Australian Government

Department of Health

Therapeutic Goods Administration

Prescription medicine clinical units

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TGA Health Safety Regulation

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Introduction

This guidance is for sponsors of prescription medicines.

Our prescription medicine evaluators are organised into units based on the therapeutic indications of the medicines they evaluate. We have five prescription medicine clinical units (PMCUs).

Prescription medicine clinical unit 1

Analgesia

Neurological disorders

- migraine
- muscle relaxants
- insomnia
- disorders of the inner ear

Excludes:

- cerebrovascular disorders (PMCU 3)

Psychiatric/Psychological/Behavioural disorders

- addiction
- insomnia
- disorders of libido not due to hormonal deficiency

Excludes:

- disorders of libido due to hormonal deficiency (PMCU 5)

Anaesthesia

- general anaesthesia
- local anaesthesia
- muscle relaxants

Gastrointestinal disorders

- pancreatic exocrine enzyme deficiency
- vomiting
- combination products (antibiotic + anti-ulcer) for *Helicobacter pylori*

Excludes:

- vomiting induced by chemotherapy (PMCU 4)

Poisoning

- Opioid antagonists

Nutrition

- Vitamins
- parenteral and enteral nutrition

Disorders of the mouth

- topical oral preparations
- dental products (including local anaesthetics for dentistry)

Excludes:

- topical oral anti-infective agents (PMCU 2)

Disorders of the skin

- topical therapies
- topical anaesthetics for use on skin
- systemic therapies

Excludes:

- topical skin anti-infective agents (PMCU 2)

Prescription medicine clinical unit 2

Infectious diseases

- antibacterials
- antivirals
- antirickettsials
- antifungals
- antiparasitics
- anthelmintics
- topical anti-infectives (e.g. skin, eye, ear)

Excludes:

- combination products (antibiotic+anti-ulcer) for H. pylori (PMCU 1)

Vaccination against infectious diseases

- Human papillomavirus vaccines (HPV) for prevention of cervical cancer

Immunological disorders

- immunosuppression following organ transplantation
- chronic fatigue syndrome
- systemic sclerosis

Excludes:

- autoimmune disorders are allocated according to body system

Other

- radiological agents (e.g. contrast media)
- adjuncts to radiopharmaceuticals and contrast media use
- diagnostic tests for infections
- allergens (diagnostic or therapeutic)
- antivenenes
- radiopharmaceuticals for cancer (diagnostic)

Prescription medicine clinical unit 3

Cardiac disorders

Lipid disorders

Inherited metabolic disorders

Vascular disorders

- cerebrovascular disease
- hypertension
- pulmonary Hypertension
- Deep Venous Thrombosis (DVT)/pulmonary embolus
- surgical haemostasis (non-plasma products)

Excludes:

- surgical haemostasis (plasma products – PMCU 4)

Musculoskeletal disorders

- disorders of joints, muscle
- disorders of bone
- drug/device combinations for non-union of fractures

Excludes:

- muscle relaxants (PMCU 1)
- osteoporosis (PMCU 5)
- Paget's disease of bone (PMCU 5)

Disorders of the male reproductive system

- erectile dysfunction
- benign prostatic hypertrophy

Excludes:

- infertility (PMCU 5)
- disorders of libido (PMCU 1)

Renal & urinary tract disorders

Excludes:

- dialysis solutions (PMCU 5)

Disorders of the ear

- topical otic preparations

Excludes:

- topical otic anti-infective preparations (PMCU 2)
- disorders of the inner ear (e.g. Meniere's disease – PMCU 1)

Poisoning

- heavy metal poisoning
- cyanide poisoning

Excludes:

- antivenenes (PMCU 2)

Prescription medicine clinical unit 4

Neoplastic disorders

Includes:

- solid tumour oncology
- hormonal effects of functioning carcinoid neoplasms
- radiopharmaceuticals for solid tumours (therapeutic)

Excludes:

- haematological malignancies (PMCU6)
- hormonal effects of other functioning neoplasms (e.g. pituitary, thyroid, adrenal - PMCU 5)
- HPV vaccines for prevention of cervical cancer (PMCU 2)

Prescription medicine clinical unit 5

Contraception

Infertility

Obesity

Osteoporosis

Paget's disease of bone

Endocrine disorders

- disorders of libido due to hormonal deficiency

Excludes:

- hormonal effects of functioning carcinoid neoplasms (PMCU 4)
- disorders of libido not due to hormonal deficiency (PMCU 1)

Disorders of the female reproductive system

- endometriosis

Pregnancy and labour

- post-partum haemorrhage

Fluid & electrolyte disorders

- hypovolaemia/shock
- dialysis solutions

Excludes:

- hypercalcaemia of malignancy (PMCU 4)
- cardioplegia solutions (PMCU 3)

Disorders of the eye

Excludes:

- topical ocular anti-infective agents (PMCU 2)

Respiratory disorders

Excludes:

- pulmonary hypertension (PMCU 3)

Disorders of the nose, paranasal sinuses and upper airway

Excludes:

- topical nasal anti-infective agents (PMCU 2)

Prescription medicine clinical unit 6

Haematological disorders, including haematological malignancies

Includes:

- radiopharmaceuticals for haematological malignancies (therapeutic)

Other

- surgical haemostasis (plasma products)

Excludes:

- surgical haemostasis (non-plasma products - PMCU 3)
- vascular thrombosis (PMCU 3)

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication Title: Guidance 4: Prescription medicine clinical units (PMCU) – previously ARGPM Appendix 4: Drug safety and evaluation branch clinical evaluation sections	Office of Medicines Authorisation	12/07/2013
V2.0	Update to reflect change in clinical unit structure Title has been shortened.	Prescription Medicines Authorisation Branch with the Regulatory Guidance Team	April 2016
V2.1	Update to the six clinical evaluation streams and the functions each unit provides	Prescription Medicines Authorisation Branch	August 2017

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