Handbook 15: AID-Financed Commodities Chapter 6: Special Commodity Procurement Arrangements Section 6A: Introduction

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CHAPTER 6

SPECIAL COMMODITY PROCUREMENT ARRANGEMENTS

6A. Introduction

For certain kinds of commodities, AID requires special methods of purchasing or additional procedures. This chapter provides information and guidance for these special situations. Section 6B describes AID's special procedures for the centralized procurement of contraceptives and related family planning supplies. Section 6C covers the eligibility standards and technical rule for purchasing pharmaceuticals. Section 6D describes AID's fertilizer procurement process. Section 6E provides instructions for obtaining AID financing for used, rebuilt and reconditioned equipment. Section 6F provides procedures on purchasing from UNICEF.

Handbook 15: AID-Financed Commodities Chapter 6: Special Commodity Procurement Arrangements Section 6B: Contraceptives and Other Family Planning Commodities

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6B. <u>Contraceptives and Other Family Planning Commodities</u>

1. Introduction

a. This section outlines procurement policies and procedures applicable to contraceptives and other family planning supplies for projects. Although these commodities are normally eligible under nonproject Commodity Import Programs, project requirements account for almost all AID-financed purchases. The procurement procedures differ considerably for the two types of assistance. See Chapter 2C and Appendix B of this Handbook for eligibility criteria applicable to the procurement of these items under Commodity Import Programs.

b. In order to assure that contraceptives and related supplies are commensurate with AID's project goals, acceptable and responsive to the needs of recipient countries, consistent with uniform quality standards, and represent the lowest unit prices available, AID uses standard specifications, special funding procedures, and consolidated procurement methods. Unless otherwise specifically authorized by the Science & Technology Directorate of Population (S&T/POP), contraceptives and related family planning supplies for all AID projects, including those supported through bilateral programs as well as those that secure their funding through grants or contracts with private organizations, must be procured through AID's consolidated procurement contracts following procedures described in this section.

2. Procedures

a. Major Contraceptives

Major contraceptives are those products which AID annually acquires through consolidated procurement contracts. Major contraceptives currently include: condoms, oral contraceptives, IUDs, and vaginal foaming tablets. The list of products identified as major contraceptives may be changed from year to year in accordance with changes in AID program needs. Annual estimates of contraceptive requirements are carried out each year between October 1 and December 31. All Missions with population programs that require contraceptives fill out Contraceptive Procurement Tables (CPTs) that identify the quantity of each product that will be needed during the following two calendar years. Cooperating agencies receiving AID funding for family planning services and related contraceptives supplies also fill out CPTs to cover their anticipated program needs. Technical teams are available from S&T/POP to assist Missions with the completion of the CPTs. Specific instructions for estimating program needs and instructions for the transmission of funds and of desired shipping schedules are part of the CPT guidance materials which are provided to Missions and cooperating agencies each year by S&T/POP to assist in the preparation of annual estimates.

S&T/POP aggregates CPTs to determine the amounts of each commodity that will be required in the next procurement cycle. S&T/POP then notifies regional bureaus of the funds required from each Mission program to cover required procurements. Missions are asked to authorize <u>budget allotment transfers</u> through their respective geographic bureaus to S&T/POP to cover these procurements and related shipping costs. Where prior year or Economic Support (ESF) funds must be used, a <u>single funded</u> <u>Project Implementation Order/Commodities (PIO/C)</u> is to be provided to S&T/POP. <u>Budget allotment</u> transfers and PIO/Cs must be provided to S&T/POP prior to March 1 so that procurement solicitations can be issued. The Mission's list of required products and desired shipping schedules are to be transmitted by cable to S&T/POP.

b. Other Family Planning Commodities

Procurement requirements for other family planning commodities are submitted as PIO/C worksheets, in accordance with instructions in Appendix 5A, to AID/W for issuance to GSA for procurement. When quantities warrant, GSA negotiates annual or quantity contracts with suppliers. USAIDs are advised of contract awards by circular messages and furnished with item purchase description and specifications, unit cost, name of supplier, and ordering and shipping instructions. The following items are currently on GSA contract: contraceptive foam kits and contraceptive jelly.

c. AID Emblems

AID emblem requirements have been waived for shipments of contraceptives and related supplies to projects operated by AID grantee organizations. USAIDs may also specify in PIO/C worksheets that AID emblems should be omitted.

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6C. Pharmaceuticals

1. Introduction

a. Over the years, pharmaceuticals have had an important place in AID project and nonproject assistance activities. Due to their importance to human life and health, AID gives especially careful consideration to the procurement of AID-financed pharmaceuticals. Particular emphasis is placed on quality assurance and the appropriateness of the prices paid.

b. The procedures set forth in this section are applicable to project and nonproject assistance.

c. Policies related to the eligibility of pharmaceuticals for AID financing are included in Chapter 4C3 of Handbook 1, Supp B. Additional information is contained in Appendix B, Part II of Handbook 15.

d. See paragraph 6F of this Chapter for procedures to be used for procuring pharmaceuticals through UNICEF.

2. Procedures

a. Any of the procurement methods described in Chapter 3 of this Handbook may be utilized to procure pharmaceuticals. To achieve the most effective implementation, the method chosen should give consideration to the dual objectives of obtaining the lowest competitive price and assuring product quality and service.

b. Certain U.S. Government agencies, such as the General Services Administration and the Veterans Administration, are often used as procurement services agents for AID or the host country for pharmaceuticals, since they offer special expertise in this area, specifically mandated quality assurance and reasonable prices. (See Chapter 5 of this Handbook.)

c. All procurement authorizations, solicitations and contracts (PIO/C, IFB, RFQ, P.O., etc.), must meticulously describe the items(s) and the terms and conditions of purchase. Some key points to be covered include:

(1) Nomenclature and labeling - labeling with medical (generic) name.

(2) Product Specifications - Exact name, dosage form, special requirements and minimum remaining shelf life.

- (3) Packaging requirements Adequate for environment ent. Cold storage, if necessary.
- (4) Trade terms FAS, C.I.F., etc.
- (5) Delivery date.
- (6) Bid or performance bond requirement, if any.
- (7) Payment terms.
- (8) Quality assurance standards.
- (9) Special requirements for controlled substances, where applicable.
- (10) Applicability of AID Special Provisions 40.1 40.3.

3. Quality Assurance

a. Pharmaceuticals financed by AID from U.S. sources must comply with all applicable U.S. laws and

regulations enforced by the FDA. FDA assistance is available to ensure compliance with these requirements.

b. When the U.S. Government purchases pharmaceuticals, the FDA administers a government-wide quality assurance program. (Information on the program is available from SER/OP/COMS.) Pharmaceutical or medical device procurements must be sensitive to the requirements of the FDA program, which provides that:

(1) Prior to the award of a contract, in evaluating the responsibility of the bidder, the procuring authority determines through FDA whether the low bidder can meet the applicable standards relating to the quality of the product being procured.

(2) FDA laboratories perform all testing associated with the procurement, when necessary.

(3) FDA receives, evaluates, and as necessary, follows up on any quality-related product complaints.

M/SER/OP/COMS maintains liaison with the procuring agency and with the FDA in carrying out this program.

c. Where FDA quality assurance is impractical or for justifiable reasons inappropriate, the procuring authority can, with the concurrence of M/SER/OP, monitor compliance with quality by utilizing an approved independent testing laboratory.

d. When procuring pharmaceuticals of non-U.S. source, quality assurance must be considered on a case-by-case basis, in accordance with criteria requiring that information be available which adequately attests to the safety, efficacy and acceptable quality of the product. An adequate attestation from the manufacturer must show that the product meets an established pharmacopoeia standard in terms of identity, purity, potency, uniformity and bioavailability. The contract should provide for testing by an independent inspection of the product supplied and certification by the inspection firm that quality standards have been met.

