GUIDELINES FOR DONATIONS OF MEDICINES AND HEALTH CARE EQUIPMENT IN NIGERIA

BY

The Federal Ministry of Health, Nigeria
in collaboration with
The World Health Organisation

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FOREWORD

I am delighted to write the foreword to these *Guidelines for Donations of Medicines and Healthcare Equipment in Nigeria*.

The publication of the guidelines is in line with Government's drive to ensure good quality healthcare for the Nigerian people. The *National Drug Policy*, which is a component of the Health Sector Reform Programme of Government, provides for the development of guidelines for medicines and healthcare equipment donations. The aim is to coordinate the current haphazard donation of medicines and healthcare equipment to Nigeria. I am, therefore, pleased that this aspect of the Reform Programme has been accomplished, after due consultations with the relevant stakeholders.

The donation of medicines and healthcare equipment would, henceforth, enjoy a certain measure of control as the guidelines clarify issues relating to donations and facilitate the involvement of all actors in the donation process. The guidelines would ensure that any donations made would be relevant to the emergency situation in question and also ensure that the medicines and equipment donated would be safe and of good quality. We shall always welcome the kind gesture of donors who have always extended a helping hand to us in times of emergency.

In conclusion, I would like to appreciate the commitment of the National Medicine and Healthcare Equipment Donation Guidelines Committee. I commend also the inputs of the various stakeholders to this document. The technical and financial support of the World Health Organisation is highly appreciated.

I hereby enjoin all who will be involved in the implementation of these guidelines at the different levels of government and agencies (Federal, State, LGAs, wharfs, airports, etc.) to adopt positive attitudes that will facilitate all aspects of implementation. Government shall endeavour to provide the enabling environment for the effective implementation of the guidelines.

Professor Eyitayo Lambo
Honourable Minister of Health

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Federal Ministry of Science & Technology

GHAIN/ Family Health International

Health & Human Services Department, Federal Capital Territory

Nasarawa State Ministry of Health

National Action Committee on AIDs

National Agency for Food, Drug Administration and Control

National Emergency Management Agency

National Primary Healthcare Development Agency

Niger State Ministry of Health

Partnership for Transforming Health Systems (PATHS)

Pharmaceutical Manufacturing Group of the Manufacturers' Association of Nigeria

Pharmaceutical Society of Nigeria

Pharmacists' Council of Nigeria

Planned Parenthood Federation of Nigeria

University of Nigeria Teaching Hospital, Enugu

ABBREVIATIONS & ACRONYMS

FMOH – Federal Ministry of Health

GMP – Good Manufacturing Practice

INN – International Non-Proprietary Names

LGA – Local Government Area

NAFDAC – National Agency for Food, Drug Administration and Control

SMOH – State Ministry of Health

WHO – World Health Organisation

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PREFACE

In situations of suffering and disaster, there is a natural human impulse to help those in need. The provision of pharmaceutical supplies/medicines and medical equipment is usually viewed as a pragmatic way of alleviating suffering. Donations of such items are then shipped off to the relevant agencies active in the disaster region.

Unfortunately, experience has shown that not all drug donations are beneficial as some donated drugs have often not been relevant to the emergency situation for which they were donated (i.e., for the disease pattern or level of care needed). Some donated drugs have caused more harm than good. They may sometimes be unknown to local health professionals and patients and may not comply with the policies and standards of the disaster region.

In light of this, the World Health Organisation (WHO) has developed General Guidelines for drug donation to be adapted by member countries, in line with their drug policies. Consequently, the Federal Ministry of Health, in collaboration with WHO, set out to develop Guidelines for Donations of Medicines and Healthcare Equipment in Nigeria. This document is the outcome of the initiative.

A series of meetings were held with the different stakeholders which included the following:

1. National Emergency Management Agency,
2. National Agency for Food, Drug Administration and Control,
3. Pharmacists' Council of Nigeria,
4. Pharmaceutical Society of Nigeria,
5. National Primary Healthcare Development Agency,
6. Pharmaceutical Manufacturing Group of the Manufacturers' Association of Nigeria,
7. Federal Ministry of Science & Technology,
8. University of Nigeria Teaching Hospital, Enugu,
9. Department For International Development,
10. Partnership for Transforming Health Systems,
11. Planned Parenthood Federation of Nigeria,
12. National Action Committee on AIDs,
13. Health & Human Services Department, Federal Capital Territory,
14. GHAIN/ Family Health International,
15. Centre for Disease Control,
16. Niger State Ministry of Health, and
17. Abia State Ministry of Health.

There were also extensive consultations with the stakeholders who made valuable contributions. It was the general consensus that the donation of drugs in the country was uncoordinated and needed to be controlled. It was established that the problem was common to both foreign and in-country donations. Instances were cited where individuals or organizations had donated medicines to Nigerian health centres, orphanages, schools, etc., without official certification of quality. It was agreed that the relevant authorities, as well as the donors and recipients had important roles to play in order to evolve a workable set of guidelines for donations of medicines and healthcare equipment in Nigeria.

As a result of the deliberations, six groups of actors were identified as follows:

i. The Approval Authority (Federal Ministry of Health),
ii. The Regulatory Authority (NAFDAC),
iii. The Nigerian Diplomatic Mission in the Donor Country,
iv. The Regulatory Authority in the Donor Country,
v. The Donor, and
vi. The Recipient.

