Work standards of faculty in autonomous medical institutes

3202. SHRI JAGAT PRAKASH NADDA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether Government had set up a Committee under Dr. Sneh Bhargava to recommend work standards for the faculty of autonomous medical education institutions under the Ministry;
- (b) whether Government has received the report of the committee, and the recommendations thereof; and
 - (c) the reasons for the work standards not been notified till date?

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

- (b) Yes.
- (c) The Committee constituted under Dr. Sneh Bhargava, former Director, AIIMS, New Delhi to determine the work standards of faculty in autonomous medical institutes under the department submitted its report on 29/10/2011 which was circulated to various medical institution under this department vide letter dated 02/01/2012. Thereafter, a meeting was taken by Secretary, HFW on 22/06/2012 with Heads of the autonomous institutes to discuss the issue and draft minutes were circulated on 12/07/2012. Subsequently, based on the commonly agreed issues, the draft guidelines were circulated among the heads of all the autonomous institutes

of Medical Education seeking further comments vide letter dated 21/25th September, 2012. Because of further examination of the issue and consultation with the concerned institutes, the final guidelines have not been notified till date.

Provisions for compensation and penalisation in clinical trials

3203. SHRI NARESH GUJRAL: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether Government is planning to define compensation rules and penal provisions in case of clinical trials;
- (b) if so, the details thereof including time-frame for introduction, types of compensation and other provisions; and
 - (c) if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (c) The Drugs and Cosmetics Rules, 1945 have been amended *vide* Gazette notification number G.S.R. 53 (E) dated 30.1.2013 for making specific provisions for grant of compensation in case of injury or death of the trial participant during the clinical trial and laying down procedures for examination of serious adverse events and payment of compensation.

The Drugs and Cosmetics Rules, 1945 have further been amended vide Gazette notification number G.S.R. 63(E) dated 1.2.2013 for making specific provisions for penalizing the Investigator(s), Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors by debarring them from conducting any clinical trial in the future.

The Drugs and Cosmetics (Amendment) Bill, 2007 introduced in the Rajya Sabha on 21.8.2007 also contain penal provisions for violations of the laws pertaining to clinical trials.

Import of medicines from China

3204. SHRI D.P. TRIPATHI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that a number of medicines have been imported from China;