

Critical analysis of India's National Mission on Medicinal Plants (NMMP) in providing access to quality botanical drugs to improve public health

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ABSTRACT

Drugs play an important role in improving health of the population. Medicinal plants help in addressing the health issues of a large section of the population – especially the low and middle-income people. However, there are some concerns about the supply, efficacy and safety in using them. This study reviews India's major initiative toward medicinal plants namely, the National Mission on Medicinal Plants to meet medicinal plants challenges. The study analyzed the mission's probable shortcomings due to its design and operational details. This study used "content analysis" approach for analysis of mission's publicly available documents, viz. "Operational guidelines" and its two amendments. The study identified prevalent 28 shortcomings in the original document related to clarity of the document; accountability, transparency and stakeholders' representation. These challenges were partially addressed in two amendments, which indicate persistence of shortcomings in design and operational details. The mission can help in improving and strengthening the Ayurveda, Yoga, Unani, Siddha and Homeopathy program by addressing those shortcomings.

Key words: Content analysis, herbal medicine, medicinal plant policy, National mission on medicinal plants, the Indian herbal policy

INTRODUCTION

Drugs are an important ingredient for any nation's health system and issues-related to quantity, quality, affordability and accessibility of drugs can jeopardize a nation's ability to meet its health needs. Botanical drugs play an important role in meeting the health needs of low and middle-income countries through traditional medical system.^[1-5] In addition, around 57% of top allopathic drugs are constituted from at least one medicinal plant-based active ingredient.^[6]

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However, the decrease in medicinal plants natural stocks through deforestation and over-extraction has led to a reduction in medicinal plants availability and increase in adulterated botanical drugs thereby affecting affordability of good quality botanical drugs.^[7]

Any medication efficacy depends on the purity of active compound (s), and safety depends on the presence (more so absence) of undesirable compounds. The problem of efficacy can be addressed by preventing adulteration in medicinal plant and by controlling the variability in active ingredient's concentration. Some of ways of tackling the challenge of efficacy and safety is by promoting and regulating the cultivation, improving the cultivation practices, providing awareness about good cultivation practices and improving processing practices/techniques. The India's supply chain of medicinal plants is un-organized and relies on the collection from wild which has resulted in adulteration of the raw material and over-exploitation of its resources.

India took a major policy initiative in addressing these challenges by launching "launching Mission on Medicinal Plants (NMMP's)" in 2008 under the aegis of National Medicinal Plants Board (NMPB), Department of Ayurveda, Yoga, Unani, Siddha and Homeopathy (AYUSH), Ministry

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of Health and Family Welfare. The mission promotes cultivation and provides an opportunity for value addition through processing and trade through market initiatives. It had been provided with total budgetary allocation of Rs. 630 crores for year 2008–2012 for addressing the national and global botanical drugs' needs and India's economic growth needs.^[7] The recommendation for continuation of the scheme was put forth by the "Steering Committee on Department of AYUSH for 12th Five Year Plan."^[2] However, report by steering committee on AYUSH revealed mission's inability to achieve desired outcomes^[2] of increasing value added products market share, cultivation area, plant production and rural livelihood and reduced dependence on wild.^[7] This indicates inadequacies which can be either at design or implementation level. This study analyzes NMMP documents for mission's probable shortcomings based on the document's design and operational details for the scheme.

METHODOLOGY

A qualitative content analysis approach, a systematic technique to analyze and interpret the textual content of the data,^[8,9] were used to understand the design and operational details of the mission and its inherent hurdles. It differs from general review in the terms that it follows a well-defined step by step approach to arrive at any result. The content analysis tool had been used by different researchers for health sector policies analysis for Australia,^[10] Belgium,^[11] Canada,^[12] Denmark^[13] and Pakistan.^[14]

In this study, the NMMP policy documents available in the public domain were used as the data set for this study. In total three documents were found namely "operational guidelines (2008),"^[7] "operational guidelines (2011)"^[15] and "proposed operational guidelines (2012)."^[16] These documents did not contain any personnel information of any kind; hence no ethical clearance for the study was required. A preliminary analysis of the document showed that the document of 2008 was the "original document", while the other two documents were its subsequent amendments. The "original document" was used to understand mission's probable shortcomings owing to the document's design and operational details of the mission, while the subsequent amendments were used to determine the reduction in probable shortcomings.

