

F. no. 50018/2/2022-NIPER  
**Government of India**  
**Ministry of Chemicals and Fertilizers**  
**Department of Pharmaceuticals**

Dated 1<sup>st</sup> October, 2025

**Guidelines for Promotion of Research and Innovation in Pharma MedTech (PRIP)**  
**Sector Scheme (“Scheme guidelines”)**

**1. Introduction**

1.1 These are the Scheme guidelines referred to in the Promotion of Research and Innovation in Pharma MedTech (PRIP) Sector Scheme. The said Scheme, as it currently stands, is contained in the Schedule to Notification no. 50018/2/2022-NIPER, dated 1.10.2025.

1.2 They are to be read in conjunction with the said Scheme. The Central Government reserves the right to amend the said Scheme and these guidelines from time to time.

1.3 Expressions used in these guidelines have the same meaning as in the said Scheme.

**2. Component A**

2.1 Centres of Excellence (CoEs) established at the National Institutes of Pharmaceutical Education and Research (NIPERs) will help in building specific research capacities in the identified priority areas in a focussed time-bound programme, for which they will take the following actions:

- (a) The institutes will actively seek collaboration with well-established industry partners (domestic or international) having significant market presence and demonstrated expertise in their respective research fields. The industry partner will work jointly with the institutes to develop the CoEs and strengthen industry-academia linkage.
- (b) Research under Component A will be undertaken at the respective CoE. The research programme and associated time-bound deliverables of the CoE will be proposed by the institute with the recommendations of its Board of Governors (BoG) and submitted for consideration of and finalisation by the Steering Committee.
- (c) Rules and instructions of the Central Government applicable to financial management and maintenance of accounts will constitute the framework for financial matters, and financial activity at the CoE will be subject to approval of and oversight by the BoG and, where applicable, the Central Government.

2.2 The institutes will ensure the following in respect of the CoEs:

- (a) The proposing institute will furnish an undertaking that—
  - (i) no expenditure will be incurred from the financial assistance provided under the Scheme towards the salary and allowances payable to any regular employee;

- (ii) it will bear expenditure incurred on any employees engaged for the CoE for period beyond the Scheme period; and
- (iii) it will ensure that the CoE achieves self-sufficiency within the Scheme period.
- (b) The institute will delineate the precise allocation and utilisation of funds and provide a detailed breakup of the financial resources deployed. Such breakup will outline the allocation for essential activities, such as development of research infrastructure, procurement of equipment, operations etc.
- (c) The institute will ensure prudent fiscal management and effective resource utilisation aligned with the objectives of the Scheme.
- (d) In carrying out the activities of the CoE, the institute will adhere to the provisions of the General Financial Rules, 2017 and related instructions issued by the Ministry of Finance.

2.3 *Steering Committee:* The Steering Committee will be chaired by Secretary, Department of Pharmaceuticals and will have the Financial Advisor to the Department, the Head of Wing and the Head of Division dealing with the Scheme in the Department, the representative of the Central Drugs Standard Control Organisation and such technical experts as the committee may coopt as its members. The committee will have the following functions:

- (a) To review implementation of approved proposals and the research programme and associated deliverables finalised by the committee;
- (b) To consider and decide requests received from institutes for revision of ceilings applicable to expenditure under various non-recurring and recurring heads, within the overall outlay for Component A; and
- (c) To consider and decide requests for modification in the research programme and associated deliverables for the CoE.

### **3. Component B**

#### **3.1 Academia**

3.1.1 Reputed Government academic and research institutions eligible for collaboration to develop, translate and commercialise institutional intellectual property and to augment institutional research capacities are specified in the Appendix 1 (“Academia”).

3.1.2 In case of in-licensing of intellectual property (IP) from Academia, the applicant will, as part of the application, submit the following:

- (a) A valid contract executed between the applicant and Academia, and in case such contract has not yet been executed, an academic intent letter, signed by an officer of Academia duly authorised in this behalf, in the form downloadable from the Scheme portal accessible using the link for the Scheme on the website of the Department of Pharmaceuticals (“Scheme portal”); and
- (b) A valuation report of the IP proposed to be in-licensed from Academia, furnished by an agency from among those specified for this purpose on the Scheme portal based on fair value assessment of such IP, and in case such assessment has not been done, include the estimate of the value of that IP in the project plan as

referred to in paragraph 3.4.5 and in the aforesaid valid contract or academic intent letter.

### 3.2 *Strategic Priority Innovation projects*

3.2.1 The following areas of India's public health concern for which market potential is relatively lower are specified for Strategic Priority Innovation (SPI) projects under paragraph 3.2.5(b)(ii) of the Scheme:

- (a) Diseases relevant to India from among those referred to as "neglected tropical diseases" by the World Health Organization (WHO);
- (b) Rare diseases in India, as listed in the National Policy for Rare Diseases, 2021;
- (c) Addressing antimicrobial resistance in respect of multidrug resistant and extensively drug-resistant pathogens listed as critical, high or medium priority in the India Priority Pathogens List published by the Department of Biotechnology on its website;
- (d) Addressing the priority pathogens that cause outbreaks or pandemics, as listed in the WHO List of Priority Pathogens and Diseases;
- (e) Vaccines for diseases listed by WHO as vaccine-preventable diseases (including pipeline); and
- (f) Such other diseases, pathogens or vaccines as the Department of Health Research, Ministry of Health and Family Welfare may specify in this policy.

3.2.2 A list of the areas specified for SPI projects is in Appendix 2. The said list may be updated from time to time.

### 3.3 *Eligibility*

3.3.1 Every entity registered in India that meets the following criteria is eligible for financial assistance under Component B of the Scheme:

- (a) It is a company registered under the Companies Act, 2013 or under any previous company law and is other than a company that meets any of the following criteria ("company"):
  - (i) It has only one person as a member; and
  - (ii) It does not have any limit on the liability of its members; payment of any dividend to its members is prohibited under law; its objects include promotion of commerce, art, science, sports, education, research, social welfare, religion, charity, protection of environment or any such other object; and, under law, its profits if any or other income may be applied only for promoting the said objects;
- (b) It is a Limited Liability Partnership registered under the Limited Liability Partnership Act, 2008 ("LLP"); and
- (c) It is partnership firm other than a sole proprietorship firm and is registered under the Indian Partnership Act, 1932 ("registered partnership firm").

*Note:* For purposes of these guidelines, all subsequent references to "company", "LLP" and "registered partnership firm" will be construed as a reference to a company, Limited Liability

Partnership or partnership firm that meets the criteria referred to in clause (a), (b) and (c) respectively.

3.3.2 In case of an Early Stage Project, such company, partnership or firm is required to meet the following additional eligibility criterion:

- (a) It is a startup having a valid certificate granted by the Inter-Ministerial Board of Certification under the Department for Promotion of Industry and Internal Trade notification G.S.R. 127(E), dated 19.2.2019; or
- (b) It is a micro, small and medium enterprise (MSME) having a valid Udyam Registration Certificate as referred to in the Ministry of Micro, Small and Medium Enterprises notification S.O. 2119(E), dated 26.6.2020.

