

Review Article

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Counterfeit Herbal Medicines and Herbal Medicinal Products (HMP) - A Global Threat

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Abstract

The use of herbal remedies, nutraceuticals, and dietary supplements has increased greatly over the past four decades. Much of the increase in use can be attributed to the common belief that natural ingredients are inherently safer and healthier than synthetic ingredients. Estimates of the scale of the global trade in counterfeit medications vary widely. According to the Food and drug administration (FDA), 6%-10% of medicines sold worldwide are counterfeit. Counterfeit drugs are often manufactured under unsafe conditions and may contain too little, too much, or no active pharmaceutical ingredients. Adulterations possess serious health implications to the body. Drugs such as Sibutramine and fenfluramine are used treat obesity and have been found in some natural herbal products for weight loss. Sibutramine increases the risk of cardiovascular conditions like increased blood pressure and heart rate. Fenfluramine on the other hand is associated with severe lung and heart valve disease. The mass production of fake and substandard medications is growing global problems with deleterious impact on the individuals who ingest them. Without adequate safeguards and quality control mechanisms, there is no assurance that the concentrations of active ingredient are consistent from batch to batch or even that these supplements contain the ingredients they purport to contain. Pharmacists must also cope with an environment in which there is relatively little regulation of herbal therapies by FDA.

Keywords: Counterfeit herbal medicine, global threat, WHO survey, misidentification, undeclared synthetic pharmaceuticals, health safety concern.

Organized Crime and Terrorist Threats:

Annual profits of \$200 billion generated from counterfeit drugs now represent more than the world's combined heroin and cocaine markets, which total \$160 billion [1]. The International Institute of Research Against Counterfeit Medications (IRACM) has labeled counterfeit medications as "the new face of organized crime." Well-funded organized global crime syndicates produce counterfeit drugs from all major therapeutic classes of medications, and they are doing so in more than 100 countries [2].

Counterfeit drug profits are estimated to be from 10 to 20 times more profitable than heroin. For example, crime syndicates investing \$1,000 can return \$20,000 through counterfeit currency or heroin distribution, \$43,000 from counterfeit cigarettes, or \$200,000 to \$450,000 from counterfeit drugs [2].

The mass production of fake and substandard medications is a growing global problems with deleterious impact on the individuals who ingest them. Estimates of the scale of the global trade in counterfeit medications vary widely. According to the Food and Drug Administration (FDA), 6%-10% of medicines

sold worldwide are counterfeit. The use of herbal remedies, nutraceuticals, and dietary supplements has increased greatly over the past 40 years. Much of the increase in use can be attributed to the common belief that natural ingredients are inherently safer and healthier than synthetic ingredients. Products sold as "dietary supplements" are subject to significantly less regulation and are often not required to have safety testing or FDA approval before they enter the market. Without adequate safeguards and quality control mechanisms, there is no assurance that the concentrations of active ingredient are consistent from batch to batch or even that these supplements contain the ingredients they purport to contain.

In recent years with ever-growing commercialization in the field of herbal medicines, there has been an instant demand for quality control of drugs used in this system. For this standardization is usually recommended as the solution to the problem.

Unfortunately, many of these licensed herbal products have been found to contain non-prescription or even prescription drugs such as phosphodiesterase-5 inhibitors, e.g. sildenafil, tadalafil, verdenafil and their analogues. The imperceptible use of these analogues is very dangerous because they have not been tested

formally for safety and efficacy. In view of the potential harm to the public health, more effective and proactive measures are required to guard against the illicit use of pharmaceutical analogues.

Slimming drugs e.g. sibutramine HCl, des methyl sibutramine, diethyl propion, phenolphthalein, phentermine, Orlistat, Xenical, mazindol, pencil amine, phendimetrazine tartarate, methyl phenidate, anti-histamine e.g.; anti-diabetic like liraglutide; antidepressant e.g. fluoxetine HCl; antihypertensive e.g. tenormin; laxative like ducolax; psychostimulants like benz; meth and dextro amphetamine, are commonly found admixed with herbal drugs, inspite of fact that some of the synthetic drugs are banned e.g. Phenolphthalein as it causes cancer and Sibutramine HCl due to its side effects.

Analgesics e.g. paracetamol, indomethacin, diclofenac are frequently found adulterated in herbal analgesics. Most of the cholesterol lowering herbal medicines contain Statistins, e.g. Pravastatin, Simvastatin Atrovastatin; Steroidal drugs e.g. Cortisone, cyproheptadine HCl, are found in many of the herbal medicines. Antidiabetic herbal drug contains sulphonyl ureas e.g., glibenclamide, tolbutamide, metformin, rosiglitazone and many of them are found to contain two at a time. The abnormal presence of sulphonyl urea and it's over dose causes profound hypoglycemia.

Chocolate and slimming chocolate drinks are found to contain PDE-5 inhibitors and Phenolphthalein respectively. Coffee Sachets from Hong Kong and Korea were found to contain Sibutramine HCl. Herbal Medicinal Products include Honey and Henna containing phosphor diesterase 5 inhibitors (PDE-5) and para phenylene di amine (PPD). Adulterations found and identified in different classes of medicines are dealt in the present paper.

Any medicine herbal or otherwise might have adulteration and has the potential to have adverse effects. In the case of herbal medicinal products, the adulterated chemicals are obviously not shown in the list of ingredients; hence the severity is many folded as physicians and pharmacists are not aware of those undeclared chemicals, for any advice, causing serious risk to the public.

In a survey done by WHO it has been estimated that 80% of more than 7000 million i.e. (7 billion) inhabitants of the world rely mainly on traditional medicine for their primary health care needs and it can safely be presumed that a major part of the traditional therapy involves the use of plant extracts or their active principles.

In developed countries too plant derived drugs are considered important. In USA for e.g. 25% of all the prescriptions dispensed from community pharmacies contain plant extracts or their active principles, prepared from higher plants.

But unfortunately, quite a number of these drugs are frequently adulterated with cheap, less potent and spurious plant materials either posing danger to the public health or not as efficacious as expected, hence quality studies are very important:

Quality control analyses of herbal medicines is more difficult as compared to modern drugs which in majority contain only one/two active ingredients whereas the herbals/botanical drugs contain many chemical constituents and with the increasing number of ingredients (Drugs containing more than one plant) the constituents are multiplied accordingly.

Examples:

Mis-identification of two Chinese plants (in a slimming preparation)

is believed to be responsible for serious toxicity (Renal Intestinal Fibrosis) experienced by some 70 Belgium women, 30 of them needed dialysis or Kidney transplantation. This was a confusion between *Stephania tetrandra* and *Aristolochia fangchi* and is thought to have arisen because of the similarities for the two plants.

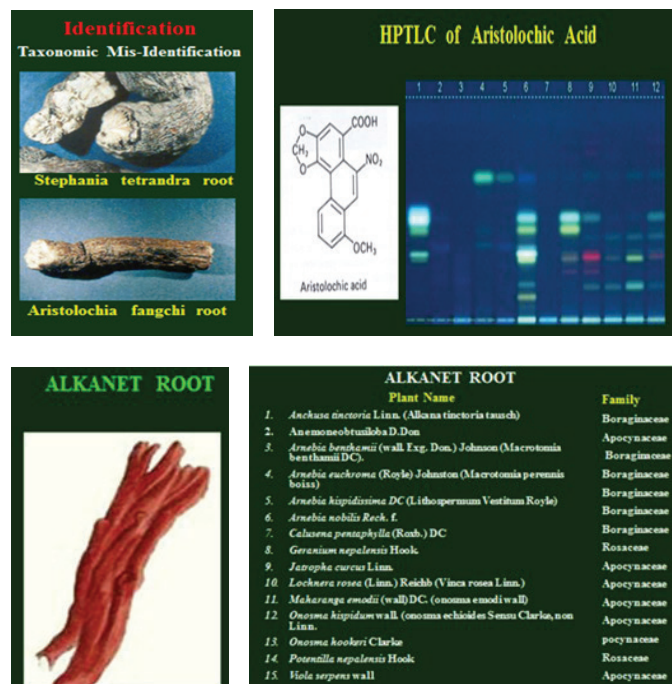


Figure 1

I have identified an emerging trend where over-the-counter herbal products, frequently represented as dietary supplements, contain undeclared or hidden active ingredients that could be harmful. In the best interest of public health safety. The present paper includes practical laboratory experience for four possibilities of counterfeit in herbal medicines:

1. The first one is herbal medicines adulterated with undeclared Synthetic pharmaceuticals,
2. With undeclared heavy metals,
3. Herbal medicines without active ingredient and
4. Herbal medicines with wrong active ingredient.

