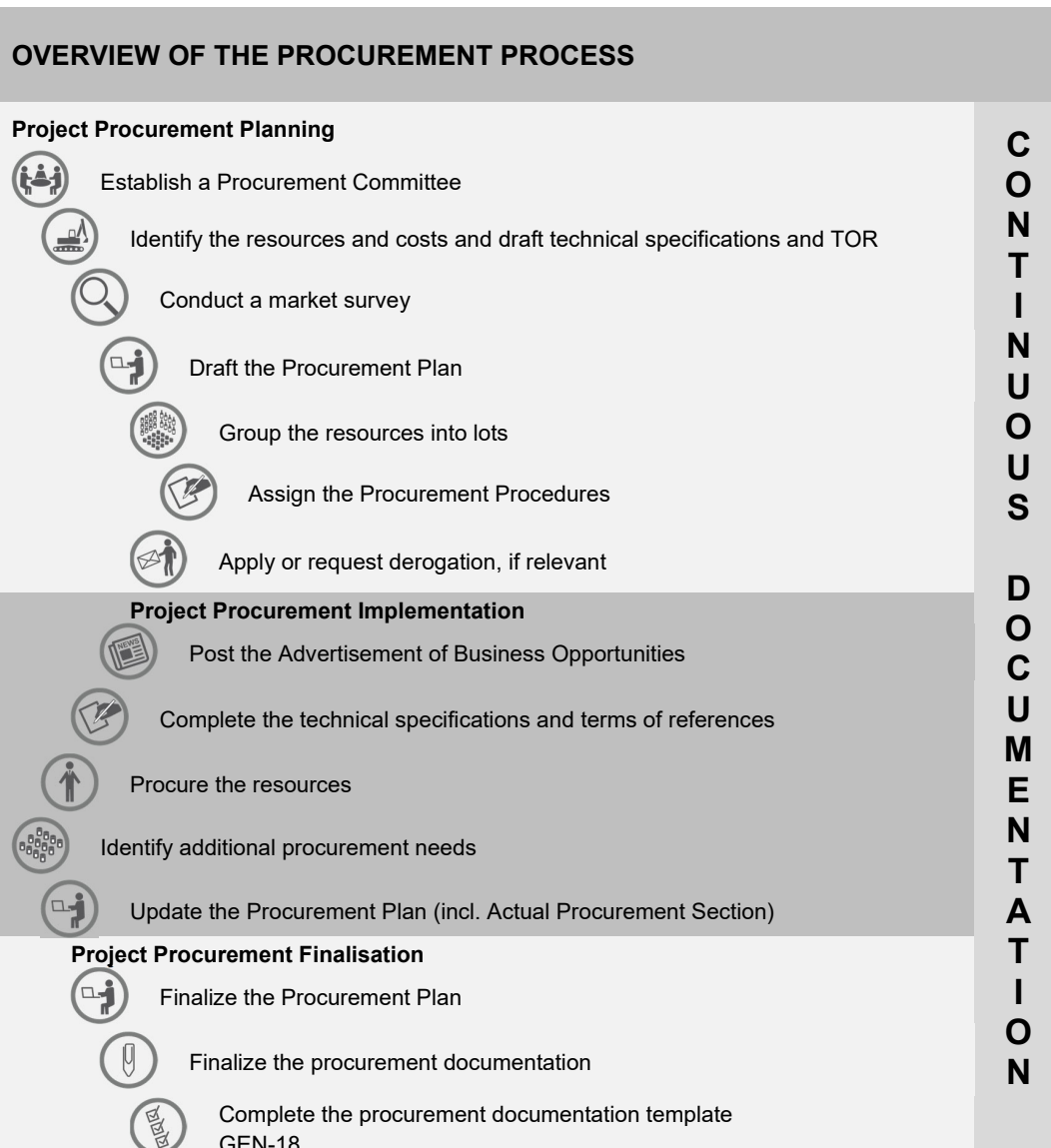


4 PROCUREMENT PLANNING

Procurement is a process that begins when projects are designed and ends when projects are completed. Careful and timely procurement planning is a very important aspect of procurement and is crucial to ensure effectiveness, efficiency, quality and donor compliance in projects. When planning a project, please determine which resources are required to be procured (supplies, services, works), when shall they be delivered, the needed standards for the resources, timeframes, costs and which Procurement Procedure shall be followed for each contract. This is all part of drafting the Procurement Plan, which is covered in section 4.1. Lack of careful procurement planning may result in a waste of funds, serious delays in implementation, undermining of the principles and ultimately that the costs may be declared ineligible.





Learn more about the procurement process from the online e-training number 1: [Procurement in the Project Cycle](#).

4.1 THE PROCUREMENT PLAN

A Procurement Plan is the project's intention for what is going to happen in Procurement. The main purpose of the Procurement Plan is to answer the questions of "what to buy?", "when to buy?", "how to buy?" and "who will buy", and to include estimated prices of the goods and services to purchase.

Irrespective of donor, the Procurement Committee is responsible for the availability of a Procurement Plan as part of the project's planning phase. The benefits of early planning are many and include:

Benefits of Procurement Planning at project proposal stage

- procurement and logistics costs are included in the project budget,
- project inputs or resources are grouped into lots based on market intel,
- procurement time constraints are considered in the project activity plan,
- human resources requirement and timing for the procurement procedures become evident,
- project implementation can begin without any delays when the contract is signed,
- the plan supports a smooth, timely and effective project without compromising the principles of accountability and transparency and
- the plan helps demonstrate that procurement takes time and creates realistic expectations among project staff who might expect their requests to be met on short notice.

In addition to the above benefits, the Procurement Plan provides Project Management with a quick and easy overview of the status of the procurement implementation, functions as a reporting tool and creates a link to procurement and finance files. The latter is very helpful when the Contracting Authority is undergoing an audit. When drafting the Procurement Plan please consider relevant procurement topics covered in sections 4.2 – 4.14. The Procurement Plan template is available in GEN 7-1. A sample Procurement Plan is available in GEN 7-2.



Learn how to prepare the Procurement Plan from online e-training number 3: [Step Guide to The Procurement Plan](#).

Step Guide:

1

Identify Required Resources and Costs



In cooperation with relevant project staff, please establish which resources to procure (supplies, services, works). At this stage it is important to determine the minimum technical specifications and terms of references (section 4.12.1). Moreover considerations regarding the use of Humanitarian Procurement Centers (HPCs), community involved procurement, framework contracts, cash and vouchers etc., shall be considered in the planning of procurement and integrated into the Procurement Plan, if relevant.



Please provide input to the budget on expenses for logistics, such as transport, clearance, import costs, insurance, warehousing and distributions. See template SUP 9 for Guidelines on Transport and Storage.



For products with a limited shelflife, it may be necessary to plan for partial deliveries



or special transport which may increase cost.

For Works Contracts it may be necessary to hire an engineer to supervise the administration of the contract. This is a Service Contract and please include costs in the budget.

Please identify capacity building needs and include these as expenses in the project proposal, e.g. consulting services from a procurement expert, workshop expenses, training expenses for the procurement and financial management staff etc.

Please identify if translation of this Manual and relevant templates into other languages is needed and if possible, include this in the budget and Procurement Plan.



MANDATORY TEMPLATE

GEN 7-1: Template for Procurement Plan

SUPPORT TEMPLATE

GEN 7-2: Sample of Procurement Plan

SUP 9: Guidelines on Transportation and Storage

2

Know the Donor Requirements



For each project it is important to investigate the specific donor requirements for procurement. This Manual represents the DCA minimum mandatory requirements to procurement. If a donor stipulates stricter Procurement Procedures, the donor requirements shall prevail. Examples are requirements to the country of origin of supplies, special quality requirements, ineligible products or stricter threshold for procedures. If the donor has no or less strict requirements to procurement, the rules described in this Manual shall prevail.

3

Conduct Market Survey



Once the required resources have been identified a market survey shall be carried out to establish:



- **The availability of the required resources.** The market survey shall address prices, trade customs, availability and quality of resources.



- **The availability of suppliers/candidates.** At this stage, potential suppliers and candidates shall be mapped and registered and their record and reputation identified.

- **To support the regional economy** and the development of markets, the Contracting Authority shall, whenever appropriate and possible, seek to procure resources in the project implementation area. Please ensure that procurement activities will not distort the local market, increase prices, or cause harm to the environment.

- **The existing import regulations and restrictions.** If resources need to be imported and to avoid delays, it is important to contact the customs authorities and a clearing agent regarding the import procedures and the requirement for import license and other related documentation. This is particularly important when procuring pharmaceutical products, medical equipment, radio and satellite

communication equipment, mine detectors, plastic explosives and foods.

