

(b) Specific provisions have been made for examination of reports of Serious Adverse Events (SAEs) of injury or death in clinical trials and payment of compensation by the sponsor or his representative, in case of clinical trial related injury or death. Accordingly, Rule 122DAB and Appendix XII of Schedule Y of the Drugs and Cosmetics Rules, 1945 has been amended *vide* G.S.R. 53(E) dated 30-01-2013. The formulae for determining the quantum of compensation in cases of clinical trial related injury and death have also been finalized.

(c) Clinical trials are required to be conducted as per the approved protocol and Good Clinical Practices (GCP) guidelines published by the Central Drugs Standard Control Organization. Schedule-Y of the Drugs and Cosmetics Rules, 1945 prescribes the responsibilities of the Sponsor, Investigator and Ethics Committee to protect the rights, safety and well-being of clinical trial subjects. A series of measures have been taken in the recent past to strengthen the regulation of clinical trials in the country. These include evaluation of the New Drug Advisory Committees (NDACs)/ Subject Expert Committees (SECs)/ Investigational New Drugs (IND) Committee, review of their recommendations by the Technical Committee and, thereafter, approval by the Apex Committee.

Amendments have also been made in the Drugs and Cosmetics Rules, 1945 for safeguarding the rights, safety and well-being of trial subjects. The procedures to analyze the reports of SAEs occurring during clinical trials have also been laid down. Compensation is required to be paid in case of trial related injury or death within the prescribed timelines. Conditions have been specified for conduct of clinical trials, authority for conducting clinical trial inspections, and action in case of non-compliance. It has also been decided that with effect from 30.11.2013, in all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual informed consent will be recorded in respect of each trial subject. This will include the procedure to be adopted for providing information to the subject, and recording his/her understanding on such consent while adhering to the principles of confidentiality.

#### **Status of H1N1 disease in the country**

2645. SHRI BAISHNAB PARIDA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) the status of H1N1 *i.e.* swine flu in the country;
- (b) whether certain deaths have been reported because of this disease in the country during the last one year;
- (c) if so, the details thereof;

(d) whether Government has organized an awareness drive in the country to help guard against this virus; and

(e) if so, the details thereof ?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA) : (a) Influenza A H1N1 virus that caused the Influenza Pandemic during 2009-10 continues to circulate in the community causing sporadic outbreaks in various parts of the country. Most of the sporadic cases are reported from Rajasthan, Gujarat, Karnataka, Maharashtra and Kerala.

(b) and (c) Details provided by the States/UTs of laboratory confirmed deaths for the current year and last year is given in the Statement (*See below*).

(d) and (e) During the Pandemic phase (2009-2010) Government had launched massive print and visual media campaign for awareness generation among public.

***Statement***

*Laboratory confirmed deaths caused by Influenza A H1N1: State/ UT-wise  
(1st Jan., 2013 to 30th November, 2014)*

| Sl.No. | State                       | Jan., 2013 | Jan., 2014      |
|--------|-----------------------------|------------|-----------------|
|        |                             | Dec., 2013 | 30th Nov., 2014 |
|        |                             | Deaths     | Deaths          |
| 1      | 2                           | 3          | 4               |
| 1.     | Andaman and Nicobar Islands | 0          | 0               |
| 2.     | Andhra Pradesh              | 8          | 5               |
| 3.     | Arunachal Pradesh           | 0          | 0               |
| 4.     | Assam                       | 0          | 0               |
| 5.     | Bihar                       | 0          | 0               |
| 6.     | Chandigarh (UT)             | 5          | 0               |
| 7.     | Chhattisgarh                | 1          | 0               |
| 8.     | Dadra and Nagar Haveli      | 0          | 0               |
| 9.     | Daman and Diu               | 0          | 0               |
| 10.    | Delhi                       | 16         | 0               |
| 11.    | Goa                         | 0          | 1               |
| 12.    | Gujarat                     | 196        | 55              |
| 13.    | Haryana                     | 41         | 0               |

| 1                | 2                | 3   | 4   |
|------------------|------------------|-----|-----|
| 14.              | Himachal Pradesh | 0   | 0   |
| 15.              | Jammu & Kashmir  | 2   | 0   |
| 16.              | Jharkhand        | 0   | 0   |
| 17.              | Karnataka        | 19  | 33  |
| 18.              | Kerala           | 1   | 14  |
| 19.              | Lakshadweep      | 0   | 0   |
| 20.              | Madhya Pradesh   | 32  | 8   |
| 21.              | Maharashtra      | 149 | 42  |
| 22.              | Manipur          | 0   | 0   |
| 23.              | Meghalaya        | 0   | 0   |
| 24.              | Mizoram          | 1   | 0   |
| 25.              | Nagaland         | 0   | 0   |
| 26.              | Odisha           | 0   | 0   |
| 27.              | Puducherry       | 0   | 0   |
| 28.              | Punjab           | 42  | 6   |
| 29.              | Rajasthan        | 165 | 30  |
| 30.              | Sikkim           | 0   | 0   |
| 31.              | Tamil Nadu       | 6   | 5   |
| 32.              | Telangana        |     | 5   |
| 33.              | Tripura          | 0   | 0   |
| 34.              | Uttarakhand      | 7   | 0   |
| 35.              | Uttar Pradesh    | 8   | 0   |
| 36.              | West Bengal      | 0   | 0   |
| CUMULATIVE TOTAL |                  | 699 | 204 |

**Anaemia and mineral deficiencies in tribal rural areas**

2646. SHRIMATI RAJANI PATIL:

SHRI MOHD. ALI KHAN:

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

(a) whether it is a fact that a large population of women and children are facing several diseases like anaemia and other mineral deficiencies in the country particularly in tribal/rural areas;