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CREDIT NUMBER 3777 IN

# Development Credit Agreement

(Food and Drugs Capacity Building Project)

between

INDIA

and

INTERNATIONAL DEVELOPMENT ASSOCIATION

Dated September 29, 2003

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**CREDIT NUMBER 3777 IN**

**DEVELOPMENT CREDIT AGREEMENT**

AGREEMENT, dated September 29, 2003, between INDIA, acting by its President (the Borrower) and INTERNATIONAL DEVELOPMENT ASSOCIATION (the Association).

WHEREAS (A) the Borrower, having satisfied itself as to the feasibility and priority of the Project described in Schedule 2 to this Agreement, has requested the Association to assist in the financing of the Project;

(B) certain activities under the Project will be carried out by the States of the Borrower (the Project States) with the Borrower's assistance, and as part of such assistance, the Borrower will make available to each of the Project States part of the proceeds of the Credit as provided in this Agreement; and

WHEREAS the Association has agreed, on the basis, *inter alia*, of the foregoing, to extend the Credit to the Borrower upon the terms and conditions set forth in this Agreement;

NOW THEREFORE the parties hereto hereby agree as follows:

**ARTICLE I**

**General Conditions; Definitions**

Section 1.01. The "General Conditions Applicable to Development Credit Agreements" of the Association, dated January 1, 1985 (as amended through October 6, 1999) (the General Conditions), constitute an integral part of this Agreement.

Section 1.02. Unless the context otherwise requires, the several terms defined in the General Conditions and in the Preamble to this Agreement have the respective meanings therein set forth and the following additional terms have the following meanings:

(a) "Eligible Categories" means Categories (1), (2), (3) and (4) set forth in the table in Part A.1 of Schedule 1 to this Agreement;

(b) "Eligible Expenditures" means the expenditures for goods, works and consultants' services referred to in Section 2.02 of this Agreement;

(c) "Environmental Management Plan" means the Environmental Management Plan furnished to the Association on December 17, 2002, which provides for certain environmental and social impact mitigation measures to be undertaken by the

Borrower as part of the implementation of the Project, as the same may be amended from time to time by agreement between the Borrower and the Association;

(d) "Financial Monitoring Report" means each report prepared in accordance with Section 4.02 of this Agreement;

(e) "HACCP" means Hazard Analysis Critical Control Point;

(f) "IEC" means information, education and communication;

(g) "Letter of Undertaking" means the letter of undertaking to be executed and furnished to the Borrower by each of the Project States pursuant to Section 3.01 (c) of this Agreement;

(h) "MIS" means management information system;

(i) "Midterm Review" means the midterm review to be carried out pursuant to paragraph 4 of Schedule 4 to this Agreement;

(j) "MOHFW" means the Borrower's Ministry of Health and Family Welfare;

(k) "NGO" means a non-profit legal entity, determined by the Borrower and the Association as capable of assisting in the fulfillment of the objectives of the Project;

(l) "PCU" means the Program Coordination Unit referred to in Part A.1 of Schedule 2 and paragraph 2 (a) of Schedule 4 to this Agreement;

(m) "Project Implementation Plan" means the Project Implementation Plan of the Borrower dated April 28, 2003, which sets out details of all procedures, guidelines, timetables and criteria required for the Project, including the financial, institutional and implementation arrangements relating to the carrying out of the Project, as the same may be amended from time to time by agreement between the Borrower and the Association;

(n) "Project Year" means the twelve (12) month period beginning from the Effective Date and ending twelve (12) months thereafter and each successive twelve (12) month period following thereafter;

(o) "Report-based Disbursements" means the Borrower's option for withdrawal of funds from the Credit Account referred to in Part B.2 of Schedule 1 to this Agreement;

(p) "Special Account" means the account referred to in Part B of Schedule 1 to this Agreement; and

(q) "SACS" means a State Aids Control Society established and registered within a Project State under the applicable Societies Registration Act, as amended, which is assigned financial management functions with respect to the participation of the Project State in the Project.

## ARTICLE II

### The Credit

Section 2.01. The Association agrees to lend to the Borrower, on the terms and conditions set forth or referred to in the Development Credit Agreement, an amount in various currencies equivalent to thirty nine million seven hundred thousand Special Drawing Rights (SDR 39,700,000).

Section 2.02. The amount of the Credit may be withdrawn from the Credit Account in accordance with the provisions of Schedule 1 to this Agreement for expenditures made (or, if the Association shall so agree, to be made) in respect of the reasonable cost of goods, works and services required for the Project and to be financed out of the proceeds of the Credit.

Section 2.03. The Closing Date shall be June 30, 2008 or such later date as the Association shall establish. The Association shall promptly notify the Borrower of such later date.

Section 2.04. (a) The Borrower shall pay to the Association a commitment charge on the principal amount of the Credit not withdrawn from time to time at a rate to be set by the Association as of June 30 of each year, but not to exceed the rate of one-half of one percent (1/2 of 1%) per annum.

(b) The commitment charge shall accrue: (i) from the date sixty (60) days after the date of this Agreement (the accrual date) to the respective dates on which amounts shall be withdrawn by the Borrower from the Credit Account or canceled; and (ii) at the rate set as of the June 30 immediately preceding the accrual date and at such other rates as may be set from time to time thereafter pursuant to paragraph (a) above. The rate set as of June 30 in each year shall be applied from the next date in that year specified in Section 2.06 of this Agreement.

