



UKHSA publications gateway number: GOV-15882

Measles, mumps and rubella vaccine Patient Group Direction (PGD)

This PGD is for the administration of measles, mumps and rubella (MMR) vaccine to individuals from one year of age for routine immunisation, or from 6 months of age if early protection is required, in accordance with the national immunisation programme and the <u>National measles</u> guidelines.

This PGD is for use by registered healthcare practitioners identified in <u>Section 3</u>, subject to any limitations to authorisation detailed in <u>Section 2</u>.

Reference no: MMR Vaccine PGD

Version no: v5.00

Valid from: 29 February 2024 Review date: 31 July 2026 Expiry date: 31 January 2027

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly-funded immunisation in England in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in <u>Section 2</u> by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)¹. **The PGD is not legal or valid without signed authorisation in accordance with <u>HMR2012 Schedule 16 Part 2</u>.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter <u>Section 3</u> (Characteristics of staff).

Sections 2 and 7 can be edited within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of UKHSA PGD templates for authorisation can be found from: Immunisation patient group direction (PGD) templates.

Any concerns regarding the content of this PGD should be addressed to: immunisation@ukhsa.gov.uk.

¹ This includes any relevant amendments to legislation

MMR Vaccine PGD v5.00 Valid from: 29 February 2024 Expiry: 31 January 2027 Page 1 of 17

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: england.nwsit@nhs.net for Lancashire, South Cumbria, Cheshire and Merseyside.

Change history

Version	Change details	Date
V1.00	V1.00 New PHE PGD template	
V2.00	 PHE MMR PGD amended to: include additional healthcare practitioners (pharmacists, paramedics, physiotherapists) in Section 3 amend age from 12 months to one year move neurological conditions from exclusions to cautions to align with the Green Book Chapter 6 guidance revise cautions clarify dose and frequency of administration section add paragraph on patient consent to the off-label section reference the protocol for ordering, storage and handling of vaccines refer to vaccine incident guidelines include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	26 January 2018
V3.00	 PHE MMR PGD amended to: remove live vaccine intervals table and refer to the Green Book Chapter 11 revise recommendations relating to MMR second dose before 18 months of age add sentence to neurological conditions paragraph in cautions section include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs 	18 December 2019
V4.00	PHE MMR PGD amended to: • update organisation from PHE to UKHSA • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs	16 February 2022
V5.00	 UKHSA MMR PGD amended to: include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change, gateway requirements and other UKHSA PGDs amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 replace Public Health England and PHE with UKHSA, including updated contact details include updated references, including the National measles guideline 2023 include detail of phenylalanine content in the vaccine and National Society for Phenylketonuria (NSPKU) advice clarify dose schedule for individuals vaccinated before the age of one include updated adverse effect profile and expected physical appearance upon reconstitution for Priorix® and MMRVAXPRO® update information on co-administration of MMR with varicella and varicella zoster vaccines 	25 January 2024

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist - Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA	Chichum	22 January 2024
Doctor	Dr Mary Ramsay CBE Director of Public Health Programmes and Consultant Epidemiologist, Head of Immunisation and Vaccine Preventable Diseases Division, UKHSA	Mary Ramony	22 January 2024
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisations, Immunisation and Vaccine Preventable Diseases Division, UKHSA	Dagen.	22 January 2024

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Committee.

Expert Panel

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Public Health Commissioning NHS England (NHSE) Midlands
Rosie Furner	Specialist Pharmacist - Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacist Services (SPS)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Primary Care Based, Southborne Surgery
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol, North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nikki Philbin	Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London
Laura Smeaton	IDPS Programme Projects Manager and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme, NHSE

2. Organisational authorisation

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England – North West authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services

Immunisations services in Lancashire, South Cumbria, Cheshire and Merseyside commissioned by NHS England – North West.

Limitations to authorisation

Users of this PGD should note that where they are commissioned to immunise certain groups, this PGD does not constitute permission to offer immunisation beyond groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Medical Director for Primary Care, NHS England – North West	Dr Paula Cowan	Poyers.	04/02/2024

Additional signatories acco	Additional signatories according to locally agreed policy			
Role	Name	Sign	Date	
Adoption by Independent Contractor/Provider				

Local enquiries regarding the use of this PGD may be directed to england.nwsit@nhs.net for Lancashire, South Cumbria, Cheshire and Merseyside providers.