A general inductive approach was used for the textual analysis of the policy^[10,17] and was an iterative process involving repeated readings to identify the major themes of the document. In general, the first step in the process was reading, which involved repeated reading of the document

for the language, content and format. The second step in the process was coding, which involved grouping the text (phrase to whole sections) into different themes. The third step in the process was collation, which involved compiling all the data into broader themes. The fourth and final step in the process was interpretation, which involved analyzing and interpreting the thematically grouped data contextually and theoretically.^[18,19]

In this study, all the steps were performed by the authors and the "interpretation" step lead to the identification of the NMMP's design and operational details with its possible shortcomings and its subsequent attempts to minimize those shortcomings. Content analysis studies are generally perspective oriented studies and personnel bias in such studies was negated by performing content analysis over large set of policy documents and using multiple analysts to achieve better consistency and consensus in the results. However, due to the recent implementation of the mission only three policy documents could be obtained.

RESULTS AND DISCUSSIONS

The study identified six major themes in the policy documents namely current status/issues, mission objectives and targets, strategy, governance, stakeholders and financing.

Shortcomings in the original document

Current status/issues

National Mission on Medicinal Plants "NMPP'sa Mis guidelines" (2008) had identified three hurdles. The first challenge of unsustainable supply of medicinal plants was addressed by promotion of cultivation. The NMMP inherently assumed that the current minor cultivated fraction uses sustainable practices, and the promotion of cultivation would reduce harvesting from the wild and improve the quality of medicinal plants. However, along with cultivation, the NMMP did not address the strategies for reducing harvesting from the wild which is the major fraction.

The second challenge of low global outreach and acceptability of AYUSH system was addressed by improving the medicinal plants quality through Good Agricultural Practice/organic compliance. However, the concept of quality, high variability of active ingredient and absence of adulterants was not elaborated, which could have an affect on the efficacy and safety of botanical drugs.

Finally, the challenge of poor global herbal market share of the country was addressed by creating and promoting value added products. However, mission failed to provide strategy to address quality control of the value added

products, which could be of grave concern in export. Further, NMMP focused on non-AYUSH export market without providing a reason for not targeting non-AYUSH domestic market.

The document used the word “herbal” and “neal” interchangeably which makes it difficult to understand the market share as various non-AYUSH systems like medicinal plant based allopathic drugs and traditional Chinese medicine could also form the part of the global herbal trade. In addition, though the NMPB’s (existing since 2000) one of the objectives being domestic and global supply/demand scenario assessment,^[7] the mission document failed to provide an adequate basis for supply/demand scenario and its correlation with the identified hurdles.

Mission objectives and targets

The main objectives of the mission included improving AYUSH system and its acceptability, providing livelihood to farmers and increase value added products export, while secondary objectives included promoting cultivation, coordination and linkage between different users, creating a linkage between allied services and market and implementing and supporting quality certification system for medicinal plants. In the light of absence of any background information regarding the current collection based system, NMMP’s document failed to consider the impact of and on the current collection based system, which may result in landless collectors with no livelihood option. Qualitative and quantitative targets for the mission had been mentioned without baselines for set targets, no linkages with the challenges and potential solutions (like medicinal plant production target) and inadequacies of the targets.

Strategy

The NMMP strategy focused on promoting cultivation and creating an end-to-end support and linkages through plant material production, cultivation, postharvest management, value addition, and marketing. However, externalities like other commercial crop intervention, land use change and harvesting from the wild had not been considered. While, there was direct mention of some accredited planting material supply unit, no mention of other backward linkages. Forward linkage was mentioned by promoting the value added products through postharvest management units, linkage with the buyers, as well as marketing support for both cultivators and value added products manufacturers. The strategy of horizontal linkages was provided by establishing labs to test the quality of medicinal plants and value added products.

Strategy of financial incentives for cultivators to bring down cultivation cost and thereby help compete with

collectors reflects NMMP’s lack of understanding of collection systems. The strategy of maintaining geographical proximity for better coordination and communication was through cluster-based promotion of cultivation and processing. However, cluster definition in terms of its geographical coverage, total area under cultivation and number of cultivators/other users was not provided. Further, subsidizing the noncultivation activities, infrastructure set-up outside the cluster (with linkage with the cultivation cluster) questions the practicality of the cluster. In addition, lack of quality mandate for several applicants and activities makes it difficult to address the issue of poor product quality and competition from the existing collection based system.

