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# Manufacturing risk: *reframing the discourse of safety of commodified potent substances*

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ABSTRACT

*Ethnopharmalogical relevance:* The rapid commodification of plant-based medicines has led to the development of regulatory guidelines and standards by the World Health Organization to ensure the safety of these products. However, these standards have been identified to be selectively implemented, if implemented at all, in many contexts. A primary concern for proving the safety of intrinsic factors of plant-based medicines, may result in less attention paid to the often more problematic extrinsic factors of mass production. This article critically examines the normative global discourse of safety concerning plant-based medicines and problematises many of the assumptions identified in this discourse.

*Materials and methods:* This qualitative research was conducted in the Traditional Medicine Unit of the Western Pacific Regional Office of the World Health Organization (WHO) and in field work in the rural Philippines. Data was collected through archival research, analysis of WHO data sets, semi-structured and structured interviews and surveys, participant observation concerning local plant-based medicine use in the Philippines and participant observation in WHO meetings regarding future strategies for traditional Asian medicines.

*Results:* Although informants reported concerns of safety for every aspect of the production, marketing and sales of plant-based medicines, this research has identified that the implementation (WHO guidelines) has been uneven and inconsistent over the past ten years in the Western Pacific Region of the WHO. Differences in local contexts that are not consistent with global guidelines and standards were reported by informants. Issues have also been identified in the inconsistent regulation of plant-based medicines as pharmaceuticals within only certain, rather than all, processes of production.

*Conclusions:* It is imperative to understand plant-based medicines as the potent substances they are, whose rapid global commodification may affect both their potency and safety. The WHO discourse of the need for safety in the use of plant-based medicines has justified the need for biomedical oversight through processes of commodification. Yet, it is often through these very processes of commodification and mass production that safety may be compromised. This research suggests that the discourse concerning the safety of the plant-based medicines needs to be reframed from a primary focus on the intrinsic factors of plant-based medicines to a greater focus on the extrinsic factors of global commodification.



## 1. Introduction

As many of the articles in this volume have argued, plant-based medicines *are* potent substances. Yet, the importance of the potency of plant-based medicines may be buried in a discourse of global commodification that comprises numerous and often contradictory classifications, regulations, and uses of these substances. Although, the global commodification of plant-based health care products has been justified as the means by which to prove and improve the intrinsic effectiveness, quality and especially safety of the plants intended for human health, this article will identify how the extrinsic factors of production, marketing and regulation of these plants may raise more significant concerns of safety. The global discourse of plant-based medicines may need to be reframed to more accurately balance the myriad sources of risk resulting from the extrinsic factors of commodification and production.

The potential risk that is embedded in the large-scale manufacture of plant-based medicines is illustrated in the commodification of *Herba ephedra*. *Herba ephedra* appears in the Chinese Materia Medica as Mahuang (麻黄) and is used in traditional Chinese medicine (TCM) for expelling the pathogens of external wind and cold and thereby can treat the associated symptoms of the TCM pattern diagnosis of a wind/cold invasion. *Herba ephedra* is one of several plants used in

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Chinese formulae for this purpose and will be used for a specific period of time. However, with commodification *Herba ephedra*, and the active ingredient, ephedrine, have been frequently incorporated into both non-prescription "diet pills" and "sexual stimulants" that are usually unregulated as "dietary supplements" in several countries including the United States. At certain doses the alkyloid ephedrine can become a cardiotonic and has resulted in hypertension, tacyarrhythmia, hepatic failure and multiple cases of mortality from overdose (Stoynova and Getov, 2010). The safe use of *Herba ephedra* products can also be compromised by the methods of growing and harvesting the plant, the hygienic conditions of the manufacturing process, the inclusion of contaminants, the substitution of ingredients and the packaging and storage of the final product.

The commonality shared by all of these factors is that they occur at some point in the commodification process of the plant and thereby are external risk factors to any internal risk of the safety of the plant itself. This distinction is important to establish, for the global discourse concerning the safety of plant-based medicines portrays the plant itself as the primary source of risk, whose safe use is purportedly contingent on the commodification and manufacturing of the plant. Mahady (2001) states: "Careful scientific evaluation of safety and efficacy is essential before herbal medicines can be officially incorporated into primary healthcare systems and before there can be global acceptance of their health benefits." (1121 s). Framing safety thusly, may result in overlooking the risks that can arise throughout the manufacturing and production of plant-based medicines. This article critically examines the normative global discourse of safety concerning plant-based medicines.

