

The Court of Justice of the European Union overturns the decision to reject the marketing authorization for Hopveus®: a new hope for patients.

March 14th, 2024 marks a decisive step forward in the marketing authorization (MA) process for Hopveus®, a medicine candidate developed by D&A Pharma targeting the treatment of alcohol dependence. On this date, the Court of Justice of the European Union (CJEU) sets aside the judgement of the General Court of the European Union dated March 2, 2022, and annuls the previous refusal decisions of the European Medicines Agency (EMA) and the European Commission concerning the MA of Hopveus®.

This cancellation decision, a rare enough event to be highlighted, ends many years of proceedings marred by irregularities¹. More than a legal victory, this decision represents tangible hope for patients suffering from alcohol dependence - a serious pathology recognized as a major public health issue by the EMA and the WHO, and which to date is cruelly lacking in effective therapeutic options.

D&A Pharma, a family-owned company with 100% French capital, dedicated to pharmaceutical innovation and based in Houdan (France), has dedicated nearly two decades and considerable investments to research against alcohol dependence. This decision underlines the legitimacy of D&A Pharma's commitments.

Indeed, Hopveus® is an advancement over Alcover® syrup, a therapeutic solution approved and successfully used for over 20 years in Italy and Austria in the treatment of alcohol dependence and containing sodium oxybate, i.e., the same active substance as Hopveus®.

Considering this decision and the scientific data available on Hopveus®, D&A Pharma is confident that its medicine will be made available to patients and health professionals as soon as possible, thus marking a turning point in the fight against alcohol dependence.

According to Santé Publique France, alcohol is responsible for more than 40,000 annual deaths at a social cost of around 100 billion euros, only for France².

About D&A Pharma:

D&A Pharma is a pharmaceutical laboratory founded in 2006 by Patrice Debrégeas. The laboratory's mission is to help people live better without their addictions. Since 2007, D&A Pharma has been developing treatments for addictions and orphan diseases based on already known active ingredients, formulated by experts working in collaboration with competent European clinicians, statisticians and regulatory experts. For almost 20 years, D&A has been developing a medication based on sodium oxybate for the treatment of alcohol dependence.

→ Link to the website: www.da-pharma.com

¹ Link to CJEU press release: <https://curia.europa.eu/jcms/upload/docs/application/pdf/2024-03/cp240046en.pdf>

² Santé publique France: <https://www.santepubliquefrance.fr/les-actualites/2020/consommation-d-alcool-en-france-ou-en-sont-les-francais>