Detailed Project Report for Investment in Innovative Pharma: Establishing Pharma Funds

National Institute of Public Finance and Policy

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1 Background

Venture capital (VC) funds make equity or equity-linked investments in young growth-oriented firms. The VC industry developed as a financing solution for high-risk, potentially high-reward projects that, due to the lack of substantial tangible assets, expected years of negative earnings, and uncertain prospects, are unable to raise funding from more traditional sources like banks or capital markets.

Pharma R&D projects are a typical example of such "high-risk, potentially high-reward" projects that struggle to raise funding in the absence of a well-developed local VC industry. The Feasibility Report argued that providing a Government 'push' for the development of a focussed VC industry would promote entrepreneurship in the pharma R&D sector and support the development of a self-sustaining environment for pharma R&D in India. It also discussed several 'public venture capital' models that have been adopted both in India and abroad to achieve this objective. The proposed implementation model for the project draws on the positive features of these experiences to construct a blueprint for one or more 'Pharma Funds' that are professionally managed, mobilise investments from both the Government and private investors, and focus on investing in pharma R&D projects.

This document sets out in detail the design for the project and the manner in which each Pharma Fund will be established and managed, the identities and roles of key stake-holders, and estimated event schedules and time-lines.

2 Structure and Organisation of Pharma Fund(s)

Fund structuring is driven by several considerations including the location of investee companies, location of investors, legal requirements, and tax considerations. It is intended that the Government will give Fund Managers complete flexibility to structure the Pharma Fund(s) in any manner that is effective for the particular specifications of the Pharma Fund established by them. However, in order to provide context about the requirements of the Government and about aspects of the project design, this section describes a typical structure of a domestic venture capital fund with domestic investors (Fund). It may be noted that the principles of the project design specified in this document are intended to be made applicable to every Pharma Fund, regardless of its structure or the form of its organization. The legal organisation of a Fund would be in the form of a trust (Trust) created by means of a trust deed entered into between the settlor of the trust and the selected trustee (Trustee). All investments in the Fund would, in law, constitute contributions to the Trust and would be held and managed for the benefit of the investors (Investors) who would be the beneficiaries of the Trust. The Trustee would, under the trust deed, be responsible for managing all the affairs of the Trust and have the power to administer the assets of the Trust and authorise transactions on behalf of the Trust. The trust deed would however empower the Trustee to appoint one or more professional fund managers (Fund Manager) to manage, administer and advise the Fund and delegate to such fund manager certain functions of management and administration of the Fund in terms of an investment management agreement entered into between them, which would record the terms and conditions of the appointment and delegation. The Fund Manager may be an individual, a set of individuals or a set of individuals organized in the form of a company; and in the latter case would typically be referred to as an 'asset management company'.

The Fund Manager would normally be responsible for raising capital from the Investors, reviewing and selecting investee companies (Targets), disbursing of funds to the Targets, overseeing Target investments, managing exits from Target investments and providing returns to Investors, as well as winding-down the fund at the end of its life cycle. The Investors would be passive investors whose role is limited to providing the monies that they have committed to the fund, as and when capital calls are made by the Fund Manager, and receiving returns when they become due. Their participation in the decision-making process of the fund would be confined to certain major decisions such as a change in the composition of the Trustee or Fund Manager or objectives of the Fund; and they would rely on the expertise and experience of the Fund Manager for all investment-related decisions. The mutual rights and obligations of the Investors, Trustee and Fund Manager would be recorded in a contribution agreement.

The documents for the Fund would typically specify a period within which all investments would be made by the Fund (Investment Period). The Investors would be required to specify upfront the amount of contribution that they are willing to make during the Investment Period (Capital Commitment). However, the Capital Commitment from the Investors would only represent a promise to invest monies as and when the the monies are required and the Fund Manager issues a notice for draw-down; the Investors would not be required to invest their respective Capital Commitments upfront. The monies contributed by the Investors would be utlised towards making investments in the Target, as well as in meeting the expenses of the Fund and remunerating the Trustee and Fund Manager for the services rendered to the Fund. All returns from the investments in the Targets would be distributed to the Investors after meeting the expenses of the Fund; the order and ratio of such distribution, known as the 'distribution waterfall', would be specified in the contribution agreement. In return for the services provided to the Fund, the Fund Managers, in addition to the fixed fees charged as remuneration for services rendered (typically, but not necessarily, about 2 percent annually of the total monies committed to be invested in the Fund by the Investors), would also require a performance-based incentive, known as the 'carried interest' (typically, but not necessarily, about 20 percent of the total returns (i.e., excluding amount of capital contributed) distributed to the Investors, which incentive would be distributed after the capital contributed and a certain specified return, known as the 'preferred return', has been distributed to the Investors).

In terms of the proposed project design, the Government would be a Investor whose contribution to the Trust would be managed by the Fund Manager in terms of the contribution agreement entered into between the Government, Trustee and Fund Manager. In order to be eligible for investment by the Government, the terms of each Fund would need to be subject to certain specifications of the Government and, in return, be entitled to certain financial incentives, as set out in the next section.

3 Terms of Pharma Fund(s)

The terms of each Pharma Fund would be largely market-driven. The Government would, in the first instance, allocate a total amount of INR 500 crores to be invested between all the Pharma Funds set up in pursuance of this Project. However, in order to be eligible for Government investment, the Pharma Fund would need to fulfill the criteria specified below and, in return, be entitled to the additional benefits specified below.

3.1 Eligibility Criteria

Each Pharma Fund would be subject to a two-fold eligibility test: funds proposed to be invested in Pharma R&D and eligibility of the Fund Managers proposing to establish the Pharma Fund.

3.1.1 Investment in Pharma R&D

Government criteria for investment would require that each Pharma Fund commit to investing at least such amount in Indian companies for their Pharma R&D activities (Innovative Pharma Companies) as is, the higher of: (i) INR 150 crores, and (ii) 4 times the amount sought as investment from the Government. Beyond the amount required to be invested in Innovative Pharma Companies, the Government would not seek to pre-determine the nature of the investments that may be made by the Pharma Fund, in order to permit the Fund Managers to formulate and implement a business model and investment strategy that is effective and marketable.

Existing literature and international experience suggest that, for this purpose, a broad and flexible definition of Innovative Pharma Companies would increase the level of participation in the program. For example, companies engaged in developing platform technologies that result in potentially patentable pharma products, new drug delivery systems, contract research and manufacturing providers that are higher up in the value chain (at least developing 'active pharmaceutical ingredients' or involved in critical aspects of core drug discovery research), novel bio-pharma processes etc., could also be considered as Innovative Pharma Companies.

An appropriate definition could be companies developing 'innovative' pharma, i.e. products or processes that are patentable or require 'New Drug Application' or equivalent regulatory approvals and including platform technologies that will result in the development of such pharma products or processes, and whether for themselves or by way of contract research. The investment objective of the fund should include meeting the Novel Drug Delivery Systems (NDDS) and New Chemical Entities (NCE) research related fund requirements of pharma units.

3.1.2 Eligbility of Fund Managers

Potentially eligible Fund Managers should include local and foreign individuals, companies, joint ventures, consortia or management teams with relevant experience as set out below who would finally be selected through a tender process. The advisors to the project should not be permitted to participate in the tender process for selection of Fund Managers, other than as advisors to the Government and/or the Administrator (as described later), without the prior written approval of the Government. Further, global pharma companies with more than INR 2500 crores of revenues during their latest financial year and their affiliates will not be permitted to participate in the tender process.

Fund Managers would be required to demonstrate strengths and past experience both in fund raising and management and in the pharma sector, as set out below. Every Fund Management team should have at least 2 key persons (Key Persons) who satisfy the criteria set out below. In the event that the team is structured in the form of a company or any other form of legal entity: (i) Key Persons must hold (together with the other Key Persons), 51 percent of the control of such entity, and (ii) each Key Person must hold at least 10 percent of the control of such entity. In the event that the entity is promoted by an existing asset management company, the Key Persons would not be required to hold 51 percent of the control of such entity, as long as the holding of the Key Persons and the existing asset management company is 51 percent in the aggregate.

The Key Persons must satisfy at least one of the following minimum eligibility criteria: (i) One Key Person satisfies the requirements for 'Investment Management Experience' specified below and the other for 'Pharma Experience' specified below, (ii) One Key Person satisfies the requirements for 'Investment Management Experience' specified below and the other for 'Alternate Pharma Experience' specified below, (iii) One Key Person satisfies the requirements for 'Alternate Investment Management Experience' specified below and the other for 'Pharma Experience' specified below, or (iv) One Key Person satisfies the requirements for 'Alternate Investment Management Experience' specified below, with the caveat that their venture capital experience in managing and raising capital must be in relation to pharma development companies with a minimum amount of INR 500 crores, and the other for 'Alternate Pharma Experience' specified below.

- 1. **Investment Management Experience**: The Key Person is required to have a minimum of 7 years of proven managerial experience, in India or abroad, in the venture capital space and have managed at least INR 1500 crores and raised at least INR 500 crores in that period.
- 2. Alternate Investment Management Experience: The Key Person is required to have a minimum of 4 years of proven managerial experience, in India or abroad, in the venture capital space and have managed at least INR 750 crores and raised at least INR 250 crores in that period.
- 3. **Pharma Experience**: The Key Person is required to have a minimum of 7 years of proven senior managerial experience in a company in the pharma development field, in India or abroad, during which should have raised at least INR 200 crores. This should include experience of

pharma product(s) in different stages of development, including clinical stages, and reaching developmental stages in which such companies requested and obtained approvals from the relevant regulatory authorities.

