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| **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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| **Steps Involved in the Planning and Implementation of Procurement of Medical Devices:** |
| **Step** | **When** | **Task** | **Description** | **Template** |
| **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 an ECHO recognised 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: 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** | Implementa-tion | Purchase Request and final Technical Specifications | The Purchase Request Form is issued, and technical specifications finalised. | GEN 1-1: Purchase Request Form |
| **9** | Implementa-tion | Approach HPC | Approach the HPC, which was identified at the planning phase. |  |
| **10** | Implementa-tion | Purchase Order | Issue the Purchase Order. | SUP 6: Purchase Order |
| **11** | Implementa-tion | 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. |  |
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| **Scenario B: The Contracting Authority ensures 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: 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** | Implementa-tion | Advertisement of Business Opportunities | A general Advertisement of Business Opportunities is published. | GEN 8: Advertisement of Business Opportunities |
| **9** | Implementa-tion | Purchase Request and final Technical Specifications | The Purchase Request Form is issued, and the technical specifications are finalized. | GEN 1-1: Purchase Request Form SUP 2: Request for Quotation |
| **10** | Implementa-tion | Source Suppliers | Enough suppliers are sourced. |  |
| **11** | Implementa-tion | Short List  | Suppliers registered with authorities are shortlisted - 4-8 suppliers are recommended. | GEN 13: List of Suppliers and Tender Receipt Form |
| **12** | Implementa-tion | Request for Quotation | Prepare the RFQ and submit it simultaneously to all shortlisted suppliers. | SUP 2: Request for Quotation |
| **13** | Implementa-tion | Evaluation | Evaluate quotations in writing by using the Evaluation Grid. | SUP 4: Evaluation Grid for Negotiated Procedure |
| **14** | Implementa-tion  | Optional Negotiation  | There is an option to negotiate the terms of the contract. Rules are described further in this chapter. |  |
| **15** | Implementa-tion | 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** | Implementa-tion | Letter to Unsuccessful Suppliers | Unsuccessful suppliers shall be notified of the result of the procedure. | SUP 8: Letter to Unsuccessful Suppliers |
| **17** | Implementa-tion | Award Notice | To be published in a suitable procurement media. | GEN 17: Award Notice (Optional below EUR 30,000) |
| **18** | Implementa-tion | 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. |  |
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* 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 Class**

Medical devices consist of a wide range of equipment/devices/accessories that serves for diagnostics, treatment and prevention of diseases and medical conditions. According to the Global Medical Device Nomenclature (GMDN) system[[1]](#footnote-1) 12 categories of medical devices exist, which consist of more than 10,000 generic groups. These categories are all divided into three classes related to health and safety risks (four classes in Japan). Class I being the lowest risk and III being the highest risk class. Please see below examples of medical devise classifications:

Class I: Wheelchair, bandage, thermometers and oxygen masks.

Class II: Syringes, test kits, blood transfusion kits, catheters and blood pressure cuffs

Class III: Implants, defibrillators and pacemakers

Class I medical devices will in most countries be available as ‘over the counter’ products in shops and pharmacies and authorities may not require that class I products are licensed/marked. Class II and III products will require licencing and sourcing from suppliers approved by the National Regulatory Authority[[2]](#footnote-2). It is important to obtain this knowledge at the planning phase of a project. Documentation requirements apply accordingly.

* + 1. **Draft Technical Specifications**

In cooperation with the project staff (e.g. medic) establish the basic technical specification of each medical device. Depending on the class and 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 registered suppliers (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; Unauthorised pharmacies/shops and suppliers exists 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 suppliers registed with autorties or purchase very small amounts from local shops or pharmacies will 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. See step 5, scenario B for requirements. If this is not possible in the context of operation, a formal derogation must to be applied for.

* + 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 know the specific donor requirements applicable to the procurement of medical devices for the project. The rules and procedures outlined in this document 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, the procedures described in this document 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 an ECHO recognised HPC** |

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

At this stage of the planning phase we carry out a market survey related to the appointment of an [ECHO recognised Humanitarian Procurement Centr](https://www.dgecho-partners-helpdesk.eu/actions_implementation/procurement_in_humanitarian_aid/hpc)e (HPC). The market survey shall be carried out to establish:

* **Availability of HPCs**

It shall be established if there is an ECHO recognised HPC in the country of operation which can deliver the required medical devices.

If no HPCs are based in the country of operation it is recommended to contact a HPC outside the country of operation. This however require that the Contracting Authority can obtain an import licence for the medical devices. Note that import of medical devices may be regulated by complex laws and the timeframe for import may be very long and, in some cases, not possible.

If neither local sourcing via HPC or 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. 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.

Even though it is possible to procure from a HPC it is still necessary to understand the national regulations. E.g. some items may have to be sourced from government appointed suppliers, and there may be specific national requirement to the administration, storage and disposal of medicines that shall be adhered to. To be able to adhere to National legislation a formal request for derogation to the donor may be required.

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

* **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 products. 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 (Template 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’](https://fabo.org/course/Working_with_Lots) and [‘Step Guide to the Procurement Plan’](https://fabo.org/course/Step_Guide_to_Procurement_Plan).

* 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 (Template GEN 2-1).
	1. **Purchase Request and Finalise Technical Specification** (implementation phase)

At this step the formal purchase request is issued to authorise the procurement of the medical devises. The purchase request is issued outside the Procurement Department (e.g. project staff or medic) and includes the final technical specification, ensures sufficient budget, it authorises the procurement of the medical devices and requests the procurement responsible staff to procure the items. 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 is only required to approach a single HPC irrespective of the contract value. This because ECHO recognised HPCs are already approved by ECHO to deliver quality medical devices that meets the principles of best price.

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 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:

Provide clear and thorough technical specifications 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.

Never delete or make alterations to the GTC for Supply Contracts Ver5 2020. If articles in GTC needs ammendmends, this is described in the special conditions of the Purchase Order.

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.

Medical devices shall always be subject to proper administration, and appropriate and safe storage and disposal. Please also refer to the [Logistics Manual chapter 2](file:///C%3A/Users/kaf/Downloads/Logistics_Manual_2nd%20%283%29.pdf): Warehouse and Stock Management for more information.

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

If the Contracting Authority has found that it is not possible to appoint an ECHO recognised HPC, the Contracting Authority are responsible for ensuring that only suppliers who can provide pre-qualified medical devices are shortlisted to participate in a Negotiated Procedure. Depending on the class of the producs, the context and the legal framwork, this may be a complex and time consuming process which takes planning and research skills. 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**

Medical devices must live up to international quality standards and the Contracting Authority shall identify suppliers who are registered with the authorities and can provide products that live up to below minimum requirements:

Is produced and labelled in accordance with the International Medical Device Regulators Forum (IMDRF) essential requirements[[3]](#footnote-3). This is certified via the below licences and markings and international standards.

Is recognised by at least one of the regulatory authorities and labelled accordingly: ARTG registration[[4]](#footnote-4) (Australian Register of Therapeutic Goods); Medical Device Active License Listing[[5]](#footnote-5) (MDALL Canada), CE Mark[[6]](#footnote-6) (MDR EU); MAH or Manufacturere License (PMDA Japan); and/or PMA Approval Letter / 510 (k) Substantially-equivalent Letter/ Registration and Device Listing[[7]](#footnote-7) (FDA USA) – or an equivalent entity. Suppliers shall provide proof hereof.

Note that some of the above authorities only register and licence for class II and III medical devises and thus requirements to proof of registration/licensing applies accordingly.

Priority shall be given to suppliers who can privide proof of one of the following standards: ISO13485[[8]](#footnote-8), Japan QS Standard for medical devices 1128, the FDA SQR (21 CFR part 820), and/or other equivalent standards which are in comformity with the IMDRF essential requirements.

The Contracting Authority may find that other relevant ISO standards[[9]](#footnote-9) and/or other equivalent standards shall be added to ensure quality, efficiency and safety for patients.

Only suppliers who can deliver medical devices which live up to the above requirements can 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 requirements and 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 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. A formal request for derogation may have to be submitted to the donor.

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 e.g. 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**

In most contexts it is the National Drug Regulatory Authority (NDRA) which carry out pre-qualification of medical devices. Their quality and control systems in place shall be based on a wide range of requirements and standards defined by the GHTF. As mentioned earlier most developing countries have limited or no medical device regulation and often do not have such systems in place. Thus, the above requirements to licensing, standards and marking shall be applied.

* 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 (Template 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’](https://fabo.org/course/Working_with_Lots) and [‘Step Guide to the Procurement Plan’](https://fabo.org/course/Step_Guide_to_Procurement_Plan).

* 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 document, 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. **Advertisement of Business Opportunities** (implementation phase)

The publishing of an general 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 the overall business opportunities and to source suppliers for shortlisting. This is a general advertisement and can include other goods, services and/or works. See section 4.11.1 in the Procurement Manual for more information on advertisement of business opportunities.

If there is an additional or specific need to identify suppliers who can provide pre-qualified medical devices a separate advertisement can be published. The template in SUP 11-3 can be utilized.

In the advertisement the requirements listed in step 5 (section B) shall be included as mandatory requirements to products and suppliers shall be informed of their obligation to provide proof, upon submission of quotes. Suppliers shall also be informed that registration with authorities is a requirement and they shall provide proof of a valid registration to be shortlisted.

1. Before any procurement is initiated the members of the Procurement Committee shall sign the Declaration of Impartiality and Confidentiality (Template GEN 2).
	1. **Purchase Request and Final Technical Specifications** (implementation phase)

At this step the formal Purchase Request Form (Template GEN 1-1) is issued to authorise the procurement of the medicine. The purchase request is issued outside the Procurement Department (e.g. project staff or medic) and includes the final technical specification, ensures enough budget, it authorises the procurement of the medical devises and requests the procurement responsible staff to start procurement procedure.

At the planning phase the basic technical specification of the medical devices was drafted. At this stage they shall be finalised by staff outside the Procurement Department (e.g. a medic or doctor) and included in the Request for Quotation (RFQ). Depending on the technical complexity and classisfication 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 number of qualified suppliers may have been identified to be shortlisted.

If the outcome of the advertisements was not enough 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 are registered with authorities and can provide pre-qualified medical devices or e.g. a relevant UN Agency or INGO 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 (Template SUP 11-3) in relevant magazines or webpages.

Irrespective of the sourcing method, suppliers who show interest in being shortlisted shall provide proof of registration with authorities and state that their products live up to the quality requirements and standards specified in step 5 and 12 (section B).

The Procurement Committee shall always verify registrations and 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 suppliers registred with authoritues and who can provide pre-qualified medical devises. The shortlisting shall be documented in the procurement file using the template in 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-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 must, to the extend possible, be factored into the amount of suppliers to be shortlisted.

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

The Request for Quotation in Template SUP: 2 shall be prepared with considerations to:

* Clear and thorough technical specifications
* Product performance and functionality requirement.
* Include the mandatory requirement that quoted producst shall be recognised by at least one of the regulatory authorities and labelled accordingly: ARTG registration[[10]](#footnote-10) (Australian Register of Therapeutic Goods), Medical Device Active License Listing[[11]](#footnote-11) (MDALL Canada), CE Mark[[12]](#footnote-12) (MDR EU), MAH or Manufacturere License (PMDA Japan); and/or PMA Approval Letter / 510 (k) Substantially-equivalent Letter/ Registration and Device Listing[[13]](#footnote-13) (FDA USA) – or an equivalent entity. Suppliers shall provide proof hereof with their quotation.

(Note that some of the above authorities only register and licence for class II and III medical devises and thus requirements to proof of registration/licensing applies accordingly.)

* Evaluation criteria’s

The evaluation criterias shall specify that priority is given to suppliers who can privide proof of one of the following standards: ISO13485[[14]](#footnote-14), Japan QS Standard for medical devices 1128, the FDA SQR (21 CFR part 820), and/or other equivalent standards which are in comformity with the IMDRF essential requirements.

* Special requirements to packing, storage, transport, shelflife (e.g. 2/3 left of shelflife upon reciept) etc.
* Delivery terms (e.g. partial deliveries, Incoterms).
* 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.
* Required documentation to be submitted (standards, registrations, Licences, certifications, product sheets etc.).
* List of references.
* Ethical criteras.
* Is there a need for suppliers providing financial guarantees? (Please read section 9.3 in the Procurement Manual for more information on finance guarantees).
* The inclusion of additional internationally recognised standards.
* Manufacturer authorisation/information/certifications 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.

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 a coverletter with the RFQ, or by personal contac, provide 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 receipt of enough quotes it is recommended to contact all shortlisted suppliers 1-2 days after submitting the RFQ, to enquire if they intend to submit a quote. When a short deadline is required, it is particularly good practice to follow up with the suppliers and explain the importance of completing the Quotation 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 Template 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 Template 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. 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, including that products live up to pre-qualification requirements. Quotes from suppliers who fail to provide proof of products beting recognised by one of the listed authorities in step 5 and 12 (pre-qualified products) shall be declined.

The Procurement Committee shall always verify the received license, registrations and certificates. Make sure to check for validity and that the product description actually corresponds with the quoted medical devices. Such documents shall always be filed in the procurement file. Note that some authorities, eg FDA USA, provide databases on suppliers/manufacturers of approved medical devises. If avaialbe these databases can also be consulted for verification.

**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)

The Purchase Order is issued by the Procurement Committee in accordance with the template in 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 Ver5 2020. 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 Purchase Order 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 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 the template in 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 staff and safety or harm its interests. See section 4.7.1 in the Procurement Manual - Blanket Derogation k.

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, registration or licences 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 Templates for the procurement of medical devices** |  |
| GEN 1-1 | Purchase Request Form | Mandatory | Scenario A+B |
| GEN 2-1 | Declaration of Impartiality and Confidentiality  | Mandatory | Scenario A+B |
| GEN 7-1 | Procurement Plan | Mandatory | Scenario A+B |
| SUP11-3 | 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. Production shall be in conformity with the [IMDRF Essential Principles of Safety and Performance of Medical devices and IVD Medical Devices](http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf) and IMDRF [Principles of Labelling for Medical Devices and IVD Medical Devices](http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-pl-md-ivd.pdf) [↑](#footnote-ref-3)
4. <https://www.tga.gov.au/medical-devices-overview> [↑](#footnote-ref-4)
5. <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/licences/medical-devices-active-licence-listing.html> [↑](#footnote-ref-5)
6. <https://laegemiddelstyrelsen.dk/en/devices/ce-marking/> / <https://ec.europa.eu/growth/sectors/medical-devices_en> [↑](#footnote-ref-6)
7. <https://www.fda.gov/medical-devices> [↑](#footnote-ref-7)
8. [ISO 13485](https://www.iso.org/standard/59752.html) 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. [↑](#footnote-ref-8)
9. 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-9)
10. <https://www.tga.gov.au/medical-devices-overview> [↑](#footnote-ref-10)
11. <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/licences/medical-devices-active-licence-listing.html> [↑](#footnote-ref-11)
12. <https://laegemiddelstyrelsen.dk/en/devices/ce-marking/> / <https://ec.europa.eu/growth/sectors/medical-devices_en> [↑](#footnote-ref-12)
13. <https://www.fda.gov/medical-devices> [↑](#footnote-ref-13)
14. [ISO 13485](https://www.iso.org/standard/59752.html) 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. [↑](#footnote-ref-14)