

Comments on the draft report of the Joint Expert Commission on the Classification of Substances: ‘Opinion on the classification of herbal products used in traditional Chinese medicine (No. 01/2026)’

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Summary

Chinese medicinal substances that, by virtue of their explicit or implicit intended purpose, are intended for the treatment or alleviation of diseases should consistently be regulated within the legal framework applicable to medicinal drugs. Particular attention should be paid to concealed indications relating to specific diseases, for example when products are named after traditional Chinese herbal formulas. This approach would largely prevent the quality deficiencies described in this statement, including incorrect identification, contaminants, and adulteration.

This should not affect products that are clearly intended to be used as foods, such as teas consumed for enjoyment or nourishing soups, which may continue to be classified as foods, provided that toxicological assessment does not preclude their use as food. However, the current market situation for dietary supplements reveals a largely insufficiently controlled market that frequently circumvents existing legal requirements and jeopardizes consumer protection. This market should therefore be subject to more effective regulatory oversight than is currently the case.

With only a few exceptions, the use of Chinese herbal medicine is not suitable for self-medication but requires sound professional expertise, including fundamental knowledge of potential risks and adverse effects. The professional societies endorsing this statement have incorporated the relevant knowledge into their training programmes.

The Centre for Safety of Chinese Herbal Medicine (CTCA) serves as a TCM-specific pharmacovigilance centre for the German-speaking countries. It systematically collects knowledge and experience relating to the safety of Chinese herbal medicines and makes this information available to healthcare professionals. When quality-assured medicines are used under appropriate professional supervision, we consider Chinese herbal medicine to be a comparatively safe therapeutic approach.

In response to the statement of the Joint Expert Commission on the Classification of Substances of the Federal Office of Consumer Protection and Food Safety (BVL) and the Federal Institute for Drugs and Medical Devices (BfArM) [1], the undersigned professional societies provide the following comments, with reference to the corresponding numbered paragraphs in the document.

(120–126) “For the classification of a given product as a functional medicinal product pursuant to Section 2(1) No. 2(a) of the German Medicinal Products Act (Arzneimittelgesetz, AMG), it is necessary to demonstrate that physiological functions are restored, corrected, or otherwise influenced through a pharmacological, metabolic, or immunological action. Such evidence is likely to be lacking for the majority of TCM herbal medicines. Likewise, there is generally insufficient robust evidence to support

their classification as presentation medicinal products pursuant to Section 2(1) No. 1 AMG. Based on these findings, TCM products remain classified as food.”

In our view, it is not correct to state that evidence is lacking for the herbal medicines commonly used in Chinese medicine demonstrating that physiological functions are restored, corrected, or influenced through pharmacological, metabolic, or immunological effects. On the contrary, a substantial body of pharmacological research exists for almost all herbal medicines commonly used in Europe, demonstrating effects on physiological functions, including metabolic and immunological functions.

Furthermore, reviews are available for many herbal medicines that, in addition to listing their constituents, provide a summary of their pharmacological properties. Although it is not possible to provide a comprehensive overview here, the following reviews may be cited as examples, deliberately focusing on herbal medicines that are not among those most frequently used.

- on *Amomum villosum*, Fructus: Feng et al., 2024 [2]
- on *Angelica dahurica*, Radix: Zhao et al., 2022 [3]
- on *Astragalus complanatus*, Semen: Chen et al., 2026a [4]
- on *Caesalpinia sappan*, Lignum: Chen et al. 2026b [5]
- on *Commiphora momol*, myrrha, Resina: Yang et al., 2024 [6]
- on *Cornus officinalis*, Fructus: Cui et al., 2025 [7]
- on *Corydalis yanhusuo*, Rhizoma: Wu et al., 2025 [8]
- on *Daemonorops draco*, Resina: Du et al., 2026 [9]
- on *Dendrobium nobile*, Caulis: Jain et al., 2024 [10]
- on *Dioscorea nipponica*, Rhizoma: Ou-Yang et al., 2018 [11]
- on *Gentiana macrophylla*, Radix: Cui et al., 2026 [12]
- on *Myristica fragrans*, Semen: Luo et al., 2026 [13]
- on *Santalum album*, Lignum: Han et al., 2025 [14]
- on *Tetradium ruticarpum*, Fructus: Li und Wang, 2020 [15]
- on *Viola yedoensis*, Herba: Li et al., 2025 [16]
- on *Viscum coloratum*, Herba: Di et al., 2025 [17]

