(c) the possibility of the eradication of TB from the country?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) Yes.

(b) As per the 'Report on Causes of Death: 2001-03, Office of Registrar General, India', TB accounts for about 6% of the deaths in India.

(c) As per the STOP-TB Strategy of the WHO and the STOP-TB Partnership the member states are urged to work towards TB elimination *i.e.* less than 1 case per million population per year by the year 2050.

Establishment of medical colleges and hospitals in every district

†1942. SHRIMATI BIMLA KASHYAP SOOD: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government has decided to establish medical college and hospital in each district of the country during the Twelfth Five Year Plan;

(b) if so, the details of the medical colleges and hospitals going to be established in the country under the National Rural Health Mission (NRHM) district-wise; and

(c) the details of the estimated amount to be spent on these medical colleges and hospitals?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (c) There is a proposal in the Twelfth plan to support establishment of new medical colleges in some districts of underserved states by upgrading existing district hospitals. Opening of the new medical colleges and funds to be released for these medical colleges will depend *inter-alia* on the plan allocation and priorities finalized.

Availability of vaccines and drugs to control vector-borne diseases

1943. SHRI BHUPENDER YADAV: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether sufficient quantity of drugs and vaccines are available to control vectorborne diseases including Japanese Encephalitis in the country;

† Original notice of the question was received in Hindi.

(b) if so, the details thereof and if not, the reasons therefor;

(c) the details of research projects undertaken to study the prevalence of these diseases and develop drugs/vaccines to curb them in the country;

(d) the funds earmarked and allocated for the purpose, project-wise; and

(e) the details of achievements made as a result thereof indicating the present status of vaccine/drug development *vis-a-vis* vector-borne diseases in the country?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) Sufficient quantities of drugs are available for control of vector borne diseases like Malaria, Kala-azar and Lymphatic Filariasis. There is no specific drug for dengue, chikungunya and Japanese Encephalitis (JE). The treatment is symptomatic.

The drugs like Artemisinin Combination Therapy (ACT) for treatment of falciparum malaria cases and miltefosine capsule for Kala-azar are procured centrally and supplied to the States/UTs according to their assessed technical requirement. During the year 2012, the drugs supplied centrally are as under:

1. For Malaria: Artemisinin Combination Therapy (ACT) - 13,15,862 doses
2. For Kala azar:
    - Capsule Miltefosine (50 mg for adult) - 54,880
    - Capsule Miltefosine (10 mg for children) - 47,600

The Central Government provides cash assistance for procuring anti-malarial drugs namely Chloroquine tablet, Primaquine tablet, Quinine tablet, Quinine Injection and anti-filarial drugs DEC and Albendazole as these have been decentralized.

Vaccination is available for JE only and was started in high disease burden districts in the country through campaign mode followed by JE vaccination under Routine Immunization (RI) after 6 months. As of now, JE vaccination have been incorporated into Routine Immunization in 113 districts in 15 States as these districts have completed the JE campaign during the period from 2006 to 2011. There is sufficient availability of JE vaccine to carry out this activity. Details of availability of JE vaccine are given as under:

During 2012-13, nearly 117 lakh doses have been supplied. Further, the stock available as on 01.11.2012 with 15 States is 20 lakh doses and 11 lakh doses are available in Government Medical Store Depots.

(c)• The Indian Council of Medical Research (ICMR) carried out disease burden studies from time to time in the country and has undertaken studies on vaccine development and drug trials. Details are given in Statement I (*See* below).

- NVBDCP has supported studies for malaria and kala-azar and the details are given in Statement II (*See* below).

(d)• ICMR supports research on VBDs through its extramural and intramural programmes. The Extramural funds are usually disbursed to non-ICMR. Institutes and Medical Colleges. The total budget spent on Extramural research on VBDs in the year 2011-12 was Rs. 1,91,75,381 and 2012-13 (till 30th Nov) is 1,60,28,147. As mentioned in part (c) of the answer, several of the ICMR Institutes are routinely involved in research on various aspects of VBDs mainly through the intramural funds sanctioned to them and there is no specific budget earmarked for these activities.

- The allocation of funds for NVBDCP supported projects are :

  I. Monitoring the therapeutic efficacy of anti-malarial medicines in India for estimated cost of Rs. 692.16 lakhs.(ongoing)

  II. Pharmacovigilance for antimalarial medicines in India (NIMR) for estimated cost of Rs. 125.4 lakhs, (ongoing)

  III. Estimating the annual incidence of kala-azar in two highly endemic blocks of Bihar : Rs. 44.60 Lakhs (Completed)

  IV. Sentinel Surveillance of Visceral Leishmaniasis in endemic areas of Bihar: Rs. 86.86 Lakhs (ongoing)

  V. Pharmaco-vigilance with miltefsoine in treatment of Kala-azar in endemic areas of Bihar: Rs. 14.03 Lakhs (ongoing)

(e) The details of achievements made in the ICMR and NVBDCP supported projects are indicated given in Statement I and II (*See* below)

Status of vaccine in respect of JE: at present following vaccines are being manufactured/under developmental phase in India:

- Inactivated S A-14-14-2 manufactured by Biological -E.
- Vero cell derived inactivated JE vaccine by Bharat Bio-tech's.
- Chimerivax-JE-CV (IMOJEV)-live attenuated JE vaccine by Sanofi Pasteur
- Vero cell derived inactivated JE vaccine by Panacea Biotech.

