



**Provisions on medical and food supplies
applicable to actions funded under the
EU Humanitarian Partnership Certificate
2021 – 2027**

Version 1.0
December 2020

Ensuring high quality levels of medical and food supplies distributed by humanitarian partners falls within the European Commission's humanitarian financing priorities. To this end, the European Commission, as one of the leading donors of humanitarian aid in the world, decided to introduce in the Grant Agreements signed under the 2008 and 2014 Framework Partnership Agreements provisions on quality assurance.

Following the same line, Annex 5 to Grant Agreements to be awarded under the EU Humanitarian Partnership Certificate 2021 – 2027 states that “*when implementing humanitarian aid operations, the beneficiaries must ensure compliance with the quality standards for medical supplies, devices and food established by the granting authority*”. To this extent, the present document is the reference source providing binding provisions to reflect this firm commitment.

Contents

- 1. Definitions 4
- 2. Medical supplies 8
 - 2.1 Procurement through Humanitarian Procurement Centres 8
 - 2.2 Procurement through pre-certified suppliers 8
 - 2.3 Prequalification of medical supplies 9
 - 2.3.1 Pre-qualification of Finished Pharmaceutical Products (FPP) 9
 - 2.3.2 Pre-qualification of medical devices 9
 - 2.4 Proofs of quality 10
 - 2.5 Derogations 10
 - 2.6 Destruction of Medical Supplies 11
- 3. Food supplies 12

1. Definitions

For the purposes of this document:

Finished Pharmaceutical Product (FPP)¹ means a medicine presented in its finished dosage form that has undergone all stages of production, including packaging in its final container and labelling.

Food supplies include bulk consumable commodities, such as mixed foods, ready-to-use foods, fortified foods with added vitamins and minerals, and supplementary foods to address moderate malnutrition. They do not include seeds for agricultural purposes.

Humanitarian Procurement Centres (HPCs) are non-profit organisations specialising in the procurement of supplies and services necessary for the delivery of humanitarian aid and the provision of related technical assistance, supply purchasing or logistics services. An HPC may either be an independent entity or a specialised supply or procurement department of a non-governmental organisation or an international organisation, provided that it has the appropriate levels of specialisation and discretion in procurement decisions.

The Commission (DG ECHO) maintains a Register of suitably qualified HPCs, recognised in accordance with set procedures and criteria. The criteria for recognition as an HPC include, among others, appropriate legal personality and registration, non-profit nature, a non-discriminatory sales and fair pricing methodology and policy (including all overheads and mark-ups), expertise in procurement and related activities, well-documented and fair procurement procedures and quality assurance provisions, and an adequate financial and administrative capacity.

HPCs play an important role in the global humanitarian aid effort, and as such are expected to conduct themselves with high levels of integrity, transparency and respect of procurement principles such as best value for money and absence of conflict of interest. To verify compliance with above procedures, criteria and principles, the Commission performs periodic on-site examinations of recognised HPCs.

There is no contractual relation between the Commission and the HPC. The recognition by the Commission of an organisation as an HPC does not constitute an assurance with respect to the quality of individual products and services provided by the HPC or with respect to the HPC's compliance with contractual obligations towards third parties.

IMDRF and GHTF: The Global Harmonization Task Force (GHTF)² was a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. The founding members were Australia, Canada, the European Union, Japan and the United States.

The purpose of the GHTF was to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices, promoting technological innovation and facilitating international trade. GHTF was replaced by the International Medical Device Regulators Forum (IMDRF) in October 2011, when

¹ https://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/index6.html

² <http://www.imdrf.org>

representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, the European Union, Japan and the United States, as well as the World Health Organization (WHO) met in Ottawa to address the establishment and operation of this new Forum.

The International Council on Harmonization (ICH)³ of Technical Requirements for Pharmaceuticals for Human Use is an initiative that brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product development and registration. Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner. Since its announcement of organisational changes in October 2015, ICH has grown as an organisation and now includes 16 Members and 32 Observers.

