E: ImmunisationPolicy@gov.scot

SHINGLES VACCINATION PROGRAMME: INTRODUCTION OF SHINGRIX® VACCINE FOR THE WHOLE PROGRAMME AND EXPANSION OF ELIGIBLE COHORTS

Dear Colleague

 We are writing to provide information on the changes to the 2023/24 shingles vaccination programme which will run from 1 September 2023 to 31 August 2024.

Background

- 2. The aim of the national shingles vaccination programme is to protect those most at risk from shingles and its complications such as post herpetic neuralgia. Although shingles can occur at any age, the risk and severity of shingles and its complications increases with age and is high in individuals who are severely immunosuppressed. It is important to ensure that those at greatest risk are vaccinated at an earlier age and this forms the basis of the Joint Committee on Vaccination and Immunisation (JCVI) recommendations.
- 3. The shingles vaccination programme was introduced in Scotland in 2013 for those aged 70 years old.
- 4. A catch up programme for those aged 71 to 79 years old was also introduced at this time, and was rolled out over a number of years.
- Zostavax[®], a live vaccine, was routinely offered to those eligible and not contraindicated to the vaccine. Since September 2021, Shingrix[®], a non-live vaccine, has been available to immunocompromised individuals aged 70 to 79 years, who are contraindicated to receive Zostavax[®], as part of the NHS shingles vaccination programme.



From the Chief Medical Officer for Scotland Chief Nursing Officer Chief Pharmaceutical Officer Professor Sir Gregor Smith Professor Alex McMahon Professor Alison Strath

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For action

NHS Board Immunisation Coordinators NHS Board Medical Directors Nurse Directors, NHS Boards Directors of Public Health Infectious Disease Consultants CPHMs Secondary Care Clinicians

For information

NHS Board Chief Executives Directors of Pharmacy Consultant Physicians Public Health Scotland Chief Executive, NHS Health Scotland NHS 24 General Practitioners Scottish General Practitioners Committee

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Changes to the Programme

- The JCVI recommended that Shingrix[®] should replace Zostavax[®] in the routine programme (see Annex A). From 1 September 2023, all newly eligible individuals will be offered the non-live shingles vaccine Shingrix[®]. This is a two-dose schedule vaccine. Zostavax[®] will no longer be used.
- 7. In addition to this, eligibility will change to allow individuals to be protected at an earlier age. The choice of age group was based on JCVI assessment of impact and cost effectiveness.
- The eligible age for immunocompetent individuals will change from 70 to 60 years of age for the routine cohort, in a phased implementation over a 10 year period.
- 9. From 1 September 2023, eligibility will also be expanded to all those who are severely immunosuppressed and aged 50 years and over, with no upper age limit (as per the <u>Green Book</u> definition).

2023/24 Programme Eligibility

10. This year, eligibility for the 2023/24 programme is as follows:

- Vaccination of those aged 50 years and over and are severely immunosuppressed (no upper age limit).
- Vaccination of 65 and 70 year olds (defined by the patient's age at 1 September 2023).
- Catch up programme for those aged 71–79 years of age who have not previously been vaccinated (defined by patient's age at 1 September 2023).
- Vaccination of those aged 18 years and over and have received a stem cell transplant. This includes adults recipients of allogeneic transplant, autologous transplant or a CAR-T or similar therapy.
- Individuals aged 50 years and over anticipating immunosuppressive therapy should be assessed for vaccine eligibility before starting treatment.
- 11. In order to provide timely vaccination for patients anticipating immunosuppressive therapy, vaccine appointments must be available from 1 September 2023 to 31 August 2024.

- 12. The shingles vaccination programme is not seasonal therefore can be administered at any time of the year. Shingrix[®] can be given concomitantly with unadjuvanted inactivated influenza vaccine and/or pneumococcal polysaccharide vaccine (PPV23).
- 13. Studies are ongoing on the co-administration of Shingrix® vaccine with adjuvanted influenza vaccine. The <u>Green Book</u> advises that interim data from a US study on co-administration of Shingrix® with adjuvanted seasonal influenza vaccine is reassuring. On that basis, in aligning with the Green Book recommendation, an appointment for administration of the seasonal influenza vaccine may also offer an opportunity to provide Shingrix® vaccine. In the event where Shingrix® vaccine is given at the same time as another vaccine, the vaccines should be given at separate sites, preferably in different limbs, and if given in the same limb, they should be given at least 2.5cm apart.

Shingrix[®]

- 14. Shingrix[®] is a recombinant (non-live) vaccine and contains varicella zoster virus glycoprotein E antigen. Shingrix[®] should be offered to all those who are eligible for shingles vaccination unless contraindicated.
- 15. Shingrix[®] requires a two dose schedule, with the second dose administered from two months up to twelve months after the first dose for immunocompetent individuals.
- 16. Those who are severely immunosuppressed should receive their second dose eight weeks to six months after their first. A risk assessment should be carried out to determine the timing of the vaccination, taking into consideration individual treatment plans.
- 17. For those who are anticipating immunosuppressive therapy, eligible individuals who have not previously been vaccinated should receive Shingrix[®] at the earliest opportunity and at least 14 days before starting treatment, although leaving one month would be preferable if a delay is possible.

Prioritisation

- 18. Those who are severely immunosuppressed represent the highest priority for vaccination given their risk of severe disease. The following order of prioritisation for the first dose of vaccination is outlined below:
 - Severely immunosuppressed
 - Those aged 70 years old, and the catch up programme (71-79 years of age)
 - Those aged 65 years old.

- 19. Health Boards should aim to offer both first and second doses to those who are severely immunosuppressed before embarking on the routine age cohorts. Thereafter, age cohorts should all receive a first dose before embarking on second doses.
- 20. Where Health Boards are able to complete the 2023/24 programme in a short time frame they may exert operational flexibility to suit their local needs.

How We Are Calling Patients

- 21. Scotland has changed the way vaccinations are delivered through the Vaccination Transformation Programme (VTP). Invitations to people eligible for certain adult programmes are now undertaken using centrally agreed coding criteria. Health Boards are responsible for delivering vaccination programmes, and should exert operational flexibility best suited to their local needs.
- 22. Health Boards should invite eligible individuals for their appointments given there is no national call/recall system.
- 23. Clinicians should refer patients anticipating immunosuppressive therapy via their Board referral pathway (see local referral guidance e.g. Board intranet). If clinicians are unsure of their local referral pathway, they should contact their local Immunisation Co-ordinator.

Action

- 24. Health Boards are requested to action this guidance and ensure that their vaccination teams and primary and secondary care colleagues are aware of it. Further information is included in the Annex set out below.
- 25. We are very grateful for your continued support and hard work in delivering the Scottish Immunisation Programme to the people of Scotland.

Yours sincerely,

Gregor Smith	Alex McMahon	Alison Strath
Professor Sir Gregor Smith Chief Medical Officer for Scotland	Professor Alex McMahon Chief Nursing Officer	Professor Alison Strath Chief Pharmaceutical Officer

Annex A

2022/23 SHINGLES (HERPES ZOSTER) VACCINATION PROGRAMME

Immunisation against Infectious Disease (The Green Book)

- Full details on use, dosage, administration, concomitant administration with other vaccines, contraindications, consent and reporting of adverse reactions with Shingrix[®] is set out in chapter 28a of the Green Book (from 1 September 2023). This is available online at: <u>Green Book chapter shingles 28a</u> (publishing.service.gov.uk).
- 2. The shingles Green Book chapter outlining the details for both Zostavax[®] and Shingrix[®] vaccination will remain online until the 31 August <u>Shingles (herpes zoster): the green book, chapter 28a GOV.UK (www.gov.uk).</u>

JCVI Recommendation

3. Minutes of 06 February 2019 JCVI main meeting: <u>Box | Simple online</u> <u>collaboration</u>.

Changes to Eligibility

- 4. Individuals who have already received two doses of Shingrix[®] do not need revaccination.
- 5. Vaccination should not be commenced in anyone immunocompetent aged 80 years and over, even if they have previously been eligible (defined by person's age at 1 September 2023).
- The eligible age for immunocompetent individuals will change from 70 to 60 years of age for the routine cohort, in a phased implementation over a 10 year period as outlined below:

Implementation stages	Delivery period	Eligible for first dose
Stage 1 (5 year duration)	1 Sept 2023 to 31 Aug 2028	Vaccination of 65 and 70 year olds (defined by the person's age at 1 September) each year.
Stage 2 (5 year duration)	1 Sept 2028 to 31 Aug 2033	Vaccination of 60 and 65 year olds (defined by the person's age at 1 September) each year.

Implementation stages	Delivery period	Eligible for first dose
Ongoing routine offer	1 Sept 2033 onwards	Vaccination of 60 year olds (defined by the person's age at 1 September).

Call and Recall

- 7. There will be no centralised letter inviting eligible people for the shingles programme. Health Boards are expected to use local call/recall systems.
- 8. There is a proposed national digital solution for a call/recall system for the shingles programme that is currently being discussed as part of the NSS digital commission. It is not anticipated this will be in place for 2023/24.

Cohort Data Extracts

- 9. An annual file for immunocompetent individuals will be made available to Health Boards ahead of 1 September 2023.
- 10. A quarterly file extract for those who are severely immunosuppressed will be made available to Health Boards to allow capture of those individuals becoming newly eligible within this category throughout the reporting period (1 September 2023 – 31 Aug 2024).

Vaccination Uptake for 2023/24

- 11. Health Boards are expected to participate in performance improvement activity led by Public Health Scotland (PHS), with an inclusion and equity lens applied to the programme. Targets and aspirations will be agreed and shared in advance of the start date.
- 12. All of the programmes must include an element of proactive inclusion work in an effort to reduce health inequalities, with a particular focus on areas of highest deprivation and certain ethnicities who may have lower uptake.
- 13. It is important that every effort is made to ensure vaccination uptake is as high as possible. Health Board robust management of 'Did Not Attends' including proactive work to encourage uptake, for both doses, is vital. The benefits of shingles vaccine should be communicated and vaccination made as accessible as possible for those eligible.

Patient Group Direction (PGD)

14. A national specimen Patient Group Direction (PGD) for administration of Shingrix® will be produced by PHS.

Clinicians' Role

15. Clinicians are reminded of their responsibility in advising their patients if they are severely immunosuppressed and are eligible for the shingles vaccine.

Funding

16. A funding letter was issued on the 19 June 2023 highlighting the funding arrangements for the 2023/24 shingles vaccination programme.

Supply

17. Shingrix[®] should be ordered through NHS Board Vaccine Holding Centres. Remainder of Zostavax[®] stocks should be exhausted prior to ordering Shingrix[®] in order to minimise wastage.

Storage

18. Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light. All vaccines may be sensitive to some extent to heat and cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Do not freeze as freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents.

Vaccine Stock Management

- 19. Please ensure sufficient fridge space is available for the vaccine. Each site holding vaccine is asked to review current stocks of all vaccines. No more than two weeks of stock is recommended and higher stock levels should be reduced to this level. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme.
- 20. Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage, including the use of appropriate cool boxes/bags for transporting the vaccine during home/care home visits. Local protocols should be in place to keep vaccine wastage to a minimum. Even small percentage reductions in vaccine wastage have a major impact on the financing of vaccine supplies.

Adverse Events

21. Please be reminded of the PHS Vaccination Adverse Event Management Protocol published on 16 March 2023. Adverse events are expected to be escalated to PHS as appropriate.

Reporting of Adverse Reactions

22. Suspected adverse drug reactions (ADR) to vaccines should be reported via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard). Chapter 9 of the Green Book gives detailed guidance about which ADRs to report and how to do so. Additionally, Chapter 8 of the Green Book provides detailed advice on managing adverse events following vaccination. Information on the side effects of Shingrix is available in Chapter 28a of the Green Book. These chapters are available at: Immunisation against infectious disease - GOV.UK (www.gov.uk).

Communication Materials for Patients

- 23. PHS will produce an information leaflet to support informed consent, invitation letter templates, screensavers, a social media toolkit and posters. These will be available to Health Boards ahead of the programme commencing to help inform those eligible. Members of the public should be directed to <u>www.nhsinform.scot/shingles.</u>
- 24. The PHS shingles toolkit will be updated in advance of the new programme at <u>www.publichealthscotland.scot/shingles.</u>

Workforce Education Resources for Healthcare Practitioners

- 25. NHS Education for Scotland (NES), in partnership with Public Health Scotland and stakeholders, are developing educational resources for healthcare practitioners in relation to the introduction of Shingrix vaccine for the whole programme and expansion of eligible cohorts. These will be available on Turas Learn.
- 26. NES and PHS are currently developing an eligibility calculator tool for the age based cohorts that will be available to aid identification of those eligible based on their age (65 and 70 to 79 years). This will be hosted on NHS Inform with an aim to have this available by 1 September 2023. This is additional to those eligible on account of immunosuppression.