturing is best avoided. If necessary, should be done after infiltration with RIG
- RIG should be administered before starting on AVR
- Avoid initiation 2-1-1 schedule of IM-ARV or 8 site ID-ARV following RIG
- Administration of RIG or ARV on the buttocks is not recommended as absorption is poor
  - In small children with multiple bites , if the volume is insufficient for infiltration in and around the wounds, dilute the RIG with sterile N. Saline up to double or 3 times.
- Human to human transmission of rabies has not been reported( except through corneal or organ graft)
- For any person who has had direct or indirect contact with a rabies patient PET is not recommended except in special situations( Gen Circular No; 01-

22/2004 on “ Guidelines for procedure to followed in a case of death due to human rabies and disposal of the body)

- Laboratory confirmation of rabies should always be encouraged.
- In institutions where the animal is not vaccinated, encouraged the owner to vaccinate the animal concerned after the observation period
- Pregnancy is not a contra indication for RIG and ARV therapy when indicated.
- All patients who receive rabies PET should be given a document /card clearly stating the date, month and year of vaccination and the type of vaccine used.
- Rabies PET is not recommended following house rat bites.

## **9.0 Management of patients following previous rabies PET**

9.1 For both major and minor exposures: If the animal is apparently healthy and observable, PET could be delayed while observing the animal for 14 days.

9.2 If the animal is proven rabid, suspicious of having rabies or unobservable:

9.2.1 After a full course of ARV:

- a) Up to 06 months from the last dose of ARV - PET is not indicated.
- b) From 6 months -5 years from the last dose of ARV- 2 site ID-ARV 2 doses each or IM-ARV one dose each should be given on D0 and D3
- c) Up to 05 years from the last dose of ARV, RIG is not indicated.
- d) After 5 years: full course of ARV with or without RIG (depending on the category of exposure and animal screening) is recommended.

9.2.2 After 3 doses of ARV (D0, D3, D7)

- a) Within 30 days: continue the original course of ID-ARV on D30, D90.
- b) From 1 to 6 months from the last dose of ARV: ID-ARV 2 doses or IM-ARV one dose should be given on D0 (on the day the patient reports) and D3.
- c) From 6 months to 5 years from the last dose of ARV: a full course of 2 site ID-ARV or IM-ARV should be given.
- d) After 5 years: full course of ARV with or without RIG (depending on the category of exposure and animal screening) is recommended.

Please note that all health care staff managing anti Rabies PET patients, should strictly adhere to the guide lines given in this protocol. For any clarification, contact Consultant Virologist, Dept of Rabies and Vaccines, MRI. Telephone numbers: 011 2698660,011 2693532 - 4.

## Annexure I

It is essential that all institutions using RIG and ARV should send a monthly return (Annexure I) to Consultant Virologist, Dept. of Rabies and Vaccine QC, MRI, Director, Public Health Veterinary Services, 6th Floor, 555/5, Elvitigala Mw, Colombo 05 and to the Director/MSD, before collection of the next months vaccine supplies from MSD/RMSD. Any adverse reactions following rabies PET should be reported to Director/MSD, D/MT &S and Virologist/Dept. Rabies, MRI.

### **Method of sensitivity testing (ST) for Equine Rabies Immunoglobulin (ERIG)**

Control - Inoculate 0.1 ml of N. saline intradermally (ID) on flexor aspect of the forearm. Test - Prepare a 1: 10 dilution of rabies equine serum with sterile N. Saline and inoculate 0.1 ml intradermally (ID) on flexor aspect of the opposite forearm.

Separate needles and syringes should be used for each patient. Patient is kept under observation and the ST should be read after 20 minutes. Examine for itching, induration or urticaria or any systemic effects of anaphylaxis. Induration over 10mm in diameter, large area of erythema or any systemic reaction should be considered as positive ST.

Drug of choice in anaphylaxis is 1:1000 adrenaline 0.5mg given intramuscularly (IM) or subcutaneously (SC) immediately. Mild sensitivity reactions could be managed with antihistamine therapy. Oral or parenteral steroids should not be administered as it depresses the immune response.

**Monthly return for vaccine consumption**

Name of the institution.....

Year .....Month.....

Type of Vaccine	No of patients treated				
Serum					
ERIG					
HRIG					
	1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose	4 <sup>th</sup> dose	5 <sup>th</sup> dose
Intramuscular					
5 dose schedule					
2-1-1 schedule					
Intradermal					
2 schedule					
8 schedule					
Balance	Serum		Vaccine		
opening balance					
Received					
Consumption during month					

.....  
Signature

.....  
Designation

.....  
Date

General Circular No: 01-22/2004

My No: EPID/MH/117/2004

Office of the Director General of Health Services,  
Ministry of Health, "Suwasiripaya"

Colombo 10.

