*** 156 [The questioner was absent.]**

Rules governing drug testing on humans

*156. SHRI DEREK O'BRIEN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Ministry is conducting clinical trials of all the drugs which are released into the country for usage, if so, the details thereof;

(b) if not, the reasons for the same and the list of the drugs which have skipped the clinical trials in India;

(c) the number of people who have lost their lives during the clinical trials of drugs in the last three years, the details thereof; and

(d) the initiatives/rules imposed on the private companies for drug testing on humans by the Central Drugs Standard Control Organisation, and the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI ANUPRIYA PATEL): (a) to (d) A Statement is laid on the Table of the House.

Statement

(a) and (b) Central Licensing Authority is giving permission to the applicants for conduct of clinical trial before usage of new drugs in the country, unless waiver of clinical trial is given as per provisions of Drugs and Cosmetics Rules, 1945. Under certain conditions, such as for drugs indicated in life threatening/serious diseases or diseases of special relevance to the Indian health scenario and in public interest, the clinical data requirements may be abbreviated, deferred or omitted, as deemed appropriate by the Licensing Authority.

The list of the new drugs approved for manufacture/marketing in the country without local clinical trial in accordance with the regulatory provisions and guidelines is given in the Annexure-I (*See* below).

(c) Death may occur during clinical trial due to various reasons such as the disease from which the patient may be suffering or due to the investigational product or any other reason. The number of persons who died during clinical trial in the last three years and the number of such cases which are related to clinical trial is given in the Annexure-II (*See* below).

(d) Clinical trials of new drugs are regulated under Rules 122 DA, 122DAB, I22DAC, 122DD, 122E and Schedule-Y of the Drugs and Cosmetics Rules, 1945.

Various measures taken by the Government for strengthening the regulatory provisions in respect of clinical trials nclude amendments in the Drugs and Cosmetics Rules, 1945 laying down:–

(i) the procedures to analyse the reports of Serious Adverse Events (SAEs) and payment of compensation in case of trial related injury or death;

(ii) conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance;

(iii) requirements and guidelines for registration of Ethics Committee;

(iv) audio-video recording or informed consent process in case of vulnerable subjects in clinical trials of new chemical entity/new molecular entity (NCE/ NME). In case of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent has been specified;

(v) further, it has been made mandatory to submit the following details in the clinical trial/new drug application of New Chemical Entity and Global Clinical Trials:-

- Assessment of risk versus benefit to the patients.
- Innovation *vis-a-vis* existing therapeutic option.
- Unmet medical need in the country.

(vi) Expert Committees have been constituted to examine the reports of deaths in clinical trials. These Expert Committees have prepared detailed guidelines for examination of reports of deaths and also prepared formula(s) for determining the quantum of compensation in case of clinical trial related deaths and injury (other than death).

In compliance of the order dated 03.01.2013 of the Hon'ble Supreme Court, a system of supervision of clinical trial has been put in place by constituting an Apex Committee under the chairpersonship of Secretary, Health and Family Welfare; and a Technical Committee under chairmanship of Director General, Health Services (DGHS). Accordingly, clinical trial proposals of new chemical entities (NCEs) are evaluated through a three tier system comprising: (i) Subject Expert Committee (SEC), (ii) a

Technical Committee and (iii) the Apex Committee. Other clinical trial proposals are evaluated through a two tier system of SEC and Technical Committee.

Annexure-I

List of new drugs approved for manufacture/marketing

Sl. No.	Name of New Drugs approved
1.	Sofosbuvir
2.	Bedaquiline
3.	Pasireotide
4.	Gadobutrol
5.	Ceritinib
6.	Ibrutinib
7.	Ledipasvir+ Sofosbuvir
8.	DaclatasvirDihydrochloride
9.	Enzalutamide
10.	Nintedanib
11.	Fomepizole
12.	Tofacitinib
13.	Panobinostat
14.	Palbociclib
15.	Midodrine Hydrochloride
16.	Phospholipid Fraction from Bovine Lung (surfactant)
17.	Dolutegravir
18.	Lenvatinib
19.	Perampanel
20.	Carfilzomib
21.	Trametinib
22.	Dabrafenib
23.	Alectinib
24.	Eliglustat
25.	Dienogest

