VALIDATION OF MINOR AMENDMENTS TO ADULT & PAEDIATRIC REGIMENS IN ARIA

Objective

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure to be followed when applying minor amendments or updates to chemotherapy or other SACT regimens (referred to as chemotherapy regimens) and symptom management plans (referred to as support regimens) in the ARIA electronic prescribing system (referred to as ARIA). All chemotherapy and support regimens will be built in the ARIA Planner app, then tested and validated in the Planner and Manager apps.

Scope

This SOP ONLY applies to the validation of changes to adult and paediatric chemotherapy and support regimens, where such changes fall in to the stated sections of **KMCCEP023 Building & Validating Adult & Paediatric Chemotherapy Regimens and Symptom Management (Support) Plans** as listed in the Build SOP ref column of the checklist. All other changes should be validated using the full validation process as outlined on the ARIA regimen validation SOP. This SOP does not address minor amendments to clinical trial regimens.

Responsibilities

- The ARIA system administrator is responsible for allocating and overseeing the building and validation of all chemotherapy and support regimens in ARIA as stated in **KMCCEP001 Aria Regimen Building and Validation Process Following Protocol Approval**. The validation of chemotherapy regimens must always be carried out by someone other than the person who built the regimen on ARIA Planner.
- The following checklist should be completed by the authorised technician or pharmacist who makes the changes to the regimen on ARIA and the changes validated by a second authorised pharmacist.

Method

- Reference should be made to the latest **KMCCEP023 Building & Validating Adult & paediatric Chemotherapy Regimens and Symptom Management (Support) Plans**.
- Requests for amendments should be made by the relevant NOG or following an update to a K&M SACT protocol then submitted to the system administrator. In exceptional circumstances, there may be instances where a regimen is copied as a support regimen and this SOP should also be used to document that process.
- The amendment should be checked both in Planner and Manager, as outlined below.
- When testing the amendments in Manager, the test patient from the original validation should be used. The regimen can be discontinued and re-prescribed but orders from the previous regimen should never be amended, deleted or errored.
- When updating an approved regimen, if Amendments Mandatory is ticked on the current Approved regimen, the regimen **MUST** be copied then re-built to remove this tick and **NOT** amended. If the changes to the copied regimen meet the criteria of a minor amendment then this SOP may be followed.

Regimen name		**Regimen version**		**Regimen Date***	Regimen Date
Copied regimen name (if applicable)		**Regimen version**		**Regimen Date***	Regimen Date
Test patient name from full validation		**CCF number and/or KMCC protocol version**		**Build SOP version**	

*** Regimen date should be the date the regimen was first created. This can be found in the Modify Plan window – Definition tab. Click on the Audit symbol and enter the created date.**

Build SOP ref	DESCRIPTION OF CHANGE (state details of change made in the box)	Tick if completed
PLANNER CHECKS		
DEFINITION (MODIFY PLAN)		
1.1.1	**Amendment to the plan name (only for copied regimens)**	✘
1.1.3	**Amendment to the display name**	✘
1.1.10	**'Amendments Mandatory' box must NOT be ticked** **Check and action on ALL regimens**	✘
1.2.3	**Change to Classification type box** If copying a regimen to make a support regimen, remove disease site and cancer categories and add in appropriate 'Problem'	✘
1.4	**Change to Authorized Users**	✘
MODIFY PHASE		
2.14	**Description Box:** If text is present it should be deleted	✘
2.3	**Phase Name:** Complete only for support regimens	✘
2.6	**Change to modality**	✘
2.10	**Change number of cycles** Regimens with cyclical agents only. Amend / check under modify phase.	✘
PRINT EVENT LIST IF A CHANGE HAS BEEN MADE TO THE NUMBER OF CYCLES		
MODIFY AGENTS		
4.1.16–4.1.18	**Changes to the diluent details within Details Tab** Including diluent, infusion mode, volume, duration and rate.	✘
4.2	**Change to the free text within the Admin tab.** Ensure no additional changes to the Details tab or Schedule Events are required as a result of this change.	✘

PLAN SUMMARY		
9	**Change to the free text within the Plan Summary** Ensure no additional changes to the Details tab or Schedule Events are required as a result of this change.	✘

MANAGER CHECKS (Validating pharmacist only)

LOG INTO ARIA MANAGER AT "TEST LOCATION - OUTPATIENT" FOR ADULT REGIMENS OR TWH Paed – TEST LOCATION FOR PAEDIATRIC REGIMENS AND CREATE OR SELECT THE APPROPRIATE TEST PATIENT. OPEN THE MEDICATIONS WINDOW BY CLICKING ON THE "Rx" ICON ON THE TOOLBAR. SELECT THE RELEVANT CANCER DISEASE SITE FOR THE REGIMEN THAT YOU WILL BE TESTING. HIGHLIGHT THEN ORDER YOUR REGIMEN FOR THE TEST PATIENT

- Are all the agents still in the correct administration sequence as shown in Planner? For regimens with more than one scheduled treatment day, all 'Internal' agents are listed first, followed by all 'Pickup - Internal' agents.
- Are all the agents correct in terms of routes of administration, diluents, infusion volumes and durations?
- For each agent click on the Administration Instructions box and check that the administration instructions are correct

TAKE A SCREENSHOT OF THE CHANGE

Errors detected requiring correction (list test numbers) and errors found that were not covered in Checklist procedure:

Builder (Print Name)		**Signed**	
Designation		Date	
I CONFIRM THAT THE REGIMEN HAS PASSED ALL REQUIRED TESTS			
Validated by (Print Name)		**Signed**	
Designation		Date	