Appropriate roles and responsibilities were, therefore, assigned as follows:

1. **THE FEDERAL MINISTRY OF HEALTH**

Two agencies of the Ministry were identified and charged with the following respective responsibilities:

A. Food & Drug Services Dept.

- Coordination of all drug donations within the country
- Issuance of approvals to prospective recipients of drugs from external donors
- Monitoring the use and distribution of both externally and internally generated donor drugs
- Developing a management information system to keep track of all information pertaining to donated drugs
- Ensuring the distribution of donated drugs in accordance with the normal principles of good health care practice
- Keeping a proper record of the monetary value of drug donations received

B. Hospital Services Dept.

- Coordination of all donations of health care equipment in the country

2. **NAFDAC**
    - Ensuring that feedback on the status of all approved drug donations is sent to the relevant office in the Federal Ministry of Health
    - Seizure & destruction of all drugs (both internally and externally generated) that do not meet the required standards
    - Issuing appropriate permits for drug donations
    - Impounding unsolicited drug donations that do not meet specifications

3. **THE RECIPIENT**
    - Application to FMOH for approval of drugs being solicited from external donors
    - Application to NAFDAC for clearance of the FMOH approval
    - Bearing the cost of destruction of any sub-standard drugs received
    - Informing FMOH of unsolicited drug donations

4. **THE DONOR**
    - Informing recipients of drugs being considered for donation

5. **THE REGULATORY AUTHORITY OF THE DONOR COUNTRY**
    - Authentication of the medicines and healthcare equipment slated for donation to Nigeria

6. **THE NIGERIAN DIPLOMATIC MISSION IN THE DONOR COUNTRY**
    - Certification of the medicines and healthcare equipment slated for donation to Nigeria

After initial consultations, a draft which had been developed from the *WHO General Guidelines* was circulated to all 36 States of the Federation for their inputs. Responses were received from five States (including the F.C.T.) as follows:

i. Niger State Ministry of Health,
ii. Abia State Ministry of Health,
iii. Delta State Ministry of Health,
iv. Nasarawa State Ministry of Health, and
v. Health and Human services Dept. of the Federal Capital Territory.

Nasarawa State, Delta State and the F.C.T endorsed the draft as presented, while Niger and Abia States made useful comments, some of which have been incorporated into the final draft.

Emergency lists of medicines and equipment are included in the *Guidelines* to guide both donor and recipient agencies in times of emergency. Two checklists for assessing medicines and medical equipment donations have also been included in the *Guidelines* – one for donors and the other for recipients.

BACKGROUND AND JUSTIFICATION

In situations of need there is a natural human impulse to help. Nigeria as a developing country receives donor assistance in meeting her needs for health care equipment and medicines. Such needs could arise as a result of a disaster, new/emerging diseases, gaps in national supplies or research endeavours. The provision of pharmaceutical supplies and medical equipment and devices is usually viewed as a pragmatic way of providing much needed assistance in such situations. Donations of such items are then shipped off to the areas of need.

Unfortunately, the donations do not always achieve their intended objectives. Some have caused more problems than they set out to solve. An emotional appeal may be issued without a proper assessment of the needs and priorities. Health care equipment may end up lying idle because the technology and human resources required for their operation are not available locally. The equipment may require huge maintenance costs beyond the capability of the recipient. Donated equipment may be removed from service in the hospitals of an industrialised country and donated to developing countries. Such equipment may never work. Where they work, lack of trained operators, support facilities and spare parts may turn such donations into a liability for the recipients.

The commonly encountered problems with medicines and medical equipment donations may be summarised as follows:

- Donated medicines are often not relevant for the emergency situation, the disease condition or the level of trained human resources available to administer health care. They may be unknown to local health professionals, and not in line with the country's drug policies and treatment guidelines;
- Donated medicines may arrive unsorted and there may be problems with adequate storage and distribution. These may waste valuable human and financial resources;
- Many donated medicines may be labelled in a language that is not understood in the recipient country. They may also be labelled with trade names, which are not registered for use in Nigeria and carry no generic name;
- The quality of donated medicines does not always comply with standards in the donor country. Donated medicines may have expired before reaching the recipient country, or they may be free samples returned by health professionals;

- The donor agency sometimes ignores local administrative procedures for receiving and distributing medical supplies. The distribution plan of the donor agencies may conflict with the wishes of national authorities;
- Donated medicines may have a high-declared value leading to high import taxes. The inflated value of donations may be deducted from the government drug budget;
- Medicines may have been donated in the wrong quantities, and some stock may have to be destroyed. This is wasteful and creates problems of disposal at the receiving end; and
- Consumables and other items required for the effective functioning of donated medical equipment may not be available locally.

These problems arise owing to several factors. A critical factor is the general lack of communication between donor and recipient. Another important factor is the belief that in a disaster situation, any type of donation is better than none at all. With wrong donations, the total handling cost may be higher than the total value of donated items. Excess medicines and equipment, when stockpiled in the system will encourage pilferage and black market sales. Health care needs and required professional competences vary amongst various levels in the country. Consequently, it is imperative that aid interventions in the form of medicines and health care equipment be linked to the technology, expertise and expressed need within the Nigerian health care delivery system.

Core Principles

The following *Guidelines* for the donation of medicines and health care equipment are based on four core principles as follows:

- The donation should benefit the recipient. Donations should, therefore, be based on expressed need. Unsolicited donations of medicines, medical equipment and devices are to be discouraged and donations must not be sent unannounced;
- A donation should be made with full respect for the wishes and authority of the recipient, and should be supportive of existing government health policies and administrative arrangements;
- There should be no double standards in quality; if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation; and

- An effective two-way communication channel must exist between the donor and the recipient. Donations must be based on a plan formulated by both parties.

Core principles for a donation:

- **Maximum benefit to the recipient**
- **Respect for the wishes and authority of the recipient**
- **No double standards in quality**
- **Effective communication between donor and recipient**

SCOPE

The *Guidelines* shall be applicable to all donations of medicines and health care equipment within Nigeria and shall include donations emanating from internal as well as external donors.

External donors refer to governments of other countries and corporate bodies, acting directly or through voluntary organisations, non-governmental organisations and individuals wishing to make donations from outside Nigeria.

Internal donors refer to corporate bodies, organisations and individuals operating and /or residing within Nigeria and wishing to make donations at any level of the health care delivery system in Nigeria.

1. INITIATION AND SOURCING OF DONATIONS OF MEDICINES AND MEDICAL EQUIPMENT

1.1 Initiation of Donations

All donations of medicines and medical equipment should be based on an expressed need and be relevant to the disease pattern and available technology in Nigeria.

Donations should not be sent without the prior consent of the recipient. The recipient should prepare the request, clearly identifying the needs and prioritising them.

The written request should be backed up by an approval from a competent authority in Nigeria.

The health facility receiving the medicines and equipment should be required to acknowledge receipt of the donated items.