(c) The commitment charge shall be paid: (i) at such places as the Association shall reasonably request; (ii) without restrictions of any kind imposed by, or in the territory of the Borrower; and (iii) in the currency specified in this Agreement for the purposes of Section 4.02 of the General Conditions or in such other eligible currency or currencies as may from time to time be designated or selected pursuant to the provisions of that Section.

Section 2.05. The Borrower shall pay to the Association a service charge at the rate of three-fourths of one percent ( $3/4$  of 1%) per annum on the principal amount of the Credit withdrawn and outstanding from time to time.

Section 2.06. Commitment charges and service charges shall be payable semiannually on June 1 and December 1 in each year.

Section 2.07. (a) Subject to paragraphs (b), (c) and (d) below, the Borrower shall repay the principal amount of the Credit in semiannual installments payable on each June 1 and December 1 commencing December 1, 2013 and ending June 1, 2038. Each installment to and including the installment payable on June 1, 2023 shall be one and one-fourth percent ( $1-1/4\%$ ) of such principal amount, and each installment thereafter shall be two and one-half percent ( $2-1/2\%$ ) of such principal amount.

(b) Whenever: (i) the Borrower's per capita gross national product (GNP), as determined by the Association, shall have exceeded for three consecutive years the level established annually by the Association for determining eligibility to access the Association's resources; and (ii) the Bank shall consider the Borrower creditworthy for Bank lending, the Association may, subsequent to the review and approval thereof by the Executive Directors of the Association and after due consideration by them of the development of the Borrower's economy, modify the repayment of installments under paragraph (a) above by:

(A) requiring the Borrower to repay twice the amount of each such installment not yet due until the principal amount of the Credit shall have been repaid; and

(B) requiring the Borrower to commence repayment of the principal amount of the Credit as of the first semiannual payment date referred to in paragraph (a) above falling six months or more after the date on which the Association notifies the Borrower that the events set out in this paragraph (b) have occurred, provided, however, that there shall be a grace period of a minimum of five (5) years on such repayment of principal.

(c) If so requested by the Borrower, the Association may revise the modification referred to in paragraph (b) above to include, in lieu of some or all of the increase in the amounts of such installments, the payment of interest at an annual rate agreed with the Association on the principal amount of the Credit withdrawn and outstanding from time to time, provided that, in the judgment of the Association, such revision shall not change the grant element obtained under the above-mentioned repayment modification.

(d) If, at any time after a modification of terms pursuant to paragraph (b) above, the Association determines that the Borrower's economic condition has

deteriorated significantly, the Association may, if so requested by the Borrower, further modify the terms of repayment to conform to the schedule of installments as provided in paragraph (a) above.

Section 2.08. The currency of the United States of America is hereby specified for the purposes of Section 4.02 of the General Conditions.

### **ARTICLE III**

#### **Execution of the Project**

Section 3.01. (a) The Borrower declares its commitment to the objectives of the Project as set forth in Schedule 2 to this Agreement, and, to this end, shall carry out the Project with due diligence and efficiency and in conformity with appropriate administrative, financial, public health and environmental practices, and shall provide, promptly as needed, the funds, facilities, services and other resources required for the Project.

(b) Without limitation upon the provisions of paragraph (a) of this Section and except as the Borrower and the Association shall otherwise agree, the Borrower shall carry out the Project in accordance with the Implementation Program set forth in Schedule 4 to this Agreement.

(c) Without limitation or restriction upon any of its obligations under the Development Credit Agreement, the Borrower shall cause each of the Project States to: (i) execute and furnish to the Borrower a letter of undertaking, in form and substance satisfactory to the Association; and (ii) carry out its respective activities under the Project in accordance with its Letter of Undertaking.

(d) Without limitation or restriction upon any of its obligations under the Development Credit Agreement, the Borrower shall take all actions, including the provision of funds, facilities, services and other resources, necessary or appropriate to enable each Project State to perform all the obligations of the Project State set forth in this Agreement and in the respective Letter of Undertaking of the Project State. The Borrower shall not take or permit to be taken any action which would prevent or interfere with such performance.

(e) The Borrower shall establish and implement arrangements, satisfactory to the Association, to make available for the benefit of each Project State a portion of the proceeds of the Credit to cover the amounts required by such Project State in carrying out its portion of the Project.

Section 3.02. Except as the Association shall otherwise agree, procurement of the goods, works and consultants' services required for the Project and to be financed out of

the proceeds of the Credit shall be governed by the provisions of Schedule 3 to this Agreement.

Section 3.03. For the purposes of Section 9.06 of the General Conditions and without limitation thereto, the Borrower shall:

(a) prepare, on the basis of guidelines acceptable to the Association, and furnish to the Association not later than six (6) months after the Closing Date or such later date as may be agreed for this purpose between the Borrower and the Association, a plan for the future operation of the Project; and

(b) afford the Association a reasonable opportunity to exchange views with the Borrower on said plan.

Section 3.04. The Borrower and the Association hereby agree that the obligations set forth in Sections 9.03, 9.04, 9.05, 9.06, 9.07 and 9.08 of the General Conditions (relating to insurance, use of goods and services, plans and schedules, records and reports, maintenance and land acquisition, respectively) in respect of the Project shall be carried out by each Project State pursuant to the terms of its respective Letter of Undertaking.

