PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF MEDROXYPROGESTERONE ACETATE 150MG IN 1ML INJECTION (DEPO-PROVERA®)

CLASSIFICATION OF DOCUMENT:	Patient Group Direction
PURPOSE:	Supply/administration of medroxyprogesterone acetate 150mg in 1mL injection (Depo-Provera®) to clients without prescription under a PGD.
Document Number:	US – 0615/03
Version Number:	1.0
Controlled Document Sponsor:	Medical Director
Controlled Document Lead:	Lead Consultant Umbrella Service
Approved By:	MMAG
On:	14th July 2015
Review Date:	July 2017
Expiry Date:	31st July 2018
Distribution: **Essential Reading for:** **Information for:**	 All registered pharmacists supplying or administering medroxyprogesterone acetate 150mg in 1mL injection (Depo-Provera®) against this PGD All registered healthcare workers working in Sexual Health Services

Pharmacy to which the PGD applies.	Pharmacies offering supply of medroxyprogesterone acetate 150mg in 1mL injection (Depo-Provera®) under the Umbrella Consortium for Sexual Health Services in Birmingham.
Description of the medication to which the direction applies.	Medroxyprogesterone acetate 150mg in 1mL injection (Depo-Provera®)
Group of professional staff who are authorised to administer/supply under this PGD.	Pharmacists working under the Umbrella Consortium for Sexual Health Services in Birmingham who have undertaken appropriate training, been assessed and deemed competent to supply medroxyprogesterone acetate 150mg in 1mL injection (Depo-Provera®) under this PGD.
Training and method of assessment of competence.	Registered Pharmacists who have undertaken training on contraception which includes CPPE e-learning and assessment which has been, approved by the Umbrella Consortium for Sexual Health Services in Birmingham and who have completed an assessment for the supply of medroxyprogesterone acetate 150mg in 1mL injection (Depo-Provera®) and have had anaphylaxis training **AND** Has undertaken recognised training in the use of Patient Group Directions The assessment of competence must be recorded on a competence sheet and retained within the respective Pharmacy. **<u>Continued professional development</u>** The pharmacist must also complete: 1. Attendance at additional training updates in the use of the PGD every three years and which also covers anaphylaxis training . 2. Attendance at additional training updates if any changes made to the PGD within three years.

	Training and updating will include: • An explanation of the PGDs • Discussion of typical cases, including cases with exclusion criteria
Clinical situation to which this direction applies.	To prevent pregnancy in women of childbearing age. Women who request parenteral contraception and where after assessment the treatment of choice is Depo-Provera® or where compliance with oral methods is unsatisfactory. Where previously established on this method by other provider and method of choice for client wishing to use a long acting and effective method and continuing with depo provera injection. Fraser Competence must be assessed for all patients under 16 years of age and recorded on the appropriate pro-forma.

Exclusion criteria	• First time supply to those aged under 18years or over 45 years • Known hypersensitivity to medroxyprogesterone acetate or any ingredient of the vehicle injection • Established users of over 2 yrs who have not been seen in Umbrella service or GP practice and had a discussion to assess individual situations, benefits and risks including osteoprosis • Pregnant or any risk of pregnancy • Known or suspected history of breast cancer or cervical cancer • Unexplained vaginal bleeding • More than oneisk factors for cardiovascular disease (such as older age ≥35yrs, smoking, diabetes, hypertension and obesity) • Current or history of ischaemic heart disease • Current or history of cervical cancer • History of hypertension even if adequately controlled (or current BP systolic >160mmHG or diastolic >90mmHg) • Current or history of venous thromboembolism • Known thrombogenic mutations (e.g. factor V leiden, prothrombin mutation, protein S, protein C and antithrombin deficiences • History of cerebrovascular accident (CVA) including transient ischemic attack (TIA) • Migraine • Risk factors for osteoporosis (e.g. family history, smoking, corticosteroids, excessive alcohol, anorexia nervosa, celiac disease) • Diabetes • Gall bladder disease • Liver disease • Known hyperlipidaemias • Systemic Lupus Erythematosus (SLE) • <6 weeks post partum and breast feeding • HIV +ve using antiretrovirals If the client is receiving any concomitant medication or treatment it is the responsibility of the Registered Pharmacist to ensure that treatment with the drug detailed in this Patient Group Direction is appropriate. This information must be sought from a parent or