### 1.1. Methodology

The following analysis is based on qualitative research conducted by the author between 2008 and 2011, in field work in the rural Philippines and as a researcher working with the Traditional Medicine Unit (TRM) of the Western Pacific Regional Office of the World Health Organization (WHO). Data collection included: archival research, analysis of WHO data sets, semi-structured interviews with purposive and snowball sampling of pertinent stakeholders, participant observation concerning local plant-based medicine use in the Philippines and participant observation in WHO meetings regarding future strategies for traditional Asian medicines.

### 1.2. The "visible hand" of the market: the rapidly growing commodification of plant-based medicines

Since 1994, the global demand for plant-based medicinal products has increased at an annual rate of 8% (WHO-WPRO, 2012). The World Bank reports that "trade in medicinal plants, botanical drug products and raw herbs is growing at an annual rate between 5 and 15%" (Citarasu, 2010:403). The total value of the global herbal medicine market was estimated to be U.S. $83 billion in 2009 (Heinrich et al., 2012) "and is expected to grow to $5 trillion by the year 2050" (Citarasu, 2010:403).

In the United States, the public spent $4.2 billion on plant-based medicines, or nearly one-quarter of the $17.8 billion spent on all dietary supplements in 2001 (Citarasu, 2010:404). "The European market for herbal supplements and herbal medicines is currently worth about $7.4 billion. Germany is the largest European market, with a 27% share, followed by France (24%), Italy (12%) and the UK (9%)" (Heinrich et al., 2012:4).

China's herbal drug production alone has been estimated to be worth export values of $8 billion (Heinrich et al., 2012). Europe has more than 300 suppliers of Chinese medicine for export sales of US $151.15 million in 2005 and accounts for 44.5% of the global plant-based medicine market share (Pricewaterhousecoopers, 2009). The rapid globalisation of these products has, at least in part, been supported by the ability to purchase them from the internet (Heinrich et al., 2010). Clearly, plant and food-based health care products have become a significant and profitable globally traded commodity within a relatively short period of time.

### 1.3. The current situation: minding the gaps between rapid commodification and "safety"

A predominant concern for the WHO, and for many countries importing plant-based health care products, is whether standards of safety have been able to keep up with the pace of the rapidly expanding commodification of these products. In a situational analysis performed for the Western Pacific Regional Office (WPRO) of the WHO in 2010 for their current global strategy for Traditional Medicine, the following was identified.

The WHO currently lists 193 member states of which only 94 (or 49%) are identified to have laws, standards or regulations for "herbal medicines" (WHO-WPRO, 2010). Hence, approximately half of all WHO member states either do not have laws or regulations for herbal medicines or have not reported any to the WHO. This has been identified as a particular cause for concern for the WHO and for importing nations as more countries enter the global plant-based medicinal market.

This is not to say that there has not been any growth in national laws or regulations for herbal products. During the period from 1987–2003, two or more WHO member states have reported national laws or regulations for herbal products every year (World Health Organization, 2010). However, several issues have been identified with these regulatory processes. The majority of countries who identified the type of law or regulation they had in place for plant-based medicines was commonly listed as the same law or regulation as was currently in place for biomedical pharmaceuticals. Yet, to regulate plant-based medicines as though they are the same as biomedicines may present its own set of challenges. For example, unlike many biomedical pharmaceuticals plant-based preparations often consist of numerous plant species in a formula, rather than a single pharmacologically active substance (Edwards et al., 2011).

Furthermore, plant-based health care products do not share the same globally standardised prescription/non-prescription classificatory system used to distinguish the purchase and use of biomedical pharmaceuticals. Rather, counties employ a classification system appropriate for their given context. For example, in the UK a plant-based product intended for health care use can be classified as a *licensed herbal medicine*, a *traditional herbal medical product* or an *unlicensed herbal medicine*. None of these require the intervention of a practitioner for prescription and even licensed herbal medicines may "rely on bibliographic evidence to support efficacy and safety, rather than being required to carry out new controlled clinical trials [and] stringent testing" (Heinrich et al., 2012:6). In contrast, plant-based medicines in the United States are usually regulated as dietary supplements and thereby are not carefully regulated. Though "limited therapeutic claims may be made … dietary supplements do not have to be assessed for safety and effectiveness … prior to marketing" in the U.S. (Heinrich et al., 2012:8).

Furthermore, these classifications may change over time in different locations. For example, *Ginkgo biloba* was considered a food until recently in the UK and now is regulated as a traditional herbal medical product in the UK, an herbal medical product in Germany and a food supplement in the U.S. (Heinrich et al., 2012:5). Thus, regulating plant-based health care products in this manner potentially confuses boundaries between what is to be considered, and thereby regulated as, a food, a dietary supplement and/or a medical product.

Less than half of all WHO member states legally permit herbal and plant-based medical products to be associated with therapeutic claims and less than a third permit herbal products to include any