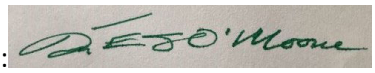
Master Medicine Protocol for the Administration of Priorix (MMR - Measles, Mumps and Rubella) live vaccine for MMR catch-up vaccination programme and in the event of an outbreak

This medicine protocol is a specific written instruction for the administration of Priorix (MMR) vaccine included in Statutory Instruments S.I. No. 422 of 2023 to vaccine recipients including healthcare workers by healthcare professions included in Statutory Instruments S.I. No. 698 of 2020, S.I. No. 81 of 2021 and S.I. No. 245 of 2021 who are registered with their respective regulatory body. This medicine protocol is valid for the 2024/2025 Health Service Executive (HSE) MMR catch-up vaccination programme and in the event of an outbreak as advised by Public Health.
This medicine protocol enables healthcare professionals employed in the voluntary and statutory services of the HSE including mass vaccination clinics, congregated settings, temporary clinics and mobile units who have undertaken the required education and training programmes to administer Priorix (MMR) vaccine with reference to and guidance from the National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for Priorix (MMR) vaccine as detailed by the Health Products Regulatory Authority (HPRA) at www.hpra.ie

- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*: Royal College of Physicians of Ireland National Immunisation Advisory Committee available at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
- National Immunisation Advisory Committee (2023) *Anaphylaxis: Immediate Management in the Community* available at:https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/
- National Immunisation Office (2023/2024) *Supporting Information for Staff: Schools Immunisation Programme* available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf
- National Immunisation Office (2024) *Clinical information to support HSE Immunisation Teams to deliver MMR Catch-up Vaccination.* Available at https://www.hse.ie/eng/health/immunisation/hcpinfo/mmrcatchup24/mmr-catch-up-supporting-info-for-staff.pdf
- National Immunisation Office (2022) *Supporting Information for Vaccinations in General Practice* available at: https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf

The Nursing and Midwifery Board of Ireland defines medicine protocols as "written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect" (An Bord Altranais, 2007, page 35).

The HSE has developed this medicine protocol to facilitate the administration of Priorix (MMR) Vaccine to vaccine recipients according to NIAC recommendations endorsed by the Department of Health. The healthcare professionals using this medicine protocol must ensure that this medicine protocol is organisationally approved, relating to the professional cohort of vaccinators by whom the vaccine is to be administered, including requirements of registration, education, training and assessment of competency.

Document reference number	NIO March 2024
1.0 Critical elements	
Name of Organisation where medicine protocol applies	Health Service Providers/mass vaccination clinics across the voluntary and statutory services of the HSE. This Medicine Protocol applies to: • Healthcare professionals included in S.I. No. 698 of 2020, S.I. No. 81 of 2021, S.I. No. 245 of 2021 and S.I. No. 422 of 2023 who are registered with their respective regulatory body employed in the voluntary and statutory services of the HSE including mass vaccination clinics, congregated settings, temporary clinics and mobile units.
Date the medicine protocol comes into effect	June 2024 (Version 2)
Date for review of medicine protocol	June 2025
Document prepared by	National Immunisation Office, HSE
Names and Signatures of the employing authority who is authorising the implementation of the medicine protocol ***"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"***	Name: **Dr. Eamonn O'Moore** Director of National Health Protection, HSE Signature:  Name: **Dr Colm Henry**, Chief Clinical Officer, HSE Signature: 

2.0 Clinical Criteria	
Clinical condition for use of the medicine protocol	The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of measles, mumps and rubella (MMR) infection.
Circumstances in which the medicine protocol applies	The primary childhood immunisation schedule and for any subsequent presentation for first and second MMR vaccine e.g. measles outbreak, late entrants, catch-up campaigns or adult vaccination to vaccinate recipients and in the prevention and control of measles cases.
Inclusion criteria for vaccine recipients receiving Priorix (MMR) vaccine under this medicine protocol	1. All children at 12 months of age should receive a Priorix (MMR) vaccine under the primary childhood immunisation schedule, with a second dose at 4-5 years of age (usually given in junior infants) 2. Children and adults presenting late for vaccine or without a written record or reliable verbal history of previously receiving MMR. 3. Measles outbreak – during an outbreak Priorix (MMR) vaccine may be given as young as 6 months of age. A dose given < 12 months of age does not replace the dose recommended at 12 months of age. In the event of an outbreak, follow public health advice. **Note:** Priorix (MMR) vaccine can be given to those who have a history of measles, mumps or rubella infection. **For catch up vaccination** Children (≥ age 4 and older) and adults without prior MMR vaccination should be given Priorix (MMR) vaccine as soon as possible and a second dose at least 4 weeks later. Children from 12 months to 4 yrs without evidence of MMR vaccination should receive one dose of MMR vaccine and continue with routine age appropriate MMR vaccination. **Precautions** • Acute severe febrile illness, defer until recovery. • Injection with another live vaccine within the previous four weeks. Two live vaccines can be administered on the same day without causing interference e.g., MMR and Varicella. However, MMR vaccine should not be routinely administered on the same day as yellow fever vaccine as co-administration of these two vaccines can lead to suboptimal antibody responses to yellow fever, mumps and rubella antigens. If rapid protection is required, the vaccines should be given on the same day or at any interval and an additional dose of MMR should be given at least four weeks later. • Family history of primary immunodeficiency (e.g., severe combined immunodeficiency syndrome (SCID)) defer vaccination until immune status is determined. • Recent administration of blood, blood products, Human normal immunoglobulin (HNIG) or specific immunoglobulin could prevent vaccine virus replication. MMR should be deferred for specific intervals depending on product received as outlined in NIAC Chapter 2 Table 2.6. • Tuberculin skin testing should be deferred for at least four weeks after MMR vaccine as the vaccine can reduce the tuberculin response and could give a false negative result.

	• Patients who developed thrombocytopaenia within six weeks of their first dose of MMR should undergo serological testing to decide whether a second dose is necessary. The second dose is recommended if the patient is not fully immune to the three component viruses. • Live vaccines should not be given to infants after in utero exposure to infliximab for 12 months after birth. However, administration of MMR vaccine may be considered before 12 months where there is a clear clinical indication and clear benefit, if infant infliximab serum levels are undetectable or if infliximab administration was limited to the first trimester of pregnancy. • Infants of breastfeeding mothers receiving monoclonal antibody treatment (including infliximab) post-partum should be immunised with MMR vaccines according to routine schedule. If there is any doubt as to whether an infant due to receive a live attenuated vaccine such as MMR may be immunosuppressed due to the mother's therapy, specialist advice should be sought. **Note:** COVID-19 vaccines (except for COVID-19 vaccine given to children aged 6 months to 4 years where a 14-day interval is recommended) and other vaccines may be administered at the same time or at any interval.
Exclusion criteria for vaccine recipients receiving Priorix (MMR) vaccine under this medicine protocol	• Anaphylaxis to a previous dose of MMR or to any of the vaccine constituents. • Severely immunocompromised persons (see NIAC Chapter 3), e.g. primary immunodeficiency or acquired immunodeficiency (from disease (including HIV/AIDS), or immunosuppressive therapy (including biologics). • Pregnancy (there is no requirement to carry out a pregnancy test prior to vaccination). **Note: pregnancy should be avoided for 1 month after Priorix (MMR) vaccine**
Actions to be taken for those who are excluded from this medicine protocol	All recipients meeting exclusion criteria must be referred to the medical practitioner for an individual medical assessment. • Document assessment and action in clinical notes • Where Priorix (MMR) vaccine is prescribed following medical assessment, the vaccinator may administer Priorix (MMR) vaccine within their scope of practice. **Note:** In determining their scope of practice, vaccinators must make judgements about their competence to carry out a role or activity.
Description of circumstances and referral arrangements when further advice or consultation is required	Discuss the vaccine recipient with the Medical Practitioner in the event of: • Confirmed or suspected anaphylactic reaction to the vaccine itself or to a constituent of that vaccine • Other clinical concerns

