

# Medicines Governance, PGDs and Legal Mechanisms: An update session

SPS Medicines Governance Do Once Team

The first stop for professional medicines advice

June 2026

# Today's webinar

- Introducing the team and how to contact us
- Regulation changes April 2026
- Anticipated regulation changes 2026/27 and beyond
- Occupational 'flu vaccinations 26/27
- New and updated resources
- Medicines Governance Do Once Programme Update
- Website developments
- Pre-submitted Q&A discussion

# Medicines Governance Do Once Team



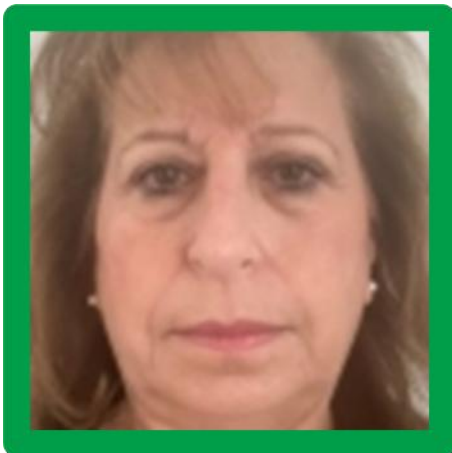
Barbara  
Parkinson



Kieran  
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Rosie  
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Sandra  
Wolper



Jo Jenkins



Anna  
Sparshatt

# Updated contact details

PGD and legal mechanisms

Email us at [spspgd@liverpoolft.nhs.uk](mailto:spspgd@liverpoolft.nhs.uk)

SPS event enquiries

[SPSEvents@liverpoolft.nhs.uk](mailto:SPSEvents@liverpoolft.nhs.uk)

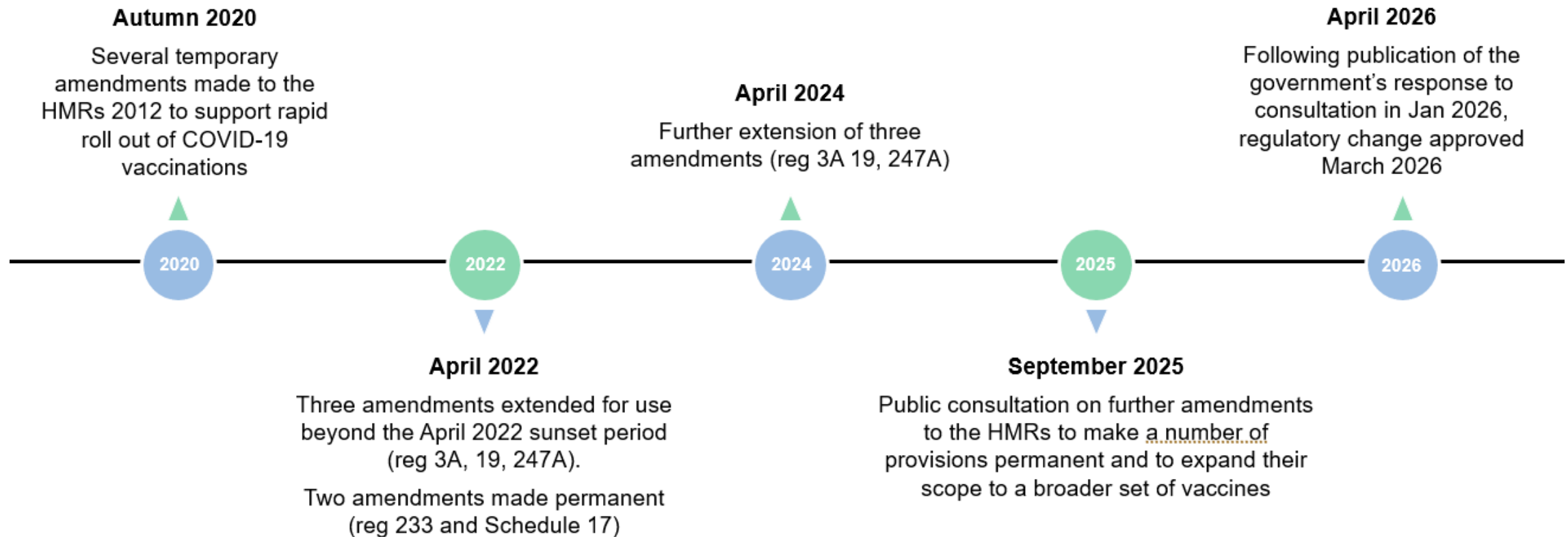
SPS MUS general enquiries

[SPSMUSEnquiries@liverpoolft.nhs.uk](mailto:SPSMUSEnquiries@liverpoolft.nhs.uk)

Medication Safety Officer (MSO) network enquiries

[SPSMSONetwork@liverpoolft.nhs.uk](mailto:SPSMSONetwork@liverpoolft.nhs.uk)

# April 2026 HMR amendments – context and history



# Regulations 3A, 19 and 233

Regulation	Changes
<b>3A</b> (amending expiry date)	<ul style="list-style-type: none"> <li>- Parts 1&amp;2 allowed to lapse so cannot prepare at scale – each vaccine should be prepared by the person administering it.</li> <li>- Parts 3&amp;4 retained - licensed wholesalers permitted to relabel thawed, frozen-stored vaccines and has been expanded to cover all virus and bacterial vaccines.</li> </ul>
<b>19</b> (movement of vaccines between end users, without a wholesaler dealer licence)	<ul style="list-style-type: none"> <li>- Certain NHS organisations permitted to move vaccines without a wholesale dealer’s licence.</li> <li>- Expanded scope and clearer definitions of distributing and receiving parties.</li> <li>- New conditions to ensure movements only occur in exceptional public health circumstances and with packaging and marketing authorisation compliant handling requirements</li> </ul>
<b>233</b> (community pharmacies)	<ul style="list-style-type: none"> <li>- Allows community pharmacies to provide commissioned vaccination services away from their registered premises.</li> <li>- Enables pharmacists and pharmacy technicians to supply, prepare, and administer vaccines off site under PGD or the new vaccine group directions</li> </ul>

# National Protocol for 'flu and COVID

- No longer within regulations from 31<sup>st</sup> March 2026 (regulation 247A).
- Had significant benefits but also some draw backs identified in practice which have been considered and addressed.
- Needed similar model but one that built on learning and would be fit for use in usual practice and in cases of outbreaks.
- New Vaccine Group Direction (regulation 235A) came into force 1<sup>st</sup> April 2026

# Vaccine Group Direction (VGD)

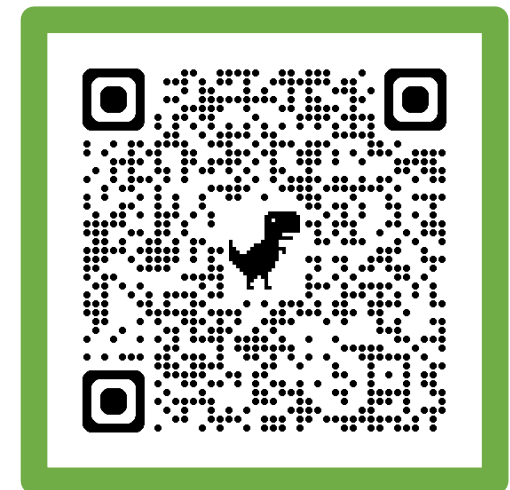
- New legal mechanism
- Permitted for any vaccination within national vaccination programme (for the prevention of disease)
- Can only be written by a national health protection body (e.g. UKHSA)
- Authorised by service commissioner
- Delegation is permitted similar to National Protocol:
  - Registered HCP in PGD regulations ONLY can undertake clinical assessment and consent
  - The same registered HCP may delegate preparation and administration and record keeping if delegation specified in the VGD
  - The delegating registered HCP must provide physical supervision of any delegated task
- First VGD has been for the COVID Spring Campaign

# Schedule 17 – OHS vaccinations

- Occupational Health Vaccinator (OHV) role - aligned with HMR 2012 Schedule 16 Part 4 which is those **registered healthcare professionals who can operate under Patient Group Directions**.
- OHV Written Instructions (WI) can be used to administer any **vaccination** provided as part of an Occupational Health Scheme
- OHV WI can be used by any Occupational Health provider whether private or public sector

# Staff 'flu vaccinations 2026/27

- 26/27 'flu plan published
- WI template will be produced by SPS alongside UKHSA PGD for IM 'flu vaccination and will be published on the SPS website
- Timescales for publication will reflect those of UKHSA
- Only one WI now for all OHS irrespective of provider type
- Expanded number of registered professions who can work as OHV **but NA/ODPs cannot work as OHVs** (would need PSD)



# Further SPS resources

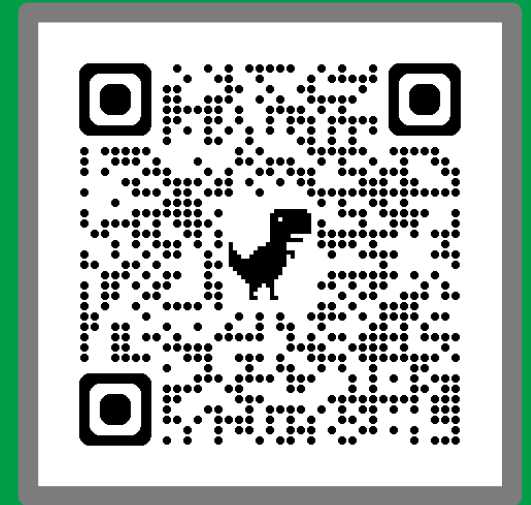
**Understanding Vaccine  
Group Directions**



**Amendments to HMR  
2012 supporting  
vaccine supply and  
deployment**



**Updated NHS SPS  
PGD and legal  
mechanisms resources**



# HMR amendments – under consideration

## Awaiting government response

Profession	Proposed change
Operating Department Practitioners (ODPs)	Enabling ODPs to supply and administer medicines using patient group directions (PGDs) including controlled drugs
Physiotherapists	Extending the list of controlled drugs that independent prescriber physiotherapists can prescribe
Paramedics	Amending the list of medicines (POM and controlled drugs) that can be administered using exemptions in HMRs
Diagnostic Radiographers	Enabling advanced practitioner diagnostic radiographers to become independent prescribers

# HMR amendments – under consideration

Profession/legal mechanism	Position
PGD use by Clinical and Biomedical Scientists	Proposal not supported by CHM. Further discussions with professional bodies/DHSC/NHSE underway. No timescale for decision.
Midwife exemptions Schedule 17	Proposal to review and update Schedule 17 exemptions available to midwives (removal and addition). If supported for progression will need to go out for consultation. No timescale for decision.
Independent Healthcare Providers – direct authorisation of PGDs for NHS/LA commissioned services	Discussions with DHSC/NHSE underway. No timescale for decision.
NHSE authorising body for PGDs post April 2027	Discussions with DHSC/NHSE underway. <b>Note ICBs will remain the legal entity for PGDs; OPICs will not be legal entities.</b> Pre April 2027 caution with clusters and processes relating to PGDs as must only be signed by an ICB as the legal entity.
Exemption extension for optometrists and contact lens opticians	Extending medicines for optometrists and contact lens opticians available to supply under Schedule 17 exemptions - consultation now closed. Awaiting government response (no timescale).

# Active discussions - non-parenteral POMs

- RCOphth advice published based on the interpretation that the legislation relates to parenteral POMs only following MHRA guidance.
- Position this advice takes is that as the eye drops are not parenteral therefore legislation does not require them to be prescribed if legally possessed.
- SPS and CQC continue to seek clarification on the wider issue of the administration of non-parenteral POMs.
- SPS, MHRA, CQC and DHSC legal advisers met July 2022 and have met regularly since.
- **CQC compiling a report for DHSC with advice anticipated from DHSC.**
- For individual organisations to decide if they wish to follow the RCOphth advice – consideration needs to be given to the governance, risk, training, accountability, possible reach etc.

# Updated SPS webpages

## Updated webpages to reflect regulation changes:

- Using PGDs in occupational health services (OHS)
- Using written instructions in occupational health services
- Seasonal influenza vaccination and occupational health services
- Influenza vaccine written instruction templates for adoption
- Options for GP practices providing influenza vaccination to staff
- Occupational health services (OHS) and medicines mechanisms
- When not to use a PGD
- Retaining legal mechanism documentation
- Pharmacy technicians working under Patient Group Directions
- Legal mechanisms to supply and administer medicines to individuals



# New and updated governance resources

## Principles of checking



Understanding what a check is; principles of an effective check; factors to consider if introducing an independent second check

## Managing Pharmaceutical Waste



Guidance and principles for managing waste generated from the use of medicines.

# Medicines Governance Do Once (MGDO) Programme

- Rolling programme in place to constantly review PGD/protocol templates in use:
  - Reviews SPCs and supporting guidance
  - Clinically significant changes will trigger PGD updates
  - Updates are undertaken promptly but require full SPS MGDO governance review so can take several months – where needed a note will be added to the relevant page to alert users to a review being underway
  - Updates highlighted via SPS LinkedIn/WhatsApp channel and via SPS email updates to registered recipients
  - Templates recently updated/new highlight on SPS templates webpage
  - Updates do not have to be adopted by organisations if not relevant



# Medicines Governance Do Once (MGDO) Programme

- Planned updates:
  - All templates are fully reviewed and new, updated versions published, every three years.
  - Aim that all updated templates are published at least 3 months before expiry of current template.
- Communication about updates:
  - All updates (in life or planned) are communicated via:
    - SPS weekly update email
    - SPS Spotlight
    - SPS WhatsApp channel and LinkedIn
    - NICE Medicines Awareness Daily/Weekly
  - Templates webpage highlights publications within past 3 months in order for ease of identification.



# MGDO – Accessibility Project

Since Autumn 2025, all new and updated SPS PGD and protocol templates have been published in an accessible format, as part of wider work to improve the accessibility of the SPS website.

- What we've done:
  - Updated the template structure with consistent heading styles
  - Improved readability (changes to font, colour contrast, layout)
  - Simplified tables and document formats
  - Added 'alt text' to tables
- The changes ensure that the templates are:
  - Accessible to users of assistive technologies
  - Easy to navigate
  - Compliant with accessibility standards

There is no requirement for organisations using previous non-accessible formats of the templates to transfer to the new accessible templates upon publication unless they wish to do so.

# New SPS PGD templates (May 25- June 26)

## ➤ Sexual Health

- Doxy-PEP
- TAF-PrEP

## ➤ Infection and infectious diseases – skin infestations (scabies)

- Malathion
- Permethrin

## ➤ Infection and infectious diseases – skin infections (prophylaxis of human and animal bites)

- Co-amoxiclav
- Doxycycline
- Metronidazole

# Fully updated SPS PGD/protocol templates (May 25-June 26)

## ➤ PMP

- Benzylpenicillin
- Terbutaline
- Omeprazole protocols

## ➤ Sexual Health

- Azithromycin
- Doxycycline
- PrEP (TD-FTC)
- Ceftriaxone
- Metronidazole

## ➤ Ambulance Trusts

- Diazepam rectal
- Diazepam (solution) injection
- Tranexamic acid

## ➤ Infection and infectious diseases - UTI

- Nitrofurantoin
- Trimethoprim

## ➤ Radiology

- Sodium chloride 0.9% flush

# Fully updated SPS PGD/protocol templates (May 25-June 26)

## ➤ Reproductive Health

- Ulipristal EC
- Levonorgestrel EC
- Lidocaine spray protocol
- Lidocaine + prilocaine protocol
- CHC patch
- CHC ring
- COC
- POP
- DMPA SC
- DMPA IM
- LNG-IUD
- Copper IUD
- **Etonogestrel implant**
- Lidocaine (IUD insertion/removal)

# Planned SPS PGD template updates (Summer/Autumn 2026)

## ➤ Infection and infectious diseases – URTI

- Sore throat
  - Penicillin V, clarithromycin, erythromycin
- Otitis media
  - Otigo drops, amoxicillin, clarithromycin, erythromycin
- Sinusitis
  - Fluticasone nasal spray, mometasone nasal spray, penicillin V, doxycycline, clarithromycin, erythromycin

# Planned SPS PGD template updates (Summer/Autumn 2026)

## ➤ Infection and infectious diseases – skin infections

- Shingles
  - Aciclovir, valaciclovir
- Impetigo
  - Hydrogen peroxide cream 1%, fusidic acid cream 2%, flucloxacillin, clarithromycin, erythromycin
- Infected insect bites/stings
  - Flucloxacillin, clarithromycin, erythromycin

# Planned SPS PGD template updates (Summer/Autumn 2026)

## ➤ Sexual Health

- Clotrimazole topical
- Clotrimazole PV
- Fluconazole
- Imiquimod
- Podophyllotoxin
- Aciclovir

# Anticipated template updates - 2026

- New RCR contrast guidance anticipated later in 2026.
- Will affect all PGD contrast templates (gadolinium and iodine) – all templates will be reviewed with RCR/SoR, updated and published as close to the updated guidance publication as possible.
- The templates will be Version 3.0 at publication due to significant changes that are anticipated.

# SPS PGD webpage navigation update

- The website contains a wealth of information on PGDs
- We've been making some changes to make it easier for you to find and read the content
- A short demo on the main changes...

# SPS PGD/legal mechanisms and governance resources

For further advice on many aspects of medicines governance, PGDs and medicines mechanisms, please visit the SPS website.



# Questions



The first stop for professional medicines advice

**When assessing competence to supply or administer medicines under a PGD, does the assessor have to be the same profession as the clinician being assessed?**

**Can locum pharmacists be authorised to work under a PGD for a nationally commissioned service (e.g. Pharmacy First) and work under that PGD in multiple pharmacies or do they need to be authorised by each pharmacy they work in?**

# What evidence base is required for a medicine to be included within a PGD?

**NICE guidance:**



**Can the same PGD be used in services provided by multiple organisations working in partnership such as several Trusts providing a shared service or across practices within a PCN?**

**Patient Group Direction use in Primary Care Network**



**Patient Group Direction use in services provided by multiple organisations**



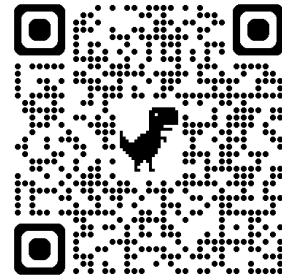
**If a PGD used by a private provider providing an NHS commissioned service needs to be amended can the private provider amend the PGD without involving the NHS commissioner?**

**Managing Patient Group Directions following amendments or changes**



**If there is no national PGD developed by UKHSA for a vaccination, but we wish to administer it within our organisation, can we still use a PGD?**

**Using PGDs in occupational health services (OHS)**



**PGDs are not required for GSL products - but does this include if they are supplied or administered in an off label context by a non-prescriber?**

**A PGD should not be used if a prescriber is involved in the patient's pathway, but can this be overridden if the prescriber's involvement is inconvenient/technically difficult?**

**Delegation of roles under a PGD**



**A person acting under a PGD cannot delegate responsibility: is this true if the responsibility was delegated to another appropriately trained individual also working under the PGD?**

**Patient Group Direction use in remote consultations**