- **Logistical needs and availability** regarding transport, special transport, storage and warehousing. Please include costs in the budget.
- **The social, labour and environmental risks** related to the resources to be procured. The obtained information helps to identify high risk sectors, countries, suppliers and candidates; the necessity of seeking alternative procurement options; if special requirements to ethical standards are to be included in the selection criteria (e.g. certifications); if there is a need for dialogue with suppliers/candidates; and if it is necessary to exclude some suppliers/candidates due to ethical reasons (e.g. use of child labour) etc.
- **The relevance of using Framework Contracts** for the purchases of supplies or services (see section 4.9)
- **The need to derogate** from mandatory rules in this manual. The market survey will reveal if there is a need to derogate from a rule or Procurement Procedure due to specific market conditions.
- **Findings from the market survey** feed cost information to the budget, activity plan (time frames) and the project proposal in general,



SUPPORT TEMPLATE

GEN 6: Market Survey Checklist

4

Grouping of Lots

Based on information obtained from the market survey and budget, please group the required resources into lots in the Procurement Plan.



Preparing lots is the process of grouping resources which can potentially be purchased from one supplier or candidate to obtain the best quality and prices for the required resources. Lots are prepared for the entire project period and are independent of project activities, geography for implementation, and the number of donors and partners for the project. See section 4.1.1 for more information on preparing lots.



MANDATORY TEMPLATE:

GEN 7-1: Procurement Plan

SUPPORT TEMPLATE

GEN 7-2: Sample of Procurement Plan



Learn more about lots in e-training number 2: ['Working with Lots'](#).

5

Assign Procurement Procedures

SIMPLE

Each lot in the Procurement Plan is assigned a Procurement Procedure. The Procurement Procedure is determined by the Contract Category and the total value of each lot. See chapter 3 for more information. For a description of the available Procurement Procedures please go to the Supply, Service or Works chapters respectively (Chapter 6-8).

LOCAL OPEN TENDER	SUPPLY	SERVICE	WORKS
	Simple	EUR 300 – 9,999	EUR 300 – 9,999
Negotiated	EUR 10,000 – 149,999	EUR 10,000 – 149,999	EUR 10,000 – 299,999
Local Open	EUR 150,000 – 299,999	EUR 150,000 – 299,999	EUR 300,000 – 2,999,999
International Open	Above EUR 300,000	Above EUR 300,000	Above EUR 3,000,000



Learn more about Contract Categories, Thresholds and the associated Procurement Procedures in e-training number 4: '[Thresholds and Procurement Procedures](#)'.

6

Timeframe Considerations



For the overall duration of the project, the timeframe for carrying out each Procurement Procedure shall be taken into account. This includes time for advertising, preparing technical specifications/TOR, issuing a Request for Quotation (RFQ), Request for Proposal (RFP) or Tender Dossier and evaluating. Please note that procurement time constraints are often underestimated.



Timely and careful planning can help prevent last minute contracts or changes to existing contracts, which may influence the contractors' ability to deliver on time and comply with the ethical principles and standards outlined in the CoC.

The below table shows the overall timeframe for the different procurement procedures.

PROCEDURE	BID FLOW	TIMEFRAME	DELIVERY TIME
Simple	NA	0 – 2 weeks	Shall be added
Negotiated	App. 2 weeks	3 – 8 weeks	Shall be added
Local Open	Min. 21 days	10 – 12 weeks	Shall be added
Int. Open	Min. 30 days	10 – 13 weeks	Shall be added

7

Apply Derogation(s)



Based on all the information collected in steps 1-6, it might be necessary to apply one of the Blanket Derogations described in section 4.7.1. Or it may be necessary to request a written approval to derogate from a rule or procedure in the Procurement Manual or donor. For further information on derogations, please see section 4.7.

4.1.1 Making Lots

Making the lots is the process of grouping resources, which can potentially be procured from one contractor into lots. The main purpose is to obtain efficiency and best quality and value for money. How to group resources into lots is foremost defined by the market structure. This means that there are no fixed solutions to what a lot includes. Thus, it is important to obtain market knowledge via the market survey. In some contexts, it is possible to group many different resources into one lot and purchase from one contractor, because this is how the market is structured. In other contexts, the same resources may have to be purchased in several lots, because the suppliers in the market have more specific product groups, and will not be able to deliver various resources.

Example: The Market and Making Lots

Most markets are structured in a way that does not offer motorcycles and computers from the same supplier. Thus; there would be two lots - one for the computers and one for the motorcycles. However, in Cambodia the market was structured in a way that made it possible to purchase both the computers and the motorcycles from the same supplier. Thus; in this context it was one lot.

After dividing the identified resources into the three Contract Categories of Supplies, Services, and Works, group the resources into lots according to how the market is structured.

Please note that lots are prepared for the entire project period and independent of project activities, geography, and the number of donors and implementing partners in the project. This means that lots are grouped in the same way regardless if a project has more than one donor, the procurement takes place across several months or years and takes place across multiple geographical locations. Consequently, if two laptops are funded by two different donors this is still to be considered one lot. The procurement will follow a procedure based on the total value of the two computers.

If a lot consists of more items, it does not necessarily result in one contract, only. A lot is usually purchased with one RFQ/RFP/Tender Dossier. If we allow suppliers or candidates to bid on one, several or all items, several suppliers may be contracted because we obtain best quality and value for money per item. While lots save cost, they can also result in an increase in the administrative burden due to multiple contracts.

Lots have several advantages: it provides suppliers or candidates with an incentive to quote lower prices due to quantity, it reduces efforts and costs and saves time when preparing the purchasing process and it reduces overhead costs (frequent advertising, bookkeeping, logistics etc.).

Lots do have some disadvantages and the related costs shall be included in the budget and the Procurement Plan. The disadvantages are increased demand for storage facilities, increased demand for liquidity, and the need for careful planning.

NOTE: Artificial splitting of lots to avoid a stricter Procurement Procedure is not allowed.



Learn more about lots in online e-training number 2: [Working with Lots](#).

Example: Making Lots**SUPPLY:**

Lot SUP 1) Field equipment:

- 1.1 Camp beds
- 1.2 Sleeping bags
- 1.3 Mosquito nets

Lot SUP 2) Computer equipment:

- 2.1 Laptop
- 2.2 Printer
- 2.3 Toner
- 2.4 UPS
- 2.5 Router
- 2.6 Keyboard

Lot SUP 3) Sand for construction:

- 3.1 Sand 1 ton
- 3.2 Sand 1 ton
- 3.3 Sand 1 ton

SERVICE:

Lot SER 1) Engineer:

Service Contract for supervision of the Works Contract

WORKS:

Lot WOR 1) Tube wells:

Works Contract for the delivery and construction of tube wells with pumps

Sub Lots

In some situations, it may be advantageous to divide an item or lot into several sub lots to promote competition and obtain the best quality and value for money. By dividing a lot into several sub lots, all

suppliers irrespective of capacity, have the opportunity to quote, as they are allowed to offer their price for one, several or all the sub lots. An example is the purchase of three tons of sand, please see above. The larger commercial players will likely be able to offer all the sand. Yet, the smaller companies in the project community might be able to offer one ton. Consequently, by dividing the three tons into three sub lots of one ton, more suppliers can submit their offers and the degree of competition is substantially increased. This may be useful in contexts where the market consists mainly of many small suppliers and in contexts where we wish to support the project community and market development or in projects with a wide geographical implementation.

Only one RFQ/RFP/Tender Dossier is issued, but several suppliers may be contracted because we obtain best quality and value for money per sub lot. Thus, sub lots may be cost saving and suppliers quoting lower prices per sub lot may be contracted, instead of the supplier quoting the overall lowest price. The disadvantage lies in having to administer multiple contracts. Please note that when dividing an item into several sub lots the total value of the entire lot remains the same and the applicable Procurement Procedure stays the same.

4.2 MULTI PARTNER PROJECTS

In projects with several implementing partners it is important to organise procurement as early in the project phase as possible. Based on the project's context, the procurement principles and the donor's demand, it is important to carefully consider the advantages and disadvantages of the three scenarios below and to select the most suitable one. The decision shall be clearly indicated in the Procurement Plan.

- **Shall each partner carry out its own procurement?**

This may be favourable in situations when the partners are situated in remote areas, resources can be sourced from the project community, the market is characterised by many small suppliers or candidates with limited capacity, and there is no economic advantage in making a joint purchase.

