

Product Update:

medroxyprogesterone acetate 104mg/0.65mL suspension for subcutaneous depot injection (Sayana® Press) (No: 896/13)

Pfizer Ltd

09 August 2013

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

medroxyprogesterone acetate injection (Sayana® Press) is accepted for use within NHS Scotland.

Indication under review: for long-term female contraception. Each subcutaneous injection prevents ovulation and provides contraception for at least 13 weeks (+/- 1 week). However, it should be taken into consideration that the return to fertility (ovulation) may be delayed for up to one year.

In adolescents (12-18years), use of medroxyprogesterone acetate injection is only indicated when other contraceptive methods are considered unsuitable or unacceptable, due to unknown long-term effects of bone loss associated with medroxyprogesterone acetate injection during the critical period of bone accretion.

Sayana® Press contains medroxyprogesterone acetate for subcutaneous injection at a similar cost to the existing deep intramuscular injection.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 10 June 2013.

**Vice Chairman
Scottish Medicines Consortium**

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