The renowned *Journal of Ethnopharmacology* (impact factor 6.8) is published approximately twice a month and contains at least one review on the pharmacology of a Chinese herbal medicine in each issue, in addition to other pharmacologically oriented studies on Chinese herbal medicines.

(128–129) “...it is not uncommon for existing TCM preparations to feature impermissible disease-related claims (e.g. ‘medicinal plant’).”

A number of herbal medicines used in Chinese medicine may appropriately also be used as foods, for example in nourishing soups or as teas consumed for enjoyment, irrespective of whether they exhibit pharmacological effects. The intended purpose is decisive for classification.

However, a large proportion of Chinese herbal medicines marketed as dietary supplements are explicitly or implicitly offered for the treatment or alleviation of diseases. Where they are not

explicitly marketed for this purpose, the intended medicinal purpose is conveyed through indirect signals — for example, the use of the traditional Chinese formula name — or through promotional material published elsewhere on the internet. The target group will generally immediately recognize that medicinal use is intended.

Use as a food for enjoyment is often precluded simply by the fact that these products have an unpleasant taste. In some cases, the products are presented as being intended to maintain health, consistent with the legitimate purpose of a dietary supplement, while the marketing is designed to lead consumers to infer an intended medicinal use. However, there is likely to be little to no evidence supporting the use of such products as dietary supplements for purposes such as maintaining health.

(139–144) “...the substances used in TCM and their preparations may raise concerns regarding their safety and, consequently, their marketability under Article 14 of Regulation (EC) No. 178/2002 where the products (1) contain toxic constituents at relevant concentrations, (2) contain contaminants such as heavy metals, mycotoxins, microorganisms, or other compounds hazardous to health, (3) are contaminated with pesticide residues, or (4) have been adulterated through the addition of undeclared medicinal substances.”

Regulation (EC) No. 178/2002 concerns food law. In this context, it should be noted that there are two possible distribution channels:

- The legally compliant procurement channel, which we advocate, as medicinal products: procurement through pharmacies specializing in Chinese herbal medicines, thereby ensuring the quality of the herbal medicines and largely excluding quality deficiencies.
- Procurement of “dietary supplements,” for which there is no guarantee of adequate quality, meaning that the risks described above may occur.

The aforementioned “addition of undeclared medicinal substances” is likely to be relevant in practice only in the case of ready-made preparations, particularly those with explicit or concealed advertising for disease-related indications. It is unlikely to be relevant to individual prescribed raw materials or granules consisting of individual herbal medicines, as the addition of such substances would scarcely serve any meaningful purpose in these products.

With regard to toxic constituents, see 367ff.

(171–174) “A traditional pharmacy in China typically stocks between 600 and 800 medicinal herbs [6]. However, it is estimated that approximately 13,000 medicinal substances and formulas are used for medicinal purposes in China overall [7, 8].”

Within the therapeutic approach of Chinese medicine, a maximum of approximately 300 to 400 herbal medicines are used in Europe, for which the constituents and pharmacological properties are relatively well characterized. An important reference for the practice of Chinese herbal medicine in Western countries is the standard work by Bensky et al., which covers a somewhat larger number of herbal medicines [18]. The overall number is therefore manageable. The range of Chinese medicinal plants offered in dietary supplements is unlikely to exceed this significantly.

(261–265) “Overall, clinical data are now available for both TCM formulas and TCM preparations ... as well as for numerous individual herbal medicines. However, it should be noted that these are predominantly smaller studies of suboptimal methodological quality, which provide only preliminary indications and require further investigation.”