3.3.3 An applicant will be ineligible if—

- (a) any of its key managerial personnel is convicted of an offence involving moral turpitude or corruption and has been sentenced to imprisonment for a term not less than six months; and
- (b) it or its holding company has filed for any insolvency, winding-up, liquidation or resolution proceedings, or is being subjected to such proceedings.

3.3.4 In case ineligibility arises at any point in time, the applicant will promptly disclose the same in writing to the Central Government.

#### 3.4 *Terms and conditions of financial assistance and financial closure*

3.4.1 Total financial assistance to applicants belonging to a related group as referred to in paragraph 3.4.2 will not exceed 5% of the total financial outlay of the Scheme, unless the Central Government decides otherwise.

3.4.2 Related group, in relation to an applicant, means the group of companies, LLPs and registered partnership firms consisting of the following:

- (a) Such applicant;
- (b) Every company, LLP and registered partnership firm that fulfils any of the following criteria:
  - (i) More than 50% of its total capital is owned by such applicant;
  - (ii) The extent of entitlement in its profits is more than 50% for such applicant;
  - (iii) Majority of the individuals comprising its governing body (its Board, in respect of a company; its designated partners in respect of an LLP; its partners, in respect of a registered partnership firm) are directors, partners or employees of such applicant;
  - (iv) It holds at least 20% of total voting power in such applicant;
  - (v) It controls or participates in the business decisions of such applicant, under an agreement;
  - (vi) Such applicant holds at least 20% of total voting power in such a company, LLP or registered partnership firm;
  - (vii) Such applicant, under an agreement, controls or participates in the business decisions of such a company, LLP or registered partnership firm; and

- (viii) It and the applicant have joint control of an arrangement whereby they have rights to the net assets of such arrangement.

3.4.3 The applicant will disclose in its application all companies, LLPs and registered partnership firms belonging to its related group, regardless of whether such a company, LLP or registered partnership firm is an applicant under the Scheme or not.

3.4.4 Financial assistance will be disbursed into a project-specific dedicated account opened by the applicant in a Scheduled Commercial Bank prior to execution of the funding agreement (“project account”). Such account will be subject to inspection and special audit, including forensic audit, by the Central Government and will fulfil other requirements specified on the Scheme portal.

3.4.5 As part of the application, the applicant will submit a plan based on sequential milestones to be achieved including the associated expenditure and timeframes for the same (“project plan”). Each milestone will consist of objective, measurable technical and non-technical markers (“milestone descriptors”), selected from a catalogue accessible on the Scheme portal. Where necessary, alternative milestone descriptors better suited to the project’s pathway may be used along with justification for the same.

3.4.6 The Central Government may consider the project plan without any modification or with such modifications as to timeframes, project cost, milestone descriptor or milestone as it may deem fit and accord its in-principle approval to such submitted or modified project plan (“in-principle approved project plan”), or include it as a waitlisted project, or reject the same. In case such in-principle approval is accorded with modifications, the communication conveying the same may either specify such modifications or require the applicant to carry out changes in such plan in line with directions contained in such communication and resubmit the plan. Such in-principle approval conveyed to the applicant will be a conditional offer, in response to which the following is required of the applicant:

- (a) Conveying of acceptance and submission, where required, of the following through the Scheme portal within a period of 10 days:
  - (i) Where the valid contract executed between the applicant and Academia has not been furnished with the application, duly authenticated copy of such contract {refer paragraph 3.1.2(a)};
  - (ii) Where IP is proposed to be in-licensed from Academia and the valuation report of such IP has not been furnished with the application, such report and, in case the assessed fair value in the report is other than the estimated value submitted in the project plan, a copy of the modified project plan duly incorporating such assessed fair value {refer paragraph 3.1.2(b)}; and
  - (iii) Where directions to carry out changes in the project plan have been conveyed, a copy of the modified project plan duly incorporating such changes.

On conveying of such acceptance and submission as aforesaid (to the satisfaction of the Central Government), the project plan or the modified project plan will be referred to as the approved project plan.

(b) Submission, within a period of 60 days from the date of conveying of acceptance and submissions under clause (a), of the following:

- (i) Documents evidencing financial closure for the approved total project cost;
- (ii) Duly signed funding agreement with the approved project plan annexed thereto;
- (iii) Where the applicant has opted for benefit-share by way of share allotment, duly signed share allotment agreement; and
- (iv) In case the Central Government has required a report to validate that the product or technology which the project proposed to take to higher TRLs is at TRL claimed in the application, such report furnished by an agency from among those specified on the Scheme portal for this purpose.

Failure of the applicant to convey acceptance or make any submission as aforesaid within such period as is specified for the same (or such extended period or periods as the Central Government may permit) will render the in-principle approval liable to be withdrawn.

3.4.7 The Central Government will have the right to call for more information in respect of financial closure and take assistance from any instrumentality of the State or from parties from whom co-funding for financial closure is to be sourced, for the purposes of verifying any documents submitted to satisfy itself as to the veracity of the financial closure claimed and such documents.

3.4.8 A waitlisted project will be retained in the waitlist for a period of 180 days from the date on which its waitlisting is communicated to the applicant, along with the approved project plan, for acceptance of the waitlisting within a period of 10 days of such communication.

3.4.9 Every beneficiary and waitlisted applicant will be required to implement the approved project plan as per the milestone descriptors and associated expenditure and timeframe specified therein, in accordance with the provisions of the Scheme and these guidelines, unless the Central Government permits modification of the same in writing. In case the Central Government permits any modification, the reference to “approved project plan” will be construed as a reference to the modified project plan.

3.4.10 In case of the share allotment option for benefit-share, an applicant company may either allot its own shares, or the shares of a company incorporated by it as a dedicated, special purpose vehicle for purposes of implementation of the project and fulfilment of all obligations of the applicant/beneficiary under the Scheme and these guidelines.

3.4.11 *Disbursement of milestone-linked financial assistance:* Disbursement of milestone-linked financial assistance will be done in the following manner:

- (a) *Number of instalments:* Disbursement of financial assistance will be made in four instalments. The fourth instalment will be at least 15% of the approved total financial assistance and will be disbursed on a reimbursement basis.

