Legal Aspects

The Mercury Puzzle

Tibetan Medicines and the Pharmaceutical Regulations in the European Union – Assessments and Opportunities

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Abstract

In the last decades, Tibetan medicine has spread around the globe. From a Western point of view, Tibetan medicine is part of Complementary and Alternative Medicine (CAM). In many Asian medicines, mercury sulphide is considered an important ingredient. Tibetan medicine is famous for its precious pills, many of which contain mercury sulphide in the form of an ash called tsotel (btso thal). In the Western, specifically in the European context, such ingredients are not accepted for human consumption. These legalities are discussed from the perspective of today’s pharmaceutical practice in Europe. Neither the law of medicinal products nor the food law allow such ingredients and place strict limits on residues of heavy metals. The CAM community is also very cautious about any use of heavy metals. This article advocates that on the global level, the production and distribution of Tibetan medicines has to consider today’s modern pharmaceutical and biomedical environment. The formulas of Tibetan medicine based solely on herbs and certain minerals could be the foundation stone for a modern pharmacopoeia of Tibetan medicine. Tibetan medicines are always a carefully blended mixture of many ingredients. This multi-compound principle could then serve as a basic concept for a modernised Tibetan medicine. Such medicines have to be investigated in their entirety, without reducing the formula to its active ingredients. This article suggests that such a herbal mixture could be understood as a new ‘man-made herb’, where the scientific tools specifically developed to investigate individual herbal constituents would be applied to the entire
formula. Tibetan medicine and its products based on pharmaceutical-grade clean herbs and minerals can offer important therapeutic options for humankind on a global level.

Keywords

Tibetan medicine – herbal medicine – European pharmaceutical and food legislation – heavy metals – contaminants – phytotherapy

Introduction

The Tibetan materia medica consists of several hundred formulas. Most of them are compounded from dried herbs and minerals, whereas only a few of them, mostly precious pills, contain mercury sulphide in the form of tsotel as well as other metallic compounds. When speaking in Asia about Tibetan medicine, the making of tsotel for the use in precious pills is often discussed as the highest art of Tibetan medicine. Such metal-containing medicines are then described as indispensable and as constitutive for Tibetan medicine or even Tibetan identity. In Western circles, precious pills containing tsotel are sometimes discussed as having almost mythical qualities, and recent publications in the social sciences show a renewed interest in this alchemical practice.

In stark contrast to this perception prevalent within the Asian context is the almost unanimous repudiation by the international health and environmental communities. Especially in Western countries, these communities are concerned about the use of heavy metals in medicines and their effects on public health. Here the discussion has to be extended beyond the ingredient of mercury in tsotel; it has to be extended to all metal-containing components, such as cinnabar, lead oxide, and so on. Other critical pharmaceutical topics are also related to this issue, such as the use of medicinal products derived from endangered plants and animals, or the concept of toxicity in general and in relation to traditional medicines. These need to be discussed in a similar manner, but are beyond the scope of this article.

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1 For details and practices of mercury purification and the production of tsotel, see Sonam Dolma and Gerke, this issue.
2 Kloos 2012.
3 As argued by Kloos 2012.
5 Gerke, this issue; Kloos 2012; Saxer 2013.
In this essay, I examine the classic division between a ‘traditional’ and a ‘modern’ pharmaceutical product of Tibetan medicine, focusing on the paradigmatic example of *tsotel*. The practice of using metallic compounds in medicine is a key concept in many Asian medical traditions such as Ayurveda, Siddha, Unani, or Chinese Medicine; therefore my examples of Tibetan medicine can also be extended to other Asian traditional medical practices using metals as ingredients.

My initial point of reference is today’s modern Complementary and Alternative Medicine (CAM) as part of the legal system of the European Union (EU) and Tibetan medicine being part of CAM in Europe. I then take a look at the laws governing the production and distribution of herbal formulas within the EU.6 Finally, I develop some key concepts for what I call a Modern Tibetan Medicine, based solely on herbal ingredients.