4. Controlled Substances

The U.S. Drug Enforcement Administration (DEA) has designated certain pharmaceuticals as "controlled substances." There are special requirements applicable to the export of such items from the U.S. M/SER/OP/COMS will assist Missions in planning and making arrangements for any such procurements. Only under the most unusual and compelling circumstances would the procurement of such items be authorized from sources other than the U.S.

5. Other Special Considerations

a. Pharmaceuticals are sometimes recalled by U.S. companies. M/SER/OP maintains current listings of drugs being recalled, based on information provided by the FDA and DEA.

b. Shelf life remaining when a pharmaceutical is shipped must be in accordance with Special Provisions 40.1 - 40.3, as applicable. These Special Provisions are found in the AID Commodity Eligibility Listing, which is included as Appendix B to this Handbook.

c. The over-ordering of items, which may result in dated pharmaceuticals, must be avoided. M/SER/OP/COMS can provide information on the shelf life of any item so as to assist the Mission in determining how much to procure for a specific period of time. Handbook 15: AID-Financed Commodities Chapter 6: Special Commodity Procurement Arrangements Section 6C: Fertilizer

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6D. <u>Fertilizer</u>

1. Introduction

a. Fertilizer has, since the mid-60's, been a matter of particular interest and concern to AID The continued adequate supply of this commodity to developing countries is an essential ingredient in AID's agricultural program to improve food production and nutrition. Whether fertilizer is in over-supply or tight supply, the complexities of fertilizer procurement have led to AID involvement in the fertilizer procurement process to a far greater degree than most commodities.

b. Other policies relating to the eligibility of fertilizer for AID financing are given in Appendix B, Section IIB of this Handbook and in Handbook I, Supp. B, Chapter 4C8. See also Chapter 21E of Handbook 1, Supp B, with respect to the Development Fund for Africa (DFA).

2. Procedures

a. Procurement Through Formal Competitive Bid Procedures

Procurement of fertilizer by cooperating country government agencies, acting on their own behalf or on behalf of private buyers, is by formal competitive procedures unless the requirement for such procedures is waived by AID (the Geographic Bureau in consultation with M/SER/OP). Invitations for Bids for fertilizer and for the required shipping are cleared by M/SER/OP and the appropriate Geographic Bureau, in consultation with GC as appropriate. Timing of the procurement, the types and quantities of fertilizer sought, and the delivery schedule are all subject to AID clearance. A frequent procedure is to call for bids on an FOB basis and have a separate procurement for ocean transportation. Awards for both fertilizer and shipping must be approved by AID and must give consideration to cargo preference requirements.

When the procurement of fertilizer financed under the Development Fund for Africa (DFA) is restricted to U.S. source, which is the general rule, the above described procedures apply. The principal AID officers of field posts in Africa may make documented exceptions to this U.S. source policy, usually for small-volume purchases of fertilizer (5,000 M/Ts or less), financed under the DFA. Small-volume purchases of fertilizer funded by the DFA do not require prior AID/W review.

b. Negotiated Procurement

Under certain conditions, AID(M/SER/OP) may determine that it is appropriate to waive the normal requirement that agencies of cooperating countries procure fertilizer through formal competitive bidding procedures. Even if a waiver is approved, AID gives no assurance that it will finance fertilizer bought through negotiation until it has reviewed and approved the contract.

3. Payment

Because of the large amounts of money which typically are involved, suppliers of fertilizer and associated ocean transportation usually receive payment under letters of commitment issued directly to them by AID A letter of credit opened under an AID letter of commitment to a bank is acceptable for smaller shipments. Direct reimbursement to a borrower/grantee may also be used. (For details on these methods

of financing, see Handbook I, Supp. B, Chapter 15.)

