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REVIEW ARTICLE

Species Adulteration in the Herbal Trade: Causes, Consequences and Mitigation

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Abstract The global economy of the international trade of herbal products has been increasing by 15% annually, with the raw material for most herbal products being sourced from South and Southeast Asian countries. In India, of the 8000 species of medicinal plants harvested from the wild, approximately 960 are in the active trade. With increasing international trade in herbal medicinal products, there is also increasing concern about the widespread adulteration and species admixtures in the raw herbal trade. The adverse consequences of such species adulteration on the health and safety of consumers have only recently begun to be recognised and documented. We provide a comprehensive review of the nature and magnitude of species adulteration in the raw herbal trade, and identify the underlying drivers that might lead to such adulteration. We also discuss the possible biological and chemical equivalence of species that are used as adulterants and substitutes, and the consequences thereof to consumer health and safety, and propose a framework for the development of a herbal trade authentication service that can help regulate the herbal trade market.

Key Points

There is increasing concern regarding widespread adulteration in the herbal trade.

The adverse consequences of species adulterations on the health and safety of consumers have recently come to light.

We propose a framework for the development of a herbal trade authentication service.

1 Introduction

The share of the international trade of herbal products and the alternative medicine market in a global economy has been increasing at a rapid rate of approximately 15% annually [1]. Approximately 29,000 herbal substances used by more than 1000 companies have annual revenues exceeding US$60 billion [1–3], with the bulk of the herbal products, or at least the raw material, being sourced from biodiversity-rich countries in Asia, Africa and South America. The annual herbal drugs exported from China are estimated to be around 120,000 tonnes compared to about 32,000 tonnes from India [4–6]. The export of medicinal plants worldwide was in the range of US$15 million [7]. A staggering 8000 medicinal plant species in India are either

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cultivated or collected from the wild, of which approximately 960 plants are in active trade, with 178 being traded in quantities exceeding 100 metric tonnes [8–10].

The burgeoning international trade in herbal medicinal products has resulted in increased concern relating to the safety and efficacy of these products [1, 11, 12]. It is widely believed that there might be rampant adulteration in the raw herbal trade due to an increase in the demand for these herbal products. Many of these plant species are in short supply due to the lack of cultivation of the species or the rarity of species in the wild [10, 13, 14]. There are presently no global standard protocols or practices to identify and evaluate the different plant species or plant parts used in herbal products [1, 10]. It is only in recent years that the adverse consequences of species adulteration on the health and safety of consumers have come to light [11]. If not contained, adulteration could adversely impact the trade of medicinal plant products in the global market [10, 15–17].

In this paper, we review the nature and magnitude of species adulteration reported in the herbal trade market and discuss the potential underlying causes of adulteration. A literature search of the Google Scholar and PubMed databases was conducted (search date 20 August 2015–13 September 2016) using various search terms such as 'species admixture in herbal products', 'adulteration of herbal products', 'plants used in Ayurveda', 'plant substitution in Ayurveda', 'global herbal market', 'herbal trade and efficacy', 'DNA barcoding of medicinal plants', and 'chemical profiling of medicinal plants'. Coverage dates were from January 2001 to August 2016. Based on the literature search and our own recent findings, we highlight the possible adverse consequences that such adulteration could have on the safety and health of consumers. In the larger context of species adulteration, we discuss the issue of biological and chemical equivalence of species and argue how this could become critical in evaluating the viability of species adulteration. Finally, we propose the need to have stringent regulations on the quality assurance of herbal trade that would help regulate herbal trade around the globe.

