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| **ANNEX SUP 11-2: Step Guide to Procurement of Medical Devices** |

Please follow the step guide below on how to plan and implement the procurement of medical devices.

Before you start applying the step guide please read the introduction to “Procurement of Medicines and Medical Devices” in section 4.13 of the Procurement Manual.

1. 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, decisions making, findings, challenges, etc.

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| **The Steps Involved in the Planning and Implementation of Procurement of Medical Devices** |
| **Step** | **When** | **Task** | **Description** | **Annex** |
| **1** | Planning | Identify Required Products | Identify what medical devices are required, their basic technical specifications, at what quantities and specific requirements. |  |
| **2** | Planning | Donor Requirements  | Establish if there are any special donor requirements. |  |
| **3** | Planning | The National Legal Framework | Understand the basics of the legal framework for medical devices. |  |
| **4** | Planning | Advice from UN Agencies and NGOs | It is recommended to seek advice and information from relevant stakeholders. |  |
| **Scenario A: The Contracting Authority Appoints a HPC** |
| **5** | Planning | Market Survey | Conduct market survey to establish availability of HPCs and what they are able to deliver in-country or via import.  | GEN 6: Market Survey |
| **6** | Planning | Prepare Lots and Draft the PP | Group resources into lots and draft the Procurement Plan.  | GEN 7-1: Template for Procurement Plan |
| **7** | Planning | Project Application and Derogation(s) | The decision to procure from a HPC is included in the Project Application. If a derogation is needed this is also included. |  |
| **8** | Implementation | Finalize Technical Specifications | The technical specifications are finalized. |  |
| **9** | Implementation | Approach HPC | Approach the HPC, which was identified at the planning phase. |  |
| **10** | Implementation | Purchase Order | Issue the Purchase Order. | SUP 6: Purchase Order |
| **11** | Implementation | Receipt and Inspection | Inspect that the supplies received comply with the Purchase Order and relevant certifications. Sign and file the proof of receipt/delivery note. |  |
| **Scenario B: The Contracting Authority ensures Pre-certification and Pre-qualification** |  |
| **5** | Planning | Market Survey | Conduct market research to establish the market structure, market capacity and the legal framework. |  |
| **6** | Planning | Prepare Lots and Draft the PP | Group resources into lots and draft the Procurement Plan.  | GEN 7-1: Template for Procurement Plan |
| **7** | Planning | Project Application and Derogation | It may be a requirement to include challenges and decision in the project application. If a derogation is needed this is also included.  |  |
| **8** | Implementation | Advertisement of Business Opportunities | A general Advertisement of Business Opportunities is published. | GEN 8:Template for Advertisement of Business Opportunities |
| **9** | Implementation | Finalize Technical Specifications | The technical specifications are finalized. | SUP 2: Request for Quotation |
| **10** | Implementation | Source Pre-Certified Suppliers | A sufficient amount of pre-certified (only) suppliers are sourced. |  |
| **11** | Implementation | Short List  | Only pre-certified suppliers are shortlisted - 4-8 suppliers are recommended. | GEN 13: List of Suppliers and Tender Receipt Form |
| **12** | Implementation | Request for Quotation | Prepare the RFQ and submit it simultaneously to all shortlisted suppliers. | SUP 2: Request for Quotation |
| **13** | Implementation | Evaluation | Evaluate quotations in writing by using the Evaluation Grid. | SUP 4: Evaluation Grid for Negotiated Procedure |
| **14** | Implementation  | Optional Negotiation  | There is an option to negotiate the terms of the contract. Rules are described further in this chapter. |  |
| **15** | Implementation | Final Evaluation and Purchase Order | After final evaluation the Purchase Order shall be issued and sent to the successful supplier. | SUP 4: Evaluation Grid for Negotiated Procedure and SUP 6: Purchase Order |
| **16** | Implementation | Letter to Unsuccessful Suppliers | Unsuccessful suppliers shall be notified of the result of the procedure. | SUP 8: Letter to Unsuccessful Suppliers |
| **17** | Implementation | Award Notice | To be published in a suitable procurement media. | GEN 17: Award Notice (Optional below EUR 30,000) |
| **18** | Implementation | Receipt and Inspection | Inspect that the supplies received comply with the Purchase Order and relevant certificates. Sign and file the proof of receipt/delivery note. |  |

1. **Identify Required Products** (Planning phase)

In cooperation with the project staff it shall be established what medical devices are required for the project, the draft technical specifications and at what quantities. It is important at this first step to consider:

