Standards for the safer use of electronic Prescribing and Medicines Administration (ePMA) systems for use in Systemic Anti-Cancer Therapy (SACT) Services

UK Chemotherapy Board

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Contents

1. Introduction

1.1. The main purpose of this document is to improve safety to patients and maintain consistency throughout the UK. The document was first published by the British Oncology Pharmacy Association (BOPA) in 2015 and updated in 2019. The current version has been extensively reviewed by representatives of the whole oncology workforce in the UK to reflect the multidisciplinary use of this document (see sections 12,13 and 14). The UK Chemotherapy Board is now the formal owner and has the responsibility to maintain and update this document.

2. Purpose of the Standards

2.1. This document outlines steps that are considered to be best practice for utilisation of electronic Prescribing (eP) and electronic Prescribing and Medicines Administration systems (ePMA) systems for systemic anti-cancer therapy (SACT). Note: For this document it shall be referred to as ePMA but this includes eP systems.

2.2. The recommendations set out in these standards are intended to guide users in the different stages of the operation of ePMA systems including the set-up, validation, prescribing, clinical verification, ordering/ preparation and administration of SACT.

2.3. Although ePMA systems are known to improve the safety of SACT prescribing their introduction does not eliminate prescribing errors and may introduce their own specific risks.

2.4. In recognising that there are a number of different manufacturers of ePMA systems, these standards aim to make generic recommendations that are universal.

2.5. Within England, NHS England in its service specification for provision of SACT services[1] requires all SACT to be prescribed using an ePMA system.

2.6. Within Wales, the health boards are moving towards mandating all SACT being prescribed using an ePMA system.

2.7. Within Scotland the CEL 30 currently recommends use of an ePMA system or a standardised SACT prescription[2].

3. Scope of the Standards

3.1. This document provides the minimum expectation for electronic prescribing of SACT. It brings together established practice and presents it in the form of standards. It does not describe any novel clinical practice.

3.2. The guidance applies to the electronic prescribing of chemotherapy and other SACT (e.g. monoclonal antibodies, oral therapies and other novel systemic therapies). It does not include hormones such as letrozole and goserelin.

3.3. For specific SACT where national guidance exists (e.g. intrathecal, advanced therapy medicinal products (ATMP), such as CAR-T therapy etc.) the requirements of the relevant national guidance must also be considered[3].

3.4. The standards are generic and are applicable to all ePMA systems used to prescribe SACT, either as standalone SACT prescribing systems or wider ePMA systems (including those that are integrated in electronic health record (EHR) systems).

3.5. These standards should be used by all staff involved in the provision of SACT services when ePMA systems are implemented, updated or replaced.

4. Limitations

4.1. These standards are intended for guidance only and represent the **minimum** requirements for the safer use of SACT ePMA systems. Healthcare professionals must exercise professional judgement in assessing the service needs, with the functional capability of the ePMA system, to meet those needs.

4.2. Although generic, it is recognised that the availability of different systems may result in variation of how these standards are put into practice. In all cases professionals responsible for implementing SACT ePMA systems should use these standards in conjunction with training and documentation supplied by system providers.

4.3. These standards have made no recommendations on workforce requirements for implementation and ongoing maintenance of electronic SACT regimens. Each organisation should have investigated these requirements within a business case for electronic prescribing and regularly review these requirements.

4.4. These standards have not included a full review of the impact of linking (interfacing) the electronic prescribing system to other systems (e.g. pharmacy dispensing, manufacturing and stock control systems, EHR systems, pathology results, patient administration systems, bar code scanning, smart infusion devices and other ePMA systems) and its effects on safety. It is important that the risks and potential inefficacy associated with using unlinked software systems are addressed by the organisation and a full risk assessment incorporating a failure modes evaluation and criticality assessment is recommended at all stages and periodically reviewed.

4.5. These standards do not cover aspects such as insurance, server reliability or similar issues which IT departments consider when tendering for an electronic system.

4.6. These standards do not cover the training required to obtain a level of competence within a clinical role. This will be at national or organisational level and set at each organisation separately. (e.g. BOPA Cancer Pharmacy Education and Training Standards [4]).

4.7. Within England, the standards set out in DCB0160[5] should be followed. This NHS Digital standard provides a set of requirements suitably structured to promote and ensure the effective application of clinical risk management by those health organisations that are responsible for the deployment, use, maintenance or decommissioning of Health IT Systems within the health and care environment.

4.8. Within England, the NHS Digital standards set out in DCB0129[6] should be followed. This standard provides a set of requirements suitably structured to promote and ensure the effective application of clinical risk management by those organisations that are responsible for the development and maintenance of Health IT Systems for use within the health and care environment.

4.9. From 2021, ePMA systems fall into the Medical Device Regulations 2002 (UK MDR 2002) that classify an ePMA system as a medical device. Suppliers should ensure that their product is appropriately registered with the Medicines and Healthcare products Regulatory Agency (MHRA) and has the appropriate CE mark or UKCA mark. Purchasers should ensure that the product they have/are purchasing has the appropriate CE mark or UKCA mark. CE marks will continue to be recognised in Great Britain until 30th June 2023. [7]

4.10. Under the terms of the Northern Ireland Protocol, the rules for placing medical devices on the Northern Ireland market differ from those applicable to Great Britain (England, Wales and Scotland). From 2021 EU Medical Device Regulations (2017/745) will apply in Northern Ireland. There is a requirement, in most cases, to register devices with the MHRA and have a UK Responsible Person if the manufacturer is based outside the UK. Although the UKCA mark is available for use in Great Britain, a CE mark is needed for devices placed on the Northern Ireland market and EU rules need to be met. Further information can be found on the Gov.uk website: Regulating medical devices in the UK - GOV.UK (www.gov.uk)

4.11. Where an ePMA system is part of a system that falls under Annex 11: Computerised Systems of the European Guidelines for Good Manufacturing Practice (GMP)[8], then the worksheet, labelling and compounding functionality should be validated to those standards and the prescribing functionality also needs to be included in the Validation Master Plan for that system.