## **ARTICLE IV**

### **Financial Covenants**

Section 4.01. (a) The Borrower shall maintain a financial management system, including records and accounts, and prepare financial statements in a format acceptable to the Association, adequate to reflect in accordance with sound accounting practices, the operations, resources and expenditures related to the Project, of the departments or agencies of the Borrower and each Project State (including those of the SACS or other relevant entity) responsible for carrying out the Project or any part thereof.

(b) The Borrower shall, and shall cause each Project State (including those of the SACS or other relevant entity) to:

- (i) have the records, accounts and financial statements referred to in paragraph (a) of this Section and the records and accounts for the Special Account for each fiscal year audited, in accordance with auditing standards acceptable to the Association, consistently applied by independent auditors acceptable to the Association;
- (ii) furnish to the Association as soon as available, but in any case not later than six (6) months after the end of each such year, (A) certified copies of the financial statements referred to in paragraph (a) of this Section for such year as so audited, and

(B) an opinion on such statements, records and accounts and report of such audit, by said auditors, of such scope and in such detail as the Association shall have reasonably requested; and

(iii) furnish to the Association such other information concerning such records and accounts, and the audit thereof, and concerning said auditors, as the Association may from time to time reasonably request.

(c) For all expenditures with respect to which withdrawals from the Credit Account were Report-based Disbursements or were made on the basis of Financial Monitoring Reports or statements of expenditure, the Borrower shall:

(i) maintain or cause to be maintained, in accordance with paragraph (a) of this Section, records and separate accounts reflecting such expenditures;

(ii) retain or cause to be retained, until at least one year after the Association has received the audit report for the fiscal year in which the last withdrawal from the Credit Account was made, all records (contracts, orders, invoices, bills, receipts and other documents) evidencing such expenditures;

(iii) enable the Association's representatives to examine such records; and

(iv) ensure that such records and accounts are included in the annual audit referred to in paragraph (b) of this Section and that the report of such audit contains a separate opinion by said auditors as to whether the statements of expenditure or the reports referred to in Part A.4 of Schedule 1 to this Agreement, as the case may be, submitted during such fiscal year, together with the procedures and internal controls involved in their preparation, can be relied upon to support the related withdrawals.

Section 4.02. (a) Without limitation upon the Borrower's progress reporting obligations set out in paragraph 3 of Schedule 4 to this Agreement, the Borrower shall prepare and furnish to the Association a financial monitoring report, in form and substance satisfactory to the Association, which:

(i) sets forth sources and uses of funds for the Project, both cumulatively and for the period covered by said report, showing separately funds provided under the Credit, and explains variances between the actual and planned uses of such funds;



- (ii) describes physical progress in Project implementation, both cumulatively and for the period covered by said report, and explains variances between the actual and planned Project implementation; and
- (iii) sets forth the status of procurement under the Project, as at the end of the period covered by said report.

(b) The first Financial Monitoring Report, to be furnished by the Borrower after the date of this Agreement, shall be furnished to the Association not later than forty five (45) days after the end of the first calendar quarter after the Effective Date, and shall cover the period from the incurrence of the first expenditure under the Project through the end of such first calendar quarter; thereafter, each Financial Monitoring Report shall be furnished to the Association not later than forty five (45) days after each subsequent calendar quarter, and shall cover the period not covered by the previous Financial Monitoring Report until the end of such calendar quarter.

## **ARTICLE V**

### **Remedies of the Association**

Section 5.01. Pursuant to Section 6.02 (l) of the General Conditions, the following additional events are specified:

- (a) the Borrower shall have waived or failed to enforce any of the provisions of any Letter of Undertaking;
- (b) any Project State shall have failed to perform any of its obligations under its respective Letter of Undertaking;
- (c) any Letter of Undertaking shall have been amended, suspended, abrogated, repealed or waived so as to affect adversely the Project; and
- (d) as a result of events which have occurred after the date of the Development Credit Agreement, an extraordinary situation shall have arisen which shall make it improbable that any Project State will be able to perform its obligations under its Letter of Undertaking.

Section 5.02. Pursuant to Section 7.01 (h) of the General Conditions, the following additional event is specified, namely, that any of the events specified in paragraphs (a), (b) and (c) of Section 5.01 of this Agreement shall occur and shall continue for a period of 60 days after notice thereof shall have been given by the Association to the Borrower.

## ARTICLE VI

### Termination

Section 6.01. The date ninety (90) days after the date of this Agreement is hereby specified for the purposes of Section 12.04 of the General Conditions.

## ARTICLE VII

### Representative of the Borrower; Addresses

Section 7.01. The Secretary, Additional Secretary, Joint Secretary, Director, Deputy Secretary or Under Secretary of the Department of Economic Affairs in the Ministry of Finance or successor thereto of the Borrower are each designated as representative of the Borrower for the purposes of Section 11.03 of the General Conditions.

Section 7.02. The following addresses are specified for the purposes of Section 11.01 of the General Conditions:

For the Borrower:

Secretary to the Government of India  
Department of Economic Affairs  
Ministry of Finance  
New Delhi 110 001  
India

Cable address:	Telex:	Facsimile:
ECOFAIRS New Delhi	953-31-66175 FINE IN	91-11-23094075

For the Association:

International Development Association  
1818 H Street, N.W.  
Washington, D.C. 20433  
United States of America

Cable address:	Telex:	Facsimile:
INDEVAS Washington, D.C.	248423 (MCI) or 64145 (MCI)	(202) 477-6391

IN WITNESS WHEREOF, the parties hereto, acting through their duly authorized representatives, have caused this Agreement to be signed in their respective names in New Delhi, India, as of the day and year first above written.