Governance

National Mission on Medicinal Plant document indicated a four tier structure at center, state, district and cluster [Figure 1] without timelines for setting up this structure. The state level governance would be under State Level Steering Committee, which comprises of Technical Support Group/Technical Screening Committee and State Level Implementation Agency. While, Technical Support Group had one governance mechanism, State Level Implementation Agency had three mechanisms [Figure 2] for choice of the implementation agency depending on agency’s efficiency and effectiveness in that state. The governance responsibility like Panchayati Raj Institutions (PRIs) involvement and provision of process of making governance decisions information publicly would be at state’s discretion, which makes accountability questionable.

National Mission on Medicinal Plant document preferred State Horticulture Mission (SHM) mechanism over State Agriculture Ministry mechanism as it was already driven in mission mode and State Medicinal Plant Board (SMPB) mechanism could be the choice of the state only in the absence of SHM. State Agriculture Ministry is the permanent department set-up by the state governments to deal with cultivation, while SHM is set-up under State Agriculture Ministry for implementing National Horticulture Mission, which is responsible for the promotion of horticulture in India. SMPB is set-up either under state forest department, State Agriculture Ministry or state health department which is at state’s discretion and is responsible for the promotion of NMMP.^[20] Further, no additional SMPB role other than the providing funds to the agriculture ministry in case of SHM and State Agriculture Ministry mechanism was mentioned. NMMP mentioned that in SHM and SMPB mechanism, State Level Implementation Agency would form a society, while in State Agriculture Ministry mechanism; District Mission Directorate would form a society without providing

