Assessment of Health Product Innovation

Under National Healthcare Innovations Portal

An Innovations gateway to the Health Systems

"Supporting Innovations for Achieving Health Assurance for all Citizens in India."

Ministry of Health & Family Welfare
Government of India

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A. Background :

India has a technological prowess in medical science and technology, which is a good as the best in the world. There is today no therapeutic or diagnostic procedure that is in regular use anywhere else in the world, which is not available in India. Moreover, one of the cornerstones of the Universal Health Coverage (UHC) initiative is access to Medical devices. Further it is usually available at costs substantially lower than what one would pay for the same in a developed nation. This attracts a large number of patients from developed and developing countries to seek medical care in India. Yet in terms of the burden of disease and preventable morbidities and mortalities, and effectively addressing these India is faced with double whammy of life styles diseases and resurgence of infectious diseases. In terms of social protection of poor from the rising costs of health care, India has one of the poorest records. To convert our phenomenal economic growth, high quality medical care and available technology into social well-being and happiness, one of the most important steps is identification, assessment and progressive uptake of innovation developed and successfully implemented in India.

Ministry of Health and Family Welfare, Government of India has encouraged piloting and scaling up of innovations and good practices to improve health outcomes. It is an essential part of National Health Mission and states are supported to pilot & field test of innovations. In the past NHSRC has served, as technical secretariat for Sector Innovations Council for Health, a part of National Innovation Council. Recently Health Technology Assessment in India (HTAIn) has been constituted for which NHSRC is a technical partner for conducting Health Technical Assessment (HTA). These innovations and good practices by the states are encouraged through national conventions to reward good practices and innovations. The government has provided more support to states through its National Health Mission. There is need to systematically identify innovations and good practices which can have a high impact to address morbidity and mortality and facilitate their prompt scale up through a platform, which provide repository, learning's, information on enabling milieu and cross-learning.

B. Healthcare Innovation definition and classification:

Many changes take place in health technologies and health systems. Innovations take place for product diversification as part of building brand images, or securing marketing advantages and profitability of health care organizations. These have value for sections that derive them and are not objectionable in them. Innovations also take place in programme delivery mechanisms primarily to move in a particular direction or

to speed up the process of achievement of desirable outcomes. But public policy in health sectors needs to actively promote and welcome only those innovation that serves the need of public health viz. increased access, quality and affordability of health care, greater health equity, increased responsiveness to health care needs, greater patient choice and autonomy in health care choices, improved public participation in decision making and above all improvement in social determinants of health care. India may have some of the best facilities to provide services to those, who can afford to pay. However, the same is not available to a large section of its population, especially for the poor. However, these may not be type of delivery models that maybe able to serve the rest of the population. Also, much of what is available have not been designed in India and there is merit in identifying Indian innovation and giving them support and visibility for their scale-up. There is particularly a strong need for supporting the innovation that are focused on improving access to quality affordable healthcare for the poor and in underserved geographies through active government intervention. For the purpose of *"identifying appropriate and effective innovation" from a "common range of existing or new products",* it is suggested that Healthcare Product Innovation is considered as below:

Product Innovation: Innovative Health Product including Medical Devices, Innovative technologies including Healthcare IT, m-health, and tele-health/e-health from a bulk of product innovations. New vaccines and Drugs follow other regulatory routes and usually get well identified and incorporated. However, medical technology innovations tend to remain unidentified due to inadequate system support.

C. Principles of Product Innovation Identification:

Given that each category of technology innovations comes with its own strengths and challenges of identification and assessment, certain guiding principles for identification of innovation or potential is a must, which could also serve *"eligibility criteria for being considered to be a product innovation". The following are the criteria.*

Exclusion Criteria: The Product Healthcare Innovation Platform excludes:

1. Incomplete Documentation of Innovation: for any innovation to be reviewed the document should include adequate information on process, human resource and infrastructure need, capacity building strategies, cost, challenges and lessons.

2. Medical products that require regulatory clearance.

3. Innovations that are at prototype stage.

Inclusion Criteria:

1. The product innovations that are relevant to existing health care needs of the population specially those who are disadvantaged and marginalized.

2. The product innovation that addresses locally endemic health problems and or diseases.

3. The product innovation that facilitates affordable and universal access of healthcare reaches to rural areas and to disadvantaged and marginalized population group.

4. The product innovation that bridges a crucial specialized skill gap required in delivery of health services.

5. Innovations, which meet criteria for uniqueness and can be scaled up.

6. Any health technology, which has undergone any one or more of the processes below.

   i. Randomized controlled trials

   ii. Systematic Reviews

   iii. Meta-analysis

Thus, one or more of the above given eligibility criteria along with classification as Emerging or Established Innovation, makes it easier for decision makers to prioritize and objectively evaluate innovations. TRL 8 & TRL 9 will be treated as established innovation and considered for further evaluation.

