**Recommendations for the Retention of Pharmacy Records (England) 2019**

|  | **Record** | **Unique record** | **Reason for keeping** | **Recommended minimum period** | **Derivation of recommendation and comments** |
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| **RECORDS THAT PERTAIN TO ALL PHARMACY SETTINGS** | | | | | |
| **Clinical governance** | Competency/training records | Yes | Reference | Clinical training: until 75th birthday or duration of employment plus 6 yrs whichever is longer.  Statutory/mandatory training: 10yrs after training completed  Other training: 6 yrs after training completed. | Records Management Code of Practice for Health and Social Care. July 2016  (RMCoP 2016) [1] |
| Clinical audit | Yes | Reference | 5 yrs | RMCoP 2016 [1] |
| External quality control records | Yes | Audit | 12 yrs | RMCoP 2016 [1] |
| Patient surveys | Yes | Audit | 5 yrs | RMCoP 2016 [1] |
| Patient complaints | Yes | Audit | 10 yrs | RMCoP 2016 [1]  Where a legal action has commenced, keep as advised by legal representative. |
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| **Clinical interventions** | Minor clinical interventions | Yes | Audit | 2 yrs | Best practice.  Two part paper form recommended, original to be added to the patient record, duplicate kept for 2 yrs.  Entries made on an electronic database should be reviewed after 2 yrs, if no longer needed, destroy or permanently delete record. |
| Significant clinical interventions | Yes | Audit | For 10 yrs after the death of the patient | Entries should be recorded directly in the patient notes / PMR. |
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| **Controlled drugs (CD)** | CD register (pharmacy, ward, theatre) | Yes | Legal | 2 yrs from date of last entry but if it contains records of destruction of CDs (including patient returns and out of date stock) then keep for 7 yrs | Misuse of Drugs Regulations 2001 [2]  A guide to good practice in the management of controlled drugs in primary care (England) [3]  Safer management of controlled drugs: a guide to good practice in secondary care (England) [4]  Controlled drugs: safe use and management [5]  Electronic CD register - see note 2.  In Secure Environments Schedule 3 CDs are also recorded in CD registers  (PSI IDTS 2010/45 [6]; Professional Standards for optimizing medicines for people in secure environments [7]) |
| Hospital CD prescriptions  (out-patient and TTA / TTO) | Yes | Legal | 2 yrs | Misuse of Drugs Regulations 2001 [2]:  All CD prescriptions should be kept for 2 yrs. (Secure Environments see Note 9). |
| Private CD prescriptions | Yes | Legal | Send to NHSBSA | The Misuse of Drugs (Amendment No. 2) Regulations 2006 [8]: Private prescriptions for Schedule 2 and 2 CDs must be sent to the relevant agency.  Relevant agency - NHS Business Services Authority (NHSBSA) |
| Destruction of patient’s own CDs | Yes | Legal | 7 yrs | Controlled drugs: safe use and management [5]  Professional guidance on the safe and secure handling of medicines [9]:  Patient’s own drugs can be removed and/or disposed of with the agreement of the patient or in the interest of the patient/general safety. |
| CD ward orders or requisitions | No | Legal | 2 yrs | Misuse of Drugs Regulations 2001 [2]  All CD prescriptions should be kept for 2 yrs. Keep in original paper form or computerised form. |
| Copy of signature for CD ward order or requisition | Yes | Validation | Duration of employment | Safer management of controlled drugs: a guide to good practice in secondary care (England) [4]  Copy of signature of each authorized signatory should be available in the pharmacy department. |
| Requisitions, orders, order books, delivery note or other record of receipt | No | Legal | 2 yrs or 2 years from date of last entry for record books. | Misuse of Drugs Regulations 2001 [2]:  All CD prescriptions should be kept for 2 yrs. Includes hospice requisitions, health and justice services & others not sent to NHSBSA. See note 3. |
| Invoices | Yes | Legal | 6 yrs | Controlled drugs: safe use and management [5]  Limitation Act 1980 [10]: 6 complete tax years. |
| CD transportation by road vehicle | Yes | Audit | Driver ID: 3 mths.  Recipients’ signature: 6 mths in original form; then up to 18 mths in reproducible form.  Orders, signed orders, requisitions, private prescriptions: 2 yrs. | Guidance for the safe custody of controlled drugs and drug precursors in transit [11] |
