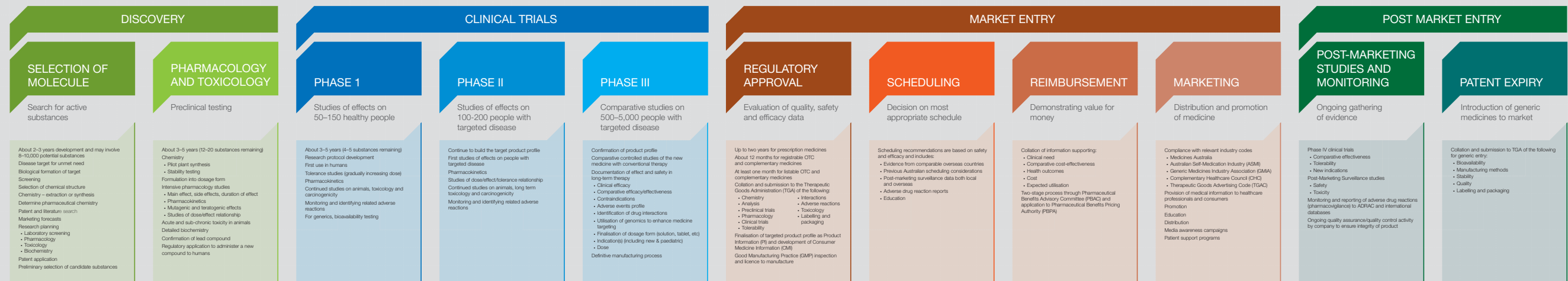


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## MEDICINES PATHWAY

In this context medicines means prescription, over-the-counter and complementary



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| <p>Selection of a novel mechanism utilising a disease pathway that has high unmet therapeutic and public health need</p> <p>Develop a target product profile that delivers safety and efficacy benefit over existing therapies</p> <p>After finding potential substances, optimise efficacy and safety profiles</p> <p>For example:</p> <ul style="list-style-type: none"> <li>Discovery of statins to reduce hypercholesterolaemia</li> <li>Discovery of atenolol eliminating serious visual side effects of practolol</li> <li>Discovery of fexofenadine, the active metabolite of terfenadine, that is not associated with adverse cardiac effects</li> <li>Development of a herbal extract with enhanced concentration of active constituents, such as proprietary St Johns Wort extracts</li> </ul> | <p>Identify lead compound with a simple and cost effective synthetic process</p> <p>Identify lead compound that has a dosage regimen conducive to maximising patient adherence</p> <p>For example:</p> <ul style="list-style-type: none"> <li>Ranitidine given twice daily vs cimetidine given five times daily</li> </ul> <p>Ensure herbal extract can be manufactured consistently from variable biological starting material</p> <p>For example:</p> <ul style="list-style-type: none"> <li>Proprietary St Johns Wort extracts</li> </ul> <p>Select generic and brand name that will maximise QUM by reducing consumer misunderstanding</p> | <p>Test that lead compound has therapeutic and pharmacokinetic profile that enables formulation to maximise convenience of dosage and administration</p> <p>For example:</p> <ul style="list-style-type: none"> <li>A liquid formulation of a drug for use in children or once daily dosage with food</li> </ul> <p>Identify evidence of safe use in humans of traditional medicines or food</p> <p>For example:</p> <ul style="list-style-type: none"> <li>Medical honey for burns</li> </ul> | <p>Choose outcome measures that are more predictive of improved health outcomes</p> <p>Consider selecting people more representative of target population</p> <p>Ensure appropriate dose finding studies are carried out so that correct clinical dose is identified early in development</p> | <p>Choose target population that best demonstrates therapeutic benefits of medicine</p> <p>Demonstrate comparative effectiveness in target population against current best practice management</p> <p>Select simplest and most cost-effective large scale manufacturing process</p> | <p>Ensure PI, CMI and labelling are clearly written and designed, consistent with QUM principles, so that health care professionals and consumers can appropriately select and use the best treatment option</p> <p>Select packaging format that optimises usability and storage</p> <p>For example:</p> <ul style="list-style-type: none"> <li>Application of consumer-focused labelling</li> <li>Dose aids such as calendar packs, counters on turbuhalers/accuhalers to assist in correct use of medicines</li> </ul> <p>Encourage regulators to facilitate timely and appropriate access for patients with high unmet medical need</p> | <p>Generate, capture and analyse evidence on clinical use and, where appropriate, use to support rescheduling</p> <p>Ensure scheduling of medicine accurately reflects the established safety and efficacy profile and improves access for target population</p> <p>Develop educational programs/ counselling aids for medicines rescheduled to OTC status</p> <p>For example:</p> <ul style="list-style-type: none"> <li>Orlistat, fluconazole</li> </ul> <p>Consider flexible scheduling according to individual consumers' knowledge and willingness to self-manage</p> | <p>PBS reimbursement application identifies appropriate place in therapy and target population, resulting in maximum cost-effectiveness of the medicine and providing best incremental health outcomes</p> <p>For example:</p> <ul style="list-style-type: none"> <li>Montelukast for asthma</li> <li>Tumour necrosis factors (TNFs) for arthritis</li> </ul> <p>Monitor use of medicines to ensure predicted cost-effectiveness is achieved in practice</p> | <p>Identify partners and processes that can assist in developing educational and information programs to support appropriate use of medicines</p> <p>Ensure the medicine reaches the right patient and is prescribed according to its position in the QUM treatment pathway</p> <p>For example:</p> <ul style="list-style-type: none"> <li>Patient support programs to improve management of conditions including adherence to treatment plan, such as weight loss programs, smoking cessation, cholesterol lowering, repeat reminders</li> <li>QUM built into industry Codes of Conduct; continual review/improvement of these documents</li> <li>Medicines Australia Continuing Education program for sales representatives</li> </ul> | <p>Include outcome measures that assist in monitoring cost-effectiveness and tolerability of medicines when used as part of "usual" practice</p> <p>Observe outcomes in post-marketing surveillance to further inform the safe, efficacious and cost-effective use of these medicines</p> <p>For example:</p> <ul style="list-style-type: none"> <li>Risk management plans for new medicines</li> <li>Appropriate and timely updating of PI and CMI</li> <li>Specific data capture for particular products and events, such as addiction</li> </ul> | <p>Intellectual property laws must be finely balanced to respect innovation while ensuring timely access to generic medicines to maintain optimal cost-effectiveness of all medicines</p> |
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Quality Use of Medicines (QUM)	1. SELECTING	2. CHOOSING	3. USING
1. SELECTING			
2. CHOOSING			
3. USING			

Intensity of shading indicates degree of contribution to QUM