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Reformulation, Plant Management and the 'Pharmaceuticalisation' of Indian 'Traditional' Medicine

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Abstract

This paper discusses one dimension of the contemporary industrialisation of ayurvedic medicine, namely the new centrality given to the collection, combination, and mass-manipulation of herbal therapeutic material. The aim is to highlight the process of 'pharmaceuticalisation', too often and wrongly taken as synonymous of a form of alignment of Ayurveda with biomedicine, its categories, and practices. Within this context, pharmaceuticalisation refers to the creation of a new world of professionals beside ayurvedic doctors, often personnel of the industry, whose role is to handle the material (rather than the clinical) dimensions of polyherbal preparations. This management of plants includes multiple dimensions: documentation of their uses, experimental research on their composition and properties, design of new simplified combinations, mass-production of ready-made specialties, and marketing. In other words, it encompasses all the attributes of pharmacy as it developed in Europe, but with the major caveat that this pharmacy has little to do with chemistry, pure substances, and molecules, since it focuses on plants, their combination, and their value as *materia medica*. The paper focuses on the series of institutions, policies, and practices regarding plant management that have emerged since 2000 with a special interests in a) the ways 'old' settings like the botanical garden have taken the turn toward industrial Ayurveda; b) how the operations of 'new' institutions, such as the National Medicinal Plant Board, have been mandated to foster supply of as well as research on 'prioritised' species.

Keywords

Ayurveda – pharmaceuticalisation – polyherbal remedies – medicinal plants – cultivation

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Introduction

The institution of pharmaceutical infrastructures in India is not new. It started in the early twentieth century with the establishment of local workshops extending the activities of traditional physicians to the realm of ready-made preparations.[1] The connection between the so-called 'Indian systems of medicine' and pharmacy has, however, experienced unprecedented developments in the last two decades, in the context of a new wave of economic and health globalisation. The markers of these deep changes include: the invention and commercialisation of 'traditional' herbal combinations with indirect, if not elusive, roots in the classical texts of the Ayurveda, Unani, or Siddha medical systems; the mass-production and circulation of these remedies in new forms, especially pills; a rapidly escalating consumption of medicinal plants; the emergence of large companies operating nation- or world-wide with the classic tools of scientific marketing.

As outlined in the introduction to this issue, the innovation processes in the contemporary Indian ayurvedic industry indicate a form of 'alternative modernity' that differs from the development model associated with the post-independence rise of the Indian chemical-pharmaceutical industry, which focused on North-South transfers of knowledge and technology.[2] The current reconfiguration of Ayurveda draws on types of knowledge other than that of the molecular paradigm prevalent in pharmaceutical research since the mid-twentieth century. The 'reformulation' regime may be characterised by the emergence of a world specialising in the production—sometimes the invention—and the marketing of polyherbal therapeutic specialties. As such, it builds on strong continuities, both conceptual and material, with 'traditional' medical systems as reshaped in post-independence India. The reformulation regime carries radical changes in the nature and scale of the 'formulation' practices associated with these forms of medicine, starting with Ayurveda. Reformulation is not only a change in the 'formulas'; it questions the economic, epistemological, and regulatory aspects of the reinvented tradition.[3]

Two terms have occasionally been used to delineate the dynamics involved in this regime: industrialisation and pharmaceuticalisation. One essential dimension of reformulation is indeed its industrial nature. Industrialisation means that the main actors in the supply chain of remedies are no longer *vaidyas*, local collectors, and merchants, or households members, but Indian

1 Banerjee 2009; Sivaramakrishnan 2006; Varier 2002.

2 Sahu 1997.

3 Gaudillière 2014.

ayurvedic drug-producing companies, some of them large enough to operate as global players seeking consumers all over Asia and possibly Europe or the United States. Industrialisation also refers to the manufacturing process and the production technologies.

Even if the introduction of mechanical grinding, pill-making machinery, or chemically-oriented quality-control assays into Indian traditional medicine can be traced to long before the 1970s, these processes remained peripheral and were often associated with the trajectory of producers crossing the boundaries between allopathic and alternative medicine and between drugs, food, and cosmetics. In contrast, in the past three decades, the search for productivity and large-scale output by using mechanised processing and automated machinery as well as the quest for standardisation through quantitative, laboratory-based, quality control have become pervasive and provided Indian ayurvedic firms with their main tools to occupy what they perceive as fast-growing urban and global markets.[4]

Contemporary drug-innovation practices in traditional Indian medicine, however, are not restricted to this mass-production and mass-distribution logic. The world of Ayurveda is reinventing its remedies and in doing so it is borrowing from various medical schools of thought and techniques. The term pharmaceuticalisation has been used to stress the importation in the new 'techno-Ayurveda' of a whole body of knowledge and practices associated with late twentieth-century 'global' pharmacy, with its ways of inventing, testing, producing, and selling molecularly- defined therapeutic agents. It is based on a chemical-screening model that appears to be 'an intellectually reductionist approach' when it is applied to the complexity of herbal substances and the learned knowledge of Ayurveda. However, one major reason why the reformulation strategies of traditional preparations promoted by Indian firms and researchers are in their essence foreign to this chemical-screening model is the strong emphasis most actors involved in the new regime place on complex polyherbal formulations and their opposition to strategies of isolation, purification, and *in vitro* synthesis.[5] Like bioprospection, which was revived by the rapid growth of biotechnology in the 1980s and 1990s, Indian firms favour the use of medicinal plants. However, unlike it, the purpose is less to control a small set of active principles than to exploit the synergetic properties of polyherbal compositions.

4 See Bode 2008; Banerjee 2009; Farkhar and Rajan 2014.

5 Pordié and Gaudillière 2014.

What is at stake with pharmaceuticalisation is therefore the question of a putatively *alternative* modernity. In the conclusion of her rich analysis of industrialised Ayurveda, Madhulika Banerjee aptly summarised the issue:

> A study of the history of the encounter between these two traditions—Ayurveda and biomedicine—shows that the encounter was mediated by unequal power. (…) The rise of Ayurvedic pharmaceutical is a response to the working of this power structure. Given that it seeks to combine the force of modern manufacturing and technological processes with the knowledge base of Ayurveda, implicit in this could have been an aspiration to a different, perhaps even an alternate, kind of modernity (…) modern because it accepted the modern challenge of validity and quality in conditions of mass- manufacture; alternative, for it worked with a knowledge system other than the familiar European one.[6]

Her conclusion is that this possibility did not materialise, and that techno-Ayurveda does not seriously engage with Ayurveda with its holistic understanding of the body, its form of care, and with the challenges of validity and quality. In other words, pharmaceuticalisation has become more or less synonymous with 'biomedicalisation' since one critical dimension that could have provided for a different path was missing, namely:

> (…) a modern capitalist enterprise that would have taken up the challenge of research and development with a vision to adapt and develop Ayurveda for the future rather than focusing narrowly on their balance sheets. The real balance that they probably required would have been between their outlays for research and development (R&D) and advertising, which are usually loaded against R&D. Most companies have followed what has been the corporate wisdom of the last forty years—projecting images sells more products than any other efforts.[7]

There are two difficulties with this understanding. The first one is that it takes too little account of the research and innovation dynamics involved in the practices of reformulation, which have expanded within and outside the industry in the past 20 years. The second is that it tends to equate 'biomedicine' and 'pharmacy'. By contrast, pointing to the material and social specificity of pharmacy as a world of practices, to its problematic historical making as an

6 Banerjee 2009, p. 288.

7 Ibid., p. 290.

autonomous domain, this paper proposes a different understanding of pharmaceuticalisation. Although any direct comparison of the modern fate of Indian and European medicines is a flawed exercise, given their entangled trajectories and colonial power relationships, keeping in mind the European history of drugs before and beyond biomedicine is helpful in this respect. Two dimensions are important, namely: 1) the autonomy and professional status of practitioners; and 2) the centrality of plant-based *materia medica* as object of manipulation.

In the nineteenth century, the professionalisation of pharmacy in Europe engendered a world of craftsmen set apart from that of clinical practice and that of experts in the collection, assemblage, and preparation of therapeutic materials—a world of surveys and experimental inquiries, of academic training and corporate monopoly, and of local manufacturing and collective certification. As a professional world, pharmacy has therefore been linked to particular forms of knowledge (botany and chemistry) and work (preparation, testing, and conservation), to specific sites and institutions (colleges of pharmacy, apothecary workshops), and to original regulation tools (the pharmacopoeia), all of which have drawn clear-cut boundaries with the world of medical and therapeutic interventions.[8] A second feature is that nineteenth-century European pharmacy was only marginally associated with chemistry as a form of knowledge. Although pharmacists actually shared many techniques with academic and industrial chemists, they rarely used them to isolate and characterise molecules or pure substances. Even a cursory glance at the national pharmacopoeia in Europe reveals that up to the 1920s, and the rapid industrialisation of drug-making, pharmacists actually mostly manipulated complex mixtures of biological origins dominated by preparations made out of medicinal plants. The interwar period was therefore not only a time of alignment with chemistry, both academic and industrial, but also a period fraught with attempts to industrialise herbal *materia medica*, not only by academic pharmacists and their entrepreneurial associates but also by those pharmacy had sought to cast out: plant collectors and herbalists.[9]

The current reformulation regime resonates strongly with this forgotten pharmaceuticalisation of drug-making in Europe. What this paper suggests is that the dynamics of reformulation entail a deep change of Ayurveda not only because they target biomedical categories and explanations of pathologies but also because they result in the emergence of a world of pharmaceutical practitioners focusing on the collection and the manipulation of medicinal plants in

8 Gaudillière and Hess (eds) 2013.

9 Gaudillière 2010.

a sphere that had thus far been basically medical and clinical, claiming a 'holistic' and individual approach to illnesses and remedies. In other words, reformulating and simplifying ayurvedic medicinal compositions in order to create new polyherbal drugs relies more on the ability to identify, collect, manipulate, and combine the plants than on any form of clinical work or encounter with patients.