* + 1. **The Product Category**

According to the Global Medical Device Nomenclature (GMDN) system[[1]](#footnote-1) 12 categories of medical devices exist and consist of more than 10,000 generic groups. Medical devices are classified into groups according to the method of operation, the location for use and the associated risks. The risks are related to e.g. whether the medical device is an active or non-active device, invasive or non-invasive device, if it is for temporary, short-term or long-term use, to be used for diagnostic or therapeutic purposes, to be used in combination with a medical drug, etc. It is important to know what category the required medical devices belong to as different regulations and quality requirements may apply. Some category 1 medical devices may be available as ‘over the counter’ products in shops or pharmacies and some may have to be imported and registered at the National Regulatory Authority[[2]](#footnote-2). It is important to obtain this knowledge at the planning phase of a project.

* + 1. **Draft Technical Specifications**

Establish the basic technical specification of each medical device. Unless a company has patent rights for a product it is not allowed to source according to brand. Depending on the complexity of the medical device(s) required it is recommended to consult a technical expert for drafting the technical specifications. It may also be an option to contact the National Regulatory Authority to gain access to a list of approved medical devices (if existent), consult a relevant UN Agency or NGO for advice, or to consult a HPC’s product catalogue.

* + 1. **Counterfeits**

Counterfeit medical devices are widespread on the medical market and especially in developing countries where regulations are limited or non-existent. Counterfeit medical devices pose a risk to patients’ health and to public health in general, as they can be non-sterile, of poor quality, consisting of wrong materials and of questionable effectiveness (e.g. the resale of used syringes or repacked expired condoms). To be able to make thorough procurement decisions and take appropriate actions it is always important to have a basic understanding of the presence of counterfeits on the market and if some product categories pose a higher risk than others. Some basic indicators of the presence of counterfeit medical devices are that: There is no appropriate regulatory system in place; The level of corruption is high; There are unauthorised pharmacies/shops and suppliers on the market; Medical devices are sold from local markets, etc. A basic internet search and search on relevant organisations webpages (e.g. WHO, national or regional associations of pharmaceutical companies/laboratories/manufactures, National Drug Regulatory Authority) will provide useful information.

* + 1. **Quantity**

It is also important to know the quantity needed as it will effect how we further plan and implement procurement. The decision of wether to appoint an ECHO recognised HPC, shortlist pre-certified suppliers or purchase from local shops or pharmacies may be influenced by the quantities required.

**Medical Devices as a Running Cost**

If the Contracting Authority needs to purchase small amounts of e.g. bandage on a running basis these cost are defined as a running cost – if they are not direct project costs (see section 4.10 on running costs in the Procurement Manual). Under such surcumstances it is permitted to purchase small amounts from government approved shops or regulated pharmacies without applying a Procurement Procedure or appointing a HPC. However, the quality requirements to products and suppliers are equal to purchasing medical devices in general.

When procuring medical devices from shops or pharmacies, they shall provide proof of registration with the National Regulatory Authority and proof of pre-qualification. Please refer to Scenario B, Step 5.

* + 1. **Requirements for Transportation and Storage**

Consider specific transport and storage requirements for the medical devices (temperature/humidity/shelf-life, etc). This may vary significantly from product to product. Transportation and storage shall be reflected in the Procurement Plan and in the budget.

1. **Donor Requirements** (planning phase)

It is important to investigate the specific donor requirements applicable to the procurement of medical devices for the project. The rules and procedures outlined in this annex to the Procurement Manual represents the minimum procurement requirements which shall be followed. If stricter Procurement Procedures are stipulated by a donor, the donor requirements shall prevail. E.g. a donor may have specific requirements in respect to the country of origin of the medical devices and nationality of suppliers or specific requirement to the Procurement Procedure. If the donor has less strict requirements for procurement, then the procedures described in this annex shall prevail.

1. **National Legal Framework** (planning phase)

During the planning phase it is important to obtain information on the legal framework for medical devices e.g. administrative regulations, standards and quality schemes, import regulations and procedures, etc. This information is important to be able to make proper and efficient decisions for the further planning and implementation of procurement of the medical devices. The scope, quality and complexity of regulations vary significantly from country to country and in most developing countries no or limited regulation on medical devices is in place. If regulations are in place they are often carried out by a National Regulatory Authority under the Ministry of Health. It is recommended to contact the relevant authority or the Ministry of Health to obtain information and seek assistance and advice on this issue.