Handbook 15: AID-Financed Commodities Chapter 6: Special Commodity Procurement Arrangements Section 6E: Used, Rebuilt or Reconditioned Equipment, Parts or Assemblies

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6E. Used, Rebuilt or Reconditioned Equipment, Parts or Assemblies

1. Introduction

a. It is AID's policy to finance only new equipment unless special circumstances justify authorizing the purchase of used, rebuilt or reconditioned equipment. The policy is set forth in Handbook 1, Supp. B, Chapter 4C6.

b. Under proper safeguards, the procurement of used equipment, which would usually be rebuilt or reconditioned, can provide certain advantages such as lower cost and quicker delivery. In addition, such equipment may be less sophisticated in design than new equipment, thus offering operational and maintenance advantages if spare parts are available.

c. This section describes the procedures, including proper safeguards, under which AID will consider approving financing for used, rebuilt or reconditioned equipment. Special requirements for rebuilt or reconditioned engines and parts or assemblies for engines and vehicles under nonproject assistance are covered in Part IIF of the Commodity Eligibility Listing (Appendix B to this Handbook).

d. Definitions

(1) "Used Equipment" is that equipment which is in other than an unused condition.

(2) "Rebuilt Equipment" is that equipment which (i) has been disassembled to the bare castings and then reassembled after replacing all parts found to be broken or worn beyond acceptable tolerances with new or re-machined parts, and (ii) is warranted to be in a condition equal to that when the equipment was originally manufactured.

(3) "Reconditioned equipment" is that equipment which (i) has been disassembled and then reassembled after having been thoroughly cleaned and after replacing all parts found to be broken or worn beyond acceptable tolerances with new or re-machined parts, and (ii) is warranted to be in good operating condition and in compliance with specifications prescribed by the purchaser and AID

2. Procedures

a. Authorization Policy

(1) AID may authorize the financing of used, rebuilt or reconditioned equipment on a case-by-case basis if the purchase is justified and the conditions and price of the equipment are acceptable to the buyer and to AID Depending on the type of equipment involved, where it is purchased, and other relevant factors, the procedures for authorizing and implementing such financing may vary.

(2) The procurement of used, rebuilt or reconditioned equipment which meets the basic requirements of 6E2b, below, may be approved by the appropriate Geographic Bureau and the Office of

Procurement (M/SER/OP), as described in 6E2c, below.

b. Authorization Procedures

(1) Buyer Application

The buyer requests AID, through the USAID, to approve a purchase of used, rebuilt or reconditioned equipment. The application must include:

(<u>1</u>) Buyer's assurance that the requirements of the program will be satisfied if the material purchased is used, rebuilt or reconditioned rather than new, and that economic considerations (e.g., remaining equipment life, spare parts supply, and relative costs) justify the procurement of used, rebuilt or reconditioned rather than new equipment. The buyer's application should also show that, through competition or other appropriate means, the procurement is assured to be from an economical and reliable source of supply which is the most advantageous to the buyer. If the used equipment is not to be rebuilt or reconditioned, the justification should address the reasons.

(2) The buyer shall include the inspection and appraisal requirement for the equipment and the name and address of the proposed inspector. The application must also include the buyer's agreement to arrange for the inspection and appraisal of the equipment by an inspector approved by AID with the understanding that the cost of such inspection and appraisal will be eligible for AID financing only if the equipment is approved for financing by AID Accordingly, the buyer must agree in writing to assume responsibility for and pay all inspection and appraisal costs in the event the transaction is not approved for AID financing.

(2) Inspection

(<u>1</u>) The buyer will contract with an inspector found acceptable by AID in writing. The contract with the inspector shall require that inspection be in accordance with the requirements approved by AID and shall provide for payment to the inspector as soon as the original inspection report has been delivered to and accepted by AID The contract shall specify that the equipment be fully examined as to utility, operating condition, spare parts availability, etc. and be appraised at current value and compared with the cost for comparable new equipment.

(2) After receipt of the inspection report, AID determines whether the inspected equipment conforms with the technical conditions specified by the buyer at a price acceptable to AID

(<u>3</u>) Used, rebuilt or reconditioned equipment may be approved for AID financing without inspection if the commodity transaction value (excluding insurance and freight) does not exceed \$25,000, and the supplier agrees to provide a warranty acceptable to the buyer and the AID Bureau engineer.