<table>
<tr><td>Documentation required for the implementation of this medicine protocol</td><td>Consent form must be completed by the parent/legal guardian for all children who receive the Priorix (MMR) vaccine. Children aged 16 years and over consent on their own behalf, once understood.
Relevant details including the batch number must be recorded on the consent form.
The following documents will be required at each vaccination session:
Vaccination session form
Blank vaccine consent forms
Vaccine Information Leaflets
Patient held record cards/vaccine passport
HPRA Adverse Reaction Reporting forms
HSE Incident/Near Miss report forms
Post vaccination advice
It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of Priorix (MMR) vaccine which includes the following:
Master Medicine Protocol for the Administration of Priorix (MMR - Measles, Mumps and Rubella) live vaccine under the HSE vaccination programme and in the event of an outbreak
NIAC (2023) Anaphylaxis: Immediate Management in the Community available at: https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/</td></tr>
<tr><td>3.0 Name of medicine</td><td>Priorix (MMR - Measles, Mumps and Rubella) live vaccine
Dose: 0.5ml
Route: Intramuscular injection
Note: Priorix (MMR) vaccine may be given subcutaneously (SC) to those with significant thrombocytopenia or bleeding disorder.
Presentation: Powder and solvent for solution for injection in a pre-filled syringe. The lyophilised Measles-Mumps-Rubella component is a white to slightly pink powder. The solvent is a clear and colourless solution. This vaccine needs to be reconstituted.
<table>
<tr><th>Patients Age</th><th>Site</th><th>Needle length & Size</th></tr>
<tr><td>Birth to <12 months</td><td>Vastus lateralis muscle</td><td>25 mm (Use a 16 mm needle in infants under 2.5 - 3 kg)
23-25 gauge</td></tr>
<tr><td>12 to <36 months</td><td>Vastus lateralis or deltoid muscle (depending on muscle mass)</td><td>25 mm
23-25 gauge</td></tr>
<tr><td>3 years and older</td><td>Deltoid muscle</td><td>25 mm
23-25 gauge</td></tr>
</table></td></tr>
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Link to Medicine **Details of product information and other data including instructions for supply and administration is available from the HPRA at www.hpra.ie**	**Link to Summary of Product Characteristics:** http://www.hpra.ie/img/uploaded/vaccines/SPC_PA1077036001.pdf **Link to Patient Information Leaflet:** http://www.hpra.ie/img/uploaded/vaccines/PIL_PA1077036001.pdf
Procedure for the reporting and documentation of errors and near misses involving the medicine	In the case of medicine errors that directly involve the vaccine recipient, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the vaccinator must remain with the vaccine recipient and closely monitor them for any adverse reactions. Vital signs should be recorded and the vaccine recipient should be reviewed by the vaccinator and/or medical practitioner. The incident must be reported to the relevant line manager as soon as possible. The incident and all actions taken must be promptly recorded in the recipient's documentation/notes and the relevant National Incident Management Report Form completed: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf For children, the child's parent and/or legal guardian must be informed of the incident. Any suspected adverse reactions associated with medicine errors should be reported to the HPRA as outlined below. Any errors and near misses not involving medicines e.g. needle stick injuries, the incident and all actions taken must be promptly recorded on the relevant National Incident Management Report form and forwarded to the relevant line manager as per local policy. Refer to 'EMI Tool Kit' (https://www.hpsc.ie/a-z/EMIToolkit/).
Procedure for reporting Adverse Drug Reactions to the HPRA	The relevant vaccination staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out online at https://www.hpra.ie or through use of the yellow card system which is available in the downloadable format from the HPRA website, or on request from the HPRA.
Resources and equipment required for administration of Priorix (MMR - Measles, Mumps and Rubella)	• Priorix (MMR) vaccine • Fridge/cool box with minimum/maximum temperature recording device to monitor the Cold chain temperature (between +2°C and +8°C) • Vaccination cool packs • Disposable kidney dishes/coloured trays • Gauze swabs/Plasters • Sharps bins, and bags for disposal of healthcare risk and non-risk waste material • HSE Policy on the Management of Sharps and Prevention of Sharp Injuries (2022). https://healthservice.hse.ie/filelibrary/staff/policy-on-the-management- of-sharps-and-prevention-of-sharp-injuries.pdf • Alcohol hand sanitizer • Face masks (if required)

