(c) if not, whether any such registry is being developed; and

(d) if so, the details thereof, if not, reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI FAGGAN SINGH KULASTE): (a) to (d) There is currently no Trauma Registry Centre in the country. However, the Government has initiated a programme namely "Capacity building for developing Trauma Care facilities in Government Hospitals on National Highways", which envisages setting up of National Injury Surveillance, Trauma Registry and Capacity building.

Presently, injury related data is collected in the emergency department of Dr. RML Hospital, which generate authentic information not only on mortality related data of the traffic injury victims but also about the crash related information (Injury Surveillance) as well as the information on pre-hospital care given to the Trauma Victims

Amending norms for clinical trials

1793. SHRI DEVENDER GOUD T.: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Government has amended norms for clinical trials;

(b) if so, how the revised ones are different from the existing ones;

(c) whether it is also a fact that academic institutions are now exempted taking permission from DCGI; and

(d) if so, the reasons therefor and how this facilitates safe and transparent trials?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI FAGGAN SINGH KULASTE): (a) to (d) Minor changes have been made in the rules relating to Clinical Trials and related guidelines in the recent past with a view to ensure patient safety and welfare and also facilitate faster decision making. The changes made include amendment in the Drugs and Cosmetics Rules, 1945 to *inter alia* provide that:–

No permission for conduct of clinical trial intended for academic purposes in respect of approved drug formulation shall be required for any new indication or new route of administration or new dose or new dosage form where,-

(a) the trial is approved by the Ethics Committee; and

(b) the data generated is not intended for submission to licensing authority.

The Ethics Committee shall, however, inform the licensing authority about the cases approved by it and also about cases where there could be an overlap between the clinical trial for academic and regulatory purposes and where the said authority does not convey its comments to the Ethics Committee within a period of thirty days from the date of receipt of communication from the Ethics Committee, it shall be presumed that no permission from the licensing authority is required. It is to be noted that the academic clinical trials in the country are required to be conducted in accordance with applicable regulations, Good Clinical Practices of Central Drugs Standard Control Organisation (CDSCO) as well as the "Ethical guidelines for Biomedical Research on Human Participants" published by ICMR.

Law regulating single parent surrogacy

1794. DR. KANWAR DEEP SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that there is no law regulating single parent surrogacy in the country;

(b) if so, whether there is a need to have such a law;

(c) how long it might take to have one; and

(d) if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI ANUPRIYA PATEL): (a) to (d) Presently there is no law regulating single parent surrogacy in the country. The Department of Health Research (DHR) is in the process of finalizing the draft "Surrogacy (Regulation) Bill, 2016" which is likely to be placed before the Parliament shortly.

Preparedness to curb dengue

1795. SHRIMATI SAROJINI HEMBRAM: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to answer to Starred Question 24 given in Rajya Sabha on 19th July, 2016 and state:

(a) how many cases of dengue related deaths have been detected in the country during the current rainy season, State-wise and how many positive cases detected;