- **Shall procurement be carried out by one partner on behalf of the other partners?**

This may be favourable when an economic and logistic advantage in centralising procurement with one partner is existent. In an ECHO project in Uganda one of the partners was a small NGO with its head office in a remote town far from the capital. It was agreed that one of the other two urban based partners would procure the vehicle, water pumps and spare parts on behalf of the smaller NGO for reasons of low procurement capacity and remoteness.

- **A combination of the above two scenarios?**

This may be favourable when it is an advantage to make a joint purchase of some products e.g. technical equipment and to buy the remaining products separately.

The applicable Procurement Procedure is dictated by the total lot value and is therefore the same for the three scenarios described above.

Example: Applicable Procurement Procedure in a Multi Partner Project

Five partners need to procure a generator, each for a unit value of EUR 2,500, and the market has a supplier that can deliver all units. Consequently, the total lot value of the procurement is EUR 12,500 and the Negotiated Procedure shall be applied. If it is decided that the partners procure separately, the procedural consequence is that all partners shall implement a Negotiated Procedure, even though each partner only procures one generator. Please refer to the definition of lots in section 4.1.1.

Procurement in Multi Country Projects

Multi country projects may take place within both multi partner and consortium contexts. For projects with two or more countries, procurement may be split between the countries. This means that it is acceptable to organize procurement with one Procurement Plan per country even though the two plans are within the

same project. In such cases and if required, it shall be highlighted in the project proposal that for economic purposes procurement will be carried out separately in each country. Please check specific donor requirements on multi country projects.

4.3 CONSORTIUM PROJECTS

A consortium project is an entity with one lead organisation and several other organisations taking part as consortium members. Both the consortium lead and the consortium members may have several implementing partners. In that way, consortium projects are like the multi-partner projects and the procurement considerations in section 4.2 above are also relevant to consortium projects with several implementing partners. A consortium project can be complex, and there are several types of organisational procurement set-ups available to consider. This makes planning, preparation and coordination important, including decisions on the division of procurement responsibilities between the consortium members.

The main procurement topics to address during the project design phase are:

- Shall the consortium lead's procurement guidelines apply for members and their implementing partners and if not, what are the implications and risks?
- Considering the project context, shall the Procurement Committee be centralised under the lead agency or be undertaken separately by each consortium member and its implementing partner(s) – or be a combination of both?
- Shall joint or individual Procurement Plans be developed?
- What are the resources required to carry out the above decisions e.g capacity building of members, implementing partners, monitoring etc.
- What are the monitoring and reporting requirements of the lead organisation?

It is important to ensure that all decisions resulting from the above discussions are captured in the Memorandum of Understanding (MOU) summarising the commitments and responsibilities of each consortium member.

4.4 CASH GRANTS AND VOUCHERS

Cash Transfer Programming (CTP) and the use of cash grants and vouchers in projects is recognised as a method to respond to a wide range of humanitarian needs. They offer greater choice to beneficiaries and help foster dignity in the receipt of assistance.

From a procurement perspective, it may be beneficial to use cash grants and vouchers in projects where it will be a challenge to implement competitive Procurement Procedures. This is often the case where products, e.g. livestock, food or non-food items will be procured from households, small village suppliers and markets in the project area.

Different types of cash grants and vouchers exist and are often referred to as cash modalities. Cash Grants and Vouchers are always conditional or unconditional, and restricted or unrestricted. The condition refers to an action required by beneficiaries to receive the cash grant or voucher. The condition could be that the beneficiary participates in a workshop or does work, and procurement rules and procedures are not relevant to such conditions. Restrictions refer to what the cash grant or voucher can be exchanged for e.g. non-food items, food, health check, etc., and where it can be exchanged. Procurement rules and procedures apply to some types of cash grants and vouchers with restrictions. Below table provides an overview of when restrictions lead to procurement rules and procedures being applicable.

NOTE: Purchase of mobile phones, tablets, services from mobile phone companies, technological solutions, Financial Service Providers (FSP), bank services, consultancies etc. required in connection with

any CTP is procurement and is subject to procurement rules and procedures. When establishing the threshold and applicable procurement procedure for FSP purchase, it is the total value of the service fee to the FSP (incl. all fees), which defines the threshold, and not to the total amount of cash to be distributed through the CTP.

COMMODITY AND SERVICE VOUCHERS		
Beneficiaries receive either electronic, mobile or paper vouchers which can only be exchanged for a fixed quantity of preselected commodities/services from predefined suppliers/service providers.		
Restricted	<p>Restrictions always apply to commodity and service vouchers because beneficiaries can only exchange the voucher for a fixed quantity of preselected commodities or services. This could be e.g. 5kg of maize; one NFI kit, one health check per household member or milling of e.g. 5 kg of maize. This from a list of preselected suppliers or service providers.</p> <p>This type of voucher is not commonly used.</p>	<p>Procurement Procedure apply</p> <p>The selection of the suppliers or service providers is based on a procurement procedure according to total value of the contract. The procurement responsible staff is the main responsible for carrying out the procurement procedure in cooperation with programme staff. Contracts are concluded with a relevant number of suppliers or service providers, who have provided the best price meeting the technical specifications/TOR for the required commodities/services.</p>
Unrestricted	Commodity and service vouchers cannot be unrestricted since they will always be tied to specific suppliers/service providers.	NA
CASH GRANTS AND VALUE VOUCHERS		
Beneficiaries receive cash grants as either cash money, mobile money or as value vouchers.		
Restricted	<p>Cash grants are restricted when the cash grant can be exchanged in designated shops, fairs and markets, and beneficiaries can choose between a variety of commodities/services (e.g. food, NFIs, building materials, healthcare, transport etc.).</p> <p>The level of restriction varies. It may be that it is only the suppliers which are predefined and there are no restrictions on what commodities beneficiaries are able to receive in exchange for the cash grant from the predefined suppliers, but restrictions can also be imposed on what commodities the suppliers can provide to the beneficiaries.</p> <p>This is the most commonly used type of cash grant and it is often provided as value vouchers as e-vouchers or printed vouchers.</p>	<p>Procurement Procedure does not apply</p> <p>A market assessment on current prices and availability of products shall be conducted and an agreement reached with selected shop owners. No fixed prices are agreed on, but often a maximum price increase of 10-20% is written into the contract with the vendor(s). Price fluctuations, ability to deliver and the quality of supplies shall be monitored during the implementation. Assessing the market, entering agreements and monitoring the market is the responsibility of the Programme staff with involvement of procurement staff when feasible.</p> <p>In some contexts, and depending on the programme objectives, it may be an advantage to select suppliers based on a Procurement Procedure, but this is not a requirement. This shall be established in cooperation between programme and</p>

		procurement staff.
Unrestricted	<p>If the cash is unrestricted, the beneficiaries receive cash or mobile money and are free to spend them with no restrictions! No predefined suppliers/service providers exist.</p> <p>This type of Cash Grant is usually provided as cash money, mobile money or via bank transfer to a bank account.</p>	<p>Procurement Procedure does not apply</p> <p>A prerequisite for unrestricted cash is that a market of a sufficient size exists. This assessment is carried out by the project / programme staff.</p>

For more information, resources and guidelines on CTP please go to the Fabo.org learning site [Cash Transfer Programming Resource Site](#) where the [DCA Cash Transfer Guidelines](#) can also be accessed. The DCA Cash Transfer Guidelines ¹covers such topics as Cash preparedness, planning, implementation, risks and monitoring, and provides specific procurement relevant information for entering Framework Contracts with FSPs, and suggestions for financial and technical criteria for sourcing FSPs².

4.5 COMMUNITY INVOLVEMENT

Community involvement in procurement is defined as the participation of beneficiaries in the procurement process and it is governed by the Procurement Procedures laid down in this Manual as well as donor requirements.

Use of Community Involved Procurement

Community involvement in procurement is often used where the community has access to the market and can provide meaningful inputs on what to buy and where to buy. Typical resources are village products such as bamboo, paddy seeds, indigenous variety of seeds, sand, bricks, boats, nets, livestock, fishing and perishable goods, etc.

Organising Community Involved Procurement

Community involvement can be organised in several ways and with varying complexity. Some common approaches are:

- Community participation in identifying material needs and providing input to the Procurement Committee on technical specifications.
- Community participation in identifying material needs, formulating technical specifications and in addition identifying suppliers and collecting quotations in the market in collaboration with the Procurement Committee.
- Communities participating in identifying material needs, formulating technical specifications, identifying suppliers, collecting quotations and in addition negotiating the prices and deciding on what to procure. This requires that the beneficiaries become members of the Procurement Committee.

NOTE: The legal relationship shall be between the implementing partner organisation and the supplier or candidate. Consequently, it is only the implementing partner organisation that can issue the Purchase Order or Contract.