Explanatory notes:

This provision stresses the point that it is the prime responsibility of the recipients to specify their needs. Recipients are empowered to refuse unwanted gifts. It is also intended to prevent unsolicited donations and those that arrive unannounced. At the end of these *Guidelines* are lists of typical medicines and equipment required in emergencies. The objective of the lists is to facilitate the process of making donations. They are intended to guide, both donors and recipients.

1.2 Sourcing of Donations

Donations of medicines and medical equipment emanating from external sources should be processed through the Federal ministry of Health (FMOH), while internal donations should be processed through the appropriate health facility. Medicines and medical devices for primary health care facilities should be routed through the Local Government Authorities; donations should not be sent directly to end-users at this level.

2. SPECIFIC REQUIREMENTS FOR DONATING MEDICINES

2.1 Approval for Use

All donated medicines or their generic equivalents should be approved for use in Nigeria and should appear on the national essential drugs list.

Explanatory note:

This provision is intended to ensure that donations comply with national drugs policies and essential drugs programmes. The aim is to maximise the positive impact of a donation and prevent the donation of medicines that are unnecessary and/or unknown in Nigeria.

Possible exception:

An exception can be made for medicines needed in sudden outbreaks of uncommon or newly emerging diseases and other specific medicines requested by the recipient.

2.2 Presentation and Formulation

The presentation, strength and formulation of donated medicines should, as much as possible, be similar to those of medicines commonly used in Nigeria.

Explanatory note:

Most health workers at different health care levels in Nigeria have been trained to use certain formulations and dosage schedules and cannot constantly change their treatment practices. They often have insufficient training in performing the necessary dosage calculations required for sudden changes.

Note for Vaccine Donations:

Donations for vaccines should only be directed to a national agency or State ministries of health (where the State is the requesting body) which have accepted roles in immunization programmes. Such organizations are able to put in place the right cold chain facility. When donations of vaccines are received at any level (Federal, State or Local Government), information on the donation should be sent to the coordinating authority.

2.3 Quality Assurance and Shelf-life

2.3.1 All donated medicines should be obtained from a reliable source and comply with quality standards in both donor country and Nigeria. The *WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce* should be used.

Explanatory note

This provision prevents double standards: medicines of unacceptable quality in the donor country should not be donated to other countries. Donated medicines should be authorised for sale in the country of origin and manufactured in accordance with international standards of Good Manufacturing Practice (GMP).

Possible exceptions:

In acute emergencies, the use of the *WHO Certification Scheme* may not be practical. However, if it is not used, a justification should be given by the donor. When donors provide funds to purchase medicines from local producers, those which comply with national standards should not be excluded, solely on the grounds that they do not meet the quality standards of the donor country.

2.3.2 No medicines should be donated that have been previously issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.

Explanation:

Patients return unused medicines to a pharmacy to ensure their safe disposal; the same applies to samples that have been received by health workers. In most countries, it is not allowed to issue such medicines to other patients, because their quality cannot be guaranteed. For this reason, returned medicines should not be donated either. In addition to quality issues, returned medicines are very difficult to manage at the receiving end because of broken packages and the small quantities involved.

2.3.3 All donated medicines should have at least 50% of its normal shelf-life on arrival in the country.

Explanation:

In many recipient countries, and especially under emergency situations, there are logistical problems. Regular distribution through different storage levels (e.g., central store, Federal, State, and primary health care facilities) may take one to three months. This provision especially prevents the donation of medicines just before their expiry, as in most cases such medicines would only reach the patient after expiry. Additionally, it is important that the recipient is fully aware of the quantities of medicines being donated, as overstocking may lead to wastage. The argument that short-dated products can be donated in cases of acute emergency because they will be used rapidly is incorrect. In emergency situations, the systems for the reception, storage and distribution of medicines are very often disrupted and overloaded and many donated medicines tend to accumulate.

Possible exceptions:

Due consideration should be given to possible exceptions to the general rule. This is to prevent unnecessary impounding and disposal of valuable donations.

2.4 Packaging and Labelling

2.4.1 All medicines should be labelled in English. The label on each individual container should contain at least the International Non-proprietary Name (INN) or generic name, drug information leaflet, batch number, dosage form, strength, name and location address of manufacturer, quantity in the container, storage conditions, date of manufacture, as well as expiry date.

Explanation:

All donated medicines, including those under brand names, should also be labelled with their INN or the official generic names. Most training programmes are based on the use of generic names. Receiving medicines under different and often unknown brand names and without their INN is confusing for health workers and can even be dangerous for patients. In the case of injections, the specific route of administration should be indicated.

2.4.2 Donated medicines should be presented in larger quantity units and hospital packs except where impracticable.

Explanation:

Large quantity packs are cheaper, less bulky to transport and conform better with public sector supply systems. This provision also prevents the donation of medicines in sample packages, which are impractical to manage.

2.4.3 All medicines for donation should be packed in strong outer cartons and be accompanied by a detailed packing list which should specify the content of each carton by generic name, quantity and expiry date. Cartons should be numbered and the contents of each carton listed in detail in the accompanying document. In addition, the contents of cartons should be marked on the outside of cartons, preferably using a code system.

Explanation:

In addition to knowing what is coming, the recipient is assisted when the consignment arrives. S/he will know just where to find items which may be needed urgently (instead of having to unpack the whole shipment) and will be able to decide where to direct items that may be intended for different centres. A code numbering system for listing contents on the outside of packs is better than the use of the names of items which can facilitate pilferage.

2.4.4 All donations of medicines should be packed in accordance with international shipping regulations, and be accompanied by a detailed list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. The weight per carton should not exceed 50 kilograms. Medicines should not be mixed with other supplies in the same carton.

Explanation:

This provision is intended to facilitate the administration, storage and distribution of donations in emergency situations. The identification and management of unmarked boxes with medicines are time-consuming and labour-intensive. This provision specifically discourages donations of small quantities of mixed medicines. The maximum weight of 50 kilograms ensures that each carton can be handled without special equipment.

2.4.5 The declared value of a donated medicine should be based upon the wholesale price of its generic equivalent in Nigeria, or if such information is not available, on the wholesale world market prices for its generic equivalent.