The pharmaceutical approach places the remedy (*pharmakon*) at the centre of the argument of efficacy and excludes for the moment the entire setting of the process of healing, which also includes social and religious elements of medical practice. The pharmaceutical approach focuses on medicine and its interactions with the physical body as the prime causal agent of the curing process. As another disclaimer, I have to add that the scientific disciplines connected with this topic are quite diverse, and each of them would require a specialist to really penetrate the layers of existing knowledge that would be necessary to arrive at a deeper understanding of the issues involved. A thorough cross-disciplinary discussion would require expertise in law, toxicology, epidemiology, pharmacology, analytical chemistry, CAM, traditional Asian medicine, and of course medical anthropology.

**Tibetan Medicine in the West as Part of CAM**

Today’s modern CAM in Europe is a mixture of various medical practices, such as herbal medicine, homeopathy, anthroposophic medicine, chiropractics, and non-European medical traditions, such as Traditional Chinese Medicine (TCM) or Indian Ayurveda.7 Among the different branches of CAM, Tibetan medicine is one of the smaller disciplines, since only an estimated 100 practitioners practise Tibetan medicine in Europe. Similar developments can be seen in many other countries worldwide. Although Tibetan medicine is considered

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6 This approach is complementary to investigations about the production of Tibetan Medicine within Asia. See, for example, Saxer 2012 and Kloos 2008.

7 Falkenberg et al. 2012.
a comparatively small CAM-discipline, it certainly can be concluded that it has reached a global level.\textsuperscript{8}

In a report to the European Parliament, the EU-commission recognised the diversity of CAM by citing those CAM practices that should be considered for inclusion in a proposed extension of the law on medicinal products, among them many Asian traditions: ‘Anthroposophic, Ayurvedic, Chinese, Kampo, Korean, Mongolian, Thai, Tibetan, Unani, or Vietnamese medicine’.\textsuperscript{9}

Most of the actively practising Tibetan medicine practitioners in Europe offer Tibetan massage called \textit{kumnye (sku mnye)} or other external therapies, such as \textit{horme (hor me)}, a treatment with hot herbal oil compresses. These practitioners are either ethnic Tibetans or trained Westerners. Few of them have an accredited academic degree as a medical professional. Depending on their legal status, some of the practitioners prescribe and dispense Tibetan formulas. A rigorous survey of Tibetan practitioners in Europe (exploring their number, field of expertise, legal status, etc.) still needs to be accomplished.

All European CAM practitioners (medical doctors, naturopaths, herbalists, etc.) have to follow the national regulations for medical personnel. Within the EU, the legal framework for practising medicine is a national matter and thus varies considerably from country to country. The opposite is true for the medicines used: they are regulated at the EU level, which means that the same set of regulations applies to all member states. Adding both strands together leads to completely different national situations regarding laws for practitioners and whether they are allowed to prescribe medicines or not.\textsuperscript{10}

\section*{CAM-Medicines in the EU}

What is the legal status of CAM-medicines in the EU? It is not a simple task to outline all legal options that could apply to the production, prescription, and dispensing of medicines in the EU. To start with a general regulation, a product intended to be ingested (in the form of pills, capsules, powder, liquid, etc.) can be classified as a medicine or as a food supplement. Under the current EU laws, we thus have two basic sets of rules, which technically could apply to traditional Tibetan formulas: the law for medicinal products and the food law. Both will be explored in the following sections.

\begin{itemize}
  \item \textsuperscript{8} Craig and Glover 2009, Craig 2012, Hofer 2008, and Kloos 2008, for example, describe various stages of expansion of Tibetan Medicine in the modern era.
  \item \textsuperscript{9} EC 2008a, p. 10.
  \item \textsuperscript{10} Wiesener et al. 2012.
\end{itemize}
**Medicinal Products**