In United Arab Emirates many herbal products and supplements that are found adulterated with undeclared synthetic pharmaceutical (Possibility 1). Many of these licensed herbal products, unfortunately have been found to contain non-prescription or even prescription drugs. The common synthetic adulterants are steroids, anti-histamines, NSAIDs, slimming agents, anti-diabetics and drugs for erectile dysfunction such as phosphodiesterase- 5 -inhibitors and their analogues. The imperceptible use of these analogues is very dangerous because they have not been tested formally for safety & efficacy. Antidepressant, antihypertensive, laxative and psychostimulants are also found being admixed with herbal drugs. Besides medicines, Chocolate, slimming drinks, Coffee Sachets and are also found to contain PDE-5 inhibitors and Phenolphthalein respectively. Herbal Medicinal Products analyzed include quite a large number of Honey and Henna samples containing PDE-5 inhibitors and PPD respectively.

(Possibility 2) MHRA has investigating reports of the use of, mercury, Lead and arsenic in unlicensed Ayurvedic and traditional Chinese medicines. Reports from U.S.A. suggest that a number of patients suffered lead poisoning following use of a range of

unspecified Ayurvedic medicines. A number of medicines analyzed here were found to contain lead much exceeding prescribed limits, besides face creams having high concentration of mercury.

(Possibility 3 and 4) Cheaper and similar wrong plants are used and replaced instead of the right one, as found in many cases, or sometimes mentioned active ingredient is found absent. This leads to severe toxic effects e.g. *Aristolochia fanchi* in place of *Stephania tetrandra*.

Unfortunately, many of the licensed herbal products have been found to contain non-prescription or even prescription drugs such as phosphodiesterase- 5 inhibitors e.g. sildenafil, tadalafil, vardenafil and their analogues, whereas herbal analgesics drugs are being adulterated with synthetic drugs e.g., paracetamol, indomethacin, diclofenac, propoxyphene HCl.

Slimming Herbal drugs are found to contain e.g., sibutramine HCl, diethylpropion, phenolphthalein, Orlistat, xenical, pencillamine, phentermine HCl, Phenformin, Amphetamine & its analogues. Cholesterol-lowering herbal drugs contain statins, e.g., pravastatin, Simvastatin, Atorvastatin, fluvastatin, rosuvastatin, etc. Steroidal drugs, e.g., cortisone, cyproheptadine HCl, are being added in many herbal products to increase its efficacy.

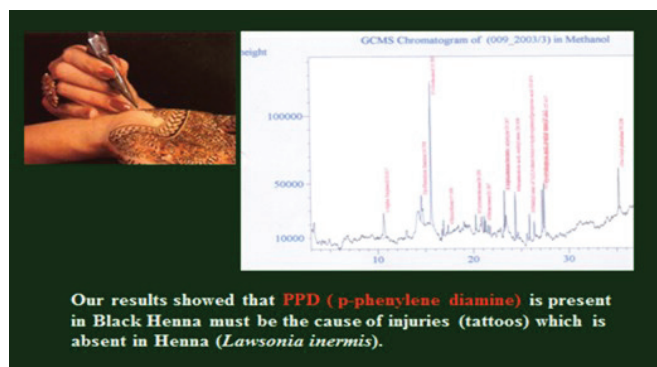


Figure 2

According to laboratory tests and studies, Satibo capsule contains a chemical substance known as Sildenafil, a main ingredient used in Viagra, which has an adverse effect on heart patients. Sildenafil interacts negatively with nitrates, such as nitroglycerin, taken by angina patients. Interaction of nitrates with chemicals present in such male impotence drugs as Viagra or Satibo could cause a serious drop in blood pressure.

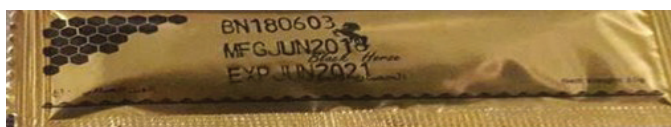


Figure 3

Black Horse Honey showed the presence of a hidden chemical compound Tadalafil, a PDE5 inhibitor marketed for treating erectile dysfunction under the name Cialis, which lead to a sharp fall in blood pressure. Hence, it can be a threat to heart patients

because it increases the heart rate, leading to angina or strokes.



