PGDs and Medicines Mechanisms: An update session

SPS Medicines Governance
Do Once Team

The first stop for professional medicines advice

May 2024

Today's webinar

- Introducing the team
- Legislation changes
- Staff seasonal vaccinations 24/25
- PGD Explainers
- New and updated resources
- Medicines Governance Do Once Programme Update
- Website developments

Medicines Governance Do Once Team

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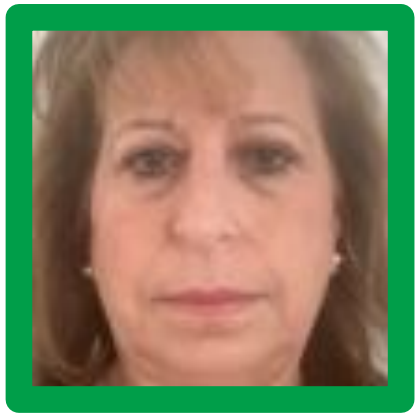

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Legislation changes

Extension of Regulations 247A, 19 and 3A to March 2026

- Pandemic legalisation to support mass vaccination
- Discussions underway regarding 247A and longer-term vision

VAT

- VAT no longer applicable to medicines supplied under PGD by community pharmacies to align with supplies via FP10

Controlled Drugs

- Nitrous oxide – Schedule 5 CD. Remains a P medicine – can be legally administered without a legal mechanism (local protocol recommended) or supplied under a PGD

Controlled Drugs continued:

The Misuse of Drugs Regulations amended 31 December 2023 to:

- Enable prescribing of five specified controlled drugs by **paramedic independent prescribers**:
  - Morphine sulphate by oral administration or by injection;
  - Diazepam by oral administration or by injection;
  - Midazolam by oromucosal administration or by injection;
  - Lorazepam by injection;
  - Codeine phosphate by oral administration
- Enable prescribing of six specified controlled drugs by **therapeutic radiographer independent prescribers**:
  - Tramadol by oral administration;
  - Lorazepam by oral administration;
  - Diazepam by oral administration;
  - Morphine by oral administration or by injection;
  - Oxycodone by oral administration;
  - Codeine by oral administration
- Allow supply of three codeine products by **registered chiropodists and registered podiatrists** (Schedule 17 HMR):
  - Co-codamol;
  - Co-dydramol;
  - Codeine phosphate
- The SI also made additional technical amendments

Anticipated legislation changes

- **PGD use by Registered Pharmacy Technicians**
  - Consultation completed and supported.
  - Following legislative process.
- **PGD use by Operating Department Practitioners**
  - CHM supported.
  - Undergoing necessary preparatory processes with Home Office and ACMD re CDs. DHSC aiming to progress later in 2024.
- **PGD use by Biomedical scientists/Clinical scientists**
  - Proposal not supported by CHM.
  - Under further review with relevant professional bodies.

Anticipated legislation changes

- **Schedule 17 exemptions dental hygienists and therapists**
  - Schedule 17 exemptions for administration/supply
  - Consultation completed – following legislative process
- **Schedule 17 exemptions expansion for registered paramedics**
  - Agreed. CHM supported now undergoing necessary preparatory processes with Home Office and ACMD regarding CDs
- **Independent prescribing by advanced practitioner diagnostic radiographers**
  - Supported by CHM. DHSC aiming to progress later in 2024

Future planning

- **Replacement for 247A**
  - discussions underway to consider amending current legislation/introducing new legislation relating to vaccinations
- **Independent healthcare providers – direct authorisation of PGDs for NHS/LA commissioned services**
  - NHSE and DHSC in early discussions/scoping. May be an interim position to support ICBs – NHSE considering proposals
- **Midwives to seek extension of Schedule 17 exemptions**
  - Part of NHSE Preventative Medicines in Pregnancy programme
- Further registered professions potentially will seek addition to PGD legislation

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 continue to seek clarification on the wider issue of the administration of non-parenteral POMs alongside the CQC.
- SPS, MHRA, CQC and DHSC legal advisers met July 2022 – advised since that DHSC lawyers have prepared advice which the MHRA are considering – awaiting outcome.
- 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.

Staff vaccinations – ‘flu and COVID 24/25

- **‘Flu**
  - 24/25 ‘flu plan published – no major changes
  - WI templates will be produced by SPS alongside UKHSA PGD for IM ‘flu vaccination and will be published on the SPS website
  - Timescales will reflect those of UKHSA

- **COVID**
  - Expected that COVID vaccination will remain non-OHS function for 24/25 – as in 23/24 health/social care staff provision will be via NHS commissioned service under PGD/NP

PGD Explainers

COMING VERY SOON!

- New resource from SPS – PGD Explainer short videos
- First series to be published shortly – more to come in due course
- Each video explains a single area of PGD use/practice
- Can be listened to alone or in combination with relevant webpages/elfh PGD e-learning programme
- Feedback very welcome – feedback button on webpage

New and updated resources

Medicines Mechanisms

Legal mechanisms pages by profession

Governance

Series of articles supporting the managing of pharmaceutical waste

Understanding unlicensed medicines

Series of articles covering aspects of procurement and use

Medicines Governance Do Once Programme

New rolling programme in place to constantly review PGD/protocol templates in use:

- Reviews SPCs and supporting guidance
- Clinically significant changes will trigger PGD updates
- Increased number of updates during late 2023/early 2024
- Updates highlighted via SPS Twitter/LinkedIn and via SPS email updates to registered recipients

Medicines Governance Do Once Programme

- **Implementation guide update** – supporting organisations in adopting PGD templates

- All SPS development processes (PGD/protocol/WI) are updated and available via the SPS website

- **Considerations for developing national PGD templates**
  - new webpage details decision where no national SPS PGD template will be developed

Planned SPS PGD templates

Smoking cessation

- Cytisinicline – awaiting NICE guidance but intention to develop national SPS PGD template
- Varenicline – PGD has been developed but will not be published until stock issues resolved

Hepatitis C

- Once finalised will be shared by NHSE with Hep C ODNs:
  - Elbasvir/grazoprevir 50mg/100mg (Zepatier®)
  - Glecaprevir/pibrentasvir 100mg/40mg (Maviret®)
  - Ledipasvir/sofosbuvir 90mg/400mg (Harvoni®)
  - Sofosbuvir/velpatasvir 400mg/100mg (Epclusa®)

New SPS PGD/protocol templates

Reproductive health

- Copper IUD protocol – support insertion of medical device by trained professionals

Radiology services

- Sodium chloride 0.9% - for multi-injector devices within imaging services

Antimicrobials

Suspected meningitis

- Benzylpenicillin injection for suspected meningitis (bacterial) and meningococcal disease

Otitis media

- Otigo (phenazone with lidocaine) ear drops for otitis media
- Amoxicillin for otitis media
- Clarithromycin for otitis media
- Erythromycin for otitis media

Sore Throat

- Penicillin V (phenoxymethylpenicillin) for sore throat
- Clarithromycin for sore throat
- Erythromycin for sore throat

Sinusitis

- Mometasone furoate monohydrate nasal spray for sinusitis
- Fluticasone furoate nasal spray for sinusitis
- Penicillin V (phenoxymethylpenicillin) for sinusitis
- Clarithromycin for sinusitis
- Doxycycline for sinusitis
- Erythromycin for sinusitis

Antimicrobials continued

Infected insect bites or stings

- Flucloxacillin for infected insect bites or stings
- Clarithromycin for infected insect bites or stings
- Erythromycin for infected insect bites or stings

Shingles

- Aciclovir for shingles
- Valaciclovir for shingles

Impetigo

- Hydrogen peroxide 1% cream for impetigo
- Fusidic acid 2% cream for impetigo
- Flucloxacillin for impetigo
- Clarithromycin for impetigo
- Erythromycin for impetigo

Uncomplicated urinary tract infections (UTIs)

- Nitrofurantoin for uncomplicated UTIs
- Trimethoprim for uncomplicated UTIs

SPS PGD webpages 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…

Volunteers needed

- We are looking for volunteers to help us evaluate some of our PGD resources

- This will consist of a 45-60 minute session via Teams
  - dates in May/June to be confirmed

- If you are interested, please email lnwh-tr.sps-pgd@nhs.net
  - include a summary of your main role(s) with PGDs (e.g. whether you mainly develop PGDs, manage PGDs or act as an authorising body signatory or have no prior PGD experience)

SPS PGD/medicines mechanism resources

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

Questions

Which PGDs are ICBs responsible for authorising?

Any PGDs for services the ICB commissions:

- If NHS provider (an authorised body for PGDs) this organisation may, with agreement of the ICB, authorise the PGDs.
- If non-NHS/LA provider (e.g. PCNs, independent healthcare providers) the ICB must authorise the PGDs.

ICBs do not need to authorise PGDs which form part of nationally or regionally commissioned NHS services:

- National NHSE: Pharmacy First, community pharmacy 'flu vaccinations, COVID vaccinations
- Regional NHSE: routine imms/vaccs (until April 2025)

Managing PGD use in medicine shortages

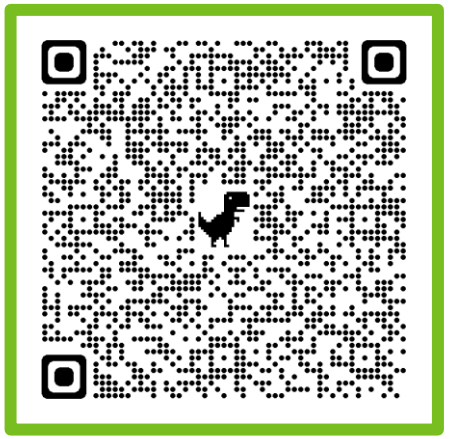
- PGDs can only be used for UK licensed medicines – if only unlicensed, imported stock becomes available a PGD cannot be used. UL medicines must be prescribed.

- PGDs can be pre-emptively written to include multiple formulations/dosages to give flexibility in product to be supplied/used.

- Serious Shortages Protocols (SSPs) do not apply to supplies made under PGDs.

Protocols for P/GSL medicines

- GSLs medicines can be supplied/administered by any trained/competent person
- P medicines can be administered by any trained/competent person
- No legal mechanism is required.
- Good governance to have a locally agreed protocol in place to cover who can administer/supply these medicines/to who/in what circumstances/at what dose and for how long.
- For local development based on service/staff profile.
- Example and more information on SPS website



PGD use in services commissioned by more than one ICB

A provider may provide services to more than one ICB and the same PGD is used in all cases. Each ICB commissioning the service authorises the PGD so repetition – can this be reduced?

- Legally can have a lead commissioner who authorises a PGD on behalf of one or more other commissioners
- However, can become complex and may work best if only a small number of commissioners involved and in an immediate geography
- Need to seek advice from legal/contracting teams
- Awareness of issue at a high level and discussions regarding legislation ongoing

What is the best way to incorporate pregnancy and lactation into PGDs, and how do we ensure the equality act is upheld?

NICE MPG 2

1.1.1 Provide the majority of clinical care involving supplying and/or administering medicines on an individual, patient-specific basis. Reserve patient group directions (PGDs) for limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability. **Consider - Is a PGD the appropriate way to manage these individuals?**

1.1.7 Ensure that off-label use of a licensed medicine is included in a PGD only when clearly justified by best clinical practice. **Consider – is pregnancy/lactation within the SPC? If not what evidence supports safety? Is this appropriately supported/endorsed?**

- PGDs must only be used where another legal mechanism is not possible, where clinical use is supported by national/local guidance and where safety is not compromised.
- Clinical signatories need to consider all these factors remembering that safety must come first and PGDs will not always be an appropriate choice in all clinical scenarios.