



Venipharm Gets European Enoxaparin Nod





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► By David Wallace

FRANCE'S VENIPHARM HAS ANNOUNCED THE APPROVAL through the European decentralized procedure (DCP) of its biosimilar enoxaparin.

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“This achievement is the result of a successful co-development with Nanjing King-Friend Biochemical Pharmaceutical,” Venipharm pointed out, describing the Chinese company as “one of the worldwide leading heparin manufacturers”.

With the UK as the reference member state, the DCP for Venipharm’s enoxaparin also involved Germany, Spain and Sweden as concerned member states.

“The national phases of the registration process are on-going and a repeat use procedure will include the other European member states,” Venipharm stated.

Noting that its enoxaparin would be distributed in Europe through “leading hospital and retail players”, the firm said this represented “an important step for Venipharm to expand its international presence in the future”.

In Europe, Venipharm faces potential enoxaparin competition from Pharmathen’s Thorinane version and Techdow Europe’s Inhixa biosimilar, which were granted pan-European centralized biosimilar authorizations by the European Commission in September 2016, as well as Laboratorios Farmacéuticos Rovi’s version which was approved through the DCP in early 2017.

Rovi Expanded Reach Last Year

Germany acted as the reference member state for Rovi’s DCP that covered 26 EU member states, excluding Lithuania, and in September 2017 the Spanish firm



chose Germany as the lead market in which to roll out the drug as Enoxaparin Becat.

In the first half of 2018, Rovi followed up the German launch by commencing marketing activities in Italy and the UK. Then in September the firm expanded further in Europe – launching its enoxaparin under its own name in Spain and introducing its Crusia version in France via a partnership with Biogaran (Also see “Rovi gets enoxaparin in Spain and France” - *Generics Bulletin*, 28 Sep, 2018.) – before in October launching in Austria, Latvia and Estonia.

As of 31 December 2018, Rovi pointed out, all EU countries where it had applied for national registration of enoxaparin had approved the application, except for Greece and Luxembourg.

Rovi’s sales of biosimilar enoxaparin reached €30.2 million (US\$34.2 million) in 2018, helping to push the firm’s group total up by 10% to €303 million.

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