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INITIATION OF THE PROCEDURE LAID DOWN IN ARTICLE 20 OF REGULATION (EC) No 726/2004

This is an official initiation by the European Commission of a procedure under Article 20 of Regulation (EC) No 726/2004

Common name(s):	**strontium ranelate**
Product Name(s):	**Protelos and Osseor**

Strontium ranelate is indicated for treatment of postmenopausal osteoporosis to reduce the risk of vertebral and hip fractures, as well as for treatment of osteoporosis in adult men at increased risk of fracture.

In the European Union there are two centrally authorised products containing strontium ranelate: Protelos and Osseor, both authorised on 21/09/2004.

Data submitted as part of the routine benefit-risk assessment within a periodic safety update report (PSUR), covering the period from 22 September 2011 to 21 September 2012, raised concern regarding cardiovascular safety beyond the already recognised risk for venous thromboembolism. As a result of this assessment, an increased risk for serious cardiac disorders, including myocardial infarction has now been identified and risk minimisation measures specifically targeting the identified risk were recommended by the CHMP. The risk minimisation measures include reducing the target population by excluding patients with high risk for ischemic cardiac disorders, and restricting the indication to patients with severe osteoporosis, who are most likely to benefit from the treatment.

In view of this newly identified risk of serious cardiac disorders including myocardial infarction and the already recognised safety concerns such as serious skin disorders and venous thrombotic events (VTE), concerns have been raised over the overall balance of benefits and risks of medicinal products containing strontium ranelate, and their place in therapy. The CHMP recommended further wide-ranging evaluation of the benefits and risks of Protelos and Osseor. It is considered important to allow available data on safety and efficacy, including upcoming analysis and possibly expert advice, to be taken into account due to overarching concerns of a potential impact on public health.

Therefore, the European Commission (EC) initiates a procedure under Article 20 of Regulation (EC) No 726/2004 and requests the Agency to assess the above concerns and their impact on the benefit risk balance for the centrally authorised medicinal products Protelos and Osseor. The EC requests the Agency to give its opinion on whether the marketing authorisation for these products should be maintained, varied, suspended or withdrawn including whether provisional measures are necessary. As the request results from the evaluation of data resulting from pharmacovigilance activities, the opinion should be adopted by the Committee for Medicinal Products for Human Use on the basis of a recommendation of the Pharmacovigilance Risk Assessment Committee, following the procedure laid down in Article 31 of Directive 2001/83/EC.

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Sabine Jülicher
Head of Unit Medicinal products - authorisations, EMA
DG Health and Consumers