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: 7th April, 2017**

To

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**Shri. Jaideep Bose**
Executive Editor,
The Times of India,
Times House,
7 Bahadurshah Zafar Marg,
New Delhi - 110 002.



**Sub:** The Times of India news "Poison in Ayurvedic Drugs"on 31st March, 2017-reg

Sir,

I am directed to refer to news entitled "Poison in Ayurvedic Drugs" published in the Times of India newspaper, Ahmedabad edition on 31st March, 2017 (**copy enclosed**).

2. This is to express displeasure of the Ministry on the above said news as the title of the news item is so generalized, derogatory and alarming that it may lead to generate distrust in the public at large regarding the safety, efficacy and overall credibility of AYUSH systems in general and about Ayurvedic drugs 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 Government has taken up optimal development and propagation of AYUSH systems and a large institutional network is in place to meet the health care needs of the people.

4. It is pertinent to note 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 Pharmacopoieal 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.

5. 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.

6. 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 TOI in labeling all Ayurvedic drugs as 'poison' and that too on the basis of incomplete information and unconfirmed reports, without verification and consultation with the regulators and after seven years of the alleged consumption 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 tantamount 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 possibly at behest of a lobby that feels threatened with the emerging interest and demand of the masses in Ayurveda and other AYUSH systems.

7. It is ironical that on 31st March, 2017 on one hand the TOI has labeled Ayurvedic drugs as 'poison' and on the other hand on the same day the Economic Times has reported the steps being taken by the Ministry of AYUSH to augment the regulatory system and to bring in greater transparency and quality control in regulation of ASU&H drugs (**copy enclosed**).

8. 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.

9. The news report under reference has not mentioned the details of the alleged Ayurvedic drugs consumed by the patient for ten months. It is not clear if it was a herbal drug or a herbo-mineral drug or whether it was really a licensed Ayurvedic medicine. It is also not clear if the alleged 'Ayurvedic drug' was prescribed by a qualified Ayurvedic physician or the patient underwent self medication with it. 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.

10. In view of the above, TOI may consider publishing a corrigendum and apology at the earliest to enlighten the readers or provide a substantial proof that the alleged product was not of appropriate quality and caused the reported health hazards.

**Yours faithfully,**

**Encl.: as above**

(K. B. Sinha)

**Under Secretary to the Govt. of India**

**Copy to:**

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1. The Secretary, Press Council of India, Soochna 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.

6375 ✓

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.

(K. B. Sinha)