Malta, 20 November 2007

Circular No. P16/2007

Dear Healthcare Professional,

Re: Protelos/Osseor® (Strontium ranelate) and severe hypersensitivity reactions.

Following the reporting of 16 cases of 'drug rash with eosinophilia and systemic symptoms (DRESS)' in patients treated with Protelos/Osseor®, two of which were fatal, the European Medicines Agency (EMEA) has agreed on the inclusion of warnings concerning the risk of severe hypersensitivity reactions in the prescribing and patient information for Protelos/Osseor®, as an urgent measure. The Medicines Authority has participated in these discussions held at the European Medicines Agency (EMEA) and is in agreement with the **press release** and **Questions & Answers document** issued by the EMEA, attached here for your perusal. The Medicines Authority will notify healthcare providers and patients in a timely fashion as new information becomes available.

Medicines Authority
198, Rue D'Argens, Gzira, GZR 03 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 email: info.mru@gov.mt