Standard Operating Procedure for the administration of vaccines

This Standard Operating Procedure for the administration of vaccines has been developed & produced by

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Change History

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INTRODUCTION

This standard operating procedure (SOP) outlines the principles of safe administration of vaccination. Vaccines are available to prevent a number of illnesses that contribute to the morbidity and mortality in adults and children and are one of the most successful public health measures. The preferred way for patients to receive medicines is for prescribers to provide care for individual patients on a one-to-one basis. However, in some cases, it may be necessary or convenient for a patient to receive a medicine directly from another healthcare professional such as a by Patient Group Direction (PGD).1

PURPOSE

The Human Medicines Regulations 2012 do not permit registered health care professionals (HCPs), who are not qualified prescribers to administer or supply prescription only medicines (POMs) unless one of three types of instruction is in place2

1. A signed prescription
2. A signed Patient Specific Direction (PSD) – the traditional written instruction, signed by a doctor, dentist, or non-medical prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis.
3. A Patient Group Direction (PGD) - a written instruction for the supply and/or administration of medicines by named health care professionals to groups of patients who meet the criteria specified in the PGD.

PharmaDoctor PGDS aim to enable suitably trained pharmacists and other healthcare professionals such as nurses to protect through immunisation or chemoprophylactic medication, an individual from infectious disease, with associated mortality, morbidity and long-term sequelae. To promote the safe administration of vaccines to patients in a community setting it is important that healthcare professionals are able to explain why vaccines are needed and immunisers need to be competent, confident, knowledgeable and up to date.

SCOPE

FMC Marketing (FMC) as the Independent Medical Agency (IMA) registered with the Care Quality Commission (CQC) and responsible for the PGD service supplied by PharmaDoctor, endorses this SOP which outlines the principles for safe administration or supply of any medicine when using an authorised PGD from PharmaDoctor, which should always be read in conjunction with PharmaDoctors’ Terms and Conditions and authorised PGDs.

PGDs and AUTHORISATION

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence.1

PharmaDoctor+ PGDs must only be used by registered healthcare professionals, Pharmacists & Nurses, who have an active PharmaDoctor+ account and who have been named and authorised to practice under it and agree to work within the terms of the PGD being used. PharmaDoctor+ account holders must be:

- Employed either directly by an implementing Pharmacy, or contracted to provide NHS services, or providing services in partnership with an Implementing Pharmacy under the direction of the authorised PGD.
- A practicing pharmacist as registered by The General Pharmaceutical Council (GPhC).
- A registered nurse with an active registration with the Nursing and Midwifery Council (NMC) working within either a GPhC or CQC registered premises.
In possession of appropriate professional indemnity.

The PharmaDoctor+ PGDs are approved by FMC and must be individually read, agreed and signed to only administer the medicines in accordance with the PGD. It is essential that a copy of the relevant PGD must be accessible when administering the vaccines to be able to check that the patient fulfils the inclusion criteria and is not excluded as outlined in individual PGDs. Authorisation to administer and supply medicines under a PGD is exclusively awarded by the authorising clinicians, upon completion or declaration of competence, training and assessments as set out by PharmaDoctor+.

Responsibility of Superintendent / line manager

The superintendent of an Implementing Pharmacy and either a registered nurse’s line manager, medical director, or their CQC authorised manager, responsible for the business registering for a PharmaDoctor+ account, must read this SOP and the relevant PGDs.

To acknowledge that the individually named healthcare professional has the required competencies and organisational authorisation to work within the PGD, a superintendent / line manager will be responsible for:

- Exclusively electing the healthcare professional to be authorised under a PharmaDoctor+ PGD.
- Ensuring that the individually named healthcare professional has been appropriately trained in the supply of the medicines, has access to the respective current PGD and are included on a list of authorised personnel held by themselves.
- Ensuring that the individually named healthcare professional has received adequate training in all areas relevant to any PGD being used including any refresher courses.
- Providing adequate up-to-date clinical resources.
- Ensuring that staff using the PGD, have access to up-to-date resources.
- Ensuring that all relevant local policies and procedures (as described in this SOP) are in place.

COMPETENCE AND TRAINING

There are currently no minimum requirements laid out or monitored by any UK regulatory body for pharmacists undertaking clinical training on vaccinations and immunisations, whether it is live training or refresher e-learning. However, it is a requirement that the pharmacist providing such a service is clinically competent and that they accept individual responsibility for their competence as stated in “Standards of conduct, ethics and performance”, July 2012, General Pharmaceutical Council.

All nurses involved in immunisation are professionally accountable for their work, and must comply with the professional standards of practice and behaviour for nurses and midwives’ set by their professional regulatory body, the Nursing and Midwifery Council (NMC).

NATIONAL TRAINING STANDARDS

The Health Protection Agency (now Public Health England (PHE)) published National Minimum standards for immunisation training in 2005 and states that the minimum duration of basic Immunisation training courses should be two days and annual updates must be attended by those who have completed basic training. The Core Curriculum document lays out the essential topics which should be incorporated into the immunisation training of all healthcare professionals involved in immunisation as they should be able to demonstrate competence, current evidence-based knowledge and understanding of the core areas of knowledge listed below.

- The aims of immunisation: national policy and schedules
• The immune system and how vaccines work
• Vaccine preventable diseases
• The different types of vaccines used and their composition
• Current issues and controversies regarding immunisation
• Communicating with patients and parents
• Legal aspects of vaccination
• Storage and handling of vaccines
• Correct administration of vaccines
• Anaphylaxis and other adverse events
• Documentation, record keeping and reporting
• Strategies for improving immunisation rates

Supervised clinical practice helps to ensure the integration of theoretical knowledge with clinical practice. It is recommended that all new vaccinators should spend a minimum set amount of time with a practitioner who has attended a comprehensive immunisation course and is experienced in giving vaccines and advising about immunisation before starting to give immunisations themselves. Assessment should involve observation of the health care professional during a minimum number of vaccinations or whole clinic sessions to demonstrate that they have attained specified clinical competencies such as those included in the Core Curriculum document.6

Medical professionals such as doctors and nurses, in addition to their professional registration standards, are governed by the CQC where there are specific annual training requirements which must be documented for clinical governance to demonstrate that clinical competence and minimum standards are being maintained.

