

Z.25023/09/2017- DCC (AYUSH)

Government of India

Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy  
(AYUSH)

AYUSH BHAWAN,

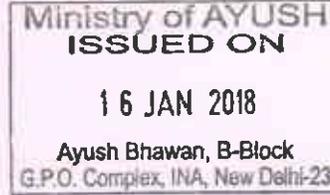
B - Block, GPO Complex,

INA, New Delhi - 110023

Dated: 15 January, 2018

To

The Executive Editor,  
'Pune Mirror',  
C/o Times of India,  
Bccl Times House,  
577, F, C Road, Shivaji Nagar,  
Near Vaishali Hotel,  
Opposite Fergusson College,  
Pune-411005 — 993



Sub: The Pune Mirror news "Ayurvedic Med Poses Life Threat" published on 25<sup>th</sup> December, 2017-reg

Sir,

I am directed to refer to news entitled "Ayurvedic Med Poses Life Threat" published in The Pune Mirror newspaper on 25th December, 2017 (copy enclosed).

2. The title of the news item is so generalized that it may lead to an overall distrust in the minds of the readers at large regarding the safety, efficacy and overall credibility of Ayurveda in general and Suvarna Bhasma- an important Ayurvedic medicine in particular.

Every medicine whether synthetic or natural has a potential risk of causing health hazard, if it is not manufactured properly with assurance of quality, safety and efficacy and not consumed judiciously without adequate medical advice from a qualified medical practitioner of concerned system of medicine.

3. You might be aware that the regulatory and quality control mechanism *inter-alia* for Ayurvedic medicines has been established in the country in accordance with the provisions of the Drugs & Cosmetics Act, 1940 and Rules thereunder which are amended from time to time. Exclusive provisions exist in the Drugs & Cosmetics Act, 1940 and Rules thereunder for the licensing, manufacturing, labeling, shelf-life and testing of these drugs. State Governments are responsible to enforce the legal provisions for Ayurvedic medicines, for which Licensing Authorities/Drug Controllers are appointed. Good Manufacturing Practices and Quality Standards for manufacturing of Ayurvedic

medicines as prescribed in the Drugs & Cosmetics Rules, 1945 and the Ayurvedic pharmacopoeia, respectively are mandatory for the manufacturers to follow. Quality and authenticity of the Ayurvedic medicines is checked on the basis of standards of identity, purity and strength prescribed in the pharmacopoeia. For this purpose Central Government has set up Pharmacopoeial Laboratory of Indian Medicine in Ghaziabad, Uttar Pradesh as an appellate laboratory and there are 27 State Drugs Testing Laboratories and 44 laboratories approved under the provisions of Drugs & Cosmetics Rules, 1945 for testing of Ayurvedic medicines and raw materials. States have appointed inspectors to inspect the Ayurvedic manufacturing units and take samples for testing or analysis. Guidelines for issue of license for the manufacturing of various categories of Ayurvedic medicines are prescribed under Rule 158-B of the Drugs & Cosmetics Rules, 1945 including the requirement of submission of proof of safety and effectiveness of the drug applied for obtaining manufacturing license from the Licensing Authority.

4. Minerals and metals form an integral part of specific category of Ayurvedic, Siddha and Unani formulations called 'Rasaushadhies'. Such ingredients are used in the preparation of medicines after subjecting them to certain pharmaceutical processes including 'shodhana (detoxification)', 'marana (incineration & calcination)', and 'amritikarana (qualitative improvement)' to render them safe and therapeutically effective, with judicious and rational use. In this regard, Part-I, Volume-VII of the Ayurvedic Pharmacopoeia of India mentions the quality standards of 21 minerals & metals for regulating the use of these ingredients in the manufacturing of Ayurvedic, Siddha and Unani drugs. Schedule-E (1) of the Drugs & Cosmetics Rules, 1945 contains the list of 69 potentially hazardous substances of plant, mineral and animal origin including heavy metals. As per Rule 161 of the Drugs & Cosmetics Rules, 1945, in case of formulations containing any of the Schedule-E (1) ingredients, it is mandatory for the manufacturer to display on the label 'Caution: to be taken under medical supervision' both in English and Hindi languages.

