(a) whether a large number of children died during human clinical trials in AIIMS during the years 2008-09 and 2009-10;

(b) if so, the details thereof;

(c) whether Government has made any investigation to find out the factors responsible for such deaths;

(d) if so, the details thereof and the outcome of such investigation; and

(e) the remedial steps taken by Government to check recurrence of such incidents in future?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) As per information provided by AIIMS, there is no report of any death during clinical trials related to children during the year 2009-10. However, it was reported in the media that 49 babies had died during clinical trials etc. during the period from January, 2006 June, 2008.

(c) and (d) The matter was investigated by an inquiry committee constituted for the purpose. Findings of the Inquiry Report stated that all studies had scientific rationale, were duly approved by Ethics Committee and Drug Controller General of India (wherever required), followed consenting procedure, and none of the deaths were attributed to the modalities tested.

(e) Does not arise.

Selling of prohibited drugs

1275. DR. JANARDHAN WAGHMARE: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that medicines which are prohibited from selling in advanced countries are sold in India; and

(b) if so, whether they have been examined/tested as to ensure that they are not harmful?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI DINESH TRIVEDI): (a) and (b) The Drug Technical Advisory Board (DTAB), a statutory body under the Drugs and Cosmetics Act examines the safety issues related to continued marketing of certain drug formulations, in context of current knowledge, which have been withdrawn/restricted in some other countries. Certain drugs or formulations withdrawn in one or some countries are continued to be marketed in India after examination by the Expert Committees set-up under DTAB, and wherever necessary, restrictions are imposed on their use for certain indications only. These are based on the risk assessment process which includes disease pattern in the country, indications and dosage of the drug permitted, availability of safe substitutes and overall safety profile of the drug.