

If GIZ procures medicines in direct context of its programmes or projects and also in case of financing and in the context of advisory services, the following criteria are compulsory to be followed:

- I. Clinical criteria: Medicines are only allowed to be procured if they are indicated in:
  - the current WHO Essential Medicines Lists (WHO-EML)<sup>1</sup>
    or
  - the current national essential medicines list (n-EML)
- II. **Quality criteria for all products**: Registration / Marketing authorization for use in the recipient country (National requirements for registration applied).
- III. **Specific quality criteria** in the case of procurements of medicinal products and diagnostics for the treatment of HIV/AIDS, malaria and tuberculosis: the products must also be:
  - listed on the current WHO Prequalification Project lists (HIV/AIDS, Malaria and Tuberculosis Drugs and Diagnostics) / WHO prequalified by WHO PQ team<sup>2</sup>
     or
  - authorized by a strict regulatory authority SRA<sup>3</sup>

The supplier of medicines issues a summary of the pharmaceutical products delivered in form of an Excel sheet indicating the products delivered and their prices. The summary must be handed over to the Recipient immediately after delivery.

In order to avoid distributing defective pharmaceutical products (e. g. for a medicine: as a result of side effects not described before, or for a production batch): If it becomes unusable prematurely or is subsequently found to be a contaminated with harmful agents, the distribution must be organized and documented in such a way that an immediate recall of a medicine or individual batches is possible. In case of a recall of a medicine the recipient of the financing identifies the recipients of the medicines and informs them immediately about the measures to be taken.

## Other provisions

The provisions set out in this Annex shall apply unless expressly contractually agreed otherwise. In the event of failure to submit the respective documents in accordance with the agreed specifications and within the meaning of the provisions set out in this Annex, this shall constitute for GIZ an event affecting the contract due to a breach of a material contractual obligation entitling GIZ to suspend payments, terminate the contract and demand repayment. Additional agreements or agreements deviating from the above provisions must be made in writing and must be recorded in the implementation concept. GIZ is entitled to schedule further reviews and approvals and to request additional documentation from the recipient.

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<sup>&</sup>lt;sup>1</sup> WHO Model List of Essential Medicines

<sup>&</sup>lt;sup>2</sup> WHO – Prequalification of Medical Products

<sup>&</sup>lt;sup>3</sup> List of Stringent Regulatory Authorities