

Procurement Policy

DNDi POLICIES

DNDi
Drugs for Neglected Diseases initiative

February 2014

I. Why a procurement policy and how does it fit into DNDi's mission and model?

DNDi's model is based on strong engagement of public and private partners who support DNDi's vision and mission (see box below). Recognizing this specificity is critical when designing a procurement policy that needs to combine the ability to effectively engage partners and providers in successfully contributing to projects with the ongoing concern of the best use of resources.

DNDi's procurement policy therefore combines strict principles with pragmatic approaches to better serve its mission and model, especially when the choice of qualified suppliers is limited. DNDi constantly strives to hold itself to the highest standards of accountability, transparency, and ethics. The development of policies and SOPs (such as for Intellectual Property, Fundraising, Access, Regulatory and Research Misconduct) have contributed to clarify DNDi's way of working

In this context, DNDi's Procurement policy aims to:

- Ensure the best use of resources to address patients' needs
- Support good partnering and contracting practices
- Set a clear framework for partners and suppliers when dealing with DNDi
- Provide trust to donors and partners

This policy is the cornerstone of DNDi's broader procurement activities, which aim to:

- Identify and formalize DNDi's needs
- Explore the best partners to work with
- Negotiate financial conditions to optimize quality/deadline/cost
- Evaluate services already performed
- Strengthen long-term relationships with partners/suppliers
- Alleviate the purchasing burden from Project Managers
- Ensure the provision of goods and services respecting quality/deadline/cost expected by the project teams.

DNDi Procurement Process will complement this Procurement Policy.

DNDi Mission [abstract]: The mission of DNDi is “to develop new treatments for patients suffering from the most neglected communicable diseases. Acting in the public interest, DNDi will bridge existing gaps [...] by initiating and coordinating drug R&D projects in collaboration with the international research community, the public sector, the pharmaceutical industry and other relevant partners. [...] DNDi's primary focus has been the development of drugs for the most neglected diseases [...] while considering engagement in R&D projects [...] to address unmet needs that others are unable or unwilling to address. In pursuing these goals, DNDi will manage R&D networks built on South South and North South collaboration. [...] DNDi will help to build additional capacity in a sustainable manner [...]”

II. Procurement principles

Building on DNDi's existing business practices and values, ethical standards of behaviors must be demonstrated by all people involved at any stage of our procurement activities, particularly regarding the notions of:

- Respect & Probity
- Conflict of interest, fraud and corruption
- Sustainability

Whereas such principles shall apply across the organization and activities, DNDi employees must particularly abide by them in the context of procurement activities.

Respect & Probity

DNDi's procurement operations comply with the basic principles of probity in procurement:

- Acting fairly, impartially and with integrity
- Respecting individual and cultural differences
- Accountability and transparency
- Trustworthiness and acting lawfully
- Securing confidential information

Conflict of interest, Fraud and Corruption

Beyond the principles stated above, employees conducting business on behalf of DNDi must comply with related policies dealing with Conflicts of interests¹, Fraud and Corruption². In particular, employees shall comply with the following:

1. DNDi employees must comply with all applicable laws and regulations within the jurisdiction where they operate, as well as DNDi internal policies.
2. Employees shall disclose to their management any identified or potential conflict of interest. When in doubt, employees should consult with their supervisor and escalate upon need.
3. Employees shall not take any personal advantage including, but not limited to, financial gains resulting from DNDi procurement activities.
4. DNDi employees shall take appropriate measures to mitigate risks associated with suppliers' business practices.

¹ A financial conflict of interest policy exist and shall be extended to all categories of conflicts of interest

² Such a policy is to be developed in 2014

Sustainability

DNDi operates within social, environmental and economic settings which are all impacted by sustainable procurement practices. Sustainable procurement means that, when buying goods and services, DNDi will consider:

- Strategies to avoid unnecessary consumption;
- Environmental impacts of the goods and services over their whole life-cycle;
- Suppliers' social responsibility practices including compliance with legislative obligation to employees and international standards

DNDi will work toward inclusion of such terms in contracts with suppliers.