2 Species Adulteration in Herbal Trade

Species adulteration in the raw herbal trade market has been suspected for a long time [18], with the proportion of adulterated herbal drugs sold in developing countries being anywhere between 10 and 80% [19]. In some African countries, the extent of adulterated herbal drugs was up to 80% due to the lack of proper identification methods and techniques [19, 20]. Only recently have these adulterations begun to be revealed using a variety of techniques. 'Omics' science, a compilation of diverse technologies such as genomics, proteomics and metabolomics, is the most recent technology being used in the identification of species adulteration [21]. For example, using techniques such as microscopy, mass spectrometry and, more recently, DNA barcoding, species adulteration have been reported in a number of herbal trade products worldwide [10]. Table 1 summarises some of the recent studies that have reported species adulteration in the raw herbal trade. Adulteration has ranged from as low as 21% (in *Crocus sativus*) to as high as 80% (in *Berberis asiatica*). In *Crocus sativus*, valued for its spice saffron, Torelli et al. found adulteration comprising seven other species using DNA Sequence Characterised Amplified Region (SCAR) markers [22] (Table 1). Employing DNA barcoding tools, Newmaster et al. reported rates of adulteration of herbal products sold on the North American herbal market as high as 59%, while in a study of species approved by the World Health Organization (WHO), Palhares et al. reported that substitutions may be as high as 71% [1, 23]. This is not surprising as workshops such as the 2014 US Pharmacopeial Convention (USP) on 'DNA for Quality Control of Botanical Products' (see http://www.usp.org) reported that 25% of samples tested were adulterated and that the actual level of adulteration may be more than 50%. The bark preparation of *Saraca asoca* is traditionally used to treat uterine bleeding in India, as well as being used in a number of Ayurvedic formulations. Beena and Radhakrishnan, as well as Begum et al., showed that the raw herbal material of this plant is often adulterated with the bark samples of *Polyalthia longifolia, Humboldtia vahliana, Shorea robusta* and *Mallotus nudiflorus* [24, 25]. Recently, Santhosh et al., using both DNA barcoding and nuclear magnetic resonance (NMR) spectroscopy, were able to demonstrate large-scale adulteration (up to 80%) in the raw herbal trade samples of *S. asoca*. These authors found several species (belonging to seven different families) in the market samples, suggesting rampant adulteration of the samples [26].

Seethapathy et al. examined the nature of the trade of the *Senna* species, known for its laxative properties, with analysis of trade samples from 30 shops in southern India showing extensive adulteration [13]. Using the DNA barcode regions *ITS*, *matK*, *rbcL*, and *psb*A-*trn*H, these authors showed approximately 50, 37 and 8% species adulteration in cases of *Senna auriculata, Senna tora*, and *Senna alexandrina*, respectively. The strict use of DNA barcoding using only *rbcL* and *matK* markers will not differentiate all herbal species. Newmaster et al. advocated for a tiered approach using several other DNA regions in the second tier, such as *ITS*, to differentiate medicinal plants [27]. Further discussions can be found in Newmaster et al. [1, 27] and de Boer et al. [14]. Zuo et al. analysed 95 different samples of Ginseng, representing all species in the

Table 1 Species admixtures in herbal trade

Sl. No.	Herbal plants/products[a]	Percentage of species admixture/substitutions[b]	Identity of species in admixture[c]	Discriminant technique	References
1	44 herbal products from 30 herbal species	68.18	Identified	DNA barcode	[1]
2	*Hordeum vulgare*	NQ	Not identified	DNA barcode	[78]
3	*Phyllanthus amarus*	24	*P. debilis, P. fraternus, P. urinaria, P. maderaspatensis* and *P. kozhikodianus*	DNA barcode	[41]
4	*Cassia fistula*	50	*Senna auriculata*	DNA barcode	[13]
5	*Ruta graveolens*	50	*Euphorbia dracunculoides*	DNA barcode	[79]
6	*Hypericum perforatum*	NQ	*Senna alexandrina*	DNA barcode	[1, 31]
7	*Piper nigrum*	22.2	*Capsicum annuum*	DNA barcode and HPLC	[36]
8	Ginseng product	50	Not identified	DNA barcode, SNP	[38, 39, 80]
9	*Crocus sativus*	21	*Arnica montana*, *Bixa orellana*, *Calendula officinalis*, *Carthamus tinctorius*, *Crocus vernum*, *Curcuma longa* and *Hemerocallis* species	DNA-SCAR marker	[22]
10	*Gingko biloba*	NQ	Not identified	HPLC and LCMS	[81]
11	*Hoodia gordonii*	NQ	Not identified	HPTLC	[82]
12	*Angelica sinensis*	50	*Angelica* species	*ITS*	[83]
13	*Berberis aristata*	80	*B. asiatica*, *B. chitria,* and *B. lycium*	Microscopy and HPLC	[42]
14	*Paris polyphylla*	NQ	*Acorus calamus*	Morphological traits	[35]
15	*Citrullus colocynthis*	NQ	*Trichosanthes palmata*	Morphological traits	[32]
16	*Swertia chirata*	NQ	*Swertia angustifolia*	Morphological traits	[32]
17	*Nardostachysjatamansi*	NQ	*Selinum* species	Morphological traits	[32]
18	*Sida cordifolia*	80	*Sida acuta*	DNA barcode	[34]
19	*Fritillaria pallidiflora*	NQ	8 species of *Fritillaria*	PCR–RFLP of *nr ITS*	[84]
20	*Cuscutare flexa*	NQ	*Cuscuta chinensis*	RAPD	[85]
21	*Glycyrrhiza glabra*	NQ	*Abrus precatorius*	RAPD	[86]
22	*Penthorum sedoides*	NQ	*Penthorum chinense*	RAPD, SCAR markers	[87]
23	*Echinacea purpurea*	NQ	Walnut	DNA barcode	[1, 53]
24	*Bacopa monnieri*	NQ	*Eclipta alba* and *Malva rotundifolia*	SCAR marker	[88]
25	*Cinnamomum verum*	70	*Cinnamomum cassia* and *Cinnamomum malabatrum*	SNPs–DNA barcode	[57]
26	*Saraca asoca*	31	*Polyalthia longifolia*, *Humboldtia vahliana, Shorea robusta* and *Mallotus nudiflorus*	TLC	[24, 25]
27.	*Saraca asoca*	80	Species from 7 different families	DNA barcoding and NMR spectroscopy	[37]
28	*Hypericum androsaemum*	NQ	*H. perforatum*	HRM	[31, 32]
29	*Piper kadsura*	NQ	*Piper wallichii*	DNA barcode	[33]
30	Herbal products	60	Different families	*ITS* and *rbc*L	[8]

