



# QUALITY ASSURANCE POLICY AND PROCEDURES

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## Abbreviations

BP	British Pharmacopoeia
DP	Direct Procurement
ERP	Expert Review Panel
EU	European Union
FDA	Food and Drug Administration
FLD	First Line Drugs
FPP	Finished Pharmaceutical Product
GDF	Global Drug Facility
GDP	Good Distribution Practices
GLC	Green Light Committee
GLI	Global Laboratory Initiative
GMP	Good Manufacturing Practices
GSP	Good Storing Practices
ICH	International Conference of Harmonization
INN	International Non-proprietary Names
Pharm Int	WHO International Pharmacopoeia
ITB	Invitation to Bid
LICB	Limited International Competitive Bid
MDR-TB	Multi Drug Resistance TB
NGO	Non Governmental Organization
OOS	Out Of Specification
PA	Procurement Agent
PIC/s	Pharmaceutical Inspection Cooperation Scheme
PPQ	Product Pharmaceutical Questionnaire
PQS	Performance Quality and Safety
PSI	Pre-Shipment Inspection
QA	Quality Assurance
QC	Quality Control
QCA	Quality Control Agent
RfP	Request for Proposal
SLD	Second Line Drugs
SRA	Stringent Regulatory Authority
TA	Technical Assistance
TAG	Technical Advisory Group
TB	Tuberculosis
TPEC	Technical Product Evaluation Committee
USP	United States Pharmacopoeia
WHO	World Health Organization
WHO EML	World Health Organization Essential Medicines List
WHO MQAS	World Health Organization Model Quality Assurance System for Procurement Agencies
WHO PQP	World Health Organization Pre-Qualification Program
WHO QSM	World Health Organization Quality System Management

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# 1 Introduction

The Global Drug Facility (GDF) is an initiative of the Stop TB Partnership to increase access to quality-assured tuberculosis (TB) medicines in line with the STOP TB Strategy. GDF is housed at the World Health Organization (WHO) headquarters in Geneva and managed by a team in the Stop TB partnership secretariat. It was launched in 2001. For more information, refer to: [http://www.stoptb.org/stop\\_tb\\_initiative/](http://www.stoptb.org/stop_tb_initiative/)

GDF, in partnership with contractual and collaborative agencies, offers three core services:

- Grant Service (first and second line anti-TB medicines, new diagnostics) for countries that are donor-dependent for some or all of their drug supply,
- Direct Procurement (DP) Service for countries, NGOs and donors wanting to buy first line anti-TB medicines and diagnostic equipment, or second line anti-TB medicines for Green Light Committee (GLC) approved projects,
- Technical Assistance (TA) Service for Grant and DP recipients (first and second line anti-TB medicines) through annual and ad hoc missions for in-country drug management monitoring and training.

## 1.1 Grant service

GDF grant service is a mechanism whereby adult and paediatric first-line anti-TB medicines are granted to approved countries to support STOP TB strategy expansion and sustainability of nationwide coverage in countries that do not have sufficient finances for their medicine needs and who lack adequate procurement capacity, including a robust quality assurance system.

GDF also offers emergency grants of one year to prevent stock outs due to factors such as insufficient funding, procurement delays, natural disasters and humanitarian crises.

GDF applies a holistic approach to TB drug procurement, by linking demand for medicines to supply and monitoring, outsourcing all services to partners on a competitive basis, using product packaging to simplify drug management and linking grants to TB programme performance.

GDF is also the procurement arm of the GLC initiative, for more information please refer to: <http://www.who.int/tb/challenges/mdr/greenlightcommittee/en/>  
Established in 2000, the GLC initiative is the mechanism that enables access to affordable, quality, second line anti-TB medicines for the treatment of multi-drug resistant-TB (MDR-TB). It ensures that programmes are technically sound so that multilateral e.g. Global Fund and UNITAID and bilateral donor agencies can continue to disburse funds for MDR-TB treatment.

