- The manufacturer has applied for DCGI's approval to carry out Phase III clinical trials in India.

(d) Vero cell derived inactivated vaccine developed by Panacea Biotech

- It is a cell culture based vaccine, in very initial stages of development.
- The company has a 10 year license agreement with National Institute of Immunology for in-licensing of technology and processes for production.

Introduction of drugs without clinical trial

†1944. SHRI KAPTAN SINGH SOLANKI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the Central Drugs Standard Control Organisation (CDSCO) has approved 33 new drugs between January, 2008 and October, 2010 without testing them through human trial;

(b) if so, whether Government has fixed the accountability of anyone in this regard;

(c) whether as per above facts, the drugs have been introduced in three or four sites in the market without undergoing any clinical trials and legal requirement; and

(d) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (d) The Department Related Parliamentary Standing Committee on Health and Family Welfare in its 59th Report on the Functioning of the Central Drugs Standard Control Organisation (CDSCO) has raised various issues pertaining to the functioning of the organisation, including alleged approval of drugs without clinical trials.

New drugs are approved by the CDSCO based on non-clinical data, clinical data of safety and efficacy of drug, regulatory status in other countries etc. as per the Guidelines and requirements specified in Rule 122A, 122B, 122D and Schedule-Y of the Drugs and Cosmetics Rules, 1945. However, as per Rule 122A(2) and Rule 122

† Original notice of the question was received in Hindi.

B (3), the requirement of clinical trial may not be necessary if the drug is of such a nature that the Licensing Authority may, in public interest, decide to grant permission to import/manufacture the new drug on the basis of data available from other countries. Further, as per clause 1(3) of Schedule Y, for drugs indicated in life threatening/serious diseases or diseases of special, relevance to the Indian health scenario, clinical data requirements may be abbreviated, deferred or omitted, as deemed appropriate by the Licensing Authority. For grant of permission to import / manufacture of the Fixed Dose Combinations (FDC), the requirements are prescribed under Appendix-VI of Schedule-Y. As per these requirements, clinical trial on Indian patients is required in certain category of FDCs

Government had constituted a three member expert committee to examine the issues raised by the Parliamentary Committee comprising Dr. V.M. Katoch, Secretary (Department of Health Research) and Director General, 1CMR, Dr. P.N. Tandon, President, National Brain Research Centre, Department of Biotechnology, Manesar and Dr. S.S. Aggarwal, former Director, Sanjay Gandhi Post-graduate Institute of Medical Sciences, Lucknow to *inter-alia* examine the validity of the scientific and statutory basis adopted for approval of new drugs without Phase-III clinical trials on Indian population. The Report of the Expert Committee has been received and the same is under consideration.

Opening of more CGHS dispensaries

1945. SHRI AAYANUR MANJUNATHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the total number of Central Government Health Scheme (CGHS) hospitals and dispensaries in the country, State-wise including Karnataka;

(b) whether the number of CGHS hospitals and dispensaries are adequate keeping in view of the number of Central Government employees in various States including Karnataka;

(c) if not, whether Government proposes to empanel more private hospitals under CGHS;

(d) if so, the details thereof, State/Union Territory-wise and, if not, the reasons therefor; and

(e) the steps taken or proposed by Government to open more CGHS dispensaries in the country including Karnataka?