<u>Section 7</u> provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration

Registered professional with one of the following bodies:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
- pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: this PGD is not relevant to privately provided community pharmacy services)
- paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC)

The practitioners above must also fulfil the <u>Additional requirements</u> detailed below.

Check <u>Section 2</u> (Limitations to authorisation) to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.

Additional requirements

Additionally, practitioners:

- must be authorised by name as an approved practitioner under the current terms of this PGD before working to it
- must have undertaken appropriate training for working under PGDs for supply and administration of medicines
- must be competent in the use of PGDs (see <u>NICE Competency</u> <u>framework for health professionals using PGDs</u>)
- must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the <u>Green Book</u>) and national and local immunisation programmes
- must have undertaken training appropriate to this PGD as required by local policy and in line with the <u>National Minimum Standards and Core</u> Curriculum for Immunisation Training
- must be competent to undertake immunisation and to discuss issues related to immunisation
- must be competent in the handling and storage of vaccines and management of the cold chain
- must be competent in the recognition and management of anaphylaxis
- must have access to the PGD and associated online resources
- should fulfil any additional requirements defined by local policy

The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.

Continued training requirements

Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).

Practitioners should be constantly alert to any subsequent recommendations from the UKHSA, NHSE and other sources of medicines information.

Note: the most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations outside of criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals from one year of age for routine immunisation, or from 6 months of age if early protection is required, for the prevention of measles, mumps or rubella (or a combination) in accordance with the national immunisation programme, National measles guidelines and recommendations given in Chapter 23 and Chapter 28 of Immunisation Against Infectious Disease: the Green Book.
Criteria for inclusion	 Individuals who: are aged one year (on or after their first birthday) or older and are either unimmunised or have incomplete, uncertain or unknown vaccination status against MMR* are between 6 months and one year of age and early protection is considered necessary, such as due to travel or an outbreak are aged 6 months and over and vaccination is indicated for measles post-exposure prophylaxis in accordance with national recommendations *See special considerations and additional information section for further detail on patient groups at particular risk from measles, mumps or rubella infection and opportunities to check immunisation status and vaccinate as appropriate.
Criteria for exclusion ²	Individuals for whom valid consent or a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent, see Chapter 2 of the Green Book). Several resources are available to inform consent (see written information to be given to individual, parent or carer section). Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of any measles, mumps or rubella containing vaccine or to any components of the vaccine. These may include neomycin or gelatine (refer to relevant SPC) • are known to be pregnant • have a primary or acquired immunodeficiency state (see the Green Book Chapter 6 for more detail) • are on current or recent high dose immunosuppressive or biological therapy (see the Green Book Chapter 6 for more detail) • have received varicella, varicella zoster or yellow fever vaccine in the preceding 4 weeks, unless protection against measles is rapidly required (see Drug interactions) • have received blood products, such as immunoglobulins, in the preceding 3 months, unless protection against measles is rapidly required (see Drug interactions) • are awaiting reading of a tuberculin (Mantoux) skin test, unless protection against measles is rapidly required (see Drug interactions) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

Exclusion under the PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required
 MMR Vaccine PGD v5.00 Valid from: 29 February 2024 Expiry: 31 January 2027 Page 6 of 17

Cautions including any relevant action to be taken

Facilities for management of anaphylaxis should be available at all vaccination sites (see <u>Chapter 8</u> of the Green Book and advice issued by the <u>Resuscitation Council UK</u>).

Individuals who are immunosuppressed or who are living with HIV, who are not contraindicated to receive this live vaccine (see the Green Book Chapter 6) may not make a full antibody response and revaccination upon cessation of treatment or clinical recovery may be required. This should be discussed with the appropriate specialist and the repeat dose administered under PSD.

If idiopathic thrombocytopenic purpura (ITP) has occurred within 6 weeks of the first dose of MMR, then blood should be taken and tested for measles, mumps and rubella antibodies before a second dose is given. Serum should be sent to the UKHSA Virus Reference Department, which offers free, specialised serological testing for such children. If the results suggest incomplete immunity against measles, mumps or rubella, then a second dose of MMR is recommended.

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis or the expected course of the condition (or both) become clear. If there is a risk of exposure, however, it may be more appropriate to counsel the patient about the benefits of protection rather than deferring. Children with a personal or close family history of seizures should be given MMR vaccine.

