CHUGAI PHARMACEUTICAL CO., LTD.
Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome,
Chuo-ku Tokyo, 103-8324 Japan
TEL:+81-(0)3-3273-0881
FAX:+81-(0)3-3281-6607
E-mail:pr@chugai-pharm.co.jp
URL:http://www.chugai-pharm.co.jp

CHUGAI
Roche Group

Translation

Approval of Partial Change of API Manufacturing Method and Pharmaceutical Formulation of the Recombinant Human Erythropoietin "Epogin® Injection"

April 22, 2009 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head office: Chuo-ku, Tokyo; President: Osamu Nagayama] (hereafter, Chugai) announced today that the company has acquired the approval for the partial change of the API manufacturing method and the pharmaceutical formulation of a recombinant human erythropoietin (trade name: Epogin® Injection Syringe, Epogin® Injection Ampoule) (hereafter, Epogin® Injection) from the Japanese Ministry of Health, Labour and Welfare (MHLW) on April 21.

With the aim to meet the expectation of patients and healthcare professionals, Chugai developed the manufacturing method not using the ingredient of bovine serum origin in the manufacturing process of the API of Epogin® Injection as well as the new formulation to attenuate the injection site pain under subcutaneous injection, and submitted the partial amendment application to the MHLW. Apart from the changes approved this time, the package design will also be changed to improve the identifiability and visibility of the product for the convenience of healthcare professionals.

Epogin® Injection has been widely used in clinical sites since its launch in 1990 for renal anaemia in patients undergoing hemodialysis and who have not yet started hemodialysis, anaemia in premature infants, and autologous blood transfusion.

Chugai is determined to research, develop, manufacture and distribute drugs from the viewpoint of patients and healthcare professionals so that they can use drugs with a sense of security and make continuous endeavors to improve the quality of life (QOL) of patients treated with the drugs.