Figure 4

Black Horse Honey showed the presence of a hidden chemical compound Tadalafil, a PDE5 inhibitor marketed for treating erectile dysfunction under the name Cialis, which lead to a sharp fall in blood pressure. Hence, it can be a threat to heart patients because it increases the heart rate, leading to angina or strokes.

Extenze is an over-the-counter male enhancement supplement marketed to boost sexual performance, stamina, and size. However, health agencies warn that it lacks clinical proof for permanent enlargement, and the FDA has previously found batches tainted with hidden prescription drugs like sildenafil. The Food and Drug Administration informed that the fake “Extenze” pills, marketed to improve male sexual performance, contain tadalafil and sildenafil, the active ingredients in Cialis and Viagra. Both drugs require a doctor’s prescription. The FDA says the counterfeit product looks like Extenze, which is an herbal supplement. It says the counterfeit products are marked with lot numbers 1110075 and F050899. The FDA says consumers should stop taking any questionable pills and contact their doctors about any side effects. An FDA official says there is a growing trend of products that are marketed as supplements but contain hidden drugs and chemicals.



Figure 5

Traditional or herbal capsule products marketed for “asam urat” (gout) and “flu tulang” (joint or bone pain) frequently receive public health and regulatory warnings (such as from health agencies like BPOM and international bodies) because they illegally contain hidden chemical drug ingredients like phenylbutazone, paracetamol, or diclofenac. These unregulated mixtures pose severe health risks.



Figure 6

Herbaeos-Zuekertec Herbal Dietary Supplement: Manufactured by: Sinar Aman Pharmaceuticals, Malaysia The following compounds are identified in the powder content of 'Herbaeos-Zuekertec Herbal Dietary Supplement on Chromatographic studies and Mass spectrometric analysis: Momordica charantia Triacotane; Azadirachta indica; Glibenclamide; Glucophage. Glibenclamide and Glucophage are present in a very high concentration.



Figure 7

An ayurvedic tablets for rheumatoid arthritis showed the presence of lead, mercury and arsenic. Lead was exceeding the permissible limits.

The press conference organized as part of the "National Consciousness Week Against Counterfeit Medicines" provided an opportunity to address the issue of fake medicines [3]. A member of the Department of Health (DOH) of Philippines stated that this scourge is badly expanding and becoming a serious concern both for governments and pharmaceutical and phyto-pharmaceutical industries. Moreover, he explained that counterfeiting is not a simple crime and became one of the most lucrative income sources for pharmaceutical terrorists and crime networks. The credibility of governments but also of the industry is coming into question.

Health Safety Concerns:

Counterfeiters are not motivated to ensure the safety and efficacy

of their products. Therefore, these criminals take whatever steps are necessary to turn a profit. Counterfeit drugs are often manufactured under unsafe conditions and may contain too little, too much, or no active pharmaceutical ingredients. Floor wax, rat poison, concrete, chalk, boric acid, road tar, paint, and antifreeze are only a few of the dangerous or toxic ingredients found in counterfeit drugs. Hence, patients taking counterfeit drugs are at risk of dangerous health consequences ranging from unexpected side effects to allergic reactions to worsening of their medical conditions. In the most severe cases, patients may experience serious injury and even death. Adulterations possess serious health implications to the body. Drugs such as Sibutramine and fenfluramine are used treat obesity and have been found in some natural herbal products for weight loss. Sibutramine increases the risk of cardiovascular conditions like increased blood pressure and heart rate. Fenfluramine on the other hand is associated with severe lung and heart valve disease. Natural skin care products have also been found to contain corticosteroids; steroidal prescription drugs used to treat inflammatory conditions, like arthritis, allergies, and skin problems like psoriasis and eczema. Corticosteroids have serious side effects and these include irregular heartbeat, increased blood pressure, stomach ulcer, blood disorders, skin, muscle and bone damage, and nervous system disorders. Antidiabetic drugs like glibenclamide and metformin have also been found in some herbal products used for the management of diabetes in other countries [4]. Glibenclamide for instance, is not recommended for people with decreased kidney and liver function; therefore, its usage as an adulterant in any herbal formulation may damage both the kidneys and liver in such people. Drugs such as sildenafil, tadalafil, and vardenafil have been found in herbal products for sexual enhancement. Increased risk of side effects like heart attack, stroke, chest pain, high blood pressure, and abnormal heartbeat is associated with the usage of these drugs in people with heart problems. Other side effects include headache, facial flushing, indigestion, dizziness, abnormal vision, and hearing loss.

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