This assessment is essentially correct. However, there are also several high-quality clinical studies providing evidence for the efficacy of specific medicinal products. Examples include studies by Yang et al., 2023 [63], Li et al., 2025 [64], and Lu et al., 2008 [65]. It should also be noted that, for the majority of European herbal medicines, there is likewise no conclusive evidence of efficacy. Only a small number have been granted the regulatory status of “well-established use.”

(283–286) “To date, there are no authorized TCM medicinal products, i.e. products with efficacy and safety demonstrated in clinical studies. Accordingly, it may be assumed that, apart from a small proportion of prescribed formula medicines, the vast majority of TCM products are on the market as non-medicinal products.”

Based on our assessment and knowledge, the market consists, on the one hand, of individually prescribed formula medicines. The components used in these formulas are obtained partly as herbal medicines through pharmacies and partly as “dietary supplements” through other distribution channels, while self-medication by patients plays only a minor role. In our view, self-administration of Chinese medicines (single herb or combination preparations) would be justifiable only for a limited number of straightforward indications, provided that authorized products were available for this purpose.

The increasing attempts by some suppliers to target patients directly through the use of specific product names (e.g. “TCM Joint Pain”) should, in our view, be rejected and are not compliant with current regulations. The least significant risk in such cases is that the products offered prove to be ineffective. The claimed effects cannot be expected with these products, which are often simplified and underdosed. Designations such as “Rheumatism Blend” also entail the risk that appropriate treatment may be omitted or delayed.

We are convinced that some of the herbal remedies offered are contraindicated during pregnancy based on experimental findings, yet the products do not warn of the risk. As a general rule, treatment with Chinese medicinal products requires supervision by a well-trained practitioner in order to ensure efficacy and safety.

(339) “Medicinal herbs that may also pose health risks are offered, such as peony petals, ...”

Peony petals are not a standard TCM medicine. The root of *Paeonia lactiflora* is used, and we are not aware of any significant risks associated with its use at the recommended dosage.

(347–351) “The increasing use of TCM products in the Western world has also drawn attention to safety concerns, adverse effects, and quality deficiencies [40, 43], despite the absence of close

monitoring comparable to pharmacovigilance systems. These issues are also recognised in China, leading to projects – both government-led and in research and development – that address them....

In China, a pharmacovigilance system is indeed in place, in the form of the *National Adverse Drug Reaction Monitoring Centre*. In 2024, 2.866 million adverse drug reactions were reported, of which traditional Chinese medicines accounted for 12.1%. Of these, 24.6% involved injectable preparations [19]. The practice of Chinese herbal medicine in Europe differs from common practice in China with regard to medicinal safety—not only in that injectable preparations are not used, but also in that higher safety standards are required [20].

For the German-speaking countries, the *Centre for Safety of Chinese Herbal Medicine* (CTCA, www.ctca.center) serves as a pharmacovigilance centre. It comprises almost all professional societies representing Chinese herbal medicine, an association of TCM pharmacies, and qualified pharmacists. Among other activities, the centre receives reports of individual cases, evaluates them, and communicates the findings back to its member organisations.

(352-359) Aristolochia nephropathy

Aristolochia nephropathy undoubtedly involves very serious incidents that have been reported not only from Belgium but also from many other countries, including cases involving Western Aristolochia species. The corresponding medicinal substances are considered obsolete within Chinese medicine [18] and have also been banned in China and Taiwan since 2004. The mandatory testing requirements applicable to herbal medicines in Germany should mean that such cases are now virtually excluded. However, isolated cases may still occur in Europe as a result of obtaining “dietary supplements” via the internet. The most recent case known to us originated in Norway and was caused by an illegally marketed product [21].

(367-368) “such mixtures may contain highly toxic medicines ...”

