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

LOK SABHA UNSTARRED QUESTION NO. 2679 TO BE ANSWERED ON 06TH MARCH. 2020

DRUGS AND COSMETICS AMENDMENT RULES, 2018

2679. SHRI C.N. ANNADURAI:

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

- (a) whether the Government proposes to take necessary measures to create new rules under the Drugs and Cosmetics Amendment Rules, 2018;
- (b) if so, the details thereof; and
- (c) if not, the reasons therefor?

ANSWER THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. HARSH VARDHAN)

(a) to (c): Amendment of Drugs & Cosmetics Rules for incorporating new provisions in accordance with the changing requirements is a continuous process. A number of such amendments have been carried out during the year 2018 which include incorporation of provision for mandatory submission of stability data of drugs, certain exemption for manufacturing of Oxygen 93%, labelling requirements for the drugs, etc.