

**GOVERNMENT OF INDIA  
CHEMICALS AND FERTILIZERS  
LOK SABHA**

UNSTARRED QUESTION NO:1819  
ANSWERED ON:04.12.2006  
DATA EXCLUSIVITY  
Kalmadi Shri Suresh

**Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:**

- (a) whether the Government is considering to grant of Data Exclusivity for the test data submitted for the marketing approval of Drugs and Pharmaceuticals;
- (b) if so, the details thereof;
- (c) whether the Government is aware of the public health implications of Data Exclusivity;
- (d) if so, the details of the major three implications of Data Exclusivity on public health and access to medicines; and
- (e) the steps taken/proposed to be taken by the Government to protect lie health in the event of the introduction of Data Exclusivity?

**Answer**

MINISTER OF THE STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS & MINISTER OF THE STATE IN THE MINISTRY OF PARLIAMENTARY AFFAIRS (SHRI B.K. HANDIQUA)

- (a) to (d): An Inter-Ministerial Committee under the Chairmanship of Secretary, Department of Chemicals and Petrochemicals is looking into the steps to be taken by the Government in the context of the provisions of Article 39.3 of the TRIPS Agreement for the protection of undisclosed information in respect of agrochemicals and Pharmaceuticals. The Committee has heard the views of most of the stakeholders.
- (e): The Committee while giving its report would ensure that enough safe guards are provided in the event Government decides to give Data Protection.