Contested Issues of Efficacy and Safety between Transnational Formulation Regimes of Tibetan Medicines in China and Europe

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Abstract

Tibetan medicines are key material objects for medical treatment and have become part of a global trend of ‘pharmaceuticalisation’, playing increasingly important political and socio-economic roles in an ‘alternative modernity’. As I argue in this paper, they also have become key ‘sites of contestation’ between different epistemic values and styles of practice related to efficacy and safety that are reproduced in and through specific formulation regimes. Based on my multisited ethnography of production, prescription, and use practices of Tibetan medicines in China and Europe, this paper conceptualises three distinct formulation regimes, offering a heuristic model for transnational comparison—a classical, an industrialised or reformulated, and a polyherbal regime. The first two are the major orientations while the polyherbal is a conjoint hybrid with either the classical or the industrialised formulation regime. Globalised national drug safety regulations legalise and confer legitimacy to industrialised Tibetan formulas that follow biomedically defined efficacy, safety, and disease categories, while classical formulas produced by private physicians or small-scale cottage pharmacies are increasingly marginalised as producing ‘unsafe’ and at times illegal medicines, and need to find new ways for adapting and circulating their formulas.

Keywords

Tibetan medicines – transnational formulation regimes – efficacy – safety – legality – China – Europe
Introduction

Tibetan medicines are key material objects for medical treatment and have become a key ‘site of contestation’ among different stakeholders in a global trend of ‘pharmaceuticalisation’.1 While Tibetan medicines have taken on ‘social lives’ of their own in various formulations,2 as patent industrialised pharmaceuticals they also play increasingly important socio-economic and political roles in a global ‘alternative modernity’.3 This development is particularly salient in China and also in Europe where growing pharmaceutical industries produce standardised, quality-controlled, industrialised Tibetan drugs based on particular ‘reformulations’ of classical multicompound formulas successfully tapping into national, increasingly globalised niche markets of ‘natural’, ‘alternative’, or ‘integrative’ medicine.4

At the same time, classical Tibetan formulas are exclusively prescribed and often still produced by private physicians trained in ‘Tibetan medicine’ (Tib. bod sman) alias Sowa Rigpa (Tib. gso ba rig pa), commonly translated as the ‘science of healing’,5 diagnosing and treating their patients according

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1 I apply the term ‘sites of contestation’ to Tibetan medicines as core therapeutic objects of a ‘living tradition’ that Tibetan medicine in all its diversity and styles of practices represents, cf. Scheid and Lei 2014. I understand ‘pharmaceuticalisation’ as a driving global force based on ‘the technological, material, and social specificity of pharmacy as a world of practices’, cf. Pordié and Gaudillière 2014b, p. 7, based on Biehl 2007. I thank my reviewers and, in particular, Sienna Craig for fruitful feedback on earlier versions of this article.


3 Petryna, Lakoff, and Kleinman (eds) 2006. On the concept of ‘alternative modernity’, see Knauft 2002; and in relation to industrialised ‘reformulated’ ayurvedic Asian pharmaceuticals, see Pordié and Gaudillière 2014a. I use the term ‘Tibetan medicines’ as well as ‘Tibetan formulas’ as umbrella terms for multicompounds produced on the basis of classical Tibetan formulas according to the three different formulation regimes outlined in this paper, and applied as therapeutic objects for medical treatment in different social, cultural, clinical, and geographical contexts.

4 On the term ‘reformulation’ in relation to the making of industrialised herbal ayurvedic medicines in India, see Pordié and Gaudillière 2014a, b; Pordié and Hardon 2015.

5 I use the English term ‘science’ as a direct translation of Tibetan rig gnas in the sense of Tibetan medicine being part of the classical ‘five major sciences’ taught in monastic curricula (Tib. rig gnas che ba lnga). Since the physicians of Tibetan medicine whom I have interviewed in Europe and China and also some pharmacists in India, were all ethnically Tibetan, I intentionally use the term ‘Tibetan medicine’ (Tib. bod sman) rather than the term Sowa.
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to fundamental Tibetan medical principles in relation to the disease-causing imbalance in the individual patient’s body and mind. Most physicians of Tibetan medicine (called henceforth TM physicians) practice within rural Tibetan or Himalayan communities in Tibetan populated areas of China (Tibet Autonomous Region TAR, Qinghai Province, Gansu Province, Sichuan Province, Yunnan Province), in Indian exile and in the historically influenced spheres of Tibetan culture of the Himalayas (Ladakh, Nepal, Bhutan), as well as in Mongolia, and Buryatia. The globalisation of Tibetan culture and religion, more recently propelled by exile-Tibetans in or from India, has also fostered the transnational movements of physicians and medicine(s). Individual TM physicians, most of them from India (fewer directly from China), were able to establish themselves in private clinics or as teachers in Europe or America. Some are also itinerant visitors prescribing classical Tibetan formulas that are circulating within specific transnational therapeutic networks.

I argue in this paper that in contrast to classical Tibetan formulations, ‘modern traditional’, industrialised medicines targeting conventional diseases and a clientele outside of the Tibetan cultural sphere, tend to become ‘independent’ of the Tibetan medical knowledge system. They are mostly prescribed by biomedically trained physicians, those of ‘complementary and alternative medicine’ (CAM) or ‘traditional Chinese medicine’ (TCM), and are marketed for niche markets of ‘natural’ or ‘herbal’ medicines in China and Europe. In other words, symptoms and diseases are diagnosed and configured according to biomedical parameters, such as diabetes, cardio-vascular, digestive, or stress-related disorders. Testing and validating clinical efficacy and safety of branded Tibetan pharmaceuticals for such symptoms and diseases is primarily done via ‘randomised controlled trials’ (RCT), while some clinical studies in both Europe and China additionally included Tibetan medical diagnostics. In China, however, conspicuously more heterogenous regimes are followed in such RCTs, including a ‘syndrome’ or ‘pattern differentiation’ (Ch. bianzheng 辩证) modelled on TCM. Similarly, Good Manufacturing Practices (GMP) employed to produce industrialised Tibetan pharmaceuticals follow the TCM Rigpa. The latter designates primarily the living tradition as it is practised in the Himalayas by non-Tibetan ethnic groups, although Sowa Rigpa has also recently become a globalised umbrella term for Tibetan medicine more generally. See Craig and Gerke (forthcoming).


7 For a systematic review of RCTs with Tibetan medicine, here called ‘traditional Tibetan medicine (TTM) modelling the name on TCM conducted in Europe, see Reuter et al. 2013; and for China, see Luo et al. 2015.
drug regime and are often perceived as incompatible with Tibetan medical values of efficacy. These new producers, prescribers, and markets follow the global ‘scientific evidence’ and pharmaceutical research validation regimes; they have thus reconfigured what is considered efficacious and safe, legal, and legitimate in Tibetan medicine(s) even though most of their parameters are based on biomedicine. Such industrialised Tibetan medicines are, in turn, legalised by national (globalised) drug regulations and laws.

Together with national regulatory regimes and the ever-growing, global wellness market these ‘pharmacoscapes’, as I argue in this paper, at the same time reinforce the marginalisation and, one could add, the making dispensable of the formula-producing and/or individually prescribing physician of Tibetan medicine, known as amchi (Tib. mchi) or menpa (Tib. sman pa) and of his personal localised knowledge. Those who still have learnt how to produce Tibetan formulas on their own from their teachers in so-called teacher-student lineages, menpa gyüpa (Tib. sman pa rgyud pa), are classically trained TM physicians and mostly senior menpa or amchi. They use their skilled sensory abilities based on the five elements—water, earth, fire, air, space—that manifest not only in the environment but specifically in plants and the human body. While I will explain the principles of the classical formulation regime later on, it is important to note that physician-cum-pharmacists are personally known and highly esteemed by colleagues and patients for producing effective medicines; in fact, their renown is often based on this. Institutionalised education, in contrast, tends to separate and specialise training in Tibetan medicine in either physician or pharmacist training, thereby decoupling skills that are important for a fine-grained prescription practice.

In contrast to the knowledge and experience for making medicines that are located in the personal skills of the TM physician, industrialised Tibetan pharmaceuticals locate and encapsulate an objectified ‘scientific’ knowledge

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8 See, in particular, Saxer 2012. For critical social science studies on GMP in Tibetan medicine, see Craig 2011b; Craig 2012, pp. 146–82; Saxer 2013, pp. 59–94. On challenges in undertaking cross-cultural clinical trials research with Tibetan medicines, see Adams et al. 2005.

9 Based on Appadurai’s (1990) definition of ‘(land)scapes’, I use the term ‘pharmacoscapes’ describing the specific professional and social networks of sourcing, distribution, and circulation built up by pharmaceutical companies that produce Tibetan pharmaceuticals, sponsor clinical research of their products, as well as target niche alternative markets of potential clients, i.e. mainly biomedically trained physicians, CAM, or TCM hospitals, patients looking for alternative ‘side-effect-free’ medicines, consumers of ‘wellness’, and so forth.

10 Cf. Schrempf 2007 on lineage physicians-cum-pharmacists in Nagchu (TAR).
within the materiality of the industrialised formula per se. It seems to embody ‘the best’ of both Tibetan and bio-medicine, i.e. bioscientifically valorised efficacy and safety based on the ‘traditional’ efficacy of Tibetan formulas tested to heal internationally and biomedically defined diseases.\textsuperscript{11} The scientisation of the formulas enables and legalises the producers of Tibetan pharmaceuticals to commercialise them in larger medical fields of biomedicine, CAM, or even TCM settings in China or Europe.