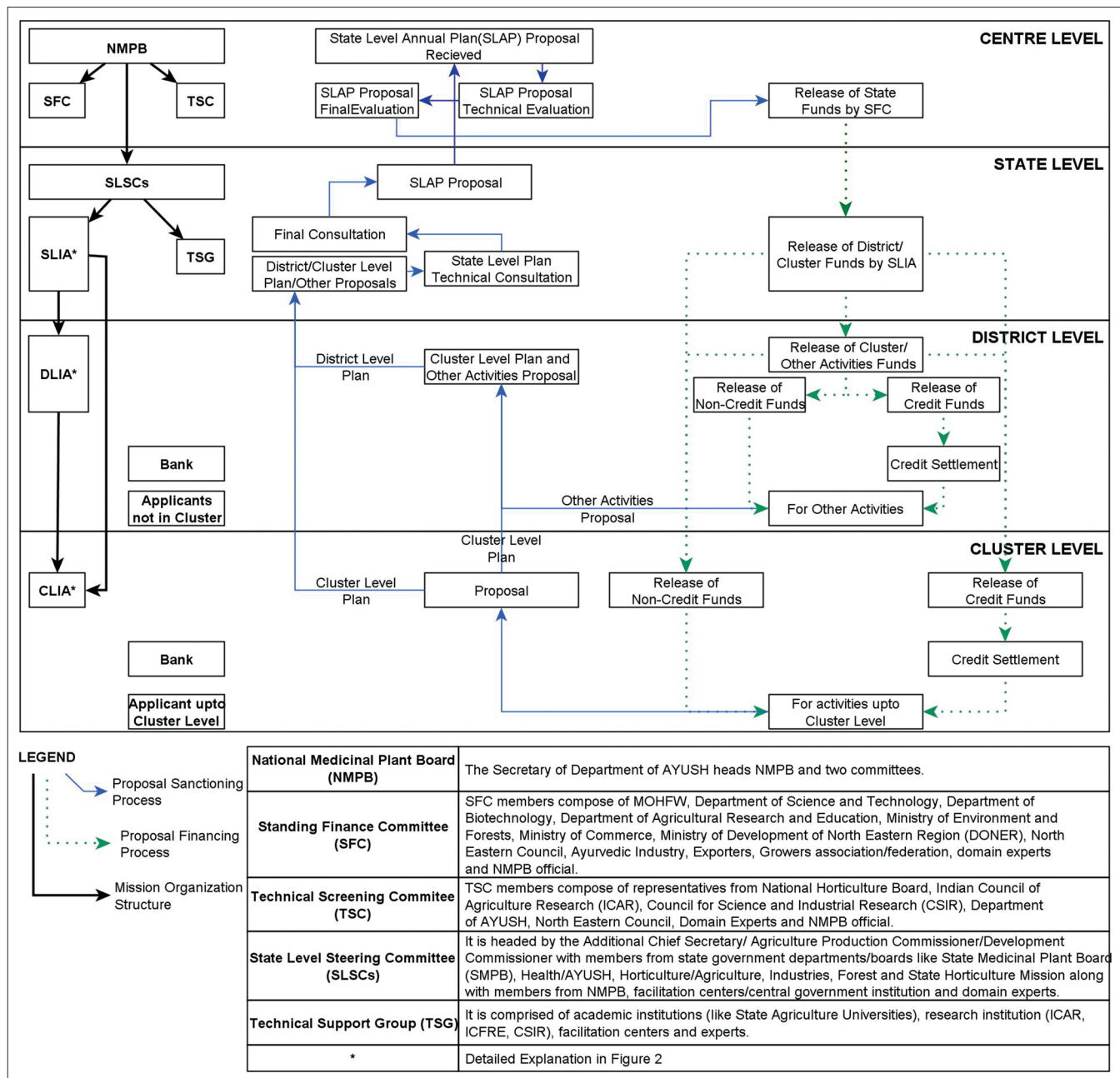


Figure 1: Basic mission organization structure, proposal sanctioning and financing process

any reason. Where Software Asset Management would be implementing SHM, the SHM mechanism of State Level Implementation Agency seems unnecessary as State Agriculture Ministry seems to be more technical competent authority. Further, upon future closure of SHM, the status of State Level Implementation Agency society would be jeopardized. In the State Agriculture Ministry mechanism, there was no mandate for the State Level Implementation Agency as well as district level committee to maintain coordination with other agencies which makes it less inclusive as compared to SHM mechanism. In SMPB mechanism, the Chief Executive Officer's selection criterion was not provided. Lack of mentioning

of facilitation centers roles and responsibilities to provide technical support may indirectly force cooperatives and Self Help Groups (SHGs) (formed by poor people) to be unable to use this facility.

National Mission on Medicinal Plants document mentioned plan preparations and implementation in a decentralized mode, while plan sanctioning and financing in centralized mode [Figure 1]. The mission was to be evaluated only twice (mid-term and end-term) by project management consultants and support staff both at the center and state level, but no information provided regarding consultant selection at center and state questioning evaluation