HPLC high-performance liquid chromatography, *HPTLC* high-performance thin-layer chromatography, *HRM* high-resolution melting, *LCMS* liquid chromatography–mass spectrometry, *NMR* nuclear magnetic resonance, *NQ* species admixtures detected but not quantified, *PCR–RFLP* polymerase chain reaction–restriction fragment length polymorphism, *RAPD* random amplified polymorphic DNA, *SCAR* sequence characterised amplified region, *SNP* single nucleotide polymorphism, *TLC* thin layer chromatography

[a] Herbal medicinal plants/products used in trade

[b] Percent admixtures detected in raw herbal trade samples obtained from markets

[c] Plants detected in species admixtures

genus, using the DNA barcodes *matK*, *rbcL*, *ITS*, and *psbA-trnH*, and reported that the combination of both *psbA-trnH* and *ITS* can successfully identify all species in the genus [28]. Similarly, Guo et al. studied the adulteration of *Scutellaria baicalensis* (Lamiaceae; herbal drug: Radix scutellariae) with *S. amoena*, *S. rehderiana*, and *S. viscidula* using *matK, rbcL,* and *psbA-trnH*, and proposed that the barcodes *rbcL* and *psbA–trnH* could be used to identify *S. baicalensis* and discriminate the adulterants [29]. These authors also validated the DNA barcode *psbA–trnH* for the commercial samples of Radix scutellariae [29]. Sui et al. analysed the adulteration of *Sabia parviflora*, a widely used Chinese traditional medicine, with six different *Sabia* species and seven adulterants using *trnH-psbA*, *rbcL-a* and *matK*, and concluded that, together, all three barcodes successfully distinguished the different species and adulterants [30].

Hypericum androsaemum, commonly used in traditional medicine for its diuretic and hepatoprotective activities, is prone to be intentionally adulterated with other genera due to its less abundance and high demand. Moreover, *H. androsaemum* is unintentionally mixed with other *Hypericum* species [31]. The presence of both *H. androsaemum* and *H. perforatum* were detected in market samples, with a confidence level of 98.9 and 99.5%, respectively, when high-resolution melting (HRM) analysis was carried out [31]. This analysis has also been proven to be reliable and cost effective for identifying different species of Thai medicinal plants, with a success rate of 99% [32]. Similarly, Yu et al. showed that *Piper kadsura*, used as a traditional medicine for limb pain and anti-inflammatory activity, is substituted with *Piper wallichii*, a closely related species that does not have any medicinal value in some parts of China due to its morphological similarity and common vernacular names [33].

