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| ***nhsRecommendations for the Retention of Pharmacy Records - prepared by the East of England NHS Senior Pharmacy Managers 2015*** | | | | | |
|  | **Record** | **Unique record** | **Reason for keeping** | **Recommended minimum period** | **Derivation of recommendation and comments** |
| **RECORDS THAT PERTAIN TO ALL PHARMACY SETTINGS** | | | | | |
| **Clinical governance** | Competency/training records | Yes | Reference | Duration of employment plus 2 yrs | Best practice, keep in personal portfolio. |
| Clinical audit | Yes | Reference | 5 yrs | Records Management – NHS code of Practice 2009. |
| External quality control records | Yes | Audit | 2 yrs | Records Management – NHS code of Practice 2009. |
| Patient surveys | Yes | Audit | 2 yrs | Records Management – NHS code of Practice 2009. |
| Patient complaints | Yes | Audit | 8 yrs | Records Management – NHS code of Practice 2009.  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.  Recommendation only applies for paper records. Two part form recommended, original to be added to the patient record, duplicate kept for 2 yrs. Entries made on an electronic database should be kept permanently. |
| Significant clinical interventions | Yes | Audit | For 10 yrs after the death of the patient | Clinically significant interventions should be recorded directly in the patients notes/  PMR. Electronic patient records must not be destroyed or deleted for the forseeable future. |
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| **Controlled drugs (CD)** | CD register | 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| Legal | 2 yrs from date of last entry but if it contains records of destruction of CDs (including patient returns and out of date stock) then keep for 7 yrs | Misuse of Drugs Regulations 2001  A guide to good practice in the management of controlled drugs in primary care (England) v3.1, updated 1 Oct 2010.  Safer management of controlled drugs: a guide to good practice in secondary care (England). Dept of Health, October 2007.  Electronic CD register - see note 2.  In Secure Environments Schedule 3 CDs are also recorded in CD registers (PSI IDTS 2010/45) |
| 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 states that all CD prescriptions should be  kept for 2 yrs. Includes hospice requisitions, prison services & others not sent to NHSBSA. See note 3. |
| Extemporaneous CD preparation worksheets | Yes | GMP | 13 yrs | See note 3. |
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| **Equipment and premises** | Cleaning logs | Yes | Reference | 1 yr | Best practice. |
| Validation of equipment & maintenance logs | Yes | GMP | For life of equipment | Best practice. |
| 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 wholesale) 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. |
|  | **Record** | **Unique record** | **Reason for keeping** | **Recommended minimum period** | **Derivation of recommendation and comments** |
| **Patient safety incidents** | Dispensing error records/incidents & associated stats | Yes | Audit | 1 yr plus current | Recommendations only apply to paper records, entries made on electronic databases should be kept permanently. |
| Dispensing incidents – serious incidents resulting in disability or death | Yes | Legal | 30 yrs | Records Management – NHS code of Practice 2009. |
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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 | Can be in hard copy or electronic.  Medicines (pharmacies/responsible pharmacist) Regulations 2008 (SI 2008/2789). |
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| **Superceded documents** | Superceded SOPs | No | Reference | 15 yrs | Best practice. As electronic record in perpetuity. |
| Superceded Patient Group Directions (PGDs) | No | Reference | 8 yrs for adult and 25 yrs for child (0-18 yrs) or for 8 yrs after a child’s death | Best practice. |
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| **Stock handling and transfer** | Picking tickets/delivery notes | Yes | Uncertain | 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. 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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| **Waste medicines** | Destruction of patients' own drugs (excluding controlled drugs) | Yes | Audit | 6 months | Revised Duthie Report (2005) states that patient's own drugs are the property of the patient and should only be destroyed with the patient's permission. If medicines are removed from a patient’s home during a domiciliary visit, record what is destroyed. |
| Waste - Non-hazardous Transfer notes | Yes | Legal | 2 yrs | Safe management of healthcare waste (version 2.0), Dept of Health & Environment Agency, 2012. |
| Waste - hazardous Consignment notes | Yes | Legal | 3 yrs | Safe management of healthcare waste (version 2.0), Dept of Health & Environment Agency, 2012. |
| **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. |
| 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. |
| CD clinical trials information | Yes | GMP | 5 yrs | This may be longer for some trials. |
| Clinical drug trials or other studies outwith 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, otherwise good practice. |
|  | **Record** | **Unique record** | **Reason for keeping** | **Recommended minimum period** | **Derivation of recommendation and comments** |