Details of developments of above vaccines are given in Statement III.

Statement I

Details of ICMR projects/studies and achievements

Vaccine development/trials:

- NIV, Pune undertook a project to develop an inactivated tissue culture vaccine against Indian strain of Japanese encephalitis virus in collaboration with Bharat Biotech International Ltd. Hyderabad. The vaccine strain developed by NIV, Pune has been transferred to Bharat Biotech for further vaccine development.
- Regional Medical Research Centre (RMRC) at Dibrugarh is carrying out a project entitled "Evaluation of safety and immunogenicity of single dose of live attenuated JE vaccine SA-14-14-2 in adults in Assam" (ongoing).

Drug trials:

- VCRC, Puducherry in collaboration with CRME, Madurai undertook a multicentric study for assessment of operational feasibility and impact of co-administration of DEC and albendazole and for DEC alone (2000-2001). The co-administration of albendazole and DEC was shown operationally feasible, safe for community use and has an edge over DEC alone in terms of reducing new infections of lymphatic filariasis. These findings have been accepted and implemented by the National Programme.
- RMRI, Patna conducted Phase III randomized, open label clinical trial of oral miltefosine to investigate the efficacy and toxicity of miltefosine in

large number of patients and in comparison with the efficacy and toxicity of amphotericin B. The trial established the safety and efficacy of oral miltefosine in the treatment visceral leishmaniasis (1999-2000).

- RMRI, Patna conducted Phase III randomized, controlled open label clinical trial comparing injectable paromomycin with amphotericin B. The results of the trial indicated the non-inferiority of injectable paromomycin to amphotericin B (2003-2004).

- NIMR, Delhi has carried out clinical trials of anti-malarial combinations namely, Artemisinin based combination therapy, Artesunate + Amodiaquine, Artesunate + Mefloquine, Dihydroartemisinm+ Piperaquine and Pyronaridine + Artesunate. Introduction of Artemisinin Based Combination Therapy (ACTs) in National Drug Policy for malaria was based on molecular and epidemiological surveys of chloroquine-resistant malaria parasites carried out by NIMR.

Statement II

Details of NVBDCP Supported Projects/Studies and achievements

I. Monitoring the therapeutic efficacy of anti-malarial medicines in India for estimated cost of Rs. 692.16 lakhs. Start date of project 17.03.2009. Project ongoing.

II. Pharmacovigilance for antimalarial medicines in India (NIMR) for estimated cost of Rs. 125.4 lakhs. Start date of project 5.06.2009. Project ongoing.

III. Estimating the annual incidence of kala-azar in two highly endemic blocks of Bihar: A Pilot study comparing snowball and house-to-house survey.

Achievements :

- House-to-house survey is two times costlier than snowball technique

- Snowball technique detected 41% less cases than detected by other techniques

- Household survey missed 28 per cent of the total case detected by adopting both the techniques.
- Snowball technique was not found to be an effective method for estimation of annual incidence of Kala-azar in two highly endemic districts of Bihar.

IV. Sentinel Surveillance of Visceral Leishmaniasis in endemic areas of Bihar. Project ongoing

V. Pharmaco-vigilance with miltefsoine in treatment of Kala-azar in endemic areas of Bihar. Project ongoing

Statement III

Vaccine manufactured/under development in India

(a) Inactivated SA-14-14-2 manufactured by Biological-E

- DCGI has approved production of this vaccine which has been developed as a part of joint development and marketing partnership of Biological E with Intercell AG.
- The vaccine is a purified, inactivated vaccine.
- The vaccine is to be administered in two doses with 4-6 week interval of 0.25 ml (3 ug) in pediatric population (upto 3 year) and 0.5 ml (6 ug) in adult population (above 18 year).

(b) Vero cell-derived inactivated Japanese Encephalitis vaccine (Bharat Biotech's Inactivated JE Vaccine)

- The strain is Thermostable Kolar Stain (JEV 821564 XY), obtained from NIV, Pune and phase II and III have been carried out.

(c) ChimeriVax-JE-CV (IMOJEV) Live Attenuated Japanese Encephalitis Vaccine developed by Sanofi Pasteur

- It is a live attenuated vaccine and is registered in Thailand and Australia (Oct. 2012 and Aug. 2012)
- Monodose and multidose (4 doses) presentations are available. The vaccine is given subcutaneously as a single dose for primary immunization.

- 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

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