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MSF
INTERNATIONAL

MSF POLICY FOR THE PROCUREMENT OF MEDICAL PRODUCTS

POLICY

INTERSECTIONAL DOCUMENT

MEDECINS SANS FRONTIERES

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LANGUAGES	EN
Feedback contact	Isabel Lucas Manzano – International Pharmacist Coordinador isabel.lucasmanzano@msf.org
	Copying: Elsa Tran – International Medical Device and In Vitro Diagnostics Coordinator; Elsa.tran@msf.org Odile Caron – International Food Quality Assurance Coordinator Odile.caron@london.msf.org
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1. INTRODUCTION

Throughout this policy the term "medical products" is used to refer to medicines, medical devices (MD), in vitro diagnostics (IVD), laboratory items and specialized food (SF) used within MSF programmes.

The following principles were agreed by the Executive Committee in 2002 and are still valid:

- Medical products are imported in countries under the legal and moral responsibility of MSF. It is therefore MSF's duty to ensure that these medical products comply with equivalent quality standards of medical products available in Highly Regulated Countries[1] (HRC).

- Medical products bought locally in the countries where MSF works must be of acceptable quality as well; even if the ultimate legal responsibility stays with the National Drug Regulatory Authorities, MSF still bears the moral responsibility of the quality of any product used in its programmes.

Since the creation of the International Quality Assurance Coordination (for medicines, MD and SF), MSF has coordinated audits of more than one thousand manufacturers and distributor/procurement agencies, both in resource-limited settings and in Highly Regulated Countries, and engaged in discussions on medical product quality with national authorities in more than fifty countries where MSF operates. This extensive work confirmed that the quality of medical products available in developing countries remains highly variable (for example, we can find products of acceptable quality beside substandard or even falsified[2] products). In fact, in the majority of the visited countries, the regulatory authorities lack the means (financial, human and/or the expertise) to adequately control their market and assure the quality of medical products manufactured, imported and distributed in their territory.[3] Consequently, some manufacturers and suppliers present in the market of countries where MSF operates apply different standards for export to HRC or domestic market/low resource settings, lowering their standards to the level of quality considered as sufficient by the recipient country/buyer.

Lack of quality in medical products may include sub or over-dosage, poor bio-availability, poor stability, lack of sterility, lack of performance, presence of impurities, cross-contamination with active principles, microbial contamination etc. that can have very serious consequences for the patients' health or for the healthcare provider.

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[1] For MD: The International Medical Device Regulators Forum (IMDRF, previously Global Harmonization Task Force (GHTF)) founding countries: USA, Canada, Japan, Australia, EU, EFTA (Norway, Iceland, Liechtenstein and Switzerland). Current members also include Brazil, China and Russia. However, for the purpose of this SOP Brazil, China, Russia and Turkey are not considered as HRCs.
For medicines and SF: Highly Regulated Countries (HRC) or Stringent Regulatory Authorities (SRA) are:

- a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented Regulatory guidance by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or
- an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or
- a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015)

[2] http://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1
[3] https://www.unicef.org/supply/files/VIC_2017_SESSION_5_WHO_RSS.pdf

Pressure to reduce costs in many countries where MSF operates can also have a negative impact on the quality of the product available on the local market.

In addition to the above, the availability and continuous supply of sources of acceptable quality is also a challenge in countries where MSF operates.

This policy is meant to avoid or at least minimize any preventable medical products-related risk for the patients' and end-users' health as well as to ensure an adequate and sustainable supply of quality products in the countries.

2. MEDICAL PRODUCTS PROCUREMENT POLICY FOR MSF MEDICAL PROGRAMS

2.1. INTERNATIONAL PROCUREMENT

"International Procurement" refers to the procurement of medical products:

- via one of the 3 MSF European Supply Centers (ESC): MSF Logistique (Bordeaux), MSF Supply (Brussels) and Amsterdam Procurement Unit (APU, Amsterdam), regardless of its supplier and/or manufacturing site location and
- approved via the qualification scheme.

The approval of medical products procured and imported by MSF ESCs, for MSF programs, builds on the MSF Qualification Schemes for International Pharmaceuticals[4], Medical Devices or Specialized Food. These schemes are based on the assessment of the manufacturing site of the product to evaluate its compliance with Good Manufacturing Practices and on the assessment of a product dossier, in line with the international standards set by WHO or other relevant normative bodies.

