

4.13 PROCUREMENT OF MEDICINE AND MEDICAL DEVICES

Procuring medicine and medical devices is complex and requires knowledge of the market, the products required, the national drug regulatory system, risk of counterfeits, as well as knowledge of pre-certification of suppliers and pre-qualification of the medical products. It is very important to obtain such knowledge at the Project Planning phase to be able to plan the purchases correctly, to ensure purchase of high-quality products and to meet donor rules and requirements. Lack of knowledge and timely planning may result in delays or cancellation of activities, waste of time and money, and cost being declared ineligible by the donor. Most importantly, the risk of purchasing counterfeits may endanger staff and beneficiaries' lives.

The main aim of procuring medicine and medical devices is to ensure high quality products which are genuine, effective, and safe for patients. Quality shall always be the number one priority. The total costs of the purchase, e.g. shelf-life, storage and transport, shall also be taken into consideration, and any intellectual property rights and patent regulation applicable in the country of operation and internationally, shall be respected.

To ensure procurement of high quality and genuine products at a competitive cost, the starting point is to procure from an ECHO recognised Humanitarian Procurement Centre (HPC).

ECHO recognized Humanitarian Procurement Centres

[ECHO recognized HPCs](#) are non-profit entities specialising in buying quality emergency and health supplies and consequently, the HPC procures pre-qualified products from pre-certified suppliers. Appointing a HPC reduces the risk of procuring counterfeits. When buying from an ECHO recognised HPC a Blanket Derogation to negotiate with a single HPC is available irrespective of the contract value (Blanket Derogation h. in section 4.7.1). Procurement from a HPC may be more costly than procuring directly from pre-certified suppliers, but to ensure procurement of safe, high quality and genuine products, the appointment of a HPC is of high priority and cost should not be an issue. It is though very important to include all costs related to appointing a HPC in the budget at the project planning phase (admin fee, transport, custom clearance, insurance, etc.). For more details about HPCs go to section 4.8.1.

Pre-certification of Suppliers and Pre-qualification of Medical Products

To ensure high quality of products, and to respect patents and national regulations in the individual countries, it is paramount to abide by international norms for procurement of medicine (incl. Therapeutic food) and medical devices. When procuring from a HPC, this is ensured by the HPC. If it is not possible to procure from a HPC, it is the responsibility of the Contracting Authority to ensure that both suppliers and medical products meet international standards for production, storage, distribution and management via sourcing only pre-certified suppliers selling pre-qualified medical products. Suppliers shall always provide proof of the company's pre-certification and pre-qualification of the products they sell. However, Risk Class I medical devices are exempted. See section 4.12.1 and 4.13.2 for more detail.

Counterfeits

The biggest threat to purchasing safe and quality medical products is falsified and sub-standard medicine and medical devices, from hereon called counterfeits. Counterfeits are an immense global problem, but most common in developing countries where thousands of people die every year due to counterfeit medicines¹. WHO defines counterfeit medicine as 'substandard and falsified medical products. Substandard medicine is authorized medical products which fail to meet either their quality standards and/or their specifications, and unregistered and unlicensed medical products also fall under this category. Falsified medicines are products which deliberately/fraudulently misrepresent their identity, composition, or source². Counterfeits are prevalent across all categories of medicine and medical devices, ranging from cough medicine and headache pills to vaccines, controlled drugs, syringes or electrical equipment. Due to counterfeits' failure to provide treatment, direct harming ability and the development of drug resistance, they pose a genuine threat to recipients' lives and public health in general. Counterfeit medicines and medical devices are widespread in the medical market and especially in developing countries. Governments with inadequate regulatory control systems, high levels of corruption and low law enforcement capacity, enable counterfeits to enter the distribution channels at no risk. In countries with high levels of corruption and instability, it is likely that counterfeits enter the market even though the National Drug

¹<https://qz.com/africa/1601659/africas-counterfeit-drug-problem-being-tackled-by-innovators/>

²https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1

Regulatory Authority³ officially applies WHO norms and standards. Appointing an ECHO recognised HPC significantly reduces the risk of purchasing counterfeits and it is always recommended to procure from a HPC if possible.

