

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

UNSTARRED QUESTION NO:2548

ANSWERED ON:12.03.2010

VACCINE FOR INFLUENZA A H N

Acharia Shri Basudeb;Bais Shri Ramesh;Bali Ram Dr. ;Dome Dr. Ram Chandra;Jagannath Dr. M.;Muttamwar Shri Vilas Baburao;Reddy Shri K. Jayasurya Prakash;Singh Shri Radha Mohan;Sivasami Shri C.

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

- (a) whether the Government has asked some international manufacturers for the selling of Influenza A H1N1 vaccines in the country;
- (b) if so, the details thereof;
- (c) the total number of dose of pandemic vaccine imported by the Government so far in the country indicating the names of the countries and companies from where these have been procured;
- (d) the progress made in the development of pandemic vaccine by the indigenous manufacturers, the fund allocated to them for the purpose and the time by which these vaccines are likely to be made available in the market;
- (e) whether the Government has made an extensive study about the behaviour of H1N1 virus in the country and assessed the safety of the vaccines in the diverse Indian conditions; and
- (f) if so, the details thereof and if not, the reasons therefor?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a)&(b) Yes, Government of India held discussions with four international manufacturers, namely M/s. Novartis, Switzerland; M/s. Sanofi Pasteur, France; Baxter, USA and GlaxoSmithKline, Belgium.

(c) Government of India purchased 1.5 million doses of Pandemic H1N1 Vaccine from M/s Sanofi Pasteur SA, Lyon, France.

(d) Development of pandemic vaccine by indigenous manufacturers is being encouraged. Four companies (Serum Institute, Pune; Panacea Biotech; Gurgaon and Bharat Biotech, Hyderabad, Zydus Cadila, Ahmedabad) are working on indigenous vaccine. Animal studies have been completed and clinical trials are underway. Indigenous vaccine is expected to be available by April-May 2010. Advance Purchase Agreement has been signed with Serum Institute, Bharat Biotech and Panacea Biotech. Advance of 10 crores each to be provided to these manufacturers.

(e)&(f) Yes. Influenza is a very labile virus and undergoes very frequent minor mutations. Indian Council of Medical Research is conducting constant virological surveillance to identify mutations. 114 isolates of the H1N1 virus has also been studied for change of its behavior to Oseltamivir susceptibility. All the isolates were found sensitive.

Both indigenous as well as the imported vaccine has to undergo safety studies (clinical trials) in different centres before the regulatory authority (Drug Controller General of India) approves it for marketing.