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Drug Discovery, Reformulation and the Market

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On a morning in March 2013, we entered the premises of a leading ayurvedic firm located in Bangalore. We came in order to meet again with senior representatives and other staff from various departments in an attempt to understand better how one of the firms invented products—today a specialty commercialised under the name of Menosan—had been developed. This drug is an intriguing therapeutic entity. It is registered as an 'Ayurvedic Proprietary Medicine', which means that it is owned by the firm and marketed under a name registered as a trademark. This form of intellectual property is based on the recognition that this drug is not a formulation mentioned in the classical medical texts, but a modified preparation stemming from Ayurveda. Menosan is actually manufactured as a polyherbal, which includes extracts of six plants and two *bhasma*—substances obtained by calcination—and is sold in the form of sugar-coated pills by (supposedly) means of prescription only. The indication targeted is menopause.

When asked about the origins of such a pharmaceutical specialty, the head ayurvedic doctor in the firm gave us a broad social and cultural explanation of the changes in Indian society and in the lives of Indian women. According to him, these changes account for the fact that menopause was not a peculiar problem in the past, certainly not an issue in Ayurveda, but has become so in the wake of 'modernity', whatever this may have meant to him. The need for a new formulation thus originated in the perceived changing health issues and challenges that an increasingly urbanised Indian society, made up of nuclear families, had to face. And indeed, in contrast to what we expected, when the

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origins of this medicine were traced, no one invoked the massive use of steroid hormones in the West for alleviating the adverse effects of the menopausal transition. Neither was the crisis mentioned, which erupted in the US in 2002 (the same year Menosan was launched) when a very large epidemiological study revealed strong linkages between hormonal replacement therapies (HRT) and increased incidence of cancer and cardiovascular problems, thus opening new venues for alternative therapies. Our interlocutors in the firm did not speak about this, because the synchronicity was fortuitous, even if the HRT crisis and the search for alternatives later became a marketing target for the company.

But how can one design an innovative yet traditional industrial preparation out of medical texts that barely mention the targeted disorder? Menopause is not considered as an autonomous and specific bodily phenomenon in classical Ayurveda. One of our interlocutors explained that the research done at the Department of Drug Discovery had involved two stages in the invention of Menosan. The first stage was based on the knowledge of the company's ayurvedic physicians (*vaidyas*) and consisted in selecting and critically examining two types of classical formulations: those linked to the health of women and their normal life trajectory on the one hand, and those linked to the specific ailments and symptoms of contemporary menopause (hot flashes, shifting mood, depression, heart disorders, etc.) on the other hand. On that basis, using ayurvedic characterisation of the therapeutic properties of plants, the local *vaidyas* 'formulated' several candidate combinations. The second phase was industry-based pharmacological screening. The formulations were tested on animals, more specifically on female rats in which an artificial menopause (equated with oestrogen deficiency) was surgically or chemically induced. The most potent combinations were then passed to biomedical and ayurvedic practitioners for trials. These trials were heterogeneous in design but even when randomisation and control groups were involved they focused on quality of life criteria rather than biological (hormonal) endpoints.

The trajectory of Menosan thus seems to mobilise two different lives: a public one and a private one. The public one is at the core of Menosan's promotion. It is that of a modern drug, standardised, tested according to the biomedical criteria of evidence-based medicine, and aimed at the management of biomedical risks. The private life of Menosan is that of in-house research. It is the life of the material composition itself, an assemblage of many plant parts and extracts with heterogeneous ayurvedic roots. It supports an alternative discourse of efficacy linking the synergies of polyherbals with the new problems ayurvedic bodies must face today.

How can we as historians and anthropologists of science and medicine read this situation? Is Menosan the sign of another stage in the biomedicalisation of ayurvedic medicine? Is the firm's discourse on new formulations based on the 'ancient science of life' another element in the panoply of complementary and alternative medicines? How to understand a practice which takes remedies away from their ayurvedic clinical context and uses them to treat biomedically-defined ailments? What is the logic and legitimacy of new plant associations reduced to just a few ingredients, when these assemblages have no equivalent in established texts?

The existence of such 'reformulations'[1] in the contemporary herbal pharmaceutical industry in India actually raises questions on the dynamics of traditional medicine. At the core of these questions is the possibility (or impossibility) to find systems of correspondence, both linguistic and material, i.e. creating modes of circulation between concepts, materials, bodily entities or protocols involved in the medical realms putatively concurring.[2] These questions have often received answers focusing on binary epistemologies opposing two medical 'systems'. Within this perspective, Menosan would probably be a new kind of biomedical cum phytotherapeutic drug since its envisioned efficacy is rooted in an allegedly standard combination of plants and not in a treatment regimen participating in a recognised ayurvedic clinical intervention. Binary epistemologies have, however, the great disadvantage of simplifying things far too much. Placing too much emphasis on the purity, coherence, and incompatibility of medical 'systems' does not only result in the impossibility of intermediates but also produces a caricature of medical, especially, clinical practices. When binary epistemologies keep open the possibility of bridging worlds, it is only in the form of an almost schizophrenic juxtaposition with little creative power.

This special issue seeks to offer a different perspective on the reformulation practices currently at play in the Indian ayurvedic industry. It stems from a French National Research Agency (ANR)-funded project named Pharmasud, which was concerned with the social study of the pharmaceutical industry in India and Brazil. A series of academic gatherings allowed researchers working on the Indian segment to collectively develop the methodological frameworks and analytic grids presented in this volume. The common ground adopted here is that the world of Ayurveda is currently reinventing its remedies and in doing so, it is borrowing from various medical schools of thought and various

1 Pordié and Gaudillière 2014.

2 Keshet 2009; Naraindas 2006; Pordié 2010.

techniques. It is also introducing modes of therapeutic practices that are neither traditional nor biomedical but mobilise and perform various levels of (sometimes incompatible) actions, thus building on the heterogeneity of Ayurveda and biomedicine. This volume looks at the innovation processes in contemporary Indian ayurvedic industry as forms of 'alternative modernity'.

In his perceptive analysis of the tensions underlying the visions of nationalist élites in colonial India, Partha Chatterjee accordingly pointed to the double nature of the modernisation discourse, which seeks to gain legitimacy and power in the 'public' through constant references to the modern creed of civil society, fundamental liberties, and individual rights, thus undermining the colonial divide between the laws and rules governing the life of Europeans and natives. This modernisation discourse simultaneously claims to be a radical alternative to the West, existing in the 'private', looking for revitalised cultures, family values, religious forms of life, and allegedly intrinsic Indian social organisations like the caste system.

> By my reading anti-colonial nationalism creates its own domain of sovereignty within colonial society well before it begins its political battle with the imperial power. It does this by dividing the world of social institutions and practices into two domains—the material and the spiritual. The material is the domain of the 'outside', of the economy and of statecraft, of science and technology, a domain where the West has proved its superiority and the East has succumbed. In this domain, then, Western superiority has to be acknowledged and its accomplishment carefully studied and replicated. The spiritual, on the other hand, is an 'inner' domain bearing the 'essential' marks of cultural identity. The greater is one's success in imitating Western skills in the material domain therefore, the greater the need to preserve the distinctiveness of one's spiritual culture. (. . .) The colonial state, in other words, is kept out of the 'inner' domain of national culture; but it is not as though this so-called spiritual domain is left unchanged. In fact, here nationalism launches its most powerful, creative, and historically significant project: to fashion a 'modern' national culture that is nevertheless not Western.[3]

Alternative modernity thus should not be understood as a process of acculturation and local adaptation to the forms of knowledge, values, and ways of acting that are originating in mostly a European modernity. Instead, it involves much more complex dynamics, in such ways that the responses to the colonial and

3 Chatterjee 1986, p. 6.

postcolonial challenges combine adaptation and resistance, alignment and alternative, heritage and invention. Alternative modernity rests on a dialectic which constantly redefines and displaces the boundaries between the 'inside' and the 'outside', between what is accepted as modern and what is promoted as tradition.

There are several reasons to adopt such a perspective when looking at the reformulation practices of ayurvedic medicine. The first may be called the 'pragmatic' gaze, which currently animates the social studies of medicine, anthropology included. If one keeps at bay a nominalist stand, which would first define Ayurveda and then seek its embodiment in the world, then the response to the question 'what is Ayurveda?', is actually 'Ayurveda is what people who practise it make out of it'. In this respect, the contemporary situation is utterly heterogeneous. The practitioners who may be associated with the forms of education, the social status, and the clinical practice that have generally been used to define the traditional *vaidya*, are by now in a small minority in India. To consider that only those and not the crowds of professionalised 'doctors' of ayurvedic medicine should be taken into account in our understanding of Ayurveda may be valuable as a normative choice but seems of little analytical benefit. A second and equally important motive to understand the present practices of the Indian herbal medicine industry as a re-invention of ayurvedic medicine lies in the latter's recent history. In the course of the last century, Ayurveda has been re-invented at least twice.[4] What has become the 'tradition' was actually imagined and stabilised in the late nineteenth and early twentieth century, when the main issue was perceived to be the defence of local healing practices put under threat by the colonial power.