(369-371) Aconitum herbs, Xanthium sibiricum, Ephedra

Some Chinese herbal medicines contain toxic substances. The Aconitum herbal medicines comprising Aconiti Radix lateralis praeparata, Aconiti Radix cocta, and Aconiti kusnezoffii Radix cocta are primarily cited in this context, and various cases of poisoning involving Aconitum herbs have been reported from China and Hong Kong. However, these cases can generally be attributed to overdosing, inadequate processing, or dispensing errors. This was demonstrated, for example, in a case series from Hong Kong comprising 44 cases in which the underlying cause could be determined. In 17 cases, an overdose had occurred; in 17 cases, Aconitum had not been prescribed but had been dispensed in error; in 7 cases, the Aconitum crude drug had not undergone adequate processing; in 2 cases, the wrong herbal medicine had been dispensed; and in 1 case, the patient had ingested a preparation intended for external use [22]. This underscores the need for knowledgeable and responsible handling by both prescribers and dispensers.

Chinese medicine developed processing methods approximately 2,000 years ago to reduce the toxicity of Aconitum medicines. Today, various processing methods are used to hydrolyse the highly

toxic diester-diterpene alkaloids (DDAs) into monoester-diterpene alkaloids and further degradation products [23]. As a result, the DDA content of *Aconiti Radix lateralis praeparata* is reduced by a factor of 38.1 to 76.5 compared with the crude drug [24]. The Chinese Pharmacopoeia (ChP) requires evidence that the DDA content does not exceed 0.020% (or 0.010% or 0.040%) [25]. Provided that *Aconitum* herbal medicines meet the established quality criteria and that dosage and contraindications are carefully observed, we consider these herbal medicines to be quite safe to use.

The CTCA is not aware of any adverse effects associated with the use of *Aconitum* preparations in Chinese medicine that have been reported or published in Europe. One exception involves the misuse of a product intended for external use – presumably brought from China – which was ingested by a Chinese man in London and caused cardiac arrhythmias. The man survived [26]. We therefore assume that Chinese *Aconitum* medicines, when used in accordance with proper professional standards, do not pose a significant safety risk.

The same applies to the fruit of *Xanthium sibiricum*: Proper processing is a prerequisite for its safe use. In reported cases of poisoning from China, this requirement had not been met, or exceptionally high doses of up to several tens of grams had been ingested (e.g. [27]). With regard to this herbal medicine as well, the CTCA is not aware of any adverse effects associated with Chinese medicine that have been reported or published in Europe.

Ephedra herb is also a component of Western phytotherapy. In particular, numerous serious adverse effects, some of them fatal, have occurred in the United States in association with “dietary supplements” containing Ephedra or ephedrine that were taken for weight loss or enhancement of athletic performance. Following the ban on these products in the United States in 2004, reports of such cases became less frequent. No comparable cases have been reported in the context of Chinese medicine. A review by Kim et al. identified only three cases of Ephedra intoxication in the Chinese literature, all of which were attributable to overdose [28]. The US Food and Drug Administration (FDA) stated: “FDA has no knowledge of any systematic collection of morbidity and mortality data on individuals treated with Ephedra in traditional medicine” [29].

With regard to Ephedra as well, the CTCA is not aware of any adverse effects associated with its use in Chinese medicine that have been reported or published in Europe. A calculation by the CTCA found that, at the maximum recommended daily dosage and based on the highest reported alkaloid content (185 mg), *Ephedrae Herba* contains less ephedrine alkaloids than the daily dose provided by the non-prescription medicinal product *Reactine duo Retardtabletten* (240 mg), and a similar amount to that contained in *Aspirin Complex* (180 mg) [30]. However, contraindications and precautions must be taken into account when using Ephedra herb. In our view, these considerations preclude self-medication with this prescription-only medicinal product.

Safe handling of toxic medicinal substances must be ensured through comprehensive training of practitioners and appropriate handling of these agents, as is also required for other medicines. Adequate treatment with Chinese herbal medicines requires in-depth knowledge of Chinese medicine, not least to ensure the likelihood of therapeutic success. The organisations endorsing this statement have given appropriate importance to safety-related aspects within their training curricula.

Serious adverse effects associated with Chinese herbal medicine are very rare. As for fatalities, since the 1990s, only three deaths have been reported in the entire Western world that have been associated with professionally administered Chinese herbal medicine: one case involving a Chinese herbal decoction, with a very high probability of causality [31]; one case involving the food supplement “Eternal Life,” of unclear composition and with possible causality [32]; and one case from the United States involving a decoction of unclear composition and a possible causal relationship [33].