Explanation:

This provision is needed solely to prevent medicine donations being valued according to the retail price of the product in the donor country. This may lead to elevated overhead costs for import tax, port clearance and handling. It may also result in a corresponding decrease in the public sector budget for medicines in the recipient country.

Possible exception:

In the case of patented medicines (for which there is no generic equivalent), the wholesale price of the nearest therapeutic equivalent could be taken as a reference.

2.4.6 The costs of international and local transport, warehousing, port clearance and appropriate storage and handling should be paid by the donor unless specifically agreed otherwise with the recipient in advance.

Explanation:

This provision prevents the recipient from being forced to spend effort and money on the clearance and transport of unannounced consignments of unwanted items. It also enables the recipient to review the list of donated items at an early stage.

3. SPECIFIC REQUIREMENTS FOR DONATING HEALTH CARE EQUIPMENT

3.1 General Quality and Safety

Donated health care equipment must be fully operational and all essential accessories and supplies should be included in the shipment. Operational and service manuals must accompany all donated equipment. Donated equipment must meet all safety and performance specifications as provided for by the manufacturer. Equipment that has not been approved by the appropriate regulatory agency in the donor country should not be donated.

3.2 Obsolete Equipment

Obsolete equipment or equipment for which replacement parts are not available should not be donated. They may be sent only on the condition that they are designated as “for spare parts only.”

3.3 Appropriate Technology

Donated medical equipment must be simple to operate. The level of technology must be in line with local capabilities. The needed operating supplies, especially disposables, must be available locally and at affordable cost. The equipment should consume low energy and it should be possible to standardise it with other equipment in use within the Nigerian health care system. The equipment should not use environmentally hazardous substances.

3.4 Installation and Operational Instructions

The donor should ensure that detailed installation instructions, site preparation and safety instructions are communicated to the recipient. Such information should include architectural drawings and floor plans.

The donor should inform the recipient of all necessary materials required for the operation of the equipment, such as cables, reagents, filters, electrodes and recording papers, etc. Test equipment for calibration as well as calibration standards must be available through the useful life of the equipment. A plan for the training of operators must be agreed upon by donor and recipient.

3.5 Maintenance

Detailed maintenance requirements, such as technician training, special tools, preventive maintenance materials and recommended maintenance schedule should be communicated to the recipient.

3.6 Used and Refurbished Equipment

Greater caution should be exercised by donors and recipients in handling refurbished equipment. Unless financial savings are considerable (e.g., costly radiographic equipment and CT scanners) and the refurbishers can provide adequate warranty, donations should be restricted to new equipment.

3.7 Packaging and Shipping

Donated equipment should be free of all patient materials and properly decontaminated, prior to packaging and shipment. Radioactive sources should be removed and properly packaged in special containers with clear identifications. Donated equipment should be adequately packaged to minimise damage in transit. Shipping documents should indicate that the equipment is a donation. Explicit labelling of shipment should be avoided to prevent theft, diversion to export or other illegal channels.

3.8 Customs Clearance

The clearance of donated equipment is the sole responsibility of the recipient. If equipment is technically complex, the recipient should ensure that unpacking is done by technically competent persons. On receipt of equipment, notice of receipt and any observed irregularities should be communicated immediately to the donor.

3.9 Installation and Commissioning

Installation should be performed according to the instructions received from donor. This should be done by a technically competent person. Commissioning should be carried out by adequately trained professionals and in line with good technical services practice. Proper and safe operation must be verified before the equipment is put to clinical use.

3.10 Evaluation and Feedback

When equipment is operational, the recipient should assess the level of operational success of the medical equipment and provide feedback to the donor. This assessment will enable both parties to learn from previous mistakes and encourage continued support by the donor.

4. ADDITIONAL WAYS FOR DONORS TO ASSIST

4.1 The New Emergency Health Kit

In the acute phase of an emergency, or in the case of displacements of refugee populations without any medical care, it is better to send a standardised kit of medicines and medical supplies that is specifically designed for this purpose. For example, the New Emergency Health Kit, which has been widely used since 1990 and was updated in 1998, contains medicines, disposable supplies and basic equipment needed for general medical care for a population of 10,000 for three months. Its contents are based on a consensus among major international aid agencies. It is permanently stocked by several major international suppliers (such as, the International Dispensary Association, Medecins Sans Frontières and the United Nations Children's Fund) and can be made available within 48 hours. It is especially relevant in the absence of specific requests.

As a general rule, equipment should not be donated in emergency situations. Donations of equipment can only be made after due confirmation that the emergency situation will persist for a long time.

4.2 Donations in Cash

Donations can be made in cash for the purchase of essential medicines, small-scale medical devices, accessories and consumables. A cash contribution is supportive to the activities of the local coordinating committee in the event of disaster management as it may be more cost-effective. In addition, prescribers and patients are usually more familiar with locally produced medicines. Locally available technical expertise will ease maintenance and operational bottlenecks

4.3 Donations as Part of Development Aid

Donations can be made between governments as humanitarian support. The Nigerian Government welcomes donations in support of programmes, emergencies and acute needs. Donations should not create an abnormal situation which may obstruct or delay national capacity building in the selection, procurement, storage, distribution and rational use of medicines and equipment. Special care should, therefore, be taken to ensure that the donated items respond to an expressed need, comply with the national health policy, and are in accordance with national treatment guidelines in Nigeria. Administratively, the medicines and equipment should be treated as if they were procured. They should be entered into the national inventory, distributed through the existing distribution channels and be subject to the same quality assurance procedures as procured items.

4.4 Donation of Professional Health Services

The principal professionals of such donor organizations must have qualifications that are certified and accredited by the relevant Nigerian professional regulatory bodies. Such services would be complemented with the supply of anticipated consumables, and the services provided must be linked to existing services. The services shall be expressed in an Action Plan that has to be approved by the Federal Ministry of Health.

5. INFORMATION AND MANAGEMENT

5.1 Advance Notification of Donations

Recipients should be informed of all considerations of donations of medicines and equipment, either already prepared or actually under way. This is essential to enable the recipient make adequate plans for the receipt of the donation and to coordinate the donation with other sources of supply. The information should include at least the following: the types and quantities of donated medicines, including their International Non-proprietary Names (INN) or generic names, strength,

dosage form, manufacturer and expiry date; type of equipment and reference to earlier correspondence (for example, the letter of consent by the recipient, approval from appropriate government agencies); the expected date of arrival and port of entry; and the identity and contact address of the donor.