Definition for TRL 8 & 9:

TRL 8 – System incorporated in commercial design

Technology has been proven to work in its final form under the expected conditions. In most of the cases, this level represents the end of true system development.

TRL 9 – System ready for full scale deployment

Here, the technology in its final form is ready for commercial deployment.

Level beyond TRL 9 - Market introduction

The product, process or service is launched commercially, marketed to and adopted by a group of customers (including public authorities).

D. Process for Innovators reaching out to innovation seeker:

1. *National Healthcare Innovation Portal* serves as an online submission window for practitioners and innovators to submit their proposals.

2. The webpage is so designed that innovator/practitioner fills the mandatory field including qualifying criteria.

3. The webpage enables submission of essential documents/reports/pictures/videos any other form of evidence online

4. Innovators submits the innovation in "product innovation"

5. Initial (first) screening will be done by National Health Systems Resource Centre through scoring criteria **(Annexure A)**, which is addressing following questions:

   i. What is the stage of development of the innovation,

   ii. How the technology targets a well-defined and substantial health problem?

   iii. Is the innovation novel and unique?

   iv. Superiority of the technology in terms of safety and efficiency.

v. Does the evidence presented indicate that the product could lead to positive health outcomes in low resource setting?

Note: In terms of the safety documentary evidence like electricity safety, fire safety of material, biocompatibility, radiation safety, whatever applicable would be considered.

6. An appraisal committee **(Annexure B)** is formed consisting of officials and experts who screen and review submission for adequacy of evidence on an annual basis.

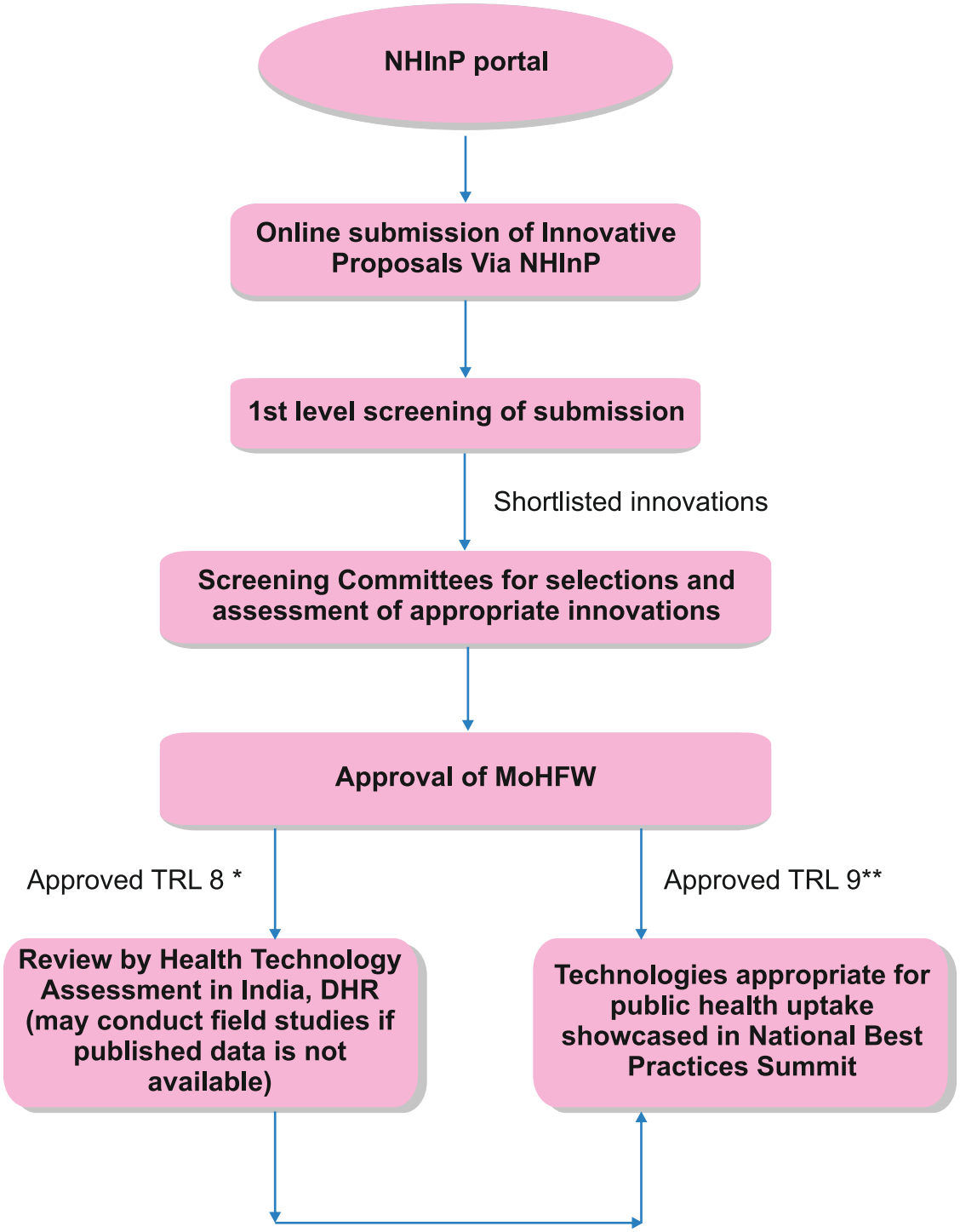
7. The committee submit their findings to MoHFW