Medicines are intended to treat diseases and are regulated Europe-wide by the EU-directive 2001/83/EC.\(^{11}\) Strict rules exist for all medicines regarding their quality and safety. Quality is governed by the various good practice rules, specifically good manufacturing practices (GMP), which also include permissible levels of contaminants such as pesticides, mould, or heavy metals. Mercury, for example, is considered a contaminant, and only a maximum of 0.1 mg/kg or 0.1 ppm\(^{12}\) of elemental mercury\(^{13}\) is allowed in medicinal material. The purity and the absence of contaminants have to be proven for each herbal ingredient contained in a medicinal product. Fig. 1 shows a certificate of analysis following the requirements of the European pharmacopoeia. Since mercury is treated as a contaminant, the discussion of whether mercury sulphide might be considered non-toxic is futile. The concept of contaminants focuses on the atom mercury, irrespective of how it is chemically bonded.

Mercury as a pharmaceutical ingredient is regarded as obsolete. Especially, since the adoption of the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) in 2007,\(^{14}\) the EU wants to ban the use of mercury-based pharmaceutical ingredients by 2020.\(^{15}\) There are minor exceptions, such as mercury-based stabilisers for vaccines and amalgam for dental fillings. Especially in Scandinavian countries, the ban on medicinally used mercury has been almost fully implemented by now. Notably, the ban on mercury was initiated by the environmentalist movement because the global cycle of mercury poses severe environmental and toxicological risks. To revoke this consensus is only imaginable if mercury-based medicines would treat diseases that cannot be treated with alternate means. This ban on mercury also ends the discussion of whether more clinical studies on animals or humans could at least prove the non-toxicity of specific mercury compounds.\(^{16}\)

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12 EDQM Council of Europe 2012.
13 Elemental mercury here refers to its atomic form, irrespective of its chemical bond.
15 Following REACH, the EU partners with UNEP and the United Nations Environment Programme in the Global Mercury Partnership. On 19 January 2013, the involved governments agreed to the text of a global legally binding instrument on mercury. This document, the ‘Minamata Convention on Mercury’, was signed at the Diplomatic Conference held from 7–11 October 2013 in Japan. In short, the Convention bans the use of mercury, although it makes the exemption for ‘products used in traditional or religious practices’, which definitely can be claimed in the regions where Tibetan medicine has been practised for centuries. See UNEP 2013, p. 61.
16 Also, the claim that specific mercury compounds are insoluble and thus not absorbed while being ingested leads to a dead-end. On the one hand, mercury is banned irrespective of
FIGURE 1  Example of a certificate of analysis of myrobalan fruits (Terminalia chebula fructus). Under the heading ‘Tests’ in the left column, the heavy metals to be tested according to the European Pharmacopoeia (Ph. Eur.) are listed. Under ‘Specification’ in the middle column, the permissible upper limits are given for lead, cadmium, and mercury, which compares to the ‘Results’ of the analysis mentioned in the right column.
Medicinal Products for CAM

In general, the legislation 2001/83/EC follows a risk-based assessment of safety. If a medicine has potentially unwanted side-effects (due to its composition), the expected clinical benefit has to outweigh the risk. Since the benefit of CAM-medicines, including phyto-medicines, is generally rated as low by the authorities, the registration practice tends to be very restrictive for such preparations. CAM-products can be registered according to the EU-directive 2001/83/EC under the following three categories:

a) Well-established Medicinal Products

This category only applies to medicines composed of herbal substances, and herbal preparations. The composition of a well-established medicinal product has to be well documented in the modern scientific literature and based on biomedical scientific principles. This implies that the number and kind of ingredients have to accomplish the desired medical effect according to scientific pharmacological principles. As a consequence, the proper amount of each component has to be derived from ‘accepted biomedical scientific principles’ and proven by clinical studies. Typical examples of this category are standardised herbal extracts from gingko, hawthorn, etc., where the active principles of the plant are present in a pharmacologically relevant quantity. In contrast to this, the composition of classical Asian medical formulas does not follow modern scientific principles. The question arises: according to modern pharmacodynamics and -kinetics, how can one prove why each component has been included in a multi-compound medicine and why exactly in a certain amount? Such questions remain unanswerable within the usual biomedical parameters and block the route to understanding complex formulas manufactured according to the principles of Tibetan medicine.