Planning of Community Involved Procurement

¹ [DCA Cash Transfer Guidelines](#) section 2.3

² [DCA Cash Transfer Guidelines](#) section 7

Planning of community involved procurement is an integrated part of preparing the Procurement Plan. A project may involve one or several activities that include community involvement in the procurement process. Before including an element of community involvement, please carefully consider the suitability and how to organise and manage this activity. Consider the following:

- If more suitable alternatives such as cash grants or vouchers could fulfil the same purpose. See section 4.4 for more information on cash grants and vouchers.
- If a project activity requires beneficiaries to contribute with e.g. sand or bricks from their land, it is paramount to include a detailed description in the project proposal. Procurement from beneficiaries fall under Blanket Derogation and the Simple Procedure is applicable irrespective of contract value (see section 4.7.1).
- Is there a market to meet the principle of competition?
- The need for capacity building of community participants in terms of the technical requirements of Procurement Procedures and record keeping.
- The substantial time needed to collect information by the community, and how to organise the procurement in the Procurement Committee.
- How to avoid conflicts of interest e.g. preventing Procurement Committee members from purchasing from family and friends and from becoming suppliers themselves.

NOTE: Beneficiaries may not use own cash subsidies to purchase a more expensive item than the item selected as a result of a Procurement Procedure. A type of item that differs from the selection in the approved Procurement Plan will be deemed ineligible.

4.6 USE OF OWN VEHICLES

If an implementing partner organisation wishes to utilize all or part of a vehicle rental budget line on a vehicle from their own existing fleet instead of concluding a rental agreement with a company, only maintenance and running costs for such a vehicle are eligible. Rental from own vehicle fleet is not allowed, except when it is allowed by the donor.

To make the running costs of the organisation's own vehicle an eligible cost, the daily or monthly rates for running costs shall be significantly lower than the current commercial vehicle rental rates indicating that the purpose is not profit making. It is therefore recommended to conduct a market survey establishing the current market price. This can be done by collecting three quotations.

The vehicle in question shall be dedicated to the project during the project time period indicated to avoid a complex monitoring procedure. Proper records of the vehicle's activities in the project must be kept in a logbook (showing location and purpose of the vehicle's movements) as well as fuel receipts.

The following information shall be established at project start and filed for reporting:

- Details of vehicle i.e. model, registration number, etc.
- Purpose of the use of the vehicle.
- Time period for use of the vehicle.
- Daily or monthly charges including details of what this includes i.e. fuel, driver costs, maintenance, insurance etc.

For guidance on fleet management, and fleet management templates, please see the [DCA Logistics Manual](#)

NOTE: The use of own vehicles technically falls outside of procurement, but it is often monitored by procurement staff, which is the reason for including it in this manual.

4.7 DEROGATIONS

All organisational or project procurement must comply with the guidelines of this Manual unless there are exceptional circumstances preventing this. For those circumstances it is possible to obtain an exemption or waiver from the guidelines. This can happen by way of a Blanket Derogation or by approval.

The Blanket Derogations are a set of predefined situations in section 4.7.1 where the Manual grants derogations without any further approval from the organisation. For all other situations, where it is not possible to comply with the rules and guidelines in this Manual, a written derogation may be requested based on the six predefined justifications set out in section 4.7.2 Derogation by Approval.

All derogations shall always be properly justified and documented. If the justifications defined in section 4.7.1 and 4.7.2 cannot support a derogation, then procurement must be undertaken and documented according to the rules and guidelines in this Manual.

NOTE: Donors may have different justifications and approval requirements than those outlined in this Manual and in such instances those requirements prevail.

4.7.1 Blanket Derogations

In exceptional circumstances it may not be possible to meet the requirements of this Manual and for the predefined situations outlined below, a Blanket Derogation is available.

A Blanket Derogation does not require prior approval but must be documented in the procurement file with reference to the relevant section below and a justification on why the Blanket Derogation is relevant.

Procurement from a Single Supplier

For the below predefined situations, a Blanket Derogation is available to negotiate with and procure from a single supplier, irrespective of contract value. The procurement shall always be documented by a Purchase Order or a Contract with complete technical specifications or TOR, proof of receipt of the supplies, services or works and an invoice.

- a. For emergency operations meeting immediate and unforeseeable humanitarian requirements generated by sudden natural or man-made disasters, such as floods, earthquakes and outbreaks of fighting or comparable situations. The concept of emergency also includes any situation, in which the implementation of the humanitarian aid operation must start immediately, and the delay incurred by sending Procurement Contracts out to tender would put lives at risk. The emergency is declared by DCA or the donor and cannot be based on circumstances attributed the Contracting Authority, such as delays due to poor procurement planning, or other delays to the procurement activities. If possible and pertinent, it is though always recommended to conduct a competitive Procurement Procedure to obtain better quality and value for money.
- b. Whenever no tenders or no suitable tenders/proposals/quotes have been submitted in response to a Negotiated or Open Tender Procedure after the initial procedure has been completed. This, provided that the original terms of the contract are not substantially altered.
- c. Whenever, due to a monopoly situation, the contract can only be awarded to a particular supplier or service provider.
- d. For additional contracts repeating services, works or supplies given to a contractor awarded an earlier contract in the same region provided that the terms of the original contract are not substantially altered. The period since the award of the first contract shall not be longer than one year.
- e. For additional supplies, works and services not included in the initial contract which, due to unforeseen circumstances, have become necessary for the performance of the activities, provided that the total amount of additional supplies, works or services does not exceed 50% of the value of the initial contract.

- f. For property rental contracts.
- g. For contracts on particularly advantageous terms, either from a supplier who is winding up its business activities or from the receivers or liquidators of a bankruptcy, an arrangement with creditors, or a similar procedure.
- h. For purchases from a recognized Humanitarian Procurement Centre (see section 4.8).
- i. For purchases where prices or rates are fixed by legislations or by regulatory bodies.

Other Exemptions

For additional specific situations a Blanket Derogation is available for:

- j. Emergency operations and situations putting the staff and beneficiaries at risk, the Contracting Authority may refrain from posting a general advertisement at the beginning of the project.
- k. Situations where posting an Award Notice will put staff, beneficiaries, the project or the winning contractor at risk, the Contracting Authority may refrain from posting an Award Notice for contracts above EUR 30,000.
- l. Purchases of products grown or produced by the beneficiaries, such as bamboo, timber, eggs, vegetables, saplings, jute, sand, gravel, stones and livestock the Contracting Authority may apply a Simple Procedure (as a minimum), irrespective of the contract value.
- m. Purchases of livestock from the general market the Contracting Authority may apply a Simple Procedure (as a minimum), irrespective of the contract value.
- n. Online purchases of supplies up to a value of EUR 9,999 issuing of a Purchase Order is optional.

NOTE: If more restrictive Procurement Procedures are stipulated by the donor, these shall always prevail.

4.7.2 Derogation by Approval

In addition to the Blanket Derogations described above, situations may arise where it is necessary to request a derogation to depart from the procurement guidelines of this Manual. Such derogations are subject to a written approval from the DCA Head of Procurement and Logistics in Copenhagen and may be granted based on the following reasons with justifications. Please refer to the box below for examples of justifications:

- Security reasons
- Operational reasons
- Technical reasons
- Ethical reasons
- Cost or delays due to transport
- Legislation

Similarly, donors may have provisions for granting derogations to their guidelines, which should be requested directly from the donor. To avoid delays, please identify and plan for derogations during the project planning phase and include these in the project application.

Examples of justifications for Derogations by Approval**Security justification**

Due to an ongoing conflict, the supply route to the area of intervention was frequently cut off, resulting in delays and loss of goods. Consequently, it was not possible to take delivery from the supplier offering the best value for money. Therefore, the written request to derogate from the Negotiated Procedure, to purchase from the two available suppliers in the project area was granted.

Operational justification

A new project involved the purchase of five motorcycles. The organisation already had a fleet of Yamaha motorcycles including a small stock of spare parts to handle most motorcycle repairs. Based on this operational situation, the project requested permission to purchase brand specific Yamaha motorcycles under a competitive procedure. The written request to purchase brand specific Yamaha motorcycles was granted.

Technical justification

For technical reasons, the mapping of a project community demanded highly advanced software for obtaining the required result. The careful market research proved that only one type of software from one provider could meet the requirements. The written request to proceed with this single source technical product was approved.

Ethical justification

In a Humanitarian Response project, there was a requirement for tents for a refugee camp. After carefully assessing the market, it was found that only one supplier of tents could provide evidence of not using child labour. The written request for derogation to purchase from this single supplier was granted.

Legislative justification

A Humanitarian Mine Action programme, was procuring the drug Morphine for first aid kits. Procurement of medicine requires a Negotiated Procedure with only pre-qualified suppliers. However, because Morphine is a restricted drug, the National Drug Regulatory Authority in the country of operation would only allow the programme to procure the drug from the government controlled Central Pharmacy. This led the Programme to submit a written request for derogation to purchase the drug from the Central Pharmacy. The derogation was granted.

4.8 HUMANITARIAN PROCUREMENT CENTRES

A [Humanitarian Procurement Centre \(HPC\)](#) is a DG ECHO recognised entity specialized in buying emergency and health supplies and related services for use in humanitarian aid operations. These entities are always non-profit and either autonomous entities or specialised procurement and logistics departments of INGOs. The overall purpose of an HPC is to facilitate efficient and safe procurement of quality products and to reduce costs for Contracting Authorities. HPCs foremost provide services within stockholding, non-stockholding and consultancy services for the following products and services: pharmaceutical products, medical devices, veterinary, foods, water and sanitation, engineering, shelter, telecommunication, transport and administration.

A HPC is a non-profit entity and overhead costs or handling fees are only to be charged by the HPC to cover its costs, never for profit making. The HPC is restricted to charge an admin fee of maximum 7% of the total direct costs, but the admin fee is often lower than the 7%. The contractual arrangements concluded with the HPC shall include the necessary provisions in this respect and shall allow the identification of the different costs. It is not necessary to request supplementary documentation relating to the relationship between the HPC and its suppliers e.g. Framework Contracts, insurance invoices,

transport documentation, etc. However, it is important to keep procurement documentation for the contractual relationship with the HPC.

The HPCs have been approved by DG ECHO to deliver quality products at competitive prices. Consequently, when purchasing from a HPC it falls under Blanket Derogation' h. in section 4.7.1 and the Contracting Authority can negotiate with a single HPC, irrespective of the contract value. Please note that even though a DG ECHO recognised HPC assumes the responsibility of ensuring the required quality of products and respecting the appropriate procedures, it is always the responsibility of the Contracting Authority, to assure that the HPC lives up to its responsibilities.

Recommendation

For the procurement of medicine and medical devices and to ensure quality in products, it is strongly recommended to use a DG ECHO recognised HPC. When buying from a HPC Blanket Derogation h. in section 4.7.1 allows procurement from a single HPC, irrespective of the contract value.

Concluding a Contract with a HPC

The contractual relation is solely between the Contracting Authority and the HPC, and it is governed by the contract signed by them. When entering a contract with a HPC the Supply and Service templates are relevant. Adjust the contract to the specific procurement task and ensure that the following issues are carefully considered and implemented in the contract:

- The HPC shall ensure the identification and breakdown of the different costs in the invoice.
- The HPC shall be able to certify that it is recognised as a HPC by DG ECHO and follow DG ECHO recognised Procurement Procedures.
- The HPC shall show compliance to international standards and quality assurances. This is a requirement for the procurement of pharmaceuticals, medical devices and food.
- The HPC shall immediately inform the Contracting Authority if a situation occurs where DG ECHO may cancel the registry of the contractor as an approved HPC.
- Delay in shipment and demurrage charges as a result of missing documentation is the sole responsibility of the HPC, unless the delay is due to the fault of the Contracting Authority.
- Provide clear and detailed technical specifications and TOR to the HPC.
- Avoid additional costs such as bank guarantees or interest payments as these are non-eligible costs.
- When awarding the contract, mention the source of funding in the Purchase Order or Contract.

4.9 FRAMEWORK CONTRACTS

A Framework Contract is a long-term (maximum four years) contract concluded between the Contracting Authority and one or several contractors. It is used to define the general terms such as subject, technical specifications, price(s), duration, procedure for the award of specific contracts, etc. for future procurement of a series of goods or services for which the precise quantity or scope and time of delivery cannot be defined at the outset of the contract. The specific conditions, quantity, date of delivery, etc. of a given purchase shall only be laid down in a Purchase Order or Contract when the goods or services are needed. Purchase Orders and Contracts under a Framework Contract shall be placed in accordance with the terms laid down in the Framework Contract.

Framework Contracts can be used for the purchase of services or supplies and do not need to be tied to a specific project or action. It is not possible to have a Framework Contract for works.

Recommendation

Framework Contracts shall be used for recurring office purchases from the same supplier e.g. telephone, internet, catering, cleaning, stationary, hall rent, audits, etc.

The Framework Contract helps reduce costs, improve efficiency in supply chain management and improves relations with reliable contractors. Framework Contracts may never be used in such a way as to prevent, restrict or distort competition.

The decision to establish or apply the Framework Contract to a series of purchases shall be made during the project proposal stage and integrated into the Procurement Plan.

Please ensure availability of an updated list of all Framework Contracts in force. Purchase Orders or Contracts placed based on a Framework Contract shall be archived in the procurement file.

Framework Contracts with a Single Contractor

A Framework Contract can be entered with a single contractor. The applicable Procurement Procedure for the award of the Framework Contract with a single contractor shall be based on the Contract Category and the total value of the contract for the entire duration of the contract. Each specific contract under the Framework Contract is ruled by the general terms laid down in the Framework Contract and is not subject to reopening of competition.

Framework Contracts with Multiple Contractors

A Framework Contract can be entered into with multiple contractors also called Multiple Framework Contracts. Each contractor has a separate Framework Contract with the Contracting Authority, but the contracts are concluded on identical terms. The applicable Procurement Procedure for awarding multiple contractors with a Framework Contract is based on the Contract Category and the total value of the contract for the entire duration of the contract. For multiple Framework Contracts the minimum number of contractors shall be at least three.

Purchase Orders or Contracts under a Framework Contract are issued based on a list of priorities without reopening competition. The Contractor who made the best quote or proposal is ranked number one. If that contractor is unavailable or not interested in the specific contract, the Purchase Order or Contract is then placed with the second contractor on the list and so forth. For this kind of multiple Framework Contract the general terms laid down in the Framework Contract is applied to the award of the specific contract.

In sectors subject to rapid price changes or technological developments (computers, software, mobile phones, etc.), Framework Contracts without reopening of competition are not recommended. However, if a Framework Contract is entered, the Framework Contracts shall contain a stipulation either on a midterm review or on a benchmarking in order to adjust the general terms to developments in the sector.

Example: Applicable Procurement Procedure for a Framework Contract

When concluding a four-year Framework Contract for demining tools with an estimated contract value of EUR 50,000 per year, the total value of the contract is EUR 200,000, and the applicable Procurement Procedure is a Local Open Tender.

4.10 RUNNING COSTS

Running costs are defined as recurring purchases and costs on a pre-determined frequency e.g. weekly or monthly and are often related to office procurement. A framework contract shall be established for any running cost, where possible. This will ensure efficient use of staff time and obtaining best quality and value for money.

NOTE: If donor rules are stricter, these shall prevail.

Examples of Running Costs

Rent and maintenance of office buildings, coffee, tea, water, fuel, maintenance of existing motor vehicles, repair of machinery, electricity, newspapers, magazines, books, cleaning articles, postage, packing, copy paper, stationary, insurance, financial services (transfer charges, bank guarantees, etc.), taxi services, catering, internet and telephone subscriptions and cleaning services.

4.11 SOURCING OF SUPPLIERS AND CANDIDATES

It is essential to source suppliers and service providers as broadly as possible to create transparency, equal opportunity, competition and to ensure that the best value for money is obtained for any given Supply-, Service- or Works Contract. Several sourcing methods exist, and some are described below. Please take note of special donor requirements such as pre-qualification of suppliers and candidates.

4.11.1 Mandatory General Advertisement

At the beginning of a project the Procurement Committee shall always ensure that a general Advertisement of Business Opportunities is published to inform the community and potential suppliers and service providers about the business opportunities offered in the project. The general advertisement helps the Procurement Committee to source new suppliers and service providers, and it will generate competition, as well as promote transparency and accountability. When posting a general advertisement in the beginning of the project please use GEN 8: Advertisement of Business Opportunities or SUP 11-3: Advertisement of Business Opportunities for Procurement of Medical Devices.

This general advertisement is mandatory and shall be published in relevant newspapers, that normally carry such notices. If newspapers or other printed media are not available or do not provide the best advertisement platform, a notice can also be posted on the internet, in a relevant trade journal, on a notice board in front of the office, at the market or in other relevant public places.