5.2 Management of Donations by the Recipient

The value of donated medicines and equipment can be considerable, and the gift should be treated with due expedition and care. Upon arrival, the medicines should be inspected and their receipt confirmed to the donor agency. They should then be stored and distributed in accordance with normal principles of good pharmacy practice, and under the responsibility of a registered pharmacist. Donated health care equipment must be handled strictly by trained professionals. There must be due vigilance to ensure that donated products are not diverted for export, commercial sale, or into illicit channels. Good donation management also includes agreed systems of accountability.

6. IMPLEMENTATION: THE ROLES AND RESPONSIBILITIES OF NIGERIAN AGENCIES AND OTHER STAKEHOLDERS

Six Nigerian and foreign agencies have been identified in the effective implementation of these *Guidelines*. They have been assigned respective responsibilities as follows:

6.1 The Federal Ministry of Health

- The Food and Drugs Services Department of the Ministry will coordinate all donations of medicines while the Hospital Services Department will coordinate all equipment donations within the country.
- The Food and Drug Services Department of the Ministry shall issue approvals to potential recipients of medicines and medical equipment donations upon the successful consideration of an application.
- The Coordinating Offices for donated medicines and equipment reserve the right to reject donations that are not in line with these laid down *Guidelines*.
- The Ministry should maintain a management information system to keep track of all information pertaining to donated medicines and equipment.

- The Ministry shall keep a record of the monetary values of all donations. The value of an expected donation should be indicated on the application form.
- The Ministry should ensure that donated equipment and medicines are distributed and used in accordance with normal principles of good health care practice.
- The Ministry shall monitor donations of medicines and equipment to ensure that they are not diverted for export, commercial sale or to other illicit channels.

6.2 The Regulatory Authority in the Donor Country

- The relevant regulatory authority for donated medicines and equipment in the donor country shall issue a certification of the quality of the donations and this shall be authenticated by the Nigerian Foreign Mission in that country.

6.3 The Nigerian Foreign Mission in the Donor Country

The Nigerian Foreign Mission in the donor country shall authenticate the documents issued by the relevant regulatory authority of the donor country in respect of the donated medicines and equipment.

6.4 The National Agency for Food and Drug Administration and Control (NAFDAC)

- All relevant documents and permits for clearance must be obtained from the Agency. Where narcotics and psychotropic medicines are involved, authorization to import and clear such medicines must be obtained from the Narcotics Office of the Agency.
- The Agency shall provide feedback to the Federal Ministry of Health on the status of all processed donations.
- The Agency shall keep on hold, at the ports of entry, all donations that do not follow approved procedures until all documentation is completed.
- The Agency shall destroy all medicine donations that are sub-standard
- The Agency shall impound unsolicited medicines that do not meet Nigerian specifications. The donor shall be responsible for the cost of destruction, storage and other associated expenses.

6.5 The Recipient

In cases where the FMOH or any of its agencies, or state MOHs or the health departments in the Local Governments initiate a request for the donation of medicines and equipment, all the roles and responsibilities required of recipients as defined in this document shall apply to them.

Specifically,

- Any organization, individual, institution or body requesting any form of donated medicines or medical equipment shall seek the approval of the FMOH, through their respective State Commissioners for Health.
- Requests for donations emanating from a Local Government should be raised by the LGA Chairman, through the State Commissioner for Health.
- Requests for donations emanating from states should be raised by the Commissioner for Health or his designated official.
- Donated medicines at the State Ministry of Health should be received by the Department of Pharmaceutical Services while equipment should be received by the Department of Hospital Services.
- At the LGAs, donated medicines and equipment shall be received by the Head, Department of Health.
- Recipients of unsolicited donations of medicines or equipment shall inform the Ministry of Health as soon as the donations arrive.
- The recipient shall be responsible for the clearance of donated medicines and health care equipment from port of entry.
- The recipient shall be responsible for all expenses incurred on donations kept at the port of entry as a result of inadequate documentation.
- Recipients of donations of medicines and medical equipment shall be required to have in their services appropriately qualified personnel to handle the donations (registered pharmacists in case of medicines).
- Recipients shall be required to provide evidence of possession of adequate storage facilities as well as adequate distribution capabilities.

6.6 The Donor

The Donor has the responsibility of:

- Informing recipients of medicines or healthcare equipment being considered for donation.

CHECKLISTS FOR ASSESSING DONATIONS OF MEDICINES AND EQUIPMENT

Table 1: CHECKLIST FOR DONORS

S/N	A. MEDICINES	YES	NO
1	Is the donation based on expressed need?		
2	Is the approval from the relevant authority given?		
3	Are the medicines of acceptable standards in the donor country?		
4	Was a consensus reached between the donor and the recipient?		
5	Is the strength of the medicines similar to the one commonly used in Nigeria?		
6	Has the quality of the medicines been certified by the WHO Scheme?		
7	Was it previously issued to patients or given as free samples?		
8	Are the medicines labelled in English?		
9	Does the packaging/labelling contain INN/generic name, batch number, dosage form, strength, name & location address of manufacturer, quantity in container, storage conditions, date of manufacture, expiry date as well as an information leaflet?		
10	Are the medicines properly packaged?		

11	Are the medicines packaged in sturdy outer cartons?		
12	Is there a detailed packing list specifying the contents of each carton by generic name, quantity and expiry date?		
13	Are the cartons numbered and the contents marked on the outside of the cartons?		
14	Are the medicines packed in accordance with international shipping regulations?		
15	Is the weight of the carton $\leq$ 50kg?		
16	Are the medicines mixed with other supplies in the same carton?		
S/N	**B. HEALTHCARE EQUIPMENT**	**YES**	**NO**
1	Was the equipment approved for use by the relevant agency in the donor country?		
2	Are there accompanying operational and service manuals?		
3	Are there detailed installation and operational instructions (i.e. architectural drawings/floor plans, safety instructions, site preparation etc)?		
4	Does the equipment use environmentally hazardous substances?		
5	Are all the essential accessories and supplies included?		
6	Is there any plan for training of operators in the case of non-availability of skilled human resources to handle the equipment?		
7	Is there adequate warranty in the case of refurbished/ used equipment?		
8	Are there any patient materials/radioactive substances present in the equipment?		