5. The Standards

5.1. General

5.1.1. An electronic system for the prescribing of all SACT in the treatment of cancer patients within the UK will be in place within the organisation (exception where non electronic prescriptions are a part of the organisations business continuity plan (BCP)). See section 7 for further details.

5.1.2. There will be a robust BCP in place in the event of a system failure (See section 7 for further details on these standards).

5.1.3. Where 'an audit trail' is stated within this document, the minimum required specification for the audit trail is: time and date stamp, user name, action and reason. The use of ambiguous reasons like 'clinical decision' or 'other' will be avoided. Where these are necessary, accompanying free text will be present. This will be freely available to view within the organisation and does not require a 3rd party to supply (may be limited to particular users within the organisation).

5.2. Training

5.2.1. All personnel operating SACT ePMA systems are appropriately trained in the relevant task(s) required of their specific role (e.g. set-up, validation, prescribing, verification, administration) and their training records retained by the organisation for 6 years after the employee leaves[9]. Roles and responsibilities of all staff groups will be clearly defined and documented.

5.2.2. Training will involve demonstrations of different types of prescriptions that may be encountered in various scenarios (for example dose reductions and how these are applied). Practising with realistic patient scenarios will provide the best preparation prior to use of a live system[10].

5.2.3. Effective mechanisms are implemented to segregate test data used in training and live data.

5.2.4. Retraining takes place at suitable intervals according to local requirements (e.g following extended leave) and as appropriate following system upgrades.

5.2.5. Additional training for relevant personnel is undertaken when a new risk identifies training issues.

5.2.6. Systems are put in place to ensure trainees who are granted security access during training are unable to act as a final signatory for a designated task until formally signed off as competent.

5.2.7. All training records are up to date and maintained regularly.

5.2.8. Additional training for specific SACT/processes are in place where relevant. i.e. intrathecal, CAR-T, GCP. This training is linked to the process within the ePMA system.

5.2.9. Where additional training is required for specific SACT/processes, it is recommended that the system can restrict certain processes to only those staff deemed competent. (e.g. only staff trained and competent can prescribe/verify/administer ATMPs/intrathecal etc. within their role).

5.2.10. Additional training for persons who set up and manage the system is in place. i.e. Building protocols, drug file maintenance, dose banding tables, checking of protocol templates etc.

5.2.11. Where additional training is required for persons who set up and manage the system, the system will restrict these processes to only those staff deemed competent. (e.g. only staff trained and competent can carry out drug file maintenance, change / build dose banding tables, check protocol templates etc. within their role).

5.3. Set-Up

5.3.1. General Set-Up

5.3.1.1. The set-up of a regimen in the ePMA system will follow the relevant organisational or clinical trial protocol for each specific regimen. It is strongly recommended that SACT protocols are written and approved by an organisational governance process before building in the ePMA system to reduce risk. In the case of exceptional circumstances please see section 5.4.4.2. For guidance on what should be included in a SACT protocol See 'BOPA Guidance on the contents of a SACT protocol' Published April 2020[11].

5.3.1.2. The written SACT protocol document will be available at the point of prescribing, clinical checking and administration. This may be on the ePMA system (e.g. pdf attachment) or an alternative place (intranet/internet) but it will be easily accessible for staff treating the patient.

5.3.1.3. Security access enabling personnel to set-up or build SACT regimen templates on ePMA systems will only be granted to approved staff who have undertaken the appropriate training and demonstrated competence.

5.3.1.4. Security access enabling personnel to modify SACT regimen templates already validated on ePMA systems will only be granted to approved staff who have undertaken the appropriate training and demonstrated competence.

5.3.1.5. Set-up of treatment regimen templates in SACT ePMA systems will be performed by approved staff familiar with SACT and trained to a suitable level within the organisation and have demonstrated competence.

5.3.1.6. For ePMA systems that are working as a standalone system (e.g. no / limited integration with existing hospital pathology results, patient administration systems), further process safeguards and risk assessments need to be put in place to reduce the risk of transcription errors, ensure traceability and timely flow of data from one system to another. E.g. Record of a double check of patient demographics/blood results if manually entered into system.

5.3.1.7. For ePMA systems that have an integration for pathology results there will be a process for how ePMA manages occasions where lab results are marked as error in the parent system and how this information filters to the ePMA system.

5.3.1.8. Where ePMA systems have drug interactions checking set up, the system will allow users to add any UK licensed medicine and ideally any medicine (with dm+d code/description). In all cases, prescribers and checkers of SACT will be mindful of potential interacting medicines that are not in the ePMA system (e.g. separate prescribing on inpatient drug chart, GP). This will be covered in system training. Where interaction checking is set up, the organisation will be mindful of alert fatigue and assess the level of alerts to flag.

5.3.1.9. The implementation phase will include a process mapping exercise to understand the needs of the implementing site. This will inform the Standard Operating Procedures (SOPs) and procedures for using the system within that specific healthcare environment and will be used to help with training. It will also help users to understand the way the system is configured and how other users in different roles will use the system. This process will include the review of configurable options of the system to ensure all settings are confirmed as appropriate for local practice. This will form part of the safety case development in England as per DCB160 (See section 6).

5.3.1.10. A nationally recognised drug code (e.g. dm+d in NHS) for each drug will be used to ensure that drugs can be correctly identified when integrating with other systems, e.g. clinical decision support functions linked to other systems, such as allergy checking against information that feeds from the patient administration system (PAS) system. Consideration should be given to what level of dm+d is required depending on the integrations in place to ensure the correct product is identified where necessary across all the systems e.g. when a prescribing system is integrated with a compounding system

5.3.1.11. All supportive non SACT medicines are prescribed within the system to accompany the SACT prescribed (and not on paper).