| Extemporaneous CD preparation worksheets | Yes | GMP | 5 yrs | 5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6. |
| Aseptic CD worksheets - adult  paediatric | Yes  Yes | GMP  GMP | 5 yrs  5 yrs | 5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6. |
| CD clinical trials information | Yes | GMP | 5 yrs | This may be longer for some trials. |
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| **Patient safety incidents** | Dispensing error records/incidents & associated stats (not serious incidents) | Yes | Audit | 10 yrs for minor harm incidents, 1 yr plus current for no harm incidents | RMCoP 2016 [1] and best practice.  Recommendations only apply to paper records; entries made on electronic databases should be kept permanently. |
| Dispensing incidents resulting in disability or death (serious incidents) | Yes | Legal | 20 yrs | RMCoP 2016 [1] |
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| **Recalls/drug alerts** | Recall documentation | Yes | Audit | 5 yrs | Recommendations from the Good Distribution Guide - especially for those with wholesale dealers licence. |
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| **Responsible pharmacist** | Responsible pharmacist records/log book | Yes | Legal | At least 5 yrs | Medicines (pharmacies/responsible pharmacist) Regulations 2008 [12]  Can be in hard copy or electronic. |
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| **Superseded documents** | Clinical protocols | No | Reference | 25 yrs | RMCoP 2016 [1] |
| Policies, strategies, standard operating procedures (SOPs) | No | Reference | Life of organization plus 6 yrs | RMCoP 2016 [1] |
| Patient Group Directions (PGDs) | No | Reference | For adults aged 18 yrs and over: 8 yrs (10 yrs in cases of implant insertion).  For a child: until the 25th birthday or for 8 yrs after a child’s death | Retaining PGD documentation [13] |
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| **Stock handling and transfer** | Picking tickets/delivery notes | Yes | Reference | 3 months | A "reasonable" period of time - for verification of order only. |
| Old order books | No | Audit | 2 yrs | Current financial yr plus 1. |
| Invoices | Yes | Legal | 6 complete tax yrs | Limitation Act 1980 [10]. See note 4. |
| Wholesale dealing records | Yes | GDP | 5 yrs | EU Guide on Good Distribution Practice (part of the Orange Guide). |
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| **Fridge** | Fridge temperature | Yes | GMP/GDP | 1 yr or longer for sites holding a Wholesale Dealers Licence | Refrigerator records to be kept for the life of any product stored therein – particularly vaccines. For sites subject to GDP inspection (licensed wholesaler) records should be kept for 5 years as with other GDP records. SOPs detailing actions required in the event of fridge failure should also be available. |
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| **Waste medicines** | Destruction of patients' own drugs (excluding controlled drugs) | Yes | Audit | 6 months | Professional guidance on the safe and secure handling of medicines [9]:  Patient’s own drugs can be removed and/or disposed of with the agreement of the patient or in the interest of the patient/general safety. |
| Waste - Non-hazardous Transfer notes | Yes | Legal | 2 yrs | Safe management of healthcare waste [14] |
| Waste - hazardous Consignment notes | Yes | Legal | 3 yrs | Safe management of healthcare waste [14] |
| **HOSPITAL PHARMACY SPECIFIC RECORDS (also applicable to Secure Environments - see Note 8)** | | | | | |
| **Clinical Trial** | IMP batch production records | Yes | GMP/GCP | 5 yrs after end of the trial | Article 9 of Directive 2003/94/EC [15]  UK implementing directive: The Medicines for Human Use (Clinical Trials) Regulations 2004 [16] |
| Protocols | Yes | Reference | 5 yrs after end of the trial | See note 1. |
| Dispensing records | Yes | Reference | 5 yrs after end of the trial | - |
| Destruction records | Yes | GMP | 5 yrs after end of the trial | The sponsor of the trial is responsible for the destruction of unused and/or returned trial material. Therefore any destruction must be authorized in writing and a dated destruction certificate supplied to the sponsor. |
| Preparation or dispensing of ATMPs | Yes | Reference | 30 yrs | ATMP = Advanced Therapeutic Medicinal Products.  Detailed guidelines on good clinical practice specific to advanced therapy medicinal products [17] |
| CD clinical trials information | Yes | GMP | 5 yrs | This may be longer for some trials. |