All health professionals responsible for immunisation must be familiar with techniques for resuscitation of a patient with anaphylaxis to prevent disability and loss of life, “Green Book” Immunisation against infectious diseases and the CQC requires annual updates.7 Annual hands-on training for basic life support (BLS) using simulation and including assessment is recommended for clinical staff by the Resuscitation Council (UK) guidelines.8

FMC endorses all of the above minimum standard training recommendations and all pharmacists and other healthcare professionals using PharmaDoctor PGDs are strongly advised to adhere to these guidelines.

CONTINUING PROFESSIONAL DEVELOPMENT (CPD)

It is the responsibility of the healthcare professionals who participate in the implementation of this SOP and the relevant PGDs, to keep up-to-date with their continued professional development, in line with PHE, NMC, or GPhC requirements to ensure clinical practice follows the most up to date clinical developments.9

TRAINING and COMPETENCY REQUIREMENTS for PharmaDoctor+ PGD authorised users

It is essential that all professionals involved with immunisation are confident, knowledgeable and up-to-date so that they are in a position to give clear, consistent, accurate advice and explain the benefits and risks of vaccines appropriately and effectively.

All healthcare professionals must have completed appropriate training to suitable professional standards to meet the theoretical and practical aspects of the PHE National Minimum standards for immunisation training to enable them to competently administer medicines under their chosen PGD or PGD package they plan to be authorised to use with PharmaDoctor+.3,4
Theoretical training around a clinical condition and the medicine related to your chosen PGD package may occasionally be supplied within your PharmaDoctor+ account in the form of e-learning modules and assessed through a series of short multiple-choice answer tests. Pharmacists are eligible for any of our e-learning courses without further practical training provided they declare themselves to be competent in administering vaccines.

In addition to the above recommendations, pharmacists and other healthcare professionals may achieve suitable professional standards of clinical competence in other ways. For example, gaining experience by working with other health professionals through mentorship, peer reviews, observing patient consultations as well as attending relevant training events.

Competencies required by all healthcare professionals using PharmaDoctor+ PGDs

- Be competent to assess the patient’s capacity to understand the nature and purpose of the supply of the medicine in order for the patient to give or refuse consent.
- Have been trained (including any refresher courses) and assessed as being competent in the delivery of the medicine covered by the relevant PGD.
- Maintain skills, knowledge and their own professional level of competence in the administration of vaccines and of medicine handling, storage and administration guidelines according to their individual Code of Professional Conduct.
- Be aware of current clinical recommendations and be competent to undertake supply and administration (where applicable) and discuss any issues that may arise.

FMC requires pharmacists and other healthcare professionals using PharmaDoctor+ PGDs to confirm that they:

- Accept full clinical responsibility for any decisions made using the PGD
- Shall not act beyond their professional competence nor outside the recommendations of the PGD.
- Have completed appropriate practical and theoretical training to suitable professional standards enabling them to competently administer medicines under the PGD.

Refresher and update courses

The national PHE guidance that supports the delivery of immunisation training and education, recommends that all staff should attend annual update courses once they have completed basic training. Any refresher training should be based around the vaccine preventable disease/s, the vaccine schedules with information on changes to the schedule, the rationale for the changes and how to access reliable, evidence based and up-to-date information. The refresher course should also provide an opportunity for discussion and reflection of complex cases and how to manage these in clinical practice as well as professional issues such as, but not limited to, consent and record keeping.

All health professionals responsible for immunisation must be familiar with techniques for resuscitation of a patient with anaphylaxis to prevent disability and loss of life, “Green Book” Immunisation against infectious diseases and the CQC requires annual updates. Annual hands-on training for basic life support (BLS) using simulation and including assessment is recommended for clinical staff by the Resuscitation Council (UK) guidelines.

A range of online certified learning resources are now being made more widely available by providers of educational solutions for the NHS medical and pharmacy workforce. E-learning may contribute to CPD as individual learning is achieved via a range of formats and settings with on-line training materials and toolkits, many of which will provide refresher learning for national vaccine schedules and campaigns such as the annual Influenza vaccine, recognition and treatment of anaphylaxis and BLS.
Practical attendance at local or national study days run by local authorities, professional registration bodies such as RPS, RCN, or by recognised industry experts or associations relevant to the vaccines and immunisation services you are providing using PharmaDoctor+ PGDs are strongly recommended to support CPD development.

**ANAPHYLAXIS PRECAUTIONS**

The Resuscitation Council (UK) 2008 states that Health Professionals have a responsibility to update their skills and knowledge. They recommend that all registered nurses and immuniser’s should attend Basic Life Support (BLS) training and anaphylaxis updates (see training standards).  

Adrenaline (epinephrine) 1:1000 (1mg/mL) for intramuscular administration must be available at each immunisation session. Access to a landline telephone in the room with outside line facility i.e. to call 999 or mobile telephone that is fully charged and with a guaranteed adequate signal.

It is an essential requirement to have an additional responsible staff member on-site to assist in an emergency situation when providing a vaccination service.

The onset of anaphylaxis is rapid, typically within minutes, and its clinical course is unpredictable with variable severity and clinical features. Due to the unpredictable nature of anaphylactic reactions it is not possible to define a particular time period over which all individuals should be observed following immunisation to ensure they do not develop anaphylaxis.

Vaccine recipients should remain under observation until they have been seen to recover from the procedure, approximately 10 – 15 minutes. Pharmacists should confirm with patients that they are fit to leave the premises. Patients should not leave if they are feeling at all unwell without speaking to the pharmacist first. If necessary a doctor or the patient’s GP should be contacted for advice.

If anaphylaxis is suspected an emergency ambulance must be called on 999. Administer adrenaline/epinephrine in cases of suspected hypersensitivity and/or anaphylactic reactions in accordance with published guidelines such as the Green Book and Resus council). Inform the patient’s GP of the event and ensure the details of the event are accurately recorded in the patient notes / risk assessment form (RAF).

The pharmacist or healthcare professional who administered the vaccine/medicine that resulted in the anaphylactic reaction must notify PharmaDoctor using the adverse clinical event (ACE) form (appendix 1) as soon as is reasonably possible after the event, but definitely within 12 hours.

Any Anaphylactic reaction experienced post vaccination must be reported to MHRA via the yellow card scheme.