Using fluorescence microscopy, Zhao examined the structure of the endodermal cell wall of *Oldenlandia diffusa* and found that this well-known component of Chinese herbal tea was adulterated by two other species, namely *O. corymbosa* and *O. tenelliflora* [34]. Several such reports of species adulteration have been identified, arising out of either unrelated species (*Paris polyphylla*, *Citrullus colocynthis*), probably driven by overt morphological similarity between the species in question, or by using closely related species within the same genera; however, in recent years, species adulteration is simply driven by profit [1, 35–37]. Apart from this, traders have also resorted to using alternate plant parts of the same species, which either have less or no pharmacological effect, in the herbal drug. While this cannot be classified as species adulteration, it still amounts to fraudulent practice. For example, Lum et al. studied the two widely used traditional Chinese medicines, i.e. Oriental ginseng (*Panax ginseng* C.A. Meyer) and American ginseng (*Panax quinquefolius*). These two species were earlier distinguished either by analysing the ginsenosides using high-performance liquid chromatography (HPLC) or by DNA barcoding [38]. Unfortunately, both these methods could not differentiate from which part of the plant (roots, rhizomes or the skin) the herbal drugs were made.

Lum et al. used the proteomic approach of two-dimensional electrophoresis (2-DE) mapping of the different parts of Oriental and American ginseng and were able to obtain 2-DE maps that contained sufficient differences to permit easy identification of the different plant parts, as well as between the wild ginseng and ginseng obtained from culture cells [38]. Similarly, Kang et al. performed NMR-based metabolomics to discriminate ginseng roots collected from different regions of Korea. The principal component analysis (PCA) of the NMR data clearly differentiated the ginseng roots originating from different regions [39]. Ivanova et al. authenticated 15 different supplements made from five different plants, namely *Echinacea purpurea, Valeriana officinalis, Ginkgo biloba, Hypericum perforatum* and *Trigonella foenum-graecum* using next-generation sequencing (NGS) [40]. This approach successfully detected almost all the manufacturer-listed medicinal plants in dry herb form supplements.

3 Drivers of Species Adulteration

Product adulteration is often due to misidentification or substitution with an allied congeneric species [1]. Using DNA barcoding, Srirama et al. showed that in *Phyllanthus amarus*, an important hepatoprotective plant, 24% of shops were adulterated with six other *Phyllanthus* species [41]. Although all six species were herbaceous and taxonomically distinct, the collectors were naive in their ability to differentiate such species. Furthermore, since many of these species co-occur, discrimination is even more compromised. *Berberis aristata* is a heavily traded Ayurvedic herbal plant used in treating several ailments, including urinary disorders; however, this species is heavily adulterated with the allied species of *Berberis* and may not necessarily have the same therapeutic effects [42]. Thus, co-occurrence of allied members of a genus, as well as the inability of collectors to phenotypically discriminate the species, could lead to species adulteration [17, 41, 43].

In the raw herbal trade in India and Southeast Asian countries, herbal collectors gather approximately 80% of medicinal plants from the wild [44, 45]. Species adulteration might also arise due to the vernacular name for different species in the various indigenous systems of medicine [25, 46, 47]. Perhaps most alarming is the fact

that adulteration might be deliberately carried out in order to maximise profits. Deliberate adulteration leads to the use of alternate plant parts other than the parts used traditionally or prescribed in the Ayurvedic pharmacopoeia (a codified Indian system of medicine). For example, the root of *Withania somnifera* is considered to be a medicinally important part of the plant due to the presence of withanolides as marker constituents according to different pharmacopoeias [48]. The root samples are marketed based on the content of withanolides; however, the aerial parts of the plant also contain the marker compounds along with flavanoid glycosides specific to the aerial parts of the plant. Due to the increase in the global herbal trade, the roots of these plants are often mixed with the aerial parts of *W. somnifera* and are then fraudulently marketed [48].

4 Adverse Consequences of Species Adulteration

Irrespective of the factors driving species adulteration, the consequences of such adulteration on the safety and health of the consumer is of utmost concern [1]. De Smet reported that tea containing the adulterant *Adenostyles alliariae* causes severe liver disease if consumed for a prolonged period [49]. Tea has also been reported to be adulterated with *Illicium anisatum* [50], aconitum [51], and *Datura metel* [52], all of which can cause neurotoxicity in the body [20]. *Echinacea* is one of the leading herbal products sold in US markets for the common cold and as an anti-inflammatory and immunomodulator. Wallace et al. reported that *Echinacea* products often contained walnut, which can lead to severe health issues such as nut allergies [53]. Newmaster et al. showed that adulteration in *Echinacea* products could have possibly arisen as *Echinacea* herbs are often bordered with walnut trees [1]. Walnut leaves, bark and fruits contain juglone, a tumorigenic agent that promotes skin tumours and causes oxidative stress in humans [54].

In one of the most notable examples of the consequences of species adulteration known to date is the case where more than 100 women suffered kidney failure due to adulteration of the roots of *Stephania tetrandra*, an anti-inflammatory agent, with the roots of the toxic herb *Aristolochia fangchi.* Adulteration could be traced to the fact that both species are referred to as 'fanchi' in Chinese traditional medicine [55, 56] and it is likely that their identity was confused during collection (Fig. 1). Similarly, *Cinnamomum verum* bark that is adulterated with *C. cassia* and *C. malabatrum* has a bitter and burning flavour [57]. *C. cassia* contains 1% coumarin, a naturally occurring flavoring substance, and causes hepatotoxicity [58]. Dondorp et al. reported that 50% of artesunate (compound extracted from *Artemisia annua* L.) tablets sold in Southeast Asia are adulterated [59]. Severe kidney damage was caused due to adulteration of *Aristolochia* species containing aristolochic acid [20].

The USA Consumer Report tested ten different brands of ginseng and revealed that the ginseng extracts were made from two different species, namely *Panax* subspecies (true ginseng) and *Eleuthero coccus* (Siberian ginseng), which do not contain the bioactive ginsenosides, although the quantity of ginseng per capsule was described in the package. The concentration of ginsenoside in the capsules varied 50-fold [60]. Most recently, the natural weight loss formulation Herbal Flos Lonicerae (Herbal Xenicol) was found to have severe adverse consequences on patients [61], who were hospitalised for various symptoms, ranging from palpitations, severe gastritis, abdominal pain, and insomnia, after taking the formulation. The formulation was tested and results showed the presence of twice the normal dose of the banned slimming agent sibutramine. The UK Medicines and Healthcare Products Regulatory Agency (MHRA) banned this formulation [61]. As is apparent from the data above, it has only been in the last few years that adverse consequences have been studied and documented. Unfortunately, little is known about these consequences in many parts of Asia and Africa, where the volume and consumption of raw herbal trade is very high. More studies are clearly required in these regions to unravel the health consequences of species adulteration in the herbal trade.

5 Chemical and Biological Equivalence of Species Admixture and Substitutes

While health hazards of species adulteration are of paramount concern, equally important are the consequences attributable to the reduced effectiveness of the product owing to the loss in chemical and biological equivalence. Interestingly, the ancient Indian medical system, Ayurveda, had recognised the importance of species substitution as an important means of circumventing species unavailability based on their biological and chemical equivalence [62]. For example, according to the Ayurvedic texts Charaka Samhita [63], Bhavaprakasha Nighantu [64] and Bhaishajya Ratnavali [65], *Plumbago zeylandica* was considered a legitimate and equally effective substitute of *Baliospermum montanum* [66]. Two morphologically different species, *Centella asiatica* (family Apiaceae) and *Bacopa monnieri* (family Scrophulariaceae), both having the common vernacular name Brahmi, are sold by Ayurvedic practitioners in India for revitalising nerves and brain cells and improving memory [67, 68]. The formulations of both these plants were shown to significantly increase the learning abilities of albino mice [69]. 'Shankhpushpi',