1. **Advice from UN Agencies and NGOs** (planning phase)

It is always recommeded to seek advise and support from relevant UN agencies and NGOs in the country of operation. They may be able provide important information and guidance on common pitfalls, the rules and regulations in the country of operation, the precense of counterfeits, time contraints for import and distribution, how to approach legal and practical challenges, etc.

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| **SCENARIO A: The Contracting Authority Appoints a HPC** |

1. **Market Survey** (planning phase)

At this stage of the planning phase we carry out a market survey related to the appointment of a HPC. The market survey shall be carried out to establish:

* **Availability of HPCs**

It shall be established if there is a HPC in the country of operation which can deliver the required medical devices. Find the full list of ECHO recognised HPCs via this link: <http://ec.europa.eu/echo/files/partners/humanitarian_aid/HPC-register_en.pdf>

If there is no HPC in the country of operation it is recommended to contact the Global Logistics Service (GLS)[[3]](#footnote-3) of IFRC as they are able to oversee the import of medical devices to 90 countries worldwide and GLS do not require a minimum order. Please contact GLS to enquire if they can oversee import to the country of operation.

If the HPC is not able to oversee the import of medical devices on behalf of the Contracting Authority the Contracting Authority shall then establish if they are able to import the medical devices. Note that import of medical devices may be regulated by complex laws and the timeframe for import may be very long.

If import via HPC is not possible, please go to Scenario B.

* **What Medical Devices can the HPC provide**

If it is possible to appoint a HPC it is important to assess what medical devices they provide and if they operate with minimum order requirements. Again GLS does not operate with a minimum order. It may also be an advantage to consult the HPC’s product catalogue to put together the list of the medical devices needed and the technical specifications. GLS provide medical devices (and medicine) to emergency operations, NGOs and Governments worldwide and will be able to provide the most common and essential medical device. See the GLS Emergency Item Catalogue: <http://procurement.ifrc.org/catalogue/>.

Due to national legislation some medical devices may have to be sourced from e.g. a government regulated source and not a HPC.

Even though it is possible to procure from a HPC it is still necessary to understand the national regulations. E.g. there may be specific national requirement to the administration, storage and disposal of medicines that has to be adhered to.

If medicines are also needed for the project they shall also be procured from a HPC – if possible.

If the Contracting Authority finds that it cannot purchase the medical devices needed from a HPC, please go to Scenario B.

* **Prices and Total Costs**

When appointing a HPC there is no requirement to compare prices as HPCs always provide the lowest price for pre-qualified products. Please be aware that HPCs charge an administration fee of a maximum of 7% of the total direct costs of the product. It is very important that the total costs of procuring from a HPC are included in the budget (admin fee, transport, custom clearance, insurance etc.)

1. **Prepare Lots and Draft the Procurement Plan** (planning phase)

Based on information obtained in the previous steps, all the required medical devices shall now be grouped into lots in the Procurement Plan (Annex GEN 7-1). For further information on grouping of resources into lots, see section 4.1.1 of the Procurement Manual. Also thoroughly consider the timeframe to appoint the HPC and the potential time delays in delivery (import, transport, etc.).

The decision to appoint a HPC shall be reflected in the Procurement Plan and, if required, in the Project Application to the donor.

To obtain general knowledge on how to work with lots and how to draft a Procurement Plan, please access the e-trainings ‘Working with Lots’ and ‘Step Guide to the Procurement Plan’ via the link: [www.procurement\_e-trainings.org](http://www.danchurchaid.org/about-us/quality-assurance/procurement-and-logistics/the-dca-procurement-manual/dca-procurement-manual-4th-edition)

1. **Project Application and Derogation** (planning phase)

It may be a requirement to include a description of challenges and how the procurement of medical devices will be carried out in the project application to the donor. This depends on donor requirements.

If the information obtained in the previous steps show that the procurement of medical devices require a derogation to the donor’s rules or the rules outlined in this annex to the Procurement Manual a written derogation shall be submitted with the project application to the donor or to the appropriate authority.

For DCA projects: A derogation shall be submitted to the Head of the Procurement and Logistics Unit in Copenhagen, unless the donor rules dictate otherwise.

1. Before any procurement is initiated the members of the Procurement Committee shall sign the Declaration of Impartiality and Confidentiality (Annex GEN 2-1)
2. **Finalize Technical Specification** (implementation phase)

At the planning phase the basic technical specification of the medical devices was drafted. At this stage they are finalized and included in the request to the HPC(s). It may be an advantage to consult the HPC’s procuct catalogue for technical specifications.

1. **Approach the HPC** (Implementation phase)

Based on the outcome of step 5 approach the HPC (from the list of ECHO recognised Humanitarian Procurement Centres). When appointing the HPC the Contracting Authority shall only negotiate with a single HPC irrespective of the contract value. Because HPCs have already been approved by ECHO to deliver quality medical devices that meets the best price, it is not a requirement to approach several HPCs for proof of pre-certification and to compare prices.

It may though be nessesary to approach several HPCs to locate the medical devices. The market survey conducted during the planning phase will have shown this.

Before selecting a HPC and issuing the Purchase Order the Procurement Committee shall verify that the HPC is on ECHO’s list of recognised HPCs.

1. **Purchase Order** (Implementation phase)

Once a HPC has been selected the Purchase Order shall be issued by the Procurement Committee, using the template in Annex SUP 6.

All contractual relations between the HPC and the Contracting Authority shall be specified in the Purchase Order and relevant annexes attached. The following shall be considered and included in the Purchase Order to the HPC:

The HPC shall ensure the identification/breakdown of the different costs in the invoice.

The HPC shall be able to certify that it is recognised as a HPC by ECHO and follow ECHO recognised Procurement Procedures.

The HPC shall show compliance to international standards and quality assurances.

The HPC shall immediately inform the Contracting Authority if a situation occurs where ECHO may cancel the registry of the HPC as an approved HPC.

Delay in shipment/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 thorough technical specifications to the HPC.

Never delete or make alterations to the GTC for Supply Contracts Ver4 2012.

The Purchase Order shall be forwarded unsigned to the selected HPC(s) and retured to the Contracting Authority with all pages duly signed. Only thereafter shall the Purchase Order be signed by the Contracting Authority. Signing the Purchase Order creates a legally binding document for both parties.

1. **Receipt and Inspection** (implementation phase)

Inspect the supplies received to ensure they comply with the Purchase Order. Proceed as described in section 6.5 of the Procurement Manual. Make sure to file proof of receipt or delivery note.

The Procurement Committee shall always verify the certificates received from a HPC. Make sure to check the certificates for validity and that the product description on the certificates actually corresponds with the delivered medical devices. Certificates shall always be filed in the procurement file.

If the appointed HPC has failed to meet quality standards or Procurment Procedures this shall be noted and reported to ECHO.

1. Medical devices shall always be subject to proper administration, and appropriate and safe storage and disposal.

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| **SCENARIO B: The Contracting Authority ensures Pre-certification and Pre-qualification**  |

If the Contracting Authority has found that it is not possible to appoint a HPC, the Contracting Authority are responsible for ensuring that only pre-certified suppliers are contracted to supply only pre-qualified medical devices. This is a complex and time consuming process which takes planning and research skills and at implementaion level it involves applying the Negotiated Procedure. Depending on the complexity of the procurement of medical devices it may be pertinent to hire or consult a specialist to assist in the formulation of the RFQ and contract administration.The Contracting Authority should set aside enough time and resources to thoroughly plan and implement the procurement of medical devices.

* 1. **Market Survey** (planning phase)

A market survey shall be carried out to establish how the market is structured and the legal framework.

**Identify Suppliers who can Deliver Pre-qualifed Medical Devices**

For the purchase of medical devices in developing countries it is often not possible to source suppliers which are already pre-certified by a stringent regulatory body, such as a national regulatory authority (as is the case for medicine). Therefore it is the responsibility of the Contracting Authority to pre-certify suppliers and ensure that the medical devices live up to international quality standards. A market survey shall be carried out to identify the availability of suppliers who can deliver medical devices which, as a minimum, meet the following requirements:

Is produced and labelled in accordance with the Global Harmonization Task Force (GHTF) essential requirements[[4]](#footnote-4). This is often certified via the below ISO standards or equivalent.

Is produced in conformity with at least one of the following standards ISO13485/2003[[5]](#footnote-5), Japan QS Standard for medical devices 1128, the FDA QS (21 CFR part 820), and/or other equivalent standards which are in comformity with the GHTF essential requirements.

Is recognised and marketed according to at least one of the regulatory authorities: MPALS License (Australia), Device License (Canada), CE Mark (EU), Device License (Japan), and Approval Letter (PMA)/510 k Device Letter (USA) – or an equivalent entity.

Only suppliers who can deliver medical devices that live up to these requirements can be considered pre-certified to be shortlisted to participate in a Negotiated Procedure. When medical devices meet the above requirements they are considered pre-qualified.

If it is not possible to source suppliers whose products live up to the above standards in the country of operation, the legal framework for import of medical devices shall be established and products identified on the market outside the country. Note that import of medical devices may be regulated by complex laws and the timeframe for import may be very long. Please make sure to include all costs related to import in the budget.