5.3.1.12. All commonly prescribed supportive non-SACT drugs are built within the ePMA system with pre-defined doses, route, frequency etc. for a prescriber to add to a regimen when needed for a specific patient. This is to reduce the risk of selection errors when they are added to a patient's prescription by a prescriber. (e.g. metoclopramide PO 10mg TDS PRN). These need to be editable by the prescriber.

5.3.1.13. When setting up or modifying a commonly prescribed supportive non-SACT drug with pre-defined criteria, there will be a robust process in place to ensure that the information is checked and subsequently approved (by another appropriate person, or forced time lapse between the build and approval) before being able to be prescribed by the prescriber. There will be an audit trail of changes made.

5.3.1.14. There will be the ability to remove the option of prescribing a commonly prescribed supportive non-SACT drug with pre-defined criteria immediately (e.g. error, market withdrawal). There will be an audit trail of changes made.

5.3.1.15. There will be a mechanism to report on all instances where a commonly prescribed supportive non-SACT drug has been prescribed previously and where it is in active treatments.

5.3.1.16. Where ePMA systems are in use across several organisations (such as a Cancer Network) it is essential to check that the set up and configuration of the system is correct for each individual organisation. An example is pathology analysers for serum creatinine assay (either Enzymatic Jaffe setting) and subsequent Wright equations for CARBOplatin dosing. This will need to be reviewed when any changes in laboratory providers or processes occur.

5.3.1.17. It is recommended that during the build of a regimen, specific results or tests can be marked essential to proceed treatment. In doing so this restricts further progress of the prescription (such as administration or release) until the interface has returned in range results or this has been manually marked as received (with an audit trail in place) by a user who is authorised within the system to complete. This can be set up per protocol (only needed for first treatment), for each cycle or system wide. E.g. Dihydropyrimidine dehydrogenase (DPD) results before a regimen containing capecitabine, Hepatitis B testing before administration of immunosuppressive SACT[12].

5.3.1.18. Where integration exists with pathology labs, it is recommended that the ePMA system has the functionality to set up ranges for critical tests (i.e. neutrophils, platelets etc.) used within SACT treatments. There will be the ability to modify ranges for each regimen and within each cycle within a regimen at the build stage. This will be subject to a robust process of checking and validating as well as an audit trail of changes and approvals within the system (see section 5.9).

5.3.1.19. The ePMA system will have the functionality to set up/build an appropriate validity period for which duration critical tests are acceptable as default. There will also be the ability to modify duration for each regimen and within each cycle within a regimen. This will be subject to a robust process of checking and validating as well as an audit trail of changes and approvals within the system (see section 5.9).

5.3.1.20. The ePMA system will have an appropriate version control audit log for the set up and validation of regimens/ drug files/ critical tests / worksheets / commonly prescribed non-SACT drugs / dose banding etc.

5.3.1.21. When using the system, if regimen selection is carried out after typing, there will be a minimum of five characters before results are shown to prevent incorrect selection of regimens.

5.3.1.22. All manually inputted patient data will be fully auditable. E.g. which user and date/time of input of weight.

5.3.1.23. The ePMA system will have the ability to retrospectively mark manually inputted data as an error. Where data inputted has been marked as an error in the ePMA system, the system will not allow this information to continue to be applied to a prescription, or a flag will be activated to clearly show that the source data is incorrect (e.g. where an incorrect Body Surface Area (BSA) has been entered, and later marked as error, the system will not retain future planned doses prescribed using this BSA and any calculations using incorrect data will be flagged). There will be a full audit trail.

5.3.1.24. Character field lengths within the ePMA system will not be restricted (i.e. users will not be forced to abbreviate names or clinical notes). Titles of regimens will be displayed in full. Care should be taken to not overcomplicate with longer than needed names.

5.3.1.25. The system will support reporting in a format that system managers can access. e.g. reports for English SACT dataset, Welsh SACT dataset, audit packages as stated within these standards.

5.3.1.26. The information standard ‘DAPB4013 Medicine and Allergy/Intolerance Data Transfer’[13], effective from the 1st of October 2021, ensures that medication and allergy and/or intolerance data is transferred between systems and locations in a machine-readable format. This will be achieved using the UK version of FHIR (Fast Healthcare Interoperability Resource). The full conformance date is the 31st of March 2023.

5.3.2. **Nomenclature**

5.3.2.1. Naming of SACT drugs and regimens will be unambiguous. The naming will be applied to avoid confusion with other drugs or regimens (e.g. acronyms used with full names, inclusion of brand name with biological medicines[14], use of Tall Man Lettering[15,16,17], inclusion of frequency, usage of dm+d descriptions). E.g. EC 90 (epiRUBicin, cyclophosphamide) q21. Ideally, SACT protocol naming should be standardised across the UK.

5.3.2.2. It is recommended that Tall Man Lettering for SACT in the UK is consistent with the version published by BOPA.[18]

5.3.2.3. In all instances, the SACT regimen will be clearly identified with the name used by the organisation and in such a way as to avoid misinterpretation with similarly named regimens.

5.3.2.4. The brand name of any biological medicines included in the regimen will be clearly identifiable at the point of prescribing, supply, clinical checking and administration where this is clinically justified.

5.3.2.5. The brand name of any medicines that have biosimilars within the market which are included in the regimen will be clearly identifiable at the point of prescribing, supply, clinical checking and administration.

5.3.2.6. Regimens where alternative dosing, route of administration or administration schedules exist will be clearly identified to avoid selection error (e.g. Bleomycin, etoposide, CISplatin 3 Day (BEP 3) (three) Day vs Bleomycin, etoposide, CISplatin 5 Day (BEP 5) (five) Day).

5.3.2.7. For clinical trials the name of the trial will be clearly identifiable against the trial protocol as well as the specific trial arm and/or regimen name to which it applies. The documentation used for the trial set-up and validation will identify the protocol version used for set up, as well as documenting subsequent reviews of updated versions and their impact (if any) on the prescribing system.

5.3.3. **Dosing**

5.3.3.1. Ensure the correct dosing schedule and dose calculation method are adopted (e.g. fixed dosing, body surface area (BSA), weight, GFR/AUC etc.).

5.3.3.2. The formula used for calculating the BSA (e.g. DuBois, Mosteller, Haycock, Boyd etc.) and GFR (Cockroft & Gault, Wright, etc.) will be appropriate for the organisation. If the ePMA system is used across several organisations (such as a network) this needs to be considered during implementation and ongoing maintenance.

5.3.3.3. Ideally the formulas used (Cockroft & Gault, Wright, DuBois, Mosteller, Haycock, Boyd etc.) should be standardised across the system within an organisation (or network).

5.3.3.4. Any variation in prescribed doses between cycles are clear and unambiguous, e.g. separate templates used – 8mg/kg vs 6mg/kg.

5.3.3.5. Standardised dose rounding (dose banding) or dose rounding is built within the ePMA system.

5.3.3.6. When building or modifying dose banding /rounding parameters, there will be a robust process in place to ensure that the information is checked for accuracy and independently approved (by another appropriate person) before being used within the system. There will be an audit trail of changes made.

5.3.3.7. Personnel involved with the set up of regimens will have access or clear visibility of dose banding or dose rounding rules and familiarise themselves with them.

5.3.3.8. There will be the ability to remove the option of dose banding /rounding parameters immediately for all patients, just new patients or both. There will be an audit trail of changes made. There will be a mechanism to report on all instances where this has been prescribed previously and where it is in active treatments.

5.3.3.9. Where applicable, maximum single and lifetime cumulative doses will be incorporated into the regimen or drug build. There will be a function to manually enter or import any doses received by a patient on other prescribing systems or another organisation. The system will be able to automatically calculate single and lifetime cumulative doses for a patient (including manually entered ‘extra’ doses). A warning will be automatically generated when cumulative doses will be breached at the point of prescribing which will require the prescriber to take action to acknowledge the warning before being able to continue. This will be audited within the system.

5.3.3.10. Ensure the correct route(s) of administration is applied according to the regimen protocol. There will be restriction in the ability to change the route of administration to only approved routes.

5.3.3.11. Run rates of infusions will be included on the SACT regimens within the system. Ideally this would be within the system but could be contained within the written protocol. It will be clear to the user how to administer the infusion. e.g. ritTUXimab, daratumumab. Nurses will have the ability to record modified run rates at the point of administration (e.g. where infusion has been prolonged).

5.3.4. **Schedule**

5.3.4.1. The correct dosing schedule is applied, particularly for multiple dosing days within a treatment cycle (e.g. PACLitaxel day 1,8,15 q21) or for treatments with alternating cycles (e.g. epiRUBicin cyclophosphamide (EC) 90 Dose Dense q14 then PACLitaxel Dose Dense q14).

5.3.4.2. Where there is more than one type of cycle, the protocol will be built within the system so as to not increase patient risk. E.g. For epiRUBicin cyclophosphamide (EC) - PACLitaxel best practice would be to have all cycles in one protocol. If a protocol is built over two regimens (e.g. epiRUBiubicin cyclophosphamide (EC) and a separate PACLitaxel) then there will be an organisational risk assessment and governance procedure in place to ensure users are aware of how this is set up within the organisation. It will be clear that another regimen is required to be prescribed to complete the protocol.

5.3.4.3. Regimens will be built so that all agents including supportive care and accompanying fluids are prescribed in the correct order of administration.

5.3.4.4. The correct cycle length is built into the system. The system will only allow changes to cycle length for a patient after an alert/prompt and acknowledgement from a user with sufficient permissions to be able to do this. This will be audited within the system including the reason.

5.3.4.5. The correct number of cycles is set: e.g. specific course length, until scheduled review or when clinically appropriate. The number of cycles will be set at regimen build/validation. Unlimited cycles will not be able to be prescribed where it is a defined course (adjuvant treatment) but will be able to be prescribed where the treatment is given to progression.

5.3.5. **Diagnosis**

5.3.5.1. Ensure that appropriate linkages are made between diagnosis, intent and line of therapy with regimens thereby reducing the risk of selecting an inappropriate regimen when prescribing.

5.3.5.2. Where relevant, apply the correct diagnosis (ICD-10, ICD-O3, SNOMED CT codes) and relevant other codes to enable data collection (e.g. SACT dataset[16] England).

5.4. Validation

5.4.1. A written, approved validation process will be in place that defines the processes involved and the personnel who are permitted to carry out the validation process within the organisation. This will be approved through appropriate organisational governance processes.

5.4.2. User Acceptance Testing (UAT) of the system

5.4.2.1. A test of the whole system needs to take place before go-live and at each system update before roll out. Pre go-live UAT and end user testing will be defined for a health organisation and relates to their specific configured workflow as defined in the process mapping documentation. These configurable options will have been identified and agreed before setting up, and reviewed against local settings.

5.4.2.2. Where systems have a test environment (which allows you to test the entire system before going live, including inputting of simulated ‘test’ patients) this will be utilised. It is recommended that several users (at least 3 to 4) from different multidisciplinary groups who use different parts of the system (and department areas if applicable) test the system in order to anticipate any potential issues.