| **Controlled Drugs** | CD ward orders or requisitions | No | Legal | 2 yrs | Misuse of Drugs Regulations 2001 states that 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 | Copy of signature of each authorized signatory should be available in the pharmacy department. Safer Management of Controlled Drugs – A guide to good practice in secondary care (England), Oct 2007. |
| CD record book (ward/theatre based) | Yes | Audit | 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 | Safer Management of Controlled Drugs – A guide to good practice in secondary care (England), Oct 2007. See note 2. |
| Aseptic CD worksheets - adult  paediatric | Yes  Yes | GMP  GMP | 13 yrs  26 yrs | See note 3. |
| CD clinical trials information | Yes | GMP | 5 yrs | This may be longer for some trials. |
| Destruction of patients' own CDs | Yes | Audit | 7 yrs | Revised Duthie Report (2005) states that patient's own drugs are the property of the patient and should only be destroyed with the patient's permission. |
| CD prescriptions (Both inpatient and outpatient) | Yes | Legal | 2 yrs | Misuse of Drugs Regulations 2001 states that all CD prescriptions should be  kept for 2 yrs. (Secure Environments see Note 9) |
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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) | Recommendations apply to previous paper based enquiry forms. [UKMI National Standard for MI services, March 2009]. Electronic enquiry database (MIDatabank) should be kept permanently. |
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| **Miscellaneous** | Doctors/nurses signatures | Yes | Reference | Duration of contract + 1 yr | Destroy 1 yr after termination of employment (not referenced, best practice). |
| Self administration records | No | Reference | Not required | Will be kept in nursing notes/main medical record. |
| Superceded IV drug administration monographs | No | Reference | 10 yrs | - |
| MR documentation | Yes | Audit | 2 yrs | As electronic record in perpetuity. See note 5. |
| Drug & Therapeutics Committee agendas, letters, minutes, drug submissions, etc. | No | Reference | 30 yrs | Dept of Health. Records Management: NHS Code of Practice, Part 2. Jan 2009. |
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| **Prescriptions**  **Prescriptions cont.** | To take out (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 | Yes | Audit | 2 yrs | According to RPSGB ethics guide this is the minimum requirement. (Secure Environments see Note 8) |
| Unlicensed medicines dispensing record | Yes | Legal | 5 yrs | Requirement of Guidance Note 14. Permanent record of batch details 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 chemo treatment | EPR will eventually hold all details - duplication of record held in notes. |
| **Record** | **Unique record** | **Reason for keeping** | **Recommended minimum period** | **Derivation of recommendation and comments** |
| Clinical drugs trials or other studies outwith 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, otherwise good practice. |
| Immunoglobulins/blood products | Yes | Reference | 30 yrs | To allow full traceability of all blood products use. |
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| **Purchase Orders** | Order & delivery notes | No | Audit/GDP | 2 yrs or 5yrs | Current financial yr plus 1. See note 4. For 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 | Uncertain | 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 | Uncertain | 3 months | Reasonable period and current practice. |
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| **Stock Control** | Stock check lists | Yes | Audit | 1 yr plus current | As in HSC 1999/053. |
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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 the longer, (Article 51(3) of Directive 2001/83). |
| Environmental monitoring results | Yes | GMP | 1 yr after expiry dates of products | As electronic record in perpetuity. |
| Validation/training of operators | Yes | GMP | Duration of employment + 5 yrs after leaving | Keep in personal portfolios. |
| Paediatric products worksheets | Yes | GMP | At least 5 yrs | Product liability extends to up to 28 yrs. See note 6. |
| Chemotherapy/aseptic worksheets | Yes | GMP | 5 yrs | Product liability extends this to 11 yrs after expiry. |
| PN worksheets | No | GMP | 5 yrs | Product liability extends this to 11 yrs after expiry. |
| 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. |
| Batch production records | Yes | GMP | 5 yrs | Product liability extends this to 11 yrs after expiry. |
| Extemporaneous dispensing records | Yes | Product liability | 5 yrs | Product liability extends this to 11 yrs after expiry. |
| Raw material request; packaging and control forms | Yes | GMP | At least 5 yrs | Part of batch record, so product liability issues apply (extends to 11 yrs after expiry). |
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| **Unlicensed medicines** | Any unlicensed medicines (ULM) documentation | Yes | Legal/Against future claims | 5 yrs | Not a specific requirement of Guidance note 14, it would be best practice to keep a permanent batch specific record of the assessment of the ULM purchased. |
| **COMMUNITY PHARMACY SPECIFIC RECORDS** | | | | | |
| **Dispensing** | PMR | Yes | Legal | For 10 yrs after the death of the patient | Records Management – NHS code of Practice 2009. Electronic patient records must not be destroyed or deleted for the forseeable future. |
| Private prescriptions | Yes | Legal | 2 yrs | The Human Medicines Regulations 2012 (regulation 253 (5)) |
| POM register | No | Legal | 2 yrs from last entry | The Human Medicines Regulations 2012 (regulation 253 (5)) |
| POM-V & POM-VPS records of receipt and supply | Yes | Legal | At least 5 yrs | Veterinary medicines regulations 2009 (SI 2297) Must keep all documents relating to the transaction. Specific requirements for what information must be included. |
|  | **Record** | **Unique record** | **Reason for keeping** | **Recommended minimum period** | **Derivation of recommendation and comments** |
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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 | The Human Medicines Regulations 2012 (regulation 170).  Product liability extends this to 11 yrs after expiry for adults and up to 28 yrs for children. See note 4. |
| Extemporaneously prepared by another pharmacy/company with external quality control | No | Legal | 5 yrs | The Human Medicines Regulations 2012 (regulation 170).  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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| **DDA / Equality Act** | Record of assessment and outcome of patients needs in respect of medicines | Yes | Reference | Minimum 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 evidence compliance with Terms of service of Pharmacists – Schedule 4, part 2, para 18 (b) to regulation 11(1)(a)(i) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. |
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| **Advanced services** | MUR records | Yes | Legal | 2 yrs | Records can be kept in electronically or in hard copy. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 require pharmacies to keep copies of the MUR consultation record 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 forms | Yes | Legal | 2 yrs | Records can be kept in electronically or in hard copy. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 require pharmacies to keep copies of the NMS consultation 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 in electronically or in hard copy. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 require pharmacies to keep records of each stoma customisation 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 require pharmacies to keep records of each AUR for at least 12 months or such longer period as the commissioner may reasonably require (Direction 12(5)(e)). |
|  | **Record** | **Unique record** | **Reason for keeping** | **Recommended minimum period** | **Comments** |
| **Enhanced services, locally commissioned services or private services**  **See Note 7** | Sexual Health service forms | Yes | Audit | For adults aged 18 and over: 10 yrs  For a child: until the 25th birthday or 10 yrs (whichever is longer) | Records Management – NHS code of Practice 2009  Clinical Standards Committee, Faculty of Sexual and Reproductive Healthcare (FSRH) of the Royal College of Obstetricians and Gynaecologists.  NB The longest license 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 | Records Management – NHS code of Practice 2009. |
| Supply of Smoking cessation therapy (not via FP10) e.g. NRT | Yes | Audit | 2 yrs | Records Management – NHS code of Practice 2009. |
| Supply of Smoking cessation therapy via PGD | Yes | Audit | 2 yrs | Records Management – NHS code of Practice 2009. |
| Minor ailments service | Yes | Audit | 2 yrs | Recommended best practice. |
| Immunisation and vaccination records | Yes | Audit | Retain until the patient’s 25th birthday or 26th if  the young person was 17yrs old at conclusion of treatment. All others retain for 10 yrs after conclusion of treatment. | Records Management – NHS code of Practice 2009 |
| NHS health check | No\* | Audit | 2 yrs | Best practice  \*If the results are forwarded to the patients GP for inclusion on the clinical record |
| 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 | Recommended best practice |
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| **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 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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| **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.** | |
| 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 CPMP/ICH/135/95. |
| 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 | Either delivery notes or invoices should be kept for 11 years as product liability records. |
| Note 5 | EPR must not be destroyed or deleted for the foreseeable future. (Department of Health. Records Management: NHS Code of Practice, Part 2. Jan 2009) |
| Note 6 | Consumer Protection Act 1987 allows patients to claim up to 10 years after a medicine has been administered (in paediatrics up to 28 years - maturity plus 10 years).  If adequate records are available in the patient's notes, the records should only need to be kept for the period stated under the recommendation. |
| 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 . (NPC 2009 A Guide to Good Practice in the Management of Controlled Drugs in Primary Care). The community pharmacy section of this document is relevant where Advanced services or additional enhanced services are commissioned. |
| 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 Best Practice. |

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