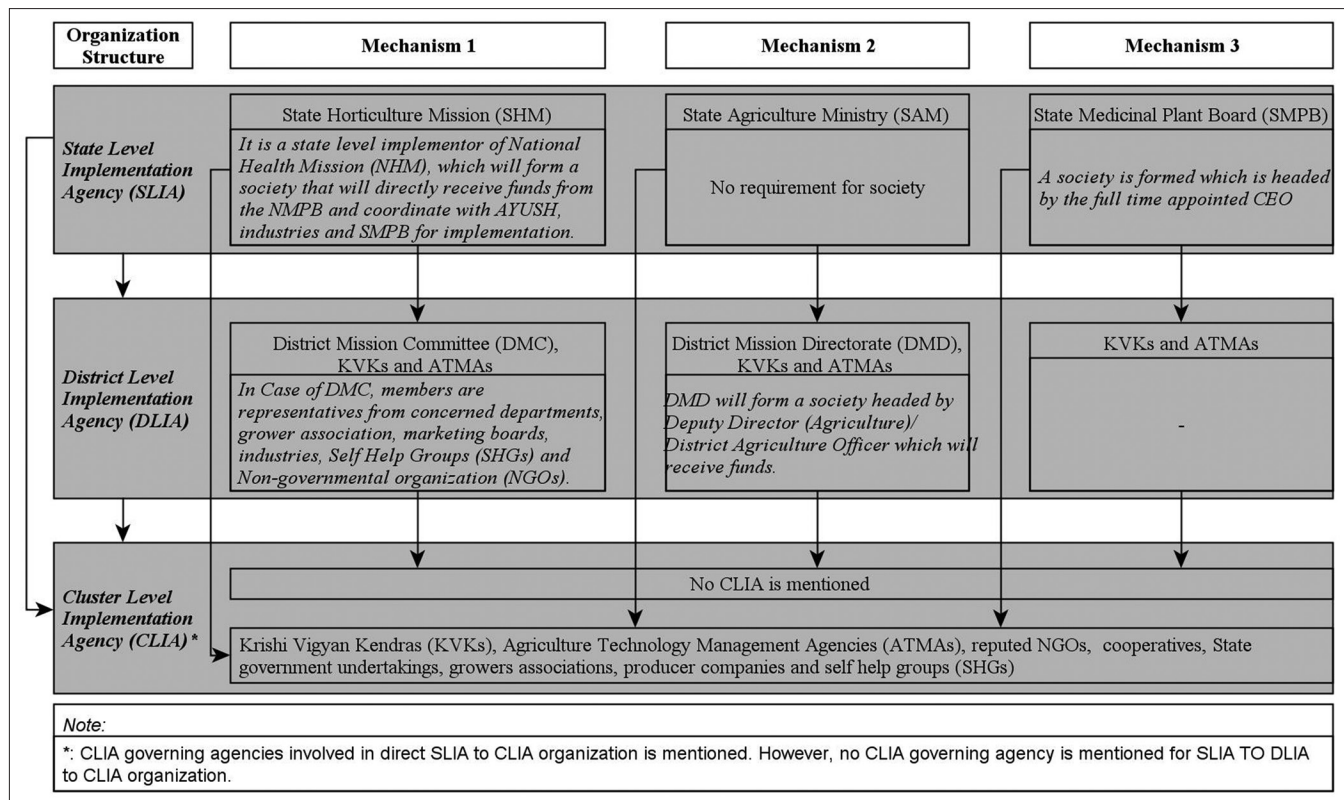


Figure 2: District and cluster level organizational structure

outcome reliability. Further, no involvement of third party monitoring and single monitoring during the mission creates the risk of poor mission accountability and transparency.

Stakeholders

The mission had considered several stakeholders, but traders, gatherers and collectors had not been identified as stakeholders even when they constitute the majority of current medicinal plant supply. Amongst the identified stakeholders, the process of selection of representatives was not provided, and local governing bodies/PRI, Civil Society Organizations (CSOs)/Non-Governmental Organizations (NGOs) and local community groups' involvement were optional. Other than stakeholders receiving financial assistance, weak mechanism for reporting and checks existed, indicating the strong possibility of toppling of the whole mission.

Financing

Even though, finance is required for multiple purposes like preimplementation studies, creation of governance system, capacity building, Facilitation Centre functioning, provisioning of subsidy and postimplementation studies; the allocation of funds for each of these was not mentioned. Though, the state could use up to 5% of the annual budget for mission management including salaries, annual plan preparation, monitoring, administration and

exposure visits, no rationale was given for funds allocation which seems insufficient for initial years. The words "financial assistance" and "subsidies" had been used interchangeably for the process of providing refunds to users' invested funds with ambiguity on two aspects; namely the time of release of funds and the release process of sanctioned subsidy.

For subsidies for various activities [Figure 3], no mechanism in place for ensuring timely sanctions and release. Planting material could be produced by both public and private agencies, but unequal norms were accorded to different applicants for different activities without explanation, creating the risk of unfair competition. For cultivation applicants, the procurement of planting material had to be from NMPB sanctioned nurseries or seed centers, and subsidy was higher for plants with longer gestation period. However, other agriculture inputs subsidy was need based, with no explanation provided about assessment process. Provision of state level subsidy cap of 30% on medicinal plants cultivation, without proper reasoning, may be difficult to achieve as review of subsidies in document revealed more than 50% medicinal plant having a subsidy exceeding 30%.

For marketing applicants, the eligibility and upper limit of a number of projects for market promotion, market intelligence and buy-back intervention was not provided.