31 st August 2004

Provincial Directors of Health Services

Deputy Provincial Director of Health Services

All Heads of Decentralised Units

Directors of Teaching Hospitals

All MSS/ DMOs / MOles

All Heads of Institutions

### Guidelines For The Procedure To Be Followed In A Case Of Death Due To Human Rabies And Disposal Of The Body

Human to human transmission of rabies has not been reported even though there is a theoretical possibility for such transmission. Duration of virus survival in a dead body is unknown, but most likely may be for a few hours. However, it is necessary to take all precautions when handling a dead body due to the risk of contamination with infected material, such as brain and saliva.

Please follow the instructions given below in a case of death due to human rabies and disposal of the body.

#### **Death in a Medical Institution**

1. Human Rabies is a notifiable disease in Sri Lanka and therefore all cases should be notified immediately to the relevant Medical Officer of Health.
2. A post-mortem is essential in all suspected cases of human rabies in order to confirm by laboratory diagnosis. A specimen of the whole brain without any preservatives should be sent to the Medical Research Institute (MRI) with a clinical history of the patient. The specimen should be transported in a leak proof container packed in ice. Blood or cerebrospinal fluid collected at post-mortem should not be sent to MRI for rabies diagnosis.
3. All staff handling the dead body and the soiled linen should wear gloves. In addition the uses of standard precautions are recommended to be adopted during a post-mortem, to wear masks, gloves, boots, apron and preferably goggles.

4. The body should be handed over to the relatives without any delay

**Death in the house / outside a Medical Institution.**

1. Notify the case to the relevant Medical Officer of Health immediately.
2. Medical Officer certifying the death should inform the coroner and request for a post-mortem.

**The rest of the steps to be followed are as in the institutional setting.**

**General Measures**

1. The body should not be handled unnecessarily. Inform the relatives to dispose, bury or cremate as early as possible.
2. Embalming of body is not recommended. However, if it is essential the undertaker should be advised to wear protective clothing, mask, gloves and boots during preparation of the body to prevent contamination.
3. Sealing the coffin is not required.
4. Relatives should be strongly discouraged from embracing or hugging the body.
5. The preparation area and any place or item, which is contaminated or could possibly be contaminated with body secretions, should also be disinfected with freshly prepared 10% sodium hypochlorite solution.
6. The patient's clothing, bed linen, and other personal items should be disinfected with soap water and boiled before reuse.
7. Post Exposure Treatment (PET) is recommended for the bystander(s) who nursed the patient and who had sexual contact with the deceased within 14 days prior to the onset of clinical signs and symptoms. No PET is required for ward and Judicial Medical Officer staff. However, specialized advice could be sought for any accidental exposure to body secretions. (Please follow the instructions given on PET, Prevention of Rabies by Anti Rabies Post Exposure Therapy, General Circular No 01-0112002 dated 01 January 2002 by the Director General of Health Services)

Any further clarification could be obtained from the Virologist, Department of Rabies, Medical Research Institute (MRI), Colombo 08 (Tel: 011-2693532-3,011-2698660), or Epidemiologist, Epidemiology Unit, 231, De Saram Place, Colombo 10 (Tel: 011 2695112,2681548).

Signed Dr. H. A. P. Kahandaliyanage

Director General of Health Services.

My No: PA/DDGPHS/PG/02/2007  
Office of the Director General of Health Services  
Ministry of Health, "Suwasiripaya"  
Colombo 10.  
11.08.2007  
General Circular No: 01 - 14/2007

Provincial Directors of Health Services  
Deputy Provincial Directors of Health Services  
All Heads of Decentralized Units  
Directors of Teaching Hospitals  
All MSS/DMOs/MOICs  
All Heads of Institutions

Amendments to the General Circular No.01-112002  
Prevention of Rabies by anti Rabies Post Exposure Therapy  
(PET)

The following amendments will replace the chapter on Intra dermal inoculation (ID) of Rabies cell culture vaccine on page 3 of General Circular No.01-0112002. Please note that new additions have been introduced for animal screening and maintenance of registers and returns. These amendments will be effective from 01.05.2007.

1. The recommended Intra dermal (ID) dose is 0.1ml per site for both Purified chick embryo cell culture vaccine (PCEC) and Purified Vera cell rabies vaccine (PVRV).

2.0 Immediate PET need not be initiated if all the following criteria are fulfilled:

2.1 In case of minor exposures:

2.1.1 To apparently healthy and observable, cats and dogs  
and

2.1.2 The animal has been vaccinated against Rabies at an age, above 3



months

and

2.1.3 The animal has had at least 1 rabies vaccination within the past 1 year and the vaccination should be 1 month before the incident.

2.2 In case of major exposures:

2.2.1 To apparently healthy and observable, cats and dogs

and

2.2.2 The animal has had at least minimum of 2 Rabies vaccinations with the last vaccine given within the last 1 year

In such situations, the patient should be advised to observe the animal for a period of 14 days. Immediate PET should be initiated if behavioral changes or sickness develops in the animal.

3. Where ever possible, hospital authorities should take necessary action to establish special rabies treatment units with facilities to handle any emergencies arising due to administration of equine rabies immunoglobulins.