**Contents of an Anaphylaxis Kit - Minimum contents should include:**

- Two ampoules of adrenaline (epinephrine) 1:1000 (1mg/ml).
- Four 23G, 25mm needles.
- Four graduated 1ml syringes so that 23G, 25mm needles can be attached.
- Anaphylaxis protocol chart from the Resus Council or the Green Book
- CPR single use Resuscitation Face Shields with one way valves or a Laerdal mask (or similar) suitable for children and adults
- The kit is clearly labelled as an anaphylaxis kit

Kits should be checked regularly to ensure the contents are within their expiry dates. It is also useful to add a label to the kit with the Pharmacy address, postcode and direct dial number as a new staff
member or a locum may not have these details readily available when calling for a 999 emergency response.

Note: Chlorphenamine (chlorpheniramine) and hydrocortisone are not first-line treatments and do not need to be included in the kit. 

**ADVERSE REACTIONS**

The pharmacist must ensure the availability of adrenaline 1:1000 (1mg/ml) for the treatment of an anaphylactic shock reaction.

If a general adverse reaction does occur:

- Inform the patient’s general practitioner
- Local reactions should be seen by either the GP or practice nurse
- Any adverse reaction experienced post vaccination must be reported via the MHRA yellow card scheme.

**REPORTING OF VACCINE INDUCED ADVERSE EFFECTS (AE)**

All suspected vaccine-induced adverse effects should be reported via the Yellow Card scheme. When submitting a Yellow Card, the vaccine brand name and batch number should be provided. Provide information on the nature, timing and severity of the suspected adverse reaction. For further guidance refer to Medicines and Healthcare Products Regulatory Agency’s website: [www.mhra.gov.uk](http://www.mhra.gov.uk)

**DEFECTIVE VACCINES AND BATCH PROBLEMS**

This may include errors in packaging, labels or leaflets or other product faults, such as particulate contamination of a vaccine. If you suspect that a vaccine is defective, do not use the product but contact Defective Medicines Report Centre (DMRC) of the MHRA via web site [www.mhra.gov.uk](http://www.mhra.gov.uk)

For further information Health Professionals should refer to the updated online Chapter 8 of The Green Book “Vaccine Safety and Adverse Events Following Immunisation” for details of what information is required when submitting reports on suspected defective medicinal products.

**ADVERSE CLINICAL INCIDENTS/EVENTS (ACE)**

It is widely acknowledged that errors and significant incidents may occur. To build a safer service provision for patients all PharmaDoctor+ account holders are encouraged to develop a culture of openness and candour. Reporting drug errors is essential if underlying problems are to be addressed. Errors can be due to many factors, which can include:-

- Poor communication within a clinical team
- Lack of supervision
- Lack of competence
- Insufficient training
- System failures
- Poor record keeping

Everyone can learn from mistakes. A fair blame approach to immunisation errors will contribute to Continuing Professional Development and a safer environment of care for patients.
WHEN AN ERROR, NEAR MISS OR SIGNIFICANT INCIDENT OCCURS THE FOLLOWING STEPS MUST BE TAKEN

- Make sure the patient is safe and if necessary call emergency services
- Fully document what has occurred in the patient’s health record / RAF
- Ensure any evidence relating to the error is retained and not tampered with (evidence will include any relevant documentation and any packaging).
- Inform line manager / superintendent immediately and complete an ACE form (appendix 1) and fax on the same day to PharmaDoctor+ on 020 7160 5208
- Inform the patients’ General Practitioner within the same day
- The Clinical Support Team at PharmaDoctor+ can be contacted for advice 0203 515 0039
- The line manager / superintendent must review all incidents involving medicines and immunisations and ensure that any need to review policies, update record keeping or provide further training is identified and acted upon.
- The PharmaDoctor Multi-Disciplinary Team (MDT) will review all incidents involving medicines/immunisations and will feedback to the CQC registered manager for FMC under CQC regulation 20 - Duty of candour, as to whether any review of policies, procedures, training systems or PGDs are required and if necessary are acted upon.

INCIDENT REPORTING

In cases where there has been a clinical incident, drug error or ‘near miss’, it is important to report it to PharmaDoctor as an incident on the ACE form (appendix 1) and fax on the same day to PharmaDoctor+ on 020 7160 5208. Inform line manager / superintendent immediately and complete any incident reports required to meet local policies and procedures. This system is a proactive way of preventing the incident from actually occurring or being repeated.

EQUALITY ACT 2010

Patients must not be discriminated against in any way. Pharmacists and other healthcare professionals must understand and will take account of protected characteristics set out in the Equality Act 2010.

This means that whilst using PharmaDoctor+ PGDs you will not discriminate, harass or victimise patients in any way on the basis of these protected characteristics. This would include direct and indirect discrimination as set out in the Equality Act 2010.12

CONSENT

Valid consent must always be obtained before administering any medication. Health professionals should ensure that the individual (or those giving consent on their behalf) fully understands which immunisation(s) are to be administered; the disease(s) against which they will protect; the risks of not proceeding; the side effects that may occur and how these should be dealt with; and any follow-up action required.13 All pharmacists administering vaccines under a PharmaDoctor+ PGD must have read and be fully aware of all points in the updated Chapter 2, Consent, of the “Green Book” online.13

Whilst using PharmaDoctor+ Patient group directions a consent signature is required on ALL Risk Assessment Forms prior to immunisation. There is no legal requirement for consent to be in writing but written consent serves to record the decision and the discussions that have taken place.

- An explanation of the use and effect of the vaccine and an opportunity to ask questions must be given to acquire valid consent.
• Where English is not easily understood, translations and properly recognised interpreters should be used in order that they can make informed consent.
• Where consent is either refused or withdrawn, this decision must be documented.
• All Health Professionals should be able to advise on sources of information available to parents, guardian’s or patients i.e. up to date websites, help-lines and leaflets to enable informed consent.

Written and verbal information should be available in a form that can be easily understood by the person who will be giving the consent. If a patient declines any recommended immunisations, explore the reasons why and offer further information and advice on risks and benefits of protecting against disease.

Consent for children:

Verbal consent must be obtained from a person with parental responsibility, or the child being immunised, if they are Fraser Competent at each immunisation visit. Whilst using PharmaDoctor+ Patient group directions a consent signature is required on ALL Risk Assessment Forms prior to immunisation.

Young people aged 16 and 17 are presumed to be competent to give consent themselves.

- If you do not have an enhanced disclosure and barring statement (DBS) certificate in place then young adults aged between 16-18 years of age must have a guardian present.
- If the immuniser is not satisfied that informed and understood consent has been given, the immunisation should be deferred.

If a young person lacks capacity to consent, then consent can be given on their behalf by a person with parental responsibility, or by a Court.\textsuperscript{13}

Mental Health Act 1983 / Mental Capacity Act 2005

Under the Mental Capacity Act 2005 a person must be assumed to have capacity unless it is established that they lack capacity. The Act defines a person who lacks capacity as a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain. It does not matter if the impairment or disturbance is permanent or temporary. People may have capacity to consent to some interventions but not to others, or may have capacity at some times but not others.\textsuperscript{14}

All decisions made on behalf of a patient who lacks capacity must be made in accordance with the act and a health professional must consider all the relevant circumstances relating to the decision in question, including, as far as possible considering:\textsuperscript{15}

- The person’s past and present wishes and feelings (in particular if they have been written down).
- Any beliefs and values (e.g. religious, cultural or moral) that would be likely to influence the decision in question and any other relevant factors.
- The other factors that the person would be likely to consider if they were able to do so.

An assessment of a person’s capacity must be based on their ability to make a specific decision at the time it needs to be made, and not their ability to make decisions in general. A person is unable to make a decision if they cannot do one or more of the following things:\textsuperscript{15}

- Understand the information given to them that is relevant to the decision
- Retain that information long enough to be able to make the decision
- Use or weigh up the information as part of the decision-making process
• Communicate their decision – this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

When determining what is in a person’s best interests” a health professional must not make assumptions about someone’s best interests merely on the basis of the person’s age or appearance, condition or any aspect of their behaviour. The Act also requires that, as far as possible, health professionals must consult other people, if it is appropriate to do so, and take into account their views as to what would be in the best interests of the person lacking capacity, especially anyone previously named by the person lacking capacity as someone to be consulted. People close to the patient (spouse/partner, family, friends and carers) may often be able to help. Treatment can be given to a patient who is unable to consent, only if:

• the patient lacks the capacity to give or withhold consent to this procedure AND
• The procedure is in the patient’s best interests

Parental Responsibility is defined in the Children Act 1989 as: “All the rights, duties, powers, responsibilities and authority which by law a parent of a child has in relation to a child and his property.”

• Mothers: automatic
• Father: if married to mother either when baby born or marries subsequently
• Unmarried father: if name appears on birth certificate (since 01.12.03) or legally acquired
• Others – legally acquired
  o A Parental Responsibility Agreement should be signed, properly witnessed and registered to Principal Registry or the Family Division (High Court)
  o Parental Responsibility Order – granted by the court
  o Residence Order – granted by the court

Gillick Competence

“Children” is a legal term and it includes all young people up to age eighteen. Children aged sixteen and over are usually presumed to be Gillick competent. Children younger than sixteen can however be deemed as Gillick competent. Young people who are Gillick competent can make decisions regarding their treatment and can give consent to treatment, even though their parents are not in agreement. If a young person who is Gillick competent, asks professionals not to share information about treatment, their wishes can be honoured, unless it is felt there are safety issues that requires the information to be shared.

SAFEGUARDING ADULTS AND CHILDREN

Mandatory training in safeguarding children and vulnerable adults is an expectation of all registered practitioners by NHS and Primary Care Trusts. This is supported by the regulatory bodies of the General Medical Council, the Nursing and Midwifery Council and the Royal Pharmaceutical Society of Great Britain among others.

PharmaDoctor strongly recommends that all pharmacists wishing to provide & perform vaccinations for children complete the most current safeguarding children and vulnerable adults’ modules provided by CPPE (Centre for Pharmacy Postgraduate Education). All other mandatory training as recommended by any regulatory authority should be adhered to.

In any situation where Health Professionals or their staff have concerns that the patient may be a vulnerable adult, or a child in need or at risk, they must follow their local safeguarding policies or procedures and discuss with their line manager / superintendent and document any outcomes.

RESTRAINING CHILDREN AND YOUNG PEOPLE
Restraint is, by definition, applied without child’s consent. However, safe parental restraint reduces the risk of needle stick injury to the child. Safe restraint means immobilisation by using limited force. It may be a method of helping children, in order to safely manage a painful procedure (RCN, 2010). This method of holding children may be used if necessary during the immunisation procedure with informed and understood parental consent. This predominately applies to the three to four year old children. Health Professionals must not hold the child in a safe position; this must be done by the parent or person with parental responsibility with guidance from staff. Clinical judgment on what advice to give parents will always be on a case by case basis, the child’s welfare and safety will always be paramount.  

THOSE WHO DECLINE IMMUNISATION

If patients, parents/guardians decline any recommended immunisations, explore the reasons why and offer further information and advice on risks and benefits of protecting against disease. Whilst, patients, parents/guardians should not be unduly pressured, they need to be given sufficient information to make an informed decision. If there is disagreement between the people with parental responsibility for a child, then immunisation should not be carried out until their dispute is resolved. Record no consent to immunisation on the patient’s notes / RAF (and Personal Child Health Record (Red Book) if appropriate). Offer any additional information to ensure the patient, parent/guardian is making an informed choice, direct them to other sources of immunisation information i.e. Department of Health web site: www.immunisation.nhs.uk

PRIVACY, DIGNITY AND CONFIDENTIALITY

All reasonable steps to respect and protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services whilst using PharmaDoctor+ PGDs must be taken.

Privacy and Dignity

Patient interviews, examinations and other associated activities require suitable accommodation for privacy. The importance of acoustic and visual privacy cannot be over emphasised and the design of the room should ensure privacy and be welcoming to patients.

You must make sure you provide the appropriate levels of privacy for patient consultations and vaccination especially as patients may need to remove several layers of clothing when being vaccinated. The option of a chaperone should be available and offered to patients whenever necessary and desirable or required for personal reasons of cultural sensitivity during consultations.

The use of electronic surveillance equipment such as cameras is not recommended in private consultation areas. However, if they have been installed, in order to guard against the potential invasion of privacy, patients would need to be told about the camera and must be given the opportunity to have it switched off, in which case the decision should be recorded in the patient medication record.

Confidentiality

Confidential discussions between the pharmacist and customers/patient and pharmacy run clinics must take place within the consultation rooms. Ensure that all staff behave professionally and with discretion towards all patients. Take all reasonable steps to prevent accidental disclosure or unauthorised access to confidential information. Never disclose confidential information without consent unless required to do so by the law or in exceptional circumstances. You must use information you obtain in the course of your professional practice only for the purposes you were given it, or where the law says you can.
MEDICATION MANAGEMENT AND STORAGE

Medication will be stored in a designated location, and will be refrigerated as needed in accordance with manufacturer instructions. As appropriate, medications will be kept securely under lock-and-key at all times. A vaccine or medication must NEVER be used beyond its expiry date. Visually inspect the vaccine for any foreign particulate matter before administration, check with the SPC on the appearance of the vaccine before administering (e.g. clear solution, or uniform suspension], and discard if otherwise.

