

Editorial

ADULTERATION OF HERBAL MEDICINES AND DIETARY SUPPLEMENTS WITH UNDECLARED SYNTHETIC DRUGS: DANGEROUS FOR HUMAN HEALTH

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The popularity of using herbal medicines, nutraceuticals or food supplement is increasing all over the world due to the obligatory side-effects, in some cases tremendous side-effects, of synthetic medicines. The vital concept in favour of the huge consumption of herbal medicine is that the marketers and manufacturers deliver the message that herbal medicines and dietary supplements are free from all sorts of side-effects and the general people believe on that perception. It is very much true that herbal medicines contain several medicinal plants which may contain lot of bioactive therapeutic molecules by dint of which the preparations exert therapeutic effects for the treatment and mitigation of diseases. Health benefit of herbal medicines and other alternative medicines from dietary or natural sources is scientifically evident from many scientific studies. Besides, herbal medicines have less or minimal side-effects compared to synthetic drugs.

Herbal medicinal plants contribute to the achievement of almost 80% of modern drug inventory. But recently different scientific and monitoring investigations reported to contain undeclared synthetic drugs in herbal medicines and dietary supplements. The hidden drugs may cause serious toxic-effects to health. Recently the United States Food and Drug Administration (US-FDA) moved against such kind of adulterated, counterfeit and dangerous dietary supplements and alternative medicaments [1]. FDA detected hidden metformin and Sitagliptin in dietary supplements and Ayurvedic medicines which are illegal. Several studies reported to contain hidden synthetic medicines, metals, or other toxic substances in high concentrations [2] which may put the health of patients at risk. Analysis of 2600 Chinese herbal medicines found that 24% of total samples contained at least one synthetic medicine [3]. A meta-analysis showed that herbal medicines contained heavy metals which are toxic for human health [4]. There is an emerging growing trend of marketing of dietary supplements or conventional foods or natural products with hidden drugs and harmful chemicals all over the world. Some under-developing countries have no specific rules and controlling system and authority for dietary supplements. Such kind of products are usually promoted and sold as pure natural or 100% natural products for the improvement of sexual dysfunction, weight reduction, body building etc. United States Food and Drug Administration already identified, reported and displayed public notification against six such kinds of products in their website [5] between January to March 2014. 'Tiger King' is such a product which was promoted as traditional Chinese medicine for sexual stimulation found to contain sildenafil, the active ingredient of Viagra which is indicated under strict prescription for erectile dysfunction. Another product is 'SexRx' which was sold as dietary supplement for male sexual performance enhancement was found to contain sildenafil and tadalafil (active ingredient of Cialis). 'Vimax' capsule was sold as dietary supplement, 100% natural product, made in Canada, was found to contain hidden chemical tadalafil. 'TINQIANGBUDOR Red Dragon' tablet promoted as pure herbal product contained sildenafil. 'Bali mojo' and 'Weekend warrior' sold as dietary supplements contained hidden chemicals tadalafil and thiosildenafil, respectively. FDA identified and issued public warning against 34, 15, 2, and 5 of such kind of counterfeit and adulterated products in the year 2013,

2012, 2011, and 2010, respectively. The increasing figure indicates that the number of adulteration of herbal drugs and dietary supplements is increasing drastically. FDA found by analysis that the products that were promoted as natural and dietary supplements for increasing sexual power or energy or body building contained one or two or up to five of the following hidden chemicals: sildenafil, sulfoildenafil, dimethylsildenafil, dimethylacetylsildenafil, hydroxyhomosildenafil, hydroxythiohomosildenafil, vardenafil, noracetildenafil, dapoxetine, tadalafil, and aminotadalafil [5]. The most alarming message is that one product (for example 'Alpha male' which was sold as 100% natural) contained five hidden chemicals with high dose having similar pharmacological activities which is not only toxic but also may be lethal to the users.

Not only dietary supplements and sexual stimulants, many other products of traditional herbal medicines were reported to be adulterated with various types of hidden synthetic chemicals having different pharmacological activities. Different studies reported the presence of glucocorticoids (dexamethasone, betamethasone, prednisolone, cortisone acetate, hydrocortisone), non-steroidal anti-inflammatory drugs (diclofenac, phenylbutazone, ibuprofen), anti-hypertensive agents (amlodipine, valsartan, clonidine, metoprolol, chlorthalidate), and so many other types of therapeutic synthetic agents as adulterants [6] in the preparations of traditional herbal medicines that are sold as 100% pure, naturally originated and free from side-effects.

Although dietary supplements are popular in the developed western world including USA, Europe and Canada, herbal medicines are mostly popular in developing countries in Asia, Africa and other areas of the world. India, China, Hong Kong, and Korea are major producer of herbal and traditional medicines. Herbal medicines are popular in almost all the Asian and African countries including Bangladesh, Nepal, Kenya, South Africa, and so on. Generally, the production and quality assurance of herbal medicines are not strictly controlled as done in case of Allopathic medicines and good manufacturing practices (GMPs) are not strictly applied in its manufacturing process. Besides, herbal and traditional medicines may contain many pharmacologically active chemicals from different parts of several plants. Therefore, it is very difficult to monitor how many chemicals are present in a preparation if the manufacturers are dishonest. Moreover, traditional and herbal medicines and supplements are not widely clinically studied for its long-term safety, drug-interaction, etc., although many studies are going on for the investigations of these matters. The growing existence of hidden synthetic chemicals in the herbal and dietary supplements of products marketed in USA (which have highly skilled detection system by FDA and penalty by applying strict country law) deliver us message that how much adulterated herbal and dietary products we may have in the developing countries. An undisclosed analytical report done in sexual, energetic, anti-diabetic herbal products of Bangladesh indicated that 48 out of 50 samples contained synthetic undeclared chemicals with high doses. In conclusion, it is recommended that the dietary supplements should be under strict controlled of the drug regulatory authority of the

country where those products have no controlling agency. The quality of those products should be monitored regularly by the drug controlling authority and should take effective steps and actions against the criminals. The patients and general people should also be aware about the possible adulteration and reliability of the product before using it. Every user should consult with a physician before using any medicament and even a dietary supplement. Herbal medicines or traditional medicines or alternative medicines and dietary supplements of course have a positive role in the treatment and mitigation of diseases and have long glorious success history. No need to insert synthetic chemicals for playing its role. The manufacturers and promoters are requested to refrain such kind of bad practice for the sake of human health and to not to destroy the glory of herbal or complementary medicines.

REFERENCES

1. Burton TM. FDA moves against alternative diabetes treatments. Wall Street Journal. 2013 July 23. Available from: <http://online.wsj.com/news/articles/SB10001424127887324>
2. Marcus DM, Grollman AP. Botanical Medicines - The need for new regulations. *New Engl J Med* 2002; 347:2073-6.
3. Ernst E. Adulteration of Chinese herbal medicines with synthetic drugs: a systematic Review. *J Inter Med* 2002; 252:107-13.
4. Ernst E, Thompson J. Heavy metals in traditional Chinese medicines: a systematic review. *Clin Pharmacol Ther* 2001; 70: 497-504.
5. U.S. Food and Drug Administration-U.S. department of health and human service. Tainted sexual enhancement products-public notifications. <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/medicationhealthfraud/ucm234539.htm> [Last accessed on 2014 March 16]
6. Haneef J, Shaharyar M, Husain A, Rashid M, Mishra R, Siddique NA, Pal M. Analytical methods for the detection of undeclared synthetic drugs in traditional herbal medicines as adulterants. *Drug Test Anal* 2013; 5:607-13.