4. Separate registers must be maintained for each treatment type (serum, 1D2 site schedule, 1D 8 site schedule, 1M 2-1-1 schedule, 1M 5 dose schedule) at the Rabies treatment clinics. The relevant column should be marked with a (√).

Format for the Register for different schedules:

Type of schedules

Serial No	Date	Name of the patient	OPD No	Serum	1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose	4 <sup>th</sup> dose	5 <sup>th</sup> dose

5. all institutions using Rabies immunoglobulin and anti rabies vaccine should send a monthly return to Consultant Virologist, Dept. of Rabies and Vaccine QC, MRI, Director, Public health Veterinary Services, 6 th Floor, 555/5, Elvitigala Mw, Colombo 05 and to the

Director/MSD, before collection of the next months vaccine supplies from MSD/RMSD.

Please note that anti Rabies serum and vaccine stocks will not be issued if the returns are not sent in time. Heads of institutions will be responsible for any shortages of supplies due to this reason.

**Monthly return for vaccine consumption**

Name of the institution.....

Year .....Month.....

Type of vaccination	Total number of patients treated with
Serum	
ERIG	

	Total number of patients treated with				
Type of	1st dose	2nd dose	3rd dose	4th dose	5th dose
<b>Intramuscular</b>					
5 dose schedule					
2-1-1 schedule					
<b>IM Total</b>					
<b>Intradermal</b>					
2 site schedule					
8 site schedule					
<b>ID Total</b>					

Vaccine Balance	
Opening Balance	
Received during the month	
Consumption	
Balance at the end of the month	

.....  
Signature                      Designation                      Date

Signed Dr. Ajith Mendis  
Director General of health Service

**ANNEXURE – V**

MyNo...../...../.....  
.....  
...../...../200.....

DHS/ Director/M.S./MOIC  
General/Base Hospital/Office of DPDHS  
.....  
.....

Sub: Re-distribution of Short Dated/ Non moving Surplus stocks  
Ref: Your letter No .....Of.....

After careful consideration of the relevant facts and statistics, following conclusions have been reached, in respect of the re-distribution or usability of the Surplus stocks  
Referred to, in the letter under reference.

- (a) Serial numbers of the items(list overleaf) that can be returned to the Institution/  
RMSD/MSD.....
- (b) Serial numbers of the Items, that can be transferred to institutions indicated in column (E) of the list overleaf (in consultations with the institution concerned).....
- (c) All, Items / except above items, mentioned in your letter can not be accepted for use/ re-distributed via RMSD/MSD

N.B. Authority granted for return/ re-distribution would lapse in.....working days and has to be revalidated there after.

.....  
.....  
Head of the institution  
(DPDHS/  
Director/M.S./MOIC)

- C.c 1. Director (M.S.D) –f.i.& n.a.
- 2. P.D.H.S.(.....) f.i.& n.a

3. O.I.C.-RMSD/Chief Pharmacist. (.....) f.i.& n.

A
---

MyNo...../...../.....  
 ...../...../200...

To All; D.P.D.H.S./ Heads of Central Government Hospitals

.....  
 .....

Re-distribution of Short Dated/ Non moving Surplus stocks

Short Dated/ Non moving Surplus stocks, that can not be used at this institution, transferred to other institutions in the, Provinces/Central Government, are listed below for your kind attention in keeping with Chapter 11 the Manual of Management of Drugs.

Estimate –store section			(3)Date of Expiry	(4)Quantity	MSD/RMSD Stocks			(D) Quantity to re-distribution	(E) Indendent Place of re-distribution	Stock controlling Officer (MSD/RMSD)
Serial Number	(1)SR.NO	(2)Items			(A)Monthly Consumption Rate	(B) Duration (mths)	(C)Min. Shelf life			
1										
2										
3										
4										

N.B.Column No(1)-(4) to be filled by the institution concerned. Only the stocks, with minimum of 06 months of shelf life ,that can not be used within the Province/Institution (Central Government)are to be included.

