WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

DRS/MtH/IEA.45 12 April 1994

DRS Information Exchange Service

ALERT No. 45

ORGOTEIN (PEROXINORM®): SUSPENDED

The Federal Health Office has suspended as from 25 March 1994 the marketing authorization for pharmaceutical products containing orgotein (Peroxinorm®: Grünenthal), powder for injection 2, 4 mg, indicated for the treatment of inflammatory arthroses; rheumatoid arthritis and other inflammatory conditions; *induratio penis plastica*, and to minimize the adverse effects of abdominal irradiation.

This action was based on the conclusion that these preparations present unjustifiable risks which outweigh their benefits. The Agency has received reports of 400 adverse reactions associated with orgotein, of which some 90 were serious. Most frequently reported were hypersensitivity symptoms (including anaphylactic shock) some of which were fatal. Causality was rated as being at least possible, especially because orgotein (bovine superoxide dismutase) is extracted from animal protein and is known to cause allergy.

The indications for Peroxinorm® were restricted in Germany in 1987 and it was withdrawn from the market in Switzerland in 1990.

Reference: BGA Pressedienst 19/1994, dated 30 March 1994.

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