In Europe, and increasingly so in China as well, private physicians-cum-pharmacists of Tibetan medicine have to find innovative ways in order to ensure that they can continue to produce their own formulas or have access to those which they trust to be produced in such a way as to ensure their maximum efficacy and safety. In contrast to the pharmaceuticalisation of Tibetan and Asian medicines more generally, little attention has so far been paid to how these recent socio-political and economic developments have contributed to asymmetrical shifts in power, legitimacy, and legality in the diverse transnational landscapes in which Tibetan medicine is practised today.\textsuperscript{12} Little is also known on how these changes have impacted the production and prescription of classical Tibetan formulations directly or indirectly, as well as on therapeutic practices of Tibetan medicine more generally in both China and Europe.

In order to better understand these shifts from the perspectives of the different stakeholders involved, I examine and compare the production, prescription, and use of Tibetan medicines in situated contexts and in relation to their respective national regulatory regimes in China (specifically Tibetan-populated areas of Qinghai Province, known among Tibetans as Amdo) and Europe (Switzerland, Germany).\textsuperscript{13} Based on my multisited ethnography, this transnational macro-perspective consists in a heuristic model of three distinct formulation regimes that exist in parallel and partly in hybridised form—

\begin{itemize}
\item \textsuperscript{11} For the International Classification of Diseases-10 (ICD-10) set up by the WHO in 1990, see URL: <http://www.who.int/classifications/icd/en/>, last accessed 12 December 2015.
\item \textsuperscript{12} At present, Stephan Kloos’ collaborative research project funded by the European Research Council focuses on industrialised Tibetan pharmaceuticals in Asia, see URL: <http://www.ratimed.net>, accessed on 15 December 2015.
\item \textsuperscript{13} I am grateful to The Wellcome Trust for funding my research (2012–15) as part of the collaborative project ‘Beyond Tradition—Styles of Practice and Ways of Knowing in East Asian Medicine 1000 to Present’, located at the EASTmedicine Research Group, University of Westminster, London. My monograph on the topic is forthcoming (Schrempf forthcoming).
\end{itemize}
a ‘classical’, a ‘reformulated’, and a ‘polyherbal’—that I developed out of my fieldwork data.\textsuperscript{14}

This study is following up on the ‘materiality of drugs’ in the anthropology of pharmaceuticals focusing on Tibetan medicines.\textsuperscript{15} It has in particular profited from comprehensive academic work undertaken on transnational studies of Asian medical practices,\textsuperscript{16} the emergence of the Tibetan pharmaceutical industry in China and the ‘social ecologies’ in Tibetan medical practices, examining the multivalent practices of efficacy and safety, including issues surrounding GMP, in China, Nepal, Tibet (TAR), and Qinghai Province.\textsuperscript{17} The globalisation of Tibetan medicines has been directly addressed as a topic,\textsuperscript{18} as well as the multiple perspectives and practices of Tibetan medicine related to efficacy in the broadest sense, and to science and religion.\textsuperscript{19} Before I explain in more detail the different formulation regimes and who their major stakeholders are, I briefly outline the salient regulatory frameworks in both China and Europe that have shaped the way in which these formulations are produced in various ways.

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\textsuperscript{14} I used mainly participant observation and semi-structured interviews with producers and physicians of Tibetan medicine, as well as observations during several conferences where issues of efficacy and safety were discussed. Earlier fieldwork was funded within the framework of the collaborative research centre SFB 640 by the German Research Foundation (DFG). A separate fieldtrip was undertaken to India in 2014 conducting fieldwork with some small-scale producers of Tibetan medicines whose formulas are used in Europe. I thank all my informants for sharing their knowledge and time.


\textsuperscript{16} Zhan 2009.

\textsuperscript{17} Craig 2012; Saxer 2013.

\textsuperscript{18} See, in particular, Janes 2002; Craig and Adams 2008; Craig 2012, 2014; also Hofer 2014; Schwabl 2013.

\textsuperscript{19} Cf. Adams, Schrempf, and Craig 2011, (eds) 2011b; Adams 2002a, b; Adams, Le, and Dhondup 2010, 2011; Craig 2011a, 2012; Czaja, this volume.
supported ‘nationality medicine and pharmacy’ (Ch. minzu yiyao 民族医药)\(^{20}\) with the initial aim to provide primary health care to rural Tibetan areas.\(^ {21}\) Deng Xiaoping’s reforms opened up the possibility for physicians of Tibetan medicine who had survived the Cultural Revolution (1966–76) to be retrained as ‘barefoot doctors’ (Tib. rkang rjen sman pa) and learn some of the basics of Chinese biomedicine, such as giving injections for administering antibiotic drugs. The latter is still common practice in most Tibetan medicine clinics and hospitals.\(^ {22}\) TM physicians initially received small township posts and were thus integrated into local government health systems in Tibetan populated areas. Producing again their own classical formulas, often with the help of a growing number of students, was usually the only medicine available. Many of these physicians stayed in government health posts, while some opened private clinics.

From the early 1980s onwards, Tibetan medical hospitals with attached pharmaceutical departments were built up in Tibetan populated areas of China that started to use mechanised production techniques in order to cater to the growing demands of their patients. As Saxer argues, these were the first steps leading to industrialised Tibetan medicines in China.\(^ {23}\) At the same time, classically trained senior physicians became the teachers for a new generation of students of Tibetan medicine. Initial training courses based mainly on the Gyüshi were later incorporated into newly established Tibetan medical departments or schools as part of university medical school curricula. From the 1990s onwards, these were increasingly based on new textbooks. Also, national pharmacopoeias were produced to comply with state efforts to integrate Tibetan medicine and drugs, at times were rather hastily incorporated into Tibetan drug standards, with monographs on common ingredients and over 200 formulas. Also a provincial Qinghai pharmacopoeia was

\(^ {20}\) I thank Lena Springer for pointing out this literal translation of minzu yiyao. While the term connotes that a particular minority nationality has its own ethnic system of medical knowledge and practice it also clearly implies to be part of China’s culture and public health system. The present politics of China’s cultural heritage including Tibetan medicine clearly point into this direction.

\(^ {21}\) Cf. Janes 1995, 1999. For comparison, see Hsu 2009 on previous processes of standardisation and institutionalisation leading to the making of TCM in China that already began during the late 1950s.

\(^ {22}\) On the plurality and diversity of healing practices in Amdo, the Tibetan populated area of Qinghai Province, see Schrempf 2011.

\(^ {23}\) Saxer 2013, p. 35. For a detailed account on the development of a Tibetan pharmaceutical industry, see Saxer 2013, chapter 2, pp. 22–58.
created.\textsuperscript{24} About a decade later they were integrated into the \textit{Drugs Standards of the Ministry of Public Health of the People’s Republic of China} and the \textit{Pharmacopoeia of the People’s Republic of China}.\textsuperscript{25}

From the late 1990s onwards, and following the privatisation of public health services and the new food and drug policies on the production of medicines in China in 2001, the pharmaceutical industry of Tibetan medicines started to boom.\textsuperscript{26} An increasing ‘scientification’ and commodification of Tibetan medicines also began to impact the curricula and medical practices as taught in governmental TM schools and at hospitals, in particular the increasing professionalisation and thus separation of a training as physician and as pharmacist, happening in parallel to, and obviously catering to, the growth of private pharmaceutical enterprises and their markets needing specialised personnel.\textsuperscript{27} Several former pharmaceutical departments of hospitals of Tibetan medicine became private enterprises in Tibetan populated areas of China.

In Europe the 1960s witnessed the very beginnings of Tibetan medicine, following the first exodus of Tibetan refugees from India arriving in Switzerland, among them also some Tibetan physicians.\textsuperscript{28} While already a century earlier the physician family lineage Badmayev, originally from Buryatia, had opened up Europe’s first Tibetan medical clinic in St. Petersburg, it was the decisive encounter between Tsultrim Badma’s grand-nephew Dr Peter Badmayev and the Swiss pharmacist Karl Lutz who had a strong interest in Tibetan medicine that triggered the making of new Tibetan pharmaceuticals in Europe based on recipes from this Buryat physician lineage. After establishing an international study and research group in Zurich on Tibetan formulas using different classical Tibetan texts and sounding out their potential applications in the West including some trials with herbal pills among Swiss physicians, Karl Lutz founded the Padma AG in 1969. The first Tibetan pharmaceutical, Padma Lax, was registered with the Swiss drug regulation agency (today Swissmedic) in 1970, followed by the flagship formula Padma 28 seven years later.

\begin{thebibliography}{9}
\bibitem{} See \textit{Krung go’i sman mdzod} 2000; also SQTF 1992; see also Czaja and Schrempf (forthcoming).
\bibitem{} See Ministry of Health 1995; State Pharmacopoeia Commission (ed.) 2015.
\bibitem{} See SFDA 2001.
\bibitem{} On the complex encounters of Tibetan medicine and Chinese biomedicine, see Adams, Schrempf, and Craig (eds) 201b.
\bibitem{} At about the same time, in 1961, the Men-Tsee-Khang (today called the Tibetan Medical and Astro Institute) was founded in Dharamsala. On the beginnings and the development of Tibetan medicine in Indian exile, see Kloos 2010, 2013.
\end{thebibliography}
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later.29 Still, Padma had to develop an elaborate network of distribution pathways between cantonal, national and international borders in order to be able to distribute their products in Switzerland and beyond. Only from about the mid-1990s onwards were exile-Tibetan physicians able to establish their first clinics or schools in Europe.30 Nevertheless, and unlike TCM, until today Tibetan medicine lacks an officially acknowledged status as an Asian medical system in Europe. This has also consequences for the practice of Tibetan medicine.

