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

LOK SABHA
STARRED QUESTION NO. 391
TO BE ANSWERED ON THE 19TH JULY, 2019
ILL-EFFECTS OF ANALGIN

***391. SHRIMATI MANEKA SANJAY GANDHI:**

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

(a) whether the Government is aware of all the ill-effects of the medicine 'Analgin' which is banned across majority of the countries in the world but not in India;

(b) if so, the details thereof and the reasons for not banning the medicine;

(c) whether the Government is planning to ban various medicines which have been banned in other countries, keeping in view their ill-effects on humans; and

(d) if so, the details thereof?

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

(a) to (d): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 391* FOR 19TH JULY, 2019

(a) & (b): The manufacture for sale, and distribution of Analgin and its formulations containing Analgin for human use was initially suspended in the country vide Gazette Notification No. G.S.R 378(E) dated 18.06.2013 on the recommendations of the New Drugs Advisory Committee (Analgesics, Anesthetics & Rheumatology).

Subsequently, Drugs Technical Advisory Board (DTAB), a statutory body to advise the Government on technical matters for administration of the Drugs & Cosmetics Act, examined the issue of suspension of manufacture and sale of the said drug in its 65th meeting held on 25.11.2013. On the basis of the recommendation of the DTAB, Government of India revoked the above notification vide No. G.S.R 86(E) dated 13.02.2014 subject to the condition that manufacturers shall mention the following on their package insert and promotional literature of the drug:

"The drug is indicated for severe pain and pain due to tumor and also for bringing down temperature in refractory cases when other antipyretics fail to do so".

(c) & (d): All drugs have some side effects. The drugs are approved and allowed to be manufactured and marketed in India based on their risk-benefit analysis. A drug banned / restricted in one country may continue to be marketed in other countries as each country examines the usage, doses, indication permitted, etc. and overall risk-benefit ratio and accordingly takes decision on the continued marketing of the drug in that country.

Regulation of various drugs available in the country is an ongoing process. These issues are assessed in consultation with the Expert Committees/ DTAB. Based on the recommendations of the Expert Committees / DTAB, the Central Government considers to regulate/ restrict/ prohibit the manufacture, sale and distribution of such drugs in the country.

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