

**Clearance to New Drugs**

345. SHRI BHAGEY GOBARDHAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of new drugs that have been cleared by the Government since 1 April, 1989 till date; and

(b) in how many cases clinical trials were conducted and the reasons for not taking trial in other cases?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI NILAMANI ROURAY): (a) and (b). The details of new drugs approved by the Government since 1st April, 1989 till date is given in Statement I below.

Out of the 14 drugs approved, 9 drugs had undergone clinical trials in the country. The remaining 5 drugs, as given in Statement II below did not undergo clinical trials for the reasons given therein and were approved in consultation with experts.

**STATEMENT—I***New Drugs Cleared from 1st April 1989 to 28th February 1990*

<i>Name of the drug</i>	<i>Category</i>
1	2
1. Famotidine	: Anti-ulcer.
2. Ciprofloxacin Hcl Monohydrate	: Anti-bacterial.
*3. Sodium Hyaluronate Solution	: Aid to intra-ocular surgery.
4. 5-aminosalicylic acid	: Ulcerative colitis.
*5. Recombinant Human Tissue Type Plasminogen activator Injection (Actilyse)	: Fibrinolytic therapy (to dissolve coronary clot in M.I.)
*6. Desmopressin intra-nasa solution/nasal Spray/injection.	: Central or neurogenic diabetes insipidus bleeding disorders nocturnal enuresis.
7. Enalapril Maleate	: All grades of hypertension.
*8. Piperacillin sodium	: Antibiotic.
*9. Flavopholipel (Flavomycin).	: Antibiotic (Veterinary).

<i>Name of the drug</i>	<i>Category</i>
1	2
10. Purified Chick Embryo Cell Tissue Culture Rabies Vaccine.	: Vaccine (Human use).
11. Lofepamine	: For depressive condition only.
12. Haloperidol Decanoate	: For chronic schizophrenia.
13. Ofloxacin	: Anti-bacterial agent.
14. Dinoprostone (PGE <sub>2</sub> )	: For induction of labour.

\*Products cleared without clinical trial

**STATEMENT—II**

*Drugs Cleared without Clinical Trial*

Name of the drug	Category	Reasons for not conducting clinical trial
1	2	3
1. Sodium Hyaluronate Solution	Aid to intra-ocular surgery	Sodium Hyaluronate solution is an aid to intra-ocular surgery. By its application, it gives mechanical advantage of steps to surgeons for ocular surgery. It is as such not an active drug. Based on the recommendations of the surgeons and its popular use, the drug was cleared.
2. Recombinant Human Tissue Type Plasminogen activator injection. (Actilyse).	Fibrinolytic therapy (to dissolve coronary clot in M.I.).	Is dissolves coronary artery clot and the experts commented clinical trial in Indian condition would be difficult and may not be ethical. Based on their recommendations, the drug was approved.
3. Desmopression intra-nasal solution/nasal spray/injection.	Central or neurogenic diabetes insipidus bleeding disorders, nocturnal enuresis.	The drug is indicated for diabetic insipidus, a life-threatening condition in children. The clinical trial with anti-nasal solution/injection was difficult to be carried out and based on the recommendations of the experts, the drug was approved.
4. Piperacillin sodium.	Antibiotic	Piperacillin sodium is a newer penicillin and experts in the country were conversant with its use in hospitals particularly for infections caused by resistant pseudo-

<i>Name of the drug</i>	<i>Category</i>	<i>Reasons for not conducting clinical trial</i>
1	2	3
5. Flavophospholipel (Flavomycin).	Antibiotic (veterinary)	<p>monas and based on the recommendation of experts, the drug was approved.</p> <p>This is a veterinary drug. The decision for approval or conducting clinical trial is taken on the advice of Animal Husbandary Commissioner in the Ministry of Agriculture. The drug was approved for marketing based on his advise.</p>