

**GOVERNMENT OF INDIA
ENVIRONMENT AND FORESTS
LOK SABHA**

UNSTARRED QUESTION NO:1707
ANSWERED ON:05.12.2005
MESHELKAR REPORT
Chakraborty Dr. Sujan

Will the Minister of ENVIRONMENT AND FORESTS be pleased to state:

- (a) Whether the Government had constituted a Task Force under Dr. Mashelkar on approval drugs derived from generic materials ;
- (b) if so, the details thereof :
- (c) whether it has submitted its report ;
- (d) if so, the details thereof; and :
- (e) the action proposed/taken thereon ?

Answer

MINISTER OF STATE IN THE MINISTRY OF ENVIRONMENT AND FORESTS (SHRINAMO NARAIN MEENA)

a&b) Yes, Sir. The Ministry of Environment & Forests had constituted a Task Force under Dr RA Mashelkar Director General, Council for Scientific and Industrial Research with a view to streamline the regulatory process for reeombinant pharma products.

c)The Task Force has submitted its report on 13th September 2005.

d & e) Taking into consideration the risks involved in the use of LMOs during the research & product development, manufacture and import from the environmental angle, the Task Force has rationalized the regulatory procedure and put it in five categories namely (a) for Indigenous product development, manufacture and marketing of pharmaceutical products; (b) for Indigenous product development, manufacture and marketing of pharmaceutical products where the end product is a LMO; (c) for Import and marketing of LMOs as Drugs/Pharmaceuticals in finished formulations; (d) for Import and marketing of LMOs as Drugs/Pharmaceuticals in bulk for making finished formulation and (e) for Import and marketing of products derived from LMOs as Drugs/Pharmaceuticals in bulk and/or finished formulations where the end product is not a LMO. An Inter-Ministerial meeting has been ; organized by this Ministry to discuss adoption of the report by the Government.