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

LOK SABHA
UNSTARRED QUESTION NO. 2511
TO BE ANSWERED ON 9TH MARCH, 2018

LABELLING NORMS FOR GENERIC DRUGS

2511. SHRI GAJANAN KIRTIKAR:
    KUNWAR HARIBANSH SINGH:
    SHRI SUDHEER GUPTA:
    SHRI ASHOK SHANKARRAO CHAVAN:
    SHRI BIDYUT BARAN MAHATO:
    SHRI A. ANWHAR RAAJHAA:
    SHRI T. RADHAKRISHNAN:
    SHRI NARANBHAI KACHHADIYA:
    SHRI S.R. VIJAYAKUMAR:

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

(a) whether the Government proposes to make it mandatory for pharma firms to carry the generic names of drugs in letter that are two font sizes larger than the brand name;

(b) if so, the details thereof along with the aims and objectives thereto;

(c) the time by which it is likely to come into force;

(d) whether the Government has consulted Indian Drug Manufacturers Association (IDMA) in this regard; and

(e) if so, the details thereof and the response of the IDMA thereto?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) to (c):   In order to ensure that the consumer is well informed about the generic medicine, Ministry of Health & Family Welfare published a draft notification for public comments vide GSR 302 (E) dated 30.03.2017 for amendment of Rule 96 to provide that the proper name of the drugs shall be printed in a conspicuous manner which shall be in the same font but at level two font size larger than the brand name or the trade name, if any. It will come to force after completion of due formalities as per the provisions of the Drugs & Cosmetics Act, 1940.

(d) & (e):   Indian Drug Manufacturers Association (IDMA) was invited to the stakeholders meeting held on 12.12.2017 in Central Drugs Standard Control Organisation (CDSCO) and they conveyed their inability to attend the meeting. However, they had already provided their suggestions/ comments on the draft notification vide letter dated, 11.05.2017 which has been received in the Ministry.