

**GOVERNMENT OF INDIA  
HEALTH AND FAMILY WELFARE  
LOK SABHA**

UNSTARRED QUESTION NO:235  
ANSWERED ON:26.07.2006  
CLEARANCE OF NEW DRUG APPLICATIONS  
Rawale Shri Mohan

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

- (a) whether a single window system is being created for clearing the new drug applications involving re-combinant Technology and Genetic Engineering;
- (b) if so, the details thereof; and
- (c) the time by which this is likely to become operational alongwith the requirement for such a clearance?

**Answer**

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (c) : Yes Sir

Under the aegis of Ministry of Environment and Forest, a task force on recombinant pharma had been constituted under the chairmanship of Dr.R.A. Mashelkar, DG, CSIR New Delhi, for streamlining the current regulatory framework on recombinant based therapeutic products which involved different agencies for clearance of these drugs. The recommendations of the committee have since been accepted by the Ministry of Environment and Forest, therefore, product which do not contain Living Modified Organisms (LMOs) in the final product (indigenously manufactured as well as imported) are now required only to obtain clearance from the office of the Drug Controller India with effect from 1.4.2006.