Cold Chain

The correct storage of vaccines and the maintenance of the cold chain is essential for safe administration of vaccines. The cold chain is the system of transporting and storing vaccines within the safe temperature range of 2°C to 8°C as there are risks to vaccines if exposed to extremes in temperature. Anyone handling vaccines should follow appropriate policies to ensure cold chain compliance including the monitoring every working day of the max/min/actual fridge temperatures. Vaccines that have not been transported or stored accordingly are no longer within the terms of the marketing authorisation (product licence) and therefore the vaccines cannot be used under any Patient Group Direction.

Ensure you have a cold chain policy that contains guidance on what to do should you have a refrigerator failure or disruption of the cold chain and how to manage a situation where vaccines that have not been stored correctly have already been administered. There is guidance in chapter 3 of the green book about the storage, distribution and disposal of vaccines, and should be read in conjunction with any local policies and the individual summaries of product characteristics (SPCs) for the vaccines.18

SHARPS SAFETY AND DISPOSAL

To prevent needlestick injuries and the transmission of blood borne viruses any locally written policies and procedures for the disposal of medicines and clinical waste including vaccines by incineration at a suitably authorised facility must be followed. Ensure you have a written sharps policy document that contains guidance on the procedure for the safe handling of sharps and how to manage a situation if a needlestick injury occurs.

Equipment used for vaccination, including used vials, ampoules or syringes should be disposed of by placing it in a UN-approved BS7320, puncture-resistant ‘sharps’ box according to local authority regulations and Health and Safety British Standards. The ‘sharps’ container should be sealed and replaced once it is two-thirds full, or at the level indicated on the box by the manufacturer.18

All detachable labels required for record keeping must be removed from the syringe barrel prior to administering the vaccine. All needles and syringes are disposed of immediately following administration into an appropriately sized sharps container. Needles must never be re-sheathed and all unused reconstituted vaccine must be disposed of in the sharps container at the end of the session. No attempt is ever made to push contents down inside the sharps container and it must be situated within easy reach of the immuniser and not obstructed from view. The container should not be accessible to any unauthorised individual.

INFECTION CONTROL

To prevent cross infection and environmental contamination and to reduce risk of inoculation injury and ensure safe management of healthcare waste, locally written infection control procedures and
policies should be used in conjunction with manufacturers’ Control of Substances Hazardous to Health (COSHH) safety data sheets.

Spillages must be cleared up quickly and gloves should be worn. The spillage should be soaked up with paper towels, taking care to avoid skin puncture from glass or needles. The area should be cleaned according to the local chemical disinfection policy or COSHH safety data sheets. Gloves, towels, etc. should be sent for incineration. Spillages on skin should be washed with soap and water. If a vaccine is splashed in the eyes, they should be washed with sterile 0.9% sodium chloride solution and medical advice should be sought.

Hand hygiene

To reduce the risk of transfer of transient micro-organisms on the healthcare workers hands, hand hygiene must be performed by washing or disinfecting hands prior to preparing injection material and giving injections.\textsuperscript{15} During hand washing any cleansing agent must be applied to all surfaces of the hands and rubbed vigorously. Always use disposable paper towels to dry hands after washing. Hands need to be washed before and after each patient contact. Using alcohol-based hand gels/rubs where appropriate will reduce the risk of spreading antimicrobial-resistant bacteria. You should follow any local infection control policies or guidelines for hand hygiene and cover any small cuts.

Clinical waste

All used cotton wool or swabs which may be contaminated with blood are disposed of in a clinical waste bin (never the ordinary waste bin) – if a clinical waste bin is not available any blood-stained material should be placed in the sharps bin as this will ultimately be incinerated.

IMMUNITY TO HEPATITIS B

It is strongly recommended that all persons delivering vaccinations be immune to Hepatitis B. All Hepatitis B vaccination courses, booster recommendations and antibody responses are described in the “green book”, chapter 18, Hepatitis B and should be followed.\textsuperscript{20} Any local policy on Hepatitis B immunisation for healthcare professionals should be followed.

HEPATITIS B DISCLAIMER

FMC Marketing recommend that vaccinators should ensure they have the right level of immunity. However, any vaccinator classified as a non-responder, or who chooses not to have a Hepatitis B vaccination course may still participate in the use of PGDs.

Non-responders or vaccinators who choose not to have a Hepatitis B vaccination course retain the theoretical risk of contracting Hepatitis B, and will carry out vaccinations at individual risk.

By signing (which can be classified as accessing your online PGDs) authorised PGD users are declaring that they understand this policy and that FMC Marketing will not be responsible for any Hepatitis B exposure. The vaccinator should pay particular attention to any local policies and procedures about needle-stick injury; the risk is small especially if the instructions to prevent needle-stick injuries are followed.

NEEDLESTICK INJURY

There is a very low risk of transferring infection from patient to a healthcare professional through needle-stick injury.
If any injury occurs, inform patient of the injury immediately and wash the wound with plenty of soap and running water and encourage the wound to bleed.

You will need to seek medical advice and assessment as baseline blood samples and prophylactic antiviral treatment may be required depending upon the risk level of the exposure by attending Accident and Emergency on the day of the incident (within 2 hours if possible exposure to HIV) occurring. Additionally you will need to establish whether or not the patient would be prepared to undertake a blood test to check for Hep B, Hep C or HIV and make arrangements to contact them once you have established from your local Accident and Emergency department the protocol for the patient as they may need to see their own GP for these blood tests.

Inform superintendent pharmacist or registered manager of injury and follow all local policies and procedures for reporting the incident.21

Accidental injury with an unused needle falls outside the guidance of this SOP. Should this eventuality arise, dispose of the undischarged vaccine as per the sharps protocol, clean and cover the wound appropriately and follow local procedures and policies for accident and incident reporting.

DOCUMENTATION AND AUDIT

Standards of records, record keeping, and audit must comply with those laid down by professional regulators.22

- The use of PGDs must be audited on an annual basis;
- Clear audit trails must be organised for each patient and the vaccine administered;
- The professional must be able to identify patients who have received vaccines under PharmaDoctor+ PGDs for audit purposes. This can be via either a computerised, or paper record;
- Monitoring and auditing the use of PGDs is important and necessary for their review.
- The authorising organisation may ask for results of local audits to inform review of these PGDs.