INDIA

By

/s/ Dr. Ranjit Banerjee  
Authorized Representative

INTERNATIONAL DEVELOPMENT ASSOCIATION

By

/s/ Michael F. Carter  
Country Director, India

## SCHEDULE 1

### Withdrawal of the Proceeds of the Credit

#### A. General

1. The table below sets forth the Categories of items to be financed out of the proceeds of the Credit, the allocation of the amounts of the Credit to each Category and the percentage of expenditures for items so to be financed in each Category:

<u>Category</u>	<u>Amount of the Credit Allocated (Expressed in SDR Equivalent)</u>	<u>% of Expenditures to be Financed</u>
(1) Civil works	8,300,000	85%
(2) Equipment, furniture, materials, consumables and supplies	16,600,000	100% of foreign expenditures, 100% of local expenditures (ex-factory cost) and 80% of local expenditures for items procured locally
(3) Consultants' services:		
(a) NGO Services, training and workshops	2,900,000	100%
(b) Other services including surveys, IEC and MIS services	3,600,000	90%
(4) Incremental Operating costs	6,300,000	80% through July 31, 2005, 70% through July 31, 2006, 60% through July 31, 2007 and 25% thereafter
(5) Unallocated	2,000,000	
TOTAL	<u>39,700,000</u>	

For the purposes of this Schedule:

2. (a) the term “foreign expenditures” means expenditures in the currency of any country other than that of the Borrower for goods or services supplied from the territory of any country other than that of the Borrower;

(b) the term “local expenditures” means expenditures in the currency of the Borrower or for goods or services supplied from the territory of the Borrower; and

(c) the term “Incremental Operating Costs” means the following additional costs incurred in the carrying out of the Project: (i) remuneration of individuals appointed under the Project and assigned to positions specifically created for purposes of the Project; (ii) the costs of: (A) office expenses under the Project, (B) operation, hiring and maintenance of vehicles, (C) operation and maintenance of equipment purchased under the Project, (D) operation and maintenance of facilities constructed under the Project, and (E) Project related domestic travel including allowances.

3. Notwithstanding the provisions of paragraph 1 above, no withdrawals shall be made in respect of:

(a) payments made for expenditures prior to the date of this Agreement, except that withdrawals, in an aggregate amount not exceeding the equivalent of SDR 158,000, may be made in respect of Categories (1), (2), (3) and (4) on account of payments made for expenditures before that date but after April 1, 2003; and

(b) expenditures incurred in or by any Project State unless the Project State has executed and furnished to the Borrower a letter of Undertaking satisfactory to the Association.

4. The Association may require withdrawals from the Credit Account to be made on the basis of statements of expenditure for: (i) expenditures for civil works under contracts costing less than \$500,000 equivalent each; (ii) expenditures for goods under contracts costing less than \$300,000 equivalent each; (iii) expenditures for services under contracts costing less than: (A) \$100,000 equivalent each in the case of consulting firms, and (B) \$50,000 equivalent each in the case of individual consultants; and (iv) incremental operating costs, all under such terms and conditions as the Association shall specify by notice to the Borrower.

5. The Borrower may request withdrawals from the Credit account to be made on the basis of reports to be submitted to the Association in form and substance satisfactory to the Association, such reports to include the Financial Monitoring Report and any other information as the Association shall specify by notice to the Borrower (Report-based Disbursements). In the case of the first such request submitted to the Association before any withdrawal has been made from the Credit Account, the Borrower shall submit to the Association only a statement with the

projected sources and applications of funds for the Project for the six (6) month period following the date of such request.

B. Special Account

1. The Borrower may open and maintain in Dollars a special deposit account in the Reserve Bank of India, on terms and conditions satisfactory to the Association.

2. After the Association has received evidence satisfactory to it that the Special Account has been opened, withdrawals from the Credit Account of amounts to be deposited into the Special Account shall be made as follows:

(a) if the Borrower is not making Report-based Disbursements, withdrawals shall be made in accordance with the provisions of Annex A to this Schedule 1; and

(b) if the Borrower is making Report-based Disbursements, withdrawals shall be made in accordance with the provisions of Annex B to this Schedule 1.

3. Payments out of the Special Account shall be made exclusively for Eligible Expenditures. For each payment made by the Borrower out of the Special Account, the Borrower shall, at such time as the Association shall reasonably request, furnish to the Association such documents and other evidence showing that such payment was made exclusively for Eligible Expenditures.

4. Notwithstanding the provisions of Part B.2 of this Schedule, the Association shall not be required to make further deposits into the Special Account:

(a) if the Association, at any time, is not satisfied that the reports referred to in Part A.5 of this Schedule 1 adequately provide the information required for Report-based Disbursements;

(b) if the Association determines at any time that all further withdrawals for payment of Eligible Expenditures should be made by the Borrower directly from the Credit Account; or

(c) if the Borrower shall have failed to furnish to the Association, within the period of time specified in Section 4.01 (b) (ii) of the Agreement, any of the audit reports required to be furnished to the Association pursuant to said Section in respect of the audit of: (i) the records and accounts for the Special Account; or (ii) the records and accounts reflecting expenditures with respect to which withdrawals were Report-based Disbursements or were made on the basis of statements of expenditure, as the case may be.