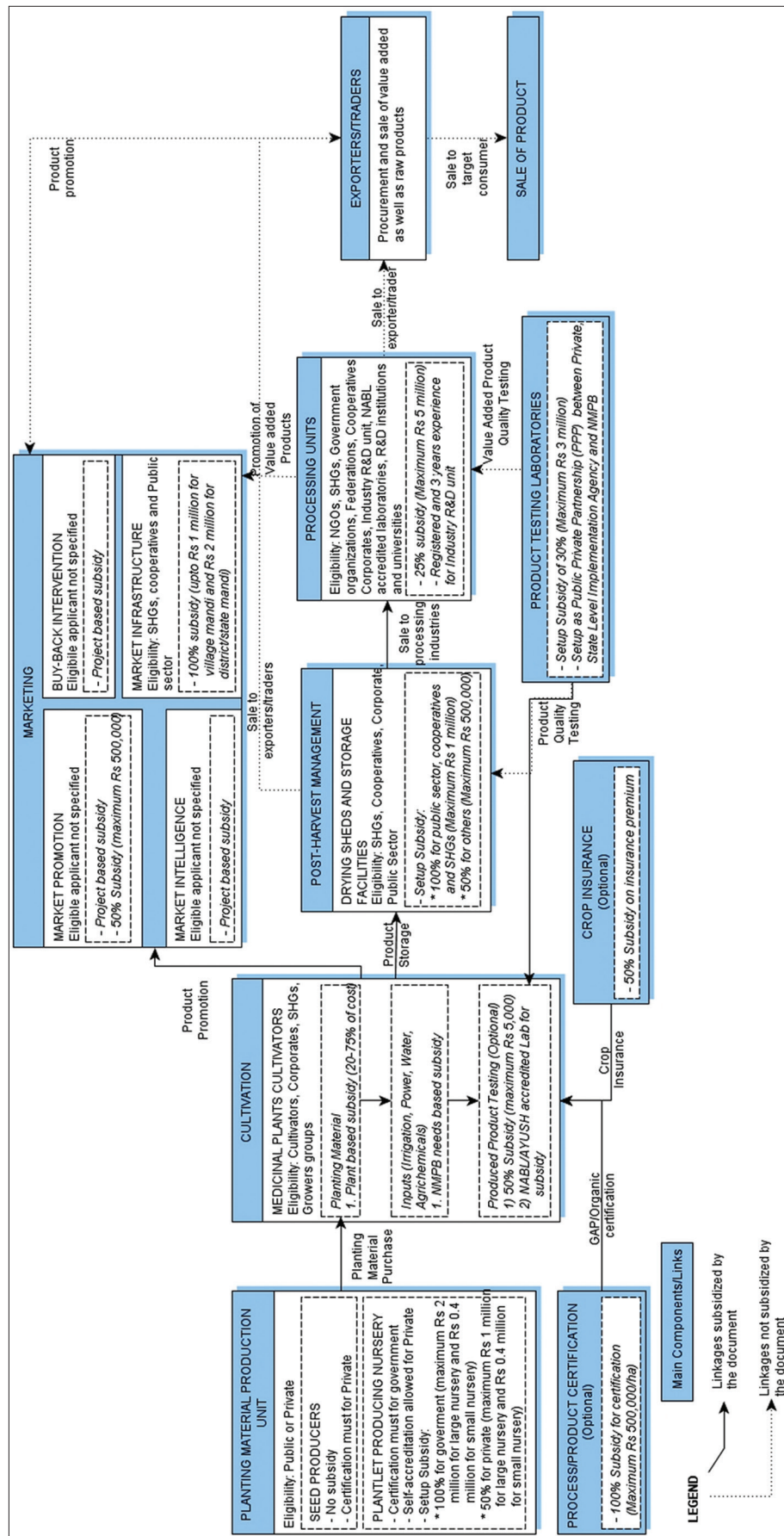


Figure 3: Linkages between different components of herbal industry and subsidies provided to different components

Table 1: Issues identified in the original document and the responses given in the two amendments

Issue number	Problems/issues identified in the original document	Requirement	Response/s in amendment	
			1 st	2 nd
Current status/issues				
I1	Proper identification of issues and focus	Modification		
I2	Adequacy of background information to support the statements	Clarification		
I3	Usage of words	Modification		
Mission objectives and targets				
I4	Objectives coverage	Modification		
I5	Information adequacy for determining target feasibility	Clarification		
I6	Synchronization between activities of identifying issues and defining objectives or targets	Modification		
I7	Targets coverage	Modification		
Mission strategy				
I8	Consideration for externalities	Modification		
I9	Defining concepts like cluster and quality requirements	Clarification	Clarification	
I10	System’s understanding	Modification	Modification	Modification
I11	Strategies adequacy like livelihood generation strategy	Modification		Modification
Mission governance				
I12	Adequacy of information regarding the process of performing certain governance activities	Clarification	Clarification	
I13	Functioning accountability and transparency	Modification	Modification	
I14	SMPB importance	Clarification		
I15	Information adequacy about consultant selection	Clarification	Clarification	
I16	Adequacy of monitoring and assessment	Modification	Modification	
I17	Reliability of monitoring and assessment	Modification	Modification	
Mission stakeholder				
I18	Adequacy of stakeholder identification	Modification		
I19	Adequacy of stakeholder representation	Clarification		
I20	Stakeholders’ accountability	Modification		
Mission financing				
I21	Funds allocation information adequacy	Clarification		
I22	Stakeholder involvement	Clarification		
I23	Usage of words	Modification		
I24	Information adequacy regarding subsidy release process	Clarification		Clarification
I25	Reasoning behind funds allocated/not allocated for different activities and applicants	Clarification		
I26	Subsidy norms	Clarification	Clarification and modification	Clarification and modification
I27	Intent to support financially weaker section	Modification	Modification	Modification
I28	Intent to promote quality products	Modification		