8. Upon review by MOHFW if found that innovation require further pilots/independent assessment, depending upon the category of innovation, they would be sent to appropriate department within the MoHFW, NHSRC, or DHR for further evaluation.

9. If found to be appropriate, specification would be formulated for "Product Innovation" for further uptake.

10. Upon acceptance of innovation by MoHFW, states will be intimated by MoHFW and its implementation mechanism. All such innovationswill be shared at National Innovation Summit organized by MoHFW.

PROCESS FLOW FOR EVALUATION AND UPTAKE OF PRODUCT INNOVATION



*TRL 8:System incorporated in commercial design. Technology has been proven to work in its final form under the expected conditions. In most of the cases, this level represents the end of true system development.

**TRL 9 System ready for full scale deployment. Here, the technology in its final form is ready for commercial deployment.

Level beyond TRL 9- Market introduction. The product, process or service is launched commercially, marketed to and adopted by a group of customers (including public authorities).

Note: TRL: Technology Readiness level.

Appraising innovation for their effectiveness, utility in desired goal, cost-effectiveness, safety and program implementation remains core principle for successful integration of innovation in public health system. It is for this reason that all stakeholders must be consulted for identifying and scaling up of innovations. Most importantly they must include state governments, NGOs, corresponding program divisions within ministry of health and family welfare apart of subject experts. For each of the product innovations component, the following appraisal committee is proposed to be constituted.

E. Institutional Structure:

NHSRC serves as the technical secretariat for National Healthcare Innovation Portal. The role of technical secretariat includes the following.

a. Consolidating the innovations submitted the National Health Innovation Portal;

b. Arranging for regular meetings of the committee.

c. The technical secretariat presents the submissions to the committee and also undertakes searches for credibility of evidence, any other related analytical evaluations or assessments of product evidences.

d. The technical secretariat funds the activities of meetings, any related activities

e. Technical secretariat supports the Health Technology Assessment in India (HTAIn), DHR for Health Technology Assessment of innovations. Technical secretariat submits to MoHFW the findings of the appraisal committees and will inform innovators about the selection of the innovation.

f. The technical secretariat would support MoHFW in informing states about the approval of the innovation.

g. The technical secretariat would support states in uptake of such innovations as felt appropriate by the states.

F. Dissemination and Scale up of Product Innovation and Good Practice:

The product innovation and good practices that meet the criteria for uptake will be presented to stake holders including state officials periodically. NHSRC will continue to be the repository of approved innovations. These will also be available on the portal.

G. General Financial Rules (GFR), 2017:

Procurement from a single source may be resorted as per GFR, 2017.

H. Categories of Recommendations:

Product could be recommended under the following headings:

a. *Pilot/Validation:*

In case validation data is not sufficient then product could be recommended for further clinical validation study and in order to evaluate the feasibility of product in Indian Public Healthcare System, the product would be recommended for the pilot study. States can propose budget for approved innovations in PIP for pilot studies

under FMR Code 18. FMR code is divided into two subcategories: State level innovations and District level innovations.

b. *Health Technology Assessment (HTA) BY DHR:*

HTA is a multi disciplinary field that addresses the clinical, economic, organizational, social, legal, and ethical impacts of a health technology, considering its specific healthcare context as well as available alternatives.

c. *Uptake in public health:*

Product approved by Central Drugs Standard Control Organization/ Atomic Energy Regulatory Board (CDSCO/AERB), FDA approved, CE Marked (Notified Body) or HTA completed by HTAIn/DHR would be recommended for uptake in the Indian Public health Facilities. It can be procured on proprietary basis as per GFR with invitation of objections from any interested party by advertising in national newspapers. The procurement on proprietary basis may be made with substantial evidence of uptake in low resource healthcare settings.

