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|  | **ANNEX SUP 11-1: Step Guide to Procurement of Medicine** |

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

Before you start applying the step guide please read the introduction to the procurement of medicines and medical devices in section 4.14 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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| **Step Guide to Procurement of Medicine:** | | | | |
| **Step** | **When** | **Task** | **Description** | **Annex** |
| **1** | Planning | Identify Required Products | Identify what medicines are required, their basic technical specifications, 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 medicine. |  |
| **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 HPC** | | | | |
| **5** | Planning | Market Survey | Conduct market survey to establish availability of HPCs and what they are able to deliver in-country or through 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 medicines comply with the Purchase Order and certificates. 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 | Sourcing | 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 suppliers. | SUP 4: Evaluation Grid for Negotiated Procedure and SUP 6: Purchase Order |
| **16** | Implementation | Letter to Unsuccessful Suppliers | Unsuccessful supplier 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 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 medicines 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**

Different categories of medicines exist and the higher the potential for abuse and addiction, the higher the restrictions on purchase, sale, use and administration. At the planning phase of a project it is a prerequisite to know if the required medicine(s) is an ‘over the counter’ (OTC) medicine, a prescription medicine or a controlled medicine, and to obtain knowledge of the rules and regulations applicable to the medicines.

**Over the Counter Medicine**

OTC medicines are sold directly to a consumer without a prescription from a healthcare professional and in most countries pharmacies and assorted stores have permission from a government regulatory body to sell OTC medicine. OTC medicine often relieves pain, or prevents or manages diseases. For OTCs risks of abuse are relatively low, but still exist. Regulations on OTC medicines vary considerably from country to country and it is important to emphazise that purchasing OTC medicine from pharmacies in countries with weak regulatory sytems in place increases the risk of buying counterfeits.

Please note that for the purchase of OTC medicine, the Negotiated Procedure still applies and the pharmacy has to provide proof of registration with the National Drug Regulatiory Authority[[1]](#footnote-1). Please refer Scenarie B, Step 5.

The purchase of small amounts of OTC medicine without applying the Negotiated Procedure is only allowed if the purchase of medicine for a project can be defined as a Running Cost. See Medicine as a Running Cost in below section d) and in section 4.10 in the Procurement Manual.

**Prescription Medicine**

A prescription medicine has a higher potential for abuse and addiction and is a licenced medicine regulated by national legislation on a stricter level than OTC medicine. In most countries the Contracting Authority will not be able to procure prescription medicine without the involvement of a licensed medicial practitioner. Always consult the National Drug Regulatory Authority or the Ministry of Health, and UN Agencies and NGO’s for advice on the procurement of prescription medicines.

**Controlled Medicine**

Some medicines, such as morphine and ketamine are also presciption medicines, but due to their high potential for abuse and addiction they are controlled by very strict national laws[[2]](#footnote-2). Most countries have a list of controlled medicines which shows the generic name and what schedule the medicine belongs to. National laws which regulate controlled medicines differ, but often practitioners (e.g. doctors, dentists, physicians) are the only parties licenced to utilize and prescribe this type of medicine, and only licenced agents or companies are allowed to procure and sell controlled medicines. Therefore it will often be a requirement to involve or hire a licenced practitioner to assist on the purchase and administration of these products. Also please note that the disposal of controlled medicines will be regulated by strict national laws. Always consult the National Drug Regulatory Authority or Ministry of Health for advice on how to procure, administrate and dispose of controlled medicines.

**Vaccines and Sera**

In most countries vaccines and sera are categoriesed as prescription medicines. But vaccines and sera are different from other medical products as they are very sensitive and complex biological products which require a highly controlled environment during the entire procurement process and until the medicine reaches the end-user. Limited shelf life and sensitivity to temperature, humidity and other factors, shall be taken into account when planning transport and storage for these products.

For further information on procurement of vaccines and sera, see the following WHO link: <http://www.who.int/immunization_supply/en/index.html>

Most Contracting Authorities do not have the technical capacity or expertise to carry out the procurement of vaccines and sera and an ECHO recognised HPC should be appointed to carry out the procurement.

If the Contracting Authority can not appoint a HPC and has to carry out procurement of vaccines themselves, please be aware that there are many companies which produce vaccines, but only a few meet internationally recognised standards on safety and effect. For a list of WHO pre-qualified vaccines please see:

<http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/>

To ensure that all requirements to procurement, storage, administration and disposal of vaccines are met, it is strongly advised to hire an expert to assist or carry out the procurement. This shall be factored into the budget.