An incisive regulatory law that affected the import of Asian medicines in 2001, the same year that China’s regulatory agencies employed the demand for GMP, was the European Union-directive 2001/83/EC. It was implemented by the European Parliament and the Council, requiring ‘traditional herbal medicinal products’ (THMP) to comply with globalised GMP quality standards and a scientific evaluation regarding efficacy and safety via clinical studies.31 Even though the later amendment of the EU directive 2004/24/EC has skipped these regulatory challenges, it insists on compound herbal formulas needing to be licenced by a Market Authorization (MA) or a Traditional Herbal Registration (THR). A THMP—strictly excluding metals and animal ingredients—is now required to demonstrate:

bibliographical or expert evidence to the effect that the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community.32

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31 URL: <http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf>, last accessed on 15 December 2015. See also Schwabl 2009 who points out that the definition of traditional herbal products is most likely following TCM phytotherapy via WHO definitions; see also Kadetz, this volume.
Schwabl and Vennos, working for and at the pharmaceutical company Padma AG, the sole producer of about 11 formulas of Tibetan medicines and dietary supplements in Europe, recommend to amend the strict rule of 15 years of documented use, since otherwise ‘European citizens will be excluded from access to high quality medical traditions with their accumulated empirical knowledge’. As Gerke points out, European legislation already impacts the production of Tibetan ‘dietary supplements’ and ‘health tonics’ in India, allowing for their access to the European market.

Private physicians—if they fully want to practice Tibetan medicine in Europe—usually find Tibetan medicines as produced by Padma AG too limited and also too expensive. On the other hand, the import of Tibetan classical compound formulas into the European Union from Asia remains a difficult issue. Physicians need to be innovative in their prescription practices, and how they access medicines due to shortage of classical formulas, and having to avoid border controls. Nevertheless, in the eyes of most practising TM physicians, no matter whether in Europe or in China, these medicines are a necessity for efficacious and safe healing. Their use also keeps the costs of medicines low for their patients and allows for their own small profit margin. In Europe, TM physicians now charge for their diagnostic skills which in many rural settings in Tibetan cultural areas were not remunerated. In the past and at present, however, classical formulations of Tibetan medicines build the very basis for the economic and professional survival of TM physicians.

In Europe classical Tibetan formulas circulate under the radar of EU regulations mainly within the personal therapeutic networks of some TM physicians with relation to both India (or Nepal) and Europe. The one notable exception is the certification of physicians of Tibetan Medicine under the regulations of EHTPA (European Herbal Traditional Practitioners Association) in the UK. It allows physicians trained in Asia to practise prescribing herbal formulas that, following TCM-modalities, need to be imported as quality-controlled single ingredients that are compounded at the time of consultation for each patient.

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33 Schwabl and Vennos 2015, p. 108.
34 The UK allows herbal products from the Men-Tsee-Khang in Dharamsala to be imported; see Gerke 2012. Tibetan Therapeutics is a London-based outlet of their Sorig Tibetan Health Products, see URL: <http://www.tibetan-therapeutics.com>, last accessed on 15 December 2015.
Transnational Formulation Regimes in China and Europe

Moving on from nationally specific regulatory regimes, we broaden our view to transnational and analytic domains. I distinguish between three distinct formulation regimes—a ‘classical’, a ‘reformulated’, and a ‘polyherbal’. These three formulation regimes are often hybridised and reconfigured in, as well as circulated through, distinct social networks of producers, distributors, physicians, and patients in both China and Europe and at different scales. To illustrate this, in the diagram above (Fig. 1) I have used vector-type arrows indicating both the relative coherence as well as dynamic flexibility of Tibetan medical production, prescription, and use practices that are ongoing in and between these three formulation regimes. These formulation regimes are conceptualised both as analytical tools and as major orientations for practices in which specific epistemes of efficacy and safety prevail and thus will structure this paper.

They serve as primary orientations in relation to the production, prescription and use of Tibetan medicines involving different groups of actors and a range of dynamic practices that co-exist in various forms. While classical formulations are the foundation of the other regimes, the primary tension, as I argue in this paper, lies between the two major orientations—the classical and the industrialised reformulation regime. The various actors involved in these formulation regimes orient themselves primarily towards culturally distinct sources and values of authenticity, legitimation, and trust that hinge on predominant values of
efficacy and safety produced and reiterated through these regimes. The third regime, the polyherbal, is a conjoint hybrid with either the classical or the industrialised reformulation as primary orientation.

The classical formulation regime is neither a uniform practice nor a thing of the past. It is (and always was) dynamic and needs to be adapted to local environments, availability of formula ingredients and, in modern times, also to changing regulations. It remains the primary orientation among physicians trained in Tibetan medicine following the fundamental principles of their living tradition. The classical formulation regime also shows the strongest continuity with those premodern practice environments that we know have existed within living memory, as well as how they used to be before the Cultural Revolution in China. I agree with Blaikie that we must critically assess the ‘classical’ as a heterogeneous and fluid, rather than homogenous, category and stress its dynamic character. Yet, as I argue, the classical formulation regime coalesces as a rather coherent practice, one based upon Tibetan medical principles with particular actors, practices, and identities attached to it and characterised by predominant sets of epistemic values of efficacy and safety that are very different from the industrialised regime. The classical formulation also builds the very basis for the professional and economic survival of physicians fully trained in Tibetan medicine and the Tibetan medical system at large, as I will demonstrate.

The reformulation regime, in contrast, is employed by a very different set of actors—pharmaceutical factories, mainly physicians trained in biomedicine, CAM, or TCM, and targeted consumer markets of an alternative medicine. This regime is built upon what Pordié and Gaudillière have coined a ‘reformulation’ for ayurvedic pharmaceuticals in India, defining it as being based on ‘what its actors call “reverse engineering”’. They describe innovative ways by which the ayurvedic herbal industry transforms ‘shastric’ (or classic) polyherbal formulas for massproduction according to GMP, and for targeting biomedical disease categories conforming to the pharmaceutical market. I adopt their term for the reformulation regime of industrialised Tibetan pharmaceuticals that are produced in China and in Europe because they conform pretty much

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36 Blaikie 2015.
37 Pordié and Gaudillière 2014a, p. 59.
38 ‘[…T]his regime consists in reformulating and simplifying ayurvedic medicinal compositions in order to create new “traditional” drugs for the biomedical disorders of an international as well as Indian clientele with a holistic claim’, Ibid.
to the same set of globalised regulations.\textsuperscript{39} In Europe, however, the regime is much more strictly implemented, and not only includes GMP but generally ‘good practice’ standards.\textsuperscript{40}

Also, the outcomes of clinical studies, including RCTs, conducted in China for validating efficacy and safety of Tibetan pharmaceuticals are often not verifiable or useful.\textsuperscript{41} More than half of the RCTs carried out to test Tibetan industrialised patent medicines were conducted in China’s biomedical hospitals, while only 22.9% were undertaken in Tibetan medical hospitals. Biomedical disease categories, such as diabetes, or simple symptoms, were mainly used as indication factors, supplemented by some ‘traditional Tibetan medicine’ (TTM), as well as TCM ‘syndromes’ or ‘pattern differentiation’.\textsuperscript{42}

Also slightly opaque is the fact that, even though patent or branded Tibetan medicines fall under the category of ‘Chinese new herbal medicines’,\textsuperscript{43} this merely seems to be an official statement following the nationally adapted category of ‘traditional medicines’ influenced by the WHO definition.\textsuperscript{44} Moreover, in China and among physicians of Tibetan medicine, the famous ‘jewel pills’ or rinchen rilbu (Tib. rin chen ril bu) are highly esteemed as being the most effective Tibetan formulas. Despite the fact that they contain ‘purified mercury’ tso-tel that is excluded as heavy metal or toxic material in the Pharmacopoeia of the People’s Republic of China, they are also produced as industrialised patent medicines. This demonstrates one of several blind spots that in this case are covered under the label ‘national heritage drugs’.\textsuperscript{45} Also, animal ingredients characteristic of the Tibetan Plateau ecology are excluded from this official Pharmacopoeia, yet in several classical Tibetan formulas they are important and used because of their special efficacy, as I will show below in the case of musk. Animal ingredients are generally maintained within both classical and reformulated formulations in China. Therefore, and in contrast to Pordié and Gaudillière’s definition, I separate the industrialised reformulation from the polyherbal regime.

\textsuperscript{39} While Tibetan medicines in India are not part of my research focus, it is noteworthy that in India a Tibetan pharmaceutical industry is only very slowly emerging, cf. Blaikie 2015.

\textsuperscript{40} For details, see Schwabl 2009.

\textsuperscript{41} Cf. Luo et al. 2015. Cf. also Craig 2011b.

\textsuperscript{42} Ibid., p. 453.

\textsuperscript{43} Ibid., referring to Zheng 2002.

\textsuperscript{44} Cf. World Health Organization 2005; Schwabl 2009; see also Kadetz, this volume, on the confluence of WHO and TCM definitions.

\textsuperscript{45} Cf. State Pharmacopoeia Commission (ed.) 2015; Saxer 2013, p. 71ff. Ironically, in Europe jewel pills are perceived as being poisonous according to bioscientific standards of safety since they contain some form of mercury, cf. Gerke 2013a.
Thus, the third polyherbal regime primarily concerns the exclusive use of usually at least five different herbal ingredients. It is slightly different in character from the two other major regimes because it is primarily oriented towards the ingredients being only herbs and some minerals. The polyherbal regime is a hybrid *per se*, one that merges either with the classical multipharmaceutical formulation into formulas that are produced and prescribed by physicians of Tibetan medicine in India and in Europe,\(^{46}\) or that merges with the reformulation regime being produced as a multipharmaceutical, such as the Tibetan medicines and supplements produced by the Padma AG in Switzerland for Europe.\(^ {47}\)

Concerning the polyherbal regime, I adapted Naraindas’ analysis of a creole formulary logic of herbal ayurvedic pharmaceuticals in India to my transnational material in a different way. He distinguishes between three forms of logic that are hybridised in specific ways—a ‘biomedical formulary’, that is based on an active ingredient (or the synthesis of several) and a specific (biomedical) cause of disease, the multipharmaceutical ‘polyherbal formulary’ of the West with an underlying biomedical nosology, and the ‘ayurvedic formulary’ based on the classical shastra literature.\(^ {48}\) However, rather than separating the biomedical from the classical (or shastric) as a distinct form of an industrialised ayurvedic formulary logic, I understand the three formulation regimes of Tibetan medicines in the contexts of China and Europe as transnational orientations driven by particular actors, and in which different epistemic values of efficacy and safety as well as medical principles are in use. At the same time biomedical and Tibetan medical notions and practices are negotiated in each of these regimes in specific ways.