5. In view of the above regulatory safeguards and steps taken by the Government to address the issue of quality of Ayurvedic drugs, the act of labeling Suvarna Bhasma as a life threatening medicine and that too on the basis of incomplete information, unconfirmed reports and without consultation with AYUSH regulators is misleading, *malafide*, uncalled for and nothing less than an act of irresponsible reporting by a newspaper of National repute. Without an iota of doubt, such a publication tantamounts to deliberately tarnishing the image of Ayurveda and infringe the faith of

people in this traditional system of medicine, most likely with some vested interest and probably on behest of a lobby that feels threatened with the revived interest of the masses in Ayurvedic drugs.

6. Moreover, as far as the issue of lead toxicity due to consumption of Ayurvedic drugs is concerned, according to the World Health Organization (WHO), Lead is a naturally occurring toxic metal found in the Earth's crust. Its widespread use has resulted in extensive environmental contamination, human exposure and significant public health problems in many parts of the world.

Lead is a cumulative toxicant whose important sources of environmental contamination include mining, smelting, manufacturing and recycling activities, and, in some countries, the continued use of leaded paint, leaded gasoline, and leaded aviation fuel. More than three quarters of global lead consumption is for the manufacture of lead-acid batteries for motor vehicles. The Institute for Health Metrics and Evaluation (IHME) has estimated that in 2013 Lead exposure accounted for 853000 deaths and 16.8 million disability adjusted life years (DALYs) due to long-term effects on health, with the highest burden in developing regions. People can become exposed to lead through occupational and environmental sources mainly from inhalation of lead particles generated by burning materials containing lead, for example, during smelting, recycling, stripping leaded paint, and using leaded gasoline or leaded aviation fuel; ingestion of lead-contaminated dust, water (from leaded pipes), and food (from lead-glazed or lead-soldered containers); and use of some traditional cosmetics and medicines containing lead.

The menace of Lead toxicity is so rampant globally that the WHO celebrated the international Lead poisoning prevention week of action from 23 to 29 October, 2016 with a particular focus on eliminating Lead paint.

Recently, the Food Safety and Standards Authority of India (FSSAI) has released an advisory against the practice of using newspapers to wrap cooked food. It has been said that the Newspaper ink contains heavy metals like lead and cadmium which may leach into the food.



7. It is imperative to note that the news report under consideration is not a complete report and is devoid of following vital information:

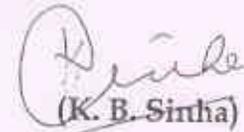
- i. the details of the alleged Ayurvedic 'concoction' that was consumed by the patient for one and a half months and which led to increase in the blood level of lead by nearly 15 times the normal level are not mentioned;
- ii. the fact that the appearance of 'Burtonian Line' on the teeth, is a characteristic of 'chronic lead poisoning' which results after years of exposure to elevated levels of lead in the blood, does not correlate with the alleged exposure of one and a half months;
- iii. it is not clear if the alleged Ayurvedic drug was prescribed by a qualified Ayurvedic physician;
- iv. it is not clear if the alleged Ayurvedic drug was taken by the patient in the prescribed dosage;
- v. it is not clear if the alleged Ayurvedic drug was consumed with appropriate 'Anupana'(vehicle);
- vi. it is not clear if appropriate do's and don't were prescribed / followed;
- vii. it is not clear what 'other bhasmas' were given to the patient along with 'suvarna bhasma.
- viii. it has been mentioned that the patient had to be treated with 'lead chelation therapy' whereas, lead is not a constituent of the suvarna bhasma;
- ix. the details of the drug analysis are also not made available; and
- x. it is not evident if the patient was on some concomitant medication which could have contributed to the deterioration in health.

8. It is pertinent to note that one bad example cannot be allowed to tarnish the credibility of the whole system of Ayurveda. In the instant case, the title of the news item is so catchy that it gives the impression as if Ayurveda as a whole is not safe for human use. The adverse effects of the Ayurvedic formulation reported in the news item are apparently due to irrational use and / or poor quality of the medicine. Moreover, the details of the drug analysis are also not made available. It is not evident if the patient was on some concomitant medication or was exposed to some other potential source of lead intoxication which could have contributed to the deterioration in health. Statements of the experts quoted in the news item are also vague and biased with an intention to malign Ayurveda.

9. In view of the above, 'The Pune Mirror' may consider publishing a corrigendum and apology at the earliest to enlighten the readers and explain to this Ministry the basis of publishing the news in such an irresponsible manner, within two weeks of this communication failing which, the matter will be taken up with the PTI and PIB. Also, the newspaper may abstain from publishing such derogatory reports which tarnish the credibility of time tested medicines.

