



# Compliance review process for listed medicines

We conduct compliance reviews of listed medicines that are on the market to check whether they meet regulatory requirements. The typical steps in the review process are:

<i>Review stage</i>	<i>Actions</i>
<b>Initiation</b>	<ol style="list-style-type: none"><li>1. We send a Request for Information notice requesting selected information about the medicine.</li><li>2. The sponsor supplies the requested information to us by the due date. If the sponsor does not provide a complete response by the due date, we may cancel the medicine under section 30 of the Act.</li></ol>
<b>Review</b>	<ol style="list-style-type: none"><li>1. We assess the information provided against relevant legislation.</li><li>2. If we do not find any compliance deficiencies based on the information provided, we will go to the Decision Stage.</li><li>3. If we identify compliance deficiencies, we will notify the sponsor using a regulatory notice<sup>1</sup>, and/or take additional regulatory actions<sup>2</sup> to address the non-compliance.</li></ol>
<b>Response</b>	<ol style="list-style-type: none"><li>1. The sponsor may choose to make a submission with evidence or justifications that the compliance deficiencies identified in the regulatory notice are invalid. The sponsor may also notify us of any actions taken to remedy the identified deficiencies and justify why these actions appropriately address the deficiencies.</li><li>2. If a response is requested in the regulatory notice and no submission is provided, then further regulatory action may be taken.</li></ol>
<b>Decision</b>	<ol style="list-style-type: none"><li>1. We make a final decision about the identified deficiencies based on the information available to us. We notify the sponsor of our final decision and any further regulatory action<sup>3</sup> we have decided to take. We will also provide a copy of the information outlining the results of the review that will be published on the TGA website.</li><li>2. The sponsor can, in some circumstances, request for our decision to be reconsidered under section 60 of the Act if they do not agree with it. This must be done within 90 days of the decision being made.</li><li>3. The sponsor has an opportunity to provide us with their comments on the proposed publication content.</li></ol>
<b>Publication</b>	<ol style="list-style-type: none"><li>1. After considering any comments made by the sponsor in relation to the proposed publication content, we publish the outcome of each compliance review on the TGA website. This includes the regulatory actions (issuing of infringement notices, cancellations from the ARTG, etc.) that have been taken.</li></ol>

<sup>1</sup> For example, a proposal to cancel notice.

<sup>2</sup> Such as a recommendation for recall, issuing of infringement notice(s), etc.

<sup>3</sup> Regulatory actions that are available to the TGA to address non-compliance are available on the [TGA website](#).