Counterfeit Facts⁴

- 10% of global medicine trade is counterfeit
- More than 30% of medicine sold in some areas of Africa and Asia are counterfeits
- WHO estimates the annual global trade in counterfeit medicine at EUR 73 billion
- 42% of detected cases of counterfeit medicine occurred in Africa
- Antibiotics, painkillers, anaesthetics, TB and malaria medicine are the most often reported counterfeits
- It is estimated that 300,000 children die every year due to counterfeit medicine in Africa alone
- China and India are main players in producing counterfeits for worldwide distribution

Safe Disposal of Medicines and Medical Devices

Recalled, damaged, unwanted, or expired medicines for human and animal consumption, and medical devices shall always be disposed of in a safe and appropriate manner in compliance with national regulations. Medicine shall always be treated as pharmaceutical waste and not as regular waste. Some medical devices can be recycled or treated as regular waste. If improper disposal of medicine has been uncovered, it is important to contact the immediate manager and subsequently follow the national rule for the correct disposal.

Depending on the product in question, different methods for safe disposal exist. Some products may be returned to the supplier, some may be handed over to government regulated pharmacies and some products will require disposal via the National Drug Regulatory Authority. National and regional rules shall be adhered to and when possible, international best practice followed. However, in some countries, there are no, or a very limited, legal framework in place and therefore no guidelines or official channels to dispose and destroy medicines and medical devices. Under such circumstances, it is advised to consult WHO or other relevant UN agencies or INGOs in the country of operation for guidance and information on how to handle safe disposal of medicine and medical devices.

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

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

4.13.1 Procurement of Medicine

Medicine, also referred to as pharmaceuticals or a finished pharmaceutical product, is the term used to define medicines which are packed and labelled, and which comprise chemical substances with intended use for medical diagnosis, cure, treatment, or prevention of disease. Examples of medicine are headache and malaria pills, vaccines, Oral Rehydration Salts (ORS), penicillin, morphine, eye drops, therapeutic food, insulin, etc.

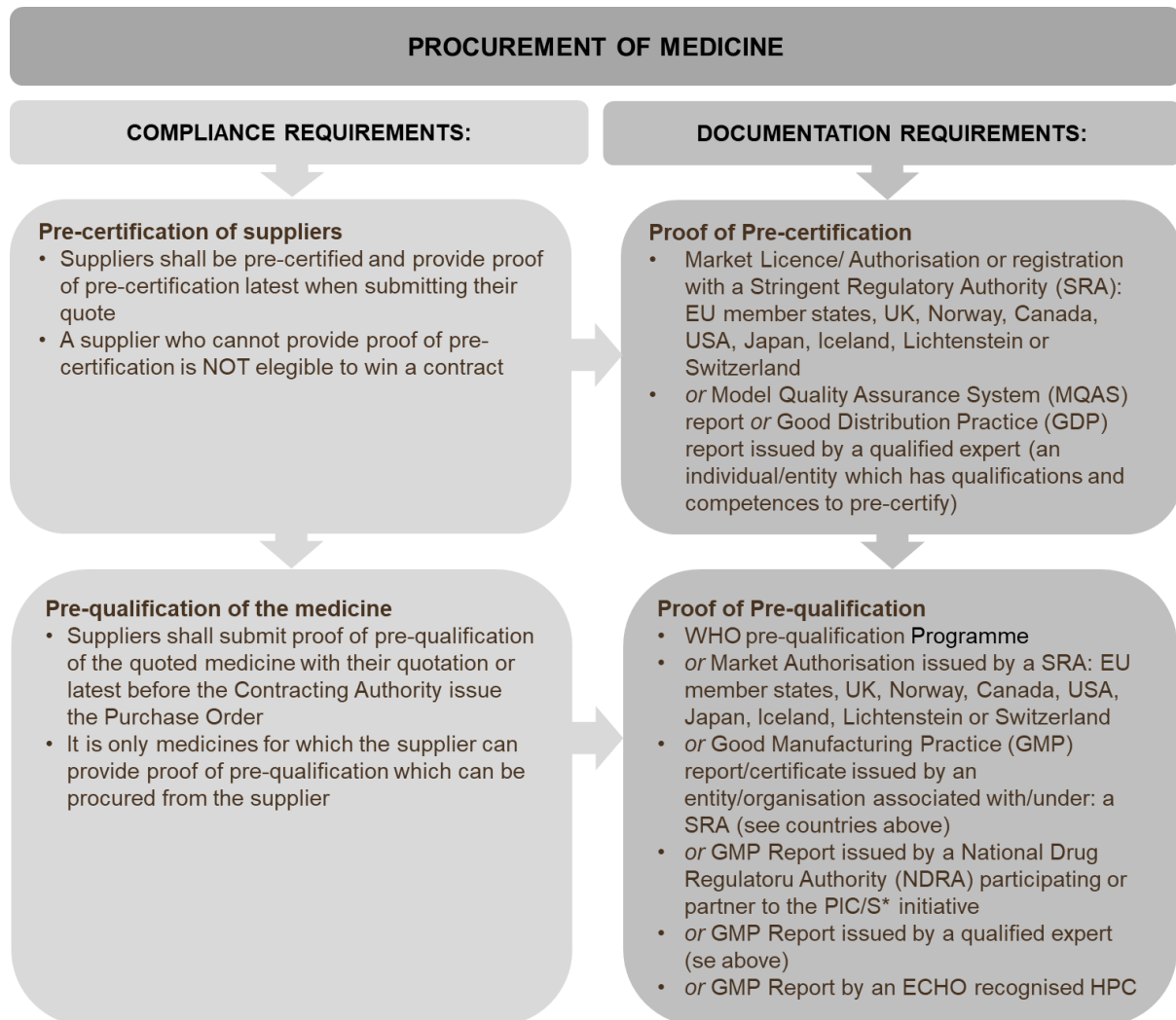
The procurement of medicine is complex and requires careful planning to ensure that procurement meets the national legal framework, and that only pre-qualified products are procured from pre-certified suppliers who are registered with the National Authorities. During the planning phase it is important to obtain information on the legal framework for medicine, e.g. administrative regulations on use and prescriptions, regulations on which companies can 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 informed and efficient decisions, it is very important to obtain this information early in the planning phase. In most countries' regulation of medicine is carried out by the

³ A National Drug Regulatory Authority is a general term used to refer to an authority under the Ministry of Health which is responsible for the regulation and administration of the laws on medicines and often also medical devices.

⁴ <https://enact-africa.s3.amazonaws.com/site/uploads/2018-11-12-counterfeit-medicines-policy-brief.pdf>
<https://www.bayer.com/en/background-information-on-counterfeit-drugs.aspx>
https://www.who.int/medicines/regulation/ssffc/publications/GSMS_Report_layout.pdf?ua=1
<https://edition.cnn.com/2019/03/11/health/fake-drugs-killing-children-study/index.html>
<https://cmpi.org/counterfeit-drugs-and-china-new>
<https://www.europeanpharmaceuticalreview.com/article/92194/the-impact-of-counterfeit-drugs-in-south-and-south-east-asia/>
<http://www.iracm.com/en/2013/06/operation-biyela-record-seizure-of-illicit-medicines-in-africa/>

National Drug Regulatory Authority and it is recommended to contact this authority and/or the Ministry of Health to obtain relevant information and seek advice.

When procuring medicine, the first step is to identify an ECHO recognised HPC which can deliver the needed medicines. If procurement from a HPC is possible, it is strongly recommended that the procurement of medicine is done via the HPC. If it is not possible, the applicable Procurement Procedure is assigned as per threshold for the total contract value. The step guides in section 7.1 – 7.4 shall be followed with below additional and mandatory pre-certification and pre-qualification requirements:



*[The Pharmaceutical Inspection Co-operation Scheme \(PIC/S\)](#)

If none of the above is possible in the country of operation, please contact your DCA counterpart to discuss the best way to ensure the purchase of genuine, safe and quality medicine.

Medicine shall always be subject to proper administration, and appropriate and safe storage and disposal. Please also refer to the [Logistics Manual](#) for more information on warehouse and stock management.

NOTE: If more restrictive Procurement Procedure or compliance rules are stipulated by a donor, these shall prevail.

Different categories (or schedules) of medicines exist and the higher the potential for abuse and addiction, the higher the restrictions for 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. Most

countries have a list of medicines which shows the generic name and what category the medicine belongs to. Irrespective of the category of medicine, only pre-qualified medicine can be procured.

Over the Counter Medicine

OTC medicines often relieve pain, prevent or manage diseases and are sold directly to a consumer in National Drug Regulatory Authority licenced pharmacies or stores, and without a prescription from a healthcare professional. Regulations and control of OTC medicines vary considerably from country to country. See more info below on buying from pharmacies.

Prescription Medicine

A prescription medicine has a higher potential for abuse and addiction than OTC medicine and regulation and control systems are stricter. In most countries the Contracting Authority will not be able to procure prescription medicine without the involvement of a licensed medical practitioner. Always consult the National Drug Regulatory Authority or the Ministry of Health and/or UN Agencies and NGO's can also be contacted for advice on the procurement of prescription medicines.

Controlled Medicine

Medicines, such as morphine and ketamine, are also prescription medicines, but due to their high potential for abuse and addiction they are controlled by very strict national laws⁵. National legislation regulating controlled medicines differ, but often practitioners (e.g. doctors, dentists, physicians) are the only entities licenced to utilize, administer and prescribe this type of medicine. Therefore, it will often be a requirement to involve or hire a licenced practitioner to assist in the purchase and administration of controlled medicines. Also please note that the disposal of controlled medicines will also be regulated by strict national laws. Always consult the NDRA or Ministry of Health for advice on how to source, procure, administer and dispose of controlled medicines.

Vaccines and Sera

In most countries vaccines and sera are categorized as prescription medicines. But vaccines and sera are different from other medical products as they are very sensitive and complex biological products. These are medical 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 procurement, administration, transport and storage of vaccines and sera and the need to hire a specialist. To ensure the procurement of genuine, safe and effective vaccines please refer to the [WHO list of pre-qualified vaccines](#).

Technical Specifications for Medicine

It is the content (active ingredients) of a medicine 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'. Generic medicines are produced by companies without restrictions or licences from the patent holder. As a consequence, some medicines are produced by several companies locally and globally, with varying quality and control. Depending upon the complexity of the medicines required, it is recommended to consult a medical practitioner or a medical staff to draft the technical specifications of each medicine. It may also be an option to contact the NDRA to gain access to the list of essential drugs or consult a relevant UN Agency or NGO for advice.

Buying from Pharmacies

Purchasing medicines from pharmacies may be an option in some countries, but in countries with weak regulatory systems in place, the risk of buying counterfeits is very high. Registration with the NDRA does not necessarily constitute sufficient documentation for pre-certification of pharmacies in developing countries. Requirements for pre-certification of a pharmacy and pre-qualification of the medical products they sell, are equal to any other supplier/medical products. Please see compliance and documentation requirements above.

Internet-based sales of medicine is a major source of counterfeits and poses a huge risk in most countries. Procurement from internet-based pharmacies can only take place if the National Drug Regulatory Authority controlling the pharmacy is based in EU, UK, USA, Japan, Canada, Iceland, Lichtenstein, Norway or Switzerland, and the pharmacy is pre-certified and sell only pre-qualified medicine.

⁵ 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.

Example of Buying Medicine

Identifying the legal framework: For a project in Africa, funded by Danida, procurement of medicine is part of a project's activity. The National Drug Regulatory Authority is not a Stringent Regularly Authority (SRA: EU, USA, Japan, Australia, Canada, Norway, Iceland, Lichtenstein, Switzerland), none of the ECHO recognized HPCs can supply to the country and import of medicine requires an import licence, which cannot be obtained. The Contracting Authority contacts the National Drug Regulatory Authority to get a list of suppliers registered with the National Drug Regulatory Authority and licenced to sell medicine in the country.

Identifying the procurement procedure: The total cost of the purchase is within the Simple Procedure and eight suppliers from the list are invited to submit a quote.