➔ Medical products used in MSF medical programs must be procured via "international procurement" except if there is a valid reason to deviate.

When starting a project or preparing an MoU with country authorities, international procurement via MSF European Supply Centers must always be considered as the first choice, and all mechanisms to make it possible should be actively used.

2.2. LOCAL PROCUREMENT

"Local Procurement" refers to the purchase of medical products (permanently or occasionally), by the Operational Center (OC), in a given country, for use in the same country.

The MSF evaluation of medical products for local purchase cannot be qualitatively compared to the MSF Qualification Scheme for International Procurement. While products supplied by the ESCs have undergone a full evaluation of the manufacturing site and the product dossier, the Medical Directors decision for local purchase is the result of a risk-benefit analysis which takes into account (not exhaustive list):

1. an analysis of the information available leading to recommendations from the section pharmacists,
2. the operational context,

[4] http://www.msf.org/en/article/msf-medical-product-qualification-scheme

3. the available options in the local market and
4. technical information about the manufacturer, wholesaler and distributor, when available.

Local Procurement shall only be approved when international procurement is not possible or for valid operational reasons, according to a careful evaluation done on a case-by-case and on a country-by-country basis.

➔ Situations where local procurement is considered:
- Exceptionally challenging emergency situations:
  - Open war context (high intensity armed conflict, making medical product delivery from abroad impossible
  - Epidemics: only if not covered by e-prep strategy or country does not officially declare the outbreak (hence importation not facilitated).
  - New emergency context. This would be for a short period of time, in the meantime the international cargo arrives.
- Legal constraints delaying the normal functioning of the project activities, after negotiation with NRAs has been exhausted.
- Impossibility to import when negotiation with NRAs have failed
- Projects in highly regulated countries (e.g. Greece)

Some of these situations allow for temporary local procurement only and international procurement should be implemented as soon as possible

Local procurement should not:
- serve as a substitute for poor forecasting and lack of stock analysis
- be the default mode to opening new projects
- be justified by delays/constraints from the ESCs
- be justified by lower prices
- be justified by proximity to sources (risk of double standards)
- be used for products/countries for which the risk of fraud is identified as high. Local procurement of medical products must always be approved by the Medical Director(s) of the concerned section(s), following the recommendations made by the Section Pharmacist; or the Medical Devices referent, supported by the International Medical Devices Coordinator and the Laboratory Advisors as appropriate; or the Specialized food referent, supported by the International Food Quality Assurance Coordinator.

This is because medical products accepted for local procurement would often not comply with the quality requirements of an international validation.

Parameters and decision making process used by Section Pharmacists when they perform these local medical market assessments for ad hoc/exceptional validation or to produce local purchase database, are defined in the "Guideline for local medical market assessment, 2016". The section pharmacists are responsible for Local Market Assessment (LMA). The recommendations issued from LMA are valid for all sections present in the country. The section pharmacists can delegate LMA to other qualified pharmacists, appropriately trained.

As a result of these LMAs, in countries where importation is not possible or highly limited like Jordan or India or other cases where importation becomes challenging or impossible, a local purchase database is created and maintained by intersectional pharmacists. This database includes information on sources available locally, rated

according to the quality information available to clearly guide prioritization and risk awareness and assessment. This database is under the responsibility of the section pharmacists.

2.3. Regional Procurement

"Regional Procurement" refers to the purchase of medical products in a given country, for use in another country in a defined region. Regional Procurement is a variation of international procurement therefore only medical products validated according to the MSF International Qualification Scheme must be procured.

➔ Regional Procurement, wherever in place, must follow the same rules as International Procurement, since medical products are imported into a country under MSF legal and moral responsibility. The Medical Director must validate any derogation to this rule.

3. Medical product procurement country assessment

The main goal of medical product procurement country assessment is to establish and periodically review the MSF medical product procurement strategy, based on the analysis of the national regulation and, if necessary, of the local market. Such assessments must be carried out by the Section Pharmacists or delegated HQ pharmacist, and the results shall apply to all the sections present in the country.