whether it is absorbed by the human body or not. The other line of the argument that it still has a beneficial effect leads to a logical contradiction: how can there be a pharmaceutical benefit if the molecule is not absorbed? One can then speculate about certain surface interactions of other molecules with the insoluble mercury in the gut, but this is even more complicated to research.

17 EC 2004, article 1.32, defines a ‘herbal preparation’ as follows: ‘Preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.’

18 This is a typical quote from a regulatory advice given by consultants and drug-regulating authorities. It is up to the authorities to define what they consider an acceptable scientific standard.
b) Traditional Herbal Products

By definition, Traditional Herbal Products are only allowed to contain herbal substances and some mineral ingredients. In this scheme, the minerals must only have an ancillary mode of action, and of course no potentially toxic ingredients are allowed. The ‘traditional use’ of the formula has to be documented for 15 years within the EU, and at least for an additional 15 years outside the EU for the formula to qualify for the registration as a Traditional Herbal Product. The same strict regulations apply to quality (see section a) above), but unlike the above category of well-established medicinal products, the composition can be a formula based solely on empirical knowledge, without biomedical scientific derivation. This opens an avenue for formulas of Asian traditions. However, because of the proven use of 15 years within EU territory, including a significant exposure to patients, only a few Tibetan formulas classify for this registration scheme. For example, it was only possible to register the formula Padma 28, which is based on the Tibetan formula Gabur 25, as a traditional herbal product in Austria (2010) and the UK (2013).

20 There are other Tibetan medical formulas registered in Switzerland, which is outside the EU and has a slightly different registration scheme. For details, see www.padma.ch.

c) Fully Licensed Medicines

From the point of view of the registering authorities, ‘unknown’ (thus ‘new’) chemical substances have to pass an extensive series of tests designed to register a New Chemical Entity (NCE). If all the tests are passed successfully, then the status of a fully-licensed medicine is granted. The category NCE applies also to formulas of Asian traditions if they cannot fit into the other two categories mentioned above. Theoretically, this would be the only valid process to legalise the use of tsotel-based medicines in the EU. The risk-based approach designed for NCEs allows even highly toxic substances (e.g. chemotherapeutics) in medicines, as long as the expected benefit (e.g. treatment of cancer) outweighs the toxic risk. Safety (adverse effects) is monitored via the EU system of pharmacovigilance, and such medicines are only allowed to be administered by trained medical doctors. This is also the avenue through which modern medicines containing metals have to be pursued. There are even modern pharmaceuticals containing precious metals (e.g. platinum or gold as part of molecules) that are registered and in use as prescription-only-medicines, but they all underwent extensive clinical and toxicological testing in order to balance risk versus efficacy. It is well-known that the cost for the registration of such a fully-licensed medicine, which has to undergo such rigorous clinical testing, surpasses several hundred million Euros. Therefore,

19 EC 2004, article 16a–16i.
in general, this route can only be considered a theoretical one for traditional Asian medicines.

There are, however, two exceptions:

**Exception 1**
In the UK, licensed herbalists can produce and dispense their own formulas. However, only herbal ingredients are allowed according to a positive list. For example, the Tara Rokpa College of Tibetan Medicine in Edinburgh, Scotland, is a member of the European Herbal & Traditional Medicine Practitioners Association\(^{21}\) in Tewkesbury, UK. For in-house production at a herbalist's laboratory, GMP is required, and only herbs are allowed to be used as ingredients.