	• Access to telephone • Resuscitation equipment and drugs in accordance with the NIAC (2023) *Anaphylaxis: Immediate Management in the Community* available at: https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ • Access to medical support • Safe storage areas for medicines and equipment • Current medicine protocol for Priorix (MMR) vaccine.
Audit process to identify appropriate use of the medicine protocol or unexpected outcomes	All documentation will be held for review and audit purposes as per local policy
4.0 Information for vaccine recipient/parent/legal guardian	
Advice to be given to the vaccine recipient/parent/legal guardian before treatment **Advice to be given to the vaccine recipient/parent/legal guardian after treatment**	Reiterate the information provided in the HSE patient information leaflet for the vaccine in the appropriate language and translator support if required. For children, Patient Information Leaflet/Fact Sheet must be supplied with the consent form to each parent/legal guardian prior to administration of the vaccine as above. **After Treatment** The vaccine recipient must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the staff who is present. **Note:** Adverse reactions are considerably less common (less than 1%) after the 2nd dose of Priorix (MMR) vaccine.
Details of any necessary follow-up, action and referral arrangements	In the event of an adverse reaction the vaccinator must ensure that all procedures are adhered to as outlined in Section 3.
5.0 Staff authorised to use this medicine protocol	
Professional qualifications, training and competence required prior to using this medicine protocol	1) Be a Registered healthcare professional, on the active register maintained by the relevant professional regulatory body in Ireland 2) An approved *Basic Life Support for Health Care Providers Course* within the last two years (For e.g. Irish Heart Foundation (IHF), American Heart Association (AHA)) 3) Initial *National Anaphylaxis Education Programme for Health Care Professionals* accessible on www.HSELanD.ie followed by a two hour classroom based skills workshop. Recertification is required every two years by completing the on-line *National Anaphylaxis Education Programme for Health Care Professionals* accessible on www.HSELanD.ie or the relevant anaphylaxis management programme approved by their professional organisation. **Note:** In addition to the above, the vaccinator must complete the education, training, and self-assessment of competence requirements as recommended by their professional organisation and regulatory authority. Registered Nurses and registered Midwives must read the section B document specific to this medicine protocol and complete the Self-Assessment of Competency Form.

References

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management.* Dublin: An Bord Altranais

GlaxoSmithKline, Ireland Limited Priorix (MMR) Vaccine *Summary of Product Characteristics and Patient Information Leaflet* available at: www.hpra.ie

Health Products Regulatory Authority available at: www.hpra.ie

HSE Policy on the Management of Sharps and Prevention of Sharp Injuries (2022). https://healthservice.hse.ie/filelibrary/staff/policy-on-the-management- of-sharps-and-prevention-of-sharp-injuries.pdf

Irish Statutory Instruments available at https://www.irishstatutebook.ie/eli/statutory.html

National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC) https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/.

National Immunisation Advisory Committee (2023) *Anaphylaxis: Immediate Management in the Community* available at: https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/

National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*: Royal College of Physicians of Ireland National Immunisation Advisory Committee available at:https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

National Immunisation Office (2023/2024) *Supporting Information for Staff: Schools Immunisation Programme* available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf

National Immunisation Office (2024) *Clinical information to support HSE Immunisation Teams to deliver MMR Catch-up Vaccination.* Available at https://www.hse.ie/eng/health/immunisation/hcpinfo/mmrcatchup24/mmr-catch-up-supporting-info-for-staff.pdf

National Immunisation Office (2022) *Supporting Information for Vaccinations in General Practice* available at: https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf