

**Patient Group Direction**

**Patient Group Direction for the Supply/administration of ….**

### *Hepatitis B vaccination to those identified as being exposed to risk factors, as detailed in Chapter 18 - The Green Book and detailed below, by accredited Community Pharmacists*

In Community Pharmacy for Isle of Wight NHS services

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| This Patient Group Direction (PGD) must only be used by registered Accredited Community Pharmacists who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. |

**Version number: 1.1**

**Change history**

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| **Version number** | **Change details** | **Date** |
| 1.1 | Draft reformatted to standard template format | 24th June 2014 |
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| PGD approval date/ Valid from: |  |
| CCG implementation date: |  |
| Review date: | June 2016 |
| Expiry Date: | July 2016 |

**PGD Accountability Record**

**PGD Development Group**

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| **Name** | **Job title and organisation** | **Signature** | **Date** |
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**PGD Authorisation**

***This PGD has been approved and authorised for use by:***

**Commissioning organisation**

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| **Name** | **Authorising Professional** | **Signature** | **Date** |
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**Provider Organisation (adoption if needed)**

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|  | **Name** | **Authorising Professional** | **Signature** | **Date** |
| **For CCG employed staff only:** |  | Manager of healthcare professional |  |  |
| **For Primary Care Practice staff only:** |  | GP/ Authorising professional |  |  |

**Training and competency of registered Pharmacists**

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|  | **Requirements of registered Pharmacists working under the PGD** |
| **Qualifications and professional registration** | Practicing pharmacists registered with the GPhC who have completed the approved training to deliver this service |
| **Initial training** | Completion of vaccination training programme provided by M and K updates; Basic life support and anaphylaxis-provided by NHS Isle of Wight trust and full understanding of PGD. |
| **Competency assessment** | Pharmacist must carry out a minimum of 20 vaccinations per year to be competent. This service involves the delivery of an intra-muscular injection to the deltoid muscle. Both Hepatitis B and seasonal influenza service require the same technique so delivery of 20 vaccinations across all services demonstrates competency. Those pharmacists not delivering a total of 20 vaccinations must complete training at 2 years |
| **Additional requirements** | Pharmacy actively engaged with Needle Exchange and supervised consumption of methadone services. |
| **Ongoing training and competency** | Annual update in BLS and anaphylaxis.  The pharmacist should be aware of any change to the recommendations for the medicine listed.  Continued professional development is the responsibility of the pharmacist. He/ She should keep up to date with developments in areas relevant to this PGD. |

*Retain a copy of each version of the Patient Group Direction for ten years. A copy of this PGD should be given to the CCG, the healthcare professional(s) listed above, their manager(s) and the original is to be retained by the Prescribing Advisor/ Manager.*

**Supply/administration of …**

### *Hepatitis B vaccination to those identified as being exposed to risk factors, as detailed in Chapter 18 The Green Book and detailed below, by accredited Community Pharmacists*

### Clinical condition

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| **Clinical condition or situation to which this PGD applies** | Immunisation against Hepatitis B |
| **Inclusion criteria** | Injecting drug users, their sexual partners, injecting partners and domestic contacts over the age of 18. Patients registered with IDAS currently on methadone or undergoing alcohol detox who are identified as at Risk. Males having sex with other men, partner of bisexual male, sex workers, regular users of sexual services, those returning from Sub-Saharan countries who have been exposed to risk |
| **Exclusion criteria** | * All patients outside the target group * Under 18 years of age * Acute severe febrile illness * Known hepatitis B positive individuals * Known HIV positive patients or immunosuppressed individuals. * A confirmed anaphylactic reaction to the vaccine or any component of the vaccine * Pregnant Women * Post exposure Prophylaxis   No valid consent. |
| **Cautions (including any relevant action to be taken)** | * Breastfeeding * Known allergy and/or hypersensitivity to Engerix B. * Thrombocytopenia. * Bleeding disorders * Febrile illness |
| **Arrangements for referral for medical advice** | Refer to GP or Sexual Health Service |
| **Action to be taken if patient excluded** | Document and refer to GP or Sexual Health Service |
| **Action to be taken if patient declines treatment** | Document and refer to GP or Sexual Health Service |

**Details of the medicine/ Description of treatment**

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| **Name, form and strength of medicine**  *Include ▼for* [*black triangle medicines*](http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/BlackTriangleproducts/index.htm) | Hepatitis B recombinant vaccine adsorbed in prefilled syringes (1ml prefilled syringe -20mcg) |
| **BNF Chapter Category** | Chapter 14 |
| **Legal category** | POM |
| ***Indicate any*** [***off-label use***](http://publications.nice.org.uk/patient-group-directions-gpg2/appendix-a-glossary#off-label-use) ***(if relevant)*** | N/A |
| **Dose and frequency** | Ultra rapid course: One dose (1ml prefilled syringe-20mcg) given at 0, 7, and 21 days. A booster dose is recommended at 12 months to provide long term protection. |
| **Route/method of administration** | Intra-muscular into left or right deltoid |
| **Total Quantity to be administered and/or supplied** | Three doses of 20mcg administered IM as per the above schedule totalling 60mcg. A booster dose is recommended at 12 months to provide long term protection |
| **Maximum or minimum treatment period** | One dose (1ml prefilled syringe-20mcg) given at 0,7, and 21 days. A booster dose is recommended at 12 months to provide long term protection. No max or min period |
| **Adverse events and side effects** | * Injection site pain * Injection site Erythema * Injection Site Induration |
| **Records to be kept** | * Completion of PharmOutcomes data capture, Best practice guidance recommends an entry in the PMR of service delivery. The pharmacist must keep a record of the consultation for at least eight years. PharmOutcomes record meets this requirement. The following should be noted in the pharmacist’s records: * Assessment of client need in relation to the intervention. * Date and time of supply and administration. * Dose given * Record of dose number as per schedule * Batch number and expiry date. * Advice given and leaflets supplied.   **All of the above are captured as part of the PharmOutcomes recording process** |

***Procedure for reporting Adverse Drug Reactions (ADRs)***

*All ADRs/ significant events/ near misses occurring in relation to the administration of this medicine under the PGD must be reported in the clinical record and the CCG incident reporting system.*

*The GP must be informed and, in a case requiring hospital admission or resulting in serious harm, the incident reported on a yellow card to the Committee on the Safety of Medicines (CSM) -* [*http://www.bnf.org/bnf/bnf/current/yellow.htm*](http://www.bnf.org/bnf/bnf/current/yellow.htm).

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| **Written information to be given to client or carer** | Provide information leaflet on Hepatitis B Vaccination – appendix 14 |
| **Follow-up advice to be given to client or carer** | * Explain common side effects of vaccination. * Obtain verbal consent to give vaccination. * Give appointment for next dose prior to client leaving the service. * Emphasise the importance of completing the vaccine course.   Offer safer sex advice and condoms. |

**Client information**

***Healthcare professionals’ agreement to practise***

**Agreement by Registered Pharmacist(s) within…………………………….(*company name*) to administer Levonorgestrel in accordance with the Levonorgestrel 1500mcg tablet(Consilient brand) or lower cost equivalent for Emergency Hormone Contraception Patient Group Direction (PGD) *I hereby confirm that I have read the above PGD and it supporting documents. I have the appropriate training and competency to safely carry out the procedures and practices mentioned above and I agree to administer the medicine in accordance with this directive:***

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| **Name** | **Position; Qualifications and professional registration number** | **Signature** | **Date** | **Reaccreditation**  **Date** | **Name of Senior representative of company authorising Pharmacist** | **Signature** | **Date** |
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**Business address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Of Pharmacy operating \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Under PGD: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**Appendix A**

***Key References***

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| 1. Diagnosis and management of chronic hepatitis B in children, young people and adults – NICE clinical guideline 165 http://www.nice.org.uk/nicemedia/live/14191/64234/64234.pdf 2. UK National guideline on the management of viral hepatitides A, B and C, 2008 <http://www.bashh.org/documents/117/117.pdf> |