Identifying the documentation: Because the National Drug Regulatory Authority is not recognised as a SRA, the suppliers are requested to submit proof that they live up to international standards for Good Distribution Practice (GDP) or the Model Quality Assurance System (MQAS). The suppliers are asked to submit proof of this pre-certification by submitting a GDP or MQAS Report issued by a qualified expert with their quotation and proof of registration with the NDRA. They are also informed that they are ineligible to win the contract if these reports/certificates are not provided.

Suppliers are also informed that each quoted medicine shall be pre-qualified, and proof hereof shall be submitted with their quotes as:

- A Market authorisation/licence issued by either EU, USA, Japan, Australia, Canada, Norway, Iceland, Lichtenstein, Switzerland, *or*
- A Good Manufacturing Practice report/certificate issued by qualified expert, *or*
- A Good Manufacturing Practice report/certificate issued by an inspection entity or organisation associated with or under EU, USA, Japan, Australia, Canada, Norway, Iceland, Lichtenstein, Switzerland or WHO (WHO pre-qualification programme) *or*
- A Good Manufacturing Practice report/certificate issued by a National Drug Regulatory Authority participating in or is a partner to the PIC/S⁶ initiative *or*
- A Good Manufacturing Practice Report issued by an ECHO recognised HPC

The Contracting Authority received five quotes. Three of the suppliers were not able to provide proof of pre-certification and were declared ineligible for further evaluation. The two remaining suppliers provided proof of pre-certification of the company and pre-qualification for the quoted medicine.

Identifying the evaluation criteria: The evaluation of the two eligible quotes included the total costs (incl. storage, shelf life, transport) and quoted medicines meeting the technical specifications. The supplier who provided the most expensive quote won because the cheapest quote did not meet the technical specifications. Before the Purchase Order was issued the validity of the submitted proof of pre-qualification and pre-certification was checked and verified.

Receipt: Upon receipt of the medicine the quantity, packing, marking, dates/shelf-life, temperature requirements, spelling of brand name, etc. was checked to ensure quality, and that the Contracting Authority had received what was agreed and ordered. If a delivery is suspected of counterfeiting, please immediately contact a manager (and medic) to discuss further action.

All mandatory and explanatory documents were filed in the procurement file.

4.13.2 Procurement of Medical Devices

Medical devices consist of a wide range of equipment, devices, supplies and accessories that serves for diagnostics, treatment and prevention of diseases and medical conditions. Examples of medical devices are walking sticks, surgical instruments, contact lens lubricants, condoms, bandages, stethoscopes, syringes, needles,

⁶ [Pharmaceutical Inspection Co-operation Scheme \(PIC/S\)](#) is a non-binding and informal cooperation agreement for Regulatory Authorities globally. The members work on harmonizing and improving inspection procedures to ensure WHO standards for Good Manufacturing Practice in the production of medicine and veterinary medicine worldwide. As per February 2021 PIC/S had 53 members.

bedpans, dressings, medical test kits, wheelchairs, hearing aids, implantable devices, Magnetic Resonance Imaging (MRI), and Computed Tomography Imaging (CTI).

According to the Global Medical Device Nomenclature (GMDN) system⁷ 12 categories of medical devices exist, which consist of more than 10,000 generic groups. These categories are all divided into three Risk Classes related to health and safety risks (four classes in Japan). Risk Class I being the lowest risk and III being the highest:

Risk Class I: Wheelchair, bandages, gauge, oxygen masks, tourniquet, burn dressings, tweezer etc.

Risk Class II: Syringes, test kits, blood transfusion kits, thermometers, catheters, condoms etc.

Risk Class III: Implants, defibrillators, pacemakers, etc.