If sourcing of pre-qualified products in the country of operation or via import is not possible, it is recommended to contact the donor for further discussion and advice on how to procure medical devices for the project.

It is always recommended to search relevant websites for information and to consult other humanitarian actors in the country or region for information and advice on how to source suppliers who can provide pre-qualified products. They may be able to provide a list of suppliers.

1. Be aware of specific donor requirements to origin and nationality

**Market Capacity**

The capacity of the identified suppliers shall be established. What amounts can be delivered? What is the delivery time? What is the average validity of offers in the context? Are suppliers interested in making business? Etc.

Dependent on the quantities and the context, it is also important to take into consideration how procurement may affect the market and ensure that it will not be affected in a negative manner.

**National Regulatory Authority**

For a National Regulatory Authority to be recognised to pre-certify suppliers and pre-qualify medical devices their quality and control systems shall be based on the above listed requirements and standards. As mentioned earlier most developing countries have limited or no medical device regulation and often do not have such systems in place.

Despite none or limited regulation and control systems, the National Regulatory Authority may apply the above standards when procuring medical devices for the public sector and they may be able to provide a list of suppliers who deliver pre-qualified medical devices (as per above requirements).

* 1. **Prepare Lots and Draft the Procurement Plan** (planning phase)

Based on the information obtained in the previous steps, all the medical devices shall now be grouped into lots in the Procurement Plan (Annex GEN 7-1). For further information on grouping of resources into lots, see section 4.1.1 of the Procurement Manual. Irrespective of the value of the lot(s) the Negotiated Procedure shall always be assigned to the lot(s).

Also thoroughly consider the timeframe for carrying out the Negotiated Procedure and possible time delays. It can take up to 8 weeks to carry out the Negotiated Procedure, to which the delivery to site shall be added. Also, if the planning of the procurement of medical devices is inadequate at the planning phase it may take additional weeks or months to carry out the Procurement Procedure during implementation.

To obtain general knowledge on how to work with lots and how to draft a Procurement Plan, please access the e-trainings ‘Working with Lots’ and ‘Step Guide to the Procurement Plan’ via the link: [www.procurement\_e-trainings.org](http://www.danchurchaid.org/about-us/quality-assurance/procurement-and-logistics/the-dca-procurement-manual/dca-procurement-manual-4th-edition)

* 1. **Project Application and Derogation** (planning phase)

It may be a requirement to include a description of challenges and how the procurement of medical devices will be carried out in the project application to the donor. This depends on the donor.

If any special agreements with the donor have been agreed to during the planning phase of the project, this shall be included in the project proposal to the donor.

If the information obtained in step 1-6 show that the procurement of medical devices require a derogation to the donor’s rules or the rules outlined in this annex, a written derogation shall be submitted with the project application to the donor or to the appropriate authority.

For DCA projects: A derogation shall be submitted to the Head of The Procurement and Logistics Unit in Copenhagen, unless the donor rules dictate otherwise.

Before any procurement is initiated the members of the Procurement Committee shall sign the Declaration of Impartiality and Confidentiality (Annex GEN 2-1)

* 1. **Advertisement of Business Opportunities** (implementation phase)

The publishing of an advertisement of business opportunities is mandatory and shall be posted in the newspaper, on a notice board or in other public places in the beginning of a project and before the procurement process is initiated. This advertisement is published to inform the suppliers of possible business opportunities and to source pre-certified suppliers for shortlisting. This is a general advertisement and can include other goods, services and/or works.

The template in Annex SUP 11-3 shall be utilized for the advertisement of business opportunities. See section 4.11.1 in the Procurement Manual for more information on advertisement of business opportunities.

The requirements to the suppliers to deliver only pre-qualified medical devices shall be informed in the advertisement and suppliers shall be informed of their obligation to provide proof that the medical devices as a minimum meets the following standards and requirements:

Is produced and labelled in accordance with the Global Harmonization Task Force (GHTF) essential requirements[[6]](#footnote-6). This is often certified via the below ISO standards or equivalent.

Is produced in conformity with at least one of the following standards ISO13485/2003[[7]](#footnote-7); Japan QS Standard for medical devices 1128, the FDA QS (21 CFR part 820), and/or other equivalent standards which are in comformity with the GHTF essential requirements.

Is recognised and marketed according to at least one of the regulatory authorities: MPALS License (Australia), Device License (Canada), CE Mark (EU), Device License (Japan), and Approval Letter (PMA)/510 k Device Letter (USA) – or an equivalent entity.