Priorix® contains 334 micrograms of phenylalanine per 0.5ml dose. MMRVAXPRO® also contains a source of phenylalanine. Though phenylalanine may be harmful to individuals with phenylketonuria (PKU), such individuals (or their parent or carer) will be well versed as to the amounts of phenylalanine tolerable in their diet. The National Society for Phenylketonuria (NSPKU) advise the amount of phenylalanine contained in vaccines is negligible and therefore strongly advise individuals with PKU to take up the offer of immunisation.

Syncope (fainting) can occur following, or even before any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Action to be taken if the individual is excluded

Individuals who have had a confirmed anaphylactic reaction to a previous dose of MMR vaccine or any components of the vaccine should be referred to a clinician for specialist advice and appropriate management.

Individuals who are pregnant should be advised to avoid contact with known or suspected cases of measles, mumps and rubella infection and report any rash illness or contact with rash illness to their GP or midwife (or both). Women who are lacking 2 documented doses of MMR should be immunised after their pregnancy, at the earliest opportunity and before any further pregnancies. Note: MMR can be given to breastfeeding mothers without any risk to their baby.

Individuals who have a primary or acquired immunodeficiency state or who are currently, or were recently on high dose immunosuppressive or biological therapy (see Chapter 6) should consult the appropriate specialist regarding the individual's immune status and suitability for receiving live

(continued over page)

Action to be taken if the MMR vaccine. Where administration of MMR is advised, a PSD will be individual is excluded required. Further information to guide suitability of the MMR vaccine for individuals living with HIV is available in Table 21.2, Chapter 21 of the (continued) Green Book. Individuals requiring immunisation against measles, mumps or rubella (or a combination of the 3) for occupational health reasons, should be referred back to their employer for appropriate management. Individuals who have been immunised against varicella, varicella zoster or vellow fever within the last 4 weeks, or received blood products in the preceding 3 months, and do not require rapid protection against MMR, should defer immunisation until the appropriate minimum interval has been observed (see Drug interactions section). Individuals who are awaiting reading of a tuberculin (Mantoux) test should delay MMR vaccination until the skin test has been read, unless protection against measles is urgently required. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as appropriate. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the GP or a prescriber as appropriate. Action to be taken if the Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Where a person individual, parent or lacks the capacity, in accordance with the Mental Capacity Act 2005, a carer declines treatment decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and the potential complications.

Document the advice given and the decision reached.

Inform or refer to the GP or a prescriber as appropriate.

Arrangements for referral for medical advice

As per local policy

5. Description of treatment

Name, strength and formulation of drug	Measles, mumps and rubella vaccine (live):
Tormalation of drug	 Priorix®, powder and solvent for solution for injection in a pre-filled syringe
	MMRVAXPRO®, powder and solvent for suspension for injection in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	Administration to infants between 6 months and 9 months of age is off-label but is in accordance with National measles guidelines and recommendations given in Chapter 21, Chapter 23 and Chapter 28 of Immunisation Against Infectious Disease: the Green Book.
	Vaccine should be stored according to the conditions detailed in the <u>Storage</u> section below. However, in the event of inadvertent or unavoidable deviations of these conditions, refer to <u>Vaccine Incident Guidance</u> . Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD.
	Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual, parent or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.
Route and method of administration	The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration.
	Administer by intramuscular injection. The deltoid muscle of the upper arm may be used in individuals over one year of age. The anterolateral aspect of the thigh is the preferred site for infants under one year old.
	When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.
	Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual or carer should be informed about the risk of haematoma from the injection.
	Priorix® is licensed to be given by either the intramuscular or subcutaneous route.
(continued over page)	The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and