**Exception 2**
As almost everywhere, accredited doctors of academic medicine with a degree (MD or Dr.med.) from a state medical university have the right to prescribe individualised formulas. Accredited academic pharmacists (with a university degree) have the right to compound such medicines according to a doctor's prescription. In Europe, this route is followed by medical doctors with an additional degree in TCM; they are allowed to issue individual prescriptions according to TCM principles, which are then compounded as *formula magistralis* by specialised pharmacies. Since the doctor is legally responsible for the individual prescription, it can be assumed that the prescription of metal-containing formulas by medical doctors will remain a rarity, limited to individual cases.

*Food Supplements*
Food is intended to maintain and support the function of the healthy body. Foodstuffs generally have to be safe for consumption. As in the case of medicines, strict quality restrictions apply to food supplements\(^{22}\) which are also governed by food laws. Since food is intended to be consumed in larger quantities than medicines, the requirements for purity and safety are sometimes even stricter than in the medical field. In the EU, the limit for mercury in food is set to a maximum of 0.10 mg/kg or 0.10 ppm.\(^{23}\)

Proper labelling of food supplements is important; no health claims are permitted on the packaging. Individual EU countries release different types of positive and negative lists of herbs, which are allowed in food supplements.

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\(^{21}\) For details, see www.ehtpa.eu.

\(^{22}\) In the USA, these kinds of products are called dietary supplements.

\(^{23}\) EC 2008b.
The European Food Safety Agency (EFSA) monitors botanicals in food supplements.\textsuperscript{24}

If an ingredient has not been known in Europe as food before 1997, the ingredient is considered a novel food. Such substances have to undergo special safety assessments, which are difficult as well as expensive procedures. This restriction limits the use of special herbs from the Himalayas, because a proof of use within Europe before 1997 cannot be substantiated.

To summarise, in the EU general health and safety restrictions have to be observed, even for food supplements. Thus any product containing adulterations or chemical residues (mercury, heavy metals, microbes, fungus, etc.) are not allowed on the market.

Summary of the Legal Options

It can be concluded here that there is currently \textit{no legal way} in Europe to produce, prescribe,\textsuperscript{25} or administer traditional medicines containing heavy metals or other potentially toxic substances. Even if traditional medicines can potentially be registered as Traditional Herbal Products, they have to be presented in a modern pharmaceutical way.\textsuperscript{26} This is different from how China\textsuperscript{27} and India deal with this issue. These countries apparently tolerate substances used in traditional medicine such as metallic compounds, although significant efforts are made to develop their pharmaceutical industry according to modern global standards. The Minamata Convention, which was signed in October 2013, will further restrict the use of mercury with a complete ban coming into effect in 2020,\textsuperscript{28} especially in the European Union. However, under this convention, ‘products used in traditional or religious practices’ are still allowed to be used; therefore Tibetan \textit{tsotel}-containing products (and similarly all other Asian medical practices dealing with mercury compounds) will probably not be affected.

The prescription of metal-containing medicines cannot be recommended for anyone working in the European professional medical context. Of course,

\begin{itemize}
\item \textsuperscript{24} EFSA 2013.
\item \textsuperscript{25} The individual prescriptions by medical doctors (see Exception 2 above and also Aschoff, this issue) will remain a rarity. As soon as the number of prescriptions rises, the health authorities would interfere.
\item \textsuperscript{26} Schwabl 2009.
\item \textsuperscript{27} Hofer 2008; Saxer 2012, 2013.
\item \textsuperscript{28} UNEP 2013.
\end{itemize}
toxicity assessments\textsuperscript{29} of these ingredients, which have to be extended towards a full benefit-risk assessment, could reverse the situation. Single toxicological studies,\textsuperscript{30} however well designed, have only pilot-character and will not change the opinion of the concerned international scientific bodies and even much less so of the responsible authorities. After having evaluated the risk, the next step is to show the clinical benefit according to the rules that apply to New Chemical Entities, as described above. Considering the costs involved, overturning the present consensus is only thinkable if governments of countries where metal-containing medicines are still allowed (e.g. China or India), utilise their political influence and make a considerable scientific effort to overturn the global consensus on the ban of mercury.