The Contracting Authority may find that other relevant ISO standards[[8]](#footnote-8) and/or other equivalent standards shall be added to ensure quality, efficiency and safety for patients.

* 1. **Finalize Technical Specifications** (implementation phase)

At the planning phase the basic technical specification of the medical devices was drafted. At this stage they shall be finalized and included in the Request for Quotation (RFQ). Depending on the technical complexity of the medical devices it may be nessesary to involve a technical expert in this process.

**Step 10: Source Suppliers** (implementation phase)

Depending on the outcome of the advertisement of business opportunities a sufficient amount of pre-certified suppliers may have been identified to be shortlisted. A supplier is considered pre-certified when he/she has proven that products are pre-qualified according to the above listed standards and requirements (step 8).

If the outcome of the advertisements was not sufficient to ensure genuine competition, additional sourcing shall be initiated. The sourcing method will vary from context to context. In some countries the National Regulatory Authority or the Ministry of Health will be able to provide a list of suppliers who can provide pre-qualified medical devices or e.g. a relevant UN Agency or NGO will be able to provide information and give advice on the matter. You may also search the internet, an existing database or contact suppliers by phone or e-mail. It is also an option to post an additional Advertisement of Business Opportunities (Annex SUP 11-3) in relevant magazines or webpages. Irrespective of the sourcing method, suppliers who show interest in being shortlisted shall provide proof of the quality requirements and standards.

It is recommended to source between 4-8 suppliers to ensure genuine competition.

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. Certificates shall always be filed in the procurement file.

**Step 11: Short List** (implementation phase)

Based on the outcome of the sourcing process prepare a short list of only pre-certified suppliers. The shortlisting of pre-certified suppliers shall be documented in the procurement file using the template in annex GEN 13.

The number of shortlisted suppliers shall be sufficient to ensure genuine competition. It is recommended to shortlist 4-8 suppliers, but the market situation for each product, technical complexity of the device, availability of pre-certified suppliers and pre-qualified products, and critical dates for delivery may determine the number of suppliers approached.

In some contexts suppliers are unwilling to participate in a Negotiated Procedure with a low contract value. This challenge shall be factored into the amount of pre-certified suppliers to be shortlisted.

**Step 12: Request for Quotation** (implementation phase)

The RFQ shall be prepared with considerations to:

* Delivery terms (e.g. partial deliveries, Incoterms).
* Technical specifications
* Product performance and functionality requirement.
* Special requirements to packing, storage, transport, shelflife (e.g. 2/3 left of shelflife upon reciept) etc.
* Specific donor requirements
* Requirements to installation, maintenance, trainings, after sales service, spare parts, product guarantees, etc.
* Deadline for receipt of quotations (it is recommended to allow a minimum of two weeks depending on the complexity of the requirements).
* Payment terms.
* Evaluation criteria (shall include documentation of pre-qualification of products).
* Required documentation (standards, registrations, certifications).
* List of references.
* Ethical critera.
* If a Tender Guarantee and/or Performance Guarantee shall be required (recommended for contracts above EUR 50,000. Please read section 9.3 in the Procurement Manual for more information on guarantees).
* The inclusion of additional internationally recognised standards.
* The selection criteria shall specify that priority is given to suppliers that comply with at least one of the following standards: Japan QS standard for medical devices 1128, ISO9002/1994, ISO 13485 or equivalent standards.
* Manufacturer authorisation/information if supplier is not the manufacturer.

The RFQ shall be prepared thoroughly and forwarded simultaneously (same day) to all the shortlisted pre-certified suppliers. This is to ensure that all suppliers are given an equal amount of time to prepare and submit their offer. At this stage it is also important to communicate the ethical principles and standards to the suppliers.

To assist and encourage suppliers to submit a quote it is recommended to submit a ‘cover letter’ with the RFQ. See annex GEN 1-2 Guidance Letter to Suppliers for an example of a RFQ cover letter. For many projects the contract value will be quite low in comparison to what the medical industry normally deal with. Therefore it is recommended to include in the coverletter, or by personal contact, an explanation as to why the supplier should support the project by delivering the required medical devices.

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| **Follow up on Submission of the RFQ**To ensure that sufficient offers will be received on time it is recommended to contact all shortlisted suppliers 1-2 days after submitting the RFQ to ask the suppliers if they intend to submit an offer before the deadline. When a short deadline is required, it is particularly good practice to follow up with the suppliers and explain the importance of completing the Submission Form and submitting the offer prior to the deadline. |

**Step 13: Evaluation** (implementation phase)

Upon receipt of the quotations, register the time when the offers were received and carry out the evaluation utilising the Evaluation Grid in annex SUP 4. Please adapt the Evaluation Grid to the RFQ. Please note that suppliers who have submitted their quotation after the deadline shall not be considered.