In Europe, herbal medicines have a long history of traditional therapeutic use. According to the European directives following WHO-regulatory regimes of ‘traditional medicines’ they should only contain herbs. Furthermore, CITES-regulations to protect endangered animal and plant species\(^ {49}\) are strictly

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\(^{46}\) I have included pharmacists producing Tibetan medicines in India in this study, because their medicines play a crucial role in the treatment of Western patients in Europe.

\(^{47}\) I am excluding here teas and ‘vitalising dietary supplements’ produced by the Men-Tsee-Khang in India for export to Europe.

\(^{48}\) Naraindas defines shastra (Skt. *śāstra*) in the context of Ayurveda as the classical ‘science of formulating drugs’ based on the principles of the ‘five elements’ (Skt. *panca mahābhūta*), the three ‘humours’ (Skt. *doṣa*) and the seven ‘tissues’ (Skt. *dhātu*), as well as on their applications. See Narinadas 2014, p. 13.

\(^{49}\) CITES or Convention on International Trade in Endangered Species of Wild Fauna and Flora is an international treaty that aims at preventing overexploitation and regulating international trade in endangered species listed in the convention.
followed in Europe, reinforced by rigorous documentation of sourcing and enforced legal penalties. In India, these regulations are known and applied to classical formulations by mostly exile-Tibetan physicians and/or pharmacists within the context of the Tibetan Medical and Astro Institute (TMAI) in Dharamsala, better known as the Men-Tsee-Khang. However, because Tibetan medicines are not yet produced as industrialised pharmaceuticals following GMP in India, the extent to which these regulations are actually followed and by whom remains to be researched.

The two major formulation regimes, the classical and the reformulated, also have the tendency to evoke as well as reiterate what Ian Hacking has defined as a ‘style of practice’.50 I differentiate between two major styles of practice in close relation to the classical and reformulated regimes, respectively. The first is a sensory based, personalised, complex diagnostic and prescription style following the fundamental principles of Tibetan medicine as defined in the classical formulation regime, and according to the constitution and imbalance of the ‘bodily dynamics’ nyépa (Tib. nyes pa) of each individual patient. The second is a one-formula disease-centred style, centring on one particular formula produced by pharmaceutical companies with standardised biotechnologies, and tested to target and cure a specific, usually biomedically defined disease.51 Interestingly, both styles are also found with regard to the application of certain formulas in historical Tibetan medical texts. For example, specific formulas for treating wounds or particular organs, such as eye medicines, are administered beyond a specific patient’s imbalance.52

50 The notion of ‘styles of practice’ is based on ‘styles of scientific thinking and doing’ as defined by Hacking 2010, 2012. It is applied here as a general analytical approach to understanding two major ‘styles of practice’ in Tibetan medicine, i.e. in the sense of ways of reasoning that we call ‘scientific’ and encompassing both biomedical and Tibetan medical principles and practice and understandings of the body; cf. Hacking 2010, p. 235. They are self-authenticating, emerging with new objects and truth claims.

51 The reason why I do not define the second style as always being biomedically oriented is that some classically formulated formulas, as produced, for example, by the Gartse monastery clinic in Rebgong (see Nianggajia, this volume), are labelled with indications in specifically Tibetan medical and Chinese medical disease categories, rather than biomedically ones. Such formulas are not produced according to GMP either, yet they target specific vernacular symptoms and diseases surrounding stomach and digestive disorders. It appears that in the case just cited, the disease orientation for producing an effective digestive medicine for a locally common disease was specifically oriented to the local market in order to increase the sales among a specific multiethnic clientele.

52 I thank Olaf Czaja for pointing this out, personal communication July 25, 2015.
The Classical Formulation Regime

The classical formulation regime is clearly characterised by the fundamental Tibetan medical principle of five elements (Tib. byung ba lnga) that make up all phenomena in the universe. As expounded in the Tibetan classical medical text, the Gyūshi, the five elements manifest in plants and other materia medica as the ‘six tastes’ (Tib. ro drug), the ‘eight potencies’ (Tib. nus pa brgyad), and the ‘three post-digestive tastes’ (Tib. zhu rjes gsum) as well as the 17 ‘attributes’ (Tib. yon tan bcu bdun). These criteria are used for identifying single materia medica and compounding medicines. The five elements also make up the ‘three bodily dynamics’ or ‘three faults’ nyépa sum (Tib. nyes pa gsum) in the human body. Together, taste, potency, and post-digestive taste constitute the ‘benefit of effect’ (Tib. phan nus) for the overall efficacy of a specific formula.

The Fourth or Subsequent Tantra (Phyi ma’i rgyud) of the Gyūshi clearly describes taste as the central sense for evaluating the material efficacy of raw medicinals, in order to validate their maximum ‘natural potency’ (Tib. ro nus). This means learning how to utilise the senses—taste, touch, smell, hearing, and vision—for differentiating and recognising the material quality and efficacy of materia medica (Tib. rdzas gyi nus pa). This is combined with the ability to diagnose the patient’s disease and underlaying individual imbalances via pulse, urine, and visual check-up, including investigation by questioning the patient on the onset and development of the disease. The classical formulation regime therefore implies a sensory-based, personalised prescription style.

The natural potency of medicinal plants that are either imported from Himalayan, Indian, and Chinese environments, or growing in the wild on the Tibetan Plateau, is dependent upon the so-called ‘seven limbs’ (Tib. yan lag bdun) used as the traditional gold standard for ensuring their efficacy and safety. Knowing when and where to collect the most potent plants, which part of the plant should be used, how to collect, clean, detoxify, and store them properly, as well as knowing how to compound them for individual patients,
constitutes the art by which a medicine-producing physician personally ensures efficacy and safety.

The physician-pharmacist stands in the centre of the classical formulation regime of Tibetan medicine. Efficacy and safety are primarily connected within the physician’s knowledge and experience in diagnosing and prescribing, and also compounding medicines in a personalised style. While I have so far focused on the materiality of drugs, their efficacy extends of course into the immaterial sphere as well. Additional sources of efficacy in the classical formulation can include tantric ritual empowerment of medicines mendrub (Tib. sman grub). For example, small quantities of formerly blessed medicines are used for empowering new medicine production, and
these embody a physician-cum-pharmacist’s lineage. Even within modern medical institutions, such as Tibetan medicine hospital pharmacies, where such practices are out of place on a formal level, senior physicians ensure, if necessary through private practice, the ritual empowerment of medicines used to treat their patients more efficiently. Among physicians of Tibetan medicine and their patients, these empowered medicines are perceived of as the only ‘true’ (Tib. ngo ma) ones in the sense of them being authentic and more efficacious. They are often juxtaposed with industrialised pharmaceuticals that are—depending upon the producer—perceived of as being ‘fake’ (Tib. rdzun ma) by comparison.

To illustrate the classical formulation regime and its relation to these fundamental principles, I now offer three ethnographic examples from Amdo, Qinghai Province. Already back in 2005, Ani Khandroma, a petite and delicate-looking, yet very energetic and self-assured 68-year-old female physician of Tibetan medicine from Amdo, felt the deep rift widening between what she called ‘old’ and ‘new’ practices. She was a famous tantric chö (Tib. gcod) practitioner, and had learnt Tibetan medicine back in the 1950s directly within a personal master-disciple apprenticeship in her home place of Rebgong (Tib. Reb gong, Ch. Tongren 同仁), a local centre of Tibetan medicine in Amdo. After the Cultural Revolution, she was able to continue her practice again, and succeeded in building up a specialised private clinic for women’s diseases—her

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56 Blaikie 2014, pp. 293ff. On empowerment rituals, see Craig 2014, and Czaja, this volume.
57 Saxer 2013 speaks here of a moral economy of Tibetanness where ethnically Tibetan owners of pharmaceutical factories are still perceived as more legitimate than Chinese. Since Saxer’s fieldwork with producers of Tibetan pharmaceuticals in China, shareholder ownership of several of these pharmaceutical companies has changed, in particular the Arura Medicine factory in Xining, Qinghai Province, has been owned for the past three years by a Chinese majority, which was perceived as very disappointing by many Tibetans I spoke with. In contrast, Jigme Phuntsok’s pharmaceuticals were less criticised and believed to be more authentic. On the Qinghai Jiumei Tibetan Medical Co. Ltd. (Ch. Qinghai Jiumei zangyao yaoye youxian gongsi 青海久美藏藥業有限公司), see Saxer 2013.
58 On a bifurcated view of reality into ‘real’ and ‘fake’ among Tibetans living in China, see Schrempf 2008, p. 131.
59 Rebgong is both a county and a county town, as well as the prefectural capital of the Malho Tibetan Autonomous Prefecture (Tib. Rma lho bod rigs rang skyong khul; Ch. Huangnan zangzu zizhizhou 黄南藏族自治州).
60 Ani Khandroma was said to be a reincarnation of a female enlightened being, a so-called ‘sky goer’ or khandroma (Tib. mkha’ ’gro ma) from Labrang Monastery (Tib. Bla brang bkra shis ’khyil, Ch. Labuleng si 拉卜楞寺) in Xiahe County (Ch. 夏河县) Gansu Province, and was very respected and revered within the Tibetan community. On Rebgong as a local hub of Tibetan medicine in Amdo, see Nianggajia, this volume.
main field of expertise—with medicinal baths near Chabcha (Tib. Chab cha cha, Ch. Gonghe 共和). With an awe-inspiring, slightly intimidating, and matter-of-fact manner of speaking, she was determined to tell me first what she thought of contemporary Tibetan medical practice in Qinghai: ‘It’s all modern these days. Even in private clinics of Tibetan medicine, they practise the modern way.’ She elaborated:

In the (old) days, medical knowledge was different—lots of seeds and leaves were dried separately in the sun. There were no students, and no hospital. The ‘modern way’ is too fast, too big, and not careful enough. Yet, everything is medicine—it just depends on the quality, and the amount and the sequence of mixing—like cooking, really. This is the old way; it is basically not practised anymore.

She pointed out that these old ways of knowledge were the most effective, something many private physicians of Tibetan medicine also stressed during my enquiries. For example, in the past physicians would only administer enough medicine for three days. If the patient was not better by then they were convinced they could not treat the patient, implying that their medicines were so strong and effective that of course they should have healed the patient within that time.

Ani Khandroma used to produce her own medicines until 1958. This was the most decisive year of twentieth-century history in the lives of Amdo Tibetans, the threshold that sharply divided the ‘old’ Tibetan society from the ‘new’ one that was strongly influenced by Chinese modernity. Ani Khandroma continued:

61 Located in the Tsolho Tibetan Autonomous Prefecture (Tib. Mtsho lho bod rigs rang skyong khul, Ch. Hainan 海南藏族自治州) of Qinghai Province. When I met Ani Khandroma during 2005 in a small apartment in Xining where she occasionally stayed, she was planning to build another clinic at the shore of Tsongonpo alias Lake Kokonor or Qinghai Hu. She sadly passed away in April 2010. Shortly after, her beloved project of building up a clinic at the shore of Lake Kokonor was dismissed and the initial buildings were torn down, allegedly because of a newly declared law on ‘nature preservation’ in this area; cf. the NGO report by Schweiger (URL: http://www.asia-ngo.de/pdf/ReiseAmdo2010.pdf, last accessed 24 November 2015).

62 As she explained, she meant the quantity and number of college students, size of schools, and hospitals, and the sheer scale of Tibetan medicine factories in big cities, such as Xining.

63 Personal communication in Xining, 25 August 2005. I thank my interlocutor at the time, Lhamo Drolma.
It is also important to know how to clean the medicinal ingredients properly, how to dry and store them, such as knowing whether to put them into a wooden container or into an animal skin pouch—which has a different effect. All this knowledge is gone these days.

She reaffirmed that she kept her ‘women’s medicines’ in special animal skin pouches, which are the best for this purpose (see also Fig. 2).\(^64\) Interrupting her explanations all of a sudden, and with a challenging look on her face, she asked me what seemed to be a leading question, ‘What do you think is the most important thing in healing, the right diagnosis or the right medicine?’ I answered diplomatically that I think both would be important, but she interjected, ‘No, no, to diagnose correctly is the most important! You can heal in so many ways, even without medicines. Yet without the right diagnosis, medicine is useless and can even be harmful’. Ani Khandroma’s statement made me think that this kind of endangered knowledge might capture the actual core of any kind of efficacy and safety in healing.

Change of scene. Moving out of Xining and travelling through rural Amdo, the area of Qinghai Province where Tibetan nomadic and farming communities live on the Tibetan Plateau, I also met a locally well-known, private physician who still handcrafted his own medicines. Based on his own experience and that of his patients, he stressed the importance of ‘true’ or ‘real’ efficacy:

I will give you an example. Patients come to me and claim that Tibetan medicine does not work. Of course that is not true in general. They show me the medicines they purchased and were taking, and I check them by tasting them. Factory-produced Agar 35 is never as effective as when I produce it myself—the factory owners cut corners where they can, so will not use the most potent, rare but also expensive best quality of *ar nag*.\(^65\) They will substitute it with another cheap ingredient or won’t even realise that they bought a ‘fake’ ingredient.\(^66\)

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\(^64\) Next to deer skin, deer blood, and musk as well as bear’s gall bladder, and in general, wild animal blood and flesh are said to be of particular importance for healing women’s diseases (Tib. *mo nad*) of which the Gyüshi enumerates about 60 specific kinds.

\(^65\) *Ar nag* is the most potent form of eaglewood, and usually identified as *Aquilaria agallocha* Roxb, a dark, heavy, and densely resinous and fragrant hardwood that is more costly than other forms of *Aquilaria* used by the pharmaceutical department in Xining, for example.

\(^66\) Agar 35 should contain a blackish and oily type of eaglewood, the most potent version of *ar nag* or *Aquilaria agallocha* Roxb. This is a common formula frequently used in both China and in Europe for general relaxation, better sleep, and less anxiety. However, as local TM physicians stated, and reconfirmed by the medical botanist Christine Leon from Kew Gardens...
This local physician from a nomadic area was renowned for producing very efficacious medicines for his patients at a small rural clinic, where he kept his compounded powders safe in glass bottles on shelves. Some of his pills were packaged but only to ensure that they would not dry out. The local county government had asked him to move to the county town and into a local hospital of Tibetan medicine, in order to attract patients and make the place more popular. However, he did not want to move away from his own home and clinic, yet in the end had to comply. Nevertheless, he was able to bargain for a deal that in London, there are many adulterations of eaglewood because it is rare and expensive, as well as being listed in CITES as an endangered species (personal communication with Christine Leon during a workshop on ‘Developing an Interdisciplinary and Multilingual Digital Knowledge Base on Tibetan Medical Formulas with a Focus on Stress-related (r lung) Disorders’, EASTmedicine Research Group, University of Westminster, London, May 8, 2015); URL: <https://www.westminster.ac.uk/news-and-events/news/2015/eastmedicine-international-workshop-0>, last accessed 15 December 2015.

67 He kept them, however, locked away, fearing unexpected food and drug safety controls that already once before had forced him to close his clinic down in 2003.
allowed him to keep his private clinic (that otherwise would have been closed down if he had not consented) and occasionally work at the county hospital. Such recruiting is a practice often used by hospitals, at times even by Peoples’ Hospitals, which shows the social importance of locally known and trusted senior physicians of Tibetan medicine for attracting patients.

Another example of using the classical formulation regime was found in a large and innovative government institution, the Tibetan Medicine Hospital of Qinghai Province (Tib. Mtsho sngon zhi chen khang; Ch. Qinghai sheng zangyiyuan 青海省藏医院) in Xining City (西宁市), which below I will refer to simply as the Qinghai Tibetan Hospital. It is considered number one among ‘seven most productive study centres’ of Tibetan medicine in China.68 Founded in 1983, the Qinghai Tibetan Hospital includes biotechnological diagnostic features and a general organisation into specialised departments similar to a biomedical hospital. It maintains Good Clinical Practices (GCP) standards, being the only hospital in Qinghai with such a high status. Somewhat ironically, the Qinghai Tibetan Hospital mainly conducts clinical research and studies on biomedical and TCM drugs, rather than Tibetan pharmaceuticals.69 Only very few studies at this institution were able to examine the efficacy of classical Tibetan formula because they lacked both the interest and money of large pharmaceutical factories usually sponsoring such studies.

Despite all these modern biotechnological influences, Qinghai Tibetan Hospital has a pharmaceutical department that is primarily oriented towards the classical formulation regime.70 This department prides itself on being based upon lineage knowledge. This is due to its co-founder, the 84 year-old Dr Nyima, the most famous senior physician at the Qinghai Tibetan Hospital.71 Over the years, he had built up this pharmaceutical department on the basis of

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68 Luo et al. 2015, p. 453.
69 See Craig 2012, p. 57.
70 One should point out that ultimately, it depends on the preference and personal style of a physician whether and how biotechnogical and Tibetan medical principles are hybridised in practice and on a case-to-case study.
71 On the biography of Akhe Nyima (Tib. A khu Nyi ma; ‘Uncle Nyima’) who holds the highest Tibetan medical degree of menpa bumrampa (Tib. sman pa ‘bum rams pa), see URL: <http://arurahp.com/tibetan/?p=341>, last accessed 15 December 2015; see also Craig 2012, pp. 66–70. Among famous teaching physicians of Tibetan medicine, their personal knowledge, lineage authority, and legitimacy is embodied within the knowledge of compounding and recipes of certain Tibetan formulas. For example, the famous scholar-physician-teach Khyenrab Norbu (Mkhyen rab nor bu, 1883–1962) taught the practice of tsotel to many TM physicians, and is used by many physicians of Tibetan medicine refer to
his personal knowledge in *materia medica* and formula production. Dr Nyima still personally tastes the quality of all the medical ingredients that arrive at the hospital’s pharmaceutical department, in order to check their quality and potency. He was also recently awarded the title of a knowledge holder of an intangible cultural heritage item of Tibetan medicine known as *sertel* (Tib. *gser thal*), a specific efficacy-enhancing practice employed for making certain jewel pills. In fact, the pharmaceutical company Arura Tibetan Medicine Co. Ltd. (Ch. Qinghai Jinge yao gufen youxian gongsi 青海金诃藏药股份有限公司), that had evolved out of the pharmaceutical department of the Qinghai Tibetan Hospital, and that produces reformulated Tibetan medicines, had applied for his acknowledgment.72

Pharmacists at the respective Qinghai Tibetan Hospital department proudly refer to Dr Nyima as the ultimate authority and perceive themselves as followers of his lineage. Dr Nyima still practises as a physician three days a week, diagnosing and treating on average more than 60 patients per day. He is also often addressed by younger or less experienced physicians at the hospital, as a last resort for helping to treat difficult cases. Dr Nyima’s unique knowledge is based on his immense experience of many decades treating thousands of patients. He also possesses the unique skill of adjusting formulas via *kha tshar*, a specially potent and efficacious practice that uses the ‘add-on’ of a single ingredient to an established base formula. Such add-ons can target a specific organ, for example, the cooling effect of *gur gum* (*L. Crocus sativus*) targets both heat and liver in ‘hot’ liver disorders. It is also used as an add-on together with the digestive base formula Sendu 4, which thus becomes Sendu Dragne, which is suitable to warm the stomach and kidneys, but at the same time does not overheat an (already ‘hot’) liver.73 If several prescribed formulas share the same ingredient(s), this can increase their specific potency, but also increase their effects too much. For these cumulative effects to be balanced properly, the physician must compound his own formula in powder form, and know the exact dosage of each single ingredient within a set formula, in order to increase or decrease the dosage of a single ingredient precisely. Only a few

72 Personal communication with Akhe Nyima via Tsering Namgyal, 20 April 2016.
73 As I was told many times by private physicians, hot liver-related problems due to an excess of ‘bile’ are very common among Tibetan patients in Amdo and China, who tend to consume, next to too much meat and dairy products, also too much oily food and hot chillies from the Chinese kitchen. See also Bassini 2013; Nianggajia, this volume.
senior physicians of Tibetan medicine, such as Dr Nyima, still know how to do this properly.