When relevant, please carry out a small-scale risk analysis on potential country or sector specific ethical risks and on the suppliers' ethical business performance e.g. risks of labour rights violations in the sector, CSR policy, safety policy, standards and ISO or SA8000 certifications (or lack of), etc. The findings can be used to inform potential suppliers and service providers of specific requirements in the Advertisement of Business Opportunities and later include the criteria in the RFQ/RFP/Tender Dossier (See section 1.5.1 for the implementation of the ethical procurement principles).

NOTE: In an emergency operation, it is optional to publish a general Advertisement of Business Opportunities. Please see Blanket Derogation 4.7.1 (j).

Visibility of the General Terms and Conditions and Code of Conduct for Contractors

In order to make future suppliers and service providers aware of the GTC and COC it is recommended that these documents are made available in a visible place in the Contracting Authority's office (e.g. on a notice board).

4.11.2 Other Sourcing Opportunities

In addition to the mandatory general Advertisement of Business Opportunities, the following list gives examples of common methods to source new suppliers and service providers and general issues to consider when sourcing.

References from other Organisations or Companies

Contact other organisations such as NGO's, UN agencies or NGO networking bodies and learn more about where they procure supplies, services and works.

Internet

Suppliers or service providers can also be sourced via the internet, through search engines such as [Google](#) or relevant national or global portals.

Chamber of Commerce

Often the Chamber of Commerce will have a website with information of their members. Alternatively contact the Chamber of Commerce and ask for a list of suppliers and service providers of the required type of product or service.

Trade Organisations

Search the market for trade organisations. Posting a general Advertisement of Business Opportunities and the Tender Notices in a trade magazine or journal is an effective way of sourcing qualified suppliers and service providers. Contacts to embassies or country representations are likely to produce useful information on trade organisations.

Yellow Pages

Look at the yellow pages or similar online portals, as well as printed directories.

Trade Fairs or Exhibitions

Visit relevant trade fairs, such as the [Medica Trade Fair](#) for medical devices.

Databases

It is highly advisable that the Contracting Authority establish and maintain a supplier database for easy sourcing during the execution of the Procurement Procedures.

Sourcing of Suppliers of Medical Devices

To source suppliers of medical devices, it is recommended that an Advertisement of Business Opportunities is published at the beginning of the year or project period. This advertisement shall invite suppliers of relevant medical devices to be prequalified and registered in the supplier database.

Requirements for suppliers of medical devices are described in section 4.13.2, and in SUP 11-1 Advertisement of Business Opportunities for Medical Devices.

Sourcing Challenges and Considerations

When sourcing new suppliers and service providers in different contexts, different challenges occur. In some contexts, suppliers or service providers may not be familiar with the procurement process and this way of doing business. In that case it is important to ensure that they are informed about the process and ensure that they fill in all the required information in the RFP/RFQ/Tender Dossier, sign and stamp the relevant pages and submit their bid according to the described requirements. Supporting and capacity building potential suppliers or service providers in attending a tender process aims at promoting competition and equal opportunity and thus enable the Contracting Authority to obtain the best quality and value for money. One way of doing this is to conduct vendor trainings where e.g. a Tender Procedure and affiliated requirements are covered. In some contexts, a consequence of not supporting suppliers or service providers in the process may be that the Contracting Authority does not obtain any valid quotes and thus run the risk of delaying project activities. Always ensure that all suppliers and service providers are treated equally and have access to the same information.

Another challenge may be that suppliers or service providers are not interested in participating in a tender procedure because they find it too complicated to submit a quote or proposal for a contract they consider to be of a very low value to them. One way of dealing with this is to keep good contact with the suppliers

and service providers and explain to them why they should submit a quote, proposal or tender. This could also be done in a cover letter submitted with the RFQ/RFP/Tender Dossier.

4.12 TECHNICAL SPECIFICATIONS AND TERMS OF REFERENCE

Technical specifications and TOR define the characteristics of a product or service and take the intended purpose into consideration. Their careful design is very important to the outcome of the procurement process and to the ultimate success of the project. Complete and comprehensive technical specifications and TOR are necessary for suppliers and service providers to respond realistically and competitively to the requirements of the Contracting Authority. They also help the bidder to plan and comment on the requirements and may have a positive effect on their ability to comply with the ethical principles and standards.

Furthermore, complete and comprehensive descriptions can prevent the unfortunate cancellation of a procurement procedure and resulting delays. More importantly, it can prevent the purchase of inadequate or incorrect equipment or services and the waste of tax-payer's money.

In the process of designing the technical specifications and TORs, please consult all relevant stakeholders and if required enlist the assistance of internal or external technical experts.

Technical Specifications

The technical specifications are the minimum standards needed. To receive several offers and to facilitate as much competition as possible, it is important to design genuine technical specifications without restrictions to a specific brand. This does not prevent the contracting Authority from getting what they want, instead it opens the market. As a result, the Contracting Authority might receive offers for suitable products they are not aware of, and for products which did not materialize during the market survey. References can be made to brand- and manufacturers' name, catalogue- and model numbers but are for references only. Such references are to indicate function, quality and performance and are typically referenced by stating 'or equivalent', 'or similar'. Consequently, quotations for other equipment with equal function, quality and performance will be given full consideration. If the contracting Authority is in a situation where only a certain brand or model is suitable, please refer to the exceptions to the competitive rules in section 4.7 Derogations.

In technical specifications for materials, equipment, workmanship and other resources, international standards shall be used as much as possible. Where e.g. a national standard is referred to, the technical specifications shall state that other standards with a quality equal to the standard mentioned will also be acceptable.

Technical specifications, including the characteristics and requirements related to a product or works include:

- Quality levels
- Environmental or social criteria e.g. certifications or equivalent proof of compliance
- Design for all requirements
- Levels and procedures of conformity assessment
- Fitness for use, durability and validity
- Safety
- Marking and visibility requirement
- Other dimensions, e.g. user instructions, testing and test methods, packaging, marking and labelling, production procedures, methods etc.

Examples of Technical Specifications

For a project the following technical specifications were applied in the procurement of Long-Lasting Insecticidal Mosquito Nets:

- Material: 100% Polyethylene (Composition ISO 1833)
- Size: L 180 x W 160 x H 150 cm
- Color: White or grey
- Fabrication: Warp knitted
- Denier: DUPRO min. 100
- Net mesh size: Min 55 holes per inch²
- Weight: Max 45 g/m²
- Shrinkage: Max +/- 5% (ISO 5077/ISO 6330)
- Bursting strength: Min 350 kPa for net material and seems (ISO 3938-1)
- Fire safety: Class 1
- Insecticide: WHOPES recommended, Long Lasting (min 4 years)
- Insecticide concentration: WHOPES recommended

To design technical specifications for works contracts the Procurement Committee is recommended to use internal or external expertise with experience in the field. If an external engineer is chosen to supervise the works, it is beneficial to involve the same engineer in the design of the technical specifications.

Terms of Reference

Programme staff are usually in charge of drafting the TOR. It is important that the TOR includes all requirements related to the service needed, to receive proposals which can fulfil the task and provide the best price and quality ratio.

The TOR aims to ensure that all issues are covered systematically and that key factors related to clarity of objectives and sustainability are considered. The minimum content of a TOR for services is as follows:

- Background information
- Contract purpose and expected results
- Assumptions and risks
- Scope of the services activities
- Timing, logistics and facilities
- Key experts and other personnel
- Subcontracting (if any)
- Reporting
- Environmental or social criteria (e.g. certifications or equivalent proof of compliance)

The SER 2-3 contain an adjustable template for the TOR as do the Request for Proposal (RFP) and the Tender Dossier for Service Contracts.



Learn more about drafting a TOR for Service Contracts in e-training number 6: [Guide to SER 2: Request for Proposal](#).

4.13 PROCUREMENT OF MEDICINE AND MEDICAL DEVICES

Procuring medicine and medical devices is complex, time consuming and requires knowledge of the market, the products required, the national drug regulatory system, occurrence of counterfeits, as well as

knowledge on pre-certification³ and pre-qualification requirements. It is very important to obtain such knowledge at the Project Planning phase in order to be able to plan the purchases correctly, ensure purchase of high-quality products and to meet donor rules and requirements. Note that import may be the only way to ensure quality of products and adherence to the procurement rules. Lack of knowledge and timely planning may result in delays or cancellation of activities, the purchase of counterfeits – with the risk of endangering beneficiaries' lives, wasted time and money, and cost being declared ineligible by donor. Thus, it is very important to set aside time to obtain the required information and ensure thorough procurement planning at the planning phase of a project. It should not be postponed until the implementation phase.