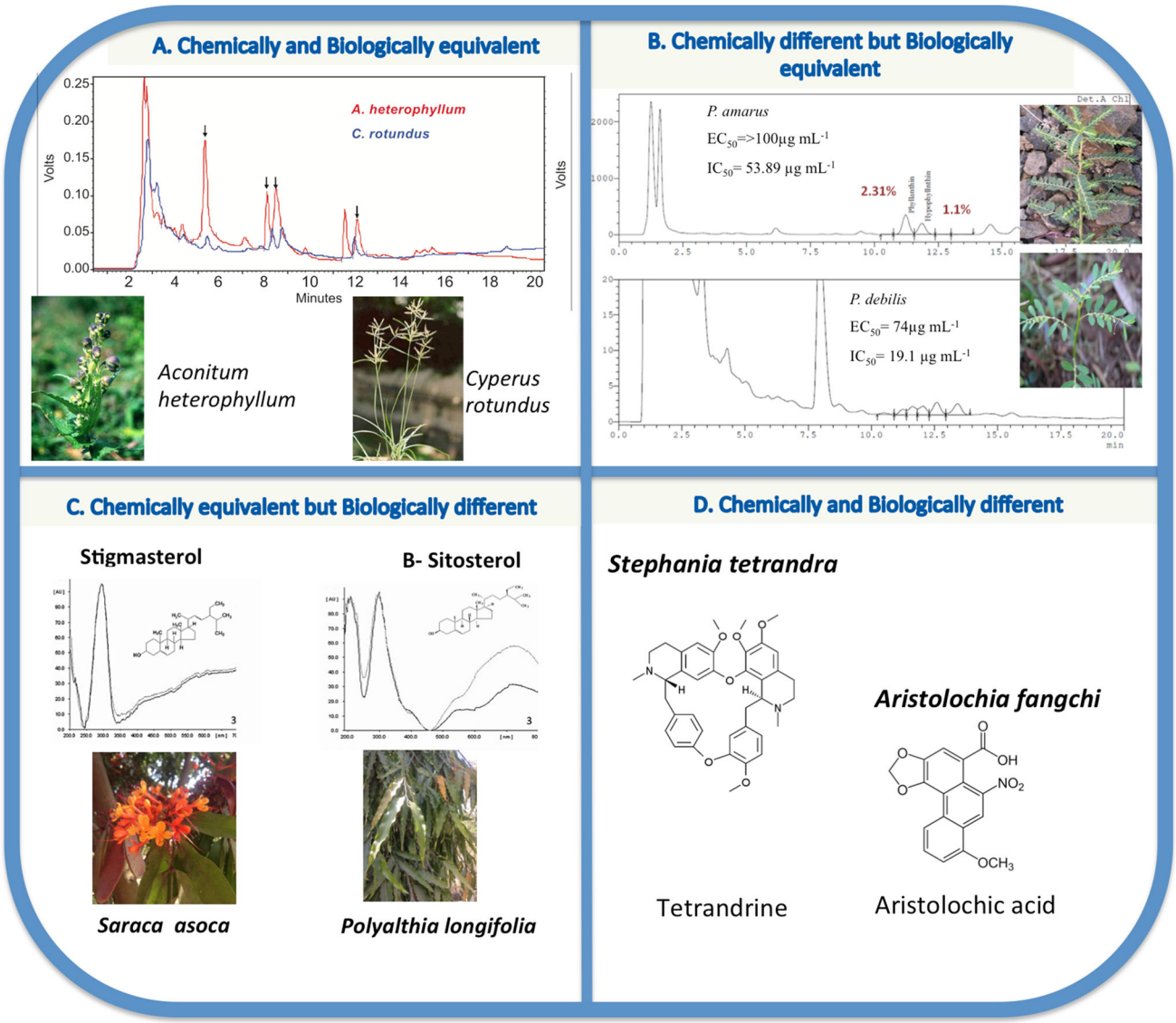

Fig. 1 Chemical and biological equivalence of species adulteration in the raw herbal trade. **a** Chemically and biologically equivalent. Despite their varied phylogenetic origins, the two species, *Aconitum heterophyllum* and *Cyperus rotundus*, bring about a similar biological effect (inhibition of diarrhoea), which might be due to them having a similar chemical profile [62]. Reproduced from Dr. P. Venkatasubramanian, Bangalore, India, with permission. The photos of *Aconitum heterophyllum* and *Cyperus rotundus* were provided by Dr. Subramanya [62]. **b** Chemically different but biologically equivalent. *Phyllanthus debilis* is one of the species of adulteration found in the trade of *P. amarus* (for its hepatoprotective property). Both species show a similar biological activity, although their chemical profiles are different [89]. **c** Chemically equivalent but biologically different. The trade of *Saraca asoca* (used in gynaecological disorders) is often adulterated with *Polyalthia longifolia.* Although these two species have overlapping and similar chemical compositions, their biological effects are different [90]. Reproduced from Dr. S. Khatoon, Lucknow, India, with permission. **d** Chemically and biologically different. The trade of *Stephania tetrandra* is often adulterated with *Aristolochia fangchi* (due to their common vernacular name); however, both of these plants share neither the chemistry nor their biological effects [55, 56]

prescribed in the Ayurvedic Pharmacopoeia for a therapeutic effect on central nervous system disorders, actually comprises one of four species: *Convolvulus pluricaulis*, *Evolvulus alsinoides, Clitorea ternatea* and *Canscora decussate* [70]. Three species, *E. alsinoides, Clitorea ternatea* and *Convolvulus pluricaulis* showed similar biological ability to enhance learning and memory and increase acetylcholine content. In addition, two of the species, *E. alsinoides* and *Convolvulus pluricaulis*, were found to contain the same active chemical principle, shankha pushpine [70].