Table 2: CHECKLIST FOR RECIPIENTS

FORM R

S/N	**A. MEDICINES**	**YES**	**NO**
1	Is the donation based on expressed need?		
2	Is the approval from the relevant authority given?		
3	Are the medicines on the EDL?		
4	Are the medicines of acceptable standards in the donor country?		
5	Was a consensus reached between the donor and the recipient?		
6	Are the medicines approved for use in Nigeria?		
7	Is the strength of the medicines similar to the one commonly used in Nigeria?		
8	Do the medicines have at least one year shelf-life at the point of receipt?		
9	Are the medicines labelled in English?		
10	Is the declared value of the donated medicines comparable to Nigerian equivalents?		
11	Do the recipients possess qualified personnel to handle the donated medicines?		
12	Does the recipient have evidence of adequate storage facilities/distribution capabilities?		

S/N	B. HEALTHCARE EQUIPMENT	YES	NO
1	Was the equipment approved for use by the relevant authority in Nigeria?		
2	Are there accompanying operational and service manuals?		
3	Are the necessary human resources and skills available in Nigeria to handle the machinery?		
4	Are there detailed installation and operational instructions (i.e. architectural drawings/floor plans, safety instructions, site preparation, etc)?		
5	Are the maintenance requirements available?		
6	Does the equipment use environmentally hazardous substances?		
7	Are the operating supplies available locally?		
8	Are all the essential accessories and supplies included?		
9	Are the replacement parts available? Otherwise was it designated “for spare parts only?”		
10	Is there any plan for training of operators in the case of non-availability of skilled human resources to handle the equipment?		
11	Is there adequate warranty in the case of refurbished/used equipment?		

Table 3: CHECKLIST FOR THE APPROVING AUTHORITY: THE FMOH

S/N	A. MEDICINES	YES	NO
1.	Is the donation based on expressed need?		
2.	Is the approval from the relevant authority given?		
3.	Are the medicines on the EDL?		
4.	Are the medicines of acceptable standards in the donor country?		
5.	Was a consensus reached between the donor and the recipient?		
6.	Are the medicines approved for use in Nigeria?		
7.	Is the strength of the medicines similar to the one commonly used in Nigeria?		
8.	Has the quality of the medicines been certified by the WHO Scheme?		
9.	Was it previously issued to patients or given as free samples?		
10	Will the medicines have at least one year shelf-life at the point of receipt?		
11	Are the medicines labelled in English?		
12	Does the packaging/labelling contain INN/generic name, batch number, dosage form, strength, name & location address of manufacturer, quantity in container, storage conditions, date of manufacture, expiry date as well as information leaflet?		
13	Are the medicines properly packaged?		
14	Is the declared value of the donated medicines comparable to Nigerian equivalents?		
15	Do the recipients possess qualified personnel to handle the donated medicines?		
16	Does the recipient have evidence of adequate facilities/ distribution capabilities?		

S/N	B. HEALTHCARE EQUIPMENT	YES	NO
1.	Was the equipment approved for use by the relevant agency in the donor country?		
2.	Was the equipment approved for use by the relevant authority in Nigeria?		
3.	Are there accompanying operational and service manuals?		
4.	Are the necessary human resources and skills available in Nigeria to handle the machinery?		
5.	Are there detailed installation and operational instructions (i.e. architectural drawings/floor plans, safety instructions, site preparation, etc)?		
6.	Are the maintenance requirements available?		
7.	Is there any patient material/radioactive substances present in the equipment?		
8.	Does the equipment use environmentally hazardous substances?		
9.	Are the operating supplies available locally?		
10.	Are all the essential accessories and supplies included?		
11.	Are the replacement parts available? Otherwise was it designated “for spare parts only?”		

12.	Is there any plan for training of operators in the case of non-availability of skilled human resources to handle the equipment?		
13.	Is there adequate warranty in the case of refurbished/used equipment?		

Table 4: CHECKLIST FOR A REGULATORY AUTHORITY: NAFDAC

S/N	A. MEDICINES	YES	NO
1	Is the approval from the relevant authority given?		
2	Are the medicines on the EDL?		
3	Are the medicines of acceptable standards in the donor country		
4	Is the strength of the medicines similar to the one commonly used in Nigeria?		
5	Has the quality of the medicines been certified by the WHO Scheme?		
6	Do the medicines have at least one year shelf-life at the point of receipt?		
7	Are the medicines labelled in English?		
8	Does the packaging/labelling contain INN/generic name, batch number, dosage form, strength, name & location address of manufacturer, quantity in container, storage conditions, date of manufacture, expiry date as well as information leaflet?		
9	Are the medicines properly packaged?		
10	Are the medicines packaged in sturdy outer cartons?		
11	Is there a detailed packing list specifying the content of each carton by generic name, quantity and expiry date?		
12	Are the cartons numbered and the contents marked on the outside of the cartons?		
13	Are the medicines packed in accordance with international shipping regulations?		
14	Is the weight of the carton $\leq$ 50kg?		
15	Are the medicines mixed with other supplies in the same carton?		
16	Is the declared value of the donated medicines comparable to Nigerian equivalents?		
17	Do the recipients possess qualified personnel to handle the donated medicines?		
18	Does the recipient have evidence of adequate storage facilities/distribution capabilities?		
S/N	**B. HEALTHCARE EQUIPMENT**	**YES**	**NO**
1	Was the equipment approved for use by the relevant agency in the donor country?		
2	Was the equipment approved for use by the relevant authority in Nigeria?		
3	Are there accompanying operational and service manuals?		
4	Is there any patient material/radioactive substances present in the equipment?		

5	Does the equipment use environmentally hazardous substances?		
6	Is there adequate warranty in the case of refurbished/used equipment		

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WHO. Guidelines for Drug Donations. Geneva: WHO, 1996. (WHO/DAP/96.2)

WHO. *Interagency Guidelines for Drug Donations, 1999.* (Published on behalf of agencies by the World Health Organization.)

