

News

The Delhi High Court will not stop Natco from producing a medication for spinal muscular atrophy.



The Swiss pharmaceutical company Roche's request for an interim injunction was denied by the court.

A single-judge ruling that refused to stop Hyderabad-based Natco Pharma from manufacturing a medication used to treat spinal muscular atrophy (SMA) was affirmed by the Delhi High Court on Thursday [**F Hoffman-LA Roche vs Natco Pharma**].

Swiss pharmaceutical company Roche's appeal was denied by a Division Bench of Justices C Hari Shankar and Ajay **Digpaul**, who concurred with the single judge that Natco had presented a convincing argument against the legality of Roche's patent for "**Risdiplam**," the

active pharmaceutical ingredient in its brand-name product "EVRYSDI®."

The Court further emphasized that discretionary orders that deny temporary injunctions should not be easily interfered with by appellate courts.

Mutations in the SMN1 gene cause SMA, a crippling neuromuscular disease that causes gradual muscle weakening and, in extreme cases, trouble swallowing and breathing.

After learning that Natco had classified the medication as one of the **"APIs under development,"** Roche submitted a 2022 patent application for a **"Improved Process for the Preparation of Risdiplam,"** arguing that the drug was a novel chemical entity separate from its previous genus patent.

Roche attempted to prevent Natco from producing or marketing the medication in India until its patents expired.

Justice Mini Pushkarna denied Roche temporary relief in March 2025.

Given Roche's own claims in foreign patent procedures and Patent Term Extension applications that **Risdiplam** could be traced back to the previous genus patent, the single judge determined that Natco had presented a viable validity issue.

Patients with SMA also testified in court, pointing out that Roche's prices made the medication unaffordable for the majority of families.

"In India, the approved medication, Risdiplam, which is sold under the brand name Evrysdi, is not reasonably priced. In the ruling issued on March 24, Justice Pushkarna stated that the public interest would have to exceed the need for an injunction if a party could produce the medicine and make it reasonably priced.

Depending on dosage and patient weight, Roche's medication can cost anywhere from ₹70 lakh to over ₹1.4 crore per year, with a bottle now costing over ₹6.2 lakh. In contrast, **Natco** has said in the open that it will lower the cost of therapy to an estimated ₹30 to 50 lakh per year by pricing its version at an MRP of ₹15,900 each bottle.

The single court was informed by intervenors **Purva Mittal and Seba PA**, both of whom have SMA, that Roche's Patient Assistance Program only touched a small percentage of patients,

leaving the majority without medication. They maintained that allowing generic supply served the general welfare.

In addition to Anand & Anand's attorneys Pravin Anand, Archana Shanker, **Shrawan Chopra**, Prachi Agarwal, **Devinder Rawat**, Elisha Sinha, Achyut Tewari, **Krishna Baweja**, Aayush Maheshwari, and Sumer Seth, Roche was represented by Senior Advocate Sandeep Sethi.

Advocates Afzal B. Khan, **Samik Mukherjee**, Amrita Majumdar, **Dominic Alvares**, **Avinash** Kr Sharma, and Sharad Besoya from S Majumdar & Co. represented Natco, along with Senior Advocate J Sai Deepak.