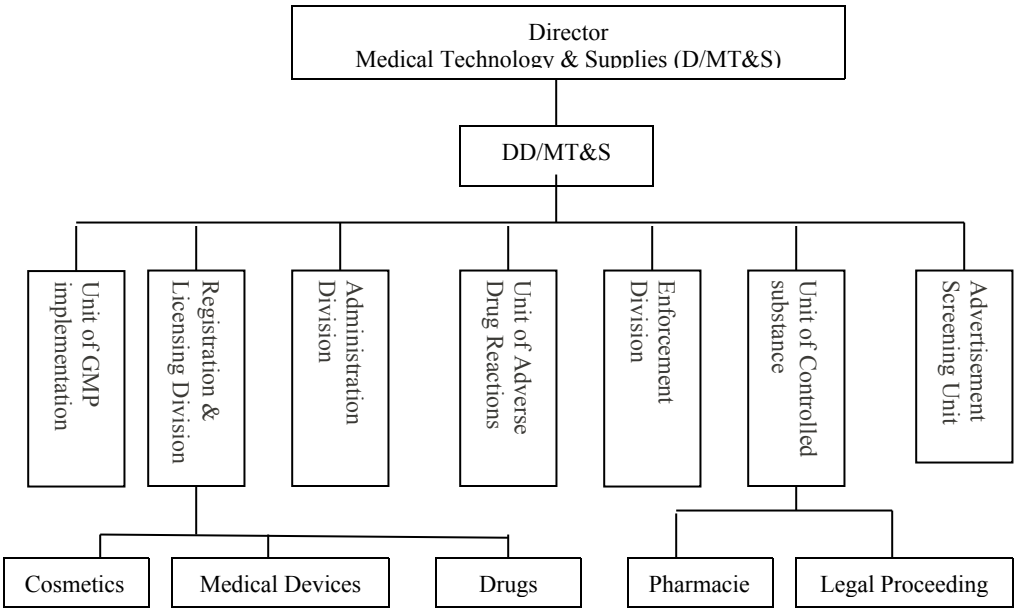
Head of the institution

(DPDHS/ Director/M.S./MOIC)

- C.c 1. P.D.H.S.(.....) f.i.& n.a
- 2. Director (M.S.D) –f.i.& n.a.

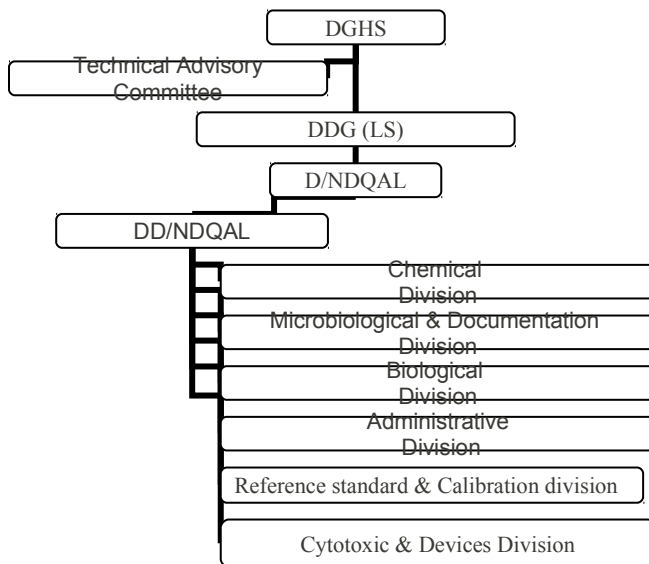
**ANNEXURE VI**

**Organizational structure of the Office of Director MT&S**



## ANNEXURE VII

### Organizational structure of the NDQAL



## **ANNEXURE VIII**

(To be amended)

My No.LAC/60/89  
Office of the Director General of Health Services  
P.O.Box 513  
Inland Revenue Building  
Colombo

To: All Provincial Directors of Health Services,  
Regional Directors of Health Services

### QUALITY ASSURANCE OF DRUGS AT PERIPHERAL UNITS, DISTRICT HOSPITALS, BASE AND PROVINCIAL HOSPITALS.

With the establishment of the new National Drug Quality Assurance Laboratory (NDQAL), it has been decided to deploy a more effective quality assurance system for drugs prescribed for patients at Peripheral Units, District Hospitals, Base and Provincial Hospitals. This is in keeping with some of the proposals agreed upon at the Objectives Oriented Planning Workshop for National Drug Quality Assurance Laboratory.

In this respect, it is proposed to select drugs for quality assurance testing using to ABC analysis of drugs and giving preference firstly to those in A Group. The first twenty drugs in the A Group have been selected for initial assessment. The Divisional Pharmacists and Drug Inspectors in Provinces/Regions (in addition to the Officers of the NDQAL) may be instructed to collect and send samples of those drugs for quality assurance.

The specific drugs to be collected and sent for quality assurance will be decided by the Director of the NDQAL and communicated at intervals to these Officers through provincial/regional Directors.

The procedure for collection and sending of samples of drugs of suspected quality and on complaints made by the prescribers, to the National Drug Quality Assurance Laboratory from Government Institutions and at the requests of Provincial/Regional Directors is indicated in Annexure I and the procedure for collection and sending of samples of drugs from Government



Institutions at the request of the Director of National Drug Quality Assurance Laboratory for the Quality Assurance Programme is indicated in Annexure II.

Further information if necessary should be obtained from the Director, National Drug Quality Assurance Laboratory, 120, Norris Canal Road, Colombo 10. Telephone No. 695173.

.....  
DIRECTOR GENERAL OF HEALTH SERVICES

## ANNEXURE IX

### Part XI – CDD Regulations

#### Procedure for taking samples for test, examination, analysis or clinical trials

85. An officer who obtains or takes a sample of any drugs under section 22(1) (a) of the Act, for test, examination, analysis or clinical trial shall, after procuring a suitable quantity according to his opinion, of the drug in question, notify the person from whom the samples were obtained of his intension to submit a sample thereof to an approved analyst for examination.