Sharing elements both with the Orientalist discourse and with an emerging nationalist culture, the 'renaissance' or revitalisation of Ayurveda was deemed an urgent task at the time since what was becoming a typically Indian mode of healing had been already neglected for centuries, i.e. since the early days of foreign domination. Allegedly turned into a caricature of itself, associated with ignorant and inefficient healers, the first re-invention of Ayurveda had to deal with restoring it to its originality through the creation of associations, the systematised teaching of the basic classical texts, and the creation of collective places of learning.[5] The second re-invention of Ayurveda concerns a substitution of the agenda of modernisation and the interplay with biomedicine with that of a 'renaissance' or 'neotraditionalism'. Chronologically

4 Arnold 2000; Berger 2013; Langford 2004; Leslie 1976; Leslie and Young 1992; Sivaramakrishnan 2006.

5 Biswamoy and Harrison 2001.

speaking, this process is more diffuse since for decades modernisation was a matter of conflict within the ayurvedic world. Modernisation succeeded with post-Independence India.[6] Its domination is deeply rooted in a process of institutionalisation, which placed the education of ayurvedic practitioners under the jurisdiction of the nation-state, aligning—at least legally—their status with that of biomedical doctors, and introducing important elements of Western (bio)medical knowledge, in particular anatomy, physiology, and pathology, in a standardised curriculum.

The connection between the so-called 'Indian systems of medicine' and pharmacy has actually gone through unprecedented developments in the last two decades, in the context of a new wave of economic and health globalisation. The implications go far beyond market trading.[7] Changes in the world of pharmacy in fact are not only related to trade and intellectual property but also have to do with standardising research and production practices, with the nature of products judged to be useful and useable, and with their use. The extension of circulation thus modified pharmaceutical practices by imposing, for instance, the requirement to adapt products originating in Asian medicine to the regulatory frameworks of certain European and North American countries and to the expectations of consumers in those parts of the world. As a result, the nature of these pharmaceutical goods, as well as their mandatory production and evaluation standards, underwent radical transformations. These frameworks were conditional for manufacturers of polyherbal drugs in order to get their products on the market more quickly and cheaply. Otherwise, they would have needed to fulfil the expensive requirements of clinical testing and evidence required of a pharmaceutical based on molecular isolates.

Our contention is therefore that if Ayurveda has already been re-invented twice, it can well be re-imagined a third time to become industrial and pharmaceutical. The markers of these deep changes include: the invention of new herbal combinations like Menosan with some roots in the classical texts of Ayurveda;[8] the mass-production and global circulation of these remedies in the form of pills;[9] new modes of intellectual property protection;[10] a rapidly escalating consumption of medicinal plants;[11] the emergence of large

6 Banerjee 2009; Bode 2008; Sujatha and Abraham 2012.

7 Leslie 1989.

8 Pordié 2015.

9 Banerjee 2009.

10 Gaudillière 2014.

11 Craig and Adams 2008; Dejouhanet 2014; Saxer 2013.

companies operating nation- or world-wide with the classical tools of scientific marketing.[12]

The present 'reformulation regime'[13] of Ayurveda is thus characterised by the emergence of a world specialising in the production, the invention, and the marketing of polyherbal therapeutic specialties building on strong continuities, both conceptual and material, with India's traditional medicines. As such, the reformulation regime carries radical changes in nature and scale of the practices associated with these forms of medicine. Reformulation is not only a change in the 'formulas'; it questions the economic, technological, epistemological, and regulatory aspects of these new products and their uses. Three terms may be used to delineate the dynamics involved in this regime: industrialisation, pharmaceuticalisation, and globalisation.

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 ayurvedic drug-producing companies. Some of these companies are large enough to operate as global players seeking consumers all over Asia and possibly Australia, Europe, or the United States. Industrialisation also refers to the manufacturing process and the production technologies, embedded in our case in a normative 'pharmaceutical nexus',[14] as shown by the new standards of Good Manufacturing Practices. 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 biomedical and ayurvedic medicine or 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 search for long-term conservation through changes in presentations and the quest for standardisation through quantitative, laboratory-based, quality control have become pervasive. They provided Indian herbal medicine firms with their main tools to occupy what they perceive as fast-growing urban and global markets.