- (b) *Co-funding*: Total co-funding will be required to the extent specified in the Scheme and would equal the approved total project cost less the approved total financial assistance, and the proportion of total co-funding to the approved total financial assistance is required to be maintained at the stage of disbursement of each instalment. Accordingly, the beneficiary is required to ensure that cumulative co-funding in said proportion to the sum of such instalment and financial assistance previously disbursed is credited into the project account before such disbursement.
- (c) *Criteria for disbursement*: On achievement of the milestones as per corresponding criteria, instalments as specified below will be disbursed, which may be utilised for the corresponding purposes:

<b>Milestone</b>	<b>Criteria for achievement of milestone</b>	<b>Milestone-linked instalment to be disbursed</b>	<b>Purposes for which instalments disbursed may be utilised</b>
Milestone 0 (M0)	<p><i>1. For all applicants:</i></p> <p>1.1 Evidencing financial closure for the approved total project cost</p> <p>1.2 Execution of funding agreement</p> <p><i>2. Further, for applicants selecting share allotment option of benefit-share:</i></p> <p>2.1 Execution of share allotment agreement</p> <p><i>3. Also, for all projects for which financial assistance exceeds ₹1 crore:</i></p> <p>3.1 Credit of requisite co-funding into the project account</p>	Instalment 1 (I-1), not exceeding 30% of total financial assistance	For expenditure associated with achievement of M1 as per approved project plan
Milestone 1 (M1)	<p><i>1. For all applicants:</i></p> <p>1.1 Achievement of M1 and submission of its completion report</p>	Instalment 2 (I-2), not less than 20% and not exceeding 40% of total	For expenditure associated with achievement of M2 as per approved project plan

	<p><i>2. Further, for applicants selecting share allotment option of benefit-share:</i></p> <p>2.1 Allotment of shares to the Central Government of aggregate value equal to I-1</p> <p><i>3. Also, for all projects for which financial assistance exceeds ₹1 crore:</i></p> <p>3.1 Credit of requisite co-funding into the project account</p>	financial assistance	
Milestone 2 (M2)	<p><i>1. For all applicants:</i></p> <p>1.1 Achievement of M2 and submission of its completion report</p> <p><i>2. Further, for applicants selecting share allotment option of benefit-share:</i></p> <p>2.1 Allotment of shares to the Central Government of aggregate value equal to I-2</p> <p><i>3. Also, for all projects for which financial assistance exceeds ₹1 crore:</i></p> <p>3.1 Credit of requisite co-funding into the project account</p>	Instalment 3 (I-3), not less than 20% and not exceeding 40% of total financial assistance	For expenditure associated with achievement of M3 as per approved project plan
Milestone 3 (M3)	<p><i>1. For all applicants:</i></p> <p>1.1 Achievement of M3 and submission of its completion report</p>	—	—



	<p><i>2. Further, for applicants selecting share allotment option of benefit-share:</i></p> <p>2.1 Allotment of shares to the Central Government of aggregate value equal to I-3</p> <p><i>3. Also, for all projects for which financial assistance exceeds ₹1 crore:</i></p> <p>3.1 Credit of requisite co-funding into the project account</p>		
Milestone 4 (M4)	<p><i>1. For all applicants:</i></p> <p>1.1 Due completion of the project (including M4) and submission of the project completion report</p> <p><i>2. Further, for applicants selecting share allotment option of benefit-share:</i></p> <p>2.1 Furnishing of undertaking that on disbursement of I-4, shares of like aggregate value will be allotted promptly to the Central Government.</p>	Instalment 4 (I-4), not less than 15% of total financial assistance	For reimbursement of expenditure associated with achievement of M3 and M4 as per approved project plan

3.4.12 Withdrawal made from the project account will be deemed to be expenditure, out of which the amount of financial assistance utilised will be deemed to be in the proportion of cumulative disbursed financial assistance to the corresponding cumulative co-funding amount credited into the project account.

3.4.13 Each claim made in the milestone completion report or the project completion report regarding achievement of a milestone descriptor is required to be evidenced by supporting documents issued by competent regulatory authority or duly verified by third-party entity that satisfies criteria specified in this behalf on the Scheme portal.

3.4.14 Completion report for each milestone is required to be submitted within a period of 10 days of expiry of the timeframe specified for this in the approved project plan, unless the Central Government permits otherwise. The Central Government will have the right to call for more information and take assistance from any instrumentality of the State, regulatory authority, verifying third-party entity or other issuer of any supporting document, for the purposes of checking, verifying such documents submitted and satisfying itself as to the veracity of claims and contents contained in the completion report and supporting documents for the purposes of deciding whether the criteria for the achievement of the milestone have been met.

3.4.15 The Central Government will have the right to inspect or cause to be inspected any project site and to require that any documents maintained in relation to milestone descriptors be made available for inspection, save to the extent necessary to prevent infringement of patent, trademark, copyright or other proprietary rights, and the beneficiary will extend full cooperation for the same.

3.4.16 Substitution of individuals named in the application as part of the project team is not permitted, save with the prior approval in writing of the Central Government.

3.4.17 *Obligation of beneficiary to refrain from incurring avoidable expenditure in the event of inability to carry on project:* If the beneficiary is unable to secure any license or use of any intellectual property or other asset necessary for carrying on the project, due to failure to have in place necessary contractual arrangements or unresolved dispute in relation to such arrangement or any reason other than approval or authorisation or clearance necessary for the project, it will—

- (a) promptly notify the Central Government regarding such inability; and
- (b) refrain from incurring avoidable expenditure on the project.

Any avoidable expenditure incurred as aforesaid will be considered as utilisation of financial assistance for purposes unconnected with the approved project and liable to clawback under paragraph 3.9.1(a).

3.4.18 The applicant/beneficiary will ensure compliance with the requirements and other provisions published on the Scheme portal from time to time and those contained in the application form, funding agreement, share allotment agreement and other documents executed under the Scheme, these guidelines and the said agreements.

### 3.5 *Manner of allotment of shares for benefit-share, securing liquidity and minority protection rights and other share related conditions*

3.5.1 In case of the share allotment option for benefit-share, the beneficiary will issue compulsorily convertible preference shares (CCPS) to the Central Government, of aggregate value equal to the financial assistance disbursed, in accordance with the share allotment agreement. On first commercialisation of the project outputs, such CCPS will be converted into common equity shares in the ratio of the total financial assistance disbursed to the fair value of the beneficiary's equity shares at the time of such commercialisation.

3.5.2 Such CCPS will be issued in accordance with applicable laws and will be convertible into equity shares on the terms specified therein and in the share allotment agreement, with provision for non-cumulative dividend of up to 0.0001% per annum, or such minimum rate as may be prescribed to preserve preference-share status under section 55 of the Companies Act, 2013.

3.5.3 The beneficiary will comply with all applicable laws and regulatory requirements, and bear all costs associated with the issuance, reporting and conversion of CCPS.

3.5.4 Share allotment agreement will specify the terms and conditions governing the issuance of, rights in, obligations in respect of and procedures applicable to the shares allotted. Except and to the extent specifically waived by the Central Government in writing, the share allotment agreement will ensure the rights of the Central Government in respect of governance and minority protection, conversion mechanics and adjustments, liquidity and exit, transfer of CCPS/equity and negative pledge / issuance cap as specified in the share allotment agreement.