86. If in the opinion of the Authorized Officer, division of the procured quantity would not interfere with the test, examination, analysis or clinical trial-

(a) He shall divide the sample in to three parts;

(b) Seal the three parts separately with his seal;

(c )Permit the person or owner from whom the sample was procured to place his seal or thumb impression, if he so desires;

(d) Deliver one part of the sample to the person or owner from whom the sample was procured.

(e) Retain one part of the sample and if the label is present on the sample procured, retain the part that contains the label for producing it in court under section 32(1) of the Act; and

(f) Forward one part of the sample to the approved analyst with the description of such sample and an extract of the relevant portion of the label, for test, examination, analysis or clinical trial

87. If in the opinion of the Authorized Officer, division of the procured quantity would interfere with the test, examination, analysis or clinical trial, he shall seal the entire quantity and permit the person or owner from whom the sample was obtained to place his seal or thumb impression, if he desires to do so and forward the same to the approved analyst with a notification as to the method, for test, examination, analysis or clinical trial.

**ANNEXURE X**

.....  
.....

Director  
National Drug Quality Assurance Laboratory  
120 Norris Canal Road  
Colombo 10

**DRUG SAMPLE FOR QUALITY TESTING (COMPLAINT / SURVEILLANCE)**

**LABEL**

1. Name of the product.
  - (a) Generic name : .....
  - (b) Brand name (if any) : .....
2. Dosage form : .....
3. Specifications (state whether B.P., U.S.P., N.F., etc.):.....
4. Strength/s of the product (i.e., active ingredients):.....
5. Composition of the drug product (i.e. Each enteric coated tablet contains ... / or each ... etc):.....  
.....
6. Batch number / Lot number : .....
7. Date of manufacture (if any) : .....
8. Date of expiry : .....
9. Manufacturer's name and full address. : .....
10. Description of the original container/pack : .....
- (if different from the submitted pack)
11. Quantity submitted Defective (YES/NO) Quantity: .....
- Unopened Packs (YES/NO) Quantity:.....
12. Stock available at the institution of the drug product of the same batch : .....
13. Storage requirements stated on the label : .....
14. Storage condition at the source : .....
15. Nature of the problem /complaint with all relevant details :  
.....
16. Any other remarks:.....

Name, Address and designation

Head of the Institute /

## ANNEXURE XI

Recall procedure for quality failed pharmaceuticals as approved by the Technical Advisory Committee

Quality failures are identified under 2 categories.

- (i) Failures due to manufacturing defects
- (ii) Failures related to improper storage

The following recommendations are made about failures due to manufacturing defects

### 1. **De-registration**

#### a) De-registration of a product

A single product which has been recommended for withdrawal by the D/NDQAL, it shall be referred to a committee comprising of DGHS (Chairman), D/MT&S, D/NDQAL, DDG(LS), Consultant/DRA and DDG/SLSI for the final decision on de-registration.

#### b) De-registration of a manufacturer

If more than one product of a particular manufacturer that has been recommended for withdrawal by NDQAL, it will be referred to the above mentioned committee for the final decision.

2. The manufacturer can re-apply for registration after making necessary improvements only after a period of 24 months from the date of de-registration of the product or the manufacturer.
3. Any changes in ownership or name of a manufacturer should be communicated to the DRA within one month of such a change; in the event of such changes, the original decision with respect to the drug or the manufacturer will stand.
4. Re-registration will not be granted until the manufacturing plant is inspected and approved by the DRA. All costs for inspections will be borne by the company concerned.
5. The final decision of the recall procedure committee shall be conveyed to the DESC and Presidents of the Professional

Associations/Colleges whose duty shall be to convey the information to the registered members of the Colleges or Associations.

6. **Quality failure of registration samples attributed to manufacturing defect/failure**

If there is a quality failure, the application will be recommended for rejection by the DESC and the manufacturer will not be allowed to re-apply for registration for the same product for a period of 12 months from the date of communicating the decision to the applicant.

In the case of local manufacturers, the DRA will take a decision after inspecting the factory and testing samples collected by the DRA

7. **The following decisions were taken on “withholds”**

Whenever there is a complaint, the Head of the Institution should initiate immediate action to withhold the batch and inform D/NDQAL with copies to D/MT&S and D/MSD. NDQAL will immediately investigate and analyse samples of the withheld batches and inform the D/MSD. D/MSD will give instructions to the Heads of Institutions on the actions to be followed.

With regard to the private sector, (SPC or private market) recall procedures according to WHO GMP Guidelines will be followed.

When quality failures are detected by the NDQAL, the D/MSD should immediately inform all respective PDHSS, RDHSS and Head of Institutions of all decisions to withhold items by fax followed by a hard copy. On receipt of this information, the PDHSS, RDHSS and Head of Institutions should immediately take actions to withhold the items and to send more samples for testing within 2 weeks of the letter sent by the D/MSD. If such samples are not available, that information should be intimated to the D/NDQAL, D/MSD and D/MT&S.