* + 1. **Draft Technical Specifications**

Establish the basic technical specification for each medicine. It is the content of a medical product which provides the technical specifications. Unless a medical company has patent rights on a medicine, it is not allowed to source according to brand. Medicines which are not patented are called ‘[generic medicines](http://en.wikipedia.org/wiki/Generic_drug)’. Generic medicines are produced by companies without restrictions or licences from the patent holder and that means that some medical products are produced by several companies – with varying quality. Dependent of the complexity of the medicines required it is recommended to consult a medical practitioner for advice on the technical specifications of each medicine.It may also be an option to contact the National Drug Regulatory Authority to gain access to the list of essential drugs, consult a relevant UN Agency or NGO for advice, or to consult a HPC’s product catalogue.

* + 1. **Counterfeits**

As mentioned earlier, counterfeit medicines are widespread on the medical market and especially in developing countries. 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 products pose a higher risk than others. Some basic indicators of availability of counterfeits are: There is no appropriate regulatory system in place; The level of corruption is high; There are unauthorised pharmacies and suppliers on the market; Medicines 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 important to know the quantity needed as it will affect how we further plan and implement procurement. The decision of wether to appoint an ECHO recognised HPC, shortlist government regulated pharmacies or pre-certified suppliers may be influenced by the quantities required.

**Medicine as a Running Cost**

When purchasing small amounts of over the counter medicine (e.g. pain killers or malaria pills) which are not a direct project cost, these cost are defined as a running costs (see section 4.10 on running costs in the Procurement Manual). Under such circumstances it is permitted to purchase small amounts from government regulated pharmacies without applying a procurement procedure or appointing a HPC. However, the quality requirements to products and suppliers are equal to purchasing medicine in general.

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| **Procurement from Pharmacies**  To ensure safe and genuine quality of the products purchased at government regulated pharmacies it is essential to know the pitfalls (e.g. unlicenced pharmacies and counterfeits) and the quality of the pre-qualification scheme applied by the National Drug Regulatory Authority. When procuring from pharmacies, the pharmacy shall provide proof of its registration with the National Drug Regulatory Authority and the National Drug Regulatory Authority must be recognised as an stringent regulatory authority. Please refer to Scenario B, Step 5. |

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

Consider specific transport and storage requirements for the products (temperature/humidity/shelf-life, etc). This may vary significantly from product to product. Some products are very sensitive to temperature and humidity and must be transported and stored correctly so as not to lose their effect or to pose a health danger to the recipients. 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 medicine for the project. The rules and procedures outlined in this Annex to the Procurement Manual represent 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 medicines 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 medicine, e.g. administrative regulations, regulations on who is allowed to procure and sell medicine, import regulations, disposal rules, etc. The scope, quality and complexity of regulations vary significantly from country to country and to be able to make proper and efficient decisions for the further planning and implementation of procurement of medicine, it is very important to obtain this information early in the planning phase. In most countries regulation of medicine is carried out by a National Drug Regulatory Authority and it is recommended to contact this authority and the Ministry of Health to obtain information and seek advice.

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

It is always recommended to seek advice 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 presence of counterfeits, time constraints 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 medicine 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 medicine on behalf of the Contracting Authority the Contracting Authority shall then establish if they are able to import the medicines. Please note that import of medicine may be illegal or regulated by very complex laws.

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

**What Medicines can the HPC Provide**

If it is possible to appoint a HPC it is important to assess what medicines 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 products needed and the technical specifications. GLS provide medicine to emergency operations, NGOs and Governments worldwide and will be able to provide the most common and essential medicines. See the GLS Emergency Item Catalogue: <http://procurement.ifrc.org/catalogue/>. Due to national legislation some products such as controlled drugs, may have to be sourced from e.g. a government regulated source and not a HPC.

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

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 the Contracting Authority finds that it cannot purchase the products 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.)

Be aware of specific donor requirements to origin and nationality.

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

Based on information obtained in the previous steps, all the required medicines shall be grouped into lots in the Procurement Plan (Annex GEN 7-1). If medicial devices are also required for the project they shall be included in the lot. For further information on the grouping of resources into lots, see section 4.1.1. in 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.

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

It may be a requirement to include a describtion of challenges and how the procurement of medicine 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 medicine requires a derogation to the donor’s rules or the rules outlined in this Annex to Procurement Manual, a written derogation shall be submitted with the project application to the donor or to the approprate authority.

For DCA projects: A derogation shall be submitted to the Head of The Procurment 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. **Finalize Technical Specification** (implementation phase)

At the planning phase the basic technical specification of the medicines 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 product 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 Humanitaian 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 medicine 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 medicines needed. 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.

**Step 10: 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.

The Purchase Order shall be forwarded unsigned to the selected HPC(s) and retured to the Contracting Authority with all pages duly sigend. 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 11: Receipt and Inspection** (implementation phase)

Inspect the supplies received to ensure they comply with the Purchase Order. Proceed as described in Section 6.5 in 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 products. Certificates shall always be filed in the Procurement File.

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

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

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

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

**Pre-certified suppliers and Pre-qualified Products**

Pre-qualification of medicines and pre-certification of suppliers shall be carried out and certified by an internationally recognised certification body which meets WHO norms and standards. Proof of pre-certification and pre-qualification shall be issued either by WHO, a stringent regulatory authority (such as a National Drug Regulatory Authority), an internationally recognised independent certification authority, or an ECHO recognised Humanitarian Procurement Centre.

It shall be established whether there are pre-certified suppliers in the country of operation who can deliver pre-qualified products. If the National Drug Regulatory Authority is recognised as a stringent regulatory authority[[4]](#footnote-4) they may be able to provide a list of pre-certified suppliers available in the country of operation and a list of pre-qualified products. The list of pre-qualified products will, in most countries, be referred to as the list of essential medicines.

If the National Drug Regulatory Authority is not recognised as a stringent regulatory authority, it is recommended to search the WHO and other relevant websites for information and to consult other humanitarian actors in the country or region for information and advice.

If the pre-qualified products cannot not be delivered by pre-certified suppliers in the country of operation, the legal framework for import of medicine shall be established and products identified outside the country of operation. Note that import of medicine may be illegal or regulated by complex laws and in some countries it will not be an option to import medicine. Please make sure to include all cost related to import in the budget. Also note that the requirements to pre-certification and pre-qualification are the same for imported medicine.

If it is not possible to source pre-certified suppliers who can deliver pre-qualified products in country of operation or via import, it is recommended to contact the donor for further discussion and advice on how to procure medicine for the project.

* **The National Drug Regulatory Authority and Pre-certification**

In most countries regulations on medicine is carried out by a National Drug Regulatory Authority. The scope and quality of regulations and quality assurance schemes vary significantly from country to country and according to WHO, only 20% of the 191 WHO member states have appropriate drug regulation in place[[5]](#footnote-5). Developing countries are likely to have weak and inadequate drug regulation in place and the risk of purchasing counterfeits are accordingly high.

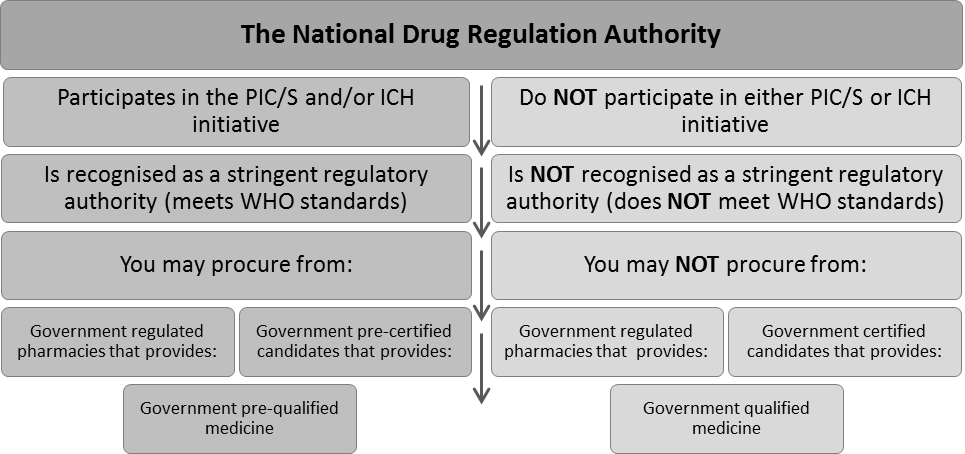
In most countries the National Drug Regulatory Authority carries out pre-qualification of medicines and pre-certification of suppliers, but for a National Drug Regulatory Authority to be recognised as a stringent regulatory authority they must apply quality assurance schemes which are based on WHO norms and standards.