5.4.2.3. There will be a pre-defined test script, with anticipated outcomes, which is followed for future updates (and updated to incorporate new features) to ensure there has been no loss of functionality.

5.4.3. UAT of Regimens

5.4.3.1. Each SACT regimen will be tested once it has been set up in the ePMA system by the organisation. This will be done by running a test prescription using a simulated ‘test’ patient to check the regimen has been correctly set up, technically, clinically, and that all the outputs are correct including any dose calculations. This will be carried out by a suitably trained person.

5.4.3.2. The degree of testing needs to be proportionate to the level of complexity of the regimen (e.g. testing calculations at extremes of BSA to ensure that limits are appropriately triggered, dose banding/rounding, critical tests, etc.).

5.4.3.3. Specific supporting validation paperwork specific to the ePMA system and the organisation will be used when testing each SACT regimen to ensure all relevant items are checked. The validation paperwork will contain sufficient information to provide an audit trail of the build and validation process, and be retained according to section 5.4.4.5.

5.4.4. **Regimens**

5.4.4.1. To validate a regimen in the system, where the written protocol has been approved by an appropriate consultant oncologist or haematologist specialising in the cancer site the regimen applies to, then the:

- build /set up of the regimen will take place by a trained member of staff who has been assessed as competent
- input and test prescription will be independently checked by a cancer pharmacist who has not built the regimen in the system.

This is to ensure all input and outputs are accurate according to the above recommendations and the relevant approved written protocol for the specific regimen. All clinical information entered into the electronic system will be on the previously approved written protocol.

5.4.4.2. Where a new protocol template is required in an emergency or as an individual patient request it is recommended that the full organisation governance process is followed (written and approved by an organisational governance process before building in the ePMA system). Where time constraints necessitate that this is not possible, and a delay will cause harm to the patient, a risk assessment will be carried out before building a regimen on the system without the relevant approved written protocol. Any occurrences of this will be reported at the organisation and monitored for trends.

5.4.4.3. A consultant cancer nurse or consultant cancer pharmacist may check the regimen set-up and/or test prescription in the system in place of a consultant oncologist or haematologist where this is considered appropriate. This is to be approved at organisation level through appropriate governance processes

5.4.4.4. A nurse specialist responsible for administering or supplying the relevant SACT regimen will also check the written SACT protocol **or** the regimen set-up / test prescription to ensure the administration details are clear and unambiguous.

5.4.4.5. A system of recording signatures verifying that the above validation steps (build, independent cancer pharmacist check, UAT of regimens.) have been completed by the appropriate personnel will be retained by the organisation for the time the software is in use plus 6 years[9]. It is recommended that current advice on retention of pharmacy records are consulted for the exact length of time that is required for prescriptions to be kept and this is applied to verifying records (e.g. ATMP records should be kept for minimum 30 years[19]). This recording of signatures will be electronically captured within the system and be fully auditable.

5.4.4.6. A regimen will not be made available for prescribing until the above steps (sections 5.4.4.1 to 5.4.4.4) have been carried out.

5.4.4.7. Where a minor modification to an existing protocol is required, (e.g. spelling error, change of antiemetic policy, implementing standard product specifications), a new version of the electronic protocol will be generated (this will automatically remove validation of the old protocol if amending an existing protocol within the system) and the input and test prescription will be independently checked by a cancer pharmacist who has not modified the regimen in the system to ensure all input is accurate according to: the above recommendations, the relevant changes for the specific regimen and the original protocol where relevant. This will be audited within the system.

5.4.4.8. Where a significant modification to an existing protocol is required, (e.g. dose change), the organisation will have a process in place for formal approval of this change to the protocol (this may be repeating the full organisation governance process (rewritten and approved)). Once approved, a new version of the electronic protocol will be generated (this will automatically remove validation of the old protocol if amending an existing protocol within the system) and the input and test prescription will be independently checked by a cancer pharmacist who has not modified the regimen in the system to ensure all input is accurate according to the relevant approval.

5.4.4.9. Where a 'one-off' non-standard protocol is required to be built in the ePMA system, it is recommended that the full organisation governance process is followed (protocol written and approved). Where use of a 'one-off' nonstandard protocol is required, to restrict use, there will be a method to:

- archive this 'one-off' nonstandard protocol within the ePMA system.
- restrict this 'one-off' nonstandard protocol to a patient and/or consultant and/or site.

5.4.4.10. There will be a process in place within the organisation to immediately be able to disable a regimen from the live system where it is deemed unsafe for use. This will include within it the process for reporting where the regimen has already been prescribed or allocated and where it is pending prescribing, verification or administration.

5.4.4.11. When ePMA systems include or link to pharmacy worksheet/label production, aseptics services staff will need to perform additional validation checks in line with Annex 11 of the European Guidelines for Good Manufacturing Practice[8] and adhere to other relevant guidance (GAMP5, Medical Device Regulation, Quality Assurance of Aseptic Preparation Standards[20] etc.).

5.4.4.12. A SOP for the validation of a new regimen, or a modification of an existing regimen, will include as a minimum the following:

- validation of the ePMA system regimen against the treatment protocol and treatment protocol against the system regimen.
- validation of any drugs new to the system, or any changes to a drug set up (e.g. new routes of administration), included in the protocol. NOTE: Where drugs are set up locally by the organisation this will be covered in a separate SOP;
- validation of the SACT prescription generated, against local prescription formats and protocols, including any calculation checks and testing the system at its limits e.g. where doses should be capped;
- validation of the pharmacy worksheet generated (where applicable) including any calculations, against local pharmacy protocols;
- the categories of personnel with any minimum qualifications and/or competencies which should be mandatorily involved in the validation process;
- the requirement that the validation process will be checked by a person(s) acting independently of the one(s) carrying out the initial build into the system

5.4.4.13. A validation procedure checklist will be in place as part of the validation process to ensure that key aspects of the validation of each regimen are not accidently missed.

