

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

UNSTARRED QUESTION NO:2412  
ANSWERED ON:15.12.2004  
APPROVAL FOR NEW DRUGS  
Chitthan Shri N.S.V.

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

- (a) the total number of Drugs given approval for manufacture in the country during the year ;
- (b) the name of the companies and the drugs permitted to be manufactured;
- (c) the number of applications pending as on date for clearance;
- (d) whether delay is taking place in clearing these applications ; and
- (e) if so, the time by which the approval is likely to be granted ?

**Answer**

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

(a) & (b): 23 new Drug molecules have been approved in the country during the current year. The list which includes names of the companies and the drug permitted to be manufactured/ marketed, is annexed.

(c) to (e): The evaluation of new drug applications is a complex process as per Schedule-Y under Drugs & Cosmetics Rules and varies according to the nature of molecule/drug, published data and information furnished by the applicants. Therefore, depending upon the nature of the application, it may take on an average 3 to 5 years for an applicant to complete all phase of trials required for approval of investigational New Drug (i.e. a drug molecule not tested on human being anywhere in the world); about 1-3 years for the first time approval of the drug already approved elsewhere but requiring confirmatory clinical trial, and about 2-3 months for subsequent applications for already approved drugs. This is however, subject to submission of all required data as per provisions of Schedule-Y of Drug & Cosmetics Rules.

More than 600 applications in respect of different categories of New Drug products have been cleared during current year on the basis of evaluation as per norms. About 900 applications are at various stages of evaluation. All efforts are made to avoid any delays in clearing such applications.

New Drugs (first time approval) approved during Current Year, 2004

1. Dutasteride M/s. Dr. Reddy`s Lab
2. Gefitinib M/s. Astrazeneca
3. Imidapril M/s. Elder Pharma
4. Adefovir M/s. Cipla
5. Etoricoxib M/s. Cadila Healthcare, Glenmark & Hetero
6. Diacerein M/s Elder Pharma
- 7 Nitazoxanide M/s. Ind-Swift Ltd.
8. Trolamine M/s. FDC Ltd.
9. Neotame M/s. Nutra Sweet Co. (India)
10. Alfuzosin M/s. Ranbaxy Labs Ltd.
11. Tiagabine M/s. Sun Pharma
- HCL
12. Ibandronic M/s. Roche Scientific Co. (India)
- Acid Pvt. Ltd.

13. Memantine M/s. Sun Pharma  
HCL
14. Pimecrolimus M/s. Novartis India Ltd.
15. Rebamipide M/s. Macleods Ltd.
16. Miglitol M/s. Glenmark
17. Citicholine M/s. Sun Pharma & M/s. Elder Pharma
18. Everolidmus M/s. Novartis India Ltd.
19. Voriconazole M/s. Pharmacia
20. Orlistat M/s. Intas Pharma
21. Deflazacort M/s. Macleods
22. Duloxetine M/s. Torrent Pharma
23. Atomoxetine M/s. Torrent Pharma