Special Price Rules for Bulk Pharmaceuticals under Commodity Import Programs (CIPs)

A Mandatory Reference for ADS Chapter 312

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Special Price Rules for Bulk Pharmaceuticals under Commodity Import Programs (CIPS).

In addition to the applicable price rules in Subpart G of AID Regulation 1, USAID will apply the following criteria in determining whether, under regulatory and statutory standards, a bulk pharmaceutical product described on the Application for Approval of Commodity Eligibility (Form AID-11) is "eligible and suitable:"

(1) USAID will not finance from an authorized source country a bulk pharmaceutical product at an FAS price which exceeds by more than 10 percent the FAS price at which the product, by whatever description, is generally available from any other free world country. With respect to a product patented in United States, USAID will compare FAS prices between the U.S. product and the identical product available in any free world country, provided such non-U.S. price was established by the patent holder or his/her licensee.

(2) USAID will not finance from an authorized source country a bulk pharmaceutical product at an FAS price which exceeds the lowest FAS price at which the same product, by whatever description, is available from the same source country.

(3) USAID will not finance from an authorized source country a bulk pharmaceutical product at a price which exceeds the price at which another lower-priced product can be obtained from any free world source, if there is evidence that the lower-priced product, although of different generic description, is, for the purpose intended, pharmacologically a substantial equivalent to the higher priced product for which USAID approval is solicited. Items which USAID has determined to be subject to this rule will be indicated in the implementing document issued by USAID which authorizes the use of USAID funds for the procurement of pharmaceutical products.

(4) USAID will not finance a bulk pharmaceutical product at a price which exceeds the lowest price charged by the supplier in any export sale of the item to any country, whether or not such sale has taken place under USAID financing. A supplier under this rule may exclude in his calculation of his lowest price, the lowest priced 5 percent of his sales volume within the most nearly relevant sales period. The "lowest price" shall take into account all sales by the supplier of the product in export, without regard to any trademark or other differentiation between items which are pharmacologically identical. USAID will not apply this special rule (d) in determining whether a product is "eligible and suitable" for USAID financing if (i) there is no U.S. patent covering the product and (ii) the proposed sale is to a buyer who is not affiliated with the seller.

While these price rules are not specifically applicable to finished dosage products, USAID may review the "eligibility and suitability" of such products under the same or comparable criteria.

With respect to any bulk pharmaceutical product for which USAID does grant commodity approval under the foregoing special rules, a supplier shall continue to

execute AID form 282 which binds the supplier to the price tests set forth in Subpart G of AID

Regulation 1. Upon post audit, a supplier of any bulk pharmaceutical product shall be held to the price tests set forth in that subpart of the regulation.

USAID will endeavor to provide a supplier, upon request, preliminary advice as to whether the price, at which the supplier proposes to sell a product in export, will be eligible for approval under the foregoing special rules prior to his entering into a contract to sell. USAID will not supply this type of advice unless the supplier provides with his request to USAID an indication that the solicitation may reasonably result in an agreement to sell.

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