To meet these requirements the National Drug Regulatory Authority shall participate in either the PIC/S (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme) and/or the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) initiatives.

Find list of members of PIC/S on: <http://www.picscheme.org/members.php>. No member list exists for ICH, but the National Drug Regulatory Authority will be able to provide information on such membership.

It is though important to be aware that, if corruption is widespread, counterfeits are very likely to enter the market even though the National Drug Regulatory Authority is recognised as a stringent regulatory authority and ‘on paper’ follows WHO norms and standards.

If a National Drug Regulatory Authority does not participate in at least one of the two initiatives, pre-certification and pre-qualification shall be carried out and documented by either WHO (only pre-qualification of medicines), another stringent regulatory authority or an international recognised certification body. Note that suppliers who are only registered by a National Drug Regulatory Authority which is not recognised as a stringent regulatory authority, do not qualify to be shortlisted to deliver medicines.



The link below provides a non exhaustive list of National Drug Regulatory Authority websites. Please be aware that this list does not indicate if the National Drug Regulatory Authorities are recognised as a stringent regulatory authority.

<http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf>

It is important to note that in some counties there may be a clash in between national regulations and the requirement to pre-qualified medicines and pre-certification of suppliers. It is always recommended to contact the National Drug Regulatory Authority, the donor and e.g. UN agencies and NGOs, to find solutions to such challenges.

**Government Regulated Pharmacies**

In countries where a National Drug Regulatory Authority is recognised as a stringent regulatory authority, government regulated pharmacies can be shortlisted to participate in the procurement procedure. Please refer to the section and table above.

The National Drug Regulatory Authority may be able to provide a list of registered pharmacies and the validity date of registration. When planning to procure from pharmacies please always crosscheck that the provided proof of registration corresponds with the list and is still valid.

Please also be aware that in developing countries, non-regulated pharmacies may be on the market and these do not qualify to deliver medicines.

Sourcing internet pharmacies is a risky business as internet-based sales of medicine is a major source of counterfeit medicines. If online pharmacies are sourced, proofs of pre-certification and pre-qualification shall be thoroughly checked for authenticity by the issuing authority.

**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.

Depending 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.

**WHO List of Pre-qualified Medicine**

WHO has developed a list of pre-qualified medicines used for HIV/AIDS, malaria, tuberculosis, influenza, reproductive health and other diseases/conditions. The list contains information on products, the respective manufacturer, packing standards, and manufacturing site. When procuring medicine for the treatment of the mentioned deceases/conditions, only medicines from this list are to be procured. The list only contains few medicines for common diseases such as diarrhoea and influenza. The list is found at: <http://apps.who.int/prequal/info_general/notes_registry.htm#3>

The rules and procedures applicable for purchasing medicine on the list are the same as for any other medicine.

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

Based on the information obtained in the previous steps, all the required medicine 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 time to site shall be added. Also, if the planning of the procurement of medicine is inadequate at the planning phase it may take additional weeks or months to carry out the procurement procedure during implementation.

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

It may be a requirement to include a describtion of challenges and how the procurement of medicine 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, these shall be included in the project proposal to the donor.

If the information obtained in step 1-6 show that the procurement of medicine requires 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 approprate authority.

For DCA projects: A derogation shall be submitted to the Head of The Procurment 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. **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 at the beginning of a project and before the procurement process is initiated. This advertisement is published to inform the suppliers of possible business opporunities and to source pre-certified suppliers for shortlisting. This is a general advertisement and can include other goods, services and/or works.

The requirements to pre-certification of suppliers and pre-qualification of the medicine shall be outlined in the advertisement and suppliers shall be informed of their obligation to provide proof of pre-certification. The template in Annex GEN 8 shall be utilized. See section 4.12.1 in the Procurement Manual for more information on advertisement of business opportunities.

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

At the planning phase the basic technical specification of the medicine was drafted. At this stage they shall be finalized and included in the Request for Quotation (RFQ). It may be nessesary to involve a practitioner in this process. It is also advised to consult the national list of essential medicines.

**Step 10: Source Pre-certified Suppliers** (implementation phase)

Depending on the outcome of the advertisement of business opportunities a sufficient amount of pre-certified suppliers may have qualified to be shortlisted to receive a RFQ. If the outcome of the advertisement was not sufficient to ensure genuine competition, additional sourcing will have to be initiated. The method to source pre-certified suppliers will vary from context to context. In some countries the National Drug Regulatory Authority will be able to provide a full list of pre-certified suppliers or a relevant UN Agency or NGO may be able to give advice where to find pre-certified suppliers. 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) in relevant magazines or webpages.