4. Alternate Pharma Experience: The Key Person should have a minimum of 4 years of senior management experience in a company in the pharma development field, in India or abroad, during which should have raised at least INR 100 crores capital. Such Key Person's managerial experience must include involvement in the development of such company's business and pharma product(s) in different stages of development, including clinical stages, in which such company requested and obtained approvals from the relevant regulatory authorities.

It may be noted that all experience requirements set forth above would be required to have been attained in the preceding 10 years. All experience attained prior to such cut-off date would not be deemed relevant. The Fund Managers that eventually receive investment from the Government would be selected on the basis of the tender process and, in the event that the applications for Government investment exceed INR 500 crores in the aggregate, a set of selection criteria would apply that would effectively narrow the list of applicants to such a set of Fund Managers whose Pharma Funds would maximize the investments directed towards Innovative Pharma Companies under this project.

3.2 Additional Benefits

Pharma Funds finally selected through the tender process would receive, in addition to the Government investment, the following additional benefits:

3.2.1 Bonus Commitment

The Government shall make a bonus capital commitment of INR 40 crores to the Pharma Fund with the largest aggregate private conditional commitments as of the first anniversary of the date of the tender.

3.2.2 Subordination of Government Returns

The preferred return of the Government will be subordinated to the preferred return due to the private investors in the Pharma Fund. This means that if, in any Pharma Fund, the preferred return is 5 percent (at simple interest), from any returns generated from investments made in target companies by the Pharma Fund, the private investors would first receive an amount equal to their capital contribution and a return of at 5 percent, and only thereafter would the Government be entitled to receive the amount contributed by it as capital and the preferred return due to it. The Government's preferred return in any Pharma Fund however would not be subordinated to the Fund Manager's carried interest.

3.2.3 Government Benefit

The distributions to the investors shall normally be made pro rata to their interests in the Pharma Fund's investments, except that the Government shall forgo a certain proportion of the distributions that the Government would have otherwise received and the other private investors shall receive additional amounts they otherwise would have not received (such amounts, the "Government Benefit"), which shall be distributed by the Pharma Fund directly to the private investors on a pro rata basis. The Government Benefit shall be calculated in accordance with the following formula:

Government Benefit = GovPR Amount * Benefit Fraction

where:

- "GovPR Amount" means, in relation to each stage of the Distribution Waterfall, the amount the Government would have received as distributions if these distributions were made on a Pro Rata Basis at such stage of the Distribution Waterfall;
- "Benefit Fraction" means a fraction equal to the product of the Leverage Ratio multiplied by 0.2 provided such fraction may not be greater than 0.8 (i.e., Benefit Fraction = (Leverage Ratio * 0.2); and
- "Leverage Ratio" means the ratio between the aggregate Private Partners' Capital Commitment to the Pharma Fund and the Government's Capital Commitment in the Pharma Fund (not including any Bonus Government Commitment).

4 Role and Appointment of Administrator

The Government would hire an 'Administrator' to manage and operate the day-to-day functions of the project. The Administrator, will be an independent agency, selected by the Government through a tender process to run and manage the project. It will not be permitted to participate in the tender for Fund Managers, either as a Fund Manager or as an advisor to any Fund Managers.

4.1 Role of the Administrator

The Administrator's role would include the following key activities:

- Evaluating the project design, including criteria for 'innovative pharma companies', eligibility requirements for Fund Managers, Government incentive structures etc., and providing suggestions for improvement;
- Issuing invitations and scrutinising submissions in the request for information, pre-qualification and tender selection stages of choosing fund managers, and selecting eligible Fund Managers in accordance with specified guidelines;
- Finalise fund documentation in consultation with Fund Managers and ensuring compliance with the Government's and the project's specifications;
- Managing capital calls and the Government's contributions thereto in respect of each Pharma Fund that is established under the project;
- Representing the Government on the investment and advisory committees set up in each Pharma Fund, and reporting to the Government on the decisions of such committees;
- Coordinating any decisions that require the prior approval of the Government in relation to each Pharma Fund;
- Evaluating the success of the project and Fund Managers' on a periodic basis, and reporting to the Government; and
- Cooperating with the Evaluation Agency in their oversight over the Administrator's activities.

4.2 Selection of the Administrator

The Administrator will be selected based on a tender process that will comprise of two components: a technical bid and a financial bid. To bid for being the Administrator, a bidder will need to satisfy the following minimum criteria and should also fulfil the requirements of a Project Leader, as specified below.

The average financial turnover of the bidder must be at least INR 100 crores for the preceding five years, where annual financial turnover is the average of the financial turnover (including fees generated from consultancy fees only) for the preceding five financial years. The bidder should have made profits (net) in three out of the last five financial years. The bidder should have all required regulatory approval to carry out the work described above. The bidder should have the experience of providing consultancy for setting up VC fund, and preference would be given if it is in pharma/healthcare/similar field. Preference would be given to bidders with hands on experience in financial investments sector including international exposure. Further, the bidder must not have been placed on the blacklist of any Governmental agency.

The bidder must commit as many personnel as required to complete the tender. However, the bidder must provide at least one person, the project leader, with the following experience: (i) At least five years in providing financial consultancy at the post of team leader/manager. (ii) Managed/ acted as leader of a team of at least three consultation contracts. (iii) Must have acted as leader/manager for a consultancy service provided to a Gov-ernmental agency. (iv) Must have experience in consulting, or working for, the pharma and bio-pharma / similar industry or making investments in the pharmaceutical and bio-pharma / similar industry. The said person will be deemed to be the contact person for the Administrator during the existence of the project and will be responsible for the execution of the work and also be in charge of the day to day work.

Interested bidders would be required to submit their bids in two parts: the technical bid and the financial bid. These two bids should be in separate envelope and should only be marked as 'technical bid' and 'financial bid' respectively. After ten working days of the notification of the tender, a pre-bid meeting will be held for clarify doubts of the interested bidders. The selection procedure will be carried immediately after the closing of bids. The Selection Committee, comprising of two representatives from NIPFP, the Director, NIPFP who will be the chairman of the Selection committee (and may nominate any person to execute his duties), one representative from DoP and one expert on the pharma industry, nominated by the Director of NIPFP, will open the tenders and select valid technical bids. The financial bid of technically qualified bidders will be opened and the lowest financial bid will be declared an accepted bid.

The technical bid, submitted in the prescribed format, should include experience of relevant past or current assignments, nominate a maximum of three persons who are likely to be appointed as project leader(s) for the work, including their respective experience, and an essay of not more than one thousand words explaining the unique abilities of the bidder in being able to cater to this project. The identity of the bidder should not be disclosed in any manner in the technical bid. The financial bid should contain the total fees that will be charged by the bidder inclusive of all applicable taxes and levies, to execute the contract till actual operationalisation of the project. The price should not be conditional.

The successful bidder shall be required to execute a formal contract with the Government, the details of which will be provided in the tender documents.

5 Process for Selection of Fund Managers

The Administrator (on behalf of the Government) will invite potential fund managers to participate in a tender process for the selection of management teams that will each manage a new Pharma Fund to be formed in order to promote and accelerate the growth of the Indian pharma R&D industry. The tender process will be carried out in 3 stages:

- 1. 'Request for information' stage: To seek feedback from the market on the proposed project design.
- 2. '**Pre-qualification' stage**: To publish threshold requirements for eligible Fund Managers (Experience Threshold) and pre-qualify managers for participation in the tender.
- 3. 'Request for proposal' stage: To select Fund Managers based on commitments raised by tender participants.

5.1 Request for information

At this stage, the Administrator will publicly issue a 'Request for Information' (RFI) regarding the proposed formation of one or more Pharma Funds. The purposes of RFI will be to (i) collect information from fund managers and fund investors communities in India and elsewhere for the purpose of evaluating the Pharma Funds' Terms in terms of their compatibility with the interests and expectations of such communities, and (ii) receive feedback from such communities as to the Experience Threshold. Subject to the full discretion of the Government, the RFI will be used for the purpose of finalising the Pharma Funds' Terms and the terms of the pre-qualification stage and the Tender (as defined below).

The RFI will not constitute a formal solicitation or an undertaking to launch the tender or to negotiate in any way and will not create any obligation of the Government to any respondent. Nor will submitting a response to the RFI be a condition to participating in the pre-qualification stage or the Tender. However, all persons who chose to respond will be required to respond to the RFI in a short and concise manner (e.g., in bullet point format). All expenses associated with responses to the RFI shall be borne by the respondents and in no event shall respondents be entitled to any refund or monetary compensation in connection with their responses to the RFI.

The Government may share the information received from respondents with its consultants and other persons (including the Administrator). If the information provided includes components that are proprietary professional or trade secrets of the respondent, this would need to be pointed out explicitly within the relevant response, in which case, the Government may share such information only with its consultants who have executed a confidentiality agreement.

5.2 Pre-qualification

The 'request for proposal' stage (Tender) will be preceded by a pre-qualification process (the "PQ"). In order to be eligible to participate in the Tender, each management team will be required to demonstrate that some of its individual members meet a threshold of relevant experience. The purpose of the PQ will be to describe the stages of the Tender process, invite participants to participate in the PQ Stage and provide participants with general information regarding the Tender selection stage and the terms of the Pharma Funds.

During the PQ stage, participants will be required to submit PQ submissions, in order to demonstrate their compliance with the PQ requirements. The submissions will be examined by the Administrator and after a final decision is made, in consultation with the Government, eligible participants will be announced to participate in the Tender selection stage.

Any and all costs and expenses incurred by the participants in connection to their participation in the PQ Stage will be borne by such participants, and will not be reimbursed by the Government. Participation in the PQ Stage shall not confer upon any participant any right with respect to the Pharma Funds or any future proceedings which will be conducted with respect thereto, including the Tender selection stage. The Government shall reserve the right not to proceed with the PQ Stage, or with the Tender process, and may terminate or cancel the invitation or any other proceedings with respect to the Pharma Funds, at any time, in their discretion.

5.3 Request for proposal or Tender

Each Pharma Fund will eventually be managed by a dedicated professional management team that will be selected from amongst the participants that pass the Pre-Qualification stage and participate in the Tender selection stage. Prior to this stage, the tender participants may raise capital commitments from any investor other than any investor that intends to fund such capital commitments out of capital that has already been committed or allocated to Indian pharma investments prior to the commencement of the tender process.

The process for selecting Tender participants will be different depending on the number of participants that pass the Pre-Qualification Stage, receive the invitation to Tender, and notify the Administrator of their intention to participate in the Tender selection stage. In the event the requests for Government investment from all the Tender participants in the aggregate is less than or equal to INR 500 crores, the Government shall automatically grant each of these Tender participants a conditional mandate to form a Pharma Fund with a conditional Government commitment of the amount requested by way of Government investment, depending on the extent of conditional commitments raised from private participants. In the event that the applications for Government investment exceed INR 500 crores in the aggregate, a set of selection criteria would apply that would effectively narrow the list of applicants to such a set of Fund Managers whose Pharma Funds would maximize the investments directed towards Innovative Pharma Companies under this project.

In addition, notwithstanding the type of process used for selecting the Tender participants, the Government shall make a bonus capital commitment of INR 40 crores to the relevant Pharma Fund with the largest aggregate investors' conditional commitments on first anniversary of the last date of the Tender.

6 Implementation Plan and Estimated Time-lines

Here, T represents the time at which the project receives a final go-ahead from the Department.

S. No.	Particulars	Responsibility	Time-line
$ \begin{array}{c} 1. \\ 1.1 \\ 1.2 \\ 1.3 \\ 1.4 \\ 1.5 \end{array} $	Selection of Administrator Invitation for bids Pre-bid meeting Receipt of final bids Selection of Administrator Signing of contract	NIPFP NIPFP NIPFP Selection Committee Administrator	T + 1 week T + 2 weeks T + 5 weeks T + 7 weeks T + 7 weeks
$ \begin{array}{c} 2. \\ 2.1 \\ 2.2 \end{array} $	Preparation Evaluation of project design Drafting of RFI	Administrator Administrator	T + 10 weeks T + 11 weeks
3. 3.1 3.2 3.3	RFI Issue of RFI Response to RFI Drafting PQ invitation	Administrator n.a. Administrator	T + 12 weeks T + 14 weeks T + 16 weeks
4. 4.1 4.2 4.3 4.4	PQ stage Issue of PQ invitation Response to RFI Selection Drafting of RFP	Administrator n.a. Administrator Administrator	T + 17 weeks T + 21 weeks T + 23 weeks T + 25 weeks
5. 5.1 5.2 5.3	RFP stage Issue of RFP Response to RFP Selection	Administrator n.a. Administrator	T + 26 weeks T + 29 weeks T + 30 weeks
6. 6.1 6.2	Finalisation Signing of fund docs Initial closing	Administrator n.a.	T + 33 weeks T + 40 weeks

7 Project Costs and Funding

The project costs and funding is assumed in three scenarios *Realistic* (Table: 2, *Pessimistic* (Table: 3 and *Optimistic* (Table: 4. In each case, it is assumed that the Government has invested an amount of Rs. 500 crores, at a cost of funds of 8 percent over a period of 7 years. The costs are calculated over an estimated number of 20 firms, each of which receive the same amount of investment as shown in Table: 1.

It may be noted that regardless of the scenario, given the average rate of

returns that investments in VC funds typically yield, the total loss is a fraction of the investment amount and in each case there are a certain number of successes whose value for the Government and in terms of value generated and spillover effect cannot be measured in purely monetary terms of the Government returns.