To ensure the highest efficacy of treatment in more difficult patient cases, a complex style of prescription practice is used at the in-patient ward of the Qinghai Tibetan Hospital in Xining. In those cases, at least five different formulas are usually prescribed five times a day. Adjustment of dosage and medicines, if necessary, is undertaken based upon regular daily checks of pulse and urine, the dosage or type of formula being adjusted accordingly. Patient record keeping (Tib. nad tho) is meticulously maintained, as required of a government hospital. Some of it was written in Tibetan where pulse and urine diagnosis and Tibetan formulas were concerned, while technoscientific diagnostics, including blood tests, were written in Chinese. In the out-patient ward, patients would bring small patient booklets with them into which Tibetan formula names were written in Tibetan cursive script by Dr Nyima, while an assistant would type these Tibetan formula names into a computer that automatically translated them into Chinese drug names. Clearly, there are a wide range of practices adapted to a ‘Tibetan way of doing science’, each incorporated into what I call the classical formulation regime which constitutes the main framework in this example.

**Hybrid Classical-Polyherbal Formulations**

The ‘classical-polyherbal’ formulation is an important hybrid formulation based on very similar classical principles of Tibetan medicine for evaluating and ensuring efficacy and safety—yet with one crucial difference to those described above in that it completely excludes all use of animal products. This hybrid type of formulation among Tibetan medicines is mainly found in Europe and India. Polyherbal formulations have come to play an important role in meeting European and Indian patients’ dietary requirements, as well as their ethical and conservationist concerns. The main actors producing it are exiled Tibetan physicians-cum-pharmacists from India, some of whom also practise in Europe or whose products circulate in transnational therapeutic networks between the two regions.

Although the Gyüshi does mention polyherbal formulations, historically Tibetan formulas based exclusively upon medicinal herbs (Tib. sngo sbyor) appear to have been rather limited to specific localities and their ecologies, and limited or no access to crucial animal ingredients. Blakie reports that, mainly for pragmatic and economic reasons, until the late 1970s some Ladakhi physicians who were still trained within family lineages used simple, locally available

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74 Adams, Le, and Dhondup 2011.
herbal ingredients and recipes inherited from their forefathers. More recently among exiled Tibetans in India, these classical-polyherbal formulations have become related to ethical concerns. In 2004, the pharmaceutical department of the Tibetan Medical and Astro Institute (TMAI) in Dharamsala, India, better known as Men-Tsee-Khang, officially stopped using animal products at the behest of the Dalai Lama. Additionally, there are quite a considerable number of vegetarians among Indian and Western patients of Tibetan medicine. Thus, for ethical reasons formulas were adapted by substituting animal with plant ingredients of similar potency based upon the classical ‘taste’ ro criteria.

Conservationist concerns regarding CITES-listed endangered species were also taken up as necessary changes to be followed. The tradition of ahimsa or ‘non-violence’, that some Hindus and Buddhists have aligned themselves to, conveniently converges here with dietary and conservationist concerns, as well as with the WHO’s definition of ‘traditional medicine’. The polyherbal regime also feeds into the ‘alternative’ modern sensitivities and consumerism of a global health-conscious urban elite concerned with lifestyle and disease-prevention by consuming health promoting, and at best vegan, ‘slow foods’, and dietary supplements including Asian herbal medicines.

Nevertheless, as many physicians whom I had interviewed repeatedly stressed, due to the highly effective potency of certain animal ingredients, some are impossible to substitute. Not all TM physicians agree with compromising efficacy for reasons of ethics. The formula Agar 35, for example, contains musk or latsi (Tib. gla rtsi) in its classical formulation, and it is one of the most prescribed formulas in both Asia and Europe. The most potent and efficacious musk, however, comes from the wild musk deer (Tib. gla ba). Physicians of Tibetan medicine whom I have interviewed on this topic stressed conjointly that the potency and efficacy of wild musk is unsurpassed and that there is nothing more effective for treating inflammation. Thus, the farmed musk extracted from sedated animals produced by certain pharmaceutical companies in China, and which both government-run Tibetan hospital pharmacies and pharmaceutical factories in China are officially permitted to use, is not considered an equivalent substitution. This is an open secret among

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76 Ibid.
77 Personal communication with a physician-pharmacist of Tibetan medicine from India, Dharamsala, 4 November 2014.
78 Additionally, there is much fake musk in circulation, and the ‘real’ wild substance is difficult to access and expensive, thus physicians are very secretive about where they source their musk from.
TM physicians in both Asia and Europe, but one not freely talked about due to conservation policies and ethical concerns.

When I asked a senior TM physician from Amdo about polyherbal formulas, he laughed spontaneously, and said that such formulations would only be those used among poor farmer physicians who did not have the means to buy the very potent and also expensive animal ingredients (such as musk and bear bile) for making medicines. This echoes Blakie’s findings in Ladakh cited above and those by Craig in Nepal who also found a strong consonance expressed on amchi between ‘wildness’ and high potency of plants (and animals) more generally. In contrast to this statement, a senior TM physician from Indian exile was very upset when I even dared to question that the polyherbal formulation regime (presently practised) had ever been different in the past, and she denied outright the fact that classical Tibetan formulas can and do include animal ingredients. Clearly, experience, regulations, and ideology all play a role in formulation regimes, and constitute aspects of a physician’s medical and cultural-cum-ethical identity.

In Europe, the late Akong Rinpoche, a famous Tibetan lama-physician from Kham, who had promoted Tibetan medicine within the UK as well as in his homeland for several decades, had specifically ordered the production of quality-controlled, polyherbal Tibetan medicines manufactured in Xining for consumption by Western patients in his Tara Clinics in the UK. The formulas used for this followed a little known formulary booklet written by the famous scholar Ju Mipham Jamyang Namgyal Gyamtso (Ju mi pham rnam rgyal rgya mtsho, 1846–1912) that lists purely herbal formulas. Before production, Ju Mipham’s formulas were also screened in order to exclude or replace endangered plant species, targeting single ingredients that were CITES-listed, and the formulas had to be adapted accordingly. To summarise, such polyherbal formulations are not necessarily new, but they have different implications today given the scaled up and more market-based nature of the industrialisation regime and its spillover effects on all of the others which will be examined in the following.

80 On Akong Rinpoche’s life, his training as a Tibetan medical practitioner, role as a co-founder of the first Tibetan Buddhist monastery in Europe Samye Ling, and also position as strong promoter of Tibetan medicine in Europe, see URL: <http://www.khenpo.eu/tara/andtara.html>, last accessed 2 December 2015.
81 On the Tara Clinics of Traditional Tibetan Medicine, see URL: <http://www.tararokpa.org/medicine/index.html>, last accessed 2 December 2015.
The Reformulation Regime

The Jinhe or Arura Tibetan Medicine Pharmaceutical Co., Ltd. based in Xining, Qinghai Province, mainly produces Tibetan pharmaceuticals for the Chinese market. A short glimpse into the recent past of this company shows that it developed out of the pharmaceutical department of the Qinghai Tibetan Hospital, following the socialist market reforms that triggered the decentralisation and privatisation of the public health sector in China. Since the early 1990s, with the help of its enterprising director Dr Ao, a Tibetan biomedical physician, Tibetan medicines have been produced for the larger Chinese market under the brand name of ‘Jinhe’ (金诃; ‘golden myrobalan’) or ‘Arura’. Arura (Tib. a ru ra) is the ‘king’ of medicinal plants in Tibetan medicine, being endowed with all six tastes, and derived from the Sanskrit arura classifying a specific myrobalan fruit (L. Terminalia chebula Retz). In 1999, the so-called Arura Tibetan Medical Group was founded, comprising the hospital, pharmaceutical factory, research department, college of Tibetan medicine, and a museum of Tibetan culture and medicine in Xining.

As stated earlier, the year 2001 was decisive for the production of TM medicines in China, because the country entered into the World Trade Organization (WTO), with GMP and a new drug administration law being introduced for validating the efficacy and safety of drugs primarily based upon biomedical parameters and modelled upon those used for TCM. While this exempted Chinese single ‘crude drugs’ from strict quality controls, Tibetan multicompound formulas that are already formulated as pills came under tighter control. From 2003 to 2004, the Arura pharmaceutical factory opened new premises complying with the latest GMP standards. Another decisive event occurred in 2010, when the GMP law was revised under China’s general GMP-standard regulations. In 2013, Arura was the first company in Qinghai to have obtained a GMP certificate under the revised Specifications for Quality Management of Drug Production (2010 Revision).

