



Process for development, review and publication of SPS national Written Instruction templates for seasonal 'flu vaccination of healthcare staff

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Approved by Medicines Governance Do Once (MGDO) Programme Board April 2024

1. Introduction

This document describes the Specialist Pharmacy Service (SPS) process to develop, review and publish national written instruction (WI) templates for seasonal influenza ('flu) vaccination of healthcare staff.

2. Background

Medicines can be supplied or administered in the course of an Occupational Health Service (OHS) by a registered nurse acting in accordance with the written and signed instruction of a doctor, commonly called a written instruction. The use of a written instruction allows medicines to be provided under an exemption in Schedule 17 of the HMR 2012 which is applicable to OHS.

Schedule 17 of the HMR 2012 was permanently amended in April 2022 to allow occupational health vaccinators (that is registered nurses, registered midwives, registered nursing associates; operating department practitioners, paramedics or physiotherapists registered in Part 13, 8 or 9 of the Health and Care Professions Council register; and pharmacists, who are employed or engaged by a person operating an occupational health scheme) to administer 'flu or coronavirus vaccines as part of an NHS Body or Local Authority (LA) occupational health scheme in accordance with a WI. This amendment only applies to an NHS Body or Local Authority - other providers such as independent providers cannot use this amendment and these providers can only allow registered nurses to work under a WI for any medicine or vaccine.

It is intended that only seasonal 'flu vaccination to healthcare staff is delivered under a national WI in this way due to its exceptional scope. Any use of a written instruction to provide any other vaccination, immunisation or treatment to staff as part of an OHS should only be undertaken by the occupational health department providing these services to an organisation whether that is in-house provision or as a commissioned service.

Further detail on the use of WIs and OHS is available on the [SPS website](#).

3. Development of a national SPS WI templates for OHS provision of seasonal 'flu vaccinations

Each spring, in preparation for the upcoming 'flu season, SPS will develop and publish two seasonal 'flu WI templates for use by organisations when vaccinating staff. One template is for use by NHS/LA bodies and one for all other organisations. Organisations adopting the template will be responsible for the legal authorisation of the WI.

The WI templates structure reflect the legislative requirements of a WI as outlined in Schedule 17 of the HMR 2012. The clinical content reflects that of the UKHSA seasonal influenza vaccine PGD and, where additional specific advice is required relating to OHS vaccination, the Green Book/UKHSA advice specific to healthcare employees.

The draft WI templates are submitted, via email, to the OHS subgroup of the SPS PGD Advisory Service Reference Group (membership from the CQC, UKHSA, MHRA, and SPS representation) for review and comment.

SPS will complete an assurance checklist to record the completion of all the steps in development of the templates.

The finalised WI templates and assurance checklist will be submitted to the MGDO Programme Board for noting, either at the next planned meeting or, where timescales dictate, by email agreement of Board members or at a specially convened meeting. The Board will provide independent assessment

of assurance that the agreed development processes for the WI template(s) have been followed (note the Board are not asked to comment on the clinical content – this is the responsibility of the OHS subgroup).

Following approval by the Board, the WI template will be made available on www.sps.nhs.uk and shared with other electronic portals as agreed within the work programme.

4. Review of national SPS WI templates for OHS provision of seasonal ‘flu vaccinations

A rolling review of every national WI is undertaken by the SPS MGDO Working Group – this process involves continual review of all relevant Summaries of Product Characteristics (SPCs) and supporting national guidance. Where the WI templates require in-life review because there have been changes associated with the vaccine, care pathway or supporting national guidance, then the OHS subgroup will be notified. In life amendments required as a result of changes to the supporting national guidance which the OHS subgroup deem cannot wait until the next scheduled review, can be made with the agreement of the OHS subgroup members.

The review process will follow that of the development process, but with the most recent WI template forming the basis of the draft version.

Where the OHS subgroup consider publication of the updated WI templates is urgent and cannot wait until the next Programme Board meeting, a request can be made to the MGDO working group to approve the updated WI templates for publication. Where requested, the MGDO working group will approve the publication of the updated WI templates; an assurance checklist showing that all processes have been followed will be completed. If the working group decide that the changes need to be approved the Programme Board it will be referred to the next Programme Board meeting or, where timescales dictate, by email agreement of Board members or at a specially convened meeting. The updated WI templates will then be released via the SPS website (and other usual communication channels). A formal paper will be submitted to the next MGDO Programme Board meeting with details of the process undertaken, the assurance checklist.

5. Publishing new or updated national SPS WI templates for OHS provision of seasonal ‘flu vaccinations

All newly published national WI templates will be highlighted via:

- email of the SPS weekly bulletin to the people registered on the SPS website;
- X (formerly known as Twitter) @NHS_SPS;
- LinkedIn (NHS Specialist Pharmacy Service)
- the [Medicines Awareness Service](#) bulletin

Similarly, notification of all changes to national WI templates will be made via the same routes.

6. Local authorisation of a national SPS WI for OHS provision of seasonal ‘flu vaccinations

To meet the requirements of the Human Medicines Regulations 2012 individual NHS trusts will need to locally authorise the WI before it can be used in the organisation.

7. Governance arrangements

The OHS subgroup and the Board and MGDO Working Group have Terms of Reference. All members of the MGDO Working Group and the Board will complete annual declarations of interest; the OHS subgroup members complete these as part of their SPS PGD Advisory Service Reference Group membership. Any conflicts of interest will be recorded and if appropriate the member will be asked to stand down from the group.

8. Responsibilities

8.1 Responsibilities of the SPS MGDO Programme Board

The MGDO Programme Board is responsible for overseeing the programme. They will:

- abide by the Terms of Reference of the MGDO Programme Board
- complete a Declaration of Interest form at the start of the programme and annually thereafter
- oversee the programme of developing national WI templates for OHS provision of seasonal 'flu vaccinations
- support the MGDO Working Group as requested
- liaise with the SPS PGD Advisory Service Reference Group if required

8.2 Responsibilities of the SPS MGDO Working Group

The MGDO Working Group is responsible for supporting the MGDO Programme Board in delivering the programme. They will:

- abide by the Terms of Reference of the MGDO Working Group
- complete a Declaration of Interest form at the start of the programme and annually thereafter
- compile the first draft of the WI template
- collate responses from the OHS subgroup and make changes as agreed by members
- liaise with the SPS PGD Advisory Service Reference Group if required
- ensure WI templates are made available to organisations in a timely manner via agreed electronic portals.

8.3 Responsibilities of members of the SPS PGD Advisory Service Reference Group OHS subgroup

Members of the subgroup will:

- abide by the Terms of Reference of the subgroup.
- complete an annual Declaration of Interest form as required by SPS PGD Advisory Service Reference Group membership.
- have the experience, knowledge, skills and expertise required to develop the WI template
- adhere to agreed processes and procedures for the development and review of national WI templates
- respond to requests for comments and information in a timely manner
- work towards consensus wherever possible.
- alert the MGDO Working Group if early WI template review is required due to e.g. changes in best practice guidelines

8.4 Responsibilities of organisations adopting national SPS WI templates for OHS provision of seasonal 'flu vaccinations

Organisations using national WIs for OHS provision of seasonal 'flu vaccinations will:

- authorise them within their own organisation according to their clinical governance process.
- ensure staff working under the WI are appropriately trained and competent.

SPS have published separate advice to support the process required for the local authorisation and

implementation of the national WI templates which organisation should refer to for further advice².

9. References

1. Occupational health services (OHS) and medicines mechanisms
<https://www.sps.nhs.uk/articles/occupational-health-services-ohs-and-medicines-mechanisms/>
(Accessed 13/03/24)
2. Influenza vaccine written instruction templates for adoption
<https://www.sps.nhs.uk/articles/influenza-vaccine-written-instruction-templates-for-adoption/>
(Accessed 13/03/24)



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