Three additional cases occurred in connection with illegally imported products or with a mercury chloride containing preparation. An unknown number of fatal outcomes among the Belgian *Aristolochia* cases should also be taken into account [34]. These cases cannot be attributed to regular TCM treatment, as in these instances a Chinese *Aristolochia* medicinal herb was administered outside the context of Chinese medicine together with several chemically defined medications.

Thus, even when taking into account its much lower prescription rate, Chinese herbal medicine proves to be significantly safer compared to conventional pharmacotherapy. By comparison, an older study conservatively estimated 106,000 deaths attributable to adverse drug reactions among hospitalized patients in the United States alone [35]. It should also be noted that the deaths associated with Chinese herbal medicine reported in Europe occurred in countries where herbal products intended for medicinal use are classified as foods.

(395–406) Aconitum, processing methods. Although it is chemically plausible that such processing methods may alter the constituent profile of a herbal medicine and, consequently, its effects, systematic investigations into this have so far been lacking. ... As, in the view of the Ph. Eur. Commission, safe detoxification of the herbal medicine cannot be ensured, it was recently decided to discontinue the work on developing a Ph. Eur. monograph for Aconitum.”

We do not share the Commission’s view. Since the 1970s, numerous publications have addressed the safety of *Aconitum* medicines and have demonstrated effective reductions in toxicity, for example through comparative determination of constituent levels in crude and processed herbal medicines [36–44] or through significantly higher LD₅₀ values following processing of the raw materials in mice studies [23, 24, 45–47] indicating that an effective reduction in toxicity had been achieved.

A Japanese study investigated the effects of administering 0.5–8.0 g/day of a granule preparation made from *Aconiti Radix lateralis* that had been processed by autoclaving. The preparation contained 6 µg/g aconitine, 52 µg/g mesaconitine, and 28 µg/g hypaconitine and was administered as part of complex Kampo formulations to 593 patients. Regular patient inquiries revealed only four cases of mild adverse effects, including nausea, allergic symptoms, or a slight increase in blood pressure [48]. The DDA concentration in the preparation was 86 µg/g, which was within the range specified by the ChP (maximum 200 µg/g). *Aconitum* medicines are important and highly effective medicinal herbs in Chinese medicine. The extensive clinical experience indicating relatively good tolerability under regular conditions of use should therefore be given due consideration.

This is a genuine risk. It generally involves idiosyncratic hepatotoxicity, which is very rare. A Japanese study calculated the incidence of hepatotoxicity for individual Kampo formulas. The highest incidence was observed with one formula, at 15.18 cases per 100,000 treated patients; other formulas showed lower incidences, down to 0.09 cases per 100,000 patients [49]. Nevertheless, the risk of hepatotoxicity associated with Chinese medicine must be taken very seriously. The CTCA places particular emphasis on raising awareness of this risk and recommends appropriate diagnostic and precautionary measures.

This risk is not addressed in relation to food supplements, even though it may be substantially greater with some highly concentrated products than with traditionally processed herbal medicines. For example, a literature review conducted by the CTCA found no evidence of hepatotoxicity associated with *Curcuma longa* rhizome products that are compatible with the preparations traditionally used in Chinese medicine. In contrast, numerous reports and regulatory warnings exist concerning other products, such as food supplements produced by alcoholic extraction, products containing curcumin as a pure substance at high doses, or products with enhanced curcumin bioavailability (CTCA 2025, unpublished).

In some cases, hepatic reactions are also prematurely attributed to Chinese herbal medicine. The CTCA has received several case reports that, upon subsequent investigation, were found to be caused by a hepatitis E infection or the passage of gallstones. Numerous animal and cell-based experimental studies have also been published purporting to demonstrate hepatotoxicity of Chinese medicines. However, these studies are not informative in this context, as idiosyncratic hepatotoxicity cannot be reproduced experimentally in animal models [50].