8. **Recovery of cost**

In cases of quality failures, it is the responsibility of the SPC either to reimburse the cost or to replace the stocks with drugs of acceptable quality.

9. **Destruction of substandard drugs**

The PDHSS, RDHSS and Head of Institutions are responsible for destroying stocks according to the WHO guidelines after receiving circulars for withdrawals from the D/MSD.

**10. Recalls initiated by manufacturers**

When a manufacturer initiates the recall of a product available for sale, the reason for the recall should be intimated to the D/NDQAL, D/MSD and D/MT&S,. The D/MT&S and D/NDQAL should carry out complete investigations as to the reason for withdrawal by the manufacturer.

**11. Tender samples**

Until further improvements are made to the NDQAL, samples will be selected on a random basis from each consignment of DHS supplies and tested. A quality certificate of the bulk drug (active ingredient) incorporated into the product should be sent along with each consignment.

The SPC should send samples of all quality failed registered drugs submitted for tenders to the D/NDQAL.

**ANNEXURE XII**

**MEDICAL SUPPLIES DIVISION –COLD CHAIN RECORD-COLD ROOM NO”CU”YEAR 200....**

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
	Temp. at(9.00am) <sup>o</sup> C Signature of SK																															
Temp.at(1.00pm) <sup>o</sup> C Signature of SK																																
Temp.at(4.30pm)C Signature of SK																																
Sig. ofAD(Stores)Sig. Of Any Other Officer																																
Temp.at(9.00am)C Signature of SK																																
Temp.at(1.00pm)C Signature of SK																																
Temp.at(4.30pm)C Signature of SK																																
Sig . of AD (Stores) Sig. Of Any Other Officer																																

# ANNEXURE XIII

## Lot Card

SR No.....			LOT CARD			LEDGER FOLIO.....		
NAME OF ITEM .....							BIN NO	
Stock Receipts			Stock Issued					OTHER Data
RV No.	Expiry Date	Quantity	ST V NO.	Date of Issued	Quantity	Physical balance	Institute	
<i>CHECKED BY:</i> <i>CHECKED DATE:</i>								



## ANNEXURE XIV

### ABC Analysis

This is an analysis based on issue values of all drugs consumed during the year.

In this method, items are divided according to their annual usage value (unit cost x number of units consumed during the year)

When the values of items are tabulated in descending order, it is observed that a

- a) small number of items account for 70% - 80% of the total budget (A category)
- b) intermediate number of items account for 15% - 20% of the total budget ( B Category )
- c) vast majority of items account for 5% - 10% of the total budget (C Category )

Category	Value	% of items
A	80%	10 - 15
B	15%	20 - 30
C	05%	60 – 70

This analysis is very useful in reducing cost and improving efficiency in areas such as

- a. Planning procurement pattern
- b. Establishing delivery schedule
- c. Stock control and monitoring

which will lead to effective management of drugs.

**It is the responsibility of the Heads of Institutions to closely monitor the proper management of A category drugs.**

## ANNEXURE XV

### VEN Analysis

This analysis sets the priorities for selection, procurement and use according to the potential health impact of the each and every drugs.

VEN analysis assigns each drug on the Essential Medicines List to one of the following three categories.

- V-** Vital drugs are potentially lifesaving and crucial for providing basic health services. Should be available at all times.
  - Eg:- Sodium Chloride 0.9%IV infusion
  - Dextrose 5% IV infusion
  - Anti snake venom serum
  - Anti Rabies serum
  - Anti Rabies vaccine
  
- E-** Essential drugs are effective against less severe but nevertheless significant forms of illness but are not absolutely vital to providing basic health care.
  - Eg:- Paracetamol Tablets
  - Amoxicillin Capsules
  
- N-** Non essential drugs are used for minor illnesses are of questionable efficacy or have a comparatively high cost for a marginal therapeutic advantage.
  - Eg:- Nystatin

In the annual estimation process particular attention should be paid to V and E drugs. Whenever there is a shortage of funds V and E drugs will be the last eliminated from the list.

As the national formulary or Essential Medicines List is updated and as public health priorities change the VEN categories should be reviewed and up dated. Any new drug added to the list should be categorized appropriately.

The major uses of the VEN analysis are assigning priorities for drug selection, procurement, and in a supply system, guiding inventory management activities.

A drug's VEN classification may affect the following.

**Order monitoring:** Orders for vital and essential drugs should be monitored closely.

**Safety stock:** Safety stocks should be higher for vital and essential items. Inventory savings can be realized by reducing safety stocks of nonessential items.

**Order quantities:** If funds are short, the VEN system should be used to ensure that enough quantities of vital and essential drugs are bought first.

