
Sedana Medical Receives Approval for European Dossier



Sedana Medical AB (publ) today announced that the company has received a positive outcome for its European registration application for the drug Sedaconda (isoflurane) for inhaled sedation. Sedaconda is indicated for sedation of mechanically ventilated adult patients during intensive care and should only be administered via the medical device AnaConDa. From October 1st, AnaConDa will change name to Sedaconda ACD.

The application was approved through a decentralized European procedure (DCP) by the German Medicines Agency BfArM (acting as reference country) in consultation with 14 other European Medicines Agencies.

"This is the first important step towards market approval for Sedaconda. The DCP procedure has gone faster than expected thanks to the quality of our application and that the agency seems to have prioritized a fast process. The outcome means that we can apply for national approvals to launch the therapy inhaled sedation in Europe during the second half of this year, in line with our communicated time plan. The national processes take about 1-3 months. This is a crucial milestone in making inhaled sedation a global standard therapy," said Jens Lindberg, acting CEO of [Sedana Medical](#).

Sedana Medical is now working to get national market approvals as soon as possible in the countries where the DCP approval applies and plans to submit applications for additional EU countries in the coming six months.

"In connection with the launch, we are changing the name of AnaConDa to Sedaconda ACD, where ACD stands for Anaesthetic Conserving Device. The name strengthens the connection to Sedana Medical and the unique application sedation. Sedaconda is approved only to be used in combination with Sedaconda ACD and together they constitute the therapy inhaled sedation", said Jens Lindberg.

The countries included in the DCP approval are Austria, Belgium, Croatia, Denmark, Finland, France, Germany, Ireland, Netherlands, Norway, Poland, Portugal, Slovenia, Spain, and Sweden.

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