## 1.2 Direct procurement services

GDF DP service enables clients to use their own resources to procure quality-assured anti-TB medicines, diagnostics equipment, and medical supplies, through a reliable procurement agent, at prices that result in savings.

The DP service provides eligible countries and organizations which are committed to the STOP TB strategy, but who lack adequate procurement capacity, including a robust quality assurance system, with access to affordable, quality-assured anti-TB commodities and expert technical assistance to promote the effective and sustainable control of TB.

## 1.3 Harmonization of the quality assurance policy and procedures with other major international organizations and donors

In 2008, GDF initiated a revision and expansion of its Quality Assurance Policy and Procedures as part of a collaborative process to ensure harmonization with the policies of two major multi-lateral financing mechanisms (i.e. The Global Fund and UNITAID), and other organizations (i.e. The Union; UNICEF, Médecins Sans Frontières) involved in TB control and in particular to:

- ensure global consistency on quality standards set for procurement and supply of anti-TB medicines, medical as well as diagnostics items
- avoid duplication of effort.

Meanwhile, GDF continues to contribute, in an ongoing manner, to discussions with other key technical partners and donors (e.g. as part of the Inter-agency Pharmaceutical Coordination group -IPC-) on:

- exchanging information on anti-TB medicines, diagnostics and suppliers;
- sharing information on quality aspects of medicines and diagnostics and medical devices ;
- developing common tools and mechanisms.

For further information on GDF's services and operations, please refer to:  
<http://www.stoptb.org/gdf/>.

## 2 List of products supplied by GDF<sup>1</sup>

- First-line adult and paediatric anti-TB medicines as listed in the current WHO Essential Medicines List (WHO EML) and treatment guidelines
- Anti-TB medicines to treat MDR-TB including second line and third line medicines recommended by WHO and GLC and part of the current WHO EML and/or recommended in MDR-TB guidelines
- Water for injection
- Patient kits (standard patient kits for different treatment categories)
- Material and reagents necessary for diagnosis of susceptible TB
- Rapid diagnostic tools for MDR-TB
- Medical devices: syringes with needles

## 3 Quality assurance policy

### 3.1 Policy statement

GDF attaches significant importance to the quality of the products that are supplied to countries to diagnose and treat TB. Through its procurement, technical assistance and monitoring services GDF plays a key role in supporting countries in need to reliably access affordable essential TB medicines and diagnostic tools meeting adequate and globally accepted quality standards.

### 3.2 Responsibilities: product quality assurance personnel

The qualification of health products and manufacturers for procurement and supply, the monitoring of their quality and their periodic requalification are essential parts of GDF's quality assurance system.

Within GDF, the QA personnel, who work independently but in collaboration with all other sub-teams, are responsible for the definition of the QA policy and procedures and for ensuring their satisfactory implementation all along the procurement and supply chain.

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<sup>1</sup> The list shall be updated as new products are incorporated to the portfolio of products supplied by GDF

### 3.3 Scope and quality assurance principles

With the mission of ensuring the safety, efficacy and quality of products provided by GDF, the quality assurance system is based on:

- the WHO/Stop TB Strategy;
- authorization for importation and use by recipient countries;
- recommendations by the relevant WHO Programmes i.e. Prequalification of Medicines Programme (PQP); Prequalification of Diagnostics Programme and Essential Health Technologies Performance;
- authorization for marketing by a stringent national medicines regulatory authority (SRA) in the country;
- procurement and term-limited supply of products based on the recommendations and quality/clinical risk assessments of an independent Expert Review Panel comprising experts, where there are insufficient WHO prequalified or SRA approved products available<sup>2</sup>;
- monitoring programme of the quality of supplied products including independent random quality control testing and post-delivery surveillance.

### 3.4 Conflict of interest

All personnel involved in the qualification and procurement of products must not represent any real, potential or apparent conflict of interest<sup>3</sup>.

### 3.5 Confidentiality commitment

All the information related to source qualification of the products submitted to GDF is considered confidential. Therefore, in line with the need for harmonization of quality policies and qualification processes, exchanges of information on products and suppliers between GDF and key partners will be governed by signed confidentiality agreements and, where required, authorizations from the proprietors of the information.