The emergence of actors, sites, and practices focusing solely on the management of *materia medica* is of course not completely new in the trajectory of the Indian systems of medicine. Already in 1948, the Chopra report on the future of indigenous systems of medicine under the national health system stated that 'everywhere the professions of medicine and pharmacy have separated or are in the process of becoming so' and suggested that specific teaching and registration should also take place in Indian medicine.[10] The institutionalisation of Ayurveda in post-independence India accordingly brought with it the writing of a national pharmacopoeia (the first committee for this purpose was set up in 1963 by the Central Council for Research in Ayurvedic Sciences), the teaching of 'pharmacology' courses in Ayurveda colleges, and the institution of a federal laboratory with the mission to establish reference assays and standards to control the raw materials used in ayurvedic formulas. This pharmaceuticalisation was limited to its regulatory dimensions rather than the creation of an autonomous profession.

The current reformulation regime introduces different and deeper boundaries between medical practitioners, plant collectors/merchants and drugmakers, and between the sites where they operate and the forms of knowledge and expertise they command, respectively. Today, the most visible actors of pharmaceuticalisation are ayurvedic drug companies, at least the bigger ones, which integrate research, formulation, fabrication, and distribution. The emergence of an autonomous world of ayurvedic *materia medica* as component of the reformulation regime, however, mobilises other actors and public institutions. Previously, these were barely associated with Ayurveda but participated in botanical research, bioprospection, agricultural innovation, or forestry and are now increasingly committed to medicinal-plant management.

To investigate the ways in which pharmaceuticalisation questions the economic, epistemological, and regulatory aspects of contemporary Ayurveda, this paper will focus on two levels: 1) the role played by botanists, plant biochemists, and botanical gardens in the invention of new and nonetheless traditional therapeutic herbal composition; and 2) the creation of a new public infrastructure operating at the boundary between health and agriculture,

10 Indian Ministry of Health 1948.

focused on a market-oriented understanding of how 'supply and demand' of medicinal plants must be organised and regulated. The operations conducted at the Tropical Botanical Garden and Research Institute in Kerala and at the National Medicinal Plants Board show how actors who had previously little or nothing to do with Ayurveda and its existence as a medical system have entered the world of reformulation and gained a central role in it.

Botanists and the Reformulation Regime: Pharmaceuticalisation at the Tropical Botanic Garden and Research Institute in Kerala

> The ayurvedic as well as other indigenous systems of medicine are confronted with problems of fixing standards and specifications of identity, purity, strength, etc. It can very well meet this challenge if Ayurveda adopts appropriate scientific methods and practices. But this does not mean that it should adopt the parameters of modern medicines. Any attempt to evaluate and standardise the Ayurvedic medicine and for that reason any other such traditional systems of medicine with the parameters of modern medicine will be suicidal. But Ayurveda may utilise the advancement made in modern scientific knowledge, tools and technology, including the latest information technology.[11]

This quote from Dr P. Pushpangadan, the former director of the Jawaharlal Nehru Tropical Botanic Garden and Research Institute (TBGRI) in Kerala, represents his answer to a question about reformulation and the future of Ayurveda. Dr Pushpangadan is a biologist trained in biochemistry, cytogenetics, plant breeding, and ethnobotany. Before the 1990s, he had had no specific training in any Indian system of medicine and no particular interest in relating his work with Ayurveda. Indeed, his trajectory reflects the way in which the work done by the botanists at the Kerala botanic garden has changed in the past 20 years.

The TBGRI was established in 1979 as a centre for collecting, classifying, and conserving the local flora, i.e. as a botanical institution although with a mission of evaluating the nutritive or therapeutic properties of local plant resources. Following its incorporation into the new Kerala State Council for Science, Technology and Environment in 2003, it acquired a slightly different mission as it became more decisively involved in neo-development projects through closer collaboration with the biodiversity- and forest-management authorities.

11 Interview with Dr Pashpangadan, Amity, Thiruvananthapuram, January 2012.

In the late 1980s, the institute's botanists were involved in a general survey of tribal knowledge of forests plants focused on plant uses as food and healing agents, the All India Coordinated Research Project on Ethnobiology (AICRPE). As S. Rajasekharan recalls, despite its name, the AICRPE had no national framework.[12] It was organised around three levels of documentation: assessment of the ecological situation and biodiversity of the area, community uses of plants, and a social and economic evaluation of community status. Investigating 35 communities all over Kerala, TBGRI researchers at some point entered into negotiations with the Kanis living in the vicinity of Trivandrum. The standard procedure in the survey was to contact the local administration, meet the community leaders, get their agreement to present the project to the entire tribe, and—if things were orally agreed upon—pursue the survey, trying to link specific plants with their mode of manipulation and use, attaching this knowledge with putative 'carriers' identified either as individuals, families, or communities.

The first inquiry lasted until 1992. Early on, in 1987, TBGRI researchers learned about a plant named arogyappacha from their Kani partners. As the story goes, within the first few days of their stay, the ethnobotanists realised that the Kanis accompanying them were far from feeling as tired and fatigued as they themselves were and noticed that their guides regularly chewed red fruits on the way. On further (and pressing) inquiry they were told that the fruits in question were known amongst the Kanis for their anti-fatigue and rejuvenation properties. The TBGRI scientists then collected samples, which were later identified as exemplars of what botanists considered a local subspecies of *Trichopus zeylanicus*.

Taken from the forest, arogyappacha was given an experimental existence in the botanical garden. As coordinator of the AICRPE, Dr Pushpangadan became very interested in the new plant and pushed for it to be studied closely. He ultimately left his home institution, the Indian Institute of Integrative Medicine in Jammu/Srinagar, and moved to the TBGRI to follow up on the Kerala survey. As new director, Dr Pushpangadan reinforced the laboratory infrastructure and established pharmacology and phytochemistry divisions as well as animal-testing facilities.[13]

The 1990s were indeed a period of significant reorganisation at the TBGRI, including the launch of several projects related to the availability and therapeutic uses of plants. In parallel with taxonomy, inventories, and collection of local knowledge, the botanical garden increasingly addressed questions

12 Interview with Dr Rajasekharan, TBGRI, March 2013.

13 Interview with Dr Pashpangadan, Amity, Thiruvananthapuram, January 2012.

of supply and conservation of medicinal plants. The widely shared idea that increasing use was leading to overexploitation and depletion of numerous species was re-elaborated as a vicious circle of gene erosion (see figure 1) leading to the adulteration of medicine and poor health care, hindered improvement of cultivation and limited economic progress, and restricted evolution and a degraded environment.[14]

Two responses were promoted locally: 1) to develop quality control procedures to facilitate the morphological and cytological recognition of species to minimise adulteration at the market and industry level; and 2) to enlarge ex-situ conservation by setting up a 'field gene bank' in the surrounding forest of the TBGRI where 100 endangered tropical species would be planted and monitored for morphotypes, cytotypes, and chemotypes, which would in turn provide the basis for quality standards.