**Supplier selection:** Only reliable suppliers should be used for vital and essential drugs. Quality and service for new and unknown suppliers can be tested by awarding them contracts for nonessential drugs.

**Use.** Review of usage by VEN categories may suggest under use of vital or essential items or overuse of nonessential items.

**Distribution .** Use VEN analysis for the following:

**Stock control:** Special attention should be paid to stock levels of vital and essential items to avoid stock outs.

**Assignment of staff:** Inventory control staff that is more experienced or more skilled should be assigned to keep track of vital and essential items.

Sample Guidelines for VEN Category			
Characteristic of Drug or Target condition	Vital	Essential	Non-essential
Occurrence of target condition			
Persons affected (% of population)	Over 5%	1-5%	Less than 1%

Persons treated (number per day at average health center)	Over 5%	1-5%	Less than 1%
<b>Severity of target condition</b>			
Life-threatening	Yes	Occasionally	Rarely
Disabling	Yes	Occasionally	Rarely
<b>Therapeutic effect of drug</b>			
Prevents serious disease	Yes	No	No
Cures serious disease	Yes	Yes	No
Treats minor, self-limiting condition	No	Possibly	Yes
<b>Symptoms and conditions</b>			
Has proven efficacy	Always	Usually	May or may not
Has unproven efficacy	Never	Rarely	May or may not

**ANNEXURE XVI**

**REPORT OF ADVERSE REACTIONS TO MEDICINES, VACCINES, DEVICES,  
TRADITIONAL REMEDIES & COSMETICS**

(Identities of Report, Patient and Institution will remain confidential)

**PATIENT DETAILS:**

BHT/Record no.	Name & Address(Optional)	Age	Ethnicity	Sex	M
					F

**ALL MEDICINES USED BY PATIENT:**

Suspected Medicine-trade name(batch no. if available)	generic & Dose & Frequency	Route	Date Begun	Date stopped	Reason for Use

**Other Medicines**


**DESCRIPTION OF ADVERSE REACTION**

**Date of on set:**

--	--	--

**System involved:**

RESP	CVS	GIT	CNS	GUT	SKIN	OTHER

**Description of the event:**

--

**Lab investigations if any:**

--

**Out come tick “√”for yes**

Recovered	Continuing	Hospitalized	Severity				Birth defect Specify
			mild	moderate	severe	If fatal, date	
Result on discontinuation of suspected medicine			Result on reintroduction of medicine				Alternative diagnosis
Improved	Disappeared	Persisted	Not Known	Reappeared :Yes/No/Not known			

**Risk Factors present:√**

Renal Dysfunction	Cardiac Dysfunction	Hepatic Dysfunction	Previous Allergies	Smoking	Alcohol	Drug addict	Other (name)
-------------------	---------------------	---------------------	--------------------	---------	---------	-------------	--------------

**REPORT ON QUALITY PROBLEM OF DRUG/DEVICE/COSMETIC**

Device	Cosmetic	Medicine	Name(Brand& Generic)	Date of expiry
Manufacturer(Name & Address)			Model/Serial/Batch/Other number	
Description of the problem:				

REPORTING DOCTOR/PHARMACIST/NURSE/DENTIST/OTHER

Name & Designation.....

Address.....

Telephone number.....Hospital & Ward

No.....

For assistance contact: Dr. Rohini Fernandopulle or Shalini Ranganathan INFO-VIG Dept of pharmacology  
Dept of Pharmacology Faculty of Medicine, PO Box 271 Kynsey Rd, Colombo 08; Telephone 2695300 Ext  
315/400/410; Fax: 691581 Attn Dept of pharmacology, Email: [info-vig@yahoo.com](mailto:info-vig@yahoo.com). Photocopies of the  
above are accepted, or forms could be obtained from the Department

## **ANNEXURE XVII**

### **Quality Assurance of Vaccines**

Medical Research Institute (MRI) functions as the National Control Laboratory (NCL) for vaccines and related products. MRI was nominated as the NCL, under section 25 (2) of Cosmetic Devices and Drugs Act No. 27 of 1980 and was legally appointed by the Ministry of Health of the Government of Sri Lanka by gazette notification No. 1052/3 of 02.11.1998.

The key function of the NCL is technical evaluation of all vaccines used in the government immunization programme, which includes lot release and quality testing. Lot release is done as a minimum by protocol review of all batches of vaccines imported into the country and laboratory testing in special situations according to the vaccine testing policy of the NCL.

#### **Monitoring the quality and usage of vaccines and sera;**

##### **Lot release:**

All vaccine batches used in the government sector should undergo lot release from the NCL before use and the following documents and samples should be submitted.

- Summary lot protocols (including production and quality control) of single harvests, bulk and final product
- Lot release certificate from NCL of country of manufacture
- 5 vials from each lot of single dose vaccines / 3 vials from each lot of multiple dose vaccines

According to the vaccine testing policy of the NCL, routine testing of batches is done in the following situations and would require more vaccine samples .