Arura medical production combines technological know-how with ‘ancient’ Tibetan medical knowledge. Its products are encapsulated in shiny blister packages produced for the Chinese market, with indications written in

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83 URL: <http://www.arura.cn/about.aspx?classid=1>, last accessed 10 February 2016. In the following, I call this company by the shortened name Arura.

84 On the pharmaceutical factory and its development, see Adams, Le, and Dhondup 2010, 2011; Saxer 2013, pp. 45ff.

Chinese. These indications at times resemble a hodge-podge of biomedical and Chinese medical terms that can more easily be understood by Chinese-speaking customers. These Arura products are taken directly as ‘over the counter medicines’ (OTC), or can be prescribed by physicians not fully or at all trained in Tibetan medicine, and are thus much more versatile and modifiable than ever before. The Arura Tibetan Medicine Co. Ltd has its registered production centre in Xining, while its marketing centre is located in Shanghai. The company has nearly 800 employees, over 200 shops throughout China, and maintains a complete R&D (Research and Development), production, marketing, and industrial chain.

Using effective marketing, the Arura alias Jinhe Pharmaceutical Company has developed its own pharmacoscape in China, called ‘Jinhe Culture’ (Ch. jinhe wenhua 金诃文化). The first line one encounters on their Jinhe Culture website is a mission statement that could have come from the Men-Tsee-Khang in Indian exile, and where the stated aim is ‘to enhance Tibetan medicine, for the benefit of mankind’.\(^86\) Strategic objectives are stated more plainly, ‘to engage in the business of Tibetan medicine products; ‘to expand the field of Tibetan medicine’,\(^87\) and ‘to cultivate the Tibetan medicine culture industry’. The Buddhist altruistic goal of doing things for the benefit of all beings is a well-known and oft-cited slogan which has become part of a Tibetan medical identity that Saxer has called the ‘moral economy of Tibetanness’, and one also shared by the Men-Tsee-Khang in Dharamsala, for example.\(^88\)

Furthermore, Arura publically promote their own hybrid style of practice as innovative, technologically advanced, and combining global values of efficacy and safety—according to biomedical parameters—with Tibetan cultural patterns. The company has won several honorary titles, including ‘Chinese Famous Trademark’, ‘National Geographic Indications Protection Product’, ‘The Enterprise of National List of Intangible Cultural Heritage’, ‘National Contract Compliance Enterprise’, and ‘National Innovative Technology Enterprise’.\(^89\)

Their website states:

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\(^86\) 弘扬藏医药，造福全人类! URL: <http://www.arura.cn/about.aspx?classid=3>, last accessed 15 February 2016. According to Lena Springer, ‘enhance’ connotes here also ‘praise’ and ‘spread’. I also thank Matthias Bauer and Nianggajia for the translations of this website from Chinese into English.

\(^87\) Verbatim: ‘to expand the field of medical treatment with Tibetan medicine’.


\(^89\) See URL: <http://www.arura.cn/about.aspx?classid=1>, last accessed 15 February 2016.
The company has 1000 types of products including drugs, supplements, caterpillar fungus,90 health products, daily-life regime, and external therapy for 6 types of categories. Of the 1000, 68 are nationally approved medicines with 21 ‘exclusive drugs’, 5 exclusive dosage forms, 10 medicines approved for reimbursement under national health insurance, 1 national essential drug, and 10 OTC drugs.91

Agar 35 alias Sanshiwu wei chenxiang wan (三十五味沉香丸) or ‘Eaglewood Pill of 35 Tastes’ is promoted as an OTC drug by the Arura Pharmaceutical Company, for example. It is a very popular Tibetan medicine prescribed by TM physicians in both Asia and Europe as well as taken in times of stress by patients directly. It is considered to be generally effective for stress-related

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90 Until very recently, caterpillar fungus (Tib. dbyar rtsa dgun ’bu; L. Cordyceps sinensis) used to be the main cash income-generating wild crop collected by Tibetans due to a large demand on the Chinese market. It was mainly used in guanxi transactions among business people, yet prices fell in the past two years due to policy changes, and collectors have consequently suffered large losses in income.

91 公司拥有药品、保健品、冬虫夏草、健康产品、起居养生、特色外治6大类1000余种产品，其中药品共有68个国家准字号产品，独家品种21个，独家剂型5个，国家医保品种10个，国家医保品种1个，OTC品种10个。URL: <http://www.arura.cn/about.aspx?classid=1>, last accessed 2 December 2015.
symptoms, such as sleeplessness and concentration problems regardless of which underlying imbalances the patient has. It contains 35 mostly herbal ingredients with the primary one being eaglewood (Ch. *chenxiang* 沉香; *L. Aquilaria agallocha*). It also contains two animal products, ‘yak heart’ (Ch. *yeniuxin*, 野牛心) and ‘artificial musk’ (Ch. *rengong shexiang*, 人工麝香). TM physicians in Europe avoided the question of how these important animal ingredients are substituted while TM physicians and pharmacists in China pointed towards animal substitutions.

**The Hybrid Polyherbal Reformulation in Europe**

In Europe, the production of Tibetan pharmaceuticals and dietary supplements has been successfully established by the company Padma AG based in Switzerland, the sole pharmaceutical company producing Tibetan medicines in Europe. Despite the fact that Padma have only developed some 11 different polyherbal Tibetan formulas since the start of their production in 1970, Padma’s products are now the official legal face of Tibetan medicine(s) in Europe. Except for their specific formula composition, Padma’s Tibetan medical products are akin to other industrialised herbal remedies on the European market that fall under the rubric of traditional herbal medicinal products, with a standardised dosage and quality-controlled ingredients, and production methods following the pharmaceutical gold standard of good practice rules.

The efficacy and safety of their products is clinically tested, and due to RCTs, some of their products even attained the (biomedical) status of a ‘Tibetan medicine’ (German ‘Tibetisches Arzneimittel’). However, and similar to the reformulated pharmaceuticals produced by Arura for the Chinese market,
Padma's products are mainly prescribed by physicians of biomedicine and CAM, or taken directly by patients as self-medication for common symptoms or often for chronic diseases that are difficult to heal and where use of biomedical pharmaceuticals can have side effects when taken longer term. Other Padma products circulate within a growing European CAM and wellness consumer market as dietary supplements with low dosages and indicated by general symptoms.

A side remark by an employee from Padma, plainly stating that such low dosage standard indications, as required by law for dietary supplements, tend to fail to be effective at all, aroused my curiosity. Consequently, I was supposed to ‘forget about proving the “efficacy” of Tibetan medicines’. The remark was meant to signify that at the time, when clinical trials were still a requirement for proving (biomedically validated) efficacy and safety of Padma’s products, it was a very lengthy, difficult and costly process to conduct RCTs in the proper manner. Fortunately, this hurdle was overcome by the amended European directive of 2004. Depending upon a formula’s respective regime, and its legal status—and at times on any single ingredient within a given formula which might be classified as ‘toxic’ in a particular country of the EU, and also in Switzerland—its distribution may be officially restricted to cantonal or national borders. New pathways of circulation of products are international internet orders, yet again they become increasingly tricky to use due to border control regimes between countries. Even legalisation has its limits, it seems.

Padma’s Tibetan polyherbal pharmaceuticals and dietary supplements do strictly comply with European legislations and international regulations of efficacy and safety. Thus, for example, one ingredient in the so-called Padma Nerves Tonic formula (‘Nerventonikum’), alias Sogdzin 10, a slightly adapted form of the classic formula Sogdzin 11 (Srog ’dzin 11), is omitted and not substituted for obvious reasons, since it is an animal product, i.e. rabbit’s heart. Schwabl and Vennos explain that because the European diet is already high in animal protein, the missing effect of this animal ingredient in their Tibetan formula is easily compensated or additionally supporting the overall warming effect of Sogdzin 10, counterbalancing the ‘cool’ nature of the disturbed ‘wind energy’ (Tib. riung) by eating a meat bone soup instead. They elucidate the efficacy of Sogdzin 10 in both modern scientific terms of how it addresses stress systems by improving ‘better sleep’ and a ‘focused mind’, enumerating the single ingredients, in part their biochemical make-up but also their
‘Tibetan medical’ effects, such as nutmeg (Tib. dza ti) that ‘harmonizes the Lung [Tib. rlung] energy’.96

In particular, herbal ingredients that are endangered plant species listed in CITES, even those of only doubtful botanical identity, are substituted in Padma’s formulations.97 Therefore, the generally endangered CITES-listed species of eaglewood, in particular Aquilaria agallocha Roxb. (Tib. a gar; Ch. chen-xiang) is substituted with guaiacum (Lat. Guaiacum sanctum L.), like eaglewood, an aromatic wood known as ingredient for incense but obtained from South America.98 According to Herbert Schwabl, director of Padma AG, guaiacum was already used as a substitute for eaglewood in the earlier Buryat recipes of the Badma family physicians that serve as basis for Padma formulas.99 Nevertheless, different species of eaglewood continue to be used in other classical eaglewood formulas in Asia, such as Agar 8, Agar 15, Agar 20, Agar 35, and Sogdzin 11. These formulas are all based on the root formula of Agar 8, and are usually prescribed for what according to Tibetan medical concepts is meant by an imbalance related to the ‘wind’ (Tib. rlung).