SMPB: State medicinal plant board

Infrastructure subsidy for “orsiharvesting management and processing” was provided to different applicants. However, to avail subsidy industry research and development (R and D) units had to be duly registered with more than 3 years of experience in the field, while government R and D institutions and universities did not need this criterion. Further, no applicant was provided product testing subsidy, which creates cost burden for the start-ups. NMMP's document mentioned about subsidizing testing laboratories without mandating labs to AYUSH/National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation, while cultivators could avail product testing subsidy only if tested from AYUSH/NABL accredited labs thus

resulting in potential subsidy wastage. Further, lack of creation of linkage between quality of medicinal plant with the efficacy and safety standards of botanical drugs exists.

National Mission on Medicinal Plants intention to promote the mission among the financially weaker group through subsidy preference and higher subsidy, faces challenges namely; initial investment requirement, long subsidy process, no guidelines for accessing funds from financial institutions and limited activities with higher subsidy. In addition, it could create contract farming possibility for farmers and loosing the whole purpose of the subsidy to overcome financial constraint. NMMP's document lacked

the mandate of providing accreditation/certification agencies list, except for plantlet nurseries, which made access to such agencies difficult and disincentive for applicants looking for the subsidy and better process or product quality standards.

Address of shortcomings in two amendments

The study of the “hedydmen document” of NMMP identified 28 issues in six segments identified before and had been classified on the basis of the required solution type as those requiring explanation/clarification and those requiring modification [Table 1]. Twelve of the issues were of clarification type where more information was needed to have better understanding, while sixteen were of modification type which needs addressing for success of NMMP. Subsequently, the study performed both intra and inters document analysis of two amendments to check for identification and addressing of 28 problems. Constrains in the three segments; current status/issues, the mission objective and target and mission stakeholders had not been addressed, while three out of four strategy constrains, five out of six governance constrains and three out of eight financing constrains were addressed in the two amendments.

Amongst the strategy challenges, the problem “Defining concepts like cluster and quality requirements (I9)” was partially addressed in the first amendment by providing clarity on cluster size. However, sub-problem related to quality concept was not addressed. The point “System’s understanding (I10)” was responded in the first amendment, partially, by modifying subsidy norms to increase system efficiency. Only public sector, farmer groups and panchayats could claim infrastructure subsidy for noncultivation activities, anywhere, provided they can link with cultivation cluster.

Further, to enhance commitment of private sector players, subsidy would be provided only through special purpose vehicle (SPV). However, the cultivator groups had the permission to set-up units anywhere, which could potentially cause failure of geographical proximity solution. This was further addressed in the second amendment, where term “erm necessity for private” was deleted, while keeping other conditions same. The problem “Strategies adequacy like livelihood generation strategy (I11)” had been addressed partially in the second amendment by permitting plant tissue culture units under subsidy scheme.