Sl. No.	Name of New Drugs approved
26.	Prucalopride
27.	Teriflunomide
28.	Pomalidomide
29.	Sofosbuvir 400 mg +Velpatasvir 100 mg Tablet & Bulk
30.	Arqatroban Hydrate
31.	Delamanid
32.	Treosulfan
33.	Ribociclib
34.	Midostaurin
35.	Tenofovir Alafenamide Fumarate
36.	Macitentan
37.	Obinituzumab
38.	Siltuximab
39.	Nivolumab
40.	Pembrolizumab
41.	Daratumumab
42.	Idarucizumab
43.	Evolocumab
44.	Atezolizumab
45.	Alemtuzumab
46.	Ibritumomab
47.	Inactivated Poliomyelitis Vaccine

Annexure-II

Number of persons who died during clinical trial

Sl. No.	Year	No. of SAE (Serious Adverse Event) - Death reported	No. of SAE (Serious Adverse Event) - Death related to clinical trial based on available status of examination done
1.	2014	443	23
2.	2015	381	13
3.	2016	378	11

MR. CHAIRMAN: Now, Question No. 156. The questioner not present. Any supplementaries please?

SHRI MD. NADIMUL HAQUE: Sir, the daily wage earners, the poor people who are desperately poor also are often volunteering for the clinical trials and they are taking in drugs which are often resulting in their deaths. My question is: Is the Ministry aware that there is an alarming trend of deaths due to bioequivalence studies on the people in the country by the clinical research organizations and if they are aware, what actions are they taking against them?

SHRIMATI ANUPRIYA PATEL: Sir, we have actually set up a good system, a robust system after the Supreme Court's order in 2013. There is a three-level committee consisting of, the Subject-Expert Committee, the Technical Committee, the Apex-level Committee which actually gives their opinion about whether the clinical trials are to be conducted or they have to be waived off. Before 2013, we did not have a proper system of compensation in case of any serious adverse events. But post-2013, we have a proper system in place to address any such serious adverse events and we have a properly detailed formula which has been established in order to give compensation in such cases where deaths take place. There are several factors like age, occupation, which are taken into account. After these systems have come into place, the adverse events have actually gone down in number and we are making sure that compensations are being given by the sponsored investigators.

MS. DOLA SEN: Sir, will the hon. Minister let this august House know details of the implementation of recommendations of Parliamentary Standing Committee in regard to trials required to be conducted only in the 330 medical colleges that have emergency facilities? If the hon. Minister did not consider the suggestions of the Parliamentary Standing Committee in this regard, then, what is the reason therefor?

SHRIMATI ANUPRIYA PATEL: Sir, the hon. Member is actually referring to the 59th Report of the Standing Committee, wherein they had actually expressed their reservations about 33 clinical trials which were waived off. You are talking about it. After that, we constituted an Expert Committee under the Chairmanship of Ranjit Roy Chaudhuryji, who said that the exemptions to clinical trials should be given in certain specific conditions like a national emergency or urgency or, maybe, a drug which is needed for orphan disease or any such event. Post that, we came up with a system under which there are five situations, in which we give exemptions to clinical trials, which involve, maybe, a life-threatening disease, a serious disease, or if there is a disease which

is specially suited to Indian conditions or there is an unmet need. This is what we have done post the 59th Report and there was only reservation about 33 clinical trials and we have made sure that there is a proper system for giving exemptions to the clinical trials.

MR. CHAIRMAN: Question No. 157. ...*(Interruptions)*... Shri Ritabrata Banerjee. ...(Interruptions.)...

SHRIMATI ANUPRIYA PATEL: I have the Committee report with me. There is. ...*(Interruptions)*...

MR. CHAIRMAN: No, no. Please. ...*(Interruptions)*... Both the Minister and the Member, they should not talk to each other. ...*(Interruptions)*...

Impact of FRDI Bill on depositors

*157.SHRI RITABRATA BANERJEE: Will the Minister of FINANCE be pleased to state:

(a) whether it is a fact that the Financial Resolution and Deposit Insurance (FRDI) Bill will have a direct impact on the bank deposits of crores of common depositors;

(b) if so, the details thereof;

(c) if not, the reasons therefor;

(d) whether it is also a fact that the FRDI Bill will only help the banks and the financial institutions to recoup their health at the expense of crores of common depositors;

(e) if so, the details thereof; and

(f) if not, the reasons therefor?

THE MINISTER OF FINANCE (SHRI ARUN JAITLEY): (a) to (f) A Statement is laid on the Table of the House.

Statement

(a) to (c) The Financial Resolution and Deposit Insurance Bill, 2017 (FRDI Bill) seeks to provide for the resolution of certain categories of financial service providers in distress; the deposit insurance to consumers of certain categories of financial services; designation of systemically important financial institutions; and establishment of a Resolution Corporation (RC) for protection of consumers of specified service providers and of public funds for ensuring the stability and resilience of the financial system.