

GENERICS *bulletin*

THE BUSINESS NEWSLETTER FOR THE GENERIC MEDICINES INDUSTRY

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Ranbaxy teams with Teva to launch US atorvastatin

Ranbaxy will pay Teva a portion of its profits on US sales of atorvastatin calcium during a 180-day exclusivity period after the two firms struck a deal to ensure that the Indian firm got to market promptly. Ranbaxy's version entered the market on 30 November at the same time as Watson started shipping its authorised generic of Pfizer's Lipitor. On the same day, Mylan – also through a litigation settlement – introduced its rivals to Pfizer's Caduet (atorvastatin/amlodipine) tablets. Ranbaxy's authorised generic followed a week later.

Three-and-a-half years ago, Ranbaxy and Pfizer settled atorvastatin patent litigation with a deal that allowed the Indian firm to launch on 30 November 2011 with 180-day exclusivity (*Generics bulletin*, 4 July 2008, page 15). However, Ranbaxy's ability to secure the necessary regulatory approval from the US Food and Drug Administration (FDA) to enjoy that exclusivity was thrown into doubt when the agency a few months later imposed an alert barring imports of 30 generics from Indian plants in Batamandi, Dewas and Paonta Sahib (*Generics bulletin*, 3 October 2008, page 5). The FDA then invoked its Application Integrity Policy (AIP) to stop reviews of applications from the Paonta Sahib site after Ranbaxy "falsified data and test results" (*Generics bulletin*, 6 March 2009, page 1).

Having to date failed fully to address the FDA's concerns, Ranbaxy is making its atorvastatin tablets in the US at its Ohm Laboratories facility in New Brunswick, New Jersey. A company spokesperson declined to comment on whether the partnership with Teva included the Israeli company supplying the active pharmaceutical ingredient (API) for the tablets, while Teva said the "terms of the agreement will not be disclosed".

Teva has just received tentative US approval for finished-dose atorvastatin that it plans to launch when Ranbaxy's 180-day exclusivity ends in May 2012. It also holds drug master files (DMFs) for atorvastatin calcium APIs made in both Beer Sheva and Petah Tikva, Israel.

"Information about the availability of generic atorvastatin can be obtained from Ranbaxy," the FDA stated. A few weeks before generic entry, Watson's president and chief executive officer, Paul Bisaro, had predicted a "full launch" by Ranbaxy (*Generics bulletin*, 18 November 2011, page 7). Pfizer, he believed, would retain around a 40% market share during the 180-day exclusivity period, not least due to defensive tactics such as striking deals with pharmacy benefit managers and offering a card that reduces patient co-payments for Lipitor

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EMA floats biogenerics concept

Allowing a biosimilar to be authorised on the basis of a generic bioequivalence study is floated for discussion by the European Medicines Agency (EMA) in a concept paper for revising its 'overarching' biosimilars guideline.

Stressing that it is talking about "exceptional situations" – for a "very simple biological" that had been "fully characterised on the quality level" – the EMA says discussion is needed on whether a biological medicinal product could be authorised "based on a bioequivalence study only combined with an extensive quality comparability exercise".

"Recent improvements in analytical technologies allow and support this approach for certain biologicals," commented Suzette Kox, the European Generic medicines Association's (EGA's) senior director of scientific affairs. Discussing the feasibility of following the generic legal basis for some biological products was a "major step forward", she added.

Revising the biosimilars guideline – which came into force in 2005 – provided a "unique

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