

12. Strengthening facility based Newborn Care: Newborn care corners (NBCC) are being set up at all health facilities where deliveries take place; Special New Born Care Units (SNCUs) and New Born Stabilization Units (NBSUs) are also being set up at appropriate facilities for the care of sick newborn including preterm babies.
13. Home Based Newborn Care (HBNC): Home based newborn care through ASHA has been initiated to improve new born practices at the community level and early detection and referral of sick new born babies
14. Capacity building of health care providers: Various trainings are being conducted under National Health Mission (NHM) to build and upgrade the skills of health care providers in basic and comprehensive obstetric care of mother during pregnancy, delivery and essential newborn care.
15. India Newborn Action Plan (INAP) has been launched to reduce neonatal mortality and stillbirths.
16. Newer interventions to reduce newborn mortality- Vitamin K injection at birth, Antenatal corticosteroids for preterm labour, kangaroo mother care and injection gentamicin for possible serious bacillary infection.
17. Intensified Diarrhoea Control Fortnight was observed in August 2014 focusing on ORS and Zinc distribution for management of diarrhoea and feeding practices.
18. Integrated Action Plan for Pneumonia and Diarrhoea (IAPPD) launched in four States with highest infant mortality (UP, MP, Bihar and Rajasthan).

Ban on import of animal tested cosmetics

261. DR. CHANDAN MITRA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether Government proposes to ban the sale of imported cosmetics whose ingredients have been tested on animals;
- (b) if so, the details thereof;
- (c) if not, the reasons therefor; and
- (d) the steps taken by Government to prohibit import of cosmetics tested on animals and also ban the testing of cosmetics and their ingredients on animals in the country?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA): (a) and (b) The Government of India has *vide* Gazette Notification G.S.R. 718 (E) dated 13.10.2014 prohibited the import of cosmetics that has been tested on animals. The prohibition has come into effect from 13.11.2014

(c) Does not arise.

(d) In addition to prohibiting the import of cosmetics tested on animals as detailed in reply for part (a) and (b) above, the testing of cosmetics on animals in the country had already been banned *vide* Gazette Notification G.S.R. 346 (E) dated 21.05.2014.

Eligibility criteria for conducting clinical Trials

262. PROF. M.V. RAJEEV GOWDA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the parameters that have to be fulfilled before filing application for clinical trials;

(b) the total number of applications requesting clinical trials that were received in the last two years; and

(c) the safety measures that have been prescribed and laid down by the Ministry and whether these measures compare with the regulations established by the United States Food and Drug Administration?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA): (a) Rule-122DA, 122DAA, 122DAB, 122DAC, 122DD, 122E and Schedule-Y of the Drugs and Cosmetics Rules, 1945 specify the requirements for conducting clinical trials in India. These, *inter alia*, specify that clinical trials can be conducted only under and in accordance with the written permission of the Licensing Authority after payment of requisite fee and submission of the requisite details to the Licensing Authority. The requirements include providing information relating to chemical and pharmaceutical, animal pharmacology/toxicology, human clinical pharmacology, regulatory status elsewhere and the testing protocols, etc.

(b) The number of applications received by CDSCO for grant of conduct of clinical trials were 480 and 207 in 2012 and 2013, respectively.

(c) Clinical trials are required to be conducted as per the approved protocol and Good Clinical Practices (GCP) guidelines published by CDSCO, DGHS, Ministry of Health and Family Welfare. Schedule-Y of the Drugs and Cosmetics Rules, 1945