5. The Association shall not be required to make further deposits into the Special Account in accordance with the provisions of Part B.2 of this Schedule if, at any time, the Association shall have notified the Borrower of its intention to suspend in whole or in part the right of the Borrower to make withdrawals from the Credit Account pursuant to Section 6.02 of the General Conditions. Upon such notification, the Association shall determine, in its sole discretion, whether further deposits into the Special Account may be made and what procedures should be followed for making such deposits, and shall notify the Borrower of its determination.

6. (a) If the Association determines at any time that any payment out of the Special Account was made for an expenditure which is not an Eligible Expenditure, or was not justified by the evidence furnished to the Association, the Borrower shall, promptly upon notice from the Association, provide such additional evidence as the Association may request, or deposit into the Special Account (or, if the Association shall so request, refund to the Association) an amount equal to the amount of such payment. Unless the Association shall otherwise agree, no further deposit by the Association into the Special Account shall be made until the Borrower has provided such evidence or made such deposit or refund, as the case may be.

(b) If the Association determines at any time that any amount outstanding in the Special Account will not be required to cover payments for Eligible Expenditures during the six-month period following such determination, the Borrower shall, promptly upon notice from the Association, refund to the Association such outstanding amount.

(c) The Borrower may, upon notice to the Association, refund to the Association all or any portion of the funds on deposit in the Special Account.

(d) Refunds to the Association made pursuant to subparagraph (a), (b) or (c) of this paragraph 6 shall be credited to the Credit Account for subsequent withdrawal or for cancellation in accordance with the provisions of the Development Credit Agreement.

**Annex A  
to  
SCHEDULE 1**

**Operation of Special Account  
When Withdrawals Are Not  
Report-based Disbursements**

1. For the purposes of this Annex, the term “Authorized Allocation” means an amount equivalent to US\$4,500,000 to be withdrawn from the Credit Account and deposited into the Special Account pursuant to paragraph 2 of this Annex; provided, however, that, unless the Association shall otherwise agree, the Authorized Allocation shall be limited to an amount equivalent to US\$2,500,000 until the aggregate amount of withdrawals from the Credit Account, plus the total amount of all outstanding special commitments entered into by the Association pursuant to Section 5.02 of the General Conditions shall equal or exceed the equivalent of SDR 13,000,000.

2. Withdrawals of the Authorized Allocation and subsequent withdrawals to replenish the Special Account shall be made as follows:

(a) For withdrawals of the Authorized Allocation, the Borrower shall furnish to the Association a request or requests for deposit into the Special Account of an amount or amounts which in the aggregate do not exceed the Authorized Allocation. On the basis of each such request, the Association shall, on behalf of the Borrower, withdraw from the Credit Account and deposit into the Special Account such amount as the Borrower shall have requested.

(b) For replenishment of the Special Account, the Borrower shall furnish to the Association requests for deposit into the Special Account at such intervals as the Association shall specify. Prior to or at the time of each such request, the Borrower shall furnish to the Association the documents and other evidence required pursuant to Part B.3 of Schedule 1 to this Agreement for the payment or payments in respect of which replenishment is requested. On the basis of each such request, the Association shall, on behalf of the Borrower, withdraw from the Credit Account and deposit into the Special Account such amount as the Borrower shall have requested and as shall have been shown by said documents and other evidence to have been paid out of the Special Account for Eligible Expenditures. Each such deposit into the Special Account shall be withdrawn by the Association from the Credit Account under one or more of the Eligible Categories.

3. The Association shall not be required to make further deposits into the Special Account, once the total unwithdrawn amount of the Credit minus the total amount of all outstanding special commitments entered into by the Association pursuant to Section 5.02 of the General Conditions shall equal the equivalent of twice the amount of the Authorized Allocation. Thereafter, withdrawal from the Credit Account of the remaining unwithdrawn amount of the Credit shall follow such procedures as the



Association shall specify by notice to the Borrower. Such further withdrawals shall be made only after and to the extent that the Association shall have been satisfied that all such amounts remaining on deposit in the Special Account as of the date of such notice will be utilized in making payments for Eligible Expenditures.

**Annex B  
to  
SCHEDULE 1**

**Operation of Special Account  
When Withdrawals Are  
Report-based Disbursements**

1. Withdrawals from the Credit Account shall be deposited by the Association into the Special Account in accordance with the provisions of Schedule 1 to this Agreement. Each such deposit into the Special Account shall be withdrawn by the Association from the Credit Account under one or more of the Eligible Categories.
2. Upon receipt of each application for withdrawal of an amount of the Credit, the Association shall, on behalf of the Borrower, withdraw from the Credit Account and deposit into the Special Account an amount equal to the lesser of: (a) the amount so requested; and (b) the amount which the Association has determined, based on the reports referred to in Part A.5 of this Schedule 1 applicable to such withdrawal application, is required to be deposited in order to finance Eligible Expenditures during the six-month period following the date of such reports.
3. The Association shall not be required to make further deposits into the Special Account, once the total unwithdrawn amount of the Credit minus the total amount of all outstanding special commitments entered into by the Association pursuant to Section 5.02 of the General Conditions shall equal the equivalent of twice the amount of the Authorized Allocation. Thereafter, withdrawal from the Credit Account of the remaining unwithdrawn amount of the Credit shall follow such procedures as the Association shall specify by notice to the Borrower. Such further withdrawals shall be made only after and to the extent that the Association shall have been satisfied that all such amounts remaining on deposit in the Special Account as of the date of such notice will be utilized in making payments for Eligible Expenditures.