The research on arogyappacha is typical of the reordering of the TBGRI as a centre for the study of Kerala medicinal plants and their pharmaceutical uses. The first scientific paper was published in 1988 in *Ancient Science of Life*, an ayurvedic research journal edited with the support of the company Arya Vaidya Pharmacy (AVP). The aim was not to grant the plant any new botanical or

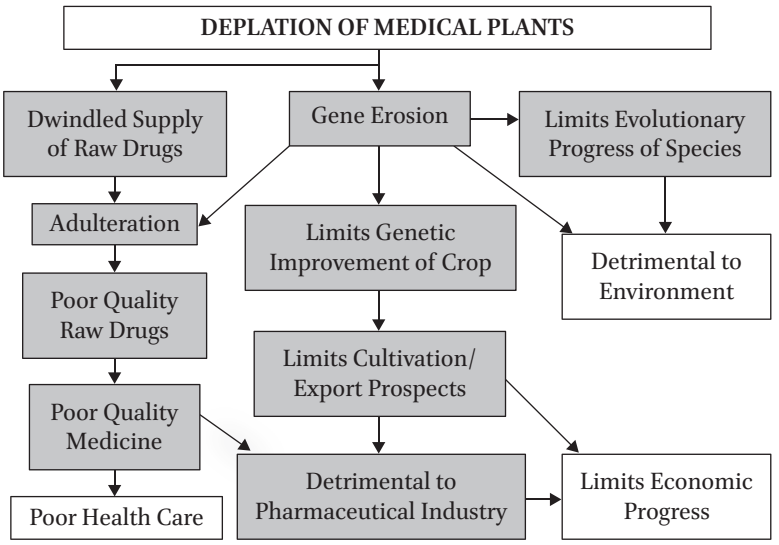

FIGURE 1 *The depletion problem as defined by botanists.*[15]

14 Mathew and Thomas 2007.

15 Mathew and Thomas 2007, p. 16. (courtesy of TBGRI).

pharmacological properties, but to argue for a specific ayurvedic identity taking into account its description as well as its anti-fatigue and rejuvenating potency. The botanists then joined ayurvedic practitioners from the Government Ayurveda College in Poojappura (a location in Trivandrum) to consider that:

> (…) [f]rom a critical survey of the various ancient Ayurvedic (sic) classics, the authors have come across with some descriptions of a plant which matched strikingly with Arogyappacha. Sushruta, while dealing with the various divine drugs along with 'Some' also described one 'Varahi'—which he described as 'Kandha sambhava'—rhizhomatous, 'Ekapatra' single leaves arising from a stem and 'Anjana samaprabha'—shining like the grey black stone. (…) Sushruta also described the plant that with its railing stem with raised leaves appears—'Krishnasarpa swarupena'—like a black cobra with its raised hood. Sushruta ascribed great rejuvenating property to the divine 'Varahi' which is very true of 'Arogyappacha'. Sushruta has also described the habitat of this plant as a shade loving herb found in the banks of rivers and natural ponds as also true for this plant. These descriptions (…) suggest that the divine 'Varahi' (…) may be about Arogyappacha.[16]

Giving arogyappacha this ayurvedic identity had many implications as this not only meant taking the plant away from oral, indigenous, tribal knowledge to bring it into the realm of a written, scholarly, institutionalised Indian system of medicine, but it also changed its potential economic status. As discussed below, once associated with a classical ayurvedic source such as Sushruta Samhita, arogyappacha could become an ingredient of formulations legally registered as 'Ayurvedic Proprietary Medicine' even if *T. zeylanicus* had never been mentioned in the numerous lists of botanical names given as equivalent to the plants used in classical shastric preparations.

Making a new formulation including arogyappacha soon became the main target of the work at the TBGRI. This choice distinguishes their pharmaceutical work from the perspective of bioprospection. There were few attempts to look for the active ingredients of arogyappacha, and no serious plan to isolate and purify them for production purposes. Though some chemical work was actually conducted at the TBGRI, it focused on the separation of entire fractions through chromatography rather than isolated molecules. This was for instance the case for alkaloids, which in the end did not prove to play a role in the anti-fatigue potency contrary to what had been expected on the basis of

16 Pushpangadan et al. 1988, pp. 13–16.

phytochemical knowledge. This procedure can be used both as an indication of the chemical quality of the final preparation or for the purpose of controlling the quality of the raw materials within the industry.[17]

Being true to the ayurvedic practice of using polyherbals did, however, imply forms of biological rationalisation. The use of entire extracts of the plants (in the case of arogyappacha, the choice was to use the leaves rather than the fruits since the former were more abundant and their collection would not endanger the reproduction of the species to the same extent) and the reliance on combinations of several plants were similarly justified with two notions: 1) the idea of 'synergies', i.e. the putative positive interactions between the ingredients contained within one plant; and 2) the complementary effects of plants with different medicinal properties.[18] The former belongs to twentieth-century phytopharmaceutical tradition; the latter originates in the very specific practice of ayurvedic formulation.

In contrast to classical formulations, which may include dozens of components, TBGRI researchers restricted their number to three or four plants. The main motive for this limitation seems to have been less the pragmatics of working on what would be a good formulation out of experimental testing and reasoning with the classical texts (30 to 35 candidate plants were initially selected) than the regulatory constraints associated with the idea that the new combination could be validated and marketed at the international level. Unlike in India, entry into the European or the US market, even as food supplements, becomes all the more difficult as the number of ingredients grows above four or five.

The procedure for selecting formulations at the TBGRI bore strong analogies with screening. Out of the 30 to 35 selected plants, the pharmacology division systematically prepared combinations of three to four ingredients, and these were tested in the same animal assay that had been used to publicise and experimentalise the anti-fatigue potency of arogyappacha. Presented in a 1989 article in *Ancient Science of Life*, the protocol borrowed directly from industrial pharmacy procedures. TBGRI scientists then conducted a mouse swimming test, looking at the duration of time mice fed with arogyappacha or complete extracts (water or alcoholic) could swim in comparison with untreated control mice.[19] Although the screening process left no published traces, it did have roots in the ayurvedic literature. The addition of *Piper longum* into many tested formulations thus originated in its status as 'enhancer'. The main driver, however,

17 Interview with Dr George, Amity, Thiruvananthapuram, January 2012.

18 Interview with Dr Pushpangadan, Amity, Thiruvananthapuram, January 2012.

19 Sharma, Pushpangadan, Chopr, Rajasekharan, and Sarada Amma 1989, pp. 212–19.

was a reinterpretation of the properties of the plants used in the broader ayurvedic *rasāyana* category including ashwagandha (*Whitania somnifera*), an ingredient in many formulations associated with immuno-modulating, rejuvenating, or psycho-stimulant effects. In a later article, Dr Pushpangadan explained the hybrid rationale for this selection on the basis of the numerous research articles linking the *rasāyana* plants with the biochemistry of secondary metabolites and their antioxidant activity:

> Ayurvedic pharmacology classifies medicinal plants into different groups according to their actions. One of these is the 'Rasayana' group. The word 'Rasayana' literally means the path that 'Rasa' takes ('Rasa': plasma; 'Ayana': path). It is believed in Ayurveda that the qualities of the 'Rasayana' influence the health of other dathus [tissues] of the body. Hence any medicine that improves the quality of 'Rasa' should strengthen or promote the health of all tissues of the body. 'Rasayana' drugs act inside the human body by modulating the neuro-endocrine-immune systems and have been found to be a rich source of antioxidants. These Rasayana plants are said to possess the following properties: they prevent ageing, re-establish youth, strengthen life and brain power, and prevent diseases, all of which implies that they increase the resistance of the body against any onslaught.[20]

Within this perspective the ayurvedic formulations are taken out of he clinical context of their use. This authorises variations in content as well as dosage of ingredients. The formulation is then equated with a stable composition of individual plants, each of them linked to specific combinations of properties and indications. If the formulation remains a unique entity permitting synergies, at a practical level it can be constructed and evaluated as a juxtaposition of ingredients, each bringing a specific type of action or potency. Hence, a) the possibility of formulating entirely new combinations of elements, all mentioned in ayurvedic texts, but that have not been put together previously; b) the need to test them in a systematic manner since the existing ayurvedic knowledge does not allow for specific predictions of the global result. The present formulation of jeevani, the anti-fatigue drug the TBGRI scientists finally chose, was accordingly selected on the basis of animal testing, which modelled two effects: anti-fatigue and immunological stimulation.

The existence of this 'screening' does not imply that this pharmacological approach of Ayurveda exhausted the process. Having enrolled ayurvedic doc-

20 Govindarajan, Vijayakumar, and Pushpangadan 2005, p. 166.

tors in the identification of arogyappacha, TBGRI scientists organised a clinical evaluation of the best formulations although—at that time—such evaluation was not mandatory for registering ayurvedic proprietary medicines.[21] Open trials were conducted in ayurvedic hospitals in Kerala and outside the state. They included 100 patients suffering from a variety of conditions (arthritis, postoperative exhaustion, etc.).

In contrast to the TBGRI plant specialists, the ayurvedic physician in charge of coordinating the clinical evaluation retrospectively estimated that this was an important step in providing Jeevani legitimacy from an allopathic perspective but that the whole attempt bore little relationship to Ayurveda. Insisting that Ayurveda was not about the plants but about the patients, he considered that industrial reformulation sought to standardise compositions and he was therefore opposed to any departure from the very notion of adaptable preparations based on local resources.[22]

This discrepancy is all the more significant when taking into account the scientific culture of the TBGRI, its focus on the botanical material and the main practical use of arogyappacha, namely the production of jeevani. Jeevani is now a polyherbal preparation sold by AVP, a company based in North Kerala. It is made out of four plants: *Trichopus zeylanicus*, *Withania somnifera*, *Piper longum*, and *Evolvulus alsinoides*. It is advertised as a restorative, immune-enhancing, anti-stress and anti-fatigue medication. Although the sales have never reached the high figures associated with major ayurvedic industrial formulations, Jeevani has become famous precisely because of its double origins in Ayurveda and in the traditional medical knowledge of the Kani tribal people.

