



**4 February 2008**

## **NORGINE OBTAINS HAMBURG DISTRICT COURT RULING TO HALT THE SALE OF PRODUCTS CONTRARY TO EU LAW**

Norgine Europe BV, the leading European specialty pharmaceutical company, has successfully obtained a court ruling against two laxatives containing macrogol, the principal active ingredient of Norgine's established medicine MOVICOL®. The judgement will be enforced but is subject to appeal.

According to the Hamburg District Court ruling, the subsidiary of Novartis known as Hexal AG and Cassella Med GmbH & Co, KG were found to be illegally distributing their respective products, Macrogol Hexal and Laxatan, as medical devices even though they need approval as medicinal products.

All medicinal products must undergo a thorough review of the product-specific dossier to ensure their quality, safety and efficacy. By incorrectly classifying their products as devices, Hexal and Cassella Med had avoided this important, product specific scrutiny by the Health Authorities. After considering all of the evidence and consulting an independent Professor of Pharmacology as an expert, the Court determined that the products in question were clearly medicinal products within the scope of the law and ruled that they can no longer be sold by Hexal and Cassella Med without a pharmaceutical marketing authorisation.

Peter Stein, CEO, Norgine stated: "I am pleased to see that the court recognised that these products are clearly medicinal products requiring a full pharmaceutical product registration. I am surprised that companies of such standing did not comply with the processes required for a medicinal product which are there to ensure a detailed, independent, assessment of the safety, efficacy and quality of products before they are made available to patients."

Dr. Marc Halphen, Vice President, Medical, Norgine, added: "This court ruling yet again demonstrates the importance and responsibility of the pharmaceutical industry in ensuring patients are protected from unlicensed medicinal products."

Norgine will carry on working with European Authorities to resolve the uncertainty in the legal framework which led to this situation. Norgine will continue to take any steps properly open to it to stop companies which seek to sell products based upon its products but circumvent pharmaceutical licensing regulations.

## ENDS

### **Notes to Editor**

Norgine is an independent, successful European specialty pharmaceutical company that has been established for over 100 years and has a presence in all the major European markets. In 2006 Norgine's sales were €188 million, the 20th consecutive year of double-digit growth. The company employs over 1000 people, of whom 350 are in sales and marketing.

Norgine's current focus is pharmaceutical products that address significant unmet clinical need in areas such as gastroenterology, hepatology and pain management. The company currently markets a range of products in its key therapeutic areas e.g. MOVICOL® and MOVICOL V®, for the treatment of chronic constipation and faecal impaction, MOVIPREP® a new generation bowel cleansing preparation, KLEAN-PREP® for bowel preparation prior to colonoscopy, and ORAMORPH® for the treatment of moderate to severe pain associated with cancer.

Norgine has an active Research and Development effort and currently has products at various stages of clinical development. Norgine has two manufacturing sites; Hengoed in the UK and Dreux, France. Norgine's website is [www.norgine.com](http://www.norgine.com)

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