

**ARGPM Appendix 4: Drug safety and evaluation branch clinical evaluation sections**

Clinical eval. section 1	Clinical eval. section 2	Clinical eval. section 3	Clinical eval. section 4	Clinical eval. Section 5
<p><b>1) Neurological Disorders</b></p> <ul style="list-style-type: none"> <li>- Migraine, muscle relaxants,</li> <li>- Insomnia, disorders of the inner ear</li> </ul> <p>Excludes: Cerebrovascular disorders (CES 3)</p> <p><b>2) Psychiatric/Psychological/ Behavioural Disorders</b></p> <ul style="list-style-type: none"> <li>- Addiction, insomnia</li> <li>- Disorders of libido not due to hormonal deficiency</li> </ul> <p>Excludes: Disorders of libido due to hormonal deficiency (CES 5)</p> <p><b>3) Anaesthesia</b></p> <ul style="list-style-type: none"> <li>- General anaesthesia</li> <li>- Local anaesthesia</li> <li>- Muscle relaxants</li> </ul> <p>Excludes: Local anaesthetics for dentistry (CES 4); Topical local anaesthesia e.g. skin, eye (CES 5)</p> <p><b>4) Analgesia</b></p> <p><b>5) Gastrointestinal Disorders</b></p> <ul style="list-style-type: none"> <li>- Pancreatic exocrine enzyme deficiency</li> <li>- Vomiting</li> <li>- Combination products (antibiotic + anti-ulcer) for <i>H. Pylori</i></li> </ul> <p>Excludes: Vomiting induced by chemotherapy (CES 4)</p> <p><b>6) Nutrition</b></p> <ul style="list-style-type: none"> <li>- Vitamins</li> <li>- Parenteral and enteral nutrition</li> </ul>	<p><b>1) Infectious Diseases</b></p> <ul style="list-style-type: none"> <li>- Antibacterials</li> <li>- Antivirals</li> <li>- Antirickettsials</li> <li>- Antifungals</li> <li>- Antiparasitics</li> <li>- Anthelmintics</li> <li>- Topical anti-infectives (eg skin, eye, ear)</li> </ul> <p>Excludes: Combination products (antibiotic+anti-ulcer) for <i>H. Pylori</i> (CES 1)</p> <p><b>2) Vaccination against Infectious Diseases</b></p> <ul style="list-style-type: none"> <li>- HPV vaccines for prevention of cervical cancer</li> </ul> <p><b>3) Immunological Disorders</b></p> <ul style="list-style-type: none"> <li>- Immunosuppression following organ transplantation</li> <li>- Chronic fatigue syndrome</li> <li>- Systemic sclerosis</li> </ul> <p>Excludes: Autoimmune disorders are allocated according to body system.</p> <p><b>4) Other</b></p> <ul style="list-style-type: none"> <li>- Radiological agents (eg contrast media)</li> <li>- Radiopharmaceuticals (diagnostic or therapeutic)</li> <li>- Adjuncts to radiopharmaceuticals and contrast media use</li> <li>- Diagnostic tests for infections</li> <li>- Allergens (diagnostic or therapeutic)</li> <li>- Antivenenes</li> </ul>	<p><b>1) Vascular Disorders</b></p> <ul style="list-style-type: none"> <li>- Cerebrovascular disease</li> <li>- Hypertension</li> <li>- Pulmonary Hypertension</li> <li>- DVT/Pulmonary embolus</li> <li>- Surgical haemostasis (non-plasma products)</li> </ul> <p>Excludes: Surgical haemostasis (plasma products – CES 4)</p> <p><b>2) Cardiac Disorders</b></p> <p><b>3) Musculoskeletal Disorders</b></p> <ul style="list-style-type: none"> <li>- Disorders of joints, muscle</li> <li>- Disorders of bone</li> <li>- Drug/device combinations for non-union of fractures</li> </ul> <p>Excludes: Muscle relaxants (CES 1); Osteoporosis (CES 5); Paget's disease of bone (CES 5)</p> <p><b>4) Disorders of the Male Reproductive