(429–430) *“However, for a large number of TCM medicines, neither their constituent profiles nor their pharmacological and toxicological effects have yet been sufficiently investigated.”*

We do not consider this statement to be accurate with regard to the known constituent profiles and pharmacological effects. For the 16 reviews mentioned above under 120ff., which cover randomly selected medicinal herbs not widely used in TCM, the following applies: on average, 206 constituents were identified per medicinal herb, with a maximum of 546 constituents identified for *Amomum villosum*. Numerous in vivo and in vitro studies are also available on pharmacological effects (see above).

However, the toxicological effects have so far been insufficiently investigated. With regard to potential adverse effects, Chinese medicine has an extensive body of empirical knowledge, although this can be considered reliable only for acute or subacute reactions. Further scientific investigation is required with regard to chronic adverse effects.

(433–435) *“Apart from the language barrier, the risk of misidentification also arises from the fact that it is often unclear which plant species or plant parts are referred to by the respective Chinese medicinal herb name.”*

The species and plant part are clearly defined in the European and Chinese Pharmacopoeias. However, the use of outdated or incomplete nomenclature may potentially lead to misunderstandings. Such ambiguities can be avoided by providing both the pharmaceutical and the Chinese (Pinyin) name, thereby allowing the plant identity to be clearly established by qualified personnel.

Species identification can also be problematic in European herbal medicine. For example, according to the World Flora Online, the species *Crataegus monogyna* has almost 400 synonyms [51]. In food supplements that are not subject to mandatory quality testing under regulatory supervision, misidentification or, particularly in the case of expensive herbal medicines, deliberate substitution can readily occur.

(437–438) “In the Chinese Pharmacopoeia, up to eight plant species may be listed under the same herbal medicine name.”

This is not a characteristic specific to Chinese herbal medicine. In Western herbal medicine, different species are also sometimes used for the same therapeutic indications, for example *Rheum palmatum* L. and *Rheum officinale* Baillon for rhubarb [52], or *Crataegus monogyna* Jacq. (Lindm.), *C. laevigata* (Poir.) DC., *C. pentagyna* Waldst. et Kit. ex Willd., and *C. azarolus* L. for *Crataegus* [53]. In the ChP, there is a discernible trend towards taking certain pharmacological differences into account and dividing broader herbal medicine monographs into separate individual monographs, for example in the case of *Puerariae Radix*, which has been divided into *Puerariae lobatae Radix* and *Puerariae thomsonii Radix* [25].

(446–465) “Quality deficiencies and the resulting health risks have long been recognised as a problem associated with TCM products [54]. ...”

(469–476) “Counterfeiting ...”

As already noted, the quality deficiencies described above can largely be avoided by legally procuring herbal medicines within the regulatory framework applicable to pharmaceuticals. In the case of dietary supplements, responsibility lies with the competent authorities, which, however, have only very limited means of control.

(477–486) Inappropriate use and application by consumers

These findings confirm the concerns we have expressed regarding the use of Chinese medicines as dietary supplements without appropriate professional supervision, unless they can be classified as foods on the basis of the absence of relevant risks. Particular attention should be paid to the risks associated with use during pregnancy.

(530–552) EU Herbal Monographs

Problems in developing European monographs for Chinese herbal medicine products arise from the EU legal framework, in particular the Traditional Herbal Medicinal Products Directive (THMPD),

which was designed specifically with European herbal medicinal products in mind. Chinese herbal medicine has particular characteristics that differ substantially from the conditions for which the THMPD was designed:

- Chinese medicinal herbs are used in combination with other medicines in most cases, with only a few exceptions. Consequently, there is little traditional-use data available for these herbs as individual medicines, which is a prerequisite for the development of a monograph on an individual medicinal herb.
- The THMPD assumes potential use by consumers on their own initiative and is limited to minor health conditions. Responsible self-medication is applicable to only a minority of the indications commonly treated in Chinese medicine. Typical indications in TCM are not limited to minor health conditions (see the clinical studies cited above).
- In addition to herbal medicines, Chinese medicine also uses mineral and animal-derived medicines, which are excluded under the THMPD.

For these reasons, European monographs on individual Chinese herbal medicines are likely to be largely unrealistic within the existing EU legal framework. Monographs on complete traditional formulas for minor indications could be envisaged, provided that they do not contain mineral or animal-derived medicines.

(577–582) “Demonstrating pharmacological, metabolic, and/or immunological effects of TCM herbal medicines on the basis of robust evidence, i.e. published scientific studies, presents a challenge. This is because TCM herbal medicines are predominantly used on the basis of a long-standing tradition, and moreover, almost always in combination with other herbal medicines; consequently, the traditional knowledge regarding their pharmacological effects can often not be verified. Potentially relevant data are frequently available only in Chinese.”

Extensive pharmacological investigations are available for most herbal medicines, based predominantly on in vivo and in vitro data (see above).

Market Situation

Based on our assessment of the market situation, the self-administered use of formulas in the sense of traditional Chinese medicine plays only a very minor role. This may only occur when patients independently continue to obtain professionally prescribed formulas; without professional supervision, prolonged use in this manner may pose safety risks. However, based on our experience, TCM pharmacies generally take care to address this issue and refer patients back to their practitioner.

The situation is different when so-called “herbal shops” trade in Chinese herbal medicines. “Herbal shops” sometimes clearly offer Chinese herbal medicines for therapeutic purposes. As they are not pharmacies, they are not subject to the quality requirements applicable to pharmacies and are likewise not subject to inspection by the regulatory authorities responsible for supervising pharmacies. In our assessment, herbal shops are not subject to adequate regulatory oversight. In our view, the distribution of Chinese herbal medicines by such establishments is illegal unless the herbs concerned are subject to statutory exemptions permitting their distribution outside pharmacies.

So-called dietary supplements should be assessed differently. These usually contain individual herbal medicines or fractions thereof and are accompanied by explicit or implicit therapeutic claims, for example for weight loss. This is a significant and growing market. Therapeutic claims are sometimes also made by third parties on the internet and can readily be found there, whereas such claims appear only partly on the products themselves.

Some products contain highly hazardous plant extracts. In 2021, for example, the CTCA reported to the food safety authorities in Baden-Württemberg that a “full-spectrum extract” of *Tripterygium wilfordii* root was being marketed in Germany as a dietary supplement and was being distributed by numerous German pharmacies (manufacturer: Novoform Pharma GmbH, 76571 Gaggenau). *Tripterygium wilfordii* root (Chinese: *Leigongteng*) is a highly toxic plant-derived product that is considered obsolete in Chinese medicine because of its risks [18].

Serious adverse effects are known to occur with this medicine, including a teratogenic risk when used during pregnancy [54]. After the CTCA report, it took approximately nine months for the products to gradually disappear from the market. They subsequently reappeared, however, and even today numerous products can be found online under names such as “Thunder God Vine,” “*Tripterygium wilfordii* capsules,” or “Dreiflügel Frucht,” including products offered by German pharmacies. Seven randomly selected examples are cited here [55–61]. Either the products contain what is declared on the label, namely a full-spectrum extract of *Tripterygium wilfordii* root, in which case they are not permissible as foods, or they contain a potentially harmless substance, in which case the product would constitute consumer fraud.

Inexplicably, these products are marketed as foods. Food safety in Germany falls under the jurisdiction of the federal states, and it appears that the states are overburdened by the task of effectively monitoring the dietary supplement market. In our view, consumer protection is not adequately ensured under these circumstances. In the case of dietary supplements, even a qualified professional is unable to determine whether a product actually contains what is listed on the packaging, what type of extract it contains, or what dose this corresponds to in terms of the crude drug. In our view, this lack of transparency is inadequate for products making health-related claims.

The extent to which the quality of medicinal products and dietary supplements can differ was demonstrated by a study of the quality of passionflower herb products conducted by the Institute of Pharmaceutical Biology and Phytochemistry at the University of Münster. Among the dietary supplements, the identity of passionflower could not be confirmed in five of the six samples, or the flavone content was found to be below the declared amount. In contrast, all five medicinal products examined complied with the specifications of the pharmacopoeia [62].

Conclusion

Chinese herbal medicines that, by virtue of their explicit or implicit intended purpose, intended for the treatment or alleviation of diseases should consistently be regulated within the legal framework applicable to medicinal products. Particular attention should be paid to concealed indications relating to diseases, for example through the use of traditional Chinese formula names. This would largely prevent the quality deficiencies identified above, including misidentification, contaminants, and adulteration.

This should not affect products that are clearly intended to be used as foods, such as teas consumed for enjoyment or nourishing soups, which may continue to be treated as foods, provided that toxicological assessment does not preclude their use as food.

The dietary supplement market should be monitored more effectively than is currently the case. In Germany, the situation is characterised by a proliferation of products that are essentially illegal or operate in a legal grey area, without adequate enforcement of, or compliance with, the applicable legal requirements. On the other hand, the requirements applicable to pharmaceuticals are very stringent. This leads consumers to obtain products such as Chinese crude medicines or granules from sources where they are offered at lower prices but without adequate quality controls. Excessively stringent requirements can therefore produce the opposite effect to that originally intended.

With only a few exceptions, Chinese herbal medicine is not suitable for self-medication but requires sound professional expertise. This includes fundamental knowledge of potential risks and adverse effects. The professional societies have incorporated relevant knowledge into their training programmes and, in some cases, also offer specialised courses and continuing education in this area.

The CTCA, as the TCM-specific pharmacovigilance centre for the German-speaking countries, represents a unique institution in Europe and beyond. It receives and evaluates reports of adverse effects associated with Chinese medicine and communicates the resulting findings back to TCM practitioners. Practitioners can also submit direct enquiries to the CTCA, for example regarding potential interactions between Chinese medicines and chemically defined drugs, and this service is widely utilized. The CTCA maintains an extensive literature collection from international and Chinese sources on the risks associated with Chinese medicine, which has been systematically compiled in databases. In our view, Chinese herbal medicine practiced professionally in German-speaking countries meets the required safety standards.

On the other hand, there is a largely unregulated market for so-called dietary supplements, which frequently circumvents legal requirements and jeopardizes consumer protection. We therefore strongly advocate the consistent classification of TCM products intended for the treatment or alleviation of diseases as medicinal products, as well as more effective market surveillance.

Author: Dr. Axel Wiebrecht, CTCA Task Force (info@ctca.center)

This statement is endorsed by the following professional societies:

Arbeitsgemeinschaft Deutscher TCM-Apotheken (TCM-Apo-AG)

Arbeitsgemeinschaft für Klassische Akupunktur und Traditionelle Chinesische Medizin (AGTCM)

Centrum für Therapiesicherheit in der Chinesischen Arzneitherapie (CTCA), supported by the Arbeitsgemeinschaft Deutscher TCM-Apotheken (TCM-Apo-AG), the Arbeitsgemeinschaft für Klassische Akupunktur und Traditionelle Chinesische Medizin (AGTCM), the ASA as the umbrella organisation of the two Swiss organisations SACAM and AGMAR, the Deutsche Ärztegesellschaft für Akupunktur (DÄGfA), the TCM Fachverband Schweiz, the

Gesellschaft für die Dokumentation von Erfahrungsmaterial der Chinesischen Arzneitherapie (DECA), the Österreichische Gesellschaft für Akupunktur (ÖGA), the Österreichische Gesellschaft für kontrollierte Akupunktur (ÖGKA), the Societas Medicinae Sinensis, Internationale Gesellschaft für Chinesische Medizin (SMS), and the Wiener Schule für TCM

Deutsche Ärztegesellschaft für Akupunktur (DÄGfA)

Gesellschaft für die Dokumentation von Erfahrungsmaterial der Chinesischen Arzneitherapie (DECA)

Societas Medicinae Sinensis, Internationale Gesellschaft für Chinesische Medizin (SMS)

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