## Introduction

This document is a current (as-is) state process map for Type 5 Major Veterinary Medicines which focuses on applications for approval of an active constituent. This page outlines the structure of the process map and a provides some guidance on how to read the map.

## **Structure of Process Maps**

All the process maps have been designed to group various item numbers with similar outcomes under the different *types* of applications. The designation of *Major* or *Minor* represents the level of general complexity associated with assessing that application. The designation of *Ag* or *Vet* identifies the registration pathway. Further details on this can be found in the Product Descriptions document on the consultation page (https://www.apvma.gov.au/news-and-publications/public-consultations/process-enhancement-initiative).

Each process map captures the key process steps, decisions, documents and subprocesses involved in delivering the relevant application assessment. Subprocesses have been captured at typical points along the application lifecycle, however these can be enabled at any time in the application progression – for example issuing an s159 Request for Further Information.

Within each **Type** the application lifecycle has been divided into distinct stages called **components** that most applications go through. These include:

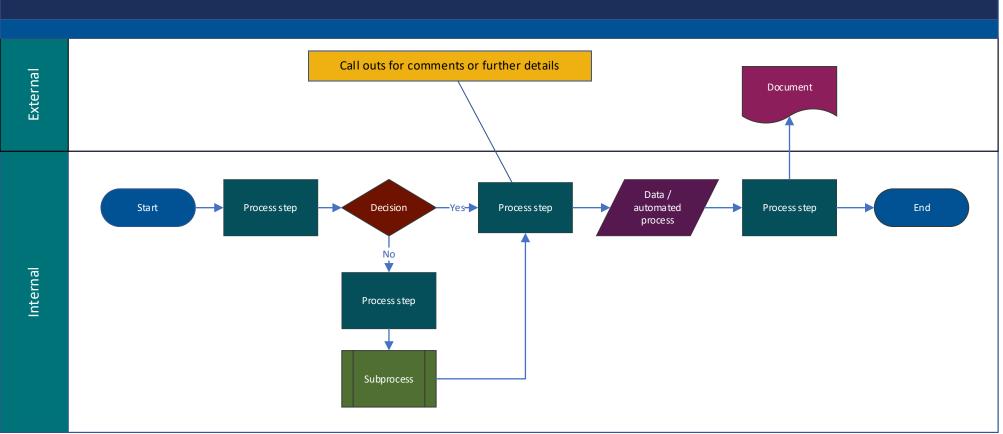
- Pre Application Assistance (PAA), Application Submission and Preliminary Assessment which covers the submission process, and the scope and approach of the application.
- Triage and Planning, Application & Technical Risk Assessment and Application recommendation are more technical in nature.
- Finalisation, Post Finalisation Support and End of Life which wrap up the application process.

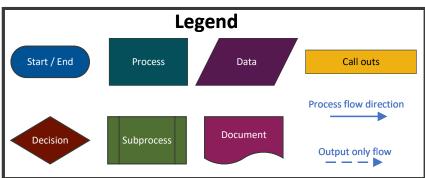
## How to read these process maps?

Each process map:

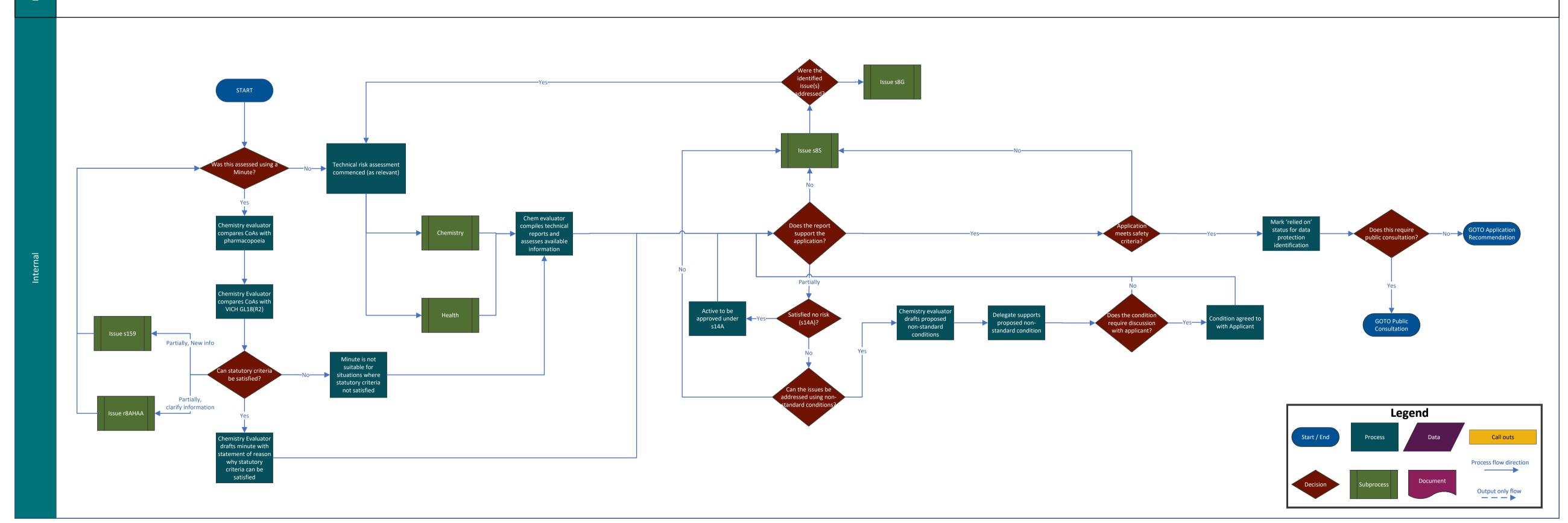
- consists of two swimlanes representing external and internