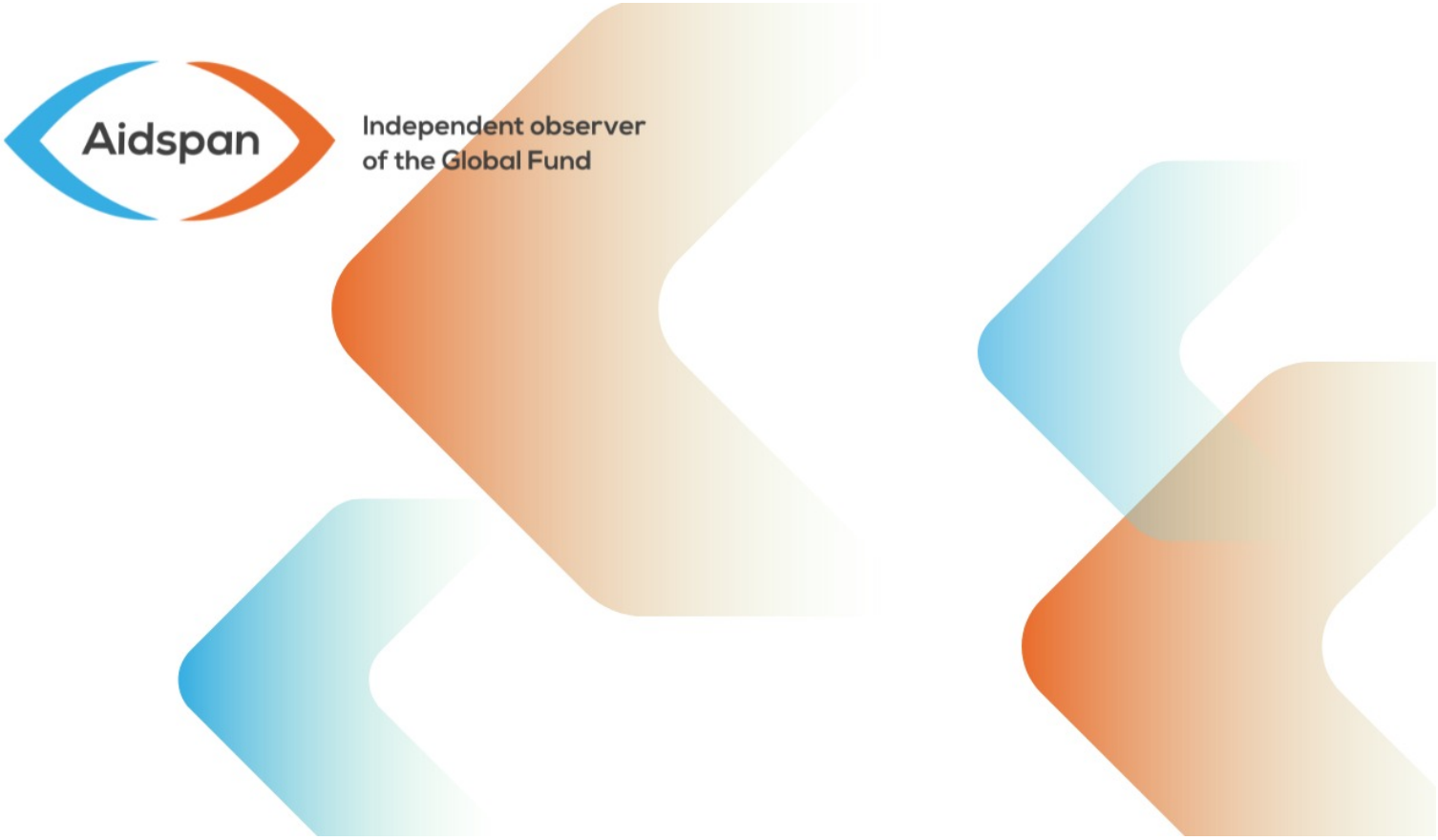

Quality Assurance of Limited Source Pharmaceutical Products

At its October 2002 meeting, the board decided that if a medicinal product is to be eligible for purchase using Global Fund grants, it must meet various requirements. One of these is that if it is a “single- or limited-source product,” it must (a) have been found to be acceptable by the WHO-initiated UN Pilot Procurement Quality and Sourcing Project, or (b) have been authorized for consumption in its country by a stringent regulatory authority, or (c) have been authorized by the national drug regulatory authority in the recipient’s country. Option (c) was originally applicable only until December 31, 2004, after which suppliers must comply with option (a) or (b).

At the November 2004 board meeting, the ability to use option (c) was extended to April 30, 2005.

At the board meeting just completed, extensive negotiations took place behind the scenes on “what to do about option (c).” These negotiations involved participants ranging from pharmaceutical company representatives to AIDS activists. An agreement, endorsed by the board, was finally arrived at. For the record, and without interpretation or summarizing, the board resolution was as follows:

“The Board decides to change its policy on quality assurance approved at the Third Board Meeting on “option (c)” by replacing the decision on Agenda Item 10(B)(4)(b)(c) with the following and eliminating the last sentence of that decision on the “option (c)” time limit.

- Once there are two or more equivalent pharmaceutical products that meet the standards in Option (a) or Option (b), then Option (c) is not applicable. Contracts entered into on or before April 30, 2005 with suppliers for products that qualified for purchase under Option (c) may be honoured by the Principal Recipient until they expire. No new purchase contracts or contract extensions for such products will be allowed after April 30, 2005.

- If the Principal Recipient determines that there is only one or no equivalent pharmaceutical product that meets the standards in Option (a) or Option (b) OR if the Principal Recipient determines that the product that meet these standards are unavailable ['Unavailable' is defined as: inability of the manufacturer to supply a sufficient quantity of finished product within 90 days from date of order] and represents the same to the Global Fund Secretariat, and the Secretariat does not object, then Global Fund resources may be used to procure other equivalent pharmaceutical products, provided that the products are selected in accordance with the following, in order of priority:
    1. the manufacturer has submitted an application for product approval to the WHO Prequalification Program or a stringent regulatory authority AND is manufactured at a site that is compliant with Good Manufacturing Practice (GMP), as certified after inspection by the WHO or a stringent regulatory authority;
    2. the product is manufactured at a GMP-compliant manufacturing site as certified after inspection by the WHO or a stringent regulatory authority.

  A Principal Recipient shall inform the Global Fund Secretariat if it procures under provisions (i) or (ii), after having followed the above process. In turn, the Secretariat, working with technical partners, shall contract an independent third-party to conduct random quality analysis of products being procured according to these criteria to ensure their quality in the absence of the Option (a) or Option (b) standard.

  In the event that (a) the submitted application for product approval is no longer under consideration, or (b) the independent third party finds the quality of the product to be unacceptable, the Principal Recipient shall promptly terminate the contract with the supplying manufacturer.

- In all cases, products purchased with Global Fund resources are subject to the monitoring product quality standards prescribed by the Fund as specified in Section 6 of the Report of the Third Board Meeting.
- Procurement of products according to criteria (i) or (ii) should be time limited and Principal Recipients should defer to Option (a) or (b) as soon as possible.

The Secretariat will monitor implementation of this decision and report to the Board at the Fourteenth Board meeting."

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