\textbf{No Modern Discourse Without the Atomic Concept}

In Western countries, heavy metals are banned for human consumption. This development paralleled the advent of modern analytical chemistry, which makes it possible to trace contaminants down to levels of parts per billion (ppb, for example, one microgram ($10^{-6}$g) of a substance contained in one kilogram of another material), or even less. This article is not the place to elaborate on standard procedures for handling heavy metals, how to detect them, or how to assess their toxicity, as ample literature exists on this topic.\textsuperscript{31}

The traditional proto-pharmaceutical techniques used to produce traditional medicinal ingredients containing metals are quite different. Such procedures can even be dubbed ‘alchemical’, because the techniques used are not based on modern, chemical-pharmaceutical knowledge. When taking Western concepts of atoms and molecules as a foundation, it is clear that a discussion about ‘metals’ is difficult between the modern/atomist and the traditional/alchemical mindsets.

This difference also applies to the terms ‘clean’ or ‘pure’ as used in the traditional alchemical context, which are not related to the atomic concept of purity. Mercury derived from natural sources, or today purchased ‘in the market’, contains—as any substance derived from nature—a range of other elements and especially other metals in traces, etc. Consequently, the traditional claim to have achieved a ‘pure’ substance via proto-pharmaceutical techniques is a different notion compared to the term ‘chemically pure’. State-of-the-art

\textsuperscript{29} Beers and Mousavi 2013 highlight some aspects of this toxicological reasoning.

\textsuperscript{30} See, for example, Sallon et al. 2006.

\textsuperscript{31} For example, Butler et al. 2010; Issaroa, Abi-Ghanema, and Bermonda 2009; or Järup 2003.
pure chemicals have a well-defined degree (e.g. up to 99.9999%) of the same atom/molecule as well as of all other relevant residues (Fig. 2).

Proto-pharmaceutical techniques do not guarantee a pure substance in the chemical-analytical sense. From the chemical-analytical point of view, any substance from natural sources or from a special chemical process contains a mixture of different sorts of molecules and atoms. Without a thorough chemical analysis it is not at all clear which other heavy metals are contained in a substance. Tsotel-based medicines are sometimes simply described as containing mercury as the only metal. From an atomist perspective, however, any analysis of tsotel has to be extended to the entire range of heavy metals (mercury, lead, cadmium, arsenic, etc.). All these elements can be found in traditional metallic preparations from different sources or production methods.32 Obviously, when following current EU legislation, none of them are acceptable for human consumption.

This is also reflected in the approach of the literature just mentioned, where no difference is made between metal components as ingredients or as unwanted contaminants. From the atomist point of view, both types are handled the same—as unwanted components of medicines or food supplements. The environmentalist initiatives have amplified this view, which as one consequence has led to the adoption of the Minamata Convention and the global ban on mercury.

From this perspective it seems almost impossible to introduce traditional metal-based medical ingredients according to modern pharmaceutical standards into the EU. Only such substances that are considered ‘clean’ from the ‘atomist’ point of view would be allowed to enter a scientific discussion, which is the necessary prerequisite for the production and distribution of modern medical preparations.

Perception of Heavy Metals in the CAM Community

As already stated above, from a Western scientific perspective heavy metals are more or less unambiguously considered harmful. Many reviews have been published on the toxicity of mercury and heavy metals in orthodox medicine. Interestingly, this view is even more pronounced in the health-conscious CAM community. This is an important fact because, as explained above, traditional Asian medicines in Europe are considered a part of CAM.