5.5. Prescribing

5.5.1. Security access enabling personnel to prescribe SACT on ePMA systems will only be granted to approved prescribers[21] (e.g. minimum ST3 for clinicians, non medical prescribers (NMPs) approved by organisation) who have undertaken appropriate training and competency assessment (e.g. All Wales competencies for review, authorisation and prescribing of SACT for adult patients[22] or equivalent). This will be reviewed in line with organisational polices.

5.5.2. There will be security access enabling appropriate access rights for all levels of prescribers within the ePMA system. This will separate the prescribing of first cycles, intrathecal, ATMPs (and where relevant, clinical trials) to staff who have done the relevant additional training and have been deemed competent within the organisation to complete this task. This access will be regularly reviewed.

5.5.3. It is recommended that the ePMA system has the ability to restrict prescribers according to their speciality (i.e. by tumour site).

5.5.4. Security access enabling personnel to allocate a treatment of SACT on ePMA systems will only be granted to approved staff (such as NMP and pharmacists) who have undertaken appropriate training and are working within specific organisational policies and procedures only. Note: Allocation of a treatment is not prescribing.

5.5.5. Where there are two or more protocols in use at any one time for a patient, there are processes in place within the organisation to ensure that a prescription is not missed. The system will have a mechanism to highlight patients with two or more concurrent prescriptions to the end user clearly. (i.e. denosumab in addition to SACT protocol)

5.5.6. There is a simple way to determine at the point of prescribing/clinical checking if a regimen is unlicensed or off label.

5.5.7. Where dose reductions are applied it will be possible to apply to one dose, one day, one cycle or the whole course. This modification will be carried over if any new cycles are added at a later date.

5.5.8. The system will never produce duplicate prescriptions (the same cycle of the same regimen for the same patient) unless expressly requested by the user. In this event then the duplicate prescription will be clearly marked as such. A full audit trail will be in place of any prescriptions booked to a patient and/or prescribed.

5.6. Verification (Pharmacy Clinical Check)

5.6.1. Security access enabling personnel to clinically check (verify) SACT prescriptions on ePMA systems will only be granted to approved pharmacists or pharmacy technicians[4,23] who have undertaken the appropriate training and competence assessment and are regularly reviewed in line with organisational polices (e.g. BOPA Cancer Pharmacy Education and Training Standards[4] or equivalent).

5.6.2. A clinical pharmacy check of the patients prescribed SACT on ePMA systems will be undertaken according to the BOPA verification standards ‘Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines[23]’ and in line with organisational polices. The clinical procedure used for this verification will be shared with the local Accountable Pharmacist in aseptics to ensure that it also meets the standards laid out in Quality Assurance of Aseptic Preparation Services[20].

5.6.3. The clinical check by pharmacy will be recorded as an electronic signature against the prescription within the ePMA system. It will be visible to all subsequent users of the system, and a clear audit trail maintained.

5.6.4. Any subsequent changes to the prescription after pharmacy verification has been completed will be identified within the system and automatic removal of the pharmacy verification from the prescription will occur. Ideally a patient

specific alert would be sent to the pharmacy /aseptics/ verifier/ all that a verification has been removed.

5.7. Printed prescriptions

5.7.1. Where printed prescriptions generated by the ePMA system are utilised for administration (see section 5.9.1) or dispensing:

5.7.1.1. The format of the printouts will be clearly presented to healthcare staff to minimise errors in administration or dispensing.

5.7.1.2. The electronic signature will appear on the printed copy if electronic verification has taken place prior to printing.

5.7.1.3. All paper copies will be destroyed when a new version of the prescription is generated. There will be a defined organisational process/ SOP for this.

5.7.1.4. There will be organisational processes in place to ensure that any changes to the paper copy are reflected in the electronic system. e.g. a process should define what actions need to be taken.

5.7.1.5. The paper copy will have a time stamp and /or version number printed on the prescription.

5.7.1.6. The system will maintain an audit trail of when prescriptions generated by the ePMA system are printed.

5.7.1.7. There will be a risk analysis carried out by the organisation concerning the use of paper prescriptions where electronic administration is available. See section 5.9.1.

5.8. Critical Tests

5.8.1. There will be processes in place within the organisation to check relevant critical tests results at each cycle. Ideally the critical tests results will be electronically available on the system via an interface.

5.8.2. Where critical tests results are available on the ePMA system, there will be an alert warning the end user of any out of range results at critical points in the pathway (prescribing/administration etc.).

5.8.3. If the alert warning for out-of-range critical tests is interruptive, it will be possible to override this. It will be possible to audit any overrides within the system.

5.8.4. There will be security access to only allow staff trained and deemed competent to override critical tests outside of range.

5.9. Administration

5.9.1. Electronic recording of drug administration will be recorded within the ePMA system. This is to ensure that all healthcare professionals (HCPs) are able to clearly check previous treatment administration. This includes a method for electronic dual signatures where legally or organisationally required.

5.9.2. Any deviations to the planned administration, including reduced drug doses, adverse events etc. will be recorded in the ePMA.

5.9.3. The electronic signature(s) of authorised staff will be recorded in the ePMA system contemporaneously to ensure up to date accurate records of administration exist in real time. Accurate information is particularly important in case of subsequent adverse reactions and/or emergency admissions. Recording of administration will include non or partial administration with reason. This is also important to ensure completeness of records and that cycles are not mistakenly skipped or duplicated.