Documentation

An electronic or paper record for recording the screening of patients prior to and subsequent to the supply of medicine under a PGD must be completed in order to allow audit of practice.

All health risk assessment, advice and medicine administration or supply record forms should be securely stored in the pharmacy or clinic. Records must be made following medicine supply and/or vaccine administered they must not be made prior to the patient’s attendance for vaccination or medication supply. The following details must be recorded:

- Patient name, address, date of birth,
- The brand of vaccine administered, batch number, expiry date, dose, route and site of administration;
- When more than one vaccine is given simultaneously, details of the sites of administration must be recorded to allow any reactions to specific vaccines to be noted, including differentiating between different sites on the same limb;
- Date of administration, and date of next dose (if applicable);
- Consent must be documented;
- The name of the professional who administered the vaccine, and their signature (or e-password) should also be recorded;
- If a vaccine is declined this must be documented as well as action taken/advice given;
- If a patient is excluded from receiving a vaccine under a PGD the reason for the exclusion must be documented in addition to action taken/advice given;
- Advice given to the patient (including side effects) should be documented;
- Details of any adverse drug reaction and actions taken including documentation, should be recorded in the patient’s medical record;

All records must be kept for 10 years after last attendance, or up to patient’s 26th birthday, if longer than 10 years away, or in accordance with local policy, where this is greater.

**Audit**

All health risk assessment, advice and medicine supply record forms should be securely stored in the pharmacy or clinic and will be audited by the Implementing Pharmacy or Clinic in order to analyse service delivery. It is recommended that an annual audit of administration of vaccines under PGD should be carried out as follows:

The superintendent/lead or registered manager will conduct an audit at an agreed time, within 1 year of approval of the PGD, a sample of notes of patients (via the pharmacy record system, or other) receiving vaccines under PGD will be audited.

Each practitioner should have 5 sets of notes audited and following areas should be audited for documented evidence of:

- Consent obtained prior to vaccination;
- Reason for administering/not administering a vaccine;
- Site of vaccination, batch number and expiry date of vaccine;
- Asking the patient/parent/person with parental responsibility about allergies, and other exclusion criteria;
- Information given to patient/parent/person with parental responsibility;
- Follow up

If a practitioner has been absent for long periods of the year, or has not had the opportunity to administer vaccines under PGD then the superintendent/lead or registered manager will undertake a separate audit appropriate to the practitioner’s clinical activity.

The findings of the audit will be discussed with the practitioner. If there are any concerns or issues about their knowledge or competence the superintendent/lead or registered manager will conduct a detailed audit of an individual’s practice within one month.

FMC have the authority to access a pharmacy or clinic to audit PGD use as described above, and to have access to all completed RAFs upon request. If the service is deemed insufficient and standards are not being upheld, the clinic or pharmacy management, the superintendent or registered manager and the implementing healthcare professional will be informed and an action plan drawn
up to remedy the service. If there are significant failings, the Travel Clinician will have their travel medicine license revoked, without a refund.

REVIEW

This SOP, individual vaccine PGDs, and related guidelines will be reviewed every two years, or sooner after discussion and approval by FMC MDT, if:

- There is a change in the status or name of the authorising organisation;
- There is a change in the licensed indications of the product(s), or a change in evidence-based clinical guidelines;
- Further guidance is issued by the Department of Health, or other appropriate organisation;
- There is a change in legislation.

CLINICAL REQUIREMENTS

The appropriately authorised PGDs must be present at the implementing pharmacy / clinic or electronically signed and accessible to the authorised healthcare professional. It is recommended to always refer to the online version of the PGD to ensure that the most up-to-date version is available for reference. PharmaDoctor+ will notify all pharmacists of any changes to individual PGD documents, however it is the pharmacist's responsibility to ensure the latest version is used when printing out a hardcopy.

Consultation Room Specification

There is a set of standards set by the GPhC, which clarifies pharmacy premises standards. Not every pharmacy can use PharmaDoctor PGDs for their clinics. All authorised pharmacies and nurse clinics need to meet a set of premises standards mapped out in the Clinic Check List to use Vaccine PGDs:

<table>
<thead>
<tr>
<th>Clinic Check List</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Private area which is confidential and suitably comfortable</strong></td>
</tr>
<tr>
<td><strong>The clinical room / consultation area is large enough for safe clinical practice</strong></td>
</tr>
<tr>
<td><strong>The clinical room / consultation area should reflect a professional image</strong></td>
</tr>
<tr>
<td><strong>Suitable hand washing facilities</strong></td>
</tr>
<tr>
<td><strong>Suitable and clear signage external to the clinical room/consultation area</strong></td>
</tr>
<tr>
<td><strong>Secure area for patient records</strong></td>
</tr>
<tr>
<td><strong>Sharps bin, pharmaceutical waste and anaphylaxis kit</strong></td>
</tr>
</tbody>
</table>
A computer with internet access in the consultation room

| This enables access to evidence based websites and professional databases. |

Access to a reliable telephone system

| This is to allow immediate calls to 999 in an emergency |

Immunisation Equipment must be available
- Vaccine supply including the manufacturer’s information leaflet
- Risk assessment forms for patient documentation
- Copy of PGD
- Access to the internet if providing a travel health consultation
- Cotton wool or gauze, Micropore tape or spot plasters
- Yellow lidded Sharps container UN-approved, BS7320
- Selection of syringes – 2ml (single use only)
- Selection of needles (single use only)
  - Green 21 gauge - 38 mm long - use for drawing up of vaccine medication
  - Blue 23 gauge - 25mm long use to administer vaccines

CONSULTATIONS FOR FLU CLINICS AND OTHER VACCINATION SERVICES.

No immunisation consultation should take place without conducting a medical risk assessment and documenting the information. The assessment forms the basis of all subsequent decisions, the advice given and the vaccines administered.

All pharmacy staff should be aware of any vaccination campaigns such as flu vaccines in the local community, where they can help with the recruitment of patients into any vaccination campaigns or services, providing general advice, handing out leaflets and taking bookings. All requests for medical advice on any vaccine or medication that is being administered or supplied by a PGD should be directed to the healthcare professional with the authority to operate within it.