Table 1 Assumptions												
Assumptions	Govt. Investment	Rate of borrowing	Average RoR	Time Interval	No. of Firms							
Case 1: Realistic	Rs 500 Crore	8%	4%-8%	7 years	10							
Case 2: Pessimistic	Rs 500 Crore	8%	2%-4%	7 years	10							
Case 3: Optimistic	Rs 500 Crore	8%	6%-10%	7 years	10							

		2	73.24	76.60	86.67	79.34	80.82	84.67	79.13	84.13	74.21	79.20	798.01		856.91	-58.90
		9	69.35	72.07	80.12	74.28	75.46	78.53	74.11	78.10	70.14	74.16	746.33		793.44	-47.11
		5 L	65.67	67.81	74.06	69.54	70.46	72.84	69.40	72.50	66.29	69.45	698.03		734.66	-36.63
		4	62.19	63.80	68.47	65.10	65.79	67.56	65.00	67.31	62.66	65.03	652.90		680.24	-27.35
		3	58.89	60.03	63.29	60.94	61.43	62.66	60.87	62.49	59.22	60.90	610.72		629.86	-19.14
		2	55.76	56.48	58.51	57.05	57.35	58.12	57.01	58.01	55.97	57.02	571.29		583.20	-11.91
			52.80	53.59	52.80	52.91	53.55	53.91	53.39	53.86	52.90	53.40	533.10		540.00	-6.90
jection	Years	Rate of Return	5.60418607078025	6.2838131251671	7.17523365855088	5.81885022819069	7.10078136811381	7.8152381420229	6.77806375712852	7.7158345864611	5.80299254852964	6.79184327673872	Total Return	Rate of borrowing	x	Govt. Profit/ Loss
Table 2 Realistic Projection		Capital	50	50	50	50	50	50	50	50	50	50		Total Capex	500	
Table '		Firm		2	3	4	ы	9	2	×	6	10				

		2	57.96	64.93	64.86	69.40	59.50	62.80	58.55	62.95	65.65	62.47	629.08		856.91	-227.83
		9	56.75	62.55	62.50	66.23	58.04	60.78	57.24	60.91	63.15	60.52	608.67		793.44	-184.77
		ŋ	55.57	60.26	60.22	63.19	56.61	58.84	55.96	58.94	60.74	58.62	588.96		734.66	-145.71
		4	54.41	58.05	58.02	60.30	55.22	56.95	54.72	57.03	58.42	56.79	569.91		680.24	-110.33
		33	53.27	55.93	55.90	57.54	53.87	55.13	53.50	55.19	56.19	55.01	551.52		629.86	-78.34
		2	52.16	53.88	53.86	54.91	52.55	53.36	52.31	53.40	54.05	53.28	533.75		583.20	-49.45
		1	51.07	51.39	51.07	51.90	51.26	51.65	51.14	51.67	51.98	51.62	514.75		540.00	-25.25
rojection	Years	Rate of Return	2.1338313381673	3.80365252295051	2.78820390289443	3.79543822663685	2.51536833484708	3.30879762141842	2.2795419201598	3.34550928505291	3.96777337160236	3.23262850423434	Total Return	Rate of borrowing	8	Govt. Profit/Loss
Table 3 Pessimistic Projection		Capital	50	50	50	50	50	50	50	50	50	50		Total Capex	500	
Table ;		Firm	1	2	3	4	ъ	9	2	×	6	10				

		7	93.91	80.63	82.67	99.57	89.84	78.92	87.72	95.88	90.34	85.17	884.64		856.91	27.72
		9	85.82	75.31	76.94	90.24	82.63	73.94	80.95	87.36	83.02	78.93	815.13		793.44	21.69
		ю	78.43	70.34	71.61	81.78	75.99	69.27	74.70	79.60	76.29	73.15	751.16		734.66	16.50
		4	71.68	65.70	66.64	74.12	69.89	64.90	68.94	72.53	70.11	67.79	692.29		680.24	12.05
		3	65.51	61.36	62.02	67.17	64.28	60.80	63.62	66.09	64.43	62.82	638.10		629.86	8.24
		2	59.87	57.31	57.72	60.88	59.11	56.96	58.71	60.22	59.21	58.22	588.22		583.20	5.02
		1	54.71	53.22	54.71	54.67	54.37	53.37	54.18	54.87	54.41	53.95	542.47		540.00	2.47
Projection	Years	Rate of Return	9.42157987603403	7.06469472056496	6.44746098484309	9.34089011349164	8.73258252987396	6.73683504921487	8.36141198254328	9.74677578656901	8.81776803272215	7.90562316448228	Total Return	Rate of borrowing	8	Govt. Profit/Loss
Table 4 Optimistic Pr		Capital	50	50	50	50	50	50	50	50	50	50		Total Capex	500	
Table 4		Firm	1	2	3	4	ы	9	2	x	6	10				

8 Critical Risks and Dependencies

At present, VC funds in India tend to be broad-based, and highly specialised funds are yet to come about. There is, therefore, no fund dedicated to the pharma industry. When the design structure imposes a requirement of apportioning a certain minimum investment into firms that qualify as Innovative Pharma Companies, then there is a possibility that not a single Pharma Fund will spring up. And so, government co-investment in such a fund might not give a big enough push towards the creation of such a fund. This could be attributed to a number of factors such as:

- Private investors in VC funds are not interested in such narrow option funds due to low diversification, among other concerns.
- The amount promised by the government fails to attract VC funds.
- There is lack of expertise with regards to the pharma industry within the venture capital community.
- The global financial scenario discourages such investments.

Some other potential disadvantages of this model include:

- 1. Companies that receive the funds are the ones that can generate some commercial interest. This implies that the Fund is likely to target the easiest and most obvious companies. It is quite likely that first stage investments might be shunned in the beginning because private investors will be have a lower risk appetite.
- 2. The innovations in the pharmaceutical industry will most probably be in commercially viable areas. Neglected diseases (where the end consumers do not have the means to pay for expensive drugs) might not see innovation through this scheme. For such innovation, the government would have to take other steps such as minimum procurement and price commitments in order to create innovation interests.
- 3. Private investors will seek exit from the companies at an early stage and therefore, there can be cases of partial innovations being sold to larger pharma companies.

9 Sub-fund Variation

In a 'sub-fund' model, in recognition of the fact that VC investors may not find the appeal in a large fund set up exclusively or primarily for the purpose of investing in pharma R&D, VC funds are permitted to establish sub-funds within their existing or proposed fund schemes, which have a similar focus area (for example, life sciences). The sub-fund receives a funding-commitment from the Government to the extent that the relevant fund manager feels comfortable in asserting an intention to invest in pharma R&D. Thereafter, any draw-downs from the government sub-fund need to be matched by investment by the larger fund (i.e. private investors).

The Government therefore invests as a minority investor and the fund takes a larger stake in any targets. However, in order to incentivise investment by the fund, the Government agrees to waive a portion of its returns in favour of the private fund investors (in accordance with the ratio of of Government to private investment in the relevant targets). Accordingly, while the Government takes a proportionate share of the risk, it does not share all of the upside in the event that the investment is a success (thereby increasing the upside available to the private investors). In addition, fund managers are incentivised by the management fees and carry they receive on the Government funding and the returns therefrom.

The scheme is administered by a Government-appointed Administrator which runs the scheme in accordance with detailed guidelines specified by the Government. The Administrator is the sole point of contact and engagement for fund managers. Other than the practical limitation on formation of pharma R&D funds, this model also has the same advantages and disadvantages as the Fund model.

The process variations in the sub-fund are two-fold:

- 1. The amount of Government commitment is determined by the appetite of the VC fund for pharma R&D investments.
- 2. The details of the management structure of the overall fund are not governed by these guidelines, but by the fund documents for the overall fund. Only the sub-fund is governed by these guidelines and any investment by the sub-fund is required to be matched by investments from the VC fund's private investors.

10 Operational Details of the Model



10.1 Managing bad loans

There is no possibility of bad loans occurring in the proposed model. The proposed model works on equity and does not include any loans to any innovator.

The SPV can make investments in two ways:

- 1. Purchase units of a venture capital fund which is focused on the pharmaceutical sector.
- 2. Purchase equity of a pharmaceutical company which has attracted VC.

10.2 How will the system work

Figure on 1 shows the structure of the system. It provides all the components of the system.

11 Detailed description of the model entities

11.1 CFI

CFI Stands for the Consolidated Fund of India. This is where money will enter the SPV after budgetary approval. The transfer of money from the CFI to the SPV will be as per government rules for transfer of money.

11.2 SPV

SPV stands for the Special Purpose Vehicle. It is a trust which is created by drawing a deed of trust and then appointing trustees.

11.2.1 Eligible Entities

There is no specific entity which can be the SPV. SPV is analogous to a bank account. The trustees will operate the SPV as per the instructions received from the Trust Company which in turn will receive instructions of the AMC.

The SPV will be an unique entity specifically created for this project.

11.2.2 Terms of reference for work

The work of creating an SPV will fall on the Trust Company and the Advocate Firm for drafting the trust deed and then making the necessary filings. Once started, legal compliance of the SPV will be done by the Trust Company.

11.3 Trust Company

The trust company's job is to maintain the SPV. Trust companies manage all the legal and accounting requirements of running the SPV.

