GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. 4054
TO BE ANSWERED ON 10TH AUGUST, 2018

INTERNATIONAL HEALTH NGOs

4054. SHRI ADHIR RANJAN CHOWDHURY:

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

(a) whether it is the fact that many international Non-Governmental Organizations (NGOs) in the country are facing the allegations of promoting the interests of certain pharmaceutical companies and if so, the details thereof;

(b) whether the Government has carried out any review of the works done by these NGOs and if so, the details thereof;

(c) whether the Government has taken note of serious lapses on part of NGOs in taking informed consent of parents, the process of taking regulatory clearances as well as conflict of interest of the NGO with certain quarters of the Government; and

(d) if so, the details thereof and the action taken so far by the Government against such NGOs?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) to (d): In the recent past, Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare, which is tasked with ensuring the safety, efficacy and quality of medicines including implementation of Good Manufacturing Practices (GMP) by pharmaceuticals companies and regulation of clinical trials, has not received any such report regarding allegations against International Non- Governmental Organizations (NGOs).

However, in the year 2009-10, there was an allegation against an international NGO, M/s PATH (Programme for Appropriate Technology in Heath) in respect of conduct of a Phase-IV post licensing clinical trial of Human Papilloma Virus (HPV) Vaccine which was granted by CDSCO. The Indian Council of Medical Research (ICMR) and the State Governments of Andhra Pradesh and Gujarat were the collaborating partners. Subsequently, a Committee appointed to enquire into "Alleged irregularities in the conduct of studies using Human Papilloma Virus Vaccine by PATH in India" reported certain discrepancies in taking informed consent, Ethics Committee's approval, reporting of serious adverse event, monitoring, etc. in the conduct of the trial.

Based on the findings of the Committee, a warning letter was issued to M/s PATH on 03.07.2012 asking them to be careful while conducting clinical trial, so as to ensure that such discrepancies/ violation are not repeated in future and it was also directed to take corrective action to ensure strict compliance with Schedule-Y of the Drugs & Cosmetics Rules, 1945 and GCP guidelines in ongoing study and also in those proposed to be started in future.

However, the matter is sub-judice as two PILs were filed before Hon’ble Supreme Court of India.