### 3.6 *One-time settlement of benefit-share obligation on voluntary basis*

3.6.1 A beneficiary may discharge its benefit-share obligation in full by paying to the Central Government, by way of settlement on one-time basis, a sum reckoned as follows:

- (a) In case of an Early Stage Project for which the beneficiary has selected one of the payout options, a settlement sum equal to the total financial assistance disbursed, less the benefit-share payout already remitted;
- (b) In case of a Later Stage Project for which the beneficiary has selected one of the payout options, a settlement sum equal to 150% of the total financial assistance disbursed, less the benefit-share payout already remitted.

The beneficiary will remit in Indian Rupees (INR) the settlement sum, within 15 days of the Central Government conveying its acceptance in writing. The beneficiary will be liable to pay simple interest at the rate of 12% per annum for delay in remittance.

### 3.7 *One-time settlement of benefit-share obligation on occurrence of certain events*

3.7.1 On occurrence of any of the following events, the Central Government will have the right to receive benefit-share by way of settlement on one-time basis:

- (a) Licensing or transfer by way of sale, hive-off, lease of assets or otherwise of, or assignment of rights or creation of encumbrance in, any project output, including intellectual property right, knowhow, dataset or prototype, by the beneficiary;
- (b) Major corporate event, including but not limited to public listing, substantial equity infusion, change in controlling interest, amalgamation, merger, demerger, combination, splitting, acquisition or restructuring that directly or indirectly transfers effective control of the project outputs, except where the Central Government has given its prior approval in writing for continuation of the project on the terms and conditions under the Scheme and such additional terms and conditions as the Central Government may specify while giving such approval;
- (c) Filing by the beneficiary or its holding company of any insolvency, winding-up, liquidation or resolution proceedings, or being subjected to such proceedings;

- (d) Failure of the beneficiary to obtain, maintain or renew any approval, authorisation or clearance related to health, safety or environment which is necessary for the project and where such failure is attributable to any lapse on the part of the beneficiary;
- (e) Conviction of the beneficiary or any of its key managerial personnel for an offence involving moral turpitude or corruption; or
- (f) Failure of the beneficiary to make reasonable efforts to utilise project outputs in India for making the same available to the public on reasonable terms.

The beneficiary will, without delay, notify the Central Government of the occurrence of any event as referred to in clauses (a) to (e).

3.7.2 On occurrence of any of the following events, the Central Government will have the right to receive benefit-share by way of settlement on one-time basis:

- (a) In case of a project for which the beneficiary has selected one of the payout options, remitting to the Central Government in INR of a settlement sum reckoned as in paragraph 3.6.1, within 15 days, and with liability to pay simple interest at the rate of 12% per annum for the period beyond 15 days from the occurrence of the related event.
- (b) In case of a project for which the beneficiary has selected the share allotment option, purchase by the beneficiary of the shares allotted to the Central Government at a fair value arrived at through valuation carried out by independent valuer(s) registered with the Securities Exchange Board of India.

3.7.3 Further, on occurrence of any of the aforesaid events, disbursement of financial assistance will cease and the consequences referred to in paragraph 3.8.2 will follow.

### 3.8 *Termination*

3.8.1 The Central Government may, on occurrence of any of the following events, at its sole discretion, terminate an approved project:

- (a) Failure of the beneficiary to achieve approved project milestones;
- (b) Submission of a request by the beneficiary to the Central Government, seeking termination of the project, subject to acceptance of the same and due fulfilment of any conditions attached with such acceptance, such as due and proper submission of reports, financial statements, etc.;
- (c) A *force majeure* event;
- (d) Denial, revocation, suspension or non-renewal of any approval, authorisation or clearance related to health, safety or environment which is necessary for the project, by the authority competent to grant the same, where such denial etc. is not attributable to any lapse on the part of the beneficiary;
- (e) Failure of the beneficiary to submit two consecutive quarterly reports; and
- (f) Failure of the beneficiary to furnish information called for by the Central Government in connection with the approved project.

The beneficiary will, without delay, notify the Central Government of the occurrence of any event as referred to in clause (d).

3.8.2 In case the Central Government so terminates an approved project, on and from the date of such termination, without prejudice to the Central Government's right to receive benefit-share for any prior or subsequent commercial realisation of project outputs, the following consequences will follow:

- (a) Disbursement of financial assistance under the Scheme will cease;
- (b) The beneficiary will, within 30 days, refund the unutilised balance of the financial assistance disbursed, together with any interest accrued thereon; and
- (c) The beneficiary will, within 60 days, submit to the Central Government a final technical progress report detailing the work completed till the date of termination and an audited statement of expenditure and utilisation certificate in the form required by the Central Government.

### 3.9 *Clawback*

3.9.1 Notwithstanding anything contained in the Scheme or its guidelines, the Central Government may, on occurrence of any of the following event, at its sole discretion, terminate an approved project and exercise its right to clawback by issuing a termination-cum-clawback order:

- (a) Utilisation, diversion or appropriation of the financial assistance by the beneficiary for purposes unconnected with the approved project;
- (b) Commission of fraud, fabrication or falsification of data, plagiarising of third-party work or wilful making of material misrepresentation in project related submissions, reports, statutory filings, etc. by the beneficiary or by its officer or key employee acting on its behalf;
- (c) Failure of the beneficiary to notify, without delay, the Central Government of the occurrence of any event as required under paragraphs 3.7 or 3.8, or to make such payment or effect such purchase as is required under paragraph 3.7 within 90 days of being required to do so;
- (d) Failure of the beneficiary to remit benefit-share payout when due, on two consecutive occasions, or material erosion of the revenue base on which benefit-share is calculated on account of resort by the beneficiary to transfer-pricing, related-party transactions or other activities; and
- (e) Failure of the beneficiary to fulfil any commitment as referred to in paragraph 3.2.9 of the Scheme.

3.9.2 In case the Central Government so terminates an approved project and exercises its right to clawback, on and from the date of such termination and exercise of right, the consequences specified in paragraph 3.8.2 and the following additional consequences will follow:

- (a) The beneficiary will, within 15 days of issuance of the termination-cum-clawback order, (i) pay to the Central Government a sum as reckoned in clause (a) of paragraph 3.6.1 for Early Stage Project or in clause (b) thereof for Later Stage Project, in the manner specified in paragraph 3.7.2(a), and (ii) pay to the Central Government interest at 12% per annum, compounded annually, calculated from the date of each disbursement, until full repayment.

- (b) The beneficiary, its promoters and any affiliate owning ten per cent or more of its equity, may be debarred for a period of up to five years from participating in any scheme of the Central Government for the promotion of research and development.
- (c) Any unpaid sum as aforesaid, together with interest due thereon, will be recoverable as an arrear of land revenue or as a public demand under the Revenue Recovery Act, 1890.
- (d) The beneficiary will indemnify and keep the Central Government harmless against any third-party claims, fines or penalties arising from the event whose occurrence is the basis for issuance of the termination-cum-clawback order, including costs of litigation and professional fees.
- (e) The Central Government may invoke any bank guarantee, corporate guarantee or recovery arrangement furnished under the funding agreement and apply the proceeds towards satisfaction of amounts due.
- (f) The Central Government may publish the default and debarment details on its official websites and notify various government entities, funding agencies and multilateral bodies.