11.3.1 Eligible Entities

There are many specific companies set up by banks and financial firms to run SPVs. SPVs as trusts are usual feature of VCs and mutual funds. Some examples of Trust Companies are:

- 1. SBICap Trustee company
- 2. ICICI Trusteeship Services Limited
- 3. IDBI Trusteeship Services Ltd

11.3.2 Terms of reference for Work

The Trust Company must:

- 1. Carry out the normal services of trusteeship provided to trusts used in the financial sector including:
 - (a) Coordinating with the Advocate Firm to draft the trust document for the SPV, which includes the features of this model.
 - (b) Appointing Trustees.
 - (c) Ensuring that the trust is operated strictly in accordance to the provisions of the Trust document.
 - (d) Ensuring the that the trust is in compliance with all laws as required.
 - (e) Ensuring that the financial records and all other relevant documents are maintained.

11.4 Asset Management Company

The Asset Management Company is the main decision making entity for the program. Whether a fund or a company meets the requirements of the program and the amount of money which will be given to such entity (as per the rules of the program) will be decided by the Asset Management Company.

11.4.1 Eligible entities

There are two types of entities who can be used for this function. First, dedicated consultancy firms may carry out this function. Some examples are:

- 1. KPMG
- 2. PWC
- 3. Delliote

The second type can be professional fund management companies which run mutual funds and other investment vehicles. Some examples are:

- 1. HDFC Asset Management
- 2. SBI Asset Management
- 3. Other Asset Management Companies which manage mutual funds

11.4.2 Terms of Reference for Work

The AMC must carry out the following functions:

- 1. Screen all applicants for funding from the SPV to check if they meet the criteria for receiving funds under the program.
- 2. Advise the trustees through the Trust Company to release funds in favour of companies/funds which pass screening.
- 3. Draft and monitor compliance of agreements between the SPV and entities receiving funds, including withholding funds in event of breach and starting legal proceedings.
- 4. Keep records of investment decisions and returns being generated.
- 5. Advise the trustees through the Trust Company to exit the investment when appropriate.

- 6. Provide the Review Committee with all information required to review the functioning of the project.
- 7. Carry out other functions asset management companies carry out with regard to investment vehicles.

11.5 Review Committee

The job of the review committee is to provide and independent review of the project to the government and the DoP.

11.5.1 Eligible entities

The eligible entities for such a project should be academic institutions such as:

- 1. National Council of Applied Economic Research
- 2. Indira Gandhi Institute of Development Research
- 3. Center for Policy Research
- 4. National Institute of Public Finance and Policy

11.5.2 Terms of Reference for Work

The review committee must:

- 1. set up a board of academics and experts in the field of finance, public health, innovation and governance.
- 2. provide the board with all information from AMC to make a review of the project.
- 3. under the guidance of the board make a report (once every three years) on the functioning of the project, its contribution and ways in which it may be improved.

11.6 Legal advice

It is important that the entire exercise of setting up the fund be legally advised by advocates for the Department of Pharmaceuticals.

11.6.1 Eligible entities

- 1. Amarchand & Mangaldas & Suresh A Shroff & Co
- 2. AZB & Partners
- 3. J. Sagar Associates

11.6.2 Terms of Reference of Work

The Advocate Firm must carry out the following functions:

- 1. Draft the agreements between:
 - (a) DoP and Trust Company
 - (b) DoP and Asset Management Company
 - (c) SPV and entities receiving funds (subject to minor modifications for each entity)
- 2. Draft the screening procedure that the Asset Management Company must carry out to check for entities eligible for funding under the project. This screening procedure must implement the requirements of this project.
- 3. Draft the Deed of Trust and carry out the required filings to set up the SPV.
- 4. Advise the DoP on all legal matters till the setting up of the project and the first investment is made.

12 Functions to be carried out before set up

There are two important functions which need to be carried out before the entire system is set up. They are:

- 1. Determination of the type of company or fund which should receive funding from the SPV with a level of detail that can be operated by the AMC.
- 2. Determination of the general terms and conditions of the investment so that investors in the VC funds are incentivised to use this programme.

12.1 Eligible Entities

The appropriate eligible entities for this project are consultancy firms like:

- 1. BCG
- 2. KPMG
- 3. PWC
- 4. Mackenzie
- 5. Delloite

NIPFP may assist the DoP in guiding such consultancy firms.

12.2 Terms of reference of Work

The consultancy firm must make a report with all the following:

- 1. what is the funding gap in the pharmaceutical sector where VC funds would work;
- 2. the type of companies/activities or VC funds that should be eligible for funding;
- 3. the detailed tests which the AMC should carry out to screen applicant companies or VC funds.
- 4. the commercial terms which should be offered to entities which receive investment including:
 - preferences to VC fund investors over the SPV in the order of pay-out in case of investment in VC funds.
 - preferences to VC funds or promoters in case of investment in companies with VC funds.

The consultancy firm must hold wide consultations with industry and experts and justify its recommendations in the report.