

DRUG HEADLINES

Court Revokes Ban on Sale of Paediatric Nimesulide

Madras High Court says the matter was not discussed with concerned parties

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Paediatric drugs nimesulide and phenylpropanolamine (PPA) will soon be available with chemists after a court order revoked a ban on manufacture and sale of these controversial formulations.

Early this year, the health ministry had banned sale of anti-inflammatory drug nimesulide for use in children below 12 years of age and decongestant formulation PPA used in cough syrups citing their adverse impacts on human health, including liver toxicity. The ban was challenged by writ petitions filed by drug makers Cipla and Unichem. Both nimesulide and PPA are non-prescription drugs and

Kill Pill		
BRAND	COMPANY	ANNUAL SALES (₹ CR)
Voveran	Novartis	166.33
Combiflam	Sanofi Aventis	103.43
Dolonex	Pfizer	72.39
Nise	Dr Reddy's	67.89
Sumo	Alkem	64.49



sold over the counter

"It is paramount consideration for the government to arrive at a subjective satisfaction in public interest," the Madras High Court said in its judgement, adding that the matter was not discussed with concerned parties.

The ban by the government is without proper recommendation and hence illegal, said advocate AA Mohan of Mohan Associates, a representative of Unichem in the case. "The ban on PPA without any reported side effects in India is completely un-thought of in as much as the drug PPA which is in use for the

last 20 years does not have any reported side effects," said Cipla in its affidavit, a copy of which is available with ET.

The total market for nimesulide in India is nearly ₹300 crore. Nimesulide sale has shrunk since the ministry's order banning the usage of the drug in children, experts said. Dr Reddy's brand Nise is the largest selling nimesulide drug in India. The company posted annual revenue of Rs ₹ crore in 2010, down from ₹70 crore in previous year. Nimesulide is banned in developed nations such as the UK, Canada, New Zealand, Australia and Denmark.

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