

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO.1868
TO BE ANSWERED ON 30TH JULY, 2021**

FLOUTING NORMS FOR MASK AND SANITIZER SPECIFICATIONS

**1868. SHRIMATI MALA RAJYA LAXMI SHAH:
SHRI KUNWAR PUSHPENDRA SINGH CHANDEL:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the Government has also taken cognizance of PPE kits, sanitizers and masks not being manufactured as per the norms laid down in the country;
- (b) if so, the details thereof, State/UT-wise along with the steps being taken by the Government in this regard;
- (c) whether the quantum of medical waste has been increasing constantly in the country; and
- (d) if so, details of steps being taken by the Government for disposal of the said waste?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)**

(a) & (b): Ministry of Health & Family Welfare issued notification vide S.O. 648 (E) dated 11.02.2020 specifying all medical devices by definition under Section 3 (b)(iv) of the Drugs and Cosmetics Act, 1940 in order to regulate them for quality, safety & performance. In addition, through G.S.R 102(E) dated 11.02.2020, mechanism for regulation of all non-notified medical devices in phased manner has also been specified. As per the above notification, PPE kits and masks which fall under class B of Medical Devices will come under license regulation after 30 months from the date of effect of the notification.

Also CDSCO has requested all States/UTs Licensing authorities through several advisories to instruct their enforcement staff to keep strict vigil especially at sensitive places on attempts at black-marketing/hoarding of Covid management drugs and to take stringent action against the offenders.

As per information available from various State Licensing Authorities, various enforcement actions like seizure, arrests of accused persons / registration of FIR etc. have been carried out by the State Licensing Authorities.

(c): The Central Pollution Control Board (CPCB) has informed that the non-COVID waste generated in the country during 2017-18, 2018-19 and 2019-20 is estimated to be 531 Tons/ Day (TPD), 608 TPD and 615 TPD respectively.

(d): The Ministry of Environment, Forest and Climate Change (MoEFCC) had notified the Biomedical Waste Management Rules, 2016 (BMWM Rules, 2016) under Environment (Protection) Act, 1986, which stipulate source segregation of the Bio-Medical waste (BMW). The Rules also stipulate technological options available to treat the source-segregated waste categories and prescribe standards for incinerator stack emission, treated effluent, autoclave/ microwave/ hydroclave and chemical disinfection. The State Pollution Control Boards/ Pollution Control Committees (SPCBs/ PCCs) issue authorisation to Healthcare Facilities, Common Biomedical Waste Treatment Facility operators; and monitor them for compliance of prescribed standards of emissions, liquid effluents and waste.