## **SCHEDULE 2**

### **Description of the Project**

The objectives of the Project are to improve the quality and safety of foods and drugs through: (i) the strengthening of consumer and other stakeholder education to enhance public awareness and knowledge of: (A) issues of food safety and quality, and (B) issues regarding drug quality and misuse of drugs; (ii) support the development of recommendations and options for appropriate policies and measures on food and drug issues; and (iii) the strengthening of: (A) the regulatory framework for food and drugs, and (B) public-private partnership.

The Project consists of the following Parts, subject to such modifications thereof as the Borrower and the Association may agree upon from time to time to achieve such objectives:

#### Part A: Policy Development, Program Coordination and Monitoring

Support development of recommendations and options for appropriate policies and measures, and strengthening of the central government food and drug directorates for improved program coordination and monitoring, including: (i) the establishment of a central Program Coordination Unit; (ii) the establishment of a computerized management information system to enhance information flows and coordination between the central and State regulatory agencies; (iii) the improvement of central physical facilities for food and drugs oversight and related staffing; (iv) provision of training and fellowships; (v) the carrying out of annual household sample surveys by independent agencies and/or consumer groups to assess public perceptions and knowledge about quality and safety of foods and drugs; and (vi) the development and implementation of an IEC strategy for the improvement of consumer behavior.

The carrying out of independent audits of private and public testing laboratories by a panel of experts appointed by MOHFW.

The implementation of environmental management plans and the carrying out of audits by a consultant agency to oversee such implementation; and assessment of compliance with said plan.

The carrying out of studies; provision of technical advisory services; workshops; the acquisition of goods, including computers and software; and the carrying out of necessary construction works.

#### Part B: Food Quality and Safety

1. The strengthening of the Borrower's oversight and regulatory capacity for food safety at the central and State levels, educate consumers and other stakeholders on

matters related to food safety and to upgrade related skills in the public and private sector, including:

(a) the building of consumer and other stakeholder awareness and knowledge of food safety issues, through: (i) the development and carrying out, with the assistance of professional media agencies, NGOs and consumer organizations, of strategies to disseminate such information to consumers, small manufacturers, retailers and street vendors and others operating in the food supply chain; and (ii) facilitating the adoption of safe practices in the handling of food within households;

(b) the enhancement of regulatory staff skills through: (i) in-service training, and joint training by national apex training centers of public and private sector personnel consisting of about 2,000 inspectors and 500 analysts in public sector laboratories and about 1000 professionals from private sector and consumer organizations; and (ii) training of personnel of about 20 umbrella consumer organizations in advocacy and other necessary skills;

(c) the development and dissemination of Hazard Analysis Critical Control Point (HACCP) standards for the domestic food industry;

(d) construction, renovation and equipping of central and State laboratories, consisting of: (i) ten (10) central laboratories in Mumbai, Ghaziabad, Kandla, Attari, Raxaul, Sonali and four other locations along the Indo-Nepal border; (ii) eleven (11) port health offices at the following cities and border sites, namely Kandla, Mumbai, Chennai, Kolkata, Delhi including ICD, Kochi, Visakhapatnam, Attari, ICD Jodhpur, Raxaul, Sonali, the National Institute of Nutrition, Hyderabad and the Central Food Technology Research Institute, Mysore; (iii) nine (9) State food testing laboratories in Visakhapatnam, Gangtok, Imphal, Chennai, Raipur, Ranchi, Rudrapur, Panaji and Gorakhpur; and (iv) six (6) existing State food testing laboratories at Shillong, Kohima, Jaipur, Baroda, Bhuj and Moreh; and

(e) the acquisition of provision of furniture, equipment and laboratory supplies for new and existing laboratories.

#### Part C: Drugs Quality and Safety

1. The development and carrying out of a program, with the assistance of professional media agencies, NGOs and consumer organizations, to improve consumer and prescriber awareness and behavior regarding the quality and rational use of drugs, including the dissemination of information to small manufacturers and retailers of drugs along the drug supply chain with a view to facilitating the adoption by consumers of quality and safety as criteria in making choices of drugs and retail outlets.

2. The enhancement of staff skills through training in Good Manufacturing Practices and Good Laboratory Practices of private and public sector personnel consisting

of about 2,000 workers from small scale industries, and 625 staff and analysts from the public sector.

3. Updating and dissemination of pharmaceutical standards, including the updating and dissemination of the Indian Pharmacopoeia.

4. (a) The construction and equipping of: (i) a new Central drug laboratory at Mumbai and the renovation of the Central India Pharmacopoeia laboratory at Ghaziabad; and (ii) five new State drug testing laboratories at Kolkata, Raipur, Ranchi, Rudrapur and Panaji and the renovation of 12 State laboratories at Hyderabad, Vijaywada, Baroda, Thiruvananthapuram, Bangalore, Bhopal, Bhubaneshwar, Pondicherry, Khandaghat, Chennai, Agartala and Lucknow.

(b) The acquisition of furniture, equipment and laboratory supplies for the State laboratories.

\* \* \*

The Project is expected to be completed by December 31, 2007.

### **SCHEDULE 3**

#### **Procurement**

##### Section I. Procurement of Goods and Works

###### Part A: General

Goods and works shall be procured in accordance with the provisions of Section I of the “Guidelines for Procurement under IBRD Loans and IDA Credits”, published by the Bank in January 1995 and revised in January and August 1996, September 1997 and January 1999 (the Guidelines) and the following provisions of Section I of this Schedule.