Route and method of administration. Should either occur, do not administer the vaccine and administration discard the syringe in accordance with local procedures. Upon reconstitution, Priorix[®] is a clear peach to fuchsia pink solution. (continued) MMRVAXPRO® forms a clear yellow liquid. Further guidance on administration is available from the product's SPC. Dose and frequency of Single 0.5ml dose per administration. administration Routine childhood immunisation schedule A total of 2 doses of 0.5ml provided at the recommended interval (see below): • the first dose should routinely be given at one year of age (on or after the first birthday) • the second dose is routinely scheduled before school entry at 3 years 4 months of age Note: The second dose is normally given before school entry but can be given routinely from 18 months (refer to Early vaccination subsection, below). **Incomplete immunisation history** Individuals who have not had a dose from one year of age should receive a dose of MMR and be brought up to date at the earliest opportunity. Doses given before the first birthday should be discounted (see section below). An individual who has already received one dose of MMR should receive a second dose according to the routine schedule or (when aged 18 months or over) at least one month after the first dose to ensure they are protected. See the vaccination of individuals with uncertain or incomplete immunisation status flow chart. Early vaccination due to travel, outbreak or contact with a probable or confirmed case of measles The MMR vaccine can be given from 6 months of age when early protection is required. The response to MMR in infants is sub-optimal where the vaccine has been given before one year of age, due to interference from maternal antibody. Therefore, if a dose of MMR is given before the first birthday, this dose should be discounted. 2 further doses of MMR should be given at the recommended ages in accordance with the routine schedule (at one year of age and a pre-school dose at 3 years 4 months). Children who are travelling to epidemic or endemic areas, or who are a contact with a probable or confirmed case of measles, who have received one dose of MMR at the routine age should have the second dose brought forward to at least one month after the first. If the child is given the second dose before 15 months of age, then another routine dose (a third dose) should be given from 18 months of age in order to ensure full protection. In cases of post-exposure vaccination, the dose should ideally be given within 3 days of exposure to maximise vaccine efficacy. **Duration of treatment** 2 doses of 0.5ml at the recommended interval (see Dose and frequency of administration above). Doses that are administered earlier than the routine schedule, given within 4 weeks of previous yellow fever, varicella or varicella zoster vaccine or within (continued over page) 3 months of receiving blood products may need to be repeated (see Drug interactions section).

Duration of treatment (continued)	Co-administration of MMR with varicella or varicella zoster vaccines on the same day should not affect the immune response and therefore repeating the dose is not advised.
Quantity to be supplied and administered	Single 0.5ml dose per administration.
Supplies	Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge. National stock may also be used for catch-up vaccination of individuals of any age.
	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3).
Storage	Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.
	After reconstitution, the vaccine should be administered promptly or stored between +2°C to +8°C and used within 8 hours of reconstitution. If not used after this time, the vaccine must be discarded.
	In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance .
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local authority arrangements and NHSE guidance (HTM 07-01): Management and disposal of healthcare waste .
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment.
	May be given at the same time as inactivated vaccines or at any interval before or after.
	MMR may attenuate the response to other live vaccines (see Table 11.3: Recommended time intervals when giving more than one live attenuated vaccine, in Chapter 11 of the Green Book). Where protection against measles is required rapidly, other live vaccines should be given at any interval. The response may be suboptimal if yellow fever and MMR vaccines are co-administered or given within a 4 week interval; an additional dose of MMR should be considered. If varicella or varicella zoster vaccines are not co-administered at the same time as MMR, a 4 week minimum interval should be observed or consideration be given to administering an additional dose of MMR.
	If protection against measles is urgently required, then the benefit of protection from the vaccine outweighs the potential interference with a tuberculin test. In this circumstance, the individual interpreting the negative tuberculin test should be made aware of the recent MMR vaccination when considering how to manage that individual.
(continued over page)	When MMR is given within 3 months of receiving blood products, such as immunoglobulin, the response to the measles component may be reduced. This is because such blood products may contain significant levels of measles-specific antibody, which could then prevent vaccine virus replication. Where possible, MMR should be given at least 1 month before or deferred until 3 months after receipt of such products. If immediate