| Clinical drug trials or other studies out with the Clinical Trials Directive | Yes | GCP / Against future claims | 5 yrs after end of the trial | For example - metabolic studies, nutritional studies.  Article 17 of Directive 2005/28/EC for Clinical trials [18], otherwise good practice.  UK implementing directive: The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 [19] |
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| **Medicines Information** | Question asked, information search & answer | Yes | Reference and audit | 8 yrs (25 yrs for child, obstetrics and mental health enquiries) | RMCoP 2016 [1]  Recommendations apply to previous paper based enquiry forms. Electronic enquiry database (MIDatabank) should be kept permanently. |
| Q&A documentation | Yes | Reference and audit | 8 yrs (25 yrs for child, obstetrics and mental health) | RMCoP 2016 [1] |
| MI audit records | Yes | Reference | 5 yrs or 2 audit cycles, whichever is longer | RMCoP 2016 [1] and best practice.  To ensure the previous two audit reports are available to inform any recommendations of a current audit. |
| Peer review records | Yes | Reference | At least 1 yr | Best practice.  To allow any trends to be tracked. Can also be used as a basis for “peer discussion” for revalidation. |
| Patient Information Leaflets (PILs) produced in-house | Yes | Reference | 6 yrs after last use | RMCoP 2016 [1] |
| Newsletters / Bulletins and other miscellaneous “news” communications | No | Reference | 6 yrs after distribution | RMCoP 2016 [1] |
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| **Miscellaneous** | Doctors/nurses signatures | Yes | Reference | Duration of contract + 1 yr | Destroy 1 yr after termination of employment.  GDPR Principle (e): Storage limitation [20]: Do not keep personal data for longer than required. |
| Self-administration records | No | Reference | 8 yrs | RMCoP 2016 [1] and best practice.  Keep the record in the patient’s medical notes after discharge. |
| Superseded IV drug administration monographs | No | Reference | 10 yrs | Best practice.  May provide useful background information for dealing with complaints regarding IV administration of drugs. |
| Medicines Reconciliation (MR) documentation | Yes | Audit | 2 yrs | See note 5. |
| Drug & Therapeutics Committee agendas, letters, minutes, drug submissions etc. | No | Reference | 20 yrs | RMCoP 2016 [1] |
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| **Prescriptions** | To take away (TTA / TTO) prescriptions | No | Audit | 2 yrs | EPR will eventually hold all details - duplication of record held in notes, see note 5. |
| Out-patient prescriptions | No | Audit | 2 yrs | EPR will eventually hold all details - duplication of record held in notes, see note 5. |
| Private prescriptions (excluding private CD prescriptions – see Controlled Drugs | Yes | Audit | 2 yrs | MEP Edition 42 July 2018 [21]. (Secure Environments see Note 8  The Human Medicines Regulations 2012 (regulation 253 (5)) [22] |
| Unlicensed medicines dispensing record | Yes | Legal | 5 yrs | The supply of unlicensed medicinal products (“specials”) [23]  The Human Medicines Regulations 2012 (regulation 170 (1)) [22]  Record of the batch number should also be kept. |
| Parenteral nutrition (PN) | No | Audit | 2 yrs | Original valid prescription should be kept in patient's notes. |
| Chemotherapy prescriptions | No | Reference | 2 yrs after last treatment | EPR will eventually hold all details - duplication of record held in notes. |
| Clinical drugs trials or other studies out with the Clinical Trials Directive | Yes | GCP / Against future claims | 5 yrs after end of the trial | For example - metabolic studies, nutritional studies.  Article 17 of Directive 2005/28/EC for Clinical trials [18], otherwise good practice.  UK implementing directive: The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 [19] |
| Immunoglobulins/blood products | Yes | Reference | 30 yrs | RMCoP 2016 [1]:  Blood Bank Register should be kept for 30 years; although there is no specific recommendation for immunoglobulins and other blood products not supplied via Blood Bank, it seems reasonable to require the same retention time.  To allow full traceability of all blood products used. |
| Pads of FP10s usage & issue sheets | Yes | Legal | 3 yrs | Security of prescription forms guidance [24]  Note: The referenced document has been superseded. However, the current document (Management and control of prescription forms: a guide for prescribers and health organisations [25]), does not include the relevant information. |
