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# What's new? Update session for professionals experienced in developing and implementing PGDs

**May 2022**

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## Outline of today's webinar

- Update on PGDs and relevant mechanisms
- Audit and PGDs
- SPS Medicines Governance Do Once Programme – national PGD templates
- SPS website and PGD resources
- Questions – session on 24<sup>th</sup> May



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# **Patient Group Directions (PGDs) and other legal mechanisms – an update**

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**SPS Specialist Pharmacist  
Patient Group Directions**

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## What has recently changed in the legislation?

- April 2022 – permanently embedding temporary/time limited legislation ‘Tranche 1’
- [Schedule 17 Human Medicines Regulations 2012](#) most relevant to Occupational Health/flu vaccinations
- Further changes to be considered and introduced in due course – Tranches 2-4. Full details [here](#)
- Legislation changes relating to CCGs/ICBs due 1<sup>st</sup> July 2022



# **Taking a step back...what has changed on legislation during the pandemic?**



## Regulation 174 of the HMR 2012

Regulation 174 waives the requirement for a medicine to hold a marketing authorisation when the sale or supply of the medicine is authorised by Ministers, on a temporary basis, in response to the suspected or confirmed spread of:

- Pathogenic agents
- Toxins
- Chemical agents or,
- Nuclear radiation



## Regulation 174A - what does this mean for PGDs?

Regulation introduced in 2020 regulation. This allows conditions to the temporary authorisation under Regulation 174 such as:

- It must only be used for the purpose for which it was given temporary licensing – it cannot be used or marketed for anything else.
- The MHRA will set out and agree the conditions under which it is made and these must be adhered to by the manufacturer

Amendments to legislation allows a medicine authorised under regulation 174 to be supplied under a PGD



## Protocols relating to coronavirus and influenza vaccinations (Reg 247A)

- Mechanism introduced for coronavirus and 'flu only as during pandemic.
- National protocol - needs to be authorised by the Secretary of State. No local authorisation allowed.
- Allows trained, competent and authorised persons (registered and non registered) to participate in delivering the programme
- Some stages of protocol limited to certain registered health care professionals





## Protocols relating to coronavirus and influenza vaccinations (Reg 247A)

- The protocol can be used by a single registered HCP undertaking the whole vaccination process, or by multiple persons undertaking the appropriate stages.
- These are clearly outlined in the protocol.
- All activity under protocol must be under a Clinical Supervisor (doctor, nurse or pharmacist).
- Likely that clinical supervision will be legislated in due course.



## Occupational Health Services

- OHS within NHS organisations can use PGDs for OHS provision for **own staff only**. However as alternative mechanism exists in legislation written instructions (Schedule 17 HHMR 2012) should be used.
- OHS within private or non-NHS/publically funded services **cannot use** PGDs and should use written instructions as allowed under legislation.
- This also applies to NHS/publically funded services providing private OHS services (e.g. to neighbouring NHS organisation or local police force).



## Written Instructions for OHS

- A written instruction must be signed by a doctor and detail the medicine/vaccine to be supplied/ administered and list who can work under it by name.
- Who can work under a WI depends on the organisation type and medicine/vaccine to be supplied/ administered but...  
**...in summary for anything other than a 'flu or coronavirus vaccine only registered nurses can work under a WI, signed by a doctor whatever organisation they work for.**



## Written Instructions for OHS – ‘flu and coronavirus vaccines

Legislation changes in 2020 to Schedule 17 HMR 2012 – retained permanently in April 2022.

**For flu and coronavirus vaccines only and for an NHS body or Local Authority only:**

- Additional registered staff can act as an **occupational health vaccinator**
- Staff must be employed or engaged by the organisation
- Now permanent legislation
- Further review of extension to private providers (Tranche 3)



## Who can work as an occupational health vaccinator?

- Registered nurse
- Registered midwife
- Registered nursing associate (in England)
- Registered operating department practitioner
- Registered paramedic
- Registered physiotherapist
- Registered pharmacist



## 2022/23 healthcare staff 'flu and COVID vaccines

- 22/23 'flu letter states that provision of 'flu vaccination to frontline health and social care staff is an OHS responsibility in 22/23 including those cohorts who were in the national eligibility criteria in 21/22 (primary care).
- Intention is WI template will be produced by SPS alongside UKHSA PGD for 'flu vaccination.
- Website will be updated when possible to advise.

<https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/>



# NHSE Medicines Mechanisms Programme

## Current phase:

- Biomedical scientists
- Clinical scientists
- Operating Department Practitioners
- NHSE led consultation undertaken late 2020 to add these professions to PGD legislation.
- Cases of need for each profession presented to CHM in July 2021 – only if they have received positive opinion will legislation change be supported and any changes will require laying before parliament before becoming law.
- To date only ODPs clearly supported by CHM but **not yet in legislation – will take time.**
- Awaiting final decision on BMS/Clinical Scientists



## NHSE Medicines Mechanisms Programme

### CHM also considered:

- exemptions for dental hygienists and therapists (supported)
- amending the current lists of controlled drugs that podiatrist independent prescribers are legally able to prescribe (not supported)
- amending the current lists of controlled drugs that physiotherapist independent prescribers are legally able to prescribe (supported)
- amending the list of medicines that paramedics can administer under Schedule 17 exemptions (supported)

**CHM recommended changes will require legislation to be amended – nothing has changed yet.**





# Scoping Project 2020/21 – professions included

## Dental

Dental hygienists  
Dental therapists

## Healthcare Scientists

Biomedical  
scientists  
Clinical  
scientists  
Hearing Aid  
Dispensers

**Pharmacy**  
Pharmacy  
technicians

## Plus.....

Anaesthesia  
Associates  
Chiropractors  
Midwives  
Nurses  
Nursing Associates  
Physician  
Associates  
Practitioner  
Psychologists

## Allied Health Professions

Art therapists  
Drama therapists  
Music therapists  
Dietitians  
Occupational therapists  
Operating department  
practitioners  
Orthoptists  
Osteopaths  
Paramedics  
Physiotherapists  
Podiatrists  
Prosthetists and orthotists  
Diagnostic radiographers  
Therapeutic radiographers  
Speech & language  
therapists



# NHSE Medicines Mechanisms Programme

## Future work

- NHSE have consulted with all registered healthcare professions (and those due to become registered) to scope medicines mechanisms potentially required in the future. Report under review by NHSEI/DHSC.
- Includes PGDs as well as exemptions and non medical prescribing.
- First phase of much longer process – 12 professions identified in report as having **potential** to consider access to additional medicine mechanisms.
- May be several years before further legislation changes realised.



## Which bodies can authorise PGDs?

Those organisation listed in the legislation as able to authorise a PGD for NHS/LA funded provision in England are:

- **Clinical Commissioning Groups (CCGs) – Integrated Care Boards (ICBs) from July 2022**
- **Local Authorities**
- **NHS trusts or NHS foundation trusts**
- Special health authorities
- NHS England
- UKHSA

An authorised signatory from the organisation must sign the PGD.



## PGDs during organisational change

- PGDs can continue to be used during organisational change if appropriate governance is in place.
- Planning is key underpinned by organisational due diligence/governance.
- Q&A available to support organisations

[Managing PGDs when healthcare organisations merge, cease to exist or services are transferred to a new provider](#)



## Working across organisations

- Cross organisation/multi organisation working is increasingly common.
- NHS and non-NHS commissioner/provider arrangements are becoming increasingly complex and varied and sub-contracting/partnership working becoming more common.
- Increasingly **local decisions** will have to be made based on the ‘set up’ in place and considered on a case by case basis when determining who authorises a PGD.



## **Working across organisations**

- Consider Memorandums of Understanding where multiple providers/commissioners are involved in services using PGDs.
- Clear line of sight required and understanding of responsibilities of all parties involved.
- Advice on SPS website:

**[Patient Group Directions in Complex Commissioning Scenarios](#)**

**[Patient Group Direction use in Primary Care Networks](#)**

**[Patient Group Direction \(PGD\) use in a service provided by multiple organisations](#)**



## Remote consultations and PGDs

- Updated SPS guidance developed with CQC and MHRA
- Reflects increasing use of remote technology in consultations.
- Remote consultations acceptable if ensures an adequate assessment can still be conducted
- Care needs to be taken with supply and avoiding delegation – full details and further advice [here](#)



## PGDs for antimicrobials

New from NHSEI/AMR Programme Board:

**Framework for risk assessment of infection management patient pathways encompassing supply of antimicrobials under a patient group direction (PGD)**

- Focused on supplies via commissioned services (e.g. community pharmacies, walk in centres, out of hours etc).
- Consider if commissioning services that involved supply of antimicrobials under a PGD.





## New PGD e-learning programme

- New PGD e-learning programme developed by SPS and eLfH.
- Replaces CPPE e-programme.
- Supports those using, developing and authorising PGDs.
- Suitable for all professions involved.
- Available via [eLfH](#)



## Audit of PGDs

- Regular audit of PGDs in use/processes recommended with NICE guidance and forms part of organisational governance relating to PGDs.
- SPS have collated an audit tool which can be used by organisations to audit PGD use.
- Aim to undertake a national baseline audit of PGD governance
- Tool available via the [SPS website](#)



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# Medicines Governance Do Once Programme

**Tracy Rogers**  
Director MUS SPS

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## Key Drivers

- Carter reviews
  - Recommendations based around efficiency and productivity
  - Specific recommendation on developing a do once system that includes PGDs
- NHS Long term plan
  - boost 'out-of-hospital' care
  - prevent unnecessary admissions to hospitals



## Process

- Workstreams proposed and considered by MGDO Programme Board. Provide governance oversight for whole process.
- Development led by MGDO working group.
- Each workstream has Short Life Working Group/s established of Subject Matter Experts
- Content supported by relevant national body/Royal College and where appropriate the NHSEI NCD/NSA
- Kept under constant review and updated on a three year cycle.



## Work programmes

- Sexual Health
- Reproductive health (contraception)
- Preventative medicines in pregnancy
- Contrast agents
- Ambulance service
- Antimicrobial

All templates available [here](#)



## Current/recent work programmes

- Preventative medicines in pregnancy – aspirin and folic acid templates published. Benzylpenicillin and terbutaline in development.
- Contrast PGD templates – updated late 21/early 22 and re-published
- Flumazenil for ambulance service – aiming for update to be published spring 22
- Updates as required to reflect guidance changes



## Benefits

- Deliver consistent care across England
- Reduce variability in PGDs
- Reflect national guidance
- Deliver increased organisational capacity
- Release significant local resource to be redeployed on optimising outcomes from medicines use
- Support organisational Governance arrangements





## Challenges

- Stakeholder engagement critical
- Everyone is committed to the process but they do have a “day job”
- Changes to national guidance
- National PGDs will only be considered for development where there is national guidance
- National priorities



## Constraints

- The programme will not develop PGDs for everything
- Local PGDs will still be necessary
- It takes time and resources to develop national PGDs



## Where to find more information

[When Patient Group Directions \(PGDs\) are not required](#)

[About the SPS Medicines Governance Do Once Programme](#)



**Email address for SPS PGD query support**

**[Inwh-tr.sps-pgd@nhs.net](mailto:Inwh-tr.sps-pgd@nhs.net)**

**Please send any questions for the May 24<sup>th</sup>  
Q&A session to this email address by  
Friday 20<sup>th</sup> May**



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# SPS website