[NOTE: For reconditioned or rebuilt aircraft, aircraft engines or aircraft parts, AID accepts an FAA Export Certificate of Airworthiness, or Airworthiness Approval Tag, as appropriate, in lieu of inspection by an independent inspection agency. The price, however, will still be subject to review and acceptance by AID See Special Provision 66, Appendix B.]

(3) AID Approval

If AID agrees to finance the purchase, AID notifies the buyer in writing that the transaction will be eligible for financing, subject to compliance with other AID requirements, including any special requirements, imposed by AID The items must be permanently marked indicating, if this is the case, that they have been rebuilt or reconditioned, and the supplier must convey to the buyer a warranty in a form to be provided by the Geographic Bureau engineer. Such warranty would normally be equal to that extended by manufacturers of similar new equipment.

c. Responsibilities

(1) Implementing Office

For the procedures outlined below, the implementing office is the appropriate Geographic Bureau engineering staff in consultation with M/SER/OP. The Geographic Bureau, on a case-by-case basis, may establish the USAID as the implementing office.

(2) Approval Procedures

(<u>1</u>) The buyer's application is submitted through the USAID to the Geographic Bureau engineer for review and approval.

(2) The Geographic Bureau engineer informs the buyer, through the USAID, of the results of its review of the application, including the acceptability of the inspector.

(<u>3</u>) For equipment valued at less than \$1,000, and under other justifiable circumstances, the Geographic Bureau may nominate USAID personnel to carry out the inspection.

 $(\underline{4})$ The inspector's report is submitted to the Geographic Bureau engineer for acceptance.

 $(\underline{5})$ The Geographic Bureau engineer, in consultation with M/SER/OP, determines whether the inspected equipment conforms with the technical conditions specified by the buyer at a price acceptable to the buyer and to AID

(<u>6</u>) The Geographic Bureau engineer, normally through the USAID, notifies the buyer of the acceptability or unacceptability of the transaction for AID financing, including any special AID requirements.

(<u>7</u>) Where the buyer's application seeks approval for a series of purchases, as requirements arise, of rebuilt or reconditioned engines and parts or assemblies for engines and vehicles, the inspection and evaluation to be required by the Geographic Bureau engineer will cover the production, testing and quality control methods used by the rebuilding or reconditioning facility. The Geographic Bureau engineer may provide eligibility under specific conditions for such engines and parts from a named supplier over the life of the project while reserving the right to require interim inspection and evaluation to determine the continued competence and reliability of the rebuilder or reconditioner.

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6F. Procurement of Commodities from UNICEF

1. Introduction

This section describes the procedure for the procurement of AID-financed commodities from UNICEF. While procurement from UNICEF is a type of host country procurement which is outside AID's normal practice, it can offer certain advantages: e.g., worldwide acceptability under uniform, understandable

labeling; compatibility with other ongoing donor and local programs; reasonable prices; quality assurance; and prompt delivery. This section provides guidance to assist USAIDs in responding to host country inquiries and furnishes information for the planning and preparation of PIO/C worksheets issued by the USAIDs for the host country purchase of UNICEF items. Procurements undertaken through UNICEF will require waivers of source/origin and competition (see 6F4, below) and must be carefully reviewed and justified.

2. Authority

Procurement is carried out under a Memorandum of Understanding between UNICEF and AID signed in September 1984. The memorandum centralizes the procurement process by establishing M/SER/OP in AID/W and UNICEF, New York, as the implementing offices for procurement. UNICEF, New York, and UNIPAC, Copenhagen, will take no implementing action until the PIO/C, issued by M/SER/OP, and the accompanying direct Letter of Commitment, issued by M/PFM/FM, have been received and accepted by UNICEF, N.Y. As part of the centralization process, UNICEF, N.Y. has issued instructions to its field offices stating that they are not authorized to enter into local arrangements with USAIDs, or other entities acting for USAIDs, for the procurement of AID-financed commodities and that all such procurement must be handled through UNICEF's New York office in accordance with the Memorandum of Understanding.