GDF has created and maintains a product database which contains all the information related to product quality, efficacy and safety. This database is managed by the GDF quality assurance personnel. Non-confidential product information such as the characteristics of medicines to be supplied will be available to interested parties i.e. eligible countries, technical partners and procurement agents.

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<sup>2</sup> Refer to section 5.4 for definition

<sup>3</sup> To confirm this, persons will be asked to sign a WHO "Declaration of Interest"



## 4 Quality assurance standards

GDF bases its QA system for supplied products on quality standards and referential norms set by WHO:

- WHO Model Quality Assurance System for Procurement Agencies (WHO MQAS);
- WHO Good Manufacturing Practices (GMP);
- WHO Good Distribution Practices (GDP), including Good Storage Practices (GSP);
- WHO technical report series;
- Monographs set by WHO International Pharmacopeia (Pharm Int), United States Pharmacopoeia (USP), British Pharmacopeia (BP) and European Pharmacopeia (EP);
- WHO Essential Medicines and Pharmaceutical Policies;
- WHO Essential Health Technologies;
- Global Laboratory Initiative (GLI).

## 5 Quality assurance for medicines<sup>4</sup>

### 5.1 Quality criteria for acceptance of product-manufacturing site

To be eligible for GDF procurement and supply, any medicine and its manufacturing site must comply with GDF QA criteria established as follows:

- all finished pharmaceutical products (FPP) need to be authorized by the relevant national medicines regulatory authority in the country of use.
- in addition, all FPP products must meet the following criteria :
  - A) Products are pre-qualified by WHO under the WHO PQP; **OR**
  - B) Products are approved by a SRA defined as either: an ICH<sup>5</sup> member country, an ICH observer or any country whose regulatory authority is associated with an ICH member through a legally binding mutual recognition agreement, or be

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<sup>4</sup> Medicines cover all anti-TB medicines and water for injection supplied by GDF.

<sup>5</sup> International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use: [www.ich.org](http://www.ich.org) (a) a member of the ICH (as specified on its website, [www.ich.org](http://www.ich.org)); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by Swiss Medic, Health Canada and the World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time).

For new members of the European Union (EU), only pharmaceutical products which were delivered a market authorization after EU integration are considered as approved by a SRA. GDF will consult with relevant WHO/QSM experts on the progress of such countries in adjusting their pharmaceutical legislation to EU laws before recognizing the approval by the national health authorities.

approved or subject to a positive opinion under the Canada S.C. 2004, c. 23 (Bill C-9) procedure, or Art. 58 of European Union Regulation (EC9 No. 726/2004) or United States FDA tentative approval.

In the absence of available<sup>6</sup> products meeting the standards A) and/or B) above, products may be approved for procurement by GDF under the following option:

C) Products shall be found acceptable to GDF for procurement through a quality/clinical risk assessment process (refer to section 5.2) managed by an independent Expert Review Panel. Products shall be eligible for this interim process under the following conditions:

1) The FPP must be manufactured at an approved site as follows:

- the site must have been inspected by WHO as a part of the WHO PQP (refer to <http://apps.who.int/prequal/>) and found to be operating at an acceptable level of compliance with WHO GMP for the specific type of product<sup>7</sup>; **OR**
- the site must have been inspected and found acceptable for the manufacture of the specific type of product by a SRA defined as either: an ICH member country, an ICH observer or any country whose regulatory authority is associated with an ICH member through a legally binding mutual recognition agreement; **OR**
- the site must have been inspected and found acceptable for the manufacture of the specific product<sup>8</sup> by inspectors of a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S)<sup>6</sup>.

2) A product prequalification or approval as described respectively under either points "A)" or "B)" is pending, i.e. manufacturers have submitted relevant product dossiers and the dossiers have been accepted for assessment either by WHO PQP or a SRA<sup>9</sup>.