In Vitro Diagnostic (IVD)⁴ medical devices are medical devices, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

Medical device include any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
- investigation, replacement, modification, or support of the anatomy, or of a physiological process,
- supporting or sustaining life,
- control of conception,
- cleaning, disinfection or sterilization of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

³ <http://www.ich.org>

⁴ <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-pl-md-ivd.pdf>

The term ‘medical device’ covers a wide range of products with different level of risk. such as: tongue depressor, crutches, catheter, pace-maker, nuclear magnetic resonance apparatus (NMR), intraocular implant, heart valve, thermometer, suture or in-vitro diagnostic tests: blood grouping test, Malaria rapid test or blood glucose monitoring device.

Medical Supplies include Finished Pharmaceutical Products (FPP) (medicines), medical devices and therapeutic food to address acute malnutrition. They do not include veterinary products and food supplies.

The **Pharmaceutical Inspection Co-operation Scheme (PIC/S)**⁵ is a non-binding, informal co-operative arrangement between regulatory authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any authority having a comparable GMP inspection system. PIC/S presently comprises 53 Participating Authorities coming from all over the world (Europe, Africa, America, Asia and Australasia).

A **qualified expert** is any entity or individual that has the necessary competences and experience to provide expertise on pre-certification of suppliers and/or pre-qualification of medical supplies.

Risk classification of medical devices⁶ is a ‘risk based’ system based on the vulnerability of the human body taking account of the potential risks associated with the devices. This approach allows the use of a set of criteria that can be combined in various ways in order to determine classification, e.g. duration of contact with the body, degree of invasiveness and local vs. systemic effect. The risk classification determines the level of stringency required for the market authorization.

Risk classification of in-vitro medical devices⁷: The Classification of an IVD medical device is based on the following criteria:

- The intended use and indications for use as specified by the manufacturer (including but not limited to specific disorder, populations, condition or risk factor for which the test is intended);
- The technical/scientific/medical expertise of the intended user (lay person or healthcare professional);
- -The importance of the information to the diagnosis (sole determinant or one of several), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician;
- The impact of the result (true or false) to the individual and/or to public health.

A Stringent Regulatory Authority (SRA)⁸ is:

⁵ <https://www.picscheme.org/en/members>

⁶ <http://ec.europa.eu/DocsRoom/documents/10337/attachments/1/translations>

⁷ [http://www.imdrf.org/docs/ghrf/final/sg1/procedural-docs/ghrf-sg1-n045-2008-principles-ivd-medical-devices-classification-080219.pdf#search="risk%20classification%20in%20vitro%20diagnostics"](http://www.imdrf.org/docs/ghrf/final/sg1/procedural-docs/ghrf-sg1-n045-2008-principles-ivd-medical-devices-classification-080219.pdf#search=)

⁸ https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

- a) a member of ICH (International Council for Harmonisation) prior to 23 October 2015, namely: the US Food and Drug Administration, the European Commission and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or
- b) an ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swissmedic and Health Canada; or
- c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein and Norway.

The recent reforms at ICH, formerly the International Conference on Harmonisation and currently the International Council for Harmonisation, prompted the WHO Pre-qualification Team medicines to reconsider the definition of SRAs as applicable to WHO's Guidelines on submission of documentation for pre-qualification of finished pharmaceutical products approved by Stringent Regulatory Authorities (Technical Report Series, No. 986, 2014, Annex 5).

A Stringent Inspection Body⁹ is:

- (a) an inspection body of the regulatory authority of a member of the ICH ; or
- (b) an inspection body of the regulatory authority or an organisation of an ICH observer (WHO, EFTA, Canada) ; or
- (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway; or
- (d) a regulatory authority participating or partner of the PIC/S.

A **Supplier¹⁰** is a person or entity engaged in the activity of providing products and/or services. The term of supplier includes also manufacturers.

⁹ <https://www.quamed.org/definitions/?lang=en>

¹⁰ [WHO Technical Report Series 957 Annex 5, 44th report, 2010](#)

2. Medical supplies

These provisions are applicable in the procurement of medical supplies by all humanitarian organisations and have as their principal objective to ensure the quality of the products purchased. They are also applicable to medical supplies received as in-kind contribution under EU-funded humanitarian actions.

Irrespective of the value of the contract to be awarded, the humanitarian organisation must procure medical supplies:

- (1) either through a Humanitarian Procurement Centre (HPC), or
- (2) through pre-certified suppliers.

2.1 Procurement through Humanitarian Procurement Centres

This point applies only to Humanitarian Procurement Centres registered by the Commission (DG ECHO)¹¹.

A humanitarian organisation may, when using the services of an HPC, apply a negotiated procedure with a single offer.

In this case, the humanitarian organisation does not have to perform pre-qualification of supplies.

The humanitarian organisation must exercise the necessary degree of care, efficiency and diligence with regard to monitoring of the timeliness and quality of the supplies or services provided by an HPC. In cases where the quality or service falls below those expected, the humanitarian organisation must inform the Commission of the shortcomings and circumstances.

2.2 Procurement through pre-certified suppliers

When the humanitarian organization does not purchase medical supplies through an HPC, it must procure them through pre-certified suppliers. A supplier is pre-certified where it has demonstrated that its premises, facilities and processes comply with the European Commission Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use¹² or the WHO Good Distribution Practices for pharmaceutical products (GDP)¹³.

When procuring through pre-certified suppliers, the humanitarian organisation must take a life-cycle costing approach, including aspects to uphold the required quality such as transportation charges, storage requirements and shelf-life.

¹¹ <https://www.dgecho-partners-helpdesk.eu/ngo/actions-implementation/procurement-in-humanitarian-aid/humanitarian-procurement-centres>

¹² <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/compliance/good-distribution-practice#legal>

¹³ https://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf

The pre-certification of a supplier does not constitute an assurance with respect to the quality of individual products and services provided by the pre-certified supplier or with respect to the supplier's compliance with contractual obligations towards third parties.

Proof of pre-certification of a supplier must be recorded in the procurement file and may be issued by a Stringent Regulatory Authority (supplier license) or by a qualified expert (MQAS or GDP report).

2.3 Prequalification of medical supplies

The humanitarian organisation is responsible for ensuring and demonstrating that the supplies are pre-qualified. A medical supply is pre-qualified if compliant with the criteria described below.

2.3.1 Pre-qualification of Finished Pharmaceutical Products (FPP)

A FPP is pre-qualified if authorised for use by the National Medicine Regulatory Authorities (NMRA) in the country where it will be used (market authorisation or import permit) and

- if pre-qualified by the WHO Pre-qualification programme¹⁴;
- or if authorised for use by a Stringent Regulatory Authority (SRA);
- or at least if the manufacturing site demonstrates compliance with the European Union (EU) Guidelines to Good Manufacturing Practice of Medicinal Products for Human and Veterinary Use¹⁵ or with WHO's Good Manufacturing Practice for pharmaceutical products (GMP)¹⁶ to a Stringent Inspectorate Body or a qualified expert.

2.3.2 Pre-qualification of medical devices

For medical devices, the quality criteria should be aligned to the risk classification.

The medical devices of the lowest risk classification can be purchased according to specifications described by the humanitarian organisation and without further investigation.

A medical device of other risk classification is pre-qualified:

- if pre-qualified by WHO Pre-qualification Programme¹⁷ (for IVD and male circumcision devices);
- or if it is pre-qualified by UNFPA¹⁸ (condoms and Intrauterine Contraceptive Devices (IUD));

¹⁴ <https://extranet.who.int/prequal/content/prequalified-lists/medicines>

¹⁵ <https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice>

¹⁶ https://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/

¹⁷ https://www.who.int/diagnostics_laboratory/en/

¹⁸ <https://www.unfpa.org/quality-assurance>

https://www.unfpaprocurement.org/documents/10157/37547/UNFPA_MLC+Prequalified+Factories.pdf

- or if authorised for use by one of the regulatory authorities of the funding members of the GHTF (Australia, Canada, EU, Japan and USA);
- or if the manufacturer demonstrates implementation of the Quality Management System (QMS) to a Conformity Assessment Body recognised to one of the GHTF country funding members or a qualified expert.

All medical supplies must respect any intellectual property rights and patent regulation applicable in the country of operation.

2.4 Proofs of quality

Proof of pre-qualification of medical supplies must be recorded in the procurement file and may be issued by:

- For FPPs:
 - the WHO pre-qualification programme;
 - or a Stringent Regulatory Authority (market authorisation);
 - or at least a Stringent Inspection Body (GMP certificate);
 - or at least a qualified expert (GMP report);
 - an HPC.

- For medical devices (except for lowest classification risk):
 - the WHO pre-qualification programme (for IVD and male circumcision device);
 - or UNFPA (condoms and IUD);
 - or a Notified Body¹⁹ (if the product is CE marked) or the regulatory authorities of USA, Japan, Canada or Australia;
 - or a conformity assessment body recognised by one of the five countries from the member of GHTF;
 - or a qualified expert;
 - an HPC.

2.5 Derogations

While no derogation from the minimum quality assurances for medical supplies may be granted, where the humanitarian organisation, for circumstances beyond its control, is unable to demonstrate compliance with internationally accepted product standards, it may demonstrate instead that the supplies offer the best quality available.

This includes a risk-based approach and compliance with standards accepted by the national regulatory authorities (national market authorisation). The Commission must be informed of, and consulted on, these exceptional cases without unjustified delay.

¹⁹ <https://ec.europa.eu/growth/tools-databases/nando/>

2.6 Destruction of Medical Supplies

When procuring medical supplies, the humanitarian organisation must ensure that adequate provisions are in place to ensure respect of national regulation and when possible internationally recognised best practices²⁰ in the destruction of any contract-related supplies that are recalled or expired.

²⁰ https://www.who.int/water_sanitation_health/publications/unwanted-pharmaceuticals/en/

3. Food supplies

These provisions are applicable to food supplies purchased and received as in-kind contribution under EU-funded humanitarian actions.

Food supplies purchased by the humanitarian organisation must comply with the quality standards laid down in the national legislation of the country of origin and/or the country of destination, whichever has the higher quality standard.

Whenever possible and advisable, having due regard to the context in which the action is implemented, and provided it does not substantially disturb the local beneficiary markets, priority must be given to purchases in the country of operation or in neighbouring countries. The humanitarian organisation must obtain evidence based on local/regional market analysis that local/regional procurement would not induce market distortions which could adversely affect vulnerable populations.

The humanitarian organisation is responsible for ensuring the quantity and quality of the supplies, including their packaging and marking:

(i) when awarding urgent contracts or contracts with a value not exceeding EUR 300 000, the humanitarian organisation may itself certify the quantity and quality of the supplies, by means of a suitably qualified member of staff;

(ii) when awarding contracts of a value exceeding EUR 300 000, the humanitarian organisation must engage an independent recognised verification or inspection entity, namely a Monitoring Agency²¹, which will assume responsibility for verifying and certifying the quantity and quality of the supplies. Where a Monitoring Agency is used, the humanitarian organisation must include in the contractual documents the necessary provisions, so as to assure the right of access for the Commission pursuant to Article 25 of the grant agreement.

Where the humanitarian organisation purchases food supplies from an HPC, it may apply a negotiated procedure with a single offer.

²¹ This includes any internationally recognised inspection company, preferably accredited to the standard norm ISO 45004 – ISO/IEC 17020 in the food production sector, contracted to verify and certify quantity, quality, packing and marking of food supplies