

Safety checks on Ranitidine medicine

1380. SHRI A. MOHAMMEDJAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the Central Drugs Standard Control Organisation has asked the State regulators to communicate to the manufacturers of Ranitidine active pharmaceutical ingredient and formulations to verify their products and take appropriate action to ensure patient safety;

(b) whether it is also a fact that cancer causing substances have been detected in antacid Ranitidine medicine; and

(c) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) to (c) Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare has asked the State Drugs Controllers to instruct the manufacturers of Ranitidine API & formulations to verify/test their products and take appropriate measures to ensure patient safety. CDSCO had also instructed zonal offices for drawing of samples for testing the level of NDMA impurity in ranitidine.

World Health Organisation has also published Information Note dated 20. 11.2019 regarding Nitrosamine impurities in certain drugs including ranitidine. In the said 'Information Note' WHO has mentioned the details of nitrosamine impurity, toxicity, test methods, regulatory action taken in various countries etc. w.r.t. Rantidine.

Considering various aspects, WHO has recommended for certain measures to control such impurity.

CDSCO has accordingly forwarded a copy of the WHO Information Note to all the State / UT Drugs Controller.

High expenditure on cancer treatment

1381. SHRI A. MOHAMMEDJAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether it is a fact that two-thirds of India's cancer patients were treated in the private sector and this forced 6 crore Indians below the poverty line because of catastrophic healthcare related expenditure on cancer;
- (b) whether it is also a fact that India's cancer burden is likely to increase from 13 lakh cases in 2018 to 17 lakh in 2035;
- (c) whether the number of newly diagnosed cases of cancer annually is about 16 lakh and that the disease kills 8 lakh people annually; and
- (d) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) to (d) As per Indian Council of Medical Research (ICMR), the estimated incidence of cancer cases in India was 15.86 lakh in the year 2018 which is projected to increase to 17.3 lakh by 2020. Projected cases of cancer is computed by using a projected incidence rate and population. The estimated mortality of cancer cases in 2018 was 8.01 lakh. Cancer is diagnosed and treated at various levels in the Government health care system, as well as in the private hospitals. While doctors with D. M. (Medical Oncology), M.Ch (Surgical Oncology) and M.D. (Radiation Oncology) treat Cancer patients in higher level tertiary care hospitals, Cancer is also being treated in hospitals by other Doctors such as General Surgeons, Gynecologists, ENT Surgeons etc., depending on the type and site of Cancer. However, the information regarding the treatment of cancer patients in private sector is not maintained centrally.

Cases registered against food adulteration

1382. SHRI K. J. ALPHONS: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) how many cases have been registered against adulteration of food during the last three years; and
- (b) in how many cases have the offenders been penalised?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) and (b) Enforcement of the provisions of Food Safety and Standards Act, 2006, Rules and Regulations made