System</b></p> <ul style="list-style-type: none"> <li>- Erectile dysfunction</li> <li>- Benign Prostatic Hypertrophy</li> </ul> <p>Excludes: Infertility (CES 5); Disorders of libido (CES 1)</p> <p><b>5) Renal &amp; Urinary Tract Disorders</b></p> <p>Excludes: dialysis solutions (CES 5)</p> <p><b>6) Lipid Disorders</b></p> <p><b>7) Disorders of the Ear</b></p> <ul style="list-style-type: none"> <li>- Topical otic preparations</li> </ul> <p>Excludes: Topical otic anti-infective preparations (CES 2); Disorders of the inner ear (eg Meniere's disease – CES 1)</p> <p><b>8) Poisoning</b></p> <ul style="list-style-type: none"> <li>- Heavy metal poisoning</li> <li>- Cyanide poisoning</li> <li>- Opioid antagonists</li> </ul> <p>Excludes: Antivenenes (CES 2)</p> <p><b>9) Inherited Metabolic Disorders</b></p>	<p><b>1) Neoplastic Disorders</b></p> <ul style="list-style-type: none"> <li>- Hormonal effects of functioning carcinoid neoplasms</li> </ul> <p>Excludes: Hormonal effects of other functioning neoplasms (eg pituitary, thyroid, adrenal – CES 5); HPV vaccines for prevention of cervical cancer (CES 2)</p> <p><b>2) Haematological Disorders</b></p> <ul style="list-style-type: none"> <li>- Surgical haemostasis (plasma products)</li> </ul> <p>Excludes: Surgical haemostasis (non-plasma products – CES 3); Vascular thrombosis (CES 3)</p> <p><b>3) Disorders of the Skin</b></p> <ul style="list-style-type: none"> <li>- Systemic therapies</li> </ul> <p>Excludes: Topical therapies (CES 5); Topical skin anti-infective agents (CES 2)</p> <p><b>4) Disorders of the Mouth</b></p> <ul style="list-style-type: none"> <li>- Topical oral preparations</li> <li>- Dental Products (including local anaesthetics for dentistry)</li> </ul> <p>Excludes: Topical oral anti-infective agents (CES 2); Systemic therapies for mouth disorders (CES 1)</p>	<p><b>1) Endocrine Disorders</b></p> <ul style="list-style-type: none"> <li>- Disorders of libido due to hormonal deficiency</li> </ul> <p>Excludes: Hormonal effects of functioning carcinoid neoplasms (CES 4); Disorders of libido not due to hormonal deficiency (CES 1)</p> <p><b>2) Disorders of the Female Reproductive System</b></p> <ul style="list-style-type: none"> <li>- Endometriosis</li> </ul> <p><b>3) Pregnancy and Labour</b></p> <ul style="list-style-type: none"> <li>- Post-partum haemorrhage</li> </ul> <p><b>4) Contraception</b></p> <p><b>5) Infertility</b></p> <p><b>6) Osteoporosis</b></p> <p><b>7) Paget's Disease of Bone</b></p> <p><b>8) Obesity</b></p> <p><b>9) Fluid &amp; Electrolyte Disorders</b></p> <ul style="list-style-type: none"> <li>- Hypovolaemia/Shock</li> <li>- Dialysis solutions</li> </ul> <p>Excludes: Hypercalcaemia of malignancy (CES 4); Cardioplegia solutions (CES 3)</p> <p><b>10) Disorders of the Eye</b></p> <p>Excludes: Topical ocular anti-infective agents (CEU 2)</p> <p><b>11) Respiratory Disorders</b></p> <p>Excludes: Pulmonary Hypertension (CES3)</p> <p><b>12) Disorders of the Nose, Paranasal Sinuses and Upper Airway</b></p> <p>Excludes: Topical nasal anti-infective agents (CES2)</p> <p><b>13) Disorders of the Skin</b></p> <ul style="list-style-type: none"> <li>- Topical therapies</li> <li>- Topical anaesthetics for use on skin</li> </ul> <p>Excludes: Systemic therapies (CES 4); Topical skin anti-infective agents (CES 2)</p>