

(d) if so, the reaction of the food industry and other stake-holders in this regard?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (d) Yes, Food Safety and Standards Authority of India (FSSAI) has issued a new advisory on 11th December, 2012 relating to sale of new or existing proprietary food products. As per Section-22 of the Food Safety and Standards Act, 2006 (FSSA), "no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic food, foods for special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf. As on date, there is no standard for these food items in India. Hence, new advisory has been issued in this regard. This advisory has been drafted after detailed consultations.

#### **Introduction of new TB drug**

3794. SHRI A. ELAVARASAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether TB is rated as a major public health problem in India and the country accounts for one-fifth of global TB cases;

(b) if so, the details thereof;

(c) whether Government is set to introduce a new TB drug, Bedaquiline, on an experimental basis;

(d) if so, the details thereof;

(e) whether the new drug, Bedaquiline, can kill the TB bacteria quicker than the existing drugs and Indian Medical Council has prepared to introduce the drug under controlled conditions at 4-5 DOTS Plus sites to assess its impact on MDR and XDR-TB; and

(f) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) Yes. The prevalence of TB cases in the country is showing a declining trend. The estimated prevalence of TB has been brought down from 586/ lakh population (1990) to 249/ lakh population in 2009 as per the WHO global report 2010.

(c) and (d) A new drug can only be introduced in the Indian market after due approval from Drug Controller General of India (DCGI), Ministry of Health and Family Welfare/Government of India.

No application under the Drugs and Cosmetic Rules has been received by the Drug Controller General (India) [DCGI] for the grant of permission to market Bedaquiline in India.

(e) and (f) According to the US-FDA news release of 31st December, 2012, the combination therapy of Bedaquiline in MDR cases achieved sputum culture conversion in lesser duration as compared to Placebo combination therapy.

Indian Medical Council or Medical Council of India does not deal with introduction of Drugs under control conditions.

#### **Directives for prescribing generic medicines**

3795. SHRI PARIMAL NATHWANI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Medical Council of India (MCI) has directed doctors, hospitals and medical colleges to prescribe generic medicines as far as possible;

(b) if so, the details thereof; and

(c) the manner in which Government proposes to ensure compliance of the directives?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (c) The duties and responsibilities of the physicians as prescribed under the Code of Medical Ethics in the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 contain the provision that every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs. These regulations prescribe for removal of registration of the errant medical professionals for violation of the provisions altogether or for a specified period. To deal with the unethical behaviour of some medical professionals in promoting/ endorsing the (costly branded) products of pharmaceutical companies in lieu of unethical gratifications/inducements, the Medical Council of India had amended the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 bringing the conduct of medical professionals in their relationship with