The UNICEF procurement must be authorized pursuant to an AID loan or grant agreement or in implementing documents issued under such agreements which establish the commodities in question to be eligible for financing. The host country's signature in Block 2I of the PIO/C which describes the UNICEF procurement will constitute specific authorization by the host country for AID to act on the host country's behalf in forwarding host country orders for supplies to UNICEF.

3. Procedures

a. When the procurement is AID-financed, the host country contracting procedure provided by the Memorandum of Understanding is as follows:

(1) USAID prepares a PIO/C in worksheet form which designates UNICEF, New York as the authorized agent. The worksheet PIO/C should provide complete details of the items to be procured based on the UNIPAC catalog and should authorize both ocean and air transportation, the latter at UNICEF's option for temperature or time sensitive items or items not able to withstand the rigors of ocean transport. The completed worksheet PIO/C should be forwarded to M/SER/OP/COMS for processing and issuance in final form to UNICEF, New York. A copy of the worksheet PIO/C should also be furnished to the local UNICEF office. The copy should be clearly marked "FOR INFORMATION ONLY, NOT FOR PROCUREMENT ACTION" in order to avoid the potential for duplicate procurement.

(2) Upon receipt of the worksheet, M/SER/OP informs UNICEF, New York, of the proposed procurement and determines item availability, source/origin eligibility and adequacy of funds in the PIO/C. Upon receipt of UNICEF's favorable reply to the above, M/SER/OP issues the PIO/C to UNICEF in final form. Upon receipt of UNICEF's letter of acceptance of the PIO/C, M/SER/OP sends a copy of the PIO/C to PFM/FM/PAFD with a request for issuance of a direct letter of commitment (DLC) to UNICEF, New York. Upon receipt of the DLC, UNICEF forwards the PIO/C to UNIPAC, Copenhagen for supply action.

(3) Funding Estimate: For PIO/C budget planning, the following may be used: Item cost as stated in UNIPAC catalogue, 15 percent for ocean transportation or 25 percent for air transportation, 6 percent for UNICEF fee and 10 percent for contingency. USAID will be advised if additional funds are required. PIO/Cs are issued on a funds controlling basis, requiring that UNICEF inform M/SER/OP of the need for additional funds before shipment is made.

(4) When shipment is made, UNICEF forwards billing invoices and supporting documents to M/SER/OP for administrative approval and subsequent certification for payment by FM/PAFD under the DLC.

(5) M/SER/OP and UNICEF, New York are designated as the contact offices for coordinating, processing and monitoring all AID-financed procurements from UNICEF.

b. Host countries may also be purchasing from UNICEF using non-AID funds. Under these circumstances, the requesting office, for example the Ministry of Health, can place its order directly with UNICEF using the UNICEF procedures described in the United Nations Children's Fund Packing and Assembly Center (UNIPAC/Copenhagen) catalog. In such cases, the transaction takes place between the host country and UNICEF with no AID involvement.

4. Requirement for Waivers

a. UNICEF procurement requires: authorization of Code 899 geographic source (see Handbook 1, Supp. B, Chapter 5B4); noncompetitive procurement (see Handbook 1, Supp. B, Chapter 12C4a(2)(c)); and code 899 flag, if U.S. flag transportation is not available from Copenhagen as UNICEF cargo is ready and available for shipment (see Handbook 1, Supp. B, Chapter 7B4).

b. The above host country contracting waivers, where appropriate, should be issued in the field (including the transportation source waiver, since the cost of transportation will not exceed 25 percent of the official's authority to waive commodity source requirements). Issuance of such waivers should precede the issuance of and be part of the PIO/C worksheet forwarded to M/SER/OP.

c. In preparing and addressing the case for waiver to allow negotiation with a single source, USAIDs should consider:

(1) Whether proprietary procurement from UNICEF is justified and whether the UNICEF items are available from only one source taking into account any special requirements. Note that UNICEF items are available only from their Copenhagen warehouse.

(2) Whether adherence to competitive procedures would result in the impairment of the United States Foreign Assistance program or would not be in the best interest of the United States.