

Phase	Pre-submission	Submission	First round assessment	Consolidated section 31 request response	Second round assessment	Expert advisory review	Decision	Post-decision
Milestone	MS1 Outcome of pre-submission planning sent	MS2 Outcome of submission consideration sent	MS3 Outcome of first round assessment sent	MS4 End of s.31 request response period	MS5 Outcome of assessments sent	MS6 Outcome of advisory committee sent	MS7 Decision made by delegate	MS8 Administrative and regulatory activities complete
Major activities	<p>PPF lodged before first of month</p> <p>Pre-submission planning</p>	<p>Dossier arrives at TGA by COB 7<sup>th</sup> or 14<sup>th</sup> of month (unless applicant advised of alternative date)</p> <p>Processing and considering submission</p>	<p>First round assessment</p> <p>Consolidated section 31 request compiled</p>	<p>Applicant preparation of response to section 31 request and first round assessment reports</p> <p>Response received by TGA or response period ends</p>	<p>Second round assessment</p>	<p>Advisory committee meeting</p> <p>Pre-ACPM response and review of reports</p> <p>Delegate overview</p> <p>Committee advice prepared</p> <p>Committee papers circulated</p>	<p>Delegate decision including PI/CMI/RMP negotiation</p>	<p>AusPAR C-i-C content review and PI/CMI requirements fulfilled</p> <p>Documents published, new/revised ARTG entry</p>
Regulatory requirements	<p>PPF and attachments lodged via eBS.</p> <p>Only PPFs lodged before first of month processed.</p> <p>PPFs that are not complete will be considered not acceptable.</p> <p>Applicants who have lodged complete PPFs will receive <i>Planning letter</i> outlining:</p> <ul style="list-style-type: none"> <li>- submission milestones</li> <li>- feedback from TGA on justifications or other aspects affecting application</li> <li>- any specific conditions for dossier lodgement.</li> </ul> <p>Pre-submission meetings are voluntary and not linked to PPF lodgement. They may occur at any stage prior to dossier lodgement and are recommended for complex applications or special cases.</p>	<p>Applications must be received by the TGA by COB 7<sup>th</sup> or 14<sup>th</sup> of the month unless otherwise advised in <i>Planning letter</i>.</p> <p>Applicants must certify that all information has been presented at the time of dossier lodgement. Only information requested by the TGA in a s.31 request, or safety-related data can be supplied after dossier lodgement.</p> <p>The TGA will process and consider submission dossiers against regulatory requirements. Applications not provided in accordance with regulatory requirements will be considered not effective and not accepted for evaluation.</p> <p>Applicants will receive a <i>Notification letter</i> advising whether the application has been accepted or not accepted for evaluation.</p>	<p>All dossier content is evaluated during this phase. Draft evaluation reports are prepared.</p> <p>If required, a consolidated s.31 request for information will be prepared. This includes requests from all evaluation units. This request is compiled in the final month of the phase and sent to the applicant on the date specified in the <i>Planning letter</i>.</p>	<p>Applicants nominate in the PPF whether they will respond to the request in 30 or 60 calendar days. The MS3 date is confirmed in the <i>Planning letter</i>.</p> <p>If applicants do not respond to a request for information by the date identified in the <i>Planning letter</i>, evaluators complete the evaluation based on the information provided in the dossier at dossier lodgement.</p> <p>Applicants have opportunity to review the first round assessment reports for factual content.</p>	<p>Evaluators consider the section 31 response (if applicable) and finalise the evaluation reports.</p> <p>Where evaluators identify outstanding issues, they will be presented in the evaluation reports for consideration by the delegate.</p>	<p>Where the delegate seeks independent advice on aspects of an application, the delegate prepares a request for advice letter.</p> <p>New innovator products, new indications, and complex applications will generally be referred to the ACPM.</p> <p>The applicant will have an opportunity to prepare a pre-committee response addressing issues raised in the delegate's request for advice letter.</p> <p>Applicants have an opportunity to review the second round assessment reports for factual content.</p> <p>Committee advice is finalised and sent to the applicant on the 15<sup>th</sup> of the month of the meeting.</p>	<p>The delegate will generally informally advise the applicant of the decision. Formal correspondence of the decision is sent to the applicant.</p> <p>If the delegate proposes to approve an application, prior to approval, any outstanding issues relating to PI, CMI, or RMPs may be negotiated with the applicant. Approval may be conditional on resolution of issues.</p> <p>If the delegate proposes to reject an application, the reasons for the decision are included in the letter of decision, with an explanation of appeal rights.</p>	<p>Registration of a new product or variation to a register entry completed.</p> <p>For applicable application types, a draft AusPAR will be compiled</p>