32 For example, Gunturu et al. 2011; Martena et al. 2010; Saper et al. 2008; Saper et al. 2004.
### Specification

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Dr. Andreas Lang

responsible laboratory manager quality control

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**FIGURE 2**  *An example of the definition of ultra-pure mercury*[^33]

[^33]: Merck 2013.
In the CAM literature, heavy metals, especially mercury, are understood to cause many diseases. Harmful effects are discussed resulting from doses even less than those that orthodox medicine would consider toxic. Asian medicine does not always have a good reputation in Western countries, one of the reasons being its use of heavy metals. Thus it can be concluded that even within CAM communities, which are the natural allies of traditional Asian medicine in Western countries, this topic remains highly sensitive.

**Key Concepts for a Global Tibetan Medicine**

In a globalised approach to Tibetan medicine, the practical solution to solve this vexed situation of the mercury puzzle seems to only use herbal and mineral ingredients. Considering the discussion above, it is logical that the ingredients have to be clean and pure according to modern standards that are set by the pharmaceutical codices. If one takes this approach, Tibetan medicine offers several hundred different formulas based solely on herbs and minerals.

To create a modern pharmacopoeia of Tibetan medicine, which contains those herbs and minerals that are described and assessed according to modern standards, would be an important step in the right direction. The ingredients should be safe for medicinal use, based on a modern risk-based assessment.

The question then arises: what is the key concept of the compounding process of Tibetan medicines? For me, it is the concept of multi-compounds. Modern pharmacology is based on the concept of single molecules as active ingredients. Herbs, however, consist chemically of a mixture of many different active molecules. Nevertheless, modern phytopharmacology advocates the use of single herbs with standardised potency, which is the approach of the so-called rationale of phytopharmacology.

Tibetan medicines enlarge this concept of single ingredients as they are always a carefully blended mixture of three to 30, or even up to 70 ingredients. Such complex mixtures are tailored to treat specific symptoms or diseases with minimised side-effects. Here, the sum of all ingredients combined in one formula is valued more than its individual components, and the entire formula is robust against variations caused by individual components. A conventional

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35 Martena et al. 2010; Saper et al. 2004. See also Banerjee, this issue.
36 HMPC 2013.
37 For example, Wichtl et al. 2004. In addition, see the scientific journals covering phytochemistry, phytopharmacology, or phytomedicine.
analytic approach to such multi-compound formulas is not sufficient; the conventional approach would investigate the action of each component alone, and then add the combined analyses. Here, we need to extend the paradigm of classical research in phytopharmacology.

The formulas have to be investigated as a whole, without breaking the formula up into its components. The synergistic and antagonistic contribution of the individual components generates the action profile of the entire mixture. Multi-compound mixtures can be understood as a new ‘man-made herb’, and the tools of phytopharmacology that were developed to investigate individual herbal constituents in themselves could be applied to the entire formula. This approach allows for an assessment and a validation of the entire formula and thus opens the door to enter the medical-scientific discourse.

As proponents of Tibetan medicine we have to think about how to take part in a globalised discourse on the contribution of traditional medicines to modern healthcare. Tibetan medicine is part of the medical heritage of the world. Since it has expanded world-wide, the proponents have to define its role on a global level. Because of its theoretical foundations, over the centuries Tibetan medical practices have been able to adapt themselves to various environmental and social contexts without losing the power to cure. We have to consider today’s modern, globalised pharmaceutical and medical environment and the needs of modern societies in both East and West, where chronic diseases and multimorbidity pose great challenges. Tibetan medicine can further evolve without losing its essence. Such a Modern Tibetan Medicine and its medicines based on herbs and minerals hold a great potential for the future. It can offer important therapeutic options for humankind on a global level.

Bibliography


38 Schwabl, Vennos, and Saller 2013.
39 Schwabl and Vennos 2006. The expression ‘man-made herb’ refers to the entire formula and sets it apart from herbs found in nature. We tried to find a better word, but terms such as ‘artificial’ or ‘synthetic’ have other connotations when referring to medicines. The German translation of ‘man-made’ is *von Menschen geschaffen* and is gender-neutral.
40 See the excellent contribution by Jigmey 2012.