5.9.4. Where electronic administration is used as the sole legal prescription/ administration record:

5.9.4.1. the audit log will be appropriately robust, to mandate entry in to all fields and where necessary, mandate unique entries (i.e. must not allow the entry of two identical electronic signatures into two separate independent nurse checks fields)

5.9.4.2. retrospective changes of entries in to fields (e.g. electronic signatures) will not be possible

5.9.4.3. have appropriate system ‘locks’ whereby when a user is in the administration screen, no further changes can be made to a prescription screen (and vice versa). This will ideally include an alert to users trying to access either screen.

5.9.5. Security access enabling personnel to record the administration of SACT on ePMA systems will only be granted to approved staff who have undertaken the appropriate training and competence assessment and are regularly reviewed in line with national or organisational polices. (e.g. UK Oncology Nursing Society (UKONS) SACT Competency Passport[24] or equivalent).

5.9.6. Separate appropriate security access may also be required and granted for staff responsible for supplying oral SACT to the patient.

5.9.7. There will be a process in place to ensure that the patient has consented to treatment before administration goes ahead. This step will be recorded within the system.

5.9.8. There will be a process in place to ensure that the patient is fit for treatment before administration goes ahead. This step will be recorded within the system. Separate appropriate security access may be required for this stage.

5.9.9. There will be a process in place within the organisation to record toxicity review and assessment of the patient at each cycle.

5.9.10. There will be processes in place within the organisation to record actual infusion rate (start and stop times). This step will be recorded within the system.

5.9.11. There will be processes in place within the organisation to record infusion reactions. This step would ideally be recorded within the system.

5.10. Patient Specific Prescription Changes

5.10.1. When a treatment is deferred this is reflected clearly in the ePMA system, and subsequent cycle dates reviewed. The reason will be recorded and auditable within the system.

5.10.2. When a treatment is cancelled, this is reflected clearly in the ePMA system. The reason will be recorded and auditable within the system. Patients will not have treatment allocated where there is no intention for it to be given.

5.10.3. The ePMA system will have a robust system in place to warn or alert the prescriber if the previous cycle was not administered as prescribed.

5.10.4. Where a dose modification within a protocol is required for a patient there will be the option to carry out the dose modification for that cycle, or subsequent cycles. Where subsequent cycles have been selected this will be carried through to all subsequent cycles for that patient. This will be fully auditable within the system and a reason documented within the system for the dose change.

5.10.5. Any changes made to a prescription will be clearly visible at the point of prescribing and clinically checking. The documented reasons will be easily accessible to subsequent users. i.e. items removed / dose changes / additions

5.11. Security

5.11.1. Levels of access or security will be determined and applied to different staff groups and/or individuals according to their professional roles and responsibilities and restricted to those who have undertaken appropriate training and competency assessment. The level of access will be regularly reviewed in line with organisational polices.

5.11.2. Certain identified staff (e.g. super-users) may require a higher level of access. Where this higher level of access allows additional access to the system outside of their role, there will be monitoring systems in place to ensure that staff do not work outside their role within the system. This will be

audited regularly at a frequency that is commensurate with the organisational risk and defined by organisational policy.

5.11.3. Restrictions will be in place for some prescriptions (e.g. intrathecal chemotherapy, ATMPs and clinical trials). These restrictions are recommended to be within the electronic system as well as within the organisation processes.

5.11.4. Regimens will only be made available for use at sites to which they are authorised to be used.

5.11.5. There will be an organisational process in place to ensure there is at least a six monthly review of all users within the system to ensure appropriateness of access.

5.11.6. There will be an organisational process in place to ensure that users have their access removed once they leave the post that requires them to have access or if their competencies expire.

5.11.7. The system will automatically lock out a user after a period of non-use. The period of non-use will be defined based on organisational policies e.g. account not used for a specified period of time.

5.12. Monitoring

5.12.1. Errors detected at all stages of the electronic prescribing and administration process will be recorded and closely monitored as part of standard organisational practice (e.g. incident reporting systems etc.). Trends or isolated incidents encountered may require swift action to prevent recurrences including system changes, re-training, re-configuration of regimen set-up and notification to system providers to implement changes to improve patient safety. There will be a SOP to cover this.

5.12.2. Errors related to SACT which are due or partly due to ePMA systems will be reported within the organisation. It is recommended that this is monitored nationally to assess for trends. This can be done by existing mechanisms in place. e.g. system user groups, national Datix group etc

5.12.3. Establish key performance indicators (KPI) to monitor ePMA system effectiveness to drive continuous improvements. KPI's should be agreed locally.

5.12.4. Any errors will be shared with the supplier. Appropriate clinical risk management should be applied with appropriate risk mitigation identified [5,6].

6. System Governance and Policies

6.1. At all times the recommendations outlined in DCB0160 and DCB0129 will be followed in England[5,6]. During systems implementation a Hazard Log will be produced with the supplier, to identify, document and share any hazards that may be specific to the ePMA system and hospitals implementation of the ePMA system. The relevant organisational governance committees will be involved. e.g. Medicines Safety Committee.

6.2. Develop local SOPs for system set up and system use. Many of the suppliers will have templates or examples for local adaptation. Where any "workarounds" are being carried out, these should be documented, as well as deviations from the suppliers recommended usage of the ePMA system.

6.3. In England, robust procedures will be in place in accordance with DCB0129[6] (for suppliers) and DCB160[5] (healthcare organisations) for accepting new updates and deployments of the ePMA system. This will include a Clinical Safety Case Report and an updated Hazard Log.

6.4. An overarching organisational policy detailing the roles and responsibilities of the various multidisciplinary teams and the glossary for key terms used in the system will be available.

6.5. Develop policies for requesting new regimens or changing existing regimens. This may be incorporated within a current medicines policy. It will include a process for approval and sign-off time-scales.

6.6. Develop procedures for validating new regimens.

6.7. Develop procedures for administering the changes to validated regimens (e.g. implementing standard product descriptions).

