

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

STARRED QUESTION NO:449

ANSWERED ON:27.08.2010

SIDE EFFECTS OF HEALTH SUPPLEMENTS

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

- (a) whether the Government monitors the quality and efficacy of calcium and such other health supplement tablets, available in the market;
- (b) if so, the details thereof;
- (c) whether as per a study of an international panel of researchers, calcium supplements have dangerous side effects on health;
- (d) if so, the details thereof alongwith the reaction of the Government thereto; and
- (e) the corrective measures taken/proposed to be taken in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE(SHRI GHULAM NABI AZAD)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 449 FOR 27TH AUGUST, 2010

(a) & (b): Formulations containing calcium intended for prophylactic and therapeutic use are regulated under the provisions of the Drugs and Cosmetics Act, 1940 & the Drugs and Cosmetics Rules, 1945 made thereunder.

(c) to (e): A report of a meta-analysis of cardiovascular events in randomised studies of calcium supplements have been published recently in The British Medical Journal (BMJ:2010:341:c3691) which suggests that calcium supplements without co-administered Vitamin-D are associated with an increased incidence of myocardial infarction. The report further suggested that a reassessment of the role of calcium supplements in the prevention and treatment of osteoporosis (porous bone) is warranted.

However,this meta-analysis has various limitations. The study has excluded comparative studies that compared co-administered calcium and Vitamin D supplements with placebo (formulation without active ingredient).

Another recent report of a study entitled "Calcium supplementation, cardiovascular disease and mortality in older women" published in The Journal of "Pharmacoepidemiology and Drug Safety", 2010, Vol.19, Pages 59-64, which undertook an observational analysis of primary care database of UK population to examine the cardiovascular effects of combined calcium and Vitamin-D supplementation, suggests that cardiovascular harm from calcium supplementation alone may either be a chance finding or represent a true biological effect which is protected against by co-supplementation with Vitamin – D. The findings of the said study also suggest that calcium and Vitamin-D supplementation in older women is not harmful. The report further states that these findings should provide reassurance to women and clinicians who decide to start or persist with the calcium and Vitamin-D supplementation for fracture prevention.