

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

UNSTARRED QUESTION NO:4556  
ANSWERED ON:18.12.2002  
INCLUSION OF OTC IN SCHEDULED ACT  
KAILASH MEGHWAL

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

- (a) whether the Government propose for inclusion of OTC medicines such as Asprin, Paracetamol, Cough Syrup and the other medicines of the category in the Scheduled Drug Act;
- (b) whether it is also a fact that such medicines are injurious to health and the use of asprin by children damages their liver and the prolonged use of anti-biotic paracetamol causes permanent damage to kidney; and
- (c) if so, by when the Government are contemplating to include O.T.C. medicines in the `Schedule Drug Act`?

**Answer**

MINISTER OF HEALTH AND FAMILY WELFARE (SHRI SHATRUGHAN SINHA)

- (a) The term OTC is not defined under the Drugs and Cosmetics Act, 1940 and rules made thereunder. Drugs like Asprin, Paracetamol and Cough syrups etc, which are non-prescription drugs are permitted to be sold at licensed premises without requiring a prescription of a Registered Medical Practitioner.
- (b) Restrictions for sale of drugs against prescription depends upon the overall safety/risk ratio. Aspirin is not recommended for use in children below 12 years of age. Paracetamol is not an antibiotic. It is a non-prescription drug all over the world and in recommended doses it is not associated with permanent damage to the kidney.
- (c) There is no proposal to separately define OTC medicines under the Schedule to the Drugs and Cosmetics Act, 1940.