Yet another example of species substitutability is the substitution of the Himalayan plant *Aconitum heterophyllum*, traditionally used to treat fevers and diarrhoea, with the common weed *Cyperus rotundus* [62] (Fig. 1). Despite being taxonomically very different, the chemical

fingerprints of the species were remarkably similar, justifying their bioequivalence [62]. Similarly, *Nardostachys jatamansi* (Valerianaceae) and *Selinum vaginatum* (Umbelliferae) are two important medicinal plants found in the Himalayan region. The roots and rhizomes of *N. jatamansi* are used in various Ayurvedic formulations to treat mental weakness, epilepsy and neurological disorders [71]. The roots of *S. vaginatum* are also used for different psychological and neurological disorders and as an analgesic; however, due to their morphological similarity, the roots of *S. vaginatum* are often used in the Indian herbal drug market as a substitute for *N. jatamansi* [72, 73]. Pandey et al. studied the antioxidant activity in both these species and reported that both species had potential antioxidants but their HPLC profiles were different. *N. jatamans*i consisted of phenolics that contained benzoic acid derivatives (protocatechuic acid and syringic acid), whereas *S. vaginatum* consisted of only hydroxycinnamic acid derivatives (chlorogenic acid and ferulic acid); however, *N. jatamansi* showed a lower half maximal inhibitory concentration [IC_{50}] (50 μg/mL) than *S. vaginatum* (165 μg/mL) [71].

In summary, species substitutions referred to in Ayurveda appear to be based on a sound rationale of biological equivalence and hence also chemical equivalence. However, most species adulteration currently practiced in the trade is not driven by this ancient principle of appropriate substitution, but is driven by negligence, ignorance or economically motivated adulteration. In the current context, and taking a cue from Ayurveda, it may be necessary to rationalise species substitution based on their biological and chemical equivalence to further regulate and stringently implement the existing regulations in the raw herbal trade.

6 The Road Ahead: Development of a Comprehensive Herbal Authentication System

Strong growth in the market for herbal medicines indicates that consumers are considering natural health products as alternative health care. This trend is placing considerable demand on raw herbal products globally; however, there is huge variation in regulatory policies for the trade of herbal medicines globally [74, 75]. Furthermore, since many of these herbal products are sold as dietary supplements and cosmetics [76, 77], the regulations that govern their trade are not under any strict governance [78]. For example, dietary supplements are regulated by the Dietary Supplement Health and Education Act (DSHEA) in the US, which allows these dietary supplements to be marketed without any approval from the quality assurance body, unlike

