

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

UNSTARRED QUESTION NO:3394
ANSWERED ON:30.08.2013
VACCINE AGAINST ROTAVIRUS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether Indian scientists have developed a vaccine against Rotavirus which causes dehydration and severe diarrhoea;
- (b) if so, the details thereof;
- (c) whether the office of the Drug Controller General of India (DCGI) has received any request seeking the marketing approval of the said vaccine; and
- (d) if so, the action taken/proposed by the DCGI thereon?

Answer

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

(a): Yes.

(b): The Department of Biotechnology (DBT), GOI and Bharat Biotech a Hyderabad based company have conducted Phase III clinical trial of a rotavirus vaccine developed in India to assess its safety and efficacy. The vaccine called 'ROTAVAC' is the first indigenously developed vaccine in the developing world. A rotavirus vaccine strain 116 E that was isolated and characterized at AIIMS was transferred to a local manufacture, Bharat Biotech International Ltd., after it was extensively tested in collaboration with National Institute of Health (NIH) and Centre for Disease Control (CDC)Atlanta. This remains one of the most successful ventures in development of an indigenous vaccine in India .

The vaccine has been found to be efficacious in preventing severe rotavirus diarrhea in low resource settings in India.

(c): Yes.

(d): No final decision on the application received has been taken by DGCI.