Encl.: as above

Yours faithfully,

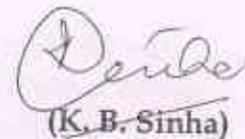


(K. B. Sinha)

Under Secretary to the Govt. of India

Copy to:

1. The Secretary, Press Council of India, Sochna Bhavan, 8-C.G.O. Complex, Lodhi Road, New Delhi-110003 with a request for issuing necessary advisory to the TOI against the news item in reference. — 994
2. The Editor-in- Chief, The Press Trust of India Limited, PTI Building, 4, Parliament Street, New Delhi - 110 001 with a request for issuing necessary advisory to the TOI against the news item in reference. — 995



(K. B. Sinha)

SIGN IN

# PuneMirror

MUMBAI MIRROR BANGALORE MIRROR AHMEDABAD MIRROR

## AYURVEDIC MED POSES LIFE THREAT

By Vicky Pathare, Pune Mirror | Updated: Dec 25, 2017, 02:30 AM IST



REPRESENTATIVE PIC FROM THINKSTOCK

### **Suvarna Bhasma consumed by 47-year-old for nearly two months increases lead levels, damages liver, kidney**

A 47-year-old Kharadi resident was suffering from minor acidity problems, but did not want to take allopathic medicines. Little did she know that the ayurvedic concoction she consumed for one-and-a-half months instead would increase the lead levels in her body, damage her vital organs and put her in a life threatening condition.

Saroj Patil (name changed) was rushed to Ruby Hall Clinic last Monday (December 18) with complaints of severe abdominal pain, recurrent vomiting, irrelevant speech and loss of balance. The hospital's screening test showed that Saroj had severe Hyponatremia, a condition where the level of sodium in the blood is too low. Hers was 105 milliequivalents per litre (mEq/L), whereas the normal level is between 135 and 145 mEq/L. Heavy metal screening showed the level of lead to be 354.60, almost 15 times more than the acceptable level in an adult's body. Her haemoglobin had dropped to seven and her liver also didn't function properly.

Dr Abhijit Lodha, consultant physician at Ruby Hall Clinic, said, "The test to find Hyponatremia showed huge amount of sugar in her urinary (PH) sample, which was alkaline and not acidic. As the sodium was passing through urine, it affected the kidneys, which were unable to retain the glucose. During examination, we found a Burton line on the gums of the patient, which is an indicator for lead toxicity (Huge amount of lead in one's body)."

Almost a couple of months ago, Saroj began suffering from acidity. So, she consulted an ayurvedic doctor who lives in the same society and practices ayurvedic medicines. She was given Suvarna Bhasma and some other Bhasma by the doctor. Saroj spent around Rs 47,000 every week for the medicines and was almost convinced by the practitioner to go for a longterm course of the Bhasmas, with assurances that she would never have an acidity problem in future. "The patient later told us about the consumption of Bhasmas, after which we came to know that the reason for Hyponatremia is the heavy metal in ayurvedic medicines. The abdominal pain in the patient was due to the lead toxicity. Even consumption of ayurvedic medicines can prove life-threatening and has side effects. The patient should be well aware of the content of the medicines. We have put her on lead Chelation therapy and she is improving well," Lodha added.

Saroj recalled her experience, saying, "The ayurvedic doctor assured me that there will be no problem of acidity in future and was even ready to give me a written assurance, so I readily agreed for it. I know that consuming allopathic medicines gives one an acidity problem, so I wanted to go for Ayurvedic medicines. I never thought that consuming these medicines can land me in such trouble. I've learnt my lesson the hard way. I would never consume ayurvedic medicines after this incident."

Dr Atul Rakshe, secretary-general of the International Ayurveda Association (IAA) said, "One should never think that Ayurvedic medicines have no side effects. There is a Good Manufacturing Practice (GMP) certification given to the manufacturing units of ayurvedic medicines as a quality check, which has to be followed. There are chances that the Bhasmas consumed by the patient might not be GMP certified. The doctor who guaranteed that the problem will be solved gave false assurances. No doctor should be doing this."

■ One should never think Ayurvedic medicines have no side effects. There is a GMP certification given to the manufacturing units of ayurvedic medicines as a quality check, which has to be followed. The Bhasmas consumed by the patient might not be GMP certified

—Dr Atul Rakshe, secretary-general, IAA