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<sup>6</sup> Refer to section 5.4 for definition

<sup>7</sup> Requirement fulfilled as long as the scope of the audit covers the specific dosage form as confirmed by the either WHO PQP, SRA or ERP experts

<sup>8</sup> Pharmaceutical Inspection Cooperation Scheme: <http://www.picscheme.org/>. For any new PIC/S members, GDF will consult with relevant WHO/QSM experts on the level of equivalence of the GMP inspection with those of old members PIC/s countries.

<sup>9</sup> A written proof of such submission and acceptance issued by WHO PQP or the relevant authority will be required.

- 3) Eligibility under point C) shall be limited to a maximum duration of 12 months from the time of the ERP recommendation, during which time manufacturers should obtain prequalification by WHO PQP or approval by a SRA<sup>10</sup>.

Note: Products approved for procurement under C) should not be considered as quality-assured to the same extent as if prequalified by WHO or approved by a SRA. For this reason they should only be procured if products approved for procurement under A) or B) are not available.<sup>11</sup>

## 5.2 Quality and clinical risk assessment process

In order to ensure continuous supply of adequate quality-assured medicines and cost-effective procurement services, when there are less than three finished pharmaceutical products (FPP) available<sup>12</sup> that are prequalified by the WHO Prequalification Programme and/or authorized by a SRA, GDF QA will publish an Expression of Interest (Eoi) for both product and manufacturing site evaluations on the basis of a quality and clinical risk assessment for procurement purposes. Such Eois will, to the extent possible, be published in collaboration with the Global Fund and other partners in the interests of harmonization and non-duplication of effort.

Quality and clinical risk assessments are carried out for products that are not prequalified by WHO PQP and/or authorized by SRAs for procurement purposes.

Such assessments are conducted by an Expert Review Panel (ERP). The ERP is an independent group of highly qualified regulatory experts identified and convened by the WHO Department of Essential Medicines and Pharmaceutical Policies and is derived from an existing pool of experts with a wide range of expertise in the pharmaceutical and medical fields.

After conducting comparative quality and clinical risk assessment reviews of submitted applications (based on the status of the quality, efficacy and safety of the products), the ERP comes up with an objection or no-objection conclusion as to the potential acceptability for procurement for a term-limited period (12 months). The FPPs must also meet the following eligibility criteria:

- a) the manufacturer of the FPP has submitted an application to the WHO PQP and has been accepted for assessment OR an application for marketing authorization to a SRA and has been accepted for assessment;
- b) the FPP is manufactured at a site that is compliant with the standards of GMP applicable to the FPP in question as verified after inspection by:

1) WHO PQP inspectors or 2) SRA inspectors or 3) A regulatory authority participating to the Pharmaceutical Inspection Cooperation Scheme (PIC/s).

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<sup>10</sup> However, GDF may, in its sole discretion, request the ERP to consider extending the ERP recommendation period for up to an additional 12 months if the FPP is not yet WHO-prequalified or SRA-authorized within the ERP Recommendation Period.

<sup>11</sup> Refer to section 5.4 for definition

<sup>12</sup> Refer to section 5.4 for definition

The following generic steps outline the Eol process for products and manufacturing site evaluations<sup>13</sup>:

1. GDF in collaboration with the relevant partners will establish the conditions, requirements, Pharmaceutical Product Questionnaire and the list of products to be included in the Eol
2. Publication of the Eol for selected anti-TB medicines (i.e. anti-TB medicines for which there are less than three FPP prequalified by WHO PQP and/or authorized by a SRA available in the market) with all the specifications and requirements
3. Submission of the dossiers by the manufacturers to the address indicated in the Eol
4. Opening and registration of submissions<sup>14</sup>
5. Screening the completeness of the submission according to the Eol requirements.
6. If dossiers submitted are complete and in compliance with the Eol requirements, they are sent to the ERP coordinator for assessment
7. ERP reviews the dossiers
8. ERP reports to the GDF and other relevant partners
9. GDF and other relevant partners send letters to the manufacturers communicating the dossier assessment conclusions.
10. Based on ERP recommendations, all FPPs eligible for procurement (within the validity period) are published and/or used as the basis for supply.