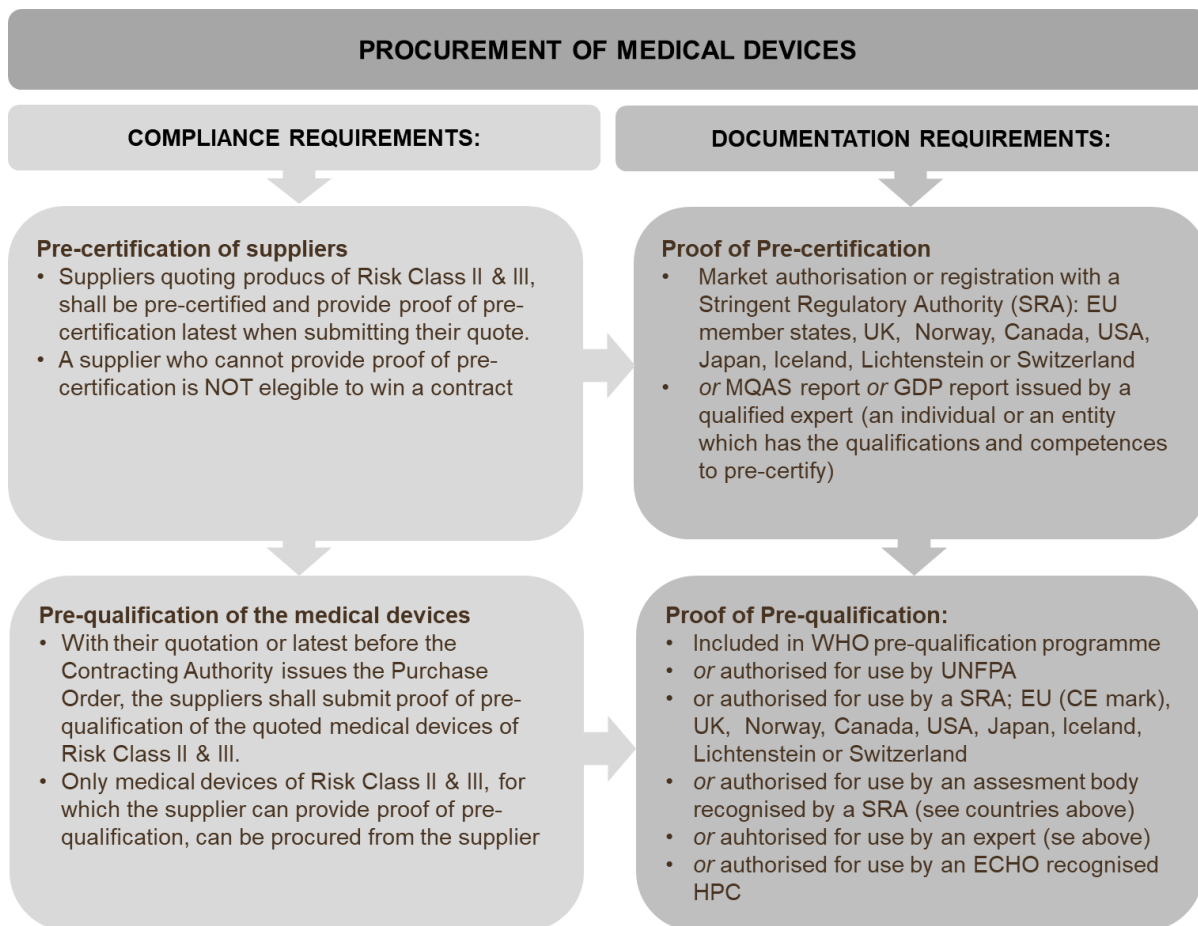
To establish if a product is defined as a medical device, the [FDA medical device database can be consulted](#). The database is administrated by the US Food and Drug Administration (FDA) and uses internationally agreed descriptions of medical devices from the GMDN system.

Like procurement of medicine, procurement of medical devices requires careful planning to ensure that procurement meets the national legal framework and that only pre-qualified products are procured from suppliers registered with the National Authorities and who are pre-certified. During the planning phase it is important to obtain information on the legal framework e.g. licence and registration requirements, administrative requirements, import regulations, disposal rules, etc. The scope, quality and complexity of regulations vary from country to country and to be able to make informed and efficient decisions, it is very important to obtain this information early in the planning phase. Regulation of medical devices is carried out by a National Regulatory Authority⁸ under the Ministry of Health and it is recommended to contact this authority and/or the Ministry of Health to obtain relevant information and seek advice.