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| **Purchase Orders** | Order & delivery notes | No | Audit/GDP | 2 yrs or 5yrs | Current financial yr plus 1. See note 4. Wholesaler Dealers EU Guide on Good Distribution Practice requires retention of all records for 5yrs. |
| Ward stock order sheets | Yes | Audit | 2 yrs | Current financial yr plus 1. |
| Ward pharmacy requests | No | Reference | 1 yr | Record of what was requested by ward pharmacist - unlikely benefit after 12 mths. |
| Ad hoc forms (e.g. dispensing request forms to stores) | No | Reference | 3 months | Reasonable period and current practice. |
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| **Stock Control** | Stock check lists | Yes | Audit | 18 months | Records Management NHS Code of Practice [26]  Note: Although the referenced document has been withdrawn, the up to date version (RMCoP 2016 [1]) does not include the relevant information. |
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| **Technical services** | Any Quality Control (QC) documentation including certificates of analysis | Yes | GMP | 5 yrs or 1 yr after expiry date of batch | Whichever is longer.  Article 51(3) of Directive 2001/83/EC [27]  UK implementing legislation: Human Medicines Regulations 2012 (regulation 170 (1)) [22] |
| Environmental monitoring results | Yes | GMP | 1 yr after expiry dates of products | RMCoP 2016 [1]  If an electronic record, keep for 10 yrs then review & destroy if no longer needed. |
| Validation/training of operators | Yes | GMP | Duration of employment + 5 yrs after leaving | Keep in personal portfolios. |
| Paediatric products worksheets | Yes | GMP | 5 yrs | 5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6. |
| Chemo/aseptic worksheets | Yes | GMP | 5 yrs | 5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6. |
| PN worksheets | No | GMP | 5 yrs | 5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note. |
| Resuscitation box worksheet | Yes | GMP | 1 yr after expiry of longest dated item | If sold or supplied across a legal boundary, 5 yrs or 1 yr after expiry date of batch as per GMP, whichever is longer. |
| Batch production records | Yes | GMP | 5 yrs | 5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6. |
| Extemporaneous dispensing records | Yes | GMP | 5 yrs | 5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6. |
| Raw material request; packaging and control forms | Yes | GMP | At least 5 yrs | Part of batch record, 5 years under GMP, but consider keeping for longer due to consumer liability legislation – see note 6. |
| Validation of equipment & maintenance logs | Yes | GMP | 11 yrs | RMCoP 2016 [1]  Starts after decommissioning of the equipment. |
| Cleaning logs | Yes | Reference | 1 yr | Best practice. |
| Medical gas pipeline systems – High hazard permits to work | Yes | Reference | For the lifetime of the pipeline system | Health Technical Memorandum 02-01: Medical gas pipeline systems [28] |
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| **Unlicensed medicines** | Any purchased unlicensed medicines (ULM) documentation | Yes | Legal/Against future claims | 5 yrs | Record of the batch number should also be kept.  The supply of unlicensed medicinal products (“specials”) [23]  The Human Medicines Regulations 2012 (regulation 170 (1)) [22] |
| **COMMUNITY PHARMACY SPECIFIC RECORDS** | | | | | |
| **Dispensing** | Patient Medical Record | Yes | Legal | For 10 yrs after the death of the patient | RMCoP 2016 [1] |
| Private prescriptions (excluding private CD prescriptions – see Controlled Drugs) | Yes | Legal | 2 yrs | MEP Edition 42 July 2018 [21]  Human Medicines Regulations 2012 (regulation 253 (5)) [22] |
| POM register | No | Legal | 2 yrs from last entry | Human Medicines Regulations 2012 (regulation 253 (5)) [22] |
| POM-V & POM-VPS records of receipt and supply | Yes | Legal | At least 5 yrs | Veterinary medicines regulations 2009 [29]  Must keep all documents relating to the transaction. Specific requirements for what information must be included. |
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| **EPS2** | Patient pharmacy nomination | Yes | Audit | 6 mths after the last prescription the collected | Best practice.  This also applies to patient authorisations for managed repeat systems. |