	carer if necessary. In case of any further doubt advice must be sought from an appropriate health professional and documented.
Action to be taken when a patient is excluded from treatment according to the PGD.	The Registered Pharmacist will discuss reasons for exclusion and refer to the Umbrella Sexual health service Document action taken.
Treatment to be supplied/ administered under the PGD.	Medroxyprogesterone acetate 150mg in 1mL injection (Depo-Provera®)
Security, storage and labelling of medicines.	Do not store above 25°C. Store in a locked cupboard in the original packaging.
Route of administration and method.	Intramuscular injection
Dose to be administered.	150mg (1mL) First injection can be given on day 1 to day 5 of period or 1st day post termination or 21st day post-partum and no other contraceptive precautions are necessary.
Frequency of administration.	One injection repeated every ten[2] to 14 weeks. If returning at 13 weeks (and up to 14 weeks) injection can still be given without the need for extra precautions.
Maximum dosage & minimum/maximum period over which the drug may be administered.	One injection 10 to 14 weekly to be repeated following both local and National RSH Guidelines
Warnings & potential adverse reactions.	The clients should wait at the clinic for 5 minutes after the 1st and 2nd injection thereafter can leave following consultation

	No evidence exists that medroxyprogesterone acetate 150mg/mL has any teratogenic effects on the foetus. A normal outcome to any pregnancy cannot be guaranteed. (every women has a 1 in 50 chance of foetal abnormality) Loss of Bone Mineral Density - see CEM/CMO/2004/10, SPC and MHRA advice and FSRH Guidelines [2]. The medroxyprogesterone acetate 150mg/mL causes menstrual disturbances. Periods can become irregular, light, and more frequent or stop altogether. Refer to Manufacturer's Product Information leaflet. Potential nuisance effects: menstrual disturbances, weight gain or loss, headache, abdominal pain or discomfort, dizziness, weakness or fatigue Pre-menstrual type depression, thrombo-embolic disorders **All adverse reactions must be documented and the patient referred to a doctor.** **In the event of an adverse reaction follow the incident reporting procedure for the Umbrella Consortium for Sexual Health Services in Birmingham.** Report serious adverse reactions directly to the Committee for the Safety of Medicines (CSM) on a yellow card. Yellow cards and guidance on their use are available at the back of the British National Formulary (BNF) or online via the link in eBNF or via the MHRA website www.mhra.gov.uk
Follow up - circumstances under which further advice should be sought and arrangements for referral.	Patients should be directed to their GP or Umbrella Sexual Health services for ongoing injections. Further injections can be administered within the pharmacy and effectiveness, concordance and client satisfaction must be ascertained Established users must be seen in Umbrella service or GP every 2 years (to assess individual situations, benefits and risks including osteoporosis of continuing with this method)
Written or verbal advice to be given to patients or carers	Advice should be given to the patient, including mode of action, possible side effects and what to do should these occur.

before, during or after treatment.	The patient should be fully informed not only of the risks, including that of possible loss of Bone Mineral Density, side effects, and benefits of medroxyprogesterone acetate 150mg/mL but also of all alternative interventions to enable her to make an informed decision. Patient should be informed that this medicine is being issued under a PGD and is not prescribed. To return at 13 weeks for the next injection.
Record keeping.	The Registered Pharmacist must record all significant information accurately and appropriately including assessment of Fraser Competence for clients under 16 years. ● Appropriate medical history as per pharmaoutcomes ● LMP ● Accurately record consultation outcome ● A record of the drug supplied, batch number and expiry dates must be documented. ● The date and time of supply, name of Registered Pharmacist and signature must be recorded.
Names of professionals who are authorised to administer/supply drug according to the PGD.	A list of the Registered Pharmacists who have undertaken training and assessment in the supply/administration of medroxyprogesterone acetate 150mg/mL will be held within the training records held by the Umbrella Consortium for Sexual Health Services in Birmingham.
Professional with responsibility for ensuring review of the PGD takes place.	A Consultant in Reproductive and Sexual Health and the Senior Nurse for the Umbrella Consortium for Sexual Health Services in Birmingham will be responsible for review of the PGD.
Staff responsible for Review of this PGD.	Chief Pharmacist UHB Lead Consultant for Umbrella Service Senior Nurse for the Umbrella Consortium for Sexual Health Services in Birmingham

References

[1] UK Medical eligibility criteria for contraceptive use 2009
http://www.fsrh.org/pdfs/UKMEC2009.pdf accessed 1st May 2013

[2] FSRH Guideline: Progesterone Only Injectable Contraception CEU December 2014http://www.fsrh.org/pdfs/CEUGuidanceProgestogenOnlyInjectables.pdfh accessed 3rd May 2013

Patient group direction approved by:	
Lead Clinician	**Signature:** **Name:** KULSUM JAFFER **Designation:** Consultant **Date:** 28.7.15
Senior Pharmacist (Head of Professional Group)	**Signature:** **Name: Inderjit Singh** **Designation: Chief Pharmacist** **Date:** 28.7.15
Medical Director (Head of Governance and Executive Director for Organisation)	**Signature:** **Name: David Rosser** **Designation: Medical Director** **Date:** 30/7/15
Date direction comes into force	1st August 2015
Date direction expires	31st July 2018