

**APPLICATION FOR
CHANGE TO THE CLASSIFICATION SYSTEM (SCUNQ*)**
(*Standard Classification of Units and National Qualifications)

SSB	PaMPITO	CONTACT	Matiu Payne, Quality Systems Manager
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DATE	9 October 2009	FIELD	Manufacturing > Pharmaceutical and Allied Products
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Domains

Add new domain	✓	New domain name		
		Good Manufacturing Practices		
Designate existing domain <i>Lapsing</i>	✓	Existing domain name		
		Pharmaceutical and Allied Products Manufacturing	To be replaced	✓
		Pharmaceutical and Allied Products Quality Assurance	To be replaced	✓
Replacement relationships	✓	From	To	
		Pharmaceutical and Allied Products Manufacturing	Good Manufacturing Practices	
		Pharmaceutical and Allied Products Quality Assurance	Good Manufacturing Practices	

Rationale for the new or changed classification

"Good Manufacturing Practices" or "GMP" is a term that is recognized worldwide for the control and management of manufacturing and quality control of foods, pharmaceutical products, and medical devices. GMPs are guidelines that outline the aspects of production that would affect the quality of a product. Many countries have legislated that pharmaceutical and medical device companies must follow GMP procedures, and have created their own GMP guidelines that correspond with their legislation.

The New Zealand Pharmaceutical and Allied Products industry is constantly audited against GMP systems to ensure compliance.

Good Manufacturing Practices is a name that better reflects the unit standards in the two current Pharmaceutical and Allied Products domains. This new GMP domain will continue to sit beneath the Pharmaceutical and Allied Products sub-field so it will be clearly distinguished as belonging to this industry.

Industry representatives have mentioned that this domain should have been called Good Manufacturing Practices from its inception yet it was lost in translation to the National Qualifications Framework.

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A change in the name of this domain and ultimately the parent qualifications will lead to an increased uptake by industry of the unit standards and qualifications related to it.

Please provide a brief rationale for the addition or change. For example, a new category of learning or training has been identified; industry terminology has changed; rationalisation or expansion of existing classification categories is required.

For a new classification, list the draft titles of the new unit standards that will be classified in each new domain (or attach the list to this form)

No new unit standards will be included in this new domain name.

SECTION 2

Impact of the change on existing unit standards, accreditations, and qualifications

Please complete the three impact sections below or attach a completed draft of the [unit standard review or revision report](#). A unit standard [review support package](#) may be needed for this process.

Impact on existing unit standards

List the registered unit standards affected by the change to the classification system.

Existing classification

Subfield	Domain	Id
Pharmaceutical and Allied Products	Pharmaceutical and Allied Products Manufacturing	21074-21077, 21364-21371, 21943-21945
	Pharmaceutical and Allied Products Quality Assurance	21071-3, 21361-3

New classification

Subfield	Domain	Id
Pharmaceutical and Allied Products	Good Manufacturing Practices	21071-21077, 21361-21371, 21943-21945

Impact on existing provider accreditations

List the domains and/or subfields for which providers currently hold accreditation and indicate how accreditation will be extended to take account of the change to the classification system.

Current Accreditation for			Accreditation will be extended to		
Nature of accreditation	Classification	Level	Nature of accreditation	Classification	Level
Subfield	Pharmaceutical and Allied Products	2	Subfield	Pharmaceutical and Allied Products	2

Impact on existing qualifications

List the registered qualifications that contain a changed classification (domain or subfield) in an elective set.

Qualification title	Subfield or Domain

Other comments

This is a minor technical amendment to this portion of the NQF. It is necessary to better reflect industry terminology and the original intention for the name of the domain.

We have consulted with and been given consent by industry for this domain change as part of a wider qualification consultation round throughout June – October 2009.

The National Certificates in Pharmaceutical and Allied Products Levels 1 and 2 [Refs: 1233, 1234] are currently under review and will be renamed to suit this change in classification. The name change will lead to increased usage by industry, and this has been confirmed in the industry consultation phase.

(Optional)