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| **Specials and unlicensed medicines** | Extemporaneously prepared on the premises with internal quality control. | Yes | Legal | 5 yrs | Human Medicines Regulations 2012 (regulation 170) [22]  See note 6. |
| Extemporaneously prepared by another pharmacy/company with external quality control | No | Legal | 5 yrs | Human Medicines Regulations 2012 (regulation 170) [22]  Should have the certificate of conformity including the source of the product; to whom, and the date on which the product was sold or supplied; the prescriber’s details; the quantity of each sale or supply; the batch number of the product; details of any adverse reactions to the product sold or supplied. See note 4. |
| Unlicensed imports | No | Legal | 5 yrs |
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| **Equality Act** | Record of assessment and outcome of patients’ needs in respect of medicines | Yes | Reference | For as long as the assessment remains valid, plus 1 yr | Best practice  Assessment should be repeated if patient circumstances change. |
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| **Public Health Campaigns** | Evidence of participation in local public health campaigns | Yes | Reference | 2 yrs | Where requested by the commissioner to do so, records should be kept to demonstrate compliance with Terms of service of NHS Pharmacists (Schedule 4, part 2, paragraph 18(b)) to regulation 11(1)(a)(i) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 [30]. |
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| **Advanced services** | Medicines Use Review (MUR) | Yes | Legal | 2 yrs | Records can be kept electronically or in hard copy.  The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 [31]: Keep records for at least two years after the date on which the consultation to which the record relates is carried out (Direction 5(1)(l)). |
| New Medicine Service (NMS) | Yes | Legal | 2 yrs | Records can be kept electronically or in hard copy.  The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 [31]: Keep records for at least two years after the date on which the service intervention is completed or discontinued (Direction 7(1)(n)). |
| Stoma appliance customisation | Yes | Legal | 12 months | Records can be kept electronically or in hard copy.  The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 [31]: Keep records for at least 12 months or such longer period as the commissioner may reasonably require (Direction 10(2)(d)). |
| Appliance use review | Yes | Legal | 12 months | Records can be kept in electronically or in hard copy.  The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 [31]: Keep records for at least 12 months or such longer period as the commissioner may reasonably require (Direction 12(5)(e)). |
| Community Pharmacy Seasonal Influenza Vaccination Advanced Service (CPSIVAS) | Yes | Legal | 8 yrs for adults aged 18 yrs and over  (2 yrs for consent forms for post payment verification) | Records can be kept in electronically or in hard copy.  The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 consolidated directions and subsequent amendments [32]  Service Specification: Community pharmacy seasonal influenza vaccination advanced service [33]: All relevant paperwork must be managed in line with RMCoP 2016 [1]  Pharmacy Influenza Vaccination PGD [34]: Keep records for audit purposes and post payment verification. |
| NHS Urgent Medicine Supply Advance Service (NUMSAS) | Yes | Legal | 2 yrs | Records can be kept in electronically or in hard copy.  The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 consolidated directions and subsequent amendments [32]  NHS Urgent Medicine Supply Advanced Service Pilot – Community Pharmacy Service Specification [35]: All relevant records must be managed in line with RMCoP [1] |
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| **Enhanced services, locally commissioned services or private services**  **See Note 7** | Sexual Health service forms | Yes | Audit | For adults aged 18 yrs and over: 8 yrs (10 yrs in cases of implant or device insertion).  For a child: until the 25th birthday or 26th birthday if the patient was 17 yrs when treatment finished. In cases of implant or device insertion, keep the record as above or for 10 years, whichever is longer. | RMCoP 2016 [1]  Service standards for record keeping [36]  NB The longest licence period for a contraceptive device is 10 years. |