### 5.3 Variations

For A) or B) products, any variation related to the manufacturer and/or product and submitted to WHO PQP or SRA must be notified by the supplier to GDF. GDF will rely on the assessment of such variations by WHO PQP and/or a SRA.

For products found acceptable through the quality/clinical risks assessment process (ERP process), no variation will be accepted since these products are expected to have successfully completed the approval process either through the WHO PQP or through a SRA before the end of the validity period of 12 months.

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<sup>13</sup> An SOP developed by GDF and relevant partners defines entire process with actions, responsibilities and timelines.

<sup>14</sup> The opening, registration and screening of dossiers submitted and communication to manufacturers will be carried out by the assigned staff from the Quality Assurance teams of GDF and relevant partners

## 5.4 Product selection for supply

### Scenario 1

If there are two, or more than two A) and/or B) products and sources<sup>15</sup> **available\*** for a given FPP then GDF will only select manufacturers of the A) and/or B) products for procurement based on a Limited International Competitive Bid (LICB).

### Scenario 2

If there are less than two A) and/or B) products and sources **available,\*** any ERP eligible source of the product(s) may be selected for supply based on GDF's LICB or other relevant selection process.

When it comes to market share allocation, eligible A) and/or B) products/manufacturing sites will be prioritized over ERP eligible products through a rating system<sup>16</sup> to be applied during the tender process.

A positive recommendation for procurement and supply of an FPP by the ERP is valid for 12 months.

*\*Please note that in both cases, “available” means the manufacturer can supply the requested quantity of the FPP within 90 days of the requested delivery date.*

## 6 Quality assurance related to the selection and assessment of services contracted by GDF: procurement agents and quality control agents

GDF contracts out services through competitive processes for specific time durations. The quality assurance personnel are responsible for establishing and evaluating all product quality-related requirements, conditions and accreditations for the respective services, which are included in the Request for Proposal (RfP).

The activities of procurement agents (PAs) - on behalf of GDF - are related to the contracting of manufacturers through Limited International Competitive Bids (LICBs)<sup>17</sup> and supplying and delivering of GDF selected products.

In all those activities the PAs will follow GDF's QA Policy and Procedures. The PAs are responsible for the coordination of the pre-shipment inspection (PSI), sampling and

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<sup>15</sup> A product is defined as per its INN, strength, form, type of packaging (HPDE container or Alu/PvC foil blister or Alu/Alu foil strips)

<sup>16</sup> Rating system: In an LICB where a product from a PQP/SRA authorized source and the same product from an ERP recommended source are eligible for supply, the rating system will accord a competitive advantage to the former. Note: Other factors such as registration of the product in the recipient country, price and delivery time will also determine the selection and market share/orders allocation of the products/manufacturers for supply.

<sup>17</sup> Only qualified product-manufacturers

quality control testing activities involving the qualified manufacturers and Quality Control Agents (QCA) by GDF following GDF's Standard Operating Procedures (SOP).

GDF is entitled to conduct pre-award audits<sup>18</sup> of PAs which respond to an RfP before a final award contract is issued. The scope of such audits includes but is not limited to:

- checking compliance to WHO Good Distribution Practices and Good Storing Practices;
- assessing whether the internal QA system at the PA is compliant with the WHO Model Quality Assurance System for Procurement Agencies for the activities run on behalf of GDF; specific attention will be given to the batch-tracking system and recall procedures;

Within its QA system, PAs should have a **written procedure on how to recall promptly and effectively any delivered product** known or suspected to be defective, with a designated person(s) responsible.

A recall could be initiated on the basis of GDF internal quality control monitoring, one of GDF beneficiary countries, a manufacturer and/or marketing authorization holder, or a PA itself. In any case, communication has to be set between GDF and the concerned PA as soon as one party is informed of a quality alert linked to a medicine or other medical item supplied by GDF. The PA will work with the product supplier to carry out appropriate recall procedures including the following:

- tracking the concerned product (quantity in stock and delivered per destination);
- informing the manufacturer or/and marketing holder where a recall is instituted by an entity other than the manufacturer;
- informing promptly all customers and competent authorities of all countries to which the pharmaceutical product which is suspected defective may have been distributed;
- carrying out the recall, storing the goods in a secure and segregated area if not being done by the supplier;
- handling records of the recall and issuing a final report including reconciliation between delivered and recovered quantities of products.