###### Part B: International Competitive Bidding

1. Except as otherwise provided in Part C of this Section, goods shall be procured under contracts awarded in accordance with the provisions of Section II of the Guidelines and paragraph 5 of Appendix 1 thereto.
2. The following provisions shall apply to goods to be procured under contracts awarded in accordance with the provisions of paragraph 1 of this Part B:

- (a) Grouping of contracts

To the extent practicable, contracts for goods shall be grouped in bid packages estimated to cost \$300,000 equivalent or more each.

###### Part C: Other Procurement Procedures

1. National Competitive Bidding

Goods estimated to cost less than \$300,000 equivalent per contract, up to an aggregate amount not to exceed \$5,260,000 equivalent, may be procured under contracts awarded in accordance with the provisions of paragraphs 3.3 and 3.4 of the Guidelines.

Works estimated to cost more than \$30,000 equivalent per contract may be procured under contracts awarded in accordance with the provisions of paragraphs 3.3 and 3.4 of the Guidelines.

2. International or National Shopping

- (a) Subject to subparagraph (b) of this paragraph, goods estimated to cost less than \$30,000 equivalent per contract, up to an aggregate amount not to exceed \$5,950,000 equivalent, may be procured under contracts awarded on the basis of national

shopping procedures in accordance with the provisions of paragraphs 3.5 and 3.6 of the Guidelines.

(b) Reference standards for identification, decomposition, impurity, quantitative analysis for the drugs, validation of analytical methods and calibration of analytical equipment used by the Central and State Government laboratories as well as the private sector, up to an aggregate amount not to exceed \$330,000 equivalent, may be procured under contracts awarded on the basis of international or national shopping procedures in accordance with the provisions of paragraphs 3.5 and 3.6 of the Guidelines.

3. Direct Contracting

Goods and works which should be procured as an extension of an existing contract or must be purchased from the original supplier to be compatible with existing equipment or are of a proprietary nature and costing \$10,000 equivalent or less in the aggregate, may, with the Association's prior agreement, be procured in accordance with the provisions of paragraph 3.7 of the Guidelines.

4. Procurement of Small Works

The following works may be procured under lump-sum, fixed-price contracts awarded on the basis of quotations obtained from three (3) qualified domestic contractors in response to a written invitation, namely: (i) new construction and renovation works estimated to cost less than \$30,000 equivalent per contract, up to an aggregate amount not to exceed \$1,730,000 equivalent; and (ii) building maintenance works estimated to cost less than \$10,000 equivalent per contract, up to an aggregate amount not to exceed \$680,000 equivalent. The invitation shall include a detailed description of the works, including basic specifications, the required completion date, a basic form of agreement acceptable to the Association, and relevant drawings, where applicable. The award shall be made to the contractor who offers the lowest price quotation for the required work, and who has the experience and resources to complete the contract successfully.

5. Force Account

The following works may, with the Association's prior agreement, be carried out by force account in accordance with the provisions of paragraph 3.8 of the Guidelines, namely: (i) works which meet the requirements of paragraph 3.8 of the Guidelines and costing \$10,000 equivalent or less per contract; and (ii) as an alternative to procurement under paragraph 4 (ii) of this Part C, works estimated to cost less than \$10,000 equivalent per contract for the maintenance of buildings, up to an aggregate amount not to exceed \$680,000 equivalent.

Part D: Review by the Association of Procurement Decisions

1. Procurement Planning

Prior to the issuance of any invitations to bid for contracts, the proposed procurement plan for the Project shall be furnished to the Association for its review and approval, in accordance with the provisions of paragraph 1 of Appendix 1 to the Guidelines. Procurement of all goods and works shall be undertaken in accordance with such procurement plan as shall have been approved by the Association, and with the provisions of said paragraph 1.

2. Prior Review

The procedures set forth in paragraphs 2 and 3 of Appendix 1 to the Guidelines shall apply with respect to: (i) each contract for goods estimated to cost \$300,000 equivalent or more; (ii) each contract for works estimated to cost \$500,000 equivalent or more; (iii) each of the first two contracts for goods estimated to cost more than \$30,000 equivalent but less than \$300,000 equivalent; and (iv) the first contract for works estimated to cost more than \$30,000 equivalent but less than \$500,000 equivalent.

3. Post Review

With respect to each contract not governed by paragraph 2 of this Part, the procedures set forth in paragraph 4 of Appendix 1 to the Guidelines shall apply.



## Section II. Employment of Consultants

### Part A: General

Consultants' services shall be procured in accordance with the provisions of Sections I and IV of the "Guidelines: Selection and Employment of Consultants by World Bank Borrowers", published by the Bank in January 1997 and revised in September 1997, January 1999 and May 2002 (the Consultant Guidelines), Paragraph 1 of Appendix 1 thereto, Appendix 2 thereto and the following provisions of Section II of this Schedule.

### Part B: Quality- and Cost-based Selection

1. Except as otherwise provided in Part C of this Section, consultants' services shall be procured under contracts awarded in accordance with the provisions of Section II of the Consultant Guidelines, and the provisions of paragraphs 3.13 through 3.18 thereof applicable to quality- and cost-based selection of consultants.