| No | Reference | Where individual patient records are kept by a sexual health team and a shorter minimum period for retaining records may be stated in the service level agreement. |
| Smoking cessation service | Yes | Audit | 2 yrs | RMCoP 2016 [1] |
| Supply of Smoking cessation therapy e.g. NRT not via FP10 or via PGD | Yes | Audit | 2 yrs | RMCoP 2016 [1] |
| Minor ailments service | Yes | Audit | 2 yrs | Recommended best practice. |
| Immunisation and vaccination records | Yes | Audit | For adults aged 18 yrs and over: 8 yrs.  For a child: until the 25th birthday or 26th birthday if the patient was 17 yrs when treatment finished. | RMCoP 2016 [1] |
| NHS health check | No\* | Audit | 2 yrs | Best practice [\*If the results are forwarded to the patients GP] |
| NHS health check | Yes\*\* | Audit | 2 yrs | Best practice [\*\*Where results are not forwarded to the GP] |
| Substance misuse service forms | Yes | Audit | 2 yrs | Best practice |
| **Invoices and consent forms** | All payment claims, invoices and patient consent forms relating to any advanced or enhanced service | Yes | Audit | 6 complete tax years | VAT regulations 2005 [37] for invoices. Individual signed consent forms support the invoiced claim.  NOTE: Enhanced service consent forms represent consent at the point in time the service is provided and are not proof of ongoing consent. |
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| **Other records** | Any other records pertaining to individual patient care in community pharmacy not covered elsewhere in this document. | Yes | Audit | 2yrs | Best practice. This recommendation only applies for paper records. It is accepted that, where appropriate, records relating to patient care (e.g. self-care, signposting, telephone queries) should be entered on the PMR, either directly or transferred from paper records. Entries made on the PMR should be kept permanently. |
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| **KEY**  **GMP = good manufacturing practice; GDP = good distribution practice; GCP = good clinical practice; MR = medicines reconciliation; MUR = medicines use review**  **Where GMP is given as the reason for keeping the record, this would be legally enforceable for all unlicensed medicines and for any manufacturing of medicines under an MHRA licence. Any reason for keeping other than ‘legal’ can be regarded as best practice.** | | | | | |

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| Note 1 | The sponsor of the trial is responsible under current legislation for keeping trial records. All clinical trial records should be retained for a longer (up to 15 years) if required by the applicable regulatory requirement(s) or if needed by the Sponsor as per Annex 1 to Directive 2001/83/EC and GCP requirements EMA/CHMP/ICH/135/1995.  Note: The provisions of Directive 2001/83/EC are brought into UK law by the Human Medicines Regulations 2012.The HMR 2012 do not, however, reproduce the detail of the 2001 directive, so the original directive text should be referred to. |
| Note 2 | Once electronic CD registers are in widespread use, the Government intends to require anyone required to keep secure copies of a CD register for up to 11 years.  (Department of Health. Safer management of CDs: Changes to the record keeping requirements, guidance for England only. Last revised February 2008) |
| Note 3 | Every requisition, order or private prescription on which a CD is supplied must be preserved by the pharmacy department for a minimum of 2 years from the date on which the last delivery under it was made. Although the mandatory period for keeping requisitions is 2 years, health care organizations may wish to store them for longer periods, as cases often come to court at a much later date. Future regulations may increase the period of time for the storage of records. (Department of Health/RPSGB, Safer management of controlled drugs – a guide to good practice in secondary care. (England) Oct 2007) |
| Note 4 | The 6-tax-years limit relates to disputes over simple contract (Limitation Act 1980). Manufacturers, and sometimes others involved in a product’s supply chain, are liable for their products under the Consumer Protection Act 1987. Therefore, it is recommended to keep delivery notes or invoices for 11 years as product liability records – see note 6. |
