CMN type	CMN sub-type	Observation	Proposed change	Rationale
Formulation	Formulation grade 1	A minor change in formulation requires an assessable CMN	Propose to consider a SACMN for minor changes in formulation such as change to imprint ink, colouring agent, flavour or fragrance	Aligns with TGA 9D notification type DFCI, DFFC
Formulation	Formulation Grade 1	The types of excipient change which fall under this category are unclear	Propose to update the guidelines to provide more information about excipient changes	Clarification for sponsors
Formulation	Formulation - Grade 1	Currently to increase or decrease or remove overage is an assessable change	Overage decreased or removed to be self assessable	To decrease/remove an overage based on stability data results can be assessed by the sponsor. This change is considered a Notification with the TGA.
Active ingredient	Active Ingredient Manufacturing site	Medsafe requires an assessable submission to capture change for Type 1 medicines	Make self assessable	No submission is required for this change with the TGA.
Active ingredient	Active ingredient manufacturing process Grade 3	Change in batch size currently assessable CMN	Propose to allow change of batch size of non sterile API to SACMN	Aligns with TGA 9D notification type AMBS
Active ingredient	Active ingredient manufacturing process - grade 3	TGA allows certain changes to API manufacturing process to be notifiable, e.g. not more than 10x increase in batch size for non-sterile API, decrease retest period etc.	To change to SACN for certain scenarios	TGA has classified this as notification (with conditions)
Active ingredient	Specifications/test methods - grade 1	Narrowing of specification limits	Change this to a Notification only	TGA do not require notficiation for specification tightening

Active ingredient	Specifications/test methods - grade 3 & 4	TGA allows certain changes to API specification and test methods to be notifiable, e.g. changes to identification tests, non-biological assay test, physiochemical test methods and limits	To change to SACN for certain scenarios	TGA has classified this as notification (with conditions)
Active ingredient	Acive ingredient manufacturing process Grade 1	Certificate of Suitability can be updated without manufacturing process	Updated Certificate of Suitability' bullet point to be removed. To be clarified by Medsafe as non-assessable notification.	The current form indicates all updates to CEPs should be submitted as CMN in this Grade. CEPs show compliance to Ph. Eur. and therefore updates shouldn't require a submission.
Excipient	Excipient specifications/test methods - Grade 1	Is a CMN actually required for a change in monograph for an excipient	Change this to a Notification only	Solely changing control from one pharmacopoeia to another for an excipient shouldn't require any assessment by Medsafe
Excipient	Specifications/test methods - grade 2 & 3	TGA allows certain excipient changes to be notifiable, e.g. new test and limit not consequential of a mfg process change, change from in-house to pharmacopoeia for certain tests etc.	To change to SACN for certain scenarios	TGA has classified this as notification (with conditions)
Excipient	Excipient specifications/test methods - Grade 2	Narrowing of specification limits	Change this to a Notification only	TGA do not require notficiation for specification tightening
Finished product	Finished product packing site – Grade 1	Currently an assessable CMN is required for secondary packing and overlabelling sites	Make it SACMN for all changes (or minimum for situations where the packing site is in NZ and has a	TGA has classified this as notification (with conditions)- for non-sterile primary packing and secondary packing for all dosge forms. If there is a Medsafe issued packing licence further

			Medsafe issued packing licence)	evaluation by Medsafe should not be required.
Finished product	Finished product packing site grade 2	A new finished product testing site is an assessable CMN	Consider a SACMN if change meets certain criteria	Aligns with TGA 9D notification type DMTR
Finished product	Finished product packing site Grade 2	Includes addition of finished product testing site not easy to locate for testing site addition only. Also unclear which grade to choose for changes to other steps of manufacture eg micronisation	Either have a separate category or change title of change to include testing site, micronisation etc	Clarification for sponsors
Finished product	Manufacturing process - grade 1	TGA allows certain FP mfg process for non-modified release dose forms changes to be notifiable, e.g. batch size, method and equipment, IPC test and limits, etc	To change to SACN for certain scenarios	Aligns with TGA 9D notification type DMEL, DMBS, DMEO, DMES, DMSE
Finished product	Finished product manufacturing process - Grade 1	There are some instances where the manufacturing site will change but there is no change to the manufacturing method.	Require a separate category for FP manufacturing site change only with lower fee	
Finished product	Finished product specifications/test methods - Grade 2	Narrowing of specification limits	Change this to a Notification only	TGA do not require notficiation for specification tightening

Finished product	Finished product specifications/test methods - Grade 3	Currently is self assessable	Change this to a Notification only	Addition of extra tests for a product otherwise controlled by a pharmacopoeia does not require a submission with the TGA
Finished product	Finished product specifications / test method - Grade 5	All changes are assessble	Specifications or test methods changes to be self assessable, where the analytical performance (accuracy, precision and/or specificity) has been demonstrated to improve.	This is consistent with TGA. Where this prerequisite is not met, current submission pathway should remain.
Product stability and packaging	Container/Closure/Packaging - Grade 2	Minor changes to packaging which don't touch product are assessable	Make new SACMN grade for minor changes to packaging eg removal of measuring device	Aligns with TGA 9D notification type CCCA
Product stability and packaging	Shelf-life/storage conditions Grade 2	Decrease in shelf-life is assessable CMN	Add new SACMN category for reduction of shelflife for commercial reasons	Aligns with TGA 9D notification type DSLD. This commonly may be done to harmonise product with another market for example.
Product stability and packaging	Container/closure/packaging - Grade 2	No self-assessable changes where container material or closure is considered to be no less permaeable or provide same level of protection as current material	Make this self-assessable	TGA has classified this as notification for solid dose forms in specific types of packaging
Indications and dosage	Contraindications, Warnings and Precautions	Excessive fee for multi-source medicine, wanting to relax CI/warnings to match the innovator	A new Grade, with lower fee, for multi-source medicine to match CI/warnings approved for innovator product, where changes do not meet SACN.	Supporting clinical data could only be the innovator source document and Medsafe assessment would not be as extensive as required for innovator product.

Other	Sponsor	$360 charged for each product (TT50)	A scale of fee depending on the number of affected products.	Fee seems exccessive, especially if a huge number of products are involved with a portfolio/company acquisition.
Other	Change in ownership	Type of submission and fee considered excessive	CMN to SACN ($360) or revert back to notification only	This was previously a non-assessable 'notification' change. The admin work for updating Medsafe database for Sponsor (SACN $360) and Ownership changes would be similar