2. The following provision shall apply to consultants' services to be procured under contracts awarded in accordance with the provisions of the preceding paragraph. The short list of consultants for services estimated to cost the equivalent of less than \$200,000 per contract, may comprise entirely national consultants in accordance with the provisions of paragraph 2.7 and footnote 8 of the Consultant Guidelines.

### Part C: Other Procedures for the Selection of Consultants

#### 1. Selection Based on Consultants' Qualifications

Services of a consulting firm or entity to carry out important studies and policy reviews identified under the policy matrix of the Project, may be procured under contracts awarded in accordance with the provisions of paragraphs 3.1 and 3.7 of the Consultant Guidelines.

#### 2. Single Source Selection

Services of the following autonomous institutions or entities may, with the Association's prior agreement, be procured in accordance with the provisions of paragraphs 3.8 through 3.11 of the Consultant Guidelines, namely: (i) nationally renowned institutions undertaking training and workshops under the Project; and (ii) any institution or entity undertaking surveys under the Project.

#### 3. Individual Consultants

Services of individual consultants for tasks that meet the requirements set forth in paragraph 5.1 of the Consultant Guidelines shall be procured under contracts awarded in

accordance with the provisions of paragraphs 5.1 through 5.3 of the Consultant Guidelines.

4. Service Delivery Contractors

Services estimated to cost less than \$20,000 equivalent per contract may be procured in accordance with procedures acceptable to the Association.

Part D: Review by the Association of the Selection of Consultants

1. Selection Planning

A plan for the selection of consultants, which shall include contract cost estimates, contract packaging, and applicable selection criteria and procedures, shall be furnished to the Association for its review in accordance with the provisions of paragraph 1 of Appendix 1 of the Consultant Guidelines. Selection of all consultants' services shall be undertaken in accordance with such selection plan as shall have been approved by the Association.

2. Prior Review

(a) With respect to each contract for the employment of consulting firms estimated to cost the equivalent of \$100,000 or more, the procedures set forth in paragraphs 2, 3 and 5 of Appendix 1 to the Consultant Guidelines shall apply.

(b) With respect to each contract for the employment of individual consultants estimated to cost the equivalent of \$50,000 or more, the qualifications, experience terms of reference and terms of employment of the consultants shall be furnished to the Association for its prior review and approval. The contract shall be awarded only after the said approval shall have been given. The provisions of paragraph 3 of Appendix 1 to the Consultant Guidelines shall also apply to such contracts.

3. Post Review

With respect to each contract not governed by paragraph 2 of this Part, the procedures set forth in paragraph 4 of Appendix 1 to the Consultant Guidelines shall apply.

#### **SCHEDULE 4 Implementation Program**

1. (a) The Borrower shall maintain the Project Implementation Plan and the Environmental Management Plan each in a form and substance satisfactory to the Association.

(b) The Borrower shall carry out the Project in accordance with the Project Implementation Plan and the Environmental Management Plan and, except as the Association shall otherwise agree, the Borrower shall not amend or waive any provision of the Project Implementation Plan or the Environmental Management Plan if, in the opinion of the Association, such amendment or waiver may materially and adversely affect the carrying out of the Project or the achievement of the objectives thereof.

(c) The Borrower shall by June 30, 2004 formulate a strategy and action plan for carrying out IEC activities under the Project and, shall, thereafter implement it in a manner satisfactory to the Association.

2. (a) The Borrower shall no later than October 31, 2003 fully establish and thereafter maintain in MOHFW a Program Coordination Unit in a form and with functions, membership, staffing and resources satisfactory to the Association. PCU shall be under the supervision of the Joint Secretary of MOHFW and its membership shall include: (i) an IEC/NGO consultant responsible for promoting consumer awareness and knowledge through media and NGO channels; and (ii) a qualified financial specialist and accountants. PCU shall also be assisted by procurement specialists and architects of MOHFW.

(b) The functions of PCU shall include: (i) coordination of Project activities with other line departments, ministries and technical agencies of the Borrower; (ii) preparation of annual action plans; (iii) monitoring and evaluation of Project activities; (iv) financial management; and (v) procurement of Project inputs.

3. The Borrower shall:

(a) maintain policies and procedures adequate to enable it to monitor and evaluate on an ongoing basis, in accordance with the indicators satisfactory to the Association, the carrying out of the Project and the achievement of the objectives thereof;

(b) furnish to the Association in the month of June of each Project Year, a report, of such scope and in such detail as the Association shall reasonably request, on progress made in the carrying out of the Project during the twelve (12) month period immediately preceding said month of June, such progress to be measured against the indicators referred to in Clause 3 (a) of this Schedule; and

(c) review with the Association in the month of July of each Project Year progress made in the carrying out of the Project and the attainment of the objectives thereof, such reviews to be based on the reports referred to in subparagraph (b) above; and thereafter take, or cause to be taken, all such action which shall have been agreed upon by the Borrower and the Association during such reviews as necessary for the efficient execution of the Project and the achievement of the objectives thereof.

4. The Borrower shall no later than December 31, 2005, carry out jointly with the Association a Midterm Review of the progress made in carrying out the Project. The Midterm Review shall cover: (i) an assessment of: (A) progress made in carrying out work programs prepared for the Project, (B) training provided under the Project, (C) procurement under the Project, (D) the extent to which the indicators referred to in Clause 3 (a) of this Schedule have been achieved, (E) plans made or proposed for updating said indicators; and (ii) such other Project related matters as the Borrower or the Association shall reasonably request.