

# 2 Cases Await Ranbaxy in Kerala

The company will face cases for failing to adhere to drug standards, selling drug as 'dietary supplement'

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Ranbaxy faces two criminal cases in Kerala — one over amoxicillin tablets that contained less of the ingredient than stated and another for selling an osteoporosis drug as a 'dietary supplement' in the state.

The Supreme Court recently paved the way for this when it dismissed twin petitions filed by the company for quashing both cases.

The Kerala High Court had refused to stay the complaints in both instances. In the first case, the state drug controller seized cartons of Roscillin AMX with two different strengths of the key ingredient amoxicillin, 250

mg and 500 mg, from Ranbaxy distributor Mohan Pharma Agencies Pvt. Ltd. The 500 mg tablets were found to contain only 302.49 mg of amoxicillin, i.e. about 51.75% of the label claim.

The distributor claimed that the company could not be held liable in this case as it had only stored the drugs at the place where they were seized and the stocks at the godown premises were not for sale. Ranbaxy also claimed that it hadn't made the drugs in question and had merely purchased them from a licensed manufacturer and stored them.

Ranbaxy on its part claimed that the sample batches, manufactured for it by the Rajasthan-based Medicamen Biotech Ltd, were recalled from the

market and destroyed.

The state of Kerala filed a criminal complaint against the three companies alleging offences under Sections 18 (A) (1), 18B, 22(3) of the Drugs Act. The magistrate then issued summons against the two companies.

Ranbaxy moved the High Court at Ernakulam for quashing of the summons but this was refused on July 22, 2011. The company then moved the top court, where Kerala, through counsel MR Ramesh Babu, again opposed quashing of the case.

Thought the top court initially stayed the High Court ruling, it ruled in favour of the state last Wednesday. In the second case, Ranbaxy will face a criminal trial for selling Rosatin Gel

Tab as a dietary supplement instead of a drug. Dietary supplements carry lower taxes than drugs.

The state claimed that rosatin was a drug as one of its ingredients, glucosamine, was defined as such and had to be manufactured and sold only under a drug manufacturing licence. Ranbaxy claimed that glucosamine was permitted as a substance to be used for infant food under the Food Safety and Standards Act, 2006. It also said that it was not registered as a drug under the Drugs Act and was marketed in India, and many other countries as a dietary supplement.

All these issues will now be decided in the lower court, state counsel Ramesh Babu said.

*Regulatory*

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