For comparison and evaluation of the quotations, the Procurement Committee shall take into consideration the criteria selected in the RFQ. Instructions are included in the Evaluation Grid (see annex SUP 4).

When evaluating the prices of the quoted medical devices, the cost of the entire treatment shall be taken into consideration (not just the cost per unit). Additionally the choice may also be influenced by other factors such as transportation charges, storage requirements and shelf-life. The total cost shall be considered. If a medicial device price database is available it shall be consulted for price comparison.

Please note, that if the quoted price for a medical device is significantly lower than the other quotes, this may indicate that the medical device is of poor quality and/or a counterfeit.

The overriding aim of the Procurement Procedure is to source high quality products which are genuine, effective and safe for patients. To this end, please keep in mind the principle of best value for money and apply the award criteria that call for the lowest price meeting the technical specifications and pre-qualification. Quotes from pre-certified suppliers who fail to provide proof of pre-qualified products shall be declined.

The Procurement Committee may apply a different evaluation procedure. This shall then be amended in the RFQ and the Evaluation Grid shall be adjusted accordingly.

The Procurement Committee shall always verify the certificates received from a supplier. Make sure to check the certificates for validity and that the product description on the certificates actually corresponds with the received medical device. Certificates shall always be filed in the procurement file.

**Step 14: Optional Negotiation** (implementation phase)

If pertinent, the Procurement Committee has the option to negotiate the terms of the Contract. Negotiations shall not entail any substantial deviation from the terms and conditions of the RFQ, but shall have the purpose of obtaining better conditions in terms of delivery date, payment conditions, etc.

Negotiations may however have the purpose of reducing the scope of the supply or revising other terms of the Contract in order to reduce the total price. This may be necessary when prices proposed by all suppliers exceed the limits of the funds made available to the Contracting Authority by its donor/funding agency.

Negotiation can also facilitate a discussion on identified ethical risks in order to find possible solutions or determine if the proposal shall be turned down.

The negotiations can be done by email, fax, phone or at a meeting. In the latter two cases, a written recap shall be prepared, filed, copied and submitted to the Supplier. There are no specific procedures on negotiations except that the General Procurement Principles shall always be respected.

When negotiating the terms, consider how requirements on e.g. lead times and price may affect the supplier’s ability to comply with the ethical principles and standards.

**Step 15: Final Evaluation and Purchase Order** (implementation phase)

If pertinent, the Procurement Committee has the option to negotiate the terms of the Contract. Negotiations shall not entail any substantial deviation from the terms and conditions of the RFQ, but shall have the purpose of obtaining better conditions in terms of delivery date, technical quality, payment conditions etc.

Negotiations may however have the purpose of reducing the scope of the supply or revising other terms of the contract in order to reduce the total price. This may be necessary when the prices proposed by all suppliers exceed the limits of the funds made available to the Contracting Authority by its donor/funding agency. In this case, all suppliers involved should be invited to participate in the negotiations and to potentially submit a new offer.

The Purchase Order is then issued by the Procurement Committee in accordance with the template in annex SUP 6. Check if the Purchase Order has to be adapted to national legislation, traditions or requirements, as appropriate. Never delete or make alterations to the GTC for Supply Contracts Ver4 2012. Incorporate in the Purchase Order all agreements reached with the selected Supplier and attach the relevant annexes.

The Purchase Order shall be forwarded unsigned to the selected Supplier and returned to the Contracting Authority with all pages duly signed.

Before signing the Purchase Order and returning the signed copy to the Supplier, the Procurement Committee shall ensure:

* That adequate and exact reference is made in the Purchase Order to the relevant RFQ.
* That the Supplier acknowledges the GTC and the Code of Conduct for Contractors without exceptions or amendments.
* That proof of pre-qualification is verified.

Only thereafter shall the Purchase Order be signed by the Contracting Authority. Signing the contract creates a legally binding document for both parties.

**Step 16: Letter to Unsuccessful Suppliers** (implementation phase)

Once the selected Supplier has returned the Purchase Order duly signed, a letter shall be sent to the unsuccessful suppliers informing them of the result of the procedure i.e. the name of successful supplier and the total contract amount. Please use the template in annex SUP 8.