III. DNDi Procurement main procedures

III.1 – A key step within DNDi global activity

Building on the principles set in the first sections, procurement activities are positioned in a broader context that needs to take into consideration:

- Strategic levels (mission, overall objectives and strategies – including at disease, Regional office or department level), especially when it comes to capacity strengthening and partnerships.
- Project roadmaps, specific objectives, timelines and resources that enable identification of buying needs.
- Opportunity of pooling buying needs across projects, diseases, department and offices.

The choice of partners is made in the design phase of a program/project upon strategic directions and project needs. Outsourcing/procurement needs shall result from identified gaps and operational decisions. Budget preparation provides guidance to the team on the expected spend, and enables management pre-approval. Procurement activities are most often subordinated to upstream processes such as (1) Disease strategy review, (2) Project planning, (3) Budget and action plan.

III.2 – Operating guidelines

Procurement

Procurement is the sourcing and purchasing of goods and services used by DNDi to achieve its objectives. All DNDi activities that involve the purchase of goods or services, either operating or capital expenditures, should be implemented following the policy and standard procurement procedures described below. Such purchases include:

- Provision of R&D-related activities (e.g. Lead optimization, CMC-Chemistry Manufacturing & Control, clinical trials, etc.)
- Provision of non-R&D related services (e.g. audit, IT, publications, events, etc.)

- Goods and services for Geneva and for Regional offices

In principle, the procurement process shall be led by the budget owner office.

Relationships with Individual consultants are managed as per HR policy.

Regional offices

The current policy applies to expenditures incurred by both Geneva and the Regional offices. Ceilings of the different procedures described below shall be adjusted to take into account local needs and circumstances.

Contracting

As part of its partnership model, DNDi is working with a variety of public and private organizations, in various jurisdictions; these collaborations are organized through different mechanisms that set mutual obligations. Contracting practices are managed by DNDi's BD&L Department (Business Development & Legal).

The procurement relationship must be formalized in a contract that specifically describes:

- Definition and scope of work
- Remuneration and payment schedule
- Intellectual Property and confidentiality issues, when appropriate
- Contact persons
- Conflict resolution principles and Governing laws
- Protocols for adjustment of the scope of work
- Any relevant appendices which define the service/work to be provided (Project team, planning and milestones, deliverables, etc.)

When the expense is below €5.000 and risks are limited (the ceiling shall be adapted to category of spend and per department or regional offices), an estimate or a quotation may suffice.

DNDi shall provide its own Terms & Conditions³ (T&C) or engage in negotiations to ensure final T&Cs are compatible with DNDi's model and do not put the organization at risk. When the relationship with a particular service provider is expected to cover several projects/engagements, a Master Service Agreement shall be put in place to simplify business relationships.

Partners and suppliers:

- Suppliers. For all activities outsourced by DNDi where business risks and costs are supported by DNDi (e.g. CROs, most non-R&D suppliers) and expected goods and services can be provided by several organizations, competitive bidding is the standard practice. Preferred provider: Minor amendments to an existing contract may be made once or twice. Demonstrated performance with several teams and cost effectiveness of a provider must

³ Appendix to be developed in the future

be documented and formalized into a Master Service Agreement. Such an agreement shall be reopened for tender on a regular basis.

- Partners. Working with partners is an intrinsic part of the DNDi model and shall be properly recognized. Such “partners” are directly taking risks associated to the project and supporting costs of specific activities, and/or associated to project decision-making. By doing so, they shall not be considered as suppliers. Such collaboration shall be properly documented⁴ and the parties shall work to identify specific in-kind or pro-bono contributions associated with the partnership. The nature of the partnership may evolve over time. Should the content of the partnership mobilize DNDi’s resources, associated goods or services shall be considered as a purchase and handled following DNDi’s procurement policy (upon the situations described below). In any case, DNDi will be diligent in avoiding conflicts of interest, and will document specific situations to clarify accountability and minimize risk.
- Sole provider. In some instances, DNDi may not be able to source goods and services through competitive bidding. Such situations include: the existence of only one supplier (no reasonable alternative or substitute), the specific relationship with a partner, an emergency situation. Lack of anticipation in project management does not fall into this particular case. A specific budget/quotation, including clarification of accountabilities and liabilities (or T&Cs), shall be asked for before goods and services are ordered and reviewed before launch to ensure best value and limitation of risks.

Decision authorities and team work:

Project leaders (usually Heads of program, Regional office or department) or someone in their team by delegation, have the final award authority on project expenses, provided they respect the following guiding principles:

- Expenses/investments shall be validated as part of the action plan and budget approved by the Executive team and the Board of directors. In situations which present significant changes or an unanticipated expense, validation has to be obtained with sufficient notice from the relevant director or Executive team if appropriate.
- Authorized persons who shall sign the contract must be consulted at the start of the process and regularly informed (even informally) of the selection process.
- Ad hoc consultation shall be organized with colleagues directly involved (e.g. regional offices).
- They shall comply with the principles set forth in this policy.

Procurement officer (Geneva) is instrumental in the roll out of the process and shall be involved from the initiation of the supply request onwards, for all expenses above €20k. He/she leads the

⁴ Template will be made available

administrative process in the context of Open consultation and Standard competitive bidding (see below) and acts as an advisor on any procurement issue internally.

He/she is the custodian of the policy/procedures and should therefore ensure compliance with the same. He/She can raise concerns to the management in situations of infringement to the current policy.

A selection committee is a good practice and must be performed for Open Competitive Bidding. This shall be organized by the Procurement Officer.

Regional procurement officer (either Regional Operations Manager, Regional Finance Manager, etc.) is in charge of the procurement activities of his/her office. He/She is responsible for the effective implementation of the regional procurement policy and shall be involved in the procurement of all supplies, which refer to the Standard/Open competitive biddings (see Appendix 2).

Finance department has to be consulted at initiation of the supply request to check associated budget and funding (the project leader remains responsible of his/her budget). They manage the process from the receipt of invoices down to payment.

Legal Counsel must be consulted in the preparation of the supplier consultation. He/She leads the contractual aspects of the negotiation (proposes standard T&Cs and contract templates, finalizes contract, supports signature process). All procurement contracts (or MSA) must be validated by Procurement / Legal department for clearance before final issuance.

The detailed process shall further clarify specific contributions.

Documentation:

All records relating to supplier selection, negotiation, award of contract and contract management must be archived. All key procurement information is stored in an appropriate Database tool.

Each decision of award must be documented, including approval by the authorized levels.

Due diligence shall be organized in the selection process to verify the ability of the supplier to fully deliver against the RFP/contract. Such information shall also be stored.

The signature policy, approved by the board, provides guidance on the authorization levels.

III.3 – Categories of consultation and associated guidelines

Competitive bidding is a principle which shall apply to all DNDi providers, no matter the category, the location, or the budget of the project in order to ensure the best match between DNDi's needs and the supplier offering (quality, delay, and cost).

For pragmatic purposes, the amount of the purchase determines the category of consultation:

- Light optional Competitive bidding (\leq €20.000)
- Standard Competitive bidding ($\text{€}20.000 < \dots \leq \text{€}200.000$)
- Open competitive bidding procedure ($>$ €200.000)

The thresholds amounts shall be adjusted by the Executive committee, to take into account DNDi's operational constraints and each regional office's unique circumstances.

Revision History

Version	Reasons and Changes	Date
Version 1.0	Key principles approved by Executive team	21 Sept. 2013
-	Regional Offices Consultation	Nov. 2013 – Jan. 2014
Version 2.4	Approved by Executive team	4 Feb. 2014