At all times, the aim of procuring medicine and medical devices is to ensure high quality products which are genuine, effective and safe for patients. Quality shall always be the number one priority when procuring medicine and medical devices. To ensure procurement of high quality and genuine products the starting point is always to appoint an ECHO recognised Humanitarian Procurement Centre (HPC).

ECHO recognized Humanitarian Procurement Centres

ECHO recognized HPCs are non-profit entities specialising in buying emergency and health supplies. The HPC conducts efficient and safe procurement and assumes responsibility for purchasing high quality and genuine medicine and medical devices. Appointing an HPC reduces the risk of procuring counterfeits, which is a very important aspect of buying medicine and medical devices. Additionally, when buying from a HPC a Blanket Derogation to negotiate with a single HPC is available (Blanket Derogation h. in section 4.7.1). This, irrespective of the contract value. Procurement from a HPC will be more costly than procuring directly from other suppliers, but to ensure procurement of safe, high quality and genuine products, the appointment of a HPC is of high priority and cost should not be an issue. It is though very important to include all costs related to appointing a HPC in the budget at the project planning phase (admin fee, transport, custom clearance, insurance, etc.). For more details on HPCs, see section 4.8.1.

Pre-certification of Candidates and Pre-qualification of Products

To ensure high quality of products, and to respect patents and national regulations in the individual countries, it is paramount to abide by international norms for procurement of medical products. When procuring from a HPC, this is ensured by the HPC. If it is not possible to procure from a HPC, it is always a requirement that the Contracting Authority shortlist only pre-certified suppliers who can deliver pre-qualified medicine and/or medical devices that meet international standards for production, storage, distribution and management. Suppliers shall always provide proof of the company's pre-certification and pre-qualification of the products they sell. If the Contracting Authority procures medicine and medical devices without appointing a HPC, the applicable Procurement Procedure is always the Negotiated Procedure – irrespective of the contract value.

Counterfeits

The biggest threat to purchasing safe quality products is falsified and sub-standard medicine and medical devices, from hereon called counterfeits. Counterfeits are an immense problem globally, but most common in developing countries where thousands of people die every year due to counterfeit medicines⁴. WHO defines counterfeit medicine as 'Substandard and falsified medical products'. Substandard medicine is authorized medical products which fail to meet either their quality standards and/or their specifications, and unregistered and unlicensed medical products. Falsified medicines are products which deliberately/fraudulently misrepresent their identity composition or source⁵. Counterfeits are prevalent across all categories of medicine and medical devices, ranging from cough medicine and headache pills to vaccines, controlled drugs, syringes or electrical equipment. Due to counterfeits' failure to provide treatment, direct harming ability and the development of drug resistance, they pose a genuine threat to

³ Pre-certified refers to a pre-approved supplier. A supplier is considered pre-certified when he/she has demonstrated to an international recognised certification body that its premises and facilities meet internationally recognised standards (based on WHO norms and standards), and that products are pre-qualified (based on WHO norms and standards) by an international recognised certification body.

⁴ <https://qz.com/africa/1601659/africas-counterfeit-drug-problem-being-tackled-by-innovators/>

⁵ https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1

recipients' lives and public health in general. Counterfeit medicines and medical devices are widespread in the medical market and especially in developing countries. States' weak and inadequate regulatory control systems, high levels of corruption and low law enforcement capacity, enables counterfeits to enter the distribution channels at no risk. In countries with high levels of corruption and instability, it is likely that counterfeits enter the market even though the National Drug Regulatory Authority⁶ which is recognised as a stringent regulatory authority who officially apply WHO norms and standards when pre-certifying candidates and pre-qualifying medical products. Appointing an ECHO recognised HPC significantly reduces the risk of purchasing counterfeits and it is always recommended to procure from a HPC.

Counterfeit Facts⁷

- 10% of global medicine trade is counterfeit
- More than 30% of medicine sold in some areas of Africa and Asia are counterfeits
- WHO estimate that global trade in counterfeit medicine is worth up to EUR 73 billion annually
- 42% of detected cases of counterfeit medicine occurred in Africa
- Antibiotics, painkillers, anaesthetics and malaria medicine are the most often reported counterfeits
- It is estimated that 300.000 children die every year due to counterfeit medicine in Africa alone
- An estimated 300.000 people die every year in China due to counterfeit medicine
- China and India are main players in producing counterfeits and distributing worldwide
- In 2013, 550 million counterfeit medicines with a market value of USD 275 million were seized in 23 African countries in a large scale coordinated operation

Safe Disposal of Medicines and Medical Devices

Recalled, damaged, unwanted or expired medicines (incl. veterinary medicines) or medical devices shall always be disposed of in a safe and appropriate manner, which lives up to national regulations and international best practices. Medicine shall always be treated as pharmaceutical waste and not as regular waste. Some medical devices can be recycled or treated as regular waste. If improper disposal of medicine has been uncovered, it is important to contact the immediate manager and subsequently follow the national rule for the correct disposal.

Depending on the product in question, different methods for safe disposal exist. Some products may be returned to the contractor, some may be handed over to government regulated pharmacies and some products will require disposal via the National Drug Regulatory Authority. National and regional rules shall be adhered to and the Ministry of Health or the National Drug Regulatory Authority shall be contacted to obtain national guidelines on disposal of medicines and medical devices. Disposal should always be undertaken in conjunction with the National Drug Regulatory Authority, but in some countries, there are no, or a limited, legal frameworks in place and therefore no guidelines and official channels to dispose and destroy medicines and medical devices. Under such circumstances, it is advised to consult WHO or other relevant UN agencies or INGOs in the country of operation for guidance and information on how to handle safe disposal of medicine and medical devices.

Read more about what medical products are considered pharmaceutical waste and to be disposed of via official channels, and which products can be recycled or treated as regular waste in the [WHO guideline section 3.4 - 3.7](#).

⁶ A National Drug Regulatory Authority is a general term used to refer to an authority under the Ministry of Health which is responsible for the regulation and administration of the laws on medicines and medical devices.

⁷ <https://enact-africa.s3.amazonaws.com/site/uploads/2018-11-12-counterfeit-medicines-policy-brief.pdf>
<https://www.bayer.com/en/background-information-on-counterfeit-drugs.aspx>
https://www.who.int/medicines/regulation/ssfc/publications/GSMS_Report_layout.pdf?ua=1
<https://edition.cnn.com/2019/03/11/health/fake-drugs-killing-children-study/index.html>
<https://cmpi.org/counterfeit-drugs-and-china-new>
<https://www.europeanpharmaceuticalreview.com/article/92194/the-impact-of-counterfeit-drugs-in-south-and-south-east-asia/>
<http://www.iracm.com/en/2013/06/operation-biyela-record-seizure-of-illicit-medicines-in-africa/>

Please note that some expired or damaged medicine and medical devices are considered hazardous waste when transferred across borders and are regulated under the [Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal](#).

4.13.1 Procurement of Medicine

Medicine, also referred to as pharmaceuticals, is the term used to define medical products comprising chemical substances with intended use for medical diagnosis, cure, treatment, or prevention of disease. Examples of medicine are headache and Malaria pills, vaccines, Oral Rehydration Salts (ORS), Penicillin, Morphine, eye drops, Insulin, etc.

The procurement of medicine is complex and time consuming and requires thorough planning and adherence to a strict Procurement Procedure during implementation. For the planning and implementation of procurement of medicine, it is mandatory to follow the step guide in SUP 11-1.

If the National Drug Regulatory Authority (NDRA) is not recognised as a stringent regulatory authority⁸ medicine can only be sourced from an ECHO recognised HPC or imported from a Country where the NDRA is recognised as a stringent regulatory authority. If this is not possible or a formal derogation has to be submitted to the donor and approved by the donor before procurement of medicine in country can take place.

Throughout the planning and implementation process it is important to keep all relevant documentation in the procurement file and make Notes to File on progress, decision making, findings, challenges, etc.

4.13.2 Procurement of Medical Devices

The term 'medical device' refers to an instrument, apparatus, implement, machines, implants, invitro reagent or a component that provides a diagnosis, cure, mitigation, treatment, or prevention of a disease or condition, which does not achieve its intended use by being metabolised or through a chemical reaction.

Examples of medical devices are walking stick, surgical instruments, contact lens lubricants, condoms, stethoscopes, syringes, needles, bedpans, dressings, bandage, medical test kits, wheelchairs, hearing aids, implantable devices, Magnetic Resonance Imaging (MRI), and Computed Tomography Imaging (CTI).

To establish if a product is defined as a medical device, it is possible to consult the [FDA medical device database](#). The database is administrated by the US Food and Drug Administration and uses internationally agreed descriptions of medical devices from the Global Medical Device Nomenclature (GMDN) system.