**Step 17: Award Notice** (implementation phase)

The purpose of the public announcement is to meet the principle of transparency with the added benefit of attracting new suppliers. Thus the award notice is useful and recommended for all contracts.

For contracts above 30.000 EUR it is mandatory to publish Award Notices in a suitable media where suppliers will notice the information and on the Contracting Authority’s website. Please refer to GEN 17 for relevant information.

The publishing of an Award Notice can be exempted if the Procurement Committee considers that a public notice might endanger the organisation’s safety or harm its interests.

1. The Procurement Committee shall take notice of any specific donor requirements for publishing an Award Notice.

**Step 18: Receipt and Inspection** (Implementation phase)

Inspect that the received medical devices comply with the Purchase Order and that the product description on the certificates corresponds with the delivered medical device. Proceed as described in section 6.5 of the Procurement Manual.

Please take the necessary steps to ascertain the quality of the medical devices upon delivery to the Contracting Authority. E.g is the packaging broken or damaged? Is the spelling or logo of the product name correct?Could the medical device be a counterfeit? Etc. Also make sure that shelf life is in accordance with the aggreed terms in the RFQ.

When relevant medical devices shall be subject to proper maintenance, and safe storage and disposal.

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| **Mandatory annexes for the procurement of medical devices** |  |
| GEN 2-1 | Declaration of Impartiality and Confidentiality  | Mandatory | Scenario A+B |
| GEN 7-1 | Template of Procurement Plan | Mandatory | Scenario A+B |
| SUP 11-3 | Template for Advertisement of Business Opportunities for Medical Devices | Mandatory | Scenario A+B |
| GEN 13 | List of Suppliers/Candidates and Tender Receipt Form  | Mandatory | Scenario B |
| SUP 2 | Request for Quotation  | Mandatory | Scenario B |
| SUP 4 | Evaluation Grid for Negotiated Procedure  | Mandatory | Scenario B |
| SUP 6 | Purchase Order  | Mandatory | Scenario A+B |
| SUP 8 | Letter to Unsuccessful Suppliers  | Mandatory | Scenario B |
| GEN 17 | Award Notice  | Mandatory (Optional below EUR 30,000) | Scenario B |

1. The Global Medical Device Nomenclature (GMDN) is a system of internationally agreed terms used to identify medical devices. It is used by regulators, hospitals and manufacturers to identify medical devices that are of the same generic type. [↑](#footnote-ref-1)
2. This authority may have a different name in the country of operation, but if established it will be an authority under the Ministry of Health. Often it will be the same regulatory authority as for the regulation of medicine. Note that in some countries medical devices are not subject to regulation or very limited regulation. [↑](#footnote-ref-2)
3. GLS webpage: <http://www.ifrc.org/en/what-we-do/logistics/key-logistics-services/> [↑](#footnote-ref-3)
4. Production shall be in conformity with the GHTF, SG1- N041R6 found at: <http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0001-bkg0001-05-sg1_n041r6.pdf> and labelling of medical devices shall be in conformity with GHTF SG1(PD) - N043R6 found at <http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0352-bkg0001-vol1.pdf> (ISO 14971/2007: Application of risk management to medical devices is in conformity with the GFT SG1(PD)). Note that GHTF is not operational anymore, a new harmonization forum was established in 2011- see <http://www.imdrf.org/>. The GHFT essential requirement are still applied. [↑](#footnote-ref-4)
5. ISO 13485 is an international recognised standard for quality management systems for medical devices defined by the International Standardization Organisation (ISO 13485 supersedes EN46001/ EN46002, and ISO13488). ISO standards are accredited by specialised certification bodies. [↑](#footnote-ref-5)
6. Production shall be in conformity with the GHTF, SG1- N041R6 fount at <http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0001-bkg0001-05-sg1_n041r6.pdf> and labelling of medical devices shall be in conformity with GHTF SG1(PD) - N043R6 found at <http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0352-bkg0001-vol1.pdf> (ISO 14971/2007: Application of risk management to medical devices is in conformity with the GHFT SG1(PD)). [↑](#footnote-ref-6)
7. ISO 13485 is an international recognised standard for quality management systems for medical devices defined by the International Standardization Organisation. ISO standards are accredited by specialised certification bodies. ISO 13485 supersedes EN46001/ EN46002, and ISO13488. [↑](#footnote-ref-7)
8. It is recommended to search the ISO webpage (<http://www.iso.org/iso/home.html>) for standards relevant to the products (e.g. ISO7886-1/1993 for syringes for single use). [↑](#footnote-ref-8)