WHO. *The New Emergency Health Kit*, 1990, Geneva

WHO. *The Use of Essential Drugs.* Geneva: World Health Organization, 1992. (Technical Report Series, 825.)

LIST OF EMERGENCY MEDICINES

1. *ANAESTHETICS*

- Diazepam - injection, 5mg/mL in 2mL ampoule
- Ketamine - injection, 10mg/mL in 20mL vial
  50mg/mL in 10mL vial
  100mg/mL in 5mL vial
- Lidocaine hydrochloride - injection, 1%, 2% in vials
  - cream/ointment, 2 – 5%
  - aerosol, 10%
  - gel/solution, 2 – 4%
  - dental cartridges, 2%

2. *ANALGESICS, ANTI-PYRETICS & NON STEROIDAL ANTI-INFLAMMATORY DRUGS*

- Acetylsalicylic acid - Capsules 300mg, tablets 500mg.
- Paracetamol - capsules 125mg, tablets 500mg,
  suspension, 125mg/5mL
  syrup 125mg/5mL
  suppository, 100mg
  injection
- Ibuprofen - capsules 400mg, tablets 200mg

3. *ANTI-ALLERGICS*

- Chlorphenamine maleate - Tablet 4mg, Syrup 2mg/5mL
  injection 10mg in 1ml ampoule
- Promethazine hydrochloride - tablet 10mg, 25mg, syrup 5mg/5mL
  injection 25mg in 1mL, 2mL ampoule
- Adrenaline HCl/acid tartrate - injection 1mg/ml in 1ml ampoule
- Hydrocortisone - injection (Sodium succinate) powder
  for reconstitution, 100mg in vial

4. *ANTI – INFECTIVE DRUGS*

- Mebendazole - tablets 100mg, 500mg
  suspension, 100mg/5mL
- Pyrantel Pamoate - tablet 125mg, Syrup 125mg/5mL
- Artemether/lumefantrine - tablet 20mg/120mg
- Artesunate/amodiaquine - tablet
- Chloroquine - capsule, tablets (phosphate or sulphate),
  150mg base (Adult), 50mg base (Child)

syrup 50mg base/5mL
injection, 40mg base/mL in 5mL ampoule

- Pyrimethamine - tablets 12.5mg, 25mg
- Pyrimethamine/sulfadoxine - tablets 25mg/500mg, syrup 25mg/500mg per 5mL. injection 25mg/500mg in 2.5mL ampoule
- Quinine - Tablet (Bisulphate or Sulphate) 300mg
  - Injection (dihydrochloride) 300mg/ml in 2mL ampoule.
- Metronidazole - tablet 200mg, oral suspension 200mg/5mL
- Amoxicillin - capsule 250mg, powder for suspension 125mg/5mL. injection 250mg, 500mg in vials
- Ampicillin/cloxacillin - capsules 250mg of each. Powder for oral suspension 125mg of each/5mL
  neonatal drops 60mg/30mg per 0.6mL
  neonatal Injection 50mg/25mg per vial
  injection powder 250mg of each in vial
- Benzylpenicillin - injection powder (sodium or potassium salts) 0.6g, 3.0g in vials
- Ciprofloxacin - tablet (hydrochloride) 250mg, 500mg
  IV Injection 2mg/ml in 50mL, 100mL vials
- Co-amoxiclav - capsule, tablet, 250mg/125mg
  - Powder for oral suspension 125mg/31.25mg per 5mLl Injection, powder for IV injection 500mg/100mg per vial; 1g/200mg per vial
- Co-trimoxazole - tablets 400mg/80mg, susp. 200mg/40mg per 5mL
- Erythromycin - capsule, tablet, 250mg, 500mg.
  oral suspension 125mg/5mL
  injection powder (lactobionate) 500mg in vial.
- Fortified Procaine Penicillin –injection powder 300mg/60mg per vial; 3g/600mg per vial
- Gentamicin Sulphate - injection 10mg/mL, 40mg/mL in 2mL vials
- Tetracycline - capsule, Tablet (Hydrochloride) 250mg
  powder for injection 100mg, 250mg in vials
- Ketoconazole - tablet 200mg, susp. 100mg/5mL, Cream 2%.

5. *ANTI-MIGRAINE DRUGS*

- Paracetamol 500mg tablets
- Acetylsalicylic acid 300-500mg tablets

6. *ANTISEPTICS AND DISINFECTANTS*

- Benzoin - compound tincture of Benzoin
- Cetrimide - dilute solution 1%, Strong solution 20-40%
- Cetrimide/chlorhexidine - solution 15% / 1.5%
- Chlorhexidine - solution (gluconate) 5%
- Hydrogen peroxide - solution 6%
- Iodine - solution
- Methylated spirit - solution
- Sodium hypochlorite - solution with chlorine 1- 10%

7. *DRUGS AFFECTING THE BLOOD*

- Ferrous salts - capsules, tablets equivalent to 60mg iron
  sustained release Caps/Tabs ≡ 105mg iron
- Folic acid - tablet 5mg
- Iron dextran - injection ≡ 50mg iron/ ml in 2mL ampoule

8. *CARDIOVASCULAR DRUGS*

- Glyceryl trinitrate - tablet, sublingual 0.5mg
- Propranolol HCl - tablet 10mg, 40mg.Injection 1mg/mLampoule
- Amlodipine besylate - tablet 5mg, 10mg
- Atenolol - tablet 50mg, 100mg
- Captopril - Tablet 12.5mg, 25mg, 50mg
- Hydralazine - tablet 25mg, 50mg
  injection powder 20mg in ampoule
- Methyldopa - tablets 250mg, 500mg
- Nifedipine - tablet 10mg, capsule 20mg
- Digoxin - tablets 0.0625mg, 0.125mg, 0.25mg
  elixir 0.05mg/mL in 60ml bottle
  injection 0.25mg/mLin 2ml ampoule and
  0.1mg/mLin 1mL ampoule
- Isoprenaline - IV injection 1mg/mL in 2mL ampoule