Jeevani was not the only formulation mobilising *Trichopus zeylanicus*. Enlarging the palette of pharmacological tests, TBGRI researchers developed at least two more formulations to be added to the preclinical stage: one was a simplification of Jeevani (without *E. alsinoides*) with diabetes as main indication; the second was an anti-cancer preparation combining *T. zeylanicus* and a second plant collected during the Kani survey, amrithapala (*Janakia arayalpathra*), which the tribe allegedly used to treat peptic ulcers and skin tumours.[23]

One final dimension of this process of pharmaceuticalisation through the invention of novel formulas is the question of intellectual-property management, because it reveals one of the major differences with the 'old' botanical pharmacy and is grounded in the mounting influence of biotechnology. In 1996,

21 Interview with the Kerala Drug Controller, March 2013.

22 Interview with Dr Kumar, Thiruvananthapuram, January 2012.

23 Amrithapala was similarly given an Ayurvedic identity. See Pushpangadan et al. 1990, pp. 215–19.

TBGRI scientists entered into negotiations with AVP to develop their new formulation as a commercial preparation.[24] That same year, the botanists also managed to patent the process for making the Jeevani formulation. Such protection may seem to contradict the status of ayurvedic medicine and its corpus as national, 'Indian' traditional knowledge, therefore as something accessible to all formulation makers, be they industrial firms or local practitioners. The conflict with the construction of an ayurvedic 'commons' seems all the more inevitable since India and its government were at the same time involved in legal opposition procedures against US and European patents on turmeric and neem extracts, which were broadly discussed as major actions against the misappropriation of biological and medical resources.[25] Patenting Jeevani also carries problematic relations with its registration as ayurvedic proprietary medicine.

These tensions are, however, less radical than one may think if one takes into account the reformulation regime. The Indian Patent Office is an integral part of this regime. Since the late 1980s it has recognised—and this was the reasoning behind the Jeevani application—that the reformulation of known medicinal plants combinations can be novel as well as innovative. What is a significant—patentable—reformulation is then a matter of practice, of examination process, and jurisprudence. This may be appreciated with the whole palette of four patents obtained by TBGRI botanists on formulations containing arogyappacha*:* 1) one on Jeevani; 2) one on the above-mentioned antidiabetic mixture; 3) one on a sports medicine made of arogyappacha only; and 4) one on an anti-cancer preparation. Let us consider the latter. Its claims are the following:

> A process for preparation of a herbal medicinal composition (phytomedicine) for cancer treatment from extracts of *Janakia arayalpathra* root and dried leaves of *Trichopus zeylanicus* in the ratio of 1:1 comprising of the following steps of i. collection of fresh leaves of *Trichopus zeylanicus* from the cultivated gardens (or wild habitat), drying and powdering in an ordinary mixer at low speed, ii. thoroughly mixing the extract of *Janakia arayalpathra* roots obtained, using state of the art methods, the dried leaf powder of Step I in the ratio of 1:1 using suspending agents like 2% gum acacia or 5% Tween 80 to obtain the herbal medicinal composition (phytomedicine) for cancer treatment. (…) The formulation is prepared

24 See the paper by H. Madhavan in this issue.

25 Gaudillière 2014.

> according to the Ayurvedic Pharmaceutical practices. The drug is free from any toxic side effects as evidenced from the toxicity studies.[26]

The argumentative structure of these patents is highly revealing of the linkage established by ayurvedic industrial 'reformulators' between the legal notions of 'innovation' and 'composition of matter' on one hand and their practice of combination and claims for synergy on the other. The text of the patent thus acknowledges the fact that both plants have been used by the Kani people (*Janakia arayalpathra* in 'peptic ulcer and tumours of external organs' and *Trichopus zeylanicus* for 'better health and vitality') but situates the innovative activity at three levels: associating the two plants in one preparation; defining a new target; and demonstrating that the whole is more active than the parts. Thus the exemplars/embodiments of the invention included in the application do not elaborate much on the preparation process, which is rather basic and non-innovative, but stress the experiments carried out on animals.

The reformulating process is described in two steps. First, the inventors discovered the anti-cancer potency of *Janakia arayalpathra* by using a classical assay with mice inoculated with ascites tumour cells, then measuring the level of resistance against cancer by defining the maximum concentration of cells a treated mouse could survive without developing tumours. Second, they took advantage of the 'adaptogenic' properties of arogyappacha, postulating that it would increase the effect of *Janakia arayalpathra*. Third, they demonstrated this to be the case by comparing resistance experiments: with *Trichopus zeylanicus* only (weak); with dried *Janakia arayalpathra* or its ethanol extracts only (significant); and with extracts of both plants (mice resisted to a doubled quantity of tumour cells).

At stake here is the objective and scientific status of the reformulation but framed in the legal context and categories. Viewed through the eyes of a patent lawyer or examiner, the key issue is that of 'prior art and traditional knowledge'. The emphasis placed on synergy thus plays several roles: 1) it differentiates the claimed composition from the Kanis' material; and 2) it addresses the problem of 'industrial utility' in the form of a typical biomedical link between preclinical tests and clinical utility. Both of these points could have been challenged but were not for obvious legal reasons. First, the Kanis might have used the two plants in association but this practice has no value for a patent examiner since the written evidence of their medical knowledge is what the TBGRI scientists recorded. Second, medical indications were not patentable in India. Moreover, at the time of examination the country had not yet accepted patents

26 Indian Patent Office 2010, Patent Number 193609.

on pharmaceutical substances (the law explicitly prohibited them until 2005). However, patents on the industrial processes for making drugs were routine. That hundreds of similar patents were granted by the Indian Patent Office in the late 1990s and early 2000s strongly testifies the rising acknowledgement of the reformulation regime.

The relationship between the patent system and reformulation as a practical, plant-based activity of therapeutic invention may therefore be analysed in terms similar to the relationship that gene sequencing has maintained with the normalisation of patents protecting the DNA sequences of genes in biotechnology. As stressed by many authors, the series of decisions made by the US patent offices and courts and later by the European ones, which have made it acceptable to establish intellectual property rights on isolated genes, starting with the famous Supreme Court Diamond v. Chakrabarty decision, have set off a looping effect. The loop originates in the fact that sequencing made it possible to defend patent applications claiming for the innovative status of an isolated genetic sequence; with the consequence that, once a few such patents were accepted, the legal precedent formed a powerful incentive for more sequencing. Indian patents on reformulation have played a similar role.[27]

This may be illustrated with Dr Pushpangadan's most recent work. Leaving the TBGRI in 1999 to become director of the National Botanical Research Institute (NBRI) in Lucknow, he transposed to this new site the same type of laboratory infrastructure for reformulation that he had developed in Kerala. By 2006, when he retired, the NBRI's reformulation activities had led to two dozen new patents. After retirement, Dr Pushpangadan set up a small biotechnology company, Amity, based in Trivandrum. The main purpose of this company was, again, the development and commercial exploitation of plant-based formulations. The work at Amity is conducted by former participants of the TBGRI-jeevani enterprise, such as V. George, and still includes trials of preparations containing arogyappacha.

Pharmaceuticalisation and Regulation of a National Plant Market: The National Medicinal Plant Board and the Policy of Cultivation

> One of the main problems the growth of Ayurvedic drug production has created is that of adulteration. The number of species that are now difficult to find or too expensive for many manufacturers has increased since 2000 and substitution is a widespread phenomenon. It can be legitimate:

27 Calvert and Joly 2011; Gaudillière et al. 2009; Kevles 2002.

> Ayurveda has always built on local resources and there are many ways to adapt a formulation. But now something else is happening. We don't know the exact extent to which adulteration, illegitimate replacement or deletion of plants, takes place in the Ayurvedic industry but it is massive. More controls and inspections will never get rid of it. Bureaucracy is not the solution, the only real solution is that all species used to make Ayurvedic drugs should become cultivated.[28]

In 2002, a new central body under the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in New Delhi called the National Medicinal Plants Board (NMPB) published a list of 32 medicinal plants considered as a high priority for the development of cultivation (see table 1).

TABLE 1 *List of Medicinal Plants considered as a high priority for cultivation*[29]

Priority Species of Medicinal Plants

The Board has identified 32 medicinal plants based on their commercial value for overall development through its schemes. The identified 32 plants are:

S. NO	Common Name	Botanical Name	English Name
1.	Amla	*Emblica officinalis* Gaertn	Indian gooseberry
2.	Ashok	*Saraca asoca* (Roxb.) de wilde	Ashok
3.	Ashwagandha	*Withania somnifera* (Linn.) Dunal	Winter cherry
4.	Atees	*Aconitum heterophyllum* Wall. ex Royle	Aconite
5.	Bel	*Aegle marmelos* (Linn) Corr.	Stone apple
6.	Bhumi amlaki	*Phyllanthus amarus* schum & Thonn. (*P. niruri* Linn.)	Bitter gooseberry
7.	Brahmi	*Bacopa monnieri* (L.) Pennell	Thyme leaved gratiola
8.	Chandan	*Santalum album* Linn.	White sandalwood
9.	Chirata	*Swertia chirata* Buch-Ham.	Chirata
10.	Daruhaldi	*Berberis aristata* DC.	Indian barberry
11.	Gudmar	*Gymnema sylvestra* R. Br.	Ram's hom

28 Interview with Dr K., botanist, member of the Kerala State Medicinal Plant Board, March 2013.

29 National Medicinal Plant Board 2007, p. 5 (Note for Lok Shaba).

TABLE 1 *List of Medicinal Plants considered as a high priority for cultivation* (cont.)