Healthcare professionals are accountable for their actions and need to be able to justify their decisions, face-to-face contact with a patient is recommended, as all personalised recommendations, discussions and advice given during the medical risk assessment process should be documented. In general, providing advice via a telephone or e-mail is controversial, time-consuming, and may make practitioners vulnerable to litigation.23

TRAVEL HEALTH VACCINATION CLINICS

All pharmacy or clinic staff should be aware of the need for travel health care in the local community. Patients going on the Muslim Hajj/Umrah pilgrimages usually require certain travel vaccinations and the demand for travel health services for travel to all destinations typically spikes during school holiday periods.

It is usually recommend getting pre travel advice at least six to eight weeks before travel. This is particularly important if the patients’ are planning a long trip or going to remote areas, as some vaccinations need to be given well in advance to allow immunity to develop and some involve multiple doses spread over several weeks.24 The majority of risks for most travellers are not vaccine preventable and so risk management will involve educating them about preventive strategies.

No travel health consultation should take place without conducting a travel risk assessment and documenting the information. The assessment forms the basis of all subsequent decisions, advice
given, vaccines administered and the malaria prophylaxis advice that is offered. This takes time to perform correctly, and for best practice practitioners should leave sufficient time.  

Booking an appointment

If a patient phones to make an appointment, any member of staff may book a date, but must not assess them or provide any recommendations on vaccination or travel health advice. Note the patient’s name a contact telephone number such as mobile phone number and confirm with the patient the time & date of the appointment when entering it into an appointment system such as the pharmacy diary. It can also be useful to note information about the traveller’s destination, date of departure and duration of stay if booking a travel clinic appointment.

When booking a travel clinic appointment it is important to allocate sufficient time to perform the risk assessment and deliver appropriate travel risk management advice. A minimum 20-minute consultation appointment per person should be allowed to exercise best practice. Travellers with more complex needs – such as backpackers, or individuals requiring malaria prevention advice relevant to their destination – may need a longer consultation time.

Initial contact without an appointment

All healthcare professionals are accountable for their actions and need to be able to justify their decisions, therefore if a patient would like more details about a consultation, this stage should exclusively be handled by the PGD authorised healthcare professional. To maintain confidentiality take the patient into the pharmacy/clinic consultation area. Patients are likely to ask which vaccines they require, how long before travel should the vaccines be started, have they got enough time to be vaccinated and enquire about the cost of the service. Explain that the vaccination or travel clinic is a private service that will need to be paid for.

A brief explanation of the process involved such as asking the patient to complete a risk assessment form prior to any consultation collating some medical information of the patient, their itinerary and destination and activity-related factors if travelling is a necessity, which will be used to identify any potential problems and hazards that a traveller might be exposed to. It would also be useful for them to bring along to their appointment a record of any vaccines or immunisations previously administered.

IMMUNISATION PROCEDURE FOR ADULTS AND CHILDREN

<table>
<thead>
<tr>
<th>Activity</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verbally confirm the identity of the patient by asking for their full name and date of birth. If the patient is unable to confirm, check identity with family/carer</td>
<td>To avoid mistaken identity if risk assessment forms have been completed prior to an appointment.</td>
</tr>
<tr>
<td>In case of a child, check accompanying adult has parental responsibility</td>
<td>To comply with consent guidelines</td>
</tr>
<tr>
<td>Introduce yourself and any colleagues involved at the contact</td>
<td>To promote mutual respect and put the patient at their ease</td>
</tr>
<tr>
<td>Provide a safe and suitable environment and have appropriate equipment available</td>
<td>To help reduce any potential errors during administration of vaccines</td>
</tr>
<tr>
<td>Ensure the correct required vaccines are available and cold chain has been maintained</td>
<td>Vaccines to be stored in accordance with manufacturer’s guidance and vaccines transported under cold chain conditions at all times.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ensure a current Patient Group Direction (PGD) is in place to cover the specific vaccine to be administered and a copy of the PGD is accessible when administering the vaccine.</td>
<td>To comply with legislation</td>
</tr>
</tbody>
</table>
| **Assessing the risk assessment form**  
Make sure that all fields are completed and that no areas are blank. Ask the patient about any omissions. | If any details contraindicate treatment supply under PGD, make the necessary recommendations or referral. If you are in doubt, refer to the PGD document or contact telephone support line. |
| Ensure patient has not previously been vaccinated or that sufficient time has lapsed since previous immunisation.  
Check for any allergies | To ensure patient does not receive inappropriate immunisations  
To reduce risk of adverse event |
| **Inclusion/Exclusion criteria**  
The criteria outlined in a PGD must be strictly adhered to, to ensure that all the conditions of the PGD are fully met, i.e. that the patient fulfils the inclusion criteria and is not excluded from any of the exclusion criteria.  
Check if any allergies to the medicine or its excipients | To ensure the supply of medicines or administration of vaccines will be authorised.  
To reduce risk of adverse event |
| Confirm that the patient or where appropriate carer understands what vaccination(s) are to be given and is aware of possible adverse drug reactions, including how to recognise the symptoms of anaphylaxis. | To gain informed and valid consent  
The onset of anaphylaxis can be delayed and it is essential that urgent medical care is sought as soon as possible |
| Decontaminate hands prior to procedure | To reduce the risk of transfer of transient micro-organisms on the healthcare workers hands |
| Risk assess use of Personal Protective Equipment (PPE), such as gloves on an individual patient basis | To comply with local infection control policies |
| Check vaccine is in date before administration.  
If required reconstitute vaccine according to the manufacturer’s instructions ensuring the vaccine is thoroughly dissolved in the diluent before administration.  
Vaccines should not be drawn up in advance of | To ensure the vaccine is not date expired  
To ensure reconstituted vaccine is thoroughly mixed |
<table>
<thead>
<tr>
<th>Instructions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspect the vaccine ensuring it is clear from particulate matter and is the correct colour according to the manufacturer’s information leaflet</td>
<td>To ensure vaccines are not administered if they are shown to be not fit for purpose</td>
</tr>
<tr>
<td>If the skin is clean, no further cleaning is necessary. Only visibly dirty skin needs to be washed with soap and water.</td>
<td>There is evidence that disinfecting the skin makes no difference to the incidence of bacterial complications of injections.</td>
</tr>
<tr>
<td>Administer the vaccine in accordance with the PGD with the patient sitting down.</td>
<td>All patients should be sitting on a chair or couch for vaccines to be administered in case of vasovagal syncope.</td>
</tr>
<tr>
<td>The preferred site for intramuscular (IM) and subcutaneous (SC) immunisation are the deltoid area of the upper arm for all adults and children over one year of age.</td>
<td>Injection site avoids major nerves and blood vessels.</td>
</tr>
<tr>
<td>Most vaccines are administered via the IM route as this route is less likely to cause local reactions.</td>
<td>To reduce the risk of bleeding</td>
</tr>
<tr>
<td>Patients with bleeding disorders may have their immunisation via deep SC route. Refer to individual specific PGDs or summary of product characteristics for more details.</td>
<td></td>
</tr>
<tr>
<td>Document &amp; Record the following: batch number and expiry date, manufacturer and specific name of vaccine &amp; dose administered, route and site(s) used – including clear description of which injection was administered in each site, especially where two injections were administered in the same limb, name &amp; signature of immuniser, date of administration</td>
<td>To comply with record keeping standards</td>
</tr>
<tr>
<td>If more than one vaccination is given, record each site used, preferably in a different limb.</td>
<td>To enable identification of vaccine regarding any localised reaction</td>
</tr>
<tr>
<td>Dispose of sharps and any other clinical waste in line with local policies.</td>
<td>If more than one injection is to be given in the same limb, they should be administered at least 2.5cm apart.</td>
</tr>
<tr>
<td>If worn, remove and dispose of Personal Protective Equipment in line with local policies.</td>
<td>To reduce risk of inoculation injury and ensure safe management of healthcare waste</td>
</tr>
<tr>
<td>Decontaminate hands following procedure</td>
<td>To prevent cross infection and environmental contamination</td>
</tr>
<tr>
<td>Discuss possible adverse effects and the management of symptoms and record that the advice has been given. If symptoms persist advise</td>
<td>To reduce the risk of transfer of transient microorganisms on the healthcare worker’s hands</td>
</tr>
<tr>
<td></td>
<td>To promote self-care of minor adverse effects.</td>
</tr>
</tbody>
</table>
the patient to contact General Practitioner or Health Professional for advice