9. *DERMATOLOGICAL DRUGS*

- Gentian Violet - aqueous solution 0.5%, tincture 1%
- Neomycin/bacitracin - cream, ointment 5mg/500 Units in 5g, 30g tubes
  dusting powder 5mg/250 Units per gram
  spray 165,000 units/12,500 units

- Silver sulphadiazine - cream 1%
- Betamethasone - cream, ointment 0.1%
- Betamethasone/neomycin - cream, ointment, Lotion 0.25%/0.25-0.5%
- Calamine lotion
- Hydrocortisone - cream, ointment 1%
- Hydrocortisone/neomycin - cream, ointment 0.5 – 1% / 0.25 – 0.5%
- Benzoic acid
- Clotrimazole - cream, ointment 1%; aerosol 1%; dusting powder 1%; pessaries 100mg, 200mg
- Miconazole - cream 2%, lotion 2%, gel 2-2.5%, vaginal ovule 200mg, 400mg
- Nystatin - cream, ointment 100, 000 Units
- Tioconazole - Cream 1%, powder, vaginal ovule 300mg
- Benzyl Benzoate - emulsion 25%

10. *DIURETICS*

- Amiloride/hydrochlorothiazide –tablet 5mg/50mg
- Hydrochlorothiazide - tablets 25mg, 50mg
- Frusemide - tablet 40mg; injection 10mg/mL in 2mL ampoule

11. *EAR, NOSE AND THROAT DRUGS*

- Chloramphenicol - ear drops 5%
- Gentamicin - ear drops 0.3%
- Betamethasone - ear drops 0.1%
- Hydrocortisone/Neomycin - ear drops 1.5% / 0.5%
- Hydrocortisone/Neomycin/Polymyxin B –ear drops 1% / 0.44% / 0.12%
- Hydrocortisone/oxytetracycline/polymyxin B –ear drops 1.5%/0.5%/0.12%
- Beclomethasone - nasal spray 0.05mg/metered spray

12. *GASTRO-INTESTINAL DRUGS*

- Aluminium hydroxide/magnesium trisilicate –tablet 120mg/250mg mixture
- Magnesium trisilicate - tablet 500mg; mixture 250mg/5mL
- Hyoscine N-butylbromide - tablet 10mg; liquid 1mg/mL; injection 20mg/mL in ampoule
- Oral Rehydration Salts (ORS) - powder

13. *HORMONES AND SYNTHETIC SUBSTITUTES*

- Insulin soluble - injection 40 units, 80 units, 100 units/mL in 10ml vials
- Insulin Zinc suspension - Injection 40 units, 80 units, 100 units/mL in 10mL vials
- Glibenclamide - tablet 5mg
- Metformin Hydrochloride - tablet 500mg

14. *IMMUNOLOGICALS*

- Antiscorpion Serum - injection 1mL in ampoule
- Antisnake-bite Serum - Injection, polyvalent. 10mL, 20mL in ampoule
- Tetanus Antitoxin - injection 1,500 Units in ampoule
  10,000 Units; 50,000 Units in vials
- Typhoid Vaccine (Vi Antigen) –injection 0.5mL/syringe; 10mL/vial; 20mL/vial
- Typhoid Vaccine (TAB) - injection 1.5mL/vial
- Yellow fever Vaccine - injection powder; 1, 5 and 10 dose vials

15. *OPHTHAMOLOGICAL DRUGS*

- Acyclovir - eye Ointment 3.0%
- Chloramphenicol - eye Drops 0.5%, Ointment 1%
- Gentamicin Sulphate - eye drops 0.3%, ointment 0.3%
- Miconazole - injection 10mg/mL, eye drops 1%
- Betamethasone - eye drops 0.1%, ointment 0.1%
- Betamethasone/Neomycin - eye drops 0.1%/0.5%; ointment 0.1%/0.5%

16. *PREPARATIONS FOR CORRECTING WATER, ELECTROLYTE AND ACID-BASE DISTURBANCES*

- Darrows Solution - injection B.P.
- Glucose - injection 5%, 10%, 50% injection
- Glucose/Sodium chloride - injection 4.3%/0.18%; 5.0%/0.9%
- Sodium chloride - injection 0.9%, 0.45%
- Water for injection - Injection 2mL, 5mL, 10mL, 20mL, 50mL ampoules/vials

17. *RESPIRATORY SYSTEM DRUGS*

- Aminophylline - tablets 100mg, 200mg
  injection 25mg/mL in 10mL ampoule
- Salbutamol Sulphate - Tablets 2mg, 4mg ; Syrup 2mg/5mL
  injection 500micrograms /mL; aerosol inhalation 0.1mg/metered dose

18. *VITAMINS AND MINERALS*

- Ascorbic acid - tablets 100mg;
  Syrup 100mg/5mL,
- Vitamin B12 - tablets 0.05mg, injection, 1mg/mL in ampoules
- Vitamin B6 - tablets 10mg, 20mg, 50mg
- Vitamin A - capsules, tablets 5000 units, 25,000 units, 50,000 units.

19. *DRESSINGS*

- Absorbent cotton wool
- Adhesive tape
- Elastic bandage
- Gauze bandage
- Gauze compresses
- Disposable gloves
- Latex gloves
- Examination gloves
- Mucus extractor
- Sutures

LIST OF EMERGENCY MEDICAL EQUIPMENT

1. Ambulance
2. Stretchers
3. Trolleys
4. Wash hand basins
5. Hand gloves
6. Drip stand
7. Sphygmomanometer
8. Stethoscopes
9. Surgical Instruments such as scissors, scalpel, blades, sutures, gauze, cotton wool, disinfectants, linings, dustbins
10. Oxygen cylinders
11. Ambu bags
12. Defibrillators
13. Microscopes
14. Blood group reagents
15. Small generators
16. Life jackets
17. Needle holders
18. Artery forceps
19. Dissecting forceps: Tooth and non-tooth
20. Intubation tubes
21. Kidney dishes
22. Galli pots
23. Disposable spatula
24. Adhesive plaster
25. Dressing tray
26. Face mask
27. Investigation sample bottles
28. Rain boot
29. Helmets