S. NO	Common Name	Botanical Name	English Name
12.	Guduchi	*Tinospora cordifolia* Miers.	Heart leaved moonseat
13.	Guggal	*Comniphora wightii* (Arn.) Bhandari	Indian bedellium tree
14.	Isabgol	*Plantago ovata* Forsk.	Physilium husk
15.	Jatamansi	*Nardostachys Jatamansi* DC.	Musk root
16.	Kalihari	*Gloriosa superba* Linn.	Malabar glory lily
17.	Kalmegh	*Andrographis paniculata* Wall. ex Nees	Kreat
18.	Kesar	*Crocus sativus* Linn.	Saffron
19.	Kokum	*Garcinia indica* Chois.	Kokum
20.	Kuth	*Saussurea costus* C. B. Clarke (*S.lappa*)	Costus
21.	Kutki	*Picrorhiza kurroa* Benth ex Royle	Picrorhiza
22.	Makoy	*Solanum nigrum* Linn.	Black night shade
23.	Mulethi	*Glycyrrhiza glabra* linn.	Liquorice
24.	Pathar chur (Coleus)	*Coleus barbatus* Benth.	Coleus
25.	Pippali	*Piper longum* Linn.	Long pepper
26.	Safed Musli	*Chlorophytum arundinaceum* Baker (C. borivillianum)	Musli white
27.	Sarpgandha	*Rauwolfia serpentina* Benth. ex Kurz	Rauwolfia
28.	Senna	*Cassia angustifolia* Vahl.	Senna
29.	Shatavari	*Asparagus racemosus* Willd.	Indian asparagus
30.	Tulsi	*Ocimum sanctum* Linn.	Holy basil
31.	Vai Vidang	*Embelia ribes Burm. f.*	Butterfly pea
32.	Vatsnabh	*Aconitum ferox* wall.	Indian aconite

The existence of this list was a major sign that a new kind of federal policy was emerging, targeting management of the plants used in Indian traditional therapeutic formulations, and claiming to integrate health, industrial pharmacy, agriculture, and forestry.

The NMPB was established in 2000 to coordinate initiatives of the relevant ministries and foster an all-embracing strategy to increase the supply of medicinal plants. As defined by the National Planning Commission (NPC) Task Force, which had recommended the formation of this board, the increasing difficulty in finding adequate quantities of medicinal plants was a mounting

problem and a major bottleneck in any attempt to increase the production of drugs, facilitate the diversification of formulas, and improve the nation's export capacity. As explained by the Task Force in a perspective similar to the TBGRI formulation of the depletion problem, although more global:

> vii) At present, 90% collection of medicinal plants is from the wild, generating about 40 million man-days employment (part and full) and since 70% of plants collections involve destructive harvesting many plants are endangered or vulnerable or threatened. (…)
>
> viii) Marketing of medicinal plants is inefficient, informal, secretive and opportunistic. As a result, the raw material supply situation is shaky, unsustainable and exploitative. This results in depletion of resource base, exploitation of rural people (who are the real stewards of the resource), adulteration and non-availability of quality herbal drugs for domestic consumption as well as for exports.
>
> ix) As the price paid to the gatherers tends to be very low, they often 'mine' the plants, as their main objective is to generate income. (…) As forest habitat disappear and over-harvesting for commercial use reduces the stocks of wild medicinal plant material, there is a corresponding drop in the availability of the plants normally used as the first and last resort for all health care by rural population.
>
> x) Despite the wealth of resources (biological, human and financial) available, the sector has not developed in the absence of suitable standardisation, quality control and efficacy of drugs. It has yet to formalize and organise marketing and trade and integrate the development of medicinal plants from production to consumption to boost export of herbal formulations.[30]

As several authors have observed, the constitution of the NMPB in 2000 was not an isolated event.[31] It had been prepared during the Ninth Five Year Plan (1997–2002), which was the first to include a complete chapter on the development of Indian systems of medicine focusing on the status of medicinal plants and pharmacy. It mandated the completion of the various pharmacopoeias, the implementation of Good Manufacturing Practices and the promotion of specific Research & Development on 'new drug formulations'. In 1998, the National Planning Commission's Task Force approached the problem of supply as an element in the assessment of the future of reformulation that

30 Planning Commission Task Force 2000, p. 6.

31 Banerjee 2009; Bode 2008.

resolutely pointed to its specificity as a plant-based practice alternative to biomedicine and chemical pharmacy:

> In general, natural products that have come into modern medicine are the result of an approach to drug development adopted over the past fifty years or more. The goal has been to find new chemical structures that have a novel biological activity. The alternative approach of finding plant-derived therapeutic agents as extracts that could be standardised and formulated, has not received attention. (...) Given the situation, production of standardised plant fraction should have priority over that of pure active substance, because of the simple technology needed and hence lower cost of the product, provided, of course, the technological testing indicates that the product is safe. It would be advisable to find out the chemical composition of the composite fraction and pharmacological action of each constituent to ensure that they are safe and compatible with each other.[32]

In addition to the existing AYUSH, the Council of Scientific and Industrial Research (CSIR) and the Indian Medical Research Council (IMRC), two new institutions, whose purpose had been discussed in the late 1990s, provided the infrastructure for this more proactive policy. The first was the Traditional Knowledge Digital Library (TKDL) intended to develop a general digital inventory of the various formulations known in the Indian systems of medicine that would become an instrument against the patenting of these formulations abroad.[33] The second was the NMPB, an inter-ministerial set-up for collaboration amongst all health, administrative, and industrial actors with stakes in the supply of medicinal plants. The official agenda of the NMPB thus included: 1) to assess supply and demand positions within the country and abroad; 2) to develop proposals and programmes to help all agencies and institutions involved in cultivation, collection, storage, and transportation of medicinal plants; 3) to inventorise and quantify the country's resource; 4) to promote cultivation and conservation both *in situ* and *ex situ*; 5) to develop protocols for cultivation and quality control including better marketing techniques; 6) to help to establish and defend patent and intellectual property rights.[34]

Given its broad mandate and mediating role, the NMPB could easily turn into a typical 'coordinating' (i.e. bureaucratic) structure, whose means,

32 Planning Commission Task Force 2000, p. 101.

33 Gaudillière 2014.

34 Ministry of Health, Department of AYUSH, Annual Report 2002.

operational role, and influence would scarcely go beyond the preservation of its precarious existence. Evaluated on the simple basis of medicinal-plant output, its achievements during its first 10 years of work are currently highly contested as the supply crisis is far from being eased.[35] Besides stimulating plant cultivation, the board has, however, accomplished other and also more lasting regulatory functions, thus confirming its role in the new pharmaceuticalisation policies.

This is well illustrated by the status of the 2002 list of prioritised plants. The first significance of the list was to deliver a reference sheet for what initially seemed the main function of the board: to provide subsidies in the form of contracts with medicinal-plant producers or collectors. Priority also meant that these plants should become targets of initiatives for their conservation (*in situ* and *ex situ*), for the standardisation of supply protocols, and for the definition and implementation of quality-control procedures.

These 32 plants were deemed important and rare enough to require a significant, if not massive, influx of public money. But how could they have been selected out of the presumed thousands of species used by the industry and sold on the local or regional markets? Given the centrality of the AYUSH, what could have been expected was a selection based on the medical benefit of the plants by taking as proxy for such benefit their occurrence in the corpus of classical formulas, the frequency of their clinical targets, or the consumption of specific remedies. This is actually one of the ways in which the Task Force members had defined R&D priorities in their 2000 report, focusing on the medical meaning of formulations and selecting a small set of plants for which major medical targets could be identified (for instance, geriatrics problems for ashwagandha or memory disorders for brahmi—*Bacopa monieri*) so that improvement of varieties and enhanced availability would result in new formulas and products 'for public benefit and for exports'.[36]

The logic of the NMPB was different. This was not a medical but an industrial and agricultural institution predicated upon the autonomy of plant management. Rather than collecting health-related data, its members focused on market indicators as main proxy for 'demand', and—if the function of markets as information processors is to be believed—for the benefits of the various species. The first list thus echoed another, tacit, selection made by the 2000 Task Force, which was based on the documentation of plants in high demand

35 The status of the board has been the topic of much parliamentary questioning, especially in 2009 and 2010 in the context of the Eleventh Five Year Plan (2007–2012). On the supply crisis, see Dejouhanet's paper in this issue.

36 Planning Commission Task Force 2000, p. 138.

grounded on a preliminary inquiry on the traded quantities. This involved half a dozen large companies.[37] A critical feature of the final list is the fact that 25 out of the 32 prioritised plants were already being cultivated in 2002. This does not necessarily imply that consumption was exclusively based on field production but that protocols for this production had been developed and were to some extent being used routinely.[38]

This was, however, a rough rationalisation of the selection, and it opened the door to many motives for contestation. For instance, as soon as the list was made public, the Kerala botanists noted the virtual absence of plants from the Western Ghats and more generally the scarcity of species from South India.[39] To strengthen the selection, one of the first initiatives of the NMPB was therefore to commission a nationwide study of the medicinal-plant markets. As the NMPB had neither the staff nor the experience to conduct a survey such as this, it was undertaken by the Foundation for Revitalisation of Local Health Tradition (FRLHT), which organised investigations on plant consumption by industrial pharmacies and households as well as a quick survey of the turnover of regional medicinal-plant markets. This 'supply and demand' assessment resulted in a series of uncomfortable conclusions when compared with the official motives of the 2000 policy turn and the NMPB mandate.[40]

First, in contrast to claims of highly diverse resources including thousands of species known for their therapeutic properties but used unevenly, the plants found in trade amounted to just 960, only 178 of which were commonplace, i.e. traded at a volume of more than 100 tonnes a year. Second, the report insisted on the massiveness of adulteration although documenting it was difficult for reasons of secrecy and also of nomenclature. The same trade names could actually designate very different botanical entities, that practitioners considered (or not) as legitimate equivalents when formulating. Third, although the list of species for which cultivation was found to be the main source (36) did include all those targeted by the board, the FRLHT study did not document the serious problems in supplying these species and the authors of the report did not see any need for new production incentives beyond questions of research and identification of improved cultivars. Fourth, the most critical supply problem identified was that of collections in the wild, primarily in wastelands since

37 NMPB, Minutes of the First Board Meeting 2001, Annex.

38 The cultivated species include: amla, ashwagandha, ashoka, atis, bael, brahmi, chandan, chirata, giloe, guggal, *Berberis aristata*, isabgol, jatamansi, kalmegh, kalihari, kutki, kokum, kerth, liquorice, pippali, shatavari, safed musli, senna, and tulsi.

39 Interview with Dr Varghese, KINFRA, Thiruvananthapuram, January 2012.

40 Verd and Goraya 2008.

collection in forests was kept at a not too dramatic level due to monitoring by the regional Forests Departments. A top priority recommendation was therefore to design a policy for these wasteland species in terms of conservation areas, good collection practices, raw-material management, sales reporting, and research on evidence-based substitution. Cultivation then only appeared as a barely mentioned and distant horizon.

Between 2002 and 2010, NMPB prioritisation followed less this conservation path, but focused more on the agricultural management of medicinal plants. Accordingly, the first effect of the inclusion of a species in the priority list was that it became eligible for financing in cultivation projects. The basic scheme negotiated between the three ministries (health, agriculture, and industry) was that individual farmers, cooperatives, or clusters committing to the cultivation of prioritised plants on a minimal acreage would receive 30 per cent of their costs as a subsidy. To avoid useless production, signing a contract was conditioned to the existence of a supply agreement with a drug producer, usually in the form of a payback contract. Priority was also a matter of 'promotional activities', which were less a matter of education or awareness than research and development initiatives ranging from the establishment of nurseries to provide enough planting material, to the study of cultivation protocols, or the definition of morphological and biochemical quality-control procedures.

A good example of this combination is provided by guggal (*Commiphora wightii*), which was included in the first list without further discussion because it was ranked fourth amongst all the plants being traded with 90 per cent of the quantities used in India being imported, mostly from Pakistan.[41] Guggal was also a good candidate for NMPB investments because of its uses. The plant is included in many classical formulations, where its gum comes under five qualities: *mahishaksha* (black-coloured), *maheneel* (extreme blue colour), *kumud* (bright white), *padma* (red colour), or *kanaka* (golden colour). As the classical properties of guggal are katu, tikta, and ushna, it is of special use in kapha—vāta disorders, sometimes translated as low energy or depression. Guggal is mostly consumed in India in the form of Guggal Kalpa, formulations where guggal is not just one amongst many ingredients but one of the most important, constituting practically 50 per cent of the combination.[42] The plant also benefited from strong interest by phyto-pharmacists and biomedical researchers, especially after guggal extracts made their appearance on the US market in

41 *Commiphora wightii* is variously called guggal, guggul, or mukul myrrh tree. In this paper, we are using 'guggal' except in citations where the term 'guggul' is used.

42 National Workshop on *Guggal*, New Dehli, August 2011, organised by the Gujarat Forest Department and the NMPB.

the late 1990s. During the following decade guggal thus became a 'hot' ayurvedic species. It was seriously considered as a source of ingredients active against obesity, atherosclerosis, and high concentration of blood lipids. Indian and US researchers then isolated a steroid-like fraction, the potency of which could be confirmed in animal models. These developments triggered a wave of clinical trials, both in India and in the United States, and a major controversy on what kind of protocol would be adequate for an 'evidence-based' Ayurveda.[43]

Between June 2001 and June 2006, the NMPB agreed to finance 3,500 farming projects covering 31,000 hectares.[44] Guggal had been amongst the rare plants selected for specific promotion with leaflets, regional meetings, and discussions about a coordinated research network amongst the four main agricultural institutions with some experience in the plant: the Central Institute of Medical and Aromatic Plants (CIMAP) in Lucknow, the National Research Centre for Medicinal and Aromatic Plants in Anand, the Arid Forest Research Institute in Jodhpur, and the Gujarat Ayurved University.

However, only a handful of the projects financed before 2006 were focused on guggal, and they covered no more than a dozen hectares. The mobilisation was therefore recognised as poorly effective, if not a resounding failure. Shifting gears, NMPB officials sought an alternative through more direct involvement of the forest departments in Gujarat and Rajasthan, two regions where the plant is endemic.[45] In November 2007, the Gujarat forest administration presented the NMPB with a programme for the mass-scale cultivation, conservation, and sustainable resource development of guggal to be financed as a promotional activity at a level of Rs 810 lakhs.

Expanding on the NMPB foundational discourse, the Gujarat foresters grounded their initiative in supposedly wrong collection practices:

> Owing to its demand in the pharmaceutical industries, poor propagation through seeds, slow growth and over exploitation in nature, [Guggul] has become an endangered species and presently listed in red list of IUCN. Therefore, conservation, as well as, development of GUGGUL in arid region is a big challenge to foresters and forestry scientists. GUGGUL (…) is depleting largely due to wrong tapping methods and over exploitation. So, this is the high time to conserve and propagate this highly traded and endangered medicinal plant both ***in situ*** and ***ex situ***. (…) Based on this, a project has been prepared to identify and carry out survey in the state,

43 Pordié and Gaudillière 2014.

44 NMPB, Minutes of the Finances Committee, 17th Meeting, June 2006.

45 Interview with Dr Sijwan, NMPB, New Delhi, November 2010.

> conduct research, develop seed stand and identify cultivars, develop protocol for raising tissue culture plants, develop media for better vegetative propagation, raise plantation on forest, to promote private plantations distribute the seedlings to the farmers at a subsidised rate.[46]

Place of choice for the implementation of the plan was the Kachchh region as this western part of the state was considered to be the only one where the tree was growing naturally in a significant manner. The conservation component consisted in setting out a dozen 'Medicinal Plants Conservation Areas' (MPCAs) where surveys of varieties and ecological constraints would be conducted and collection forbidden. Significantly, these MPCAs were labelled guggal 'gene banks'. The cultivation side of the project covered more than 3,000 hectares of state forests. It included the establishment of nurseries to supply the massive quantities of seedlings required for these public plantations but also for free distribution to farmers who would later engage in guggal production. Finally, new research on problems of fertilisation, association with other crops, sustainable harvesting of the gum, and tissue culture was to be organised under the foresters' lead in collaboration with local botanical and agricultural institutions. The financial perspective envisioned was that market prices for guggal were so high that public cultivation under the planned conditions would provide raw material with a value of more than Rs 2,000 lakhs, thus ensuring that the large public investment needed should not be viewed as economically wasteful.

Although it originated in a Forests Department, a major partner of the NMPB, the plan was not approved without criticism of its size and economic prospects. Perceived as being too administrative in design, its acceptance was conditioned on the following changes: 1) surface area reduced to a maximum 2,000 hectares; 2) more direct involvement of the local industry in order to organise the processing of guggal gum and to prepare an exit strategy for the time when funding would no longer be available; 3) a strategy to increase participation of the public. The final version thus proposed to undertake specific training sessions for farmers, NGOs, and 'other institutions' to disseminate knowledge about guggal, its uses, and cultivation. This private component was to provide for the future of the guggal supply:

46 Gujarat Forest Department 2007, *A Project on Conservation and Development for* Guggal *in Gujarat*, pp. 10 and 16, accessible online at National Medicinal Plants Board, nmpb.nic.in/WriteReadData/links/565284450725th-SFC-Minutes.pdf, last accessed 4 November 2013.

> It is proposed to undertake intensive training works in the target districts for the purpose of dissemination of the knowledge and other information on guggal. This training will cover the participants from farmers, NGOs, other institutions as well as forest department. A total of 100 such programmes, having 40–50 participants per programme are proposed to be taken up in 5 year period.[47]

Based on the available NMPB documentation, it is difficult to know what happened during the implementation of the project. It was considered successful with reporting of 2,000 hectares planted since 2009 and, more importantly, with the establishment of nurseries which had the capacity to produce tens of thousands of seedlings.[48] Beyond such rough assessment, little is known about the consequences of plantation, about the fate of the young trees, the collection practices, the production of gum, its commercialisation, or the involvement of farmers. This lack of follow-up is a general problem in NMPB-sponsored schemes.[49] Moreover, this large initiative was an isolated one. Since then, few other cultivation projects for guggal have been proposed to the NMPB and all those submitted to the finance committee before 2011 covered relatively small surface areas (less than 50 ha.).[50] All in all, the cultivation projects have therefore only marginally improved the problem of guggal supply and alleviated the need for massive importation.

What kind of consequences of the NMPB cultivation policy took place beyond the guggal case? In 2008, with the launch of a new five year plan, a considerable increase in funding for contractual farming became available (it was more than tripled) and a new scheme was put in place. The task of evaluating thousands of proposals every year could barely be achieved with the allocated staff and resources available during the first five years of the NMPB. Rather than turning the board into a larger administration of its own, the choice was made to transfer the selection and administration of projects to State Medicinal Plant Boards (SMPBs) and to integrate the cultivation of medicinal plants into the framework of a national rural mission 'covering production, post harvest management, processing and marketing'. Within this organisation, the NMPB was only to review the yearly state action plans prepared by SMPBs and the local Horticultural Mission.[51]

47 Gujarat Forest Department 2007, p. 21.

48 Interview with Dr Sijwan, NMPB, New Delhi, November 2010.

49 For another example, in Kerala, see L. Dejouhanet's paper in this issue.

50 NMPB, Standing Finance Committee, Minutes of the 7th, 10th and 11th Meetings, 2010–2011.

51 NMPB 2008a, pp. 11 and 19.

This financial and institutional reshuffling implied a strongly reinforced role for regional agricultural institutions since NMPB acted less as funding structure focusing on individualised plants to be grown, and more as coordinating center in botanico-industrial innovation. The regional agricultural institutions thus participated in the selection of a whole palette of plants, the organisation of farmers, and industry into clusters, the building of facilities, i.e. nurseries to produce enough 'high quality' planting material on the one hand, and infrastructures for storage, processing and transportation on the other. In the process, a new list of prioritised plants was established. There are now 116 species, distributed into three groups: those eligible for a subsidy covering 20 per cent of the costs (59 species), a subsidy covering 50 per cent of the costs (38 species) and a subsidy covering 75 per cent of the costs (19 species including guggal). The list has now incorporated a great majority of the species in high trade.[52] Moreover, in addition to this list, the SMPBs got specific leverage and may have included other species as part of their own local, priority lists.

The growth in funding and the diversification of priorities do not seem to have been matched with an equivalent extension of cultivation targets. The 20 state action plans agreed upon in 2010 and 2011 involved the cultivation of only 50 highly prioritised species, with 11 species appearing in most plans and representing a large proportion (three-quarters) of the associated surface areas. These eleven plants were already in high production during the first years of existence of the NMPB, namely amla, bael, ashwagandha, sarpagandha, ghritkumari, shatavari, kalihari, neem, senna, tulsi, and madhukari.[53]

In practice, prioritisation thus reflects a much more complex pattern of action than the simple market logic the NMPB brought into play as their source of information and proxy of benefits. For instance, the presence of ashwagandha (*Whitania somnifera*) within the top ten cultivated species is less to be explained by price incentives (at Rs 60–90 per kilo it is far from being very costly material) or by cumulative agricultural experience (the routine cultivation of ashwagandha is recent).[54] It may well be that its status as one of the main plants used in the *rasāyana* formulations, a species with rejuvenating and immuno-modulating properties, has created a strong *medical* demand. In contrast, atis (*Aconitum heterophyllum*) is a rare Himalayan plant, recognised

52 Out of these 92 species, 116 are included in the top list of 178 plants of the above-mentioned FRLHT survey.

53 This computation is based on the plan descriptions included in the documentation for the National Medicinal Plants Mission, Standing Finance Committee Meetings of June 2010, June 2011, and July 2011.

54 Verd and Goraya 2008.

as endangered and sold at a very high price (Rs 2000–4000 per kilo), for which cultivation protocols exist. It has not, however, become the target of any significant NMPB-sponsored project. If the FRLHT survey is to be trusted, it is massively substituted and what is sold as atis is a group of at least four species, the global supply of which easily meets total demand even though the quality is questionable.[55] This incommensurability of price signals and cultivation dynamics is a source of major difficulty in the NMPB's central policy of modifying patterns of production through the priority list and the allocation of subsidies. The National Mission Finance Committee, for instance, complains that state plans keep including species like madhukari, the supply of which is reasonably well guaranteed so that their prices, in contrast to those of most species, have started to fall.[56]

The research and development output of the NMPB may therefore be more significant for the future of medicinal-plant management than its cultivation policy. In the case of guggal, NMPB sponsorship does not seem to have induced radically new research but has certainly increased the circulation of existing inquiries and results. This is, for instance, the case for the dissemination of cultivars with increased gum yield obtained at the CIMAP or for the popularisation of studies on combined cultivation, which confirmed the possibility of intercropping guggal with millet or beans. However, the most visible outcome is the standardised cultivation norms developed by the botanists at Jai Narain Vyas University in Jodhpur (Rajasthan), which have been endorsed, published, and promoted by the board. The organisation of these guidelines is highly revealing of an operational mode leaving out the clinical and medical meaning of *materia medica*. The NMPB standards for guggal briefly allude to its therapeutic uses (without mentioning the polyherbal formulations) but otherwise combine purely botanical knowledge (morphology, floral characteristics, natural distribution, climate, and soil) with agro-technical data (available varieties, propagation, nursery technique, planting in the field, irrigation and fertilisation, disease and pest control, harvest management, and market trend). The novelty of the guidelines resides in the latter, in which any reference to traditional farming techniques has disappeared and the norms for N-P-K fertilisation or choice of pesticides have been defined.

One critical issue in the case of guggal is that of sustainable harvesting given that bad collection or harvesting practices are—in NMPB and the forest-department discourses—associated with excessive extraction, plant exhaustion, and depletion of the resource. In its project, the Gujarat forest administration

55 Ibid., p. 125.

56 NMPB, Standing Finance Committee, Minutes of 10th Meeting, June 2011.

insisted on collectors' supposedly bad practices and the urgency of setting new standards.[57] As a response, the NMPB guidelines state that 'the plant should be allowed to grow for at least five to six years before commencing incision of thick branches', that only one incision must be made and that the resin should be 'collected every week up to one month after which further exudation of gum stops'.[58]

Some of the NMPB's academic partners have developed similar guidelines for other plants in the 2002 priority list. Given the nature of the list, most of these guidelines are based on assessments of existing practices. Following the NMPB initiative, no plant collected in the wild seems to have been 'domesticated' and linked to a new field-production protocol.[59] Such a limited extension of the realm of plant cultivation is not only due to time and manpower shortage. It reflects a pervading debate amongst practitioners about the extent to which—as already mentioned in the case of *Trichopus zeylanicus*—the cultivated varieties do not represent the same potency as their homologues collected in the wild. This is given the fact that the simplified and standardised conditions of growth in the field are widely recognised to change the composition of plants and may result in loss of active ingredients.[60]

Despite its paucity of innovation, agro-technical standardisation has had significant impact. By coordinating and summing up numerous local definitions of cultivation norms, the NMPB has now established itself as a regulatory agency. Its manual for medicinal-plant agro-techniques may be considered as analogous to a pharmacopoeia in two ways. First, in terms of structure, the manual provides medicinal-plant professionals (farmers as well as agricultural institutions) with recognised, administratively sanctioned recipes for the production (cultivation and preparation) of marketable *materia medica.* Second, even if the manual is not legally binding like a pharmacopoeia, it operates as a soft-law instrument. NMPB recipes are reference points for the evaluation of projects and constitute the background for the development of 'good cultivation practices' that the NMPB intends to transform into certification standards.

The NMPB's certification policy is a development of its operations associated with the Tenth Five Year Plan. It intends to foster standardisation and quality

57 Gujarat Forest Department 2007, op. cit. p. 23.

58 NMPB 2008b, p. 67.

59 It is revealing that none of the plants for which the NMPB has published agro-techniques since 2007 belongs to the category of new crops. Similarly, all the reported research projects on crop development conducted at the CIMAP in Lucknow deal with already cultivated medicinal-plant species.

60 Interview with Dr Pushpangadan, Amity, Thiruvananthapuram, January 2012.

control. It does not aim at implementing specific agro-technical standards, which are to remain voluntary benchmarks, but to link their existence with the commitment of producers to generally defined 'Good Agricultural Practices' (GAP). The first document in this direction was developed in 2008 with the collaboration of the World Health Organisation India office. It strongly emphasised the need of proper recording and advocated relatively simple technical commitments, including preference for organic manure rather than chemical fertilisation or use of biocontrol methods instead of herbicides and pesticides.[61]

In contrast, the procedure that the NMPB is presently seeking to implement favours practices that testify to a more industrial understanding of medicinal-plant regulations. Any candidate for certification must comply with all the major criteria included in the board's list and with 95 per cent of those deemed 'minor musts'. Far from being easy to check and implement, these criteria often require sophisticated training and means of analysis. For instance, when it comes to assessing the soil conditions, a producer seeking certification must factor in an impressive range of criteria considered 'major' and for which chemical-analysis facilities are required:

> Has the soil map prepared for the farm? Is the soil optimal to the selected crop with reference to its water holding capacity and fertility? If soils with low fertility levels use soils amendments as per the specific site and requirement of species, are the latest soil test report on phsyico-chemical parameters and nutrient profile to decide the nature and quantity of soil amendments available? Has the quality of irrigation water been adequately understood and classified in the context of both soil type and the target crop in terms of total soil concentration, sodium absorption ratio, bicarbonate and boron concentration? Irrigation water is required to conform to standards of micropolluants (disinfection by products, endcrine disrupting chemicals, antibiotics, polymers, pesticides and other bioactive chemicals), heavy metals and residual pesticides if the water is vulnerable like canal water, etc? When shade loving crop is planned, availability of shade across the field should be ascertained.[62]

GAP certification will probably operate in a manner similar to the 'Good Manufacturing Practices' certification currently administered by the state drug controllers as they favour large-scale, mass-producing units rather than the capabilities of small farmers. The initial audit and yearly inspections man-

61 NMPB 2009.

62 NMPB 2011, p. 15.

dated in the certification process do allow for dissemination of norms and references, thus increasing the homogeneity of practices across production sites. This may or may not result in an improved quality of products because the crisis in supply, which is the major cause of mass-adulteration and substitution, will not be alleviated with standardisation and popularisation. In contrast, unless specific actions are taken to leave the door open to local diversity and ensure that local farmers can access the technological infrastructure to meet GAP requirements, what this certification policy will certainly favour is the concentration of cultivated medicinal-plant production.

In 2010, at the end of the Tenth Five Year Plan, NMPB officials assessed their cultivation policy. One motive for satisfaction was the growing availability of senna. Its production increased from a mere 950 ha and 107 tonnes in 2001 to 16,840 ha and 6,380 tonnes in 2005. However, the main paradox is that—although the plant was listed amongst the NMPB priority species—the supply of senna was not a medical problem.[63] The species is easily accessible and most of the production increase induced by the cultivation scheme has nurtured India's exports of medicinal plants. In terms of a policy of industrialisation and plant-supply management, this is undoubtedly a success. From a pharmacy and public health perspective, the jury is still out.

This case highlights in a powerful way the ambiguous role played by the NMPB. The board's creation clearly shows how the reformulation regime goes hand in hand with the emergence of a new institutional landscape. This granted those groups of professionals, who had previously no connection with the Indian systems of medicine, the authority and autonomy necessary to regulate the production and, to some extent, the industrial uses of medicinal plants. All this happened in the name of 'sustainability' and urgent responses to the supply crisis. However, given the emphasis placed on market incentives and cultivation, the challenges faced by the NMPB in this attempt to balance quantity and quality, industrial growth and conservation, are that the board scarcely promotes other practices than those already existing and therefore barely shifts the boundaries between the wild and the domesticated.

Conclusion

In 2000, the report of the National Planning Commission Task Force on Medicinal Plants included a figure summarising its view of herbal pharmacy (figure 2). With noticeable prescience of the coming developments, the scheme

63 Verd and Goraya 2008, p. 69.

completely left out medical and clinical actors or practices. Taken to be synonymous for 'industry' or 'drug firm', pharmacy was linked to two types of technological and economic agents: collectors and the associated traders on the one hand; cultivators and their agents on the other. The figure is therefore a good reflection of the understanding of pharmaceuticalisation as the emergence of a new world of experts in medicinal-plant mass-production and management. What the scheme leaves out, however, is the relationship of this emergence to the production of knowledge and reformulation practices. As this paper followed not only the work of an institution, such as the NMPB, but also the local activities of TBGRI botanists, it underscores this connection precisely and shows that the recent changes in the Indian traditional-medicine, techno-political landscape cannot be approached as mere administrative reshuffling.

The second lesson to be drawn from our two case studies is that they convey the centrality of medicinal plants, the form of knowledge as well as the ways of collecting, cultivating and preparing them, in such a way that the contemporary pharmaceuticalisation of Indian health traditions resonates with many controversies and problematic issues already salient in the nineteenth-century European development heading towards a separation of medicine and pharmacy. The pharmaceuticalisation of Ayurveda is, however, not a copy or a re-enactment of a forgotten modernisation trajectory. Grounded on a reformulation regime that focuses on polyherbals rather than on isolated plants, building on the deep divide between the informal knowledge of collectors and the written scholarly tradition of plant users, and embedded in a context of health and economic globalisation, the contemporary Indian trajectory of pharmaceuticalisation is less a question of professionalisation and institutionalisation than a problem of industrial technology and market construction.

As revealed by both trajectories of the TBGRI and the NMPB, the new centrality of plant management is closely attached to the rise of biotechnology and its associated practices of bioprospection, agricultural production, and biochemical quality control. However, what the TBGRI case shows more precisely is that plant-supply management is related to the design and production of new formulas in two contrasting ways. One is reformulation work as developed in companies like Oushadi, Arya Vaidya Sala Kottakkal, or Himalaya, where plants are approached as *materia medica* in an integrated manner, i.e. with teams of *vaidyas*, pharmacologists and managers trying to keep in line with the selection of (bio)medical targets, the adaptation of classical products and the choices of supply lines. The second is reformulation as applied in botanical gardens by teams of botanists, biochemists, and agricultural experts following a given plant species, looking for new ways of collecting, conserving, and cultivating, and testing radically new combinations. Since these two 'ways'

of reformulating share the same commitment to polyherbals and therefore act as alternatives to biomedicalisation, they are evidently not rooted in separate cognitive, social, and economic worlds. They are two pillars of the same rapidly expanding neo-traditional pharmacy.

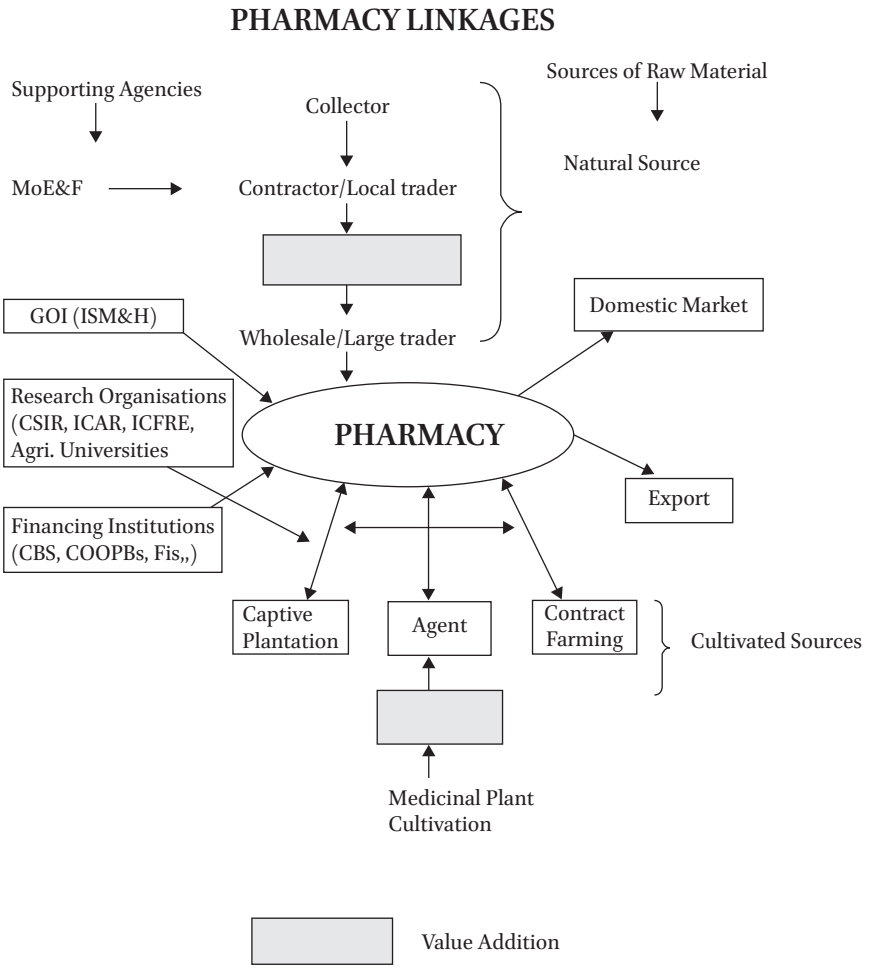

FIGURE 2 *Traditional Indian Medicine Pharmacy as viewed by the National Planning Commission.*[64]

64 See *Report of the Task Force on Conservation and Sustainable Use of Medicinal Plants*, Planning Commission 2000, p. 117.

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