GDF shall provide support all along the recall process with data available in the GDF order management system ("OMS" database) and counter-check the final PA recall report.

The effectiveness of the arrangements made for recalls should be evaluated at regular intervals. Required improvements should lead to an update of related procedures at GDF and PA levels.

For medicines and other medical items supplied directly by GDF but not through GDF's PA, GDF will be responsible for carrying out all recall required activities, as described in GDF's recall procedure.

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<sup>18</sup> By GDF QA pharmacist and/or appointed experts

From March 2009, GDF has been part of the Global Fund (and associated partners') Quality Control Initiative, using the same consignment inspection, sampling and testing capabilities and publishing jointly Request for Proposals for the selection of the common Quality Control Agents aimed at:

- Harmonization of activities
- Standardization of process and procedures
- Cost efficiency through the pooling of activities and sharing of results
- Transparency and competition

GDF QA personnel, to the extent possible, will continue participating with key partners such as Global Fund and others in the selection of QCA for anti-TB medicines and product monitoring activities.

## 7 Drug quality control and post- delivery surveillance

Quality control is an essential part of the QA system under the responsibility of the QA team.

GDF engages the services of QCAs based on the Quality Control Initiative described in Section 6 above

Selected QCAs must have valid international and national certifications as follows:

- Prequalification letter issued by WHO; **and** ISO 17025 certified by an international recognized accreditation company
- Good Laboratory Practices assessment letter issued by a SRA **and** ISO 17025 certified by an international recognized accreditation company
- Good Laboratory Practices issued by the national health authorities

### 7.1 Pre-delivery quality monitoring<sup>19</sup>

- For WHO prequalified/SRA authorized products:

- A Pre-shipment inspection is organized either by the beneficiary country and/or by GDF through the selected QCA.
- Sampling and testing are done according to a batch randomization testing plan either by the beneficiary country and/or by GDF through its selected QCA.

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<sup>19</sup> Refer to the latest GDF monitoring programme activities for detailed information



- For products selected through the ERP process:

- A PSI is organized by GDF through its selected QCA
- Sampling of all purchased/selected batches according to a randomization plan are collected and tested by the GDF selected QCA
- Procurement of the respective batches proceeds only after full compliance to specifications<sup>20</sup>, on the basis of a certificate of analysis provided by QCA to GDF and beneficiary countries.

For a product supplied to a country receiving financial support from a financial donor as the Global Fund, GDF coordinates the monitoring activities with such funding institution in order to avoid duplication of PSI and quality control testing.

In cases of non compliance, either in the quality of a product or other defects such as the packaging, the manufacturer will be requested to replace the complete batch at its own cost.

In cases of non compliant testing results, i.e. confirmed out of specifications (OOS) by GDF's independent QCA laboratory, GDF will send a complaint to the manufacturer with the following provisions<sup>21</sup>:

- In the event that the manufacturer provides within a week a complaint investigation report which is found acceptable by GDF, the latter will have the same sample retested by its QCA
- If the complaint investigation report is not provided or found not acceptable to GDF, the latter will recognize the OOS result by its QCA which will issue the final Certificate of Analysis with the OOS test results

An OOS investigation must not delay order arrival to the country's TB programme. GDF will ask the manufacturer to replace the batch at its own cost in order to service the countries needs.

## 7.2 Post delivery - surveillance

Drug monitoring activities can also be organized post delivery by GDF or can be based on beneficiary countries' drug monitoring programmes. Some countries conduct systematic laboratory testing once medicines are received by customs and while medicines are in quarantine.

GDF is willing to participate in drug surveys in collaboration with NRA, WHO/Quality and Safety of Medicine staff and/or other GDF partners.

