**Independent Healthcare**

**Medicines Governance Audit Tool**

Services are responsible for ensuring that they comply with the legal requirements and current best practice and guideline recommendations with regard to the safe, effective and secure use of medicines.

We strongly recommend that services use this tool to self-assess their service in preparation for registration and subsequent inspections.

**Medicine governance standards**

1. There are systems in place to support the safe, effective, person centred and secure prescribing, supply and administration of medicines in accordance with current legislation, national guidance and best practice
2. All staff have the skills, knowledge and training appropriate to their scope of practice
3. There is a consent/request for treatment policy and availability of medicines information for the relevant treatment(s)
4. All clinical incidents and alerts relating to avoidable harm and near miss events are documented, reviewed, and learning shared

| **1. There are systems in place to support the safe, effective and secure handling of medicines** |
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| **EVIDENCE** | **COMPLIANCE** | **COMMENTS** |
| Yes | No |  |
| 1. There is an identified:
2. clinical lead responsible for the safe, effective and secure use of medicines.
3. accountable officer if applicable (if the organisation handles controlled drugs and has more than 10 members of staff).
 |  |  |  |
| 1. All relevant staff have access to and are familiar with up to date, clinical guidelines, protocols, safe and secure handling of medicines policies/SOPs etc.

 To include detail on:1. **procurement**- medicines are obtained from a legitimate source and are safe and fit for purpose. Services are compliant with FMD requirements if applicable
2. **storage** is secure and correct according to the medicine’s legal category, specific requirements and level of risk associated
3. **prescribing** is in line with legal requirements, carried out by suitably qualified and registered prescribers, evidenced based and appropriate to patient’s individual needs (see PGDs\*).

NB If prescribing aesthetic POMs, a face to face consultation is required between patient and prescriber. Video consultations are not acceptable1. **administration** is safe, accurate and patient centred
2. **supply** to patient is packaged and labelled in line with legal requirements/good practice. Services are compliant with FMD requirements if applicable
3. **destruction**/**disposal** is in line with product, environmental and legal requirements

 vii. if service uses CDs, ensure all CD procedures comply with legal requirements and good practice guidance. The service should liaise with the Home Office to check if HO license required, |  |  |  |
| c There is a system in place for development, approval and review of the above by appropriate healthcare professional(s) including document control. |  |  |  |
| d \***Patient Group Directions (PGDs)** are written, approved and utilised according to legal requirements and good practice. |  |  |  |
| e There is a rolling programme of audits to check compliance with the medicine management processes (i-vii) above and to identify service improvements if relevant  |  |  |  |

| **2. All staff have the skills, knowledge and training appropriate to their scope of practice.** |
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| **EVIDENCE** | **COMPLIANCE** | **COMMENTS** |
| Yes | No |  |
| a.1. Staff (medical and non-medical) are appropriately qualified and trained to undertake the role
2. Staff have appropriate indemnity/insurance cover
3. Status of and authority of each prescriber can be identified and verified annually

e.g. check nurse status with NMC register V300 –independent/supplementary prescriber status**NB: A** Private Prescription code may be required from the local NHS Health Board if prescriber wishes to prescribe CDs on a private prescription |  |  |  |
| 1. Cross section of staff training records to ensure practice remains up to date and relevant (i.e. select from medical, pharmacy and nursing) and review:
2. Details of training received, specialist clinical updates etc
3. competency assessments if appropriate
 |  |  |  |

| **3. There is a consent/request for treatment policy and availability of medicines information for the relevant treatment(s)** |
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| **EVIDENCE** | **COMPLIANCE** | **COMMENTS** |
| Yes | No |   |
| 1. Service policy and example(s) of completed documentation
 |  |  |  |
| 1. If applicable, policy for obtaining consent to information sharing with the patient’s GP in accordance with General Medical Council (GMC) standards and documented evidence in case note review
 |  |  |  |
| 1. Availability of medicines information for patients and staff (to include side effects, interactions, highlight if unlicensed/off label use, how to access emergency services if needed etc)
 |  |  |  |

| 1. **All clinical incidents and alerts relating to avoidable harm and near miss events are documented, reviewed, and learning shared**
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| **EVIDENCE** | **COMPLIANCE** | **COMMENTS** |
| Yes | No |
| 1. Service incident management policy and investigation process
 |  |  |  |
| 1. System(s) for:
2. documenting and reviewing clinical incidents of avoidable harm and near miss events
3. reporting incidents to HIS (notifications) if applicable
4. documenting actions taken / changes made as a result of incident reports
5. signing up, receipt and action on relevant alerts e.g., MHRA alerts
 |  |  |  |
| 1. Local / regional / national shared learning if applicable eg if part of large, national organisation
 |  |  |  |

Healthcare Improvement Scotland’s Quality of Care Approach

<http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach.aspx>

Health and Social Care Standards

<http://www.gov.scot/Publications/2017/06/1327>

General Medical Council: Good practice in prescribing and managing medicines and devices (2013)

[www.gmc-uk.org/guidance](http://www.gmc-uk.org/guidance)

General Medical Council: Guidance for doctors who offer cosmetic interventions (2016)

[www.gmc-uk.org/guidance](http://www.gmc-uk.org/guidance)

Royal Pharmaceutical Society: Professional guidance on the safe and secure handling of medicines (2018)

<https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines>

Royal College of Nursing: Professional guidance on the administration of medicines in healthcare settings (2019)

<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/SSHM%20and%20Admin/Admin%20of%20Meds%20prof%20guidance.pdf?ver=2019-01-23-145026-567>

Human Medicines Regulations (2012)

<http://www.legislation.gov.uk/uksi/2012/1916/contents/made>

Patient Group Directions: who can use them? (2017)

<https://www.gov.uk/government/publications/patient-group-directions-pgds>

National Institute of Clinical Excellence (NICE) guidelines on Patient Group Directions (2017)

<https://www.nice.org.uk/Guidance/MPG2>

The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007

<http://www.legislation.gov.uk/uksi/2007/2154/pdfs/uksi_20072154_en.pdf>

Medicines storage on hospital in-patient wards CEL 28 (2013)

<http://www.sehd.scot.nhs.uk/mels/CEL2013_28.pdf>

Safer Use of Medicines - Medicines Reconciliation: Revised Definition, Goals and Measures and Recommended Practice Statements for the Scottish Patient Safety Programme SGHD/CMO(2013)18

<http://www.sehd.scot.nhs.uk/cmo/CMO%282013%2918.pdf>

Controlled Drugs, licence fees and returns updated 23 November 2018

<https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns>

 MHRA Guidance on implementing the Falsified Medicines Directive

<https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features>