| Note 5 | Where the electronic system has the capacity to destroy records in line with the retention schedule, and where a metadata stub can remain demonstrating that a record has been destroyed, then the Records Management Code should be followed in the same way for electronic records as for paper records with a log being kept of the records destroyed. If the system does not have this capacity, then once the records have reached the end of their retention periods they should be inaccessible to users of the system and upon decommissioning, the system (along with audit trails) should be retained for the retention period of the last entry related to the schedule.  (Records Management Code of Practice for Health & Social Care, Jul 2016) |
| Note 6 | Consumer Protection Act (CPA) 1987 allows patients to claim for injury due to a defective product (medicine) up to 10 years after a medicine has been administered.  Records of manufactured products (e.g. worksheets) can prove that the product was / was not defective. The prescription / other clinical records will only indicate that the patient was prescribed / dispensed an item but will not give any indication how the product was made and from what ingredients. If the problem is a contaminated ingredient, it is possible to partially pass the responsibility to the supplier of the defective ingredient.  **Adult patients** (18 years and over)  Keep manufacturing records for 11 years (10 years as part of CPA + 1 year best practice safety margin)  **Paediatric patients**  If a child suffers from a medications, they’ve got:   * any time up to 3 years after their 18th birthday to sue in negligence (up until they’re 21 years) * 10 years from taking the medicine to sue under CPA   RMCoP 2016 states that records relating to children should be kept until the child’s 25th birthday (26th birthday if 17 years old at time of treatment), unless there are other factors which indicate the record should be kept for longer. Therefore, in line with RMCoP recommendation, keep all paediatric manufacturing records for 25 years. |
| Note 7 | For locally negotiated services, if the minimum retention period stated in the contractual arrangement of the service level agreement (SLA) exceeds the recommendations of this document contractors must adhere to the SLA. |
| Note 8 | NHS England directly commissions healthcare in all residential Secure Environments (prisons, Immigration Removal Centres and Secure Training Centres). Prescriptions generated in these settings are therefore NHS prescriptions and not private prescriptions. The expectations for prescriptions and other record retention for these settings are in the main as for hospital settings. A wing or treatment room is considered equivalent to a hospital ward. Health and justice (HJ) prescriptions are all now held on the HJIS EPR system and thus retention of the actual hand signed prescription can be reduced to 3 months (please also see the RPS Professional Standards for optimizing medicines for people in secure environments 2017). The community pharmacy section of this document is also relevant where dispensing takes place in-house and where advanced services or additional enhanced services are delivered. |
| Note 9 | In addition to retaining the CD prescription a copy of the current CD prescription (i.e. Schedule 2 and 3) for a patient should be available on patient transfer to another secure setting. To achieve this either a scanned e-copy or a hard copy transferred with the patient is needed. This is essential for enabling continuity of supply on transfer until the prescription is reviewed. (PSI IDTS 2010/45 and RPS Professional Standards for optimizing medicines for people in secure environments, Feb 2017). |

**References**

1. Information Governance Alliance. Records Management Code of Practice for Health and Social Care 2016. July 2016. <https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/codes-of-practice-for-handling-information-in-health-and-care/records-management-code-of-practice-for-health-and-social-care-2016>
2. The Misuse of Drugs Regulations 2001 (SI 2001/3998). <http://www.legislation.gov.uk/uksi/2001/3998/contents/made>
3. National Prescribing Centre. A guide to good practice in the management of controlled drugs in primary care (England). Third edition. December 2009. <https://www.harrogateandruraldistrictccg.nhs.uk/data/uploads/medicines-management/controlled-drugs/clinical-governance/npc-controlleddrugsthirdedition-dec2009.pdf>
4. Department of Health. Safer Management of Controlled Drugs: a guide to good practice in secondary care (England). October 2007 [archived].