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<sup>20</sup> Recognized pharmacopoeias method specifications and/or recognized manufacturer's method specifications for the specific product.

<sup>21</sup> Refer to the latest version of the SOP for Out of Specifications



### **Complaint handling**

Any recipient country can report a complaint to GDF. Complaints are managed as per GDF complaint procedures.

Two reporting systems exist at GDF to deal with customer complaints. The customer can fill out a complaint form (available on GDF website). GDF also supports Customer Satisfaction Surveys on a regular basis to ensure that all clients are satisfied with its performance.

All complaints concerning potentially defective FPPs are reviewed carefully by GDF quality assurance staff and the quality systems manager so that appropriate actions can be taken including potential recall. Customer complaints received via other channels and negative reviews on returned surveys are duly investigated by GDF and its PA.

Additionally, WHO PQP inspectors, during inspection and monitoring visits, will verify if the batches purchased by GDF have been manufactured at the accepted sites and comply with the characteristics and specifications approved.

## **8 Other countries with national pharmaceutical production of anti-TB medicines**

Since some national TB treatment protocols differ from the WHO TB treatment protocols, WHO prequalified or SRA approved products may not be available for supply to these respective countries. However, the quality/clinical risk assessment process will still apply for these medicines.

For anti-TB products produced and used solely in specific countries, pursuant to the explicit recommendation of the relevant unit in the WHO Stop TB Department, and subject to the agreement of the ERP Coordinator, GDF applies the following eligibility criteria and requirements for being accepted for ERP review:

1. These Formulations are included in the WHO Model List of Essential Medicines and/or in the WHO standard treatment guidelines or in National/institutional Guidelines.
2. The product is manufactured at a site that is compliant with all standards of Good Manufacturing Practice that apply to the relevant product formulation, as verified after inspection by the WHO Prequalification Programme OR an SRA OR a regulatory authority participating to the Pharmaceutical Inspection Cooperation Scheme.

## 9 Quality assurance and diagnostics technologies

GDF bases its QA system for supplied diagnostics on quality standards and referential norms set by WHO Global Laboratory Initiative (GLI) <http://www.stoptb.org/wg/gli/default.asp>, WHO Prequalification of Diagnostics Programme [http://www.who.int/diagnostics\\_laboratory/evaluations/en/](http://www.who.int/diagnostics_laboratory/evaluations/en/), Essential Health Technologies Department <http://www.who.int/ehd/en/>.

GDF QA staff will work in close collaboration with the all relevant partners such as Global Fund, UNITAID and others in harmonizing the policies, standards, qualification of sources and monitoring processes.

GDF together with the WHO Prequalification team for diagnostics, GLI and partners will develop a mechanism for monitoring and evaluation of implementation of the quality assurance policy regarding diagnostics.

## 10 Quality assurance for medical devices

GDF bases its QA system for the medical therapeutic injectable devices on the quality standards and referential norms set by WHO Essential Health Technologies (e.g., the Performance, Quality and Safety Project. Please refer to [http://www.who.int/immunization\\_standards/vaccine\\_quality/pqs\\_prequalified\\_devices\\_e13/en/index.html](http://www.who.int/immunization_standards/vaccine_quality/pqs_prequalified_devices_e13/en/index.html)).

GDF QA team will work in close collaboration with all relevant partners such as Global Fund, UNITAID and others in harmonizing the policies, standards, qualification of sources and monitoring processes.

## 11 Ad hoc expert committees

GDF Quality Assurance personnel may convene additional advisory groups or expert committees for specific tasks related to the assessment and qualification of products for procurement and supply<sup>22</sup>.

## 12 Revision of this policy and procedures

This policy supersedes all previous policies and will be revised periodically as needed

Geneva, July 2010

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<sup>22</sup> The Technical Product Evaluation Committee (TPEC), formed early in 2009, assists GDF on Quality Assurance (QA) matters related to specific needs for the procurement and supply of second-line anti-TB drugs when the number of sources selected through established selection process are not sufficient to meet the demand of programmes.