Drug interactions measles protection is required in someone who has recently received a blood product, MMR vaccine should still be given. To confer longer-term (continued) protection, MMR should be repeated after 3 months. A detailed list of drug interactions is available in the product's SPC. **Identification and** Adverse reactions are attributed to effective replication of the vaccine viruses, with subsequent mild illness. Events due to the measles management of adverse reactions component occur 6 to 11 days after vaccination. Events due to the mumps and rubella components usually occur 2 to 3 weeks after vaccination but may occur up to 6 weeks after vaccination. Individuals with vaccineassociated symptoms are not infectious to others. The most common adverse reactions are fever and injection site reactions including pain, swelling and erythema. Rash is also commonly reported. Malaise, fever or a rash (or a combination of these) most commonly occur about a week after immunisation, lasting around 2 to 3 days. Upper respiratory tract infection was commonly reported in clinical trial data for Priorix®. Adverse reactions are less common after a second dose of MMRVAXPRO® vaccine than after the first dose; incidence and severity of adverse reactions following a second dose with Priorix® are broadly similar. Hypersensitivity reactions and anaphylaxis can occur but are very rare. In studies, parotid swelling occurred in about 1% of children of all ages up to 4 years, usually in the third week. Rare and more serious events Febrile seizures are the most commonly reported neurological event following measles immunisation. Seizures occur during the sixth to eleventh day in 1 in 1000 children vaccinated with MMR. Arthropathy (arthralgia or arthritis) has also been reported to occur rarely after MMR immunisation, probably due to the rubella component. If it is caused by the vaccine, it should occur between 14 and 21 days after immunisation. Where it occurs at other times, it is highly unlikely to have been caused by vaccination. ITP has occurred rarely following MMR vaccination, usually within 6 weeks of the first dose and resolves spontaneously. The risk of developing ITP after MMR vaccine is much less than the risk of developing it after infection with wild measles or rubella virus (see Cautions). Further details on adverse reactions following MMR vaccine can be found in the Green Book Chapter 21, Chapter 23 and Chapter 28. A detailed list of adverse reactions is available in the product's SPC. Reporting procedure of Healthcare professionals and individuals, parents or carers are encouraged adverse reactions to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.

Written information to be given to individual, parent or carer

Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.

For resources in accessible formats and alternative languages, please visit Home-Health Publications. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed in the product's SPC.

Immunisation promotional material may be provided as appropriate:

- Immunisations at one year of age
- Pre-school immunisations: guide to vaccinations (2 to 5 years)
- Think measles: patient leaflet for young people
- Measles: information for schools and healthcare centres
- Measles outbreak resources

Advice and follow up treatment

Inform the individual, parent or carer of possible side effects and their management.

Advise about likely timing of and subsequent management of a fever.

Advise where relevant that pregnancy should be avoided for one month post vaccination.

The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the <u>Yellow Card</u> reporting scheme.

When administration is postponed, advise the individual, parent or carer when to return for vaccination.

Where applicable, advise the individual, parent or carer when the subsequent dose is due.

Special considerations and additional information

Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.

Recent data suggest that anaphylactic reactions to MMR vaccine are not associated with hypersensitivity to egg antigens. All children with egg allergy should receive the MMR vaccination as a routine procedure in primary care.

MMRVAXPRO® (Sanofi Pasteur MSD) contains porcine gelatine.

Priorix® (GSK) does not contain porcine gelatine and can be offered as an alternative to MMRVAXPRO®. Health professionals should be aware of the need to order Priorix® when running clinics for relevant communities (see <u>Vaccines and porcine gelatine</u> leaflet).

MMR vaccine is recommended when protection against measles, mumps or rubella (or a combination of the 3) is required. MMR vaccine can be given irrespective of a history of measles, mumps or rubella infection or vaccination. There are no ill effects from vaccinating those who are already immune. If there is doubt about an individual's MMR immune status, MMR vaccine should still be given.

Children with chronic conditions such as cystic fibrosis, congenital heart or kidney disease, failure to thrive or Down's syndrome are at particular risk from measles infection and should be immunised with MMR vaccine without delay.

MMR vaccine can be provided to children and adults of any age over 6 months using this PGD. If a dose of MMR is given before the first birthday, either because of travel to an endemic country, or because of a local outbreak, then this dose should be ignored, and 2 further doses given at the recommended times. Maternal antibodies may reduce the response to the

(continued over page)

Special considerations and additional information (continued)

first dose of vaccination up to the age of 18 months. To provide additional protection to those who fail to respond to the first dose, therefore, the second dose should not routinely be given below 18 months of age. The decision on when to vaccinate adults needs to take into consideration the past vaccination history, the likelihood of an individual remaining susceptible and the future risk of exposure and disease (see the Green Book Chapter 23 and Chapter 28).

Entry into college, university or other higher education institutions, prison or military service provides an opportunity to check an individual's immunisation history. Those who have not received 2 doses of MMR should be offered appropriate MMR immunisation.

Pre-conceptual care, antenatal and post-natal checks provide an opportunity to assess MMR status. Individuals who have not received 2 doses of MMR at an appropriate interval should be offered pre-or post-natal MMR immunisation. Pregnancy should be avoided for at least one month following vaccination. Postpartum women who received a blood transfusion around the time of delivery and require rubella protection may experience an inhibited antibody response, due to interference from passively acquired rubella antibodies. A repeat dose of MMR is advised at a minimum interval of 3 months post transfusion. As per the <u>Duration of treatment</u> section, this PGD may be used to repeat the dose.