| Vaccine recipients should remain under observation for immediate adverse drug reactions, including observation for any signs of anaphylaxis, until they have been seen to recover from the procedure, approximately 10 – 15 minutes. | Due to the unpredictable nature of anaphylactic reactions it is not possible to define a particular time period over which all individuals should be observed following immunisation to ensure they do not develop anaphylaxis. |

**WHERE TO GET ADVICE FROM**

Individual PGDs specify any additional information that is specific to the individual vaccine or medicine, but the healthcare professional must be alert to changes in Summaries of Product Characteristics, the Green Book chapters for individual vaccines, and national and local immunisation programmes.

The authorised PGD user should be aware of general recommendations for vaccines, and the schedule for childhood immunisation in the UK, as directed by the Chief Medical Officer, Public Health England, or Department of Health.²⁶

Individual PGDs must be read in conjunction with information relevant to vaccination and immunisation such as, immunisation procedures, general exclusion criteria, common adverse effects, immunisation of individuals with underlying medical conditions, contraindications and special considerations by accessing the relevant current and updated chapters of Immunisation against Infectious Disease, the Green Book.²⁷

In some circumstances, advice may differ from that in vaccine manufacturers’ Summaries of Product Characteristics (SPCs). When this occurs, the recommendations in the “green book” (which are based on current expert advice received from the Joint Committee on Vaccination and Immunisation (JCVI) should be followed.²⁸

For healthcare professionals providing a travel vaccination service, including the Meningitis ACW₁₃₅Y vaccine for pilgrims to Saudi Arabia, due to the constantly changing nature of destination-related risks, access to up-to-date references and evidence-based online resources are essential to ensure real-time and validated information supporting best practice to educate and empower the traveller to manage his or her health during the trip through counselling and prevention messages. Information on the hazards associated with the destination and any specific requirements for travel to destinations are obtained from the National Travel Health Network and Centre (NaTHNaC) via the website TravelHealthPro.²⁹ The TRAVAX website provides travel health information free to healthcare professionals using the service for NHS purposes in Scotland. Other UK healthcare professionals may subscribe to use TRAVAX for a fee.³⁰
A telephone help line **0203 515 0039** is available for the clinical support of health professionals using PharmaDoctor+ PGDs. You will need to reference the PGD you are enquiring about so please make sure you have read the documentation thoroughly and have it with you. Our trained clinical support staff will offer advice, but cannot give directions, the decisions made after the advice is given is solely your responsibility.

**REFERENCES**

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    https://www.gov.uk/government/collections/immunisation

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    against-infectious-disease-the-green-book

    https://www.gov.uk/government/publications/immunisation-procedures-the-green-book-
    chapter-4

29. National Travel Health Network and Centre http://www.nathnac.org/pro/index.htm and
    http://travelhealthpro.org.uk/

30. Health Protection Scotland (HPS) TRAVAX website http://www.travax.nhs.uk/
## Records of an Additional Clinical Event (ACE) during or following a consultation

<table>
<thead>
<tr>
<th>Reporting Pharmacists Name</th>
<th>Pharmacy location where the ACE occurred</th>
</tr>
</thead>
</table>

### Details of incident

<table>
<thead>
<tr>
<th>Time and date of event</th>
<th>If known Patient initials and DoB. Names are not to be used as to preserve anonymity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of event,</td>
<td></td>
</tr>
<tr>
<td>Details of care or advice provided by the Pharmacist</td>
<td></td>
</tr>
<tr>
<td>Details of medicine or vaccine if related to the event</td>
<td></td>
</tr>
</tbody>
</table>

### Actions taken

<table>
<thead>
<tr>
<th>Clinical Support</th>
<th>PharmaDoctor telephone advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of care or advice provided by PharmaDoctor</td>
<td></td>
</tr>
<tr>
<td>Did the Pharmacist contact the patients GP?</td>
<td></td>
</tr>
<tr>
<td>Agreed Actions...</td>
<td></td>
</tr>
</tbody>
</table>

### Summary of Outcome and Review

<table>
<thead>
<tr>
<th>What was the outcome of this event?</th>
<th>Resolved with advice ☐</th>
<th>Ambulance called ☐</th>
<th>Referred to GP ☐</th>
<th>Referred to AED ☐</th>
<th>MHRA Yellow Card ☐</th>
<th>Other ☐</th>
<th>Please provide details below...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Could this event have been avoided and if so how? <strong>YES</strong> or <strong>NO</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This form should be sent via FAX 020 7160 5208 or email to info@pharmadoctor.co.uk