5. NICE guideline NG46. Controlled drugs: safe use and management. April 2016. <https://www.nice.org.uk/guidance/ng46>
6. Ministry of Justice. Integrated Drug Treatment System. PSI IDTS 2010/45. September 2010.
7. Royal Pharmaceutical Society. Professional Standards for optimizing medicines for people in secure environments: Prisons, Young Offender Institutions and Secure Training Centres (Edition 2). England. February 2017. <https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Optimising%20medicines%20in%20secure%20environments/Professional%20Standards%20Secure%20Environments-edition-2.pdf?ver=2017-05-18-112406-223>
8. The Misuse of Drugs (Amendment No. 2) Regulations 2006 (SI 2006/1450). <http://www.legislation.gov.uk/uksi/2006/1450/contents/made>
9. Royal Pharmaceutical Society. Professional guidance on the safe and secure handling of medicines. December 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>
10. Limitation Act 1980. Chapter 58. <https://www.legislation.gov.uk/ukpga/1980/58>
11. Home Office. Guidance for the safe custody of controlled drugs and drug precursors in transit. Version 1.3. November 2018. <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/758746/transit-guidance-v1.3-nov-2018.pdf>
12. The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 (SI 2008/2789). <http://www.legislation.gov.uk/uksi/2008/2789/contents/made>
13. Specialist Pharmacy Service. Retaining PGD documentation. 13 August 2018. <https://www.sps.nhs.uk/articles/retaining-pgd-documentation/>
14. Department of Health. Safe management of healthcare waste. Version 2.0. England. May 2012. <https://www.cannonhygiene.com/sites/default/files/Safe%20management%20of%20healthcare%20waste%20version%202.0%20%28April%202012%29.pdf>
15. Commission Directive 2003/94/EC. Article 9. <https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2003_94/dir_2003_94_en.pdf>
16. The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031). <http://www.legislation.gov.uk/uksi/2004/1031/contents/made>
17. European Commission. Detailed guidelines on good clinical practice specific to advanced therapy medicinal products. Brussels, 03/12/2009. ENTR/F/2/SF/dn D(2009) 35810. <https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2009_11_03_guideline.pdf>
18. Commissioning Directive 2005/28/EC. Article 17. <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:091:0013:0019:en:PDF>
19. The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (SI 2006/1928). <http://www.legislation.gov.uk/uksi/2006/1928/contents/made>
20. General Data Protection Regulation ((EU) 2016/679). [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679%20)
21. Royal Pharmaceutical Society. Medicines, Ethics and Practice. Edition 42. July 2018.
22. The Human Medicines Regulations 2012 (SI 2012/1916). <http://www.legislation.gov.uk/uksi/2012/1916/contents/made>
23. MHRA. The supply of unlicensed medicinal products (“specials”). MHRA Guidance Note 14. 2014. <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf>
24. NHS Project. Security of prescription forms guidance. August 2013 [archived].
25. NHS Counter Fraud Authority. Management and control of prescription forms: a guide for prescribers and health organisations. Version 1.0. March 2018. <https://cfa.nhs.uk/resources/downloads/guidance/Management%20and%20control%20of%20prescription%20forms_v1.0%20March%202018.pdf>
26. Department of Health. Records Management: NHS Code of Practice. Part 2. 2nd edition. March 2006 [archived]
27. Directive 2001/83/EC. Article 51. <https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf>
28. Department of Health. Medical Gases. Health Technical Memorandum 02-01: Medical gas pipeline systems. Part B: Operational management. May 2006. <http://www.bcga.co.uk/assets/HTM_02-01_Part_B.pdf>
29. The Veterinary Medicines Regulations 2009 (SI 2009/2297). <http://www.legislation.gov.uk/uksi/2009/2297/contents/made>
30. The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (SI 2013/349). <https://www.legislation.gov.uk/uksi/2013/349/contents/made>
31. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013. <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/193012/2013-03-12_-_Advanced_and_Enhanced_Directions_2013_e-sig.pdf>
32. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 consolidated directions and subsequent amendments. <https://psnc.org.uk/wp-content/uploads/2018/09/Advanced-and-Enhanced-Directions-consolidation-to-1-September-2018-FINAL-2.pdf>
33. NHS England. Service Specification: Community pharmacy seasonal influenza vaccination advanced service. August 2018. <https://www.england.nhs.uk/wp-content/uploads/2017/08/service-specification-for-seasonal-flu-v5.pdf>
34. NHS England. Pharmacy Influenza Vaccination Patient Group Direction (PGD). September 2018. <https://www.england.nhs.uk/wp-content/uploads/2017/08/pdg-influenza-pharmacy-service-v5-1.pdf>
35. NHS England. NHS Urgent Medicine Supply Advanced Service Pilot – Community Pharmacy Service Specification. February 2019. <https://www.england.nhs.uk/wp-content/uploads/2019/03/numsas-service-specification-february-2019.pdf>
36. Faculty of Sexual and Reproductive Healthcare of the Royal College of Obstetricians and Gynaecologists. Service standards for record keeping. July 2014. <https://www.fsrh.org/standards-and-guidance/documents/clinical-standards-recordkeeping-july14/>
37. The Value Added Tax (Amendment) (No. 2) Regulations 2005 (SI 2005/2231). <http://www.legislation.gov.uk/uksi/2005/2231/contents/made>

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