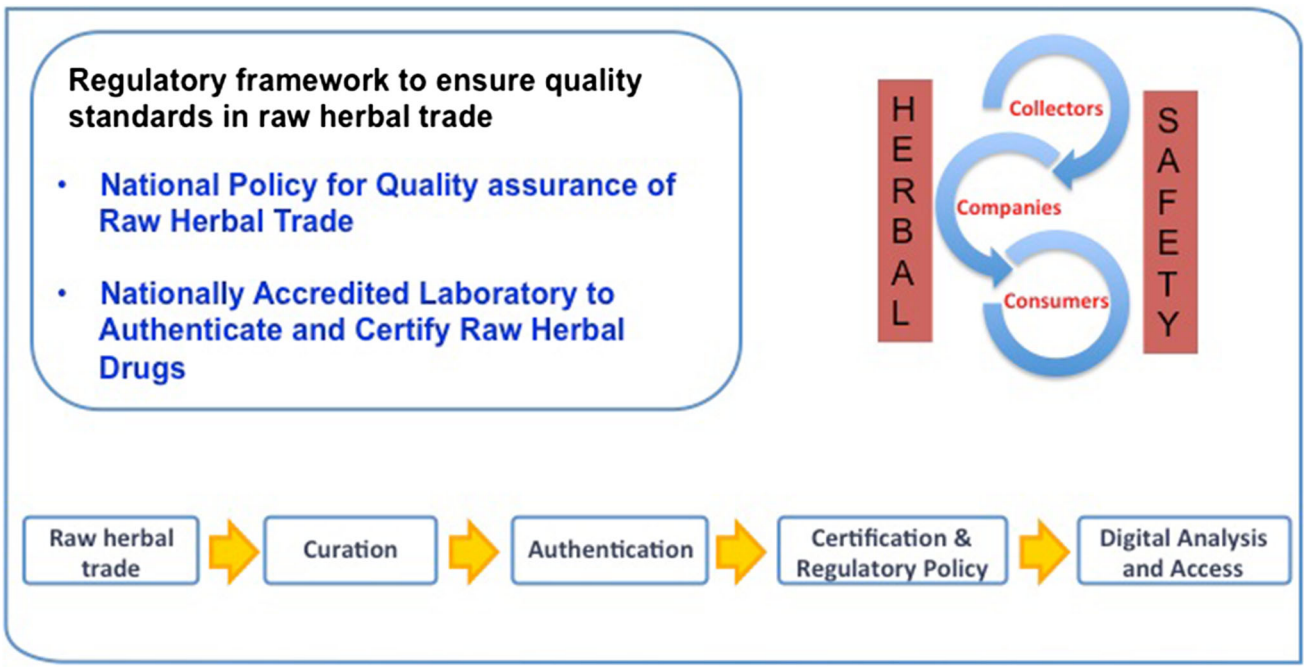

Fig. 2 Road map for a comprehensive herbal authentication system. By necessity, herbal authentication is a national endeavour, where the country exporting or importing should have necessary structures in place to ensure the credibility of the herbs in trade. Thus, a regulatory framework that involves a national-level policy for quality assurance, and a national accreditation laboratory that ensures such quality, needs to be established. The chain of events that would be required in the latter is depicted in the lower panel—from assessing raw herbal trade to its curation, identification and final documentation. In this process, the herbal product safety could be ensured, starting from collectors to companies and consumers

medicinal products [78]. This has resulted in adulteration being untraced and becoming quite common. Consequently, it is imperative that strong regulatory mechanisms and proper implementation of existing regulations need to be put in place that would ensure quality assurance, identity and safety, and allay the growing concern among consumers.

Since most herbal medicines are used in crude forms (unlike chemical drugs), have prolonged usage, and are most often used as a combination of several herbs, it is important that the species being used undergo strict authentication, safety assessment, and similar quality and regulatory approvals as the modern pharmaceutical drugs. Molecular diagnostic tools can be used commercially to assess species composition in herbal medicines, and have the potential to be used as a standard method in herbal pharmacovigilance, including adverse reactions to specific products [14]. The present review shows that a number of herbal products are adulterated due to either deliberate substitutions or mislabelling/misidentification by the collectors. Our review also highlights the fact that very few regulatory mechanisms are in place to effectively ensure the quality of the herbal product. At present, species identification is being carried out based on morphological, microscopic or chemical analysis, and, in the majority of cases, are not adequate to correctly identify the plant species [32].

Thus, it is important that a strong regulatory mechanism is put in place to monitor the quality, identity and safety of herbal products. Central to such a regulatory framework is the need to develop an efficient mechanism to assess the authenticity of the raw herbal products and link it with trade regulators, both nationally and internationally. A number of high-throughput tools are available to assess the authenticity of species, both DNA-based and metabolite-based. It might be necessary for all trading partners to develop such authentication of their respective biologically referenced material of all species in trade and use them to validate the authenticity of the material under trade. Molecular diagnostic tools, coupled with metabolite profiling, could be used to ensure the quality of the herbal medicine and make it safer, reliable, efficacious, sustainable, and marketable. Imports and exports can be governed by such validation certified by nationally recognised agencies (Fig. 2). It is important that this regulatory body also sets up a herbal authentication system wherein both the medicinal plants and its products are deposited. Furthermore, it is important that the molecular (DNA sequences) and metabolite profiles are also available, along with the plant samples. This would act as an easy reference for authentication.

In cases where a herbal product contains several herbs, it would be important that species identification is carried out prior to the herbal product being manufactured. Many Indian medicinal products contain mixtures of several herbs, making it difficult, time-consuming and expensive to meet the requirements of identification (both by DNA-based and metabolite-based technologies). However, with continued development and improvements in technology, especially high-throughput techniques being developed for barcoding and chemical analysis, a large number of samples can be handled. This could not only ensure that the raw herbal products be frequently validated but also a large number of species could be identified.

7 Conclusions

The development of a comprehensive herbal product authentication system, incorporating elements ranging from unique identifiers to trade policy, must be the way forward to regulate the raw herbal trade and regain consumer confidence. Furthermore, the establishment of multiple crude drug repositories to maintain authentic botanicals as reference standards can be developed to encourage comparative identity tests for industry, traders and researchers, and regulate the trade of certified authentic herbal products. This will also make the herbal medicines more credible and acceptable.

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Compliance with Ethical Standards

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