3.9.3 The termination and exercise of right by the Central Government under paragraph 3.9 will be without prejudice to its right to any damages, penalties or remedies available under statute, common law or equity, including by way of institution of civil proceedings and lodging of criminal complaints.

#### **4. Governance and implementation mechanisms and measures**

##### **4.1 *Empowered Committee***

4.1.1 The Empowered Committee will have such functions and responsibilities as are specified in the Scheme, these guidelines and office memorandum issued by the Central Government in this behalf.

##### **4.2 *Project Appraisal and Approval Committee***

4.2.1 The Project Appraisal and Approval Committee (PAAC) will consider for decision the recommendations of the Technical Committee (TC) in respect of the following:

- (a) The proposal and project plan contained in the application;
- (b) Disbursement of financial assistance;
- (c) Requests for modification to the approved project plan;
- (d) Requests for additional or follow-on financial assistance; and
- (e) Any other Scheme-administration related matter, other than matters that fall within the purview of the EC, which require a decision.

##### **4.3 *Technical Committee***

4.3.1 Technical Committee will be responsible for technical evaluation of projects appraised by the Project Management Agency (PMA) and submit its recommendations for consideration of the PAAC. As part of such evaluation, TC will examine and assess projects in respect of the following:

- (a) The eligibility of the project, including in terms whether the product or technology which is proposed to be taken to higher TRLs is at the TRL claimed in the application (for which the committee may require submission of a report validating the same, furnished by an agency from among those specified on the Scheme portal for this purpose), whether the proposed project outputs correspond to the Priority Areas and, where applicable, to an SPI area;
- (b) The proposal and the project plan, with reference to—
  - (i) the milestones and their corresponding milestone descriptors with associated expenditure and timeframes;
  - (ii) modifications that TC deems necessary to the project plan in respect of timeframes, reduction in project cost or omission of any milestone descriptor or milestone;
  - (iii) the selection criteria specified in the Scheme;
- (c) The appraisal of the project by the PMA, and the inputs of any professionals or expert agencies engaged by TC for such examination and assessment;
- (d) The framework for review, examination and assessment outlined by the Department of Pharmaceuticals; and
- (e) Any other aspect of the project that may be relevant for its due consideration.

4.3.2 The TC will also consider and make recommendations regarding—

- (a) claims made in the milestone completion report or the project completion report regarding achievement of a milestone descriptor;
- (b) inputs of any professionals or expert agencies engaged by it to satisfy itself as to the veracity of such claims;
- (c) requests received for modification to the approved project plan;
- (d) requests received for additional or follow-on financial assistance; and
- (e) Any other matter that may be referred to it for examination and recommendations.

#### 4.4 *Project Management Agency*

4.4.1 The Project Management Agency (PMA), during the period of its engagement, will generally perform functions related to management of the Scheme, including providing assistance to various committees and the Department of Pharmaceuticals in the performance of their functions under the Scheme.

4.4.2 Such functions will include, among other things, the following:

- (a) To facilitate applicants in registration and submissions;
- (b) To acknowledge and process the aforesaid;
- (c) To operate the Scheme portal developed by the Department of Pharmaceuticals, including its digital interfaces with applicants and other stakeholders;
- (d) To manage applicant/beneficiary communications and facilitate applicant support services, including by way of active outreach, formulation of FAQs, development of application toolkits and resolution of procedural queries;
- (e) To conduct completeness and eligibility checks in respect of project submissions;
- (f) To appraise the proposal and project plans for examination and assessment by the TC;

- (g) To monitor Scheme implementation and report on the same, and for this purpose to maintain, update and operate a dashboard that reflects the status of applications, payment of application fees, approvals, execution of agreements, issuance of shares, disbursements, milestone and project completions, submission of completion reports, intimations (regarding commercialisation of outputs and events whose occurrence is linked to ineligibility, one-time settlement, termination or clawback, etc.), benefit-share recoveries etc.;
- (h) To acknowledge and support/process applications, milestone and project completion reviews, reconciliation of disbursements, intimations and such other activities connected with Scheme management;
- (i) To appraise requests received for additional or follow-on financial assistance as required;
- (j) To provide secretarial assistance for meetings of TC, PAAC, and EC and any other meetings convened by the Department of Pharmaceuticals for purposes of the Scheme;
- (k) To maintain records for all applications, co-funding documentation, project files, milestone approvals, post-approval amendments, etc. through the Scheme portal; and
- (l) To compile and submit consolidated quarterly progress reports and any other reports sought to various committees and the Department of Pharmaceuticals.

#### *4.5 Department of Pharmaceuticals*

4.5.1 The Department of Pharmaceuticals may provide the detailed framework for review of project proposals for the purpose of making recommendations for consideration of the Project Appraisal and Approval Committee.

### **5. Monitoring framework**

5.1 To enable monitoring, each beneficiary will upload on the Scheme portal a Quarterly Progress Report and a Quarterly Financial Statement within 30 days of the close of each calendar quarter, and submit such other reports, documents and information as may be required by the Central Government from time to time.

### **6. Other terms and conditions**

6.1 Scheme terms will be governed by the laws of India and will be subject to the jurisdiction of courts in New Delhi, unless otherwise specified.

### **7. Repeal and savings**

7.1 These guidelines are made in supersession of the Operational Guidelines of the Scheme for Promotion of Research and Innovation in Pharma MedTech (PRIP) Sector published earlier on the website of the Department of Pharmaceuticals. However, any action taken under the said Operational Guidelines will be deemed to have been validly done or taken under these guidelines.



## Appendix 1

### **Reputed Government academic and research institutions eligible for collaboration under the Scheme (“Academia”)**

1. Advanced Materials and Processes Research Institute
2. All India Institute of Speech and Hearing
3. All-India Institutes of Medical Sciences<sup>1</sup>
4. Bhabha Atomic Research Centre
5. Bhopal Memorial Hospital and Research Centre
6. Central Council for Research in Ayurvedic Sciences
7. Central Council for Research in Homoeopathy
8. Central Council for Research in Siddha
9. Central Council for Research in Unani Medicine
10. Central Council for Research in Yoga and Naturopath
11. Central Drug Research Institute
12. Central Scientific Instruments Organisation
13. Centre for Cellular and Molecular Biology
14. Centre for DNA Fingerprinting and Diagnostics
15. Chittaranjan National Cancer Institute
16. CSIR Fourth Paradigm Institute, Bengaluru
17. Defence Bioengineering and Electro-medical Laboratory
18. Defence Institute of Bio-Energy Research
19. Defence Institute of High-Altitude Research
20. Defence Institute of Physiology and Allied Sciences
21. Defence Institute of Psychological Research
22. Homi Bhabha National Institute
23. Indian Institute of Chemical Biology
24. Indian Institute of Chemical Technology
25. Indian Institute of Integrative Medicine
26. Indian Institute of Science
27. Indian Institute of Toxicology Research
28. Indian Institutes of Science Education and Research<sup>2</sup>
29. Indian Institutes of Technology<sup>3</sup>
30. Institute for Plasma Research
31. Institute for Stem Cell Science and Regenerative Medicine
32. Institute of Genomics and Integrative Biology
33. Institute of Himalayan Bioresource Technology
34. Institute of Life Sciences, under the Department of Biotechnology
35. Institute of Microbial Technology
36. Institute of Minerals and Materials Technology, Bhubaneswar

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<sup>1</sup> Listed in the Table to section 27A of The All-India Institutes of Medical Sciences Act, 1956

<sup>2</sup> Listed in the Second Schedule to the National Institutes of Technology, Science Education and Research Act, 2007

<sup>3</sup> Listed in sections 2, 3 and 4 of the Institutes of Technology Act, 1961

37. Institute of Nuclear Medicine and Allied Sciences
38. Institute of Physics, Bhubaneswar
39. Jawaharlal Institute of Post-Graduate Medical Education and Research, Puducherry
40. National AIDS Research Institute
41. National Animal Resource Facility for Biomedical Research
42. National Brain Research Centre
43. National Centre for Cell Science
44. National Centre for Disease Informatics and Research
45. National Chemical Laboratory
46. National Institute for Inter-disciplinary Science and Technology, Thiruvananthapuram
47. National Institute for Research in Bacterial Infections
48. National Institute for Research in Environmental Health
49. National Institute for Research in Reproductive Health
50. National Institute for Research in Tuberculosis
51. National Institute of Animal Biotechnology
52. National Institute of Biologicals
53. National Institute of Biomedical Genomics
54. National Institute of Cancer Prevention and Research
55. National Institute of Child Health and Development Research
56. National Institute of Cholera and Enteric Diseases
57. National Institute of Immunohematology
58. National Institute of Immunology
59. National Institute of Malaria Research
60. National Institute of Medical Statistics
61. National Institute of Mental Health and Neurosciences
62. National Institute of Nutrition
63. National Institute of Occupational Health
64. National Institute of Oceanography, Goa
65. National Institute of One Health, Nagpur
66. National Institute of Pathology
67. National Institute of Plant Genome Research
68. National Institute of Research in Tribal Health
69. National Institute of Tuberculosis and Respiratory Diseases
70. National Institute of Virology
71. National Institutes of Pharmaceutical Education and Research<sup>4</sup>
72. National Institutes of Technology<sup>5</sup>
73. National JALMA Institute for Leprosy and Other Mycobacterial Diseases
74. Post-Graduate Institute of Medical Education and Research, Chandigarh
75. Rajendra Memorial Research Institute of Medical Sciences
76. Rajiv Gandhi Centre for Biotechnology

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<sup>4</sup> Listed in the Schedule to the National Institutes of Pharmaceutical Education and Research Act, 1998

<sup>5</sup> Listed in the First Schedule to the National Institutes of Technology, Science Education and Research Act, 2007

77. Regional Centre for Biotechnology, Faridabad, under the Department of Biotechnology
78. Regional Medical Research Centre, Bhubaneswar, under the Indian Council of Medical Research
79. Regional Medical Research Centre, Gorakhpur, under the Indian Council of Medical Research
80. Regional Medical Research Centre, NE, Dibrugarh, under the Indian Council of Medical Research
81. Regional Medical Research Centre, Sri Vijaya Puram, under the Indian Council of Medical Research
82. Saha Institute of Nuclear Physics
83. Sree Chitra Tirunal Institute for Medical Sciences and Technology
84. Tata Institute of Fundamental Research
85. Tata Memorial Centre
86. Translational Health Science and Technology Institute
87. University of Delhi
88. University of Hyderabad
89. Vallabhbhai Patel Chest Institute
90. Such other Government institution which is established under a Central Act or is established as a statutory or autonomous body under a ministry or department of the Central Government, as the Central Government may consider as a reputed Government academic and research institutions eligible for collaboration under the Scheme

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## Appendix 2

### List of the areas specified for Strategic Priority Innovation (SPI) projects

[see paragraph 3.2]

- 1. Diseases relevant to India from among those referred to as “neglected tropical diseases” by the World Health Organization (WHO)**
  - 1.1 Dengue and chikungunya
  - 1.2 Echinococcosis
  - 1.3 Food-borne trematodiasis
  - 1.4 Leishmaniasis
  - 1.5 Leprosy
  - 1.6 Lymphatic filariasis
  - 1.7 Mycetoma, chromoblastomycosis and other deep mycoses
  - 1.8 Rabies
  - 1.9 Scabies and other ectoparasitoses
  - 1.10 Soil-transmitted helminthiasis (e.g., roundworm, whipworm, hookworm)
  - 1.11 Snakebite envenoming
  - 1.12 Taeniasis / cysticercosis
- 2. Rare diseases in India, as listed in the National Policy for Rare Diseases, 2021**
  - 2.1 *Group 1: Disorders amenable to one-time curative treatment*
    - 2.1.1 Disorders amenable to treatment with Hematopoietic Stem Cell Transplantation:
      - (a) Such Lysosomal Storage Disorders for which Enzyme Replacement Therapy is presently not available, and severe form of Mucopolysaccharoidosis type I within first 2 years of age
      - (b) Adrenoleukodystrophy (early stages), before the onset of hard neurological signs
      - (c) Immune deficiency disorders like Severe Combined Immunodeficiency, Chronic Granulomatous disease, Wiskot Aldrich Syndrome, etc.
      - (d) Osteopetrosis
      - (e) Fanconi anaemia
    - 2.1.2 Disorders amenable to organ transplantation:
      - (a) Liver transplantation — Metabolic liver diseases:
        - (i) Tyrosinemia
        - (ii) Glycogen Storage Disorders I, III and IV due to poor metabolic control, multiple liver adenomas, or high risk for Hepatocellular carcinoma, or evidence of substantial cirrhosis or liver dysfunction or progressive liver failure
        - (iii) Maple syrup urine disease

- (iv) Urea cycle disorders
- (v) Organic acidemia
- (b) Renal transplantation:
  - (i) Fabry disease
  - (ii) Autosomal recessive Polycystic Kidney Disease
  - (iii) Autosomal dominant Polycystic Kidney Disease
- (c) Patients requiring combined liver and kidney transplants (rarely Methylmalonic aciduria, etc.)

2.2 *Group 2: Diseases requiring long-term/lifelong treatment having relatively lower cost of treatment and whose benefit has been documented in literature and annual or more frequent surveillance is required*

2.2.1 Disorders managed with special dietary formulae or food for special medical purposes:

- (a) Phenylketonuria (PKU)
- (b) Non-PKU hyperphenylalaninemia conditions
- (c) Maple syrup urine disease
- (d) Tyrosinemia type 1 and 2
- (e) Homocystinuria
- (f) Urea cycle enzyme defects
- (g) Glutaric aciduria type 1 and 2
- (h) Methylmalonic acidemia
- (i) Propionic acidemia
- (j) Isovaleric acidemia
- (k) Leucine sensitive hypoglycemia
- (l) Galactosemia
- (m) Glucose galactose malabsorption
- (n) Severe food protein allergy

2.2.2 Disorders that are amenable to other forms of therapy (hormone / specific drugs):

- (a) NTBC for Tyrosinemia type 1
- (b) Osteogenesis imperfecta — Bisphosphonates therapy
- (c) Growth hormone therapy for proven GH deficiency, Prader Willi syndrome, Turner syndrome and Noonan syndrome
- (d) Cystic fibrosis — Pancreatic enzyme supplement
- (e) Primary immune deficiency disorders — Intravenous immunoglobulin and subcutaneous therapy replacement, *e.g.*, X-linked agammaglobulinemia, etc.
- (f) Sodium benzoate, arginine, citrulline, phenylacetate (urea cycle disorders), carbamglut, megavitamin therapy (organic acidemia, mitochondrial disorders)
- (g) Others — Hemin (Panhematin) for Acute Intermittent Porphyria, high dose Hydroxocobalamin injections
- (h) Large neutral amino acids, mitochondrial cocktail therapy, Sapropterin and other such molecules of proven clinical management in a subset of disorders

2.3 *Group 3: Diseases for which definitive treatment is available but challenges are to make optimal patient selection for benefit, very high cost and lifelong therapy*

(a) Based on literature, sufficient evidence for good long-term outcomes exists for the following disorders:

- (i) Gaucher disease type I and III (without significant neurological impairment)
- (ii) Hurler syndrome [Mucopolysaccharidosis type I] (attenuated forms)
- (iii) Hunter syndrome [Mucopolysaccharidosis type II] (attenuated form)
- (iv) Pompe disease (both infantile and late onset diagnosed early before development of complications)
- (v) Fabry disease, diagnosed before significant end organ damage
- (vi) Mucopolysaccharidosis type IVA, before development of disease complications
- (vii) Mucopolysaccharidosis type VI, before development of disease complications
- (viii) DNase for cystic fibrosis

(b) For the following disorders, for which the cost of treatment is very high and either long-term follow-up literature is awaited or has been done on small number of patients:

- (i) Cystic fibrosis (Potentialators)
- (ii) Duchenne Muscular Dystrophy (Antisense oligonucleotides, Premature termination codon)
- (iii) Spinal muscular atrophy (Antisense oligonucleotides — Intravenous, oral and gene therapy)
- (iv) Wolman disease
- (v) Hypophosphatasia
- (vi) Neuronal ceroid lipofuscinosis

3. **Addressing antimicrobial resistance in respect of multidrug resistant and extensively drug-resistant pathogens listed as critical, high or medium priority in the India Priority Pathogens List published by the Department of Biotechnology on its website**

3.1 Enterobacteriaceae (*Klebsiella pneumoniae* and *Escherichia coli*)

- (a) Carbapenem-resistant
- (b) Tigecycline-resistant
- (c) Colistin-resistant

3.2 Non-fermenting bacteria (*Acinetobacter baumannii* and *Pseudomonas aeruginosa*)

- (a) Carbapenem-resistant
- (b) Colistin-resistant

3.3 *Staphylococcus aureus*

- (a) Methicillin-resistant *Staphylococcus aureus*, Heterogenous vancomycin-intermediate *Staphylococcus aureus*
- (b) Daptomycin – Non-susceptible

- (c) Linezolid-resistant
- 3.4 Enterococcus species
  - (a) Vancomycin-resistant
  - (b) Linezolid-resistant
  - (c) Daptomycin – Non-susceptible
- 3.5 Salmonella species (typhoidal and non-typhoidal)
  - (a) Azithromycin – Non-susceptible
  - (b) Third-generation cephalosporins – Non-susceptible
  - (c) Carbapenem – Non-susceptible
- 3.6 Streptococcus pneumoniae
  - (a) Cephalosporin-resistant
  - (b) Fluoroquinolones-resistant
  - (c) Linezolid-resistant
- 3.7 Staphylococcus, coagulase-negative
  - (a) Vancomycin-resistant
  - (b) Linezolid-resistant
- 3.8 Shigella species
  - (a) Third-generation Cephalosporins-resistant
  - (b) Azithromycin-resistant
- 3.9 Haemophilus influenzae
  - (a) Third-generation Cephalosporin – Non-susceptible
  - (b) Carbapenem – Non-susceptible
- 3.10 Neisseria meningitidis
  - (a) Fluoroquinolones – Non-susceptible
  - (b) Third-generation Cephalosporins – Non-susceptible
- 3.11 Mycobacteria (including Mycobacterium tuberculosis)
- 4. Addressing the priority pathogens that cause outbreaks or pandemics, as listed in the WHO List of Priority Pathogens and Diseases**

	Family	Priority Pathogens (High PHEIC risk)	Prototype pathogen
4.1	Adenoviridae	No Priority Pathogen proposed	<i>Mastadenovirus blackbeardi</i> serotype 14, Recombinant Mastadenovirus
4.2	Anelloviridae	No Priority Pathogen proposed	No Prototype pathogen proposed
4.3	Arenaviridae	<i>Mammarenavirus lassaense</i> (Lassa Fever)	<i>Mammarenavirus juninense</i> (Junin virus), <i>Mammarenavirus lassaense</i> , <i>Mammarenavirus lujoense</i>
4.4	Astroviridae	No Priority Pathogen proposed	<i>Mamastrovirus virginiaense</i>