- All new vaccines before registration
- First 03 batches of new vaccines after registration

Please note that the NCL should be contacted prior to sending the samples.

##### **Unsatisfactory clinical response, adverse reactions and bad storage conditions:**

In respect of all problems of vaccines and sera relating to unsatisfactory

clinical responses, adverse reactions and exposure to bad storage conditions has to be reported within 24 hours by telephone and followed up with samples as specified below with detail report relevant to the product (lot number, expiry date, manufacture etc.), storage conditions, maintenance of the cold chain, reactions caused, dosage applied etc (sample sending form appears in annexure XVI can be used) addressed to the National Control Laboratory (Head / Dept of Vaccine Quality Control, MRL Contact No. 2698660, 2693532-4 Res. 2597723). Advice and approval regarding further use of the batches should be sought from the Epidemiologist for all EPI vaccines and from the Director Medical Supplies Division for all Non-EPI vaccines.

Please note that the NCL should be contacted prior to sending the samples.

**Sample size for Q.A test-**

(1) Single dose vials: sterility test - 5 vials, safety test - 20 vials (2) Multiple dose vials:

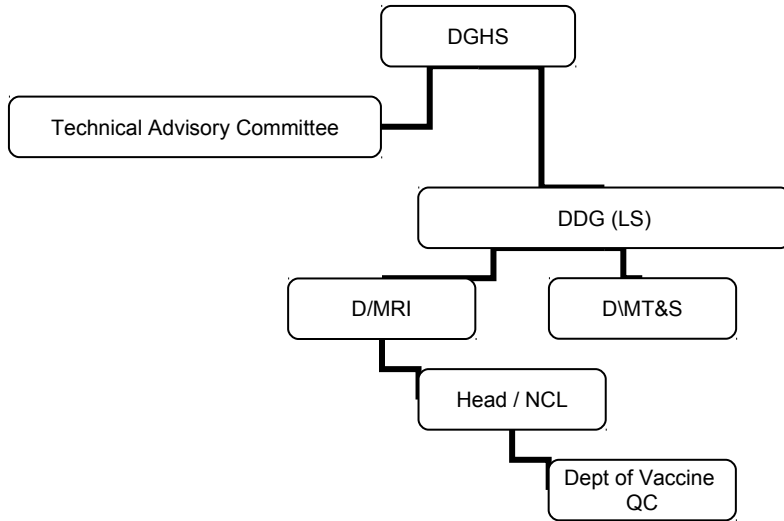
sterility test - 3 vials, safety test - 3 vials

N.B. To be sent in a vaccine carrier maintaining cold chain with copies of all relevant documents.

(2) Same procedure should be followed as pharmaceuticals regarding the handling of product recalling.



## Organization structure of the National Control Laboratory of Vaccines



## **ANNEXURE XVIII**

Circular No.WMS-02/66/2007

### **RETURN OF QUALITY FAILED MEDICAL SUPPLIES TO MSD**

The matter of recovery of cost of quality failed medical supplies was discussed at Public Accounts Committee (PAC) meeting of the Parliament. PAC has instructed that State Pharmaceuticals Corporation (SPC) should either obtain free replacement or recover the cost of quality failed (batch withdrawal / product withdrawal) items from the relevant supplier.

SPC has a difficulty in recovering the cost of items as quality failed stocks are not returned to them before the expiry of performance bond of the supplier. Suppliers are requesting for withdrawn items for free replacement or to reimburse the cost.

Accordingly SPC has requested to return to them any stocks of medical supplies withdrawn from use due to quality failures, in order to obtain free replacement or recover the cost of items from manufacturer /supplier.

In view of these facts, this matter has to be treated as a priority.

However considering the transport difficulties and non availability of adequate storage space at MSD at present, it has been decided that any withdrawn stock from use should be stored separately at the institution (not to send to MSD as informed by circular No.WMS-01/63/2007) and SPC or

Local Agents of supplier (on request of SPC) should be allowed to examine the stock at the institution to take a count of same.

SPC has been requested to examine the withdrawn stocks at the institutions in order to consolidate the withdrawn stocks in all institutions in the country.

It has been further decided that institutions should inform D/MSD such quantity of withdrawn item on or before the date specified in the circular issued for withdrawal of the particular item.

Kindly note that MSD will not accept or take any responsibility for any stock that is not informed to MSD on or before the specified date in the circular issued for withdrawal of item. In the event of failure to inform, institution should bear the responsibility.

Please treat the Circular No. WMS-01/63/2007 under reference of MSD/SCU(S)/Cir/2007 dated 20<sup>th</sup> November 2007 as cancelled.

Please bring the contents of this circular to all officers concerned in your institution/division.

.....  
Director General of Health Services.

## ANNEXURE XIX

### Specimen of Quarterly return on disposal of medical supplies

Quarter Year .....

Name of institution / Province .....

SR No:	Name of item	Quantity	Reason	Value	
				Rs	Cts
			Total		

.....  
Date:

.....  
Signature/Designation