Medical devices of Risk Class I can be purchased according to specifications described by the Contracting Authority and without further investigation. When procuring medical devices in Risk Class II and III, the first step is to identify if an ECHO recognised HPC can deliver the needed products. If procurement from a HPC is possible, it is advised to procure from a HPC. When not procuring via a HPC, the applicable Procurement Procedure is assigned as per threshold for the total contract value (incl. medicine if this can potentially be procured from the same pre-certified supplier). The step guides in section 7.1 – 7.4 shall be followed with below additional and mandatory pre-certification and pre-qualification requirements for medical devices of Class II and III:

⁷The Global Medical Device Nomenclature (GMDN) is a system of internationally agreed terms used to identify medical devices. It is used by regulating authorities, hospitals and manufacturers to identify medical devices that are of the same generic type.

⁸ 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.



If none of the above is possible in the country of operation, please contact your DCA counterpart to discuss the best way to ensure the purchase of genuine, safe and quality medicine.

As an additional quality assurance measure, suppliers can be asked to submit proof of product quality standards such as ISO13485 (Quality Management Standard for Medical Devices), the Japanese QS Standard for Medical Devices, the FDA SQR Standard or other equivalent standards which are in conformity with the International Medical Devices Regulators Forum (IMDRF) essential requirements.

NOTE: If a more restrictive Procurement Procedure or compliance rules are stipulated by a donor, these shall prevail.

Example of Buying Medical Devices

Identifying the legal framework: For a project in Africa, funded by ECHO, procurement medical devices of Risk Class I and II for local health clinics is part of the project's activity. The National Regulatory Authority is not a Stringent Regularly Authority (SRA: EU, USA, Japan, Australia, Canada, Norway, Iceland, Lichtenstein, Switzerland) and no ECHO recognized HPCs is available in country. The Contracting Authority contacts the National Regulatory Authority to obtain information on legal requirements for buying, selling and use of Medical Devices. They are informed that all suppliers selling Risk Class II and III must be approved and registered with the Ministry of Health and receives a list of registered suppliers. They are also informed that no restrictions to who can buy medical devices of Risk Class I or II exists.

Identifying the procurement procedure: The total cost of the purchase is within the Negotiated Procedure and eight suppliers from the list are shortlisted to receive the RFQ.

Identifying the documentation: Because the National Regulatory Authority is not recognised as a SRA, the suppliers are requested to submit proof that they live up to international standards for Good Distribution Practice (GDP report) or the Model Quality Assurance System (MQAS report). The GDP or MQAS Report(s) shall be issued by a qualified expert and submitted with the supplier's quotation. They are also informed that they are ineligible to win the contract if this report is not provided.

Suppliers are also informed that each quoted medical device of Risk Class II shall be pre-qualified and proof hereof shall be submitted with their quote as:

- A Market authorisation/licence issued by either EU, UK, USA, Japan, Australia, Norway, Canada, Iceland, Lichtenstein, or Switzerland *or*
- Proof of product(s) is authorised for use issued by an assessment body recognised by EU/EU member state, UK, USA, Japan, Australia, Canada, Norway, Iceland, Lichtenstein or Switzerland
- Proof of product(s) being part of WHO pre-qualification programme *or*
- Proof of product(s) is authorised for use issued by UNFPA *or*
- Proof of product(s) is authorised for use issued by a qualified expert *or*
- Proof of product(s) is authorised for use by an ECHO recognised HPC

The Contracting Authority received five quotes. One of the suppliers was not able to provide proof of pre-certification and was declared ineligible for further evaluation. The four remaining suppliers provided proof of pre-certification of their companies, but one of the suppliers could not provide valid proof of pre-qualification for the quoted medical devices of Risk Class II. Consequently, this supplier was also declared ineligible for further evaluation.

Identifying the evaluation criteria: The evaluation of the three eligible quotes included the total costs (incl. shelf life) of the quoted medical devices meeting the technical specifications. The supplier who provided the best price meeting the technical specifications and delivery criteria won the contract. Before the Purchase Order was issued the validity of the submitted proof of pre-qualification and pre-certification was checked and verified.

Receipt: Upon receipt of the medical devices the quantity, packing, marking, dates/shelf-life, temperature requirements, spelling of brand name, etc. was checked to ensure quality, and that the Contracting Authority had received what was agreed and ordered. If a delivery is suspected of including counterfeits, please contact immediately a manager (and medic) to discuss further action.

All mandatory and explanatory documents were filed in the procurement file.