

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

**LOK SABHA  
UNSTARRED QUESTION NO. 1177  
TO BE ANSWERED ON 9<sup>TH</sup> FEBRUARY, 2018**

**FEE HIKE FOR CLINICAL TRIALS AND REGISTRATION OF DRUGS**

**1177. SHRI ASADUDDIN OWAISI:**

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

- (a) whether the Government proposes to increase the fee for site registration, product registration, clinical trials etc. for drug companies in the country;
- (b) if so, the details thereof;
- (c) whether pharma companies have opposed this move of the Government;
- (d) if so, the details thereof; and
- (e) the extent to which the consumers are likely to be affected by the move and the time by which a final decision is likely to be taken in this regard?

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

(a) & (b): The Ministry of Health and Family Welfare had published draft Notification No. GSR 1011(E) dated 29.12.2015 for inviting comments from public/stakeholders regarding fee revision of various applications like:

- import license ,
- registration certificate for import ,
- license for examination, test or analysis, license for sale of drugs,
- license for manufacture and sale of drugs,
- permission to import or manufacture new drugs,
- permission to conduct clinical trials,
- license for operation of blood banks, and
- manufacture of cosmetics

(c) to (e): Representations were received from various associations and stakeholders opposing the said amendment. The comments were received from various associations such as Federation of Pharma Entrepreneurs, Indian Federation of Animal Health Companies, Mumbai; Indian Drug Manufacturers' Association, Ahmedabad; the Federation of Gujarat State Chemists & Druggists Associations, Gujarat; Tamilnadu Pharmaceutical Distributors Association etc.

Keeping in view the objections, the notification has not been finalized.