'Pharmaceuticalisation' is a useful notion as it points to the technological, material, and social specificity of pharmacy as a world of practices.[15] The dynamics of reformulation entail a deep change of Ayurveda, not only because

12 Gaudillière and Thoms 2015; Pordié 2015.

13 Pordié and Gaudillière 2014.

14 Petryna and Kleinman 2006.

15 Biehl 2007, Banerjee 2009.

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 a sphere that had previously been basically medical and clinical with practitioners 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.

A third fundamental, intertwined characteristic of these transformations concerns the 'global turn' of Asian medicine.[16] Still on the fringe of industrialised societies a few decades ago, these therapeutic practices and their products are now increasingly present world-wide. New products and new practices emerge in the context of the making of global markets and the accelerated diffusion of knowledge, ideas, and institutions.[17] The processes, significations, and social implications of globalisation are made visible by the recent emergence of new 'branches' within the same medical ensemble, as is the case for Ayurveda.[18] Each form of Asian medicine should therefore be considered in its plurality: the places where they are practiced extend beyond their original cultural field and in return fashion the way medical care is performed and medicines are produced. For instance, diverse forms of Chinese medicine are produced through 'translocal' circulations, from Shanghai to California, involving the interplay of a whole set of interactions and ruptures which form and modify medical knowledge and forge local identities of both practice and practitioner.[19]

The unprecedented international expansion of Ayurveda favours the circulation of therapists, their medicinal products, knowledge, and practices, yet at the same time reinforces their identity and cultural roots.[20] Generally speaking, Asian medicines cannot be restrained within the bounds of their source cultures and societies, and therein lie the bases of their legitimacy. Reformulations of ayurvedic products always embody fragments of society and culture, while manufacturers and distributors often use them as a marketing tool combining them with biomedical discourses on therapeutic efficacy. Indeed, Asian medicines are produced as international commodities but

16 Alter 2005; Pordié 2008; Stollberg and Hsu 2009.

17 Pordié and Simon 2013.

18 Wujastik and Smith 2008.

19 Zhan 2009.

20 Zimmermann 1995.

still consumed for their presumed 'traditional virtues'.[21] They incarnate moral values and a certain vision of the world from which emanates a remarkable seductive power in Western societies. While they follow transnational circuits and networks, these new products are an integral part of a diversity of assemblages, which, in their multiplicity and heterogeneity, produce and stratify the global.[22] Global pharmaceuticals firms clear their way through a dense network of transnational relations and socio-material influences. In a way, they are *forging* globalisation while at the same time *particularising* it.

The papers in this issue address these broad tendencies by analysing specific realms of practices, looking simultaneously at the actors involved, the targets they pursue, the tools and forms of intervention they mobilise. Altogether they provide clues for understanding the specificity of the reformulation regime along four themes. The first theme concerns the new forms of knowledge involved in the design of formulations, which do not only include 'classical' clinical Ayurveda or biomedicine but also botany and ethnopharmacy (Banerjee, Naraindas, Pordié, Zimmermann, this volume). Secondly, the process of standardisation that does not simply aim at inserting polyherbal medicine preparations into the landscape of pharmacological testing, randomised clinical trials, or chemically-based controls of batches, but addresses complex issues associated with the evaluation of the synergies between multiple ingredients (Banerjee, Naraindas, Zimmermann, this volume) or of the qualitative sensorial properties of the mixtures (Ganguly, this volume). The third theme concerns the construction of (global) markets (Madhavan, Pordié, this volume) and the mounting role of intellectual property that is illustrated by a generalised move toward patenting the new formulas while insisting on the need to protect the common ground of traditional knowledge from misappropriation (Gaudillière, Pordié, Madhavan, this volume). The fourth theme focuses on the critical and autonomous role gained by the management of plants and their experts (Dejouhanet, Gaudillière, this volume). The mounting production of new remedies results in a crisis of the supply of (mostly collected) medicinal plants. This leads to an increased substitution or adulteration on the one hand, and a threatening overharvesting and exhaustion on the other hand while the main issues advocated are the enforcement of standardised (good) collection practices and the—for the time being more theoretical than practical—replacement of collection by cultivation.

21 Janes 2002.

22 Ong and Collier 2005.

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