I. Mandatory disclosures:

Once the innovation gets selected for evaluation under any categories listed under "Categories of Recommendations" innovators are requested for the following disclosure :

1. No objection to data sharing while evaluation.
2. Disclosure with respect to possible conflict of interest.

Annexure- A

Scoring Sheet					
S. No.	**Questions**	**Criteria**	**Score**	**Innovation 1**	**Innovation 2**
1.	What is technology,s stage of development?	Yes (Commercialized)	1	0	0
		No (Yet to Commercialized)	0		
2.	Does the technology target a well-defined and substantial health problem?	Yes	1	0	0
		No	0		
3.	Is the innovation novel and unique? (as per Patent act, submission of published	Yes	1	0	0
		No	0		
4.	Superiority of the technology in terms of safety and efficiency?	Safet & Quality (i)	1	0	0
		Affordability (ii)	1		
5.	Does the evidence presented indicate that the product could read to positive health outcomes in low resources setting?	Yes	1	0	0
		No	0		
6.	Presentation		4	0	0
	Total Maximum Possible Score		**10**	0	0
7.	Recommendation				

NOTE :-

i. Documentary evidence like electrical safety, fire safety of material, biocompatability, radiation safety, whatever applicable.

ii. comparison to alternative solution as per standard Gov. referals (CGHS, DGHS etc.), for innovations rate contract and for the products which are unique and no alternatives are available manufacturer would be asked to provide Bill of Quantity (BOQ) of raw materials including software.

Annexure – B

Committee for screening & evaluation of Product Innovation (11 members)

- Director, PGIMER (Chandigarh), AIIMS, SGPGI Lucknow, NIMHANS Bangalore, JIPMER. Chairperson (by rotation every two years – To be nominated by MOHFW
- DDG /Additional DDG (ICMR)/JS (DHR)-Co-Chairperson - To be nominated by DHR
- Representative from Principal Scientific Advisor to Government of India
- Representative from Atal Innovation Mission, NITI Ayog
- Division head from MoHFW of respective subject that is to be accessed –Member - To be nominated by MOHFW
- Mission Director/representative- from two states: Member- To be nominated by MOHFW
- Representation by Department of Biotechnology (DBT)
- Chairperson, Biotechnology Industry Research Assistance Council (BIRAC)
- Technical Experts Member: Director IIT (Ropar), Scientist-G (Shri Chitra Institute, Trivandrum), Head Department of Biomedical Engineering (CMC, Vellore)- Member Scientist-F (SAMEER, DeitY, Mumbai.
- Head Division of Healthcare Technology, NHSRC-Member Secretary.
- Development Partner representative WHO/UNCIEF technical officer in relevant area Member.

Annexure – C

LIST OF PARTICIPATING EXPERTS:

S.No.	NAME	DESIGNATION	ORGANIZATION
1	Ms. Preeti Sudan	Health Secretary	MOHFW
2	Mr. Manoj Jhalani	AS&MD	MOHFW
3	Dr. Manohar Agnani	JS(P)	MOHFW
4	Dr. J B Mohapatra	PSA to Gov. Of India	Gov. of India
5	Shri Suresh Kumar	Scientist F	Office of Principal Scientific Advisor, Government of India
6	Dr. Rajni Ved	Executive Director	NHSRC
7	Dr. Teja Ram	Deputy Commissioner	MOHFW
8	Mr. N Yuvraj	Deputy Secretary	MOHFW
9	Dr. Shahsi Bhushan Sinha	Former Advisor, HCT	NHSRC
10	Dr. Ayesha Chaudhary	Atal Innovation Mission	NITI Aayog
11	Dr. Venkatesh Rao Aiyagari	Senior Advisor (Science & Technology	PHFI
12	Dr. Kavitha Rajshekhar	Scientist 'E'	DHR
13	Dr. Neeraj Jain	Country Director	PATH
14	Dr. Satya Das	Director	PATH
15	Mr. Vijai Singh	Managing Director	Innovation Curis
16	Dr. Syed Taslim Arif	CEO Director	CCAMP
17	Dr. R.K. Srivastava	Sr. Advisor	WISH Foundation
18	Er. Mohammad Ameel	Sr. Consultant	NHSRC, New Delhi
19	Er. Ajai Basil	Consultant	NHSRC, New Delhi
20	Ms. Akriti Chahar	Consultant	NHSRC, New Delhi
21	Er. Anjaney	Consultant	NHSRC, New Delhi
22	Er. Vigneshwaran PS	Consultant	NHSRC, New Delhi
23	Mr. Bharat Bhushan	Consultant	NHSRC, New Delhi
24	Ms. Rakshita Khanijou Sareen	Consultant	MOHFW
25	Mr. Mohamad Zoheb	Short Term Consultant	NHSRC, New Delhi
26	Mr. Pawan Dinodia	Fellow	NHSRC, New Delhi
27	Ms. Purnima Dhamija	Fellow	NHSRC, New Delhi

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