From a Tibetan medical point of view, this concerns in particular the pathological ‘heart wind’ (Tib. snying rlung) and the ‘life-sustaining wind’ (Tib. srog rlung) that flows through the ‘life-sustaining channel’ (Tib. srog rtsa).100 In contrast to this classification, Padma Nerves Tonic (Sogdzin 10) is described by Padma AG in alternative medical terms simply as an anti-stress formula, and as having astringent and warming effects that strengthen the nerves and calm the mind: ‘It is used in the treatment of nervousness, irritability, restlessness, and nervous tension, as well as in difficulty falling asleep and remaining asleep’.101 Recently, Padma Nerves Tonic was evaluated with a positive outcome

96 Schwabl and Vennos 2009, p. 11. It should be noted that the addressees of this journal publication mostly are Western therapists trained in Tibetan medicine by Nida Chenaktsang, the director of the largest European school of TTM (traditional Tibetan medicine). He is actively retranslating Tibetan medical treatments into Western contexts with an emphasis on the ‘energetic levels’ of body and mind, including Tibetan Buddhist teachings of the Yuthok Nyingthik (g.Yu thog snying thig); cf. Garrett 2009.

97 The problem with the correct botanical identification of eaglewood—despite its large use in Tibetan formulas across the Himalayas, Tibet, and China—is that there are similar yet different species that are difficult to differentiate from each other and therefore their correct identification and use is questionable.

98 Schwabl and Vennos 2009, p. 11.

99 Personal communication with Herbert Schwabl, Director of the Padma AG, Zurich, January 2014.

100 On the complex of wind disorders in Tibetan medicine, see Yoeli-Tlalim 2010.

101 Leaflet of Padma Nerve Tonic (alias Padma Nerven-Tonikum).
for similar symptoms related to menopause by the Institute for Naturopathy, University Hospital Zurich, Switzerland.102

Using scientific explanations for the overall synergistic ‘multitarget’ effects of the polyherbal classic Tibetan formulas, researchers associated with Padma stress a Tibetan formula’s ‘signature’ effects. ‘Signature’ is a characteristic CAM term that is used to explain simultaneous ‘holistic’ effects that whole—rather than extracts from—medicinal plants can have upon the body and mind. Furthermore, systems biology is consulted as an explanatory model for the ‘energetic understanding’ of diseases in Tibetan medicine, and how diseases are both conceptualised in the body and how phytotherapeutics can work on several levels simultaneously.104 Polyherbal Tibetan formulas are explained as ‘multi-target medicines with a pleiotropic effect profile’ endowed with a particularly complex structure that can address more than one chronic disease.105

102 Kneip 2015.
104 In systems biology, the body is conceptualised as a whole complex system consisting of interactive parts that are organised on different hierarchical levels and systems of cells, organs, and functions, and therefore in need of being addressed simultaneously. The complexity of the body (and disease) is related to the complexity of the synergistic efficacies of a single plant, as well as to a complex formula pattern; see Verpoorte, Choi, and Kim 2005.
105 Cf. Schwabl, Vennos, Saller 2013, p. 35. On the ‘holistic’ concept of ‘signature’ medicines in European CAM-medicine as entailing a combination of material and ethereal or ‘essential’
Padma is clearly trying hard to make up for their small number of products by stressing their polyvalent application potential. At the same time, they deliver new explanations on complexities of chronic and multimorbid diseases that are still little understood biomedically, or difficult to treat with conventional biomedicines. However, a study undertaken by Antonio and several physicians at the Dharamsala Men-Tsee-Khang focusing on ‘neuro-psychiatric disorders’, demonstrated just how challenging it can be to explain the complexity and efficacies of different Tibetan formulas in relation to specific biomedical disease categories by deducing these via their prescription. Ultimately, this study found that it was not possible to make any correlation between one formula being prescribed and a particular biomedical disease category.

While such explanatory models and their cultural translations between different epistemologies and systems of knowledge as used by Padma remain to be studied more closely, it is clear that Padma’s transformations and innovations of formulas do not conform to any reductionist styles of biomedical and biochemical practice that only focus upon the efficacy of active agents, and this case is similar to that of industrialised ayurvedic pharmaceuticals. Instead, and increasingly so, at least in the Western CAM milieu, concepts of efficacy pertaining to signature medicines, synergy, quantum physics, and systems biology are used to explain the ‘holistic’ and multivalent aspects of Asian medicines.

Conclusions

In this paper, I have argued that the official standards of bioscientifically validated efficacy and safety—as these are embodied in globalised, nationally specific regulatory regimes, and reiterated in the production of licensed reformulated Tibetan pharmaceuticals—transform Tibetan medical practices at large in both China and Europe in both direct and indirect ways. The heuristic model of formulation regimes I have proposed allows us to compare these developments in terms of transnational production and prescription practices of a similar style and scale. The comparison encompasses two principle groups of stakeholders and their formulation regimes. One is the classical formulation regime of small-scale producers and physicians of Tibetan medi-

107 This coincides with the studies by Pordié and Gaudillière 2014a, b on industrialised polyherbal ayurvedic reformulations.
cine reconfiguring classical formulas in a personalised style, while focusing on addressing the individual imbalance of the patient, which from their perspective is the underlying cause of the disease. Their personal medical identity is intimately articulated with Tibetan medicine as their living tradition. The other is the reformulation regime reproduced by large-scale pharmaceutical companies, who create their own pharmacoscapes that are reconfiguring in relation to, and are at the same time validated by, nationally legitimised, bioscientific regulatory regimes of efficacy and safety. The reformulated Tibetan pharmaceuticals they produce are mainly used by a majority of physicians oriented towards biomedical or CAM-parameters for targeting specific diseases.

What has also been shown is how these formulation regimes configure a direct relationship between modes of production and ways of prescribing by specific groups of physicians with distinct medical identities. Sharing the same or very similar epistemic values of efficacy and safety link actors, production, and prescription practices together in these two different professional environments. Both of their distinctive ways of sourcing, production, and registration can entail complex translation processes between classical empirical knowledge on which these formulas are based and biomedical standards of regulations. This is true not only within the reformulation regime, but also where the classical formulation is practised within governmental institutional frames, such as in the case of the Qinghai Tibetan Hospital. In China, the reformulation regime of Tibetan formulas is clearly more influenced by TCM, while in Europe it follows the herbal CAM-market dynamics. In both cases, the formula-disease-centred style of practice allows Tibetan formulas to be taken directly by patients themselves, catering to ever-growing wellness and consumer markets of alternative medicine. Formulas seem to embody an objectified efficacy per se that allows them to become independent from the medical system out of which they were originally developed, opening up new markets and also possibilities for application.

In any case, physicians of Tibetan medicine—no matter in which country they practice—prefer to use a wide spectrum of formulas produced by trusted pharmacists. They also prefer to find their own ways of continuing the circulation of medicines via personal therapeutic networks or transitional grey market zones through which the substances and formulas can pass. Another way of continuing circulation within the same national context, for example, is to rename a formula already produced by a pharmaceutical company so as to avoid impinging upon intellectual property rights (IPR), or to adapt a formulation (e.g. by substituting or omitting certain ingredients, and/or lowering the dosage) in order to legalise its existence. By way of such processes,
Tibetan formulas then also become teas, tonics, or dietary supplements in Europe, or ‘over-the-counter’ medicines in China.

Within the general field of practice I have outlined and from which ethnographic examples were given, conundrums of safety and efficacy are manifest in various ways. First of all, strict food and drug policies in Europe, as well as those implemented with increasing rigour in some Tibetan areas of China, redefine classically formulated, hand-crafted, or small-scale manufactured medicines as being neither ‘safe’ nor legal. In the wake of this, in Tibetan areas at least, some private pharmacies-cum-clinics were already temporarily closed or have been threatened with closure. Gerke has called the ‘moving from efficacy to safety’ a generally increasing legal concern (also in medical anthropological approaches to the subject). Secondly, the official legal situation in Europe clearly condemns the classical formulation regime as generally ‘unsafe’ due to its non-standardised quality and dosage controls. Consequently, the few Tibetan pharmaceuticals produced by Padma are currently the only safe and efficacious licensed Tibetan medicines in Europe. They serve, in turn, to treat a large scope of chronic ailments, much larger than their classical indications would have suggested, and are supplemented by dietary and external therapies—such as massage—of Tibetan medicine that are integrated into other nationally legalised, mainstream therapeutic practices. Tibetan medicine, extended by Tibetan forms of yoga, and a host of other mind-body-techniques, has now become part of the European CAM-landscape.

Yet another conundrum is the consensus among classically trained TM physicians that pharmaceutical companies are not able to ensure the gold standards of efficacy and safety according to the logic of the classical formulation regime. This critique entails several concerns, first and foremost of which is that the marketing of medicines as over-the-counter products can jeopardise patient safety and undermine the possibility of efficacious treatment. Furthermore, they say that the maximisation of profits in commercial production gives rise

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108 As always in China, there is no uniform implementation of policies, even at the level of a single county. I have met three individual physicians in Amdo with well-established private clinics independent of one another, partly with a lineage-based background, but also with official certificates from medical schools. They were locally or even regionally well-known for the quality of their medicines. Their clinics have either been closed down temporarily or they were threatened with closure because they had no licence for their medicines. The one whose clinic was closed down was only allowed to reopen if ‘safely’ produced, licensed Tibetan and Chinese medicines were sold on the premises. I also heard of similar reports from Lhasa in central Tibet (Xizang). However, other physicians elsewhere had never even heard of such policies.

109 Gerke 2012.
to many compromises being made in terms of collection and production of medicines, all of which can adversely impact the overall quality, safety, and thus efficacy of medicines. Finally, there is general concern about over-harvesting, shortages, and price rises of *materia medica*.

One general trend this research draws attention to is that increasing pharmaceuticalisation marginalises the classic formulation regime and its non-institutionalised agents who use a personalised style of producing and prescribing Tibetan formulas. They are being increasingly relegated to a grey zone in both Europe and China by regulatory regimes that ultimately support the production style of ‘big pharma’. The unfolding dynamics of this development should be the subject of future research.

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