6.8. Develop procedures for users to report faults or seek training and support. A local user group will be established.

6.9. A change control process will be in place to ensure that any changes made to existing regimens and other system configurations are undertaken with appropriate documentation. The change control process will include, where appropriate in England, a risk assessment in accordance with DCB0160 and aligned with wider change control processes within the organisation.

6.10. Changes or additions to processes will be communicated to the appropriate personnel.

6.11. All engagement in the system will be logged by the system (auditable) and reportable.

6.12. Suppliers will hold regular user groups to facilitate learning between purchasers and prioritise system developments.

7. Business Continuity

7.1. Procedures for scheduled downtime, business continuity and disaster recovery will be in place and regularly reviewed. They will:

7.1.1. Cover the event of loss of internet, loss of intranet, loss of only the ePMA system, loss of all systems (including pathology) and loss of all computers (i.e cannot turn them on).

7.1.2. Contain a template risk assessment which considers planned, unplanned and short, medium and long term downtime. The risk assessment will be carried out to determine whether to switch to shadow server, suspend treatment, continue on paper or other. The risk assessment will take into account expected down time, safety of patients (such as access to past dose changes).

7.1.3. Ensure that any decisions made are reviewed periodically throughout downtime.

7.1.4. Link with the organisations overarching BCP including the major incident response team and other clinical IT systems (e.g. pathology etc.).

7.1.5. Be routinely exercised including recovery from backups and ensuring validity of any pdf copies.

7.2. In the event that paper prescriptions need to be used:

7.2.1. Consider how to obtain the last prescription given/next prescription planned and access to information such as dose changes or toxicity. Consider the use of paper or pdf copies of the patients most recent prescription (such as an accurate paper (PDF) record available with time stamp of when PDF was generated) on a standalone computer at each site.

7.2.2. Consider where paper templates will be obtained from. Consider SACT protocol templates of all validated regimens with the validation record (name and time stamp) available at each site. This would ideally be automatically produced from the ePMA system at the point of regimen validation. Consider how version control would be managed.

7.3. Suppliers will work with the health organisation to provide technical measures to facilitate business continuity plans. This will align with the organisation processes for clinical IT systems.

8. Specific geographical needs

8.1. In England it is mandatory for NHS trusts to:

- submit data to the SACT dataset
- use national dose banding tables
- use national product specifications.

These should be taken into account when purchasing an ePMA solution.

8.2. In Wales there is a key performance indicator (KPI) for all NHS trusts to use the NHS England national dose banding table.

9. Glossary of Terms

ATMP	Advanced therapy medicinal products i.e. CART-T therapy etc.
AUC	Area Under Curve
BCP	Business Continuity Plan
BOPA	British Oncology Pharmacy Association
BSA	Body Surface Area
Cancer Pharmacist	A pharmacist who has undergone appropriate training within cancer care
dm+d	Dictionary of Medicines and Devices
DPD	Dihydropyrimidine dehydrogenase
GCP	Good Clinical Practice
GFR	Glomerular Filtration Rate
ICD	International Classification of Diseases
ISB	Information Standards Board
KPI	Key performance indicator
NMP	Non medical prescriber
Off label	A medicine that is being used for a specific treatment that is outside of its stated product licence within the UK
OPCS	Office of Population Censuses and Surveys
PAS	Patient administration system
Protocol	Document containing all relevant information for the safe prescribing and administration of a regimen
Regimen	A researched named combination of medicines for a specific Cancer
SACT	Systemic Anti-Cancer Therapy. To include all therapies that can be used to treat cancer. i.e. chemotherapy, monoclonal antibodies, TKIs, ATMPs etc.
SOP	Standing Operating Procedure
Unlicensed	A medicine not licensed within the UK

10. Useful Resources

User groups and discussion forums are a valuable resource and participation in them is strongly encouraged.

The eprescribing Toolkit for the NHS is a useful resource to support NHS hospitals to plan, implement and use e-prescribing systems. http://www.eprescribingtoolkit.com

Implementing an electronic prescribing and medicines administration system: a good practice guide. NHS Scotland. http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/electronic_prescribing/good_practice_guide.aspx

National Guidelines for On-Screen Display of Medicines Information. Australian Commission on Safety and Quality in Healthcare (2017). https://www.safetyandquality.gov.au/wp-content/uploads/2018/01/National-guidelines-for-on-screen-display-of-medicines-information.pdf.

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13. Consultation

The following groups were consulted prior to publication of version 3.0.

Suppliers of SACT electronic prescribing systems:

- CIS, EPIC, Mosaiq, Varian, iQ Health Tech, WellSky, Meditech and Cerner.

Devolved nations:

- A representation from Wales, Scotland, England and Northern Ireland

Technical Services:

- A Quality Assurance Specialist Pharmacist from England

UK Chemotherapy Board Member Organisations:

- The Royal College of Radiologists (RCR),
- The Royal College of Physicians (RCP),
- The Association of Cancer Physicians (ACP),
- Royal College of Pathologists (RCPath),
- British Oncology Pharmacy Association (BOPA)
- UK Oncology Nursing Society (UKONS)

If you have any further questions, please do not hesitate to contact Netty Cracknell Lead Author to the standards.

14. Document Control

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Draft	Date	Lead Author/Editor	Summary of Change
1.0	23.04.2019	Netty Cracknell	Updates to all sections. Full review of version 1.0
2.0	09.01.2020	Netty Cracknell	Addition of section 9.0 statement
3.0	04.02.2022	Netty Cracknell	Full review and convert to UKCB standards

Proposed Target Audience	Members of the UK Chemotherapy Board Chief Pharmacists NHS Scotland Boards Directors of Pharmacy National procurement leads NHS England Specialised Commissioning Cancer Pharmacists Organisation Heads of IT Organisation CIOs Organisation Heads of Chemotherapy/SACT Services
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