

# **Guide for improving the quality of drug donations for individuals and organisations that want to donate pharmaceutical materials**

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### **1. INTRODUCTION**

This information concerns all individuals and groups who are planning to organise and donate drugs and wish to improve their donation practice.

It is presented as a checklist and is meant to serve as an aid. It can be used to prepare the donation following a step by step approach. It can also be used as a general means of control once the donation is ready for shipment or to evaluate the donation once completed. Following all the steps in this checklist helps to ensure good drug donations practice (GDDP), according to the inter-agency guidelines for drug donations.

The checklist has been compiled with the aid of many people from the field. Much information was derived from the workshops on GDDP held during the expert seminar on appropriate drug donations in the Netherlands on June 11 and 12, 1999. The checklist does not pretend to be complete, nor does it suggest that all donor organisations will be able to follow all the steps presented. It is open for comments and revision and you are welcome to respond.

### **2. WHY A CHECKLIST?**

The reason for the development of a checklist was that a need was perceived for a tool with which to organise donations. This tool needed to be able to show donors whether their donation is appropriate and cost effective. If widely used the checklist might also ensure the dissemination of a minimum standard, as well as standardisation of donations, as it is based on the guidelines.

This checklist presents the whole process in varying degrees of detail and offers opportunities for the user to decide to stop the donation process but instead to direct their efforts to another kind of donation or form of aid.

### **3. STRUCTURE OF THE CHECKLIST**

The donation process can be divided into five main elements. The checklist structure presented here can help gain an insight into the structure of the donation process. The five elements of the process are:

#### **1) The preparedness of the donor.**

It is important that the donor is well prepared to handle the organisation of a donation of medical drugs or material. This is an important factor in determining whether the donor is ready to make an appropriate drug donation. It is possible that a donation of drugs at this stage might not be the most suitable donation the organisation should make. It might be better advised to donate medical material or organise medical training.

This element can be sub-divided in four steps:

- a) documents and permits
- b) supplies of pharmaceuticals
- c) transport, insurance, and storage
- d) the donor's capacity and policy

Example: delays resulting from a lack of export papers can mean medical drugs expire within a very short time of arrival. A lack of permits to store pharmaceuticals might also result in the stock being confiscated and the cancellation of the whole donation.

## **II) The relationship between the donor and the request.**

The second step is to scrutinise the requesting organisation and the situation from which the request for medical drugs or material has come. It may be possible to solve part of the problem by organising a donation but make sure the problem does indeed have a medical origin. An investment in training, be it health or logistical, such as transport, are also possible effective solutions. Here is where medical and pharmaceutical expertise comes in, as well as knowledge of the recipients' situation.

This step can be sub-divided into four steps:

- a) setting from which the request originates
- b) a request from a previously unknown organisation
- c) a request from an organisation with which a prior relationship exists
- d) the donor initiates a donation

Example: The problem might not be a lack of medical drugs but a dispute between the hospital and the regional medical supply board. By sending a donation one could make an unintended political judgement.

## **III) Evaluating the actual request.**

According to the guidelines all drug donations should be based on an expressed need and should not be sent without prior consent. Evaluation of the contents of the specified request for drugs is therefore very important. It can be sub-divided into five steps:

- a) the foundation and origin of the request
- b) the formalities of the request
- c) the contents of the request
- d) qualities requested
- e) quantities requested

Example: It has happened that a zero was unintentionally added, or forgotten, to a quantity on a request form. If the quantities delivered are too high the result might be higher storage, transport, and insurance costs. Part of the donated product will most probably expire or a parallel and often undesirable market will be encouraged.

## **IV) Logistics.**

The donor should organise the logistics of the donation in collaboration with the recipient organisation. With such sensitive products as medical drugs being part of the donation, the communication and logistics should be given the importance they deserve.

It can be sub-divided into three steps.

- a) Documentation
- b) Preparation and monitoring of transport
- c) Reception and storage of the shipment

Example: The shipment has arrived at the requesting organisation. The documents were in order, the transport organised, and the request well founded. But it turns out that the volume of certain items is vastly different from expected. As a result there is not enough cold storage space and therefore these items go to waste.

## **V) Monitoring and evaluation.**

These two elements should not be forgotten. They can make any subsequent donations more efficient, effective and successful not in the least by providing tools for learning lessons in the future. Monitoring can be achieved even better by an independent organisation. This

way an evaluation does not compromise relationships between donor and recipient organisation.

Example: For many years donations were made from a donor to a recipient. All partners seemed to be happy with the existing arrangements. But after a thorough evaluation it turned out that a part of the costs could have been saved. Many drugs donated eventually had to be destroyed because they could not be used. Unfortunately the recipient was never offered a means, a tool such as feedback or evaluation forms, through which the recipient felt confident enough to communicate these remarks.

#### **4. INDIVIDUAL STEPS ON THE CHECKLIST**

##### **I) PREPAREDNESS OF THE DONOR**

###### **A) DOCUMENTS AND PERMITS (SEE ALSO GUIDELINE NUMBER 9)**

Check whether you have all the right documents and permits for buying requested pharmaceutical products.

Check whether you have all the right documents and permits for handling and storing requested pharmaceutical products.

Check whether you have all the right documents and permits for transporting and exporting requested pharmaceutical products.

Check what legal requirements exist for a donation.

Check if the donation remains within existing rules and regulations of the donor country. For example wholesale licenses for donating organisations are obligatory in EU countries.

Check what the administrative procedures are with regard to the medical products.

Find out who is permitted to collect medical products within the organisation.

Example: Perhaps your organisation is not suited for donating medicines. You can use your resources to donate less sensitive products, or you can decide to offer your resources to an organisation who does specialise in medical donations. At the same time you can inform them how you would want them to use the donated resources. Cash donations for purchasing medicines locally is also worth considering as an alternative.

###### **B) SUPPLIES OF PHARMACEUTICALS (SEE ALSO GUIDELINES NUMBER 5,6,7)**

Check if you have your own stock of pharmaceutical supplies which is in good order and stored under acceptable conditions.

If you do not have your own stock of pharmaceutical supplies then check if you can finance the donation, or if you have the right contacts to obtain pharmaceutical products in desired quantities, strengths or dosages, appropriate to meet the request.

Make sure your supplier can deliver all the pharmaceutical products in the packaging required.

Make sure your supplier can deliver the pharmaceutical products with the appropriate labelling and strength for the country of destination.

Check whether the supplier is recognised in your country as a qualified supplier of pharmaceutical products for export and has its own pharmacist on the premises.

Check if you have the option of ordering standard emergency kits if needed for specific circumstances. [Click here](#) for a pdf version of the New Emergency Health Kit.

Make sure your supplier can deliver the quality control certificates for all items. If not then can they deliver the GMP certificates of the manufacturer. If not then check if quality control is possible at the recipients end.

Example: if you cannot guarantee appropriate pharmaceutical supplies, then try to get in touch with a recognised non-profit supplier with experience in this sector such as, IDA, Action Medeor, CHMP, or ECHO International Health Services. If not possible then either contact a medical relief organisation and ask who their suppliers are, choose another product to donate, or choose to donate standard kits.

###### **C) TRANSPORT, INSURANCE AND STORAGE (SEE ALSO GUIDELINE NUMBER 12)**

Decide whether air, sea, or road, transport is the most appropriate for the products, the project and the recipient.

Check if there has been contact with the recipient organisation about who has responsibility for the transport.

Make sure the transport company you contacted is qualified to transport pharmaceutical goods.

Make sure you have taken out insurance valid for the whole transport.

Make sure temporary storage is available if needed during the transport.

Make sure you have clarified all specific conditions clearly beforehand.

Check that you have calculated the time of arrival to fall within the expiry date of the product within your donation that will expire first. The guidelines recommend that after arrival all donated drugs should have a remaining shelf-life of at least one year. (guidelines number 6).

Example: uninsured products are lost forever. Things tend to get lost in emergency situations so make sure that this does not mean the end of the donation however difficult it might be to find an underwriter for your products, or however expensive it seems.

#### **D) THE DONOR'S CAPACITY AND POLICY**

Make sure your organisation has the finances available to fulfil the request for a drug donation.

Make sure your organisation has the logistics to deal with the request.

Make sure your organisation has the human resources available to deal with the request.

Check whether the request actually fits in with your 'pharmaceutical donations' policy if you have one.

Check if you need to sign a contract with the recipient organisation, and if so, check if you have standard contracts and make sure that the recipient organisation knows this.

Check what will happen after this supply of drugs has been used. Find out if you should expect a request for another donation.

Find out how the recipients will dispose of any unwanted, unusable, or expired drugs. [Click here for guidelines on safe disposal.](#)

Find out who is responsible for disposal.

Find out if there are ways in which the recipient's projects can be helped to become sustainable, if this is desirable.

Check if a donation of pharmaceuticals alone is sufficient or should be part of broader project.

Check how urgent the request is.

Check if you should you divide tasks within your organisation.

## **II) THE RELATIONSHIP BETWEEN THE DONOR AND THE RECIPIENT'S REQUEST**

### **A) SETTING FROM WHICH THE REQUEST ORIGINATES**

Make sure you are familiar with the requesting organisation.

Check if the requesting organisation is familiar with the inter-agency guidelines for drug donations.

Check if they have a copy of this checklist.

Consider whether you are planning to propose a partnership with the requesting organisation.

Find out which other donors were approached before you.

Ask why you were approached?

Check what is the relationship between the ministry of health and health co-ordinating body, and recipient organisation.

Check if regulations exist on the import of donated drugs in the recipient's country.

Check if the recipient organisation will ensure clearance.

Consider if you plan to exchange ideas on the means of collaborating with the recipient.

Check if you have an established means of collaborating.

Check if there are more organisations, similar to the recipients, active in the region.

Example: a donation represents money. Make sure your new partner has the best interests of the population at heart. Be aware of sensitive local relationships and make sure you do not result in financing local turf wars.

**B) A REQUEST FROM A PREVIOUSLY UNKNOWN ORGANISATION. (SEE ALSO GUIDELINE NUMBER 1)**

Make sure the requesting organisation and/or the population which the help will benefit falls within the donor's target group, (as defined in charter, by laws, or mission statement of donor)

Find out what are the levels of care given by the requesting organisation and if these fit the donor organisation's capacities.

Check if the requesting organisation is geared towards emergency care or public health.

Check if the donor wants to, or indeed can, give the specific support necessary.

Check if the requesting organisation is located in the area where it is possible for the donor to be active.

Check if the donor is able to manage the size and/or scope of the requesting organisation.

Check if the requesting organisation is a recognised institution in their country.

Find out what is the relationship between the requesting organisation and the ministry of health.

Find out if there an overt collaboration with other health institutions.

Check if the requesting organisation is familiar to the other donors working in the area.

Find out what are the levels of training of the health staff working with the requesting organisation.

Check if the requesting organisation can provide the pharmaceutical and medical expertise for dealing with the donations.

Check if the requesting organisation is supported by other donors, either on an ad hoc or a structural basis.

Consider whether the requesting organisation actually merits a donation of 'free' drugs.

Check if the requesting organisation has the logistic capacity to handle the request.

Check if the requesting organisation has the financial resources to handle the request.

Check if the requesting organisation has the staff to handle the request.

Example: make sure you know who you donate to. Ensure that your partner is not servicing the military camp nearby using your pharmaceutical products or that your donated products are not being sold on the black market.

**C) A REQUEST FROM AN ORGANISATION WITH WHICH PRIOR RELATIONSHIP EXISTS (SEE ALSO GUIDELINE NUMBER 1)**

Check if the requesting organisation has changed since the last request was received, for example in its status or target population.

Check if there has been regular contact with them since receiving the last request.

Check if they have sent in reports concerning the last donation or if there are there other outstanding matters.

Check if the effects of the last donation were evaluated by the recipient and by the donor.

Check what is the current position of the requesting organisation and why they still need 'free' drugs.

Consider if you are satisfied with the level of involvement regarding the actual request and the evaluation of the donor organisation.

**D) THE DONOR INITIATES A DONATION\***

Check if, in the case of an emergency, enough appropriate standard emergency kits can be found.

Consider whether the products available are really needed by the recipient organisation.

Consider how this need has been established and verified.

Check that you have a detailed request list, including a generic name, dosage and strength.

Consider if a cash or donation in kind is not more appropriate.

Check that before the arrival date you have prepared a list of the donated products and have you informed the recipient of their arrival.

Make sure you left the recipient a chance to refuse or revise the donation.

Example: gifts can be burdens. It takes a lot of time, effort, and often money to destroy unwanted products even when facilities exist. If not disposed of, these products will either occupy valuable storage space, create a black market, or might be used wrongly.

### **III) EVALUATING THE ACTUAL REQUEST**

#### **A) THE FOUNDATION AND ORIGIN OF THE REQUEST (SEE ALSO GUIDELINE NUMBER 2)**

Find out if the requesting organisation has a drug policy.

Make sure that a donation fits in the long term health policy of the recipient's country and does not endanger long term development.

Find out if the request is authorised by the ministry of health.

Try to analyse the public health situation where the requesting organisation is located.

Assure yourself either through outside information or by information provided by the requesting organisation, that a donation of pharmaceuticals is the appropriate way to support this organisation.

Check if a cash donation earmarked for the purchase of pharmaceuticals has been considered. This can be more effective as it leaves more choice to the requesting organisation.

Check if training or logistical support has been considered as this might increase the effectiveness of future donations.

Find out if NGO staff, or other experts working in this country, can supply information on such matters as national policies and disease profiles in order to verify claims.

Example: a recipient has specific knowledge. Your local partner might have more experience with suppliers and the specific details of the order than you. Supporting them to do the actual ordering can also be seen as training.

#### **B) FORMALITIES OF THE REQUEST (SEE ALSO GUIDELINES NUMBER 9 AND 11)**

Check the name, profession, position, address, telephone, fax, and email address of the individual requesting the donation.

Check if the person is authorised by the requesting organisation to make the request.

Check if the request is co-signed by a pharmacist.

Check who is the responsible pharmacist or medical doctor in the requesting organisation and if their qualifications are valid according to the local authorities.

Check whether there has been any official correspondence to that respect.

Check if the recipient organisation has fully agreed to receive the donation.

#### **C) CONTENTS OF THE REQUEST (SEE ALSO GUIDELINE NUMBER 2)**

Find out if any of the requested products can be bought locally, or regionally.

Check if the request is in line with the country's essential drug policy.

Check if all the requested products can be imported into the recipient's country.

Find out whether the requested products need to be registered in the recipient's country

Example: because of the much lower transport costs, intravenous fluids, which were produced locally, were considerably cheaper than the imported ones. Despite reassurances about quality donors often chose to send the fluids instead of cash.

#### **D) QUALITIES REQUESTED (SEE ALSO GUIDELINES NUMBER 2 AND 3)**

Check the name of the drug.

Check if it is generic and if not what is the justification for its inclusion in the request.

Find out what the generic name of the drug is.

Check if this name is included on the package label.

Check if the drug is part of the country's essential drug list and if not find out what is the justification for the donation.

Check if the drug is part of WHO's essential drug list and if not what is the justification for the donation.

Check whether donating a requested drug which does not appear on any of these lists is justified by a disease pattern.

Check if the general contents of the request match up with existing disease patterns of the region covered by the recipient organisation.

Find out if the request contains controlled substances or dangerous goods.

Check if specific dosages have been requested and if they are comparable to the country's customs.

Check if specific strengths have been requested and are they comparable to the country's customs.

Check if the packaging, size, and the presentation are in line with the country's customs.

Find out what is the basic unit in which the product is supplied.

Find out if there are different packaging sizes for the same product have been requested and with which this is justified.

Check if the products are supplied for different levels of health care and if they are earmarked for maximum use by these different levels.

Check if the language used on the label is appropriate.

Find out if the receiving organisation has a cold chain if necessary.

Example: follow local advice. Do not force health practitioners to change their protocols because you decided that different strengths do not matter. This can cause deaths.

#### E) QUANTITIES REQUESTED (SEE ALSO GUIDELINES NUMBER 2 AND 3)

Check the quantities for the amount of money involved using the ABC analysis.

Check the quantities for the number of provided average treatment episodes involved using reverse quantification method.

Consider if the costs relate to public health priorities by evaluating whether the number of drug treatments provided relate to the local morbidity patterns.

Check whether the quantities match the period for which they are requested.

Perform a 'what if' analysis on a spreadsheet to suit your objectives.

Print your results and submit, with your professional comments, as feedback to the requesting organisation.

Ask them to comment.

Check if the quantities expressed are in comprehensible and logical units with regard to the level of care that will be administering the products.

Check for any obvious mistakes. For example units of 10,000 instead of 1,000.

Check if the recipient has the capacity, including storage, freezers, transport and staff, to process this quantity even if the request is based on existing need.

Example: a recipient had to destroy almost half of the vaccines received as they had misjudged their cold storage capacity.

### IV) LOGISTICS

#### A) DOCUMENTATION (SEE ALSO GUIDELINE NUMBER 9)

Check the logistic features such as consignee address, means of transport and custom formalities, at the recipient's end.

Check if the insurance papers are present.

Check if the packing list shows the exact contents of the shipment including quantities, qualities, wholesale value, and number of boxes.

Check if there is an invoice.

Check if the declared value of a drug donation is based on the wholesale price of its generic equivalent in the recipient country.

Check if you have the quality certificates for the individual drugs.(see guideline 4)

Check if there are documents to show that all pharmaceutical products are registered on the market they are exported too. This may not be possible as in many countries the registration of pharmaceutical products is either absent or rudimentary.

Check, if applicable, whether the import licenses are available.

Check if the contract is included between the donating and receiving organisations stating that the products are a donation.

Check if copies of all these documents have been forwarded to the receiving organisation to avoid unnecessary delays at borders or other control points as well as to ensure that a proper inspection can be carried out upon the arrival of the goods.

Check if the drugs are accompanied by objective information not only for the health care workers but also for the eventual user.

Make sure the transport complies with the regulations of the transit countries.

Example: Sometimes regulations by the ministry of health require certain quality certificates to accompany the imported pharmaceuticals. Their absence can cause long delays which can hamper distribution.

## B) PREPARATION AND MONITORING OF TRANSPORT

Check whether the transport will be by air, sea or road, taking into consideration the difference in cost and shipping time and specific product conditions. Products which need to be kept in a cold chain should almost always be transported in the fastest way.

Make sure it is clear who will bear the costs of the transport. According to guideline 12, transport costs should be paid by the donor agency.

Make sure it is clear who pays for all additional costs which may occur 'en route' such as warehousing, port clearance, and import duties if applicable.

Make sure adequate insurance has been taken out to cover for loss, damage, third party, and theft.

Consider if split deliveries are a possibility.

Check if the packaging and labelling has been adapted to suit the final recipient, for example to a district, medical centre, or regional central pharmacy.

Check if you know the handling capacity of the recipient's organisation, and its city's port or airport, measured in cubic metres and weight.

Seek assurances that the type of packaging material will be sturdy enough to resist damage on a long journey.

Check the quality of the packaging material is of a certain minimum standard.

Seek assurances that the climatic circumstances in which the recipient organisation works are taken into consideration as the packaging of the individual products is also important.

Check if the packaging is done in such a way that the boxes can be handled without mechanical devices, for example boxes must not be too large nor exceed 25 to 50 kilograms in weight. One cannot assume that mechanical devices are always available on the other end.

Check if care has been taken to ensure where possible to pack only one type of one specific product in one box.

Check if 'control thermometers' have been packed in the cold storage boxes.

Check if the labelling on the box is appropriate and meets international standards.

Check if the labels are written in the languages of the donating, transit and recipient countries.

Ensure a final check has been made that the products will have at least 12 , or even 18 months, of remaining shelf life left upon arrival at the recipient organisation's warehouse.

Ensure that for products with a shelf life of less than 12 months that at least two thirds of the shelf life remains upon arrival.

Make sure the route of the transport, the time and the date of arrival, have been defined.

Check you are in permanent touch with the transport company to ascertain the date of arrival and the progress of shipment.

Consider if an internal evaluation of the donation should be done up to this stage in order to iron out future problems.

Example: have you made sure that maintenance and control is also under the supervision of a pharmacist? Transport can take up to six months with temperature ranges from 5 to 55 degrees Celsius.

## C) RECEPTION AND STORAGE OF SHIPMENT

Check the exact date that the shipment has arrived.

Check if there was a delay and why.

Check if the entire shipment arrived as planned, or only a part of it. If only part of it then find out why.

Check if there is any visible damage to the outside packaging, or container, or to the cartons in which the products are packed.

If there is any damage then check of what sort, for example water, dents, tears, rips, or cuts.

Check if any of the boxes carry evidence that they have been opened

Check if the contents of the shipment correspond to the itemised packing list confirming quantity, quality, and expiry date.

Check if the temperature in the cold storage boxes is acceptable and whether the temperature rose above the accepted temperature at any time during the journey.

Check if all documents are complete.

Check what duties have been paid.

Check if that is expected and, if not, then inquire what is the reason.

Check if all the conditions for the storage of the shipment are in place.

## V) MONITORING AND EVALUATION

Ensure follow-up and evaluation in collaboration with recipient organisation

Check the evaluation form for the recipients is sent with the goods encouraging the recipient to communicate.

Check the evaluation form is carefully designed and discussed beforehand.

Check the evaluation form offers feedback to the recipients and takes into account the unbalanced relationship between donor and recipient.

Check the evaluation forms are standardised with the possibility for adaptations.

Check a pharmacist is involved.

Ensure a second evaluation form is sent six months after delivery to evaluate how long supplies have been sufficient and the method of distribution.

Always work on ways to encourage the recipient and donor to undertake an auto-evaluation. [Click here for a monitoring form \(pdf file\) issued by the WHO.](#)

## COLOPHON

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Wemos is coordinator of the European NGO consortium on appropriate drug donations consisting of DIFÄM - Germany, ReMed - France, Prosalus - Spain and Wemos - The Netherlands.

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The consortium is co-financed by the European Commission, Directorate General Development.