Like procurement of medicine, the procurement of medical devices is complex, time consuming and requires thorough planning and adherence to a strict Procurement Procedure during implementation. It is mandatory to follow the step guide in SUP 11-2 for the planning and implementation of procurement of medical devices.

NOTE: Throughout the planning and implementation process, it is important to keep all relevant documentation in the Procurement File and make Notes to File on progress, decision making, findings, challenges, etc.

4.13.3 Procurement of Veterinary Medicine

Subject to the national veterinary drug regulations the Procurement Committee shall strive to assure best veterinary practices and that the product(s) comply with international standards on safety, quality and efficacy for veterinary medicine. This is to protect the health of both animals and consumers of animal products and meat. Please be aware that the risk of purchasing counterfeit veterinary medicines is high in

⁸ For information on what is required to be defined as a stringent regulatory authority, please see page 10 in Annex SUP 11-1.

developing countries. It is always recommended to consult a veterinary practitioner or qualified animal welfare expert when procuring veterinary medicines.

For the procurement of veterinary medicine, the applicable Procurement Procedure shall be established in accordance with the rules and procedures applicable to supplies, described in chapter 6 of the Procurement Manual.

To ensure the procurement of genuine and safe products the suppliers shall as a minimum be registered with the relevant regulatory authority⁹ and the product shall be licensed by this authority.

As a minimum, the following certificates shall be obtained:

- Proof of valid registration with the National Regulatory Authority
- Valid marketing authorisation or product license from the National Regulatory Authority for the product offered.

If possible and pertinent, the following additional certifications shall be obtained:

- ISO 9001:2000. Quality management systems or equivalent from contractor and manufacturer.
- GMP (Good Manufacturing Practice) certificate from manufacturer

The Procurement Committee shall always verify the certificates received from a supplier. Make sure to check the certificates for validity, name and address of the supplier and that the delivered medicines correspond with the certificate. Certificates shall always be filed in the procurement file.

Please take the necessary steps to ascertain that the quality of the product and the shelf life is sufficient upon delivery to the Contracting Authority. E.g. is the packaging broken or damaged? Is the spelling or logo of the product name correct, or could the product be a counterfeit? Etc.

Veterinary medicines shall always be subject to appropriate and safe storage and disposal.

Fatal Consequences of Purchasing Veterinary Counterfeits

For a project in Africa veterinary medicine was purchased to vaccinate app. 300 pregnant goats to ensure the survival of their kids. Proper measures were not taken to ensure the quality of the vaccines and consequently app. 150 goats and their kids died due to the vaccines being toxic counterfeits.

4.14 PROCUREMENT OF FOOD

The following special procurement rules and procedures applicable for the procurement of food are only applicable when food belongs to the category of food for human consumption (fresh and dry food)¹⁰. Included in this food category are also fortified products such as fortified or high calorie foods for prevention or avoidance of malnutrition.

Sourcing of Food Suppliers

Whenever possible and pertinent, procurement of food in the country of operation or neighbouring countries shall be given priority. It is essential to consider the context in which the action is implemented and to make sure that the procurement does not disturb the regional markets significantly and thus adversely affect vulnerable populations. Additionally, the food products shall as much as possible match the nutritional habits of the beneficiary population.

⁹ In most countries the regulation of veterinary medicines is under the National Drug Regulatory Authority.

¹⁰ The purchase of commodities such as wheat or corn/maize intended for agricultural purposes or for animal consumption is to be done in accordance with the general applicable rules and procedures. Note that USAID have special requirements on this issue.

Quality and National Legislation

The characteristics of the products and their packaging shall respect quality standards laid down in the national legislation of the country of origin or the country of destination whichever legislation has the higher quality standard. Where legislation does not exist, internationally recognized standards such as [Codex Alimentarius](#) could be taken as reference to the extent possible.

Procurement of Fresh Food

For procurement of fresh food, flexibility in dividing the fresh food procurement into several lots and with different contracts with various suppliers exists. This flexibility is introduced with consideration to the fact that fresh food is often seasonal, it is often purchased locally and from a variety of suppliers and the value of a contract is often of low or medium value (Simple Procedure or Negotiated Procedure). Splitting the procurement of fresh food into several lots may widen the variety of products, limit the risk of price inflation, reduce overall costs and support the development of the regional and national market economy. Each one of the fresh food lots will be considered individually, and not aggregated, in order to establish the applicable threshold.

Note that this flexibility in dividing procurement into several lots does not apply to the purchase of other types of food e.g. canned food, dry food, precooked food, etc. Also note that procurement of fresh food grown or produced by beneficiaries allows for Blanket Derogation I. to be applied and thus the Simple Procedure can be applied (as a minimum), irrespective of contract value.

Specifications in the RFQ or Tender Documents

For procurement of food the technical specifications shall be supplemented by the following specifications:

- The net weight and cubic meter measurements (m³) of the lots.
- The proposed price per net metric tonne of the product at the place of delivery.
- When of relevance, the transport costs from the place of loading to the place of delivery.
- The net quantity of the products offered shall be specified by the Supplier.
- The delivery deadline and timeframe e.g. where storage facilities at the delivery place are only available from a certain date.
- The accepted deviations in weight, quality and quantity and procedures for establishing reductions of price if accepted deviations are exceeded or if supplies are delivered after the agreed delivery date. Establish conditions for deliveries beyond the contracted delivery date or period.
- When required, apply the contractual Incoterm and the applicable Incoterm edition. When the Incoterm, specified in the Tender Notice, obliges the Supplier to take out a transport insurance policy, this insurance shall be for at least the awarded contract amount and shall cover all risks associated with carriage.
- Requirements to packaging and marking.

Procurement of Food above EUR 300,000

When awarding a food contract with a value higher than EUR 300,000 a monitoring agency shall be responsible for verifying and certifying the quantity, quality, packing and marking of supplies. The necessary provisions in the tender and contractual documents shall be included in order to assure the right of access and monitoring of the Monitoring Agency. If a monitoring agency is used on a regular basis, it is recommended to conclude a Framework Contract.

The award of contracts to monitoring agencies shall be in accordance with the applicable procedure for Service Contracts and shall be awarded prior to the award of the food supply contract. The Monitoring Agency shall never be involved in the selection of suppliers.

Buying from an HPC

When procuring food from an ECHO recognized HPC, the HPC assumes the responsibility of ensuring the required quality and respecting the appropriate procedures. However; the relationship shall always be monitored to assure that the HPC lives up to its contractual responsibilities. When appointing a HPC the Simple Procedure applies and the Contracting Authority can negotiate with a single HPC, irrespective of the contract value. The HPCs have already been approved by ECHO to deliver quality products at competitive prices. For more information on HPCs, please see section 4.8.1.

Therapeutic Food

Therapeutic food is special nutritional food with a therapeutic purpose of addressing moderate or acute malnutrition. This category includes therapeutic milk formulas, nutritional pastes, nutrient-fortified oat bars, etc. Therapeutic food to address moderate malnutrition is considered food supplies and shall be procured in accordance to the special rules and Procurement Procedures applicable to food supplies, see section 6.5.

Therapeutic food to address acute malnutrition is considered medical supplies and shall be procured according to the special rules and procedures for medical supplies in section 4.13.1.

4.15 PROCUREMENT IN EMERGENCY PROJECTS

Procurement in emergency situations falls under Blanket Derogation (a) and (j). Please see section 4.7.1 for details. Consequently, no competitive procedure is applicable, and the Contracting Authority can negotiate with and procure from a single supplier, irrespective of contract value. Emergency projects are also exempted from applying the general Advertisement of Business Opportunities (GEN 8) at the beginning of the project. Please note that the emergency must be declared either by the donor or DCA and cannot be based on circumstances attributed the Contracting Authority, such as delays due to lack of planning. Whenever possible and pertinent, it is recommended to conduct a competitive Procurement Procedure for high value contracts, to obtain the best quality and value for money.

Procurement in emergency projects shall be documented by a Purchase Order or Contract with complete technical specifications or TOR, proof of receipt and an invoice.

4.16 ONLINE PROCUREMENT

Online procurement is a business-to-business purchase and sale of supplies and services over the internet. Typically, web sites allow qualified and registered users to look for buyers or sellers of goods and services. Depending on the approach, buyers or sellers may specify prices or invite bids. Transactions can be initiated and completed online but be aware of fake internet shops and counterfeits available on the internet. Ongoing purchases may qualify customers for volume discounts or special offers.

For online purchases below EUR 10,000 and according to Blanket Derogation (n) in section 4.7.1, it is not a requirement to issue a Purchase Order. However, to minimize commercial risks, it is always recommended.