Children and adults coming from abroad may not have been immunised against measles, mumps and rubella. Unless there is a reliable history of appropriate immunisation, individuals should be assumed to be unimmunised. See Chapter 11 for more information. Individuals aged 18 months and over who have not received MMR, or who received a dose of measles-containing vaccine before the age of one should receive 2 doses at least one month apart. An individual who has already received one dose of MMR since their first birthday should receive a second dose to ensure that they are protected.

Post exposure

Antibody responses to the rubella and mumps components of MMR vaccine do not develop soon enough to provide effective prophylaxis after exposure to these infections. However, as vaccine-induced measles antibody develops more rapidly than that following natural infection, MMR vaccine should be used to protect susceptible contacts from suspected measles. To be effective against this exposure, vaccine must be administered very promptly and ideally within 3 days.

Even where it is too late to provide effective post-exposure prophylaxis with MMR, the vaccine can provide protection against future exposure to all 3 infections. Therefore, contact with suspected measles, mumps or rubella provides a good opportunity to offer MMR vaccine to previously unvaccinated individuals.

If the individual is already incubating measles, mumps or rubella, MMR vaccination will not exacerbate the symptoms. In these circumstances, individuals should be advised that a measles, mumps or rubella-like illness occurring shortly after vaccination is likely to be due to natural infection.

Immunoglobulin may be indicated for contacts of measles who are infants, immunosuppressed or pregnant. Provision of immunoglobulin is not covered by this PGD (see <u>National Measles Guidelines</u> for eligibility).

Records

The practitioner must ensure the following is recorded:

- that valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered
- name of immuniser
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- · quantity administered
- batch number and expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or immunisation declined
- details of any adverse drug reactions and actions taken
- supplied via PGD

Records should be signed and dated (or password-controlled on e-records).

All records should be clear, legible and contemporaneous.

This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting, appropriate health records should be kept and the individual's GP informed.

The local Child Health Information Systems (CHIS) team must be notified using the appropriate documentation or pathway as required by any local or contractual arrangement.

A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references

MMR vaccine

- Immunisation Against Infectious Disease: The Green Book <u>Chapter 21</u>, updated 31 December 2019; <u>Chapter 23</u> and <u>Chapter 28</u>, last updated 4 April 2013; <u>Chapter 6</u> updated 26 October 2017; and <u>Chapter 11</u> updated 17 March 2022
- Summary of Product Characteristic for Priorix[®], GlaxoSmithKline. 30
 April 2022. www.medicines.org.uk/emc/medicine/2054
- Summary of Product Characteristic for MMRVAXPRO[®], MSD Ltd. 15 July 2022. www.medicines.org.uk/emc/medicine/20968
- MSD Medical Information, Personal communication (via email), 13 December 2023
- UKHSA National measles guidelines. Last updated 27 October 2023 https://www.gov.uk/government/publications/national-measles-guidelines
- Vaccination of individuals with uncertain or incomplete immunisation status, UKHSA. Updated 6 September 2023
 www.gov.uk/government/publications/vaccination-of-individuals-withuncertain-or-incomplete-immunisation-status
- The National Society for Phenylketonuria (NSPKU) Medical Advisory Panel: Vaccines and PKU, issued 31 January 2023 https://nspku.org/download/vaccines-and-pku/

General

- NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Last updated March 2017 www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017 www.nice.org.uk/guidance/mpg2/resources
- UKHSA Immunisation Collection <u>www.gov.uk/government/collections/immunisation</u>
- Vaccine Incident Guidance. Last updated July 2022 <u>www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</u>

7. Practitioner authorisation sheet

MMR Vaccine PGD v5.00

Valid from: 29 February 2024 Expiry: 31 January 2027

Before signing this PGD, check that the document has had the necessary authorisations in <u>section</u> 2. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD, you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practice only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.					
Name	Designation	Signature	Date		

Authorising manager

I confirm that	the practitione	rs named above	e have declared	themselves	suitably	trained an	d
competent to	work under th	is PGD. I give au	uthorisation on l	behalf of			

insert name of organisation

for the above-named healthcare professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.