4.5	Bacteria	<i>Vibrio cholerae</i> (O139), <i>Yersinia pestis</i> , <i>Shigella dysenteriae</i> serotype 1, <i>Salmonella enterica</i> non-typhoidal serovars, <i>Klebsiella pneumoniae</i>	No Prototype Pathogen proposed
4.6	Bornaviridae	No Priority Pathogen proposed	<i>Orthobornavirus bornaense</i>
4.7	Coronaviridae	Subgenus <i>Sarbecovirus</i> (SARS-CoV-2), Subgenus <i>Merbecovirus</i> (MERS-CoV)	Subgenus <i>Merbecovirus</i> , Subgenus <i>Sarbecovirus</i>
4.8	Filoviridae	<i>Orthoebolavirus zairense</i> (Ebola Virus), <i>Orthoebolavirus sudanense</i> , <i>Orthomarburgvirus marburgense</i>	<i>Orthoebolavirus zairense</i>
4.9	Flaviviridae	<i>Orthoflavivirus denguei</i> , <i>Orthoflavivirus flavi</i> , <i>Orthoflavivirus zikaense</i> , <i>Orthoflavivirus encephalitidis</i> , <i>Orthoflavivirus nilense</i>	<i>Orthoflavivirus denguei</i> , <i>Orthoflavivirus zikaense</i> , <i>Orthoflavivirus nilense</i> , <i>Orthoflavivirus encephalitidis</i>
4.10	Hantaviridae	<i>Orthohantavirus hantanense</i> , <i>Orthohantavirus sinnombreense</i>	<i>Orthohantavirus sinnombreense</i>
4.11	Hepadnaviridae	No Priority Pathogen proposed	<i>Orthohepadnavirus hominoidei</i> genotype C
4.12	Hepeviridae	No Priority Pathogen proposed	<i>Paslahepevirus balayani</i> genotype HEV-3
4.13	Herpesviridae	No Priority Pathogen proposed	No Prototype pathogen proposed
4.14	Nairoviridae	<i>Orthonairovirus haemorrhagiae</i>	<i>Orthonairovirus haemorrhagiae</i>
4.15	Orthomyxoviridae	<i>Alphainfluenzavirus influenzae</i> H1, H2, H3, H5, H6, H7, H10	<i>Alphainfluenzavirus influenzae</i> (H1N1), <i>Alphainfluenzavirus influenzae</i> (H5Nx)
4.16	Papillomaviridae	No Priority Pathogen proposed	No Prototype pathogen proposed
4.17	Paramyxoviridae	<i>Henipavirus nipahense</i>	<i>Henipavirus nipahense</i>



4.18	Parvoviridae	No Priority Pathogen proposed	<i>Protoparvovirus carnivoran</i>
4.19	Peribunyaviridae	No Priority Pathogen proposed	<i>Orthobunyavirus oropoucheense</i>
4.20	Phenuiviridae	<i>Bandavirus dabieense</i>	<i>Bandavirus dabieense, Phlebovirus riftense</i>
4.21	Picobirnaviridae	No Priority Pathogen proposed	<i>Orthopicobirnavirus hominis</i>
4.22	Picornaviridae	<i>Enterovirus coxsackiepol</i> (Enterovirus A71, Enterovirus D68)	<i>Enterovirus alphacoxsackie 71, Enterovirus deconjecti 68</i>
4.23	Pneumoviridae	No Priority Pathogen proposed	<i>Metapneumovirus hominis</i>
4.24	Polyomaviridae	No Priority Pathogen proposed	No Prototype pathogen proposed
4.25	Poxviridae	<i>Orthopoxvirus variola, Orthopoxvirus monkeypox</i>	<i>Orthopoxvirus monkeypox, Orthopoxvirus vaccinia</i>
4.26	Retroviridae	<i>Lentivirus humimdef1</i>	<i>Lentivirus humimdef 1</i>
4.27	Rhabdoviridae	No Priority Pathogen proposed	Genus <i>Vesiculovirus</i>
4.28	Sedoreoviridae	No Priority Pathogen proposed	Genus <i>Rotavirus</i>
4.29	Spinareoviridae	No Priority Pathogen proposed	<i>Orthoreovirus mammalis</i>
4.30	Togaviridae	<i>Alphavirus chikungunya, Alphavirus venezuelan</i>	<i>Alphavirus chikungunya, Alphavirus venezuelan</i>

## 5. Vaccines for diseases listed by WHO as vaccine-preventable diseases (including pipeline)

- 5.1 Chikungunya
- 5.2 Cholera
- 5.3 COVID-19
- 5.4 Dengue
- 5.5 Diphtheria
- 5.6 Enterotoxigenic Escherichia coli
- 5.7 Group A Streptococcus
- 5.8 Group B Streptococcus
- 5.9 Haemophilus influenzae type b
- 5.10 Hepatitis
- 5.11 Herpes simplex virus
- 5.12 HIV-1

- 5.13 Human papillomavirus
- 5.14 Improved Influenza Vaccines
- 5.15 Influenza
- 5.16 Japanese encephalitis
- 5.17 Malaria
- 5.18 Measles
- 5.19 Meningococcal meningitis
- 5.20 Mumps
- 5.21 Neisseria gonorrhoeae
- 5.22 Non-typhoidal Salmonella Disease
- 5.23 Norovirus
- 5.24 Paratyphoid fever
- 5.25 Pertussis
- 5.26 Pneumococcal disease
- 5.27 Poliomyelitis
- 5.28 Rabies
- 5.29 Respiratory Syncytial Virus
- 5.30 Rotavirus
- 5.31 Rubella
- 5.32 Schistosomiasis disease
- 5.33 Shigella
- 5.34 Smallpox and mpox
- 5.35 Tetanus
- 5.36 Tick-borne encephalitis
- 5.37 Tuberculosis
- 5.38 Typhoid
- 5.39 Varicella
- 5.40 Yellow fever

**6. Areas specified by the Department of Health Research, Ministry of Health and Family Welfare**

- 6.1 Treatment and diagnostics for Acanthamoeba species
- 6.2 Treatment and diagnostics for Aspergillus species
- 6.3 Treatment and diagnostics for Bacillus anthracis
- 6.4 Treatment and diagnostics for Bacillus cereus
- 6.5 Treatment and diagnostics for Borrelia burgdorferi
- 6.6 Treatment and diagnostics for Brucella species
- 6.7 Treatment and diagnostics for Burkholderia pseudomallei
- 6.8 Treatment and diagnostics for Campylobacter species
- 6.9 Treatment for multidrug resistance to Candida species and specific species-level diagnostics for the same
- 6.10 Treatment and diagnostics for Coxiella burnetii
- 6.11 Diagnostics for enteroviruses
- 6.12 Treatment and diagnostics for HIV-2

- 6.13 Treatment and diagnostics for Kyasanur Forest Disease
- 6.14 Treatment and diagnostics for *Legionella pneumophila*
- 6.15 Diagnostics for *Leptospira* species
- 6.16 Treatments and diagnostics for *Mycobacteria* (*Mycobacterium tuberculosis* complex and non-tuberculous *Mycobacteria*)
- 6.17 Diagnostics for *Mycoplasma pneumoniae*
- 6.18 Treatment and diagnostics for *Naegleria*
- 6.19 Diagnostics for *Orientia tsutsugamushi*
- 6.20 Diagnostics for *Toxoplasma*, and treatments addressing latent *Toxoplasma* parasites
- 6.21 Diagnostics, preferably rapid-testing diagnostics, for *Vibrio* species, especially non-Cholera species
- 6.22 Diagnostics for *Yersinia enterocolitica*
- 6.23 Treatment and diagnostics for sickle cell disease
- 6.24 Treatment and diagnostics for thalassemia

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