The problem “adequacy of the information regarding the process of performing certain governance activities (I12)” was addressed partially in the first amendment by providing more clarity on Facilitation Centre roles and responsibility in mission monitoring and people

mentoring activities, which included visiting the subsidy holder at least once every 6 months and providing inputs. The regular monitoring and mentoring by state, Facilitation Centre and centre at different levels partially addressed the challenges “Functioning accountability and transparency (I13)”, “Adequacy of monitoring and assessment (I16)” and “Reliability of monitoring and assessment (I17)”. NMPB required national level experts and/or Facilitation Centre in the relevant fields along with help of the state. States were allowed to have their own consultants and field experts. However, the role of Project Monitoring Committee as the agency which would do the continuous monitoring could also provide mid-term and end-term conclusions. However, NMMP’s documents failed to address the issue of accountability and transparency involved in implementation agency related governance decision-making and functioning. The concern “Information adequacy about consultant selection (I15)” was provided only about the state chosen consultants who had to be retired officers/scientists from allied fields, but failure to provide the selection criteria for third party agencies and other consultants raises “Adequacy of monitoring and assessment (I16).”

The concern “Information adequacy regarding subsidy release process (I24)” was addressed only for cultivation and market promotion in the first amendment and SPV based activities in the second amendment. There was no mention of timing of the subsidy release as well as progress criteria for the subsidy release. Furthermore, NMMP’s documents fail to address the process of funds flow from NMPB to State Level Implementation Agency; timing of user investment in activities other than market promotion or SPV activities; subsidy release process to the user for activities other than planting material purchase, market promotion or SPV activities and timely subsidy sanctioning and release.

The problem “subsidy norms (I26)” was addressed partially with change in state cap on cultivation subsidy in the first amendment and deletion in the second amendment. Furthermore, the applicants’ eligibility norms for plantlet nurseries as well as postharvest management and processing units were changed without clarification. Marketing intelligence activities norms were clarified in the first amendment with no proper definition of procurement cost.

In the second amendment, marketing infrastructure subsidy was made credit linked back-ended, and subsidy limit for rural mandi was increased for public/SHGs and cooperatives. Other private players were also allowed to get capital cost subsidy for setting up marketing infrastructure. Organic farming norms were covering organic farming adoption cost with 50% subsidy for maximum four ha,

but with no progress evaluation clarification. Infrastructure subsidy norms for processing unit were modified to provide 40% subsidy. In the first amendment, SPV were allowed subsidy for infrastructure, but in the second amendment subsidy for management staff, marketing and management activities, operation standardization and awareness activities was also allowed.

In planting material production, both seed production units and plant tissue culture units had been provided subsidy without the provision of back-ended subsidy, while in case of plantlet based nurseries back-ended subsidy was provided. NMMP's documents failed to address subsidy norms issues related to applicants eligibility, planting material activities, cultivation activities, marketing activities and product quality as well as did not provide adequate clarification on most of the norms which were modified. The problem "Intent to support financially weaker section (I27)" was partially addressed, while addressing "system's understanding (I10)", by allowing farmer groups to set-up units outside the cluster. However, NMMP's documents failed to recognize issues related to investment and subsidy process.

CONCLUSION

The mission would be an ideal strategy for addressing the affordability, availability, quality (in terms of both increased active ingredients and decreased adulteration) of medicinal plants, while providing a steady supply of medicinal plants, thus overcoming the resource challenges faced by the botanical drugs industry. However, this study brought about the systematic analysis of the mission's "ission' operational guidelines" document and its two amendments to help achieve this strategy, while 28 challenges indicated inadequate context synchronization in document, as well as inadequate mission structure and its functionary's accountability and transparency. These challenges were addressed partially (39%) in two amendments, which made decision-making process unreliable and a potential cause of mission underachievement. The critical analysis, while raising the awareness about potential design issues, also gave areas of improvement to the policy developers.

The mission guidelines should bring about more homogenization of rules, for example provision of subsidy to only cluster groups, but irrespective of the applicant's affiliation (i.e. public, private, NGO, PRI). A similar detailed study could be used for evidence-based policy making for forthcoming amendments to minimize ambiguity in explaining various mission design and operational decisions.

The large positive impact of this mission as envisaged in the goals could help in achieving better health status by

improving living status and better access to medicines. The mission could provide new livelihood opportunities during processing of the medicinal plants as well as alternate livelihood source for the farmers by giving broader variety of crops which could be grown. The mission could be an enabler toward the development of affordable medicines (by reducing processing costs) which could address the primary health needs of the community. The mission could improve India's resource and export scenario, which indirectly would also help in meeting the global health needs, while strengthening the AYUSH program both nationally and globally. The potential of enhancing mission's contribution as compared to that envisaged by the mission document exists with better mission design clarity. Future study can help in showcasing the overall positive impact of the mission on the ground as this study was focused on document analysis.

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