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

Irrespective of the sourcing method, suppliers who show interest in being shortlisted shall provide proof of pre-certification before they can qualify to be shortlisted. Government regulated pharmacies shall provide proof of registration (or licence) with the National Drug Regulatory Authority.

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 or licenced pharmacies. The shortlisting of pre-certified suppliers 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, the nature of the medicine, availability of pre-certified suppliers and pre-qualified medicines, 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 or Incoterms).

Technical specifications.

Special requirements to packing, storage, transport, shelflife (e.g. 2/3 left of shelflife upon reciept) etc.

Specific donor requirements

If the medicine required shall be on the WHO list of pre-qualified medicines

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 medicine)

* Required documentation (standards, registrations, certifications)
* List of references.

Ethical criteria

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. If it is a high risk market internationally recognised standards can be included in the selection criteria to provide additional proof of quality and good management systems. In the RFQ the selection criteria can give priority to suppliers that comply with at least one of the following standards or equivalent: United States QS (21 CFR part 820), ISO9001/ISO9002, or ISO9001/2000.

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 1-1 Guidance Letter to Suppliers for an example of an 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 medicine.

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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).

For evaluation of the quoted price the International Drug Price Indicator[[6]](#footnote-6) or other price databases[[7]](#footnote-7) shall be consulted. The price databases aim to make price information widely available in order to improve procurement of medicine of assured quality for the lowest possible price. When comparing the costs of medicine, the cost of the entire treatment (not just the cost per unit) shall be taken into consideration. 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.

Please note, that if a quote for a medicine is significantly lower than the other quotes, this may be an indication of the product being a counterfeit.

The overriding aim of the procurement procedure is to source high quality medicines 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 medicines 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 pre-qualification certificate actually corresponds with the required medicine. 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, 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.

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)

Proceed with the final evaluation and award the contract to the supplier who is substantially responsive to the RFQ, is technically compliant, has offered the lowest price and provided proof of pre-qualified medicine. Provided further that the Supplier has demonstrated the capability and resources to carry out the contract effectively.

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. 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-certification and 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 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.

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 medicines comply with the Purchase Order and that the product description on the certificates corresponds with the received medicines. Proceed as described in section 6.5 of the Procurement Manual.

Please take the necessary steps to ascertain the quality of the product and that 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? Could the received medicine be a counterfeit? Etc.

Medicines shall always be subject to proper administration, and appropriate and safe storage and disposal.

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| **Mandatory annexes for the procurement of medicine** | | | |  |
| GEN 2 | Declaration of Impartiality and Confidentiality | Mandatory | Scenario A+B | |
| GEN 7-1 | Template for Procurement Plan | Mandatory | Scenario A+B | |
| GEN 8 | Template for Advertisement of Business Opportunities | Mandatory | Scenario A+B | |
| GEN 13 | List of Suppliers/Suppliers 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. This authority may have a different name in the country of operation, but will be an authority under the Ministry of Health. [↑](#footnote-ref-1)
2. Controlled medicine is also referred to as a controlled drug. Controlled drugs are divided into accepted (e.g. morphine or ketamine) and non-accepted (e.g. heroin) drugs for medical use. A controlled medicine is an accepted controlled drug. [↑](#footnote-ref-2)
3. GLS webpage: <http://www.ifrc.org/en/what-we-do/logistics/key-logistics-services/> [↑](#footnote-ref-3)
4. See the next paragraph for clarification on when a National Drug Regulatory Authority is recognised as a stringent regulatory authority. [↑](#footnote-ref-4)
5. <http://www.who.int/medicines/services/counterfeit/overview/en/index1.html> [↑](#footnote-ref-5)
6. The International Drug Prices Indicator is regularly updated and provides a spectrum of prices from pharmaceutical suppliers and procurement agencies, based on their current catalogues or price lists. It also contains prices obtained from international development organisations and government agencies, and represents an essential tool to be used by Contracting Authorities to compare prices. <http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=english> [↑](#footnote-ref-6)
7. Such as: the Global Fund Price and Quality Reporting tool (<http://www.theglobalfund.org/en/procurement/pqr/>) or the Price Information Exchange website (<http://www.piemeds.com/>).

   [↑](#footnote-ref-7)