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

LOK SABHA
UNSTARRED QUESTION NO. 5535
TO BE ANSWERED ON 7TH APRIL, 2017

CHANGES TO APPROVAL PROCESS

5535. SHRI PRALHAD JOSHI:

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

(a) whether the NITI Aayog has proposed changes to the approval processes in the pharmaceutical and medical research sector;

(b) if so, the details of the proposed changes and the objectives that the Aayog seeks to achieve by them; and

(c) the steps undertaken by the Government to implement the said changes and counter the challenges that the Government is facing in implementing the same?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) & (b): Yes. NITI Aayog has proposed a number of changes in the approval process in the pharmaceutical and medical research sector with the objective to boost innovation by streamlining, updating and simplification of overall process of product (drug or vaccine) development. The suggestions include:

i. Establishment of single window system for approval;
ii. Abolishment of role of Review Committee on Genetic Manipulation (RCGM) in Department of Bio-Technology and strengthening of Institutional Bio-Safety Committee (IBSC) under Ministry of Environment & Forests;
iii. Grant of permission/approval within 30 days from the date of application for Indian Innovation Projects, who have applied for global patent, failing which approval will be automatically presumed;
iv. Review of age old procedures for simplification to encourage innovation in India, etc.

(c): Ministry of Environment & Forests, Department of Health & Family Welfare, Central Drugs Standard Control Organization and Indian Council of Medical Research are involved at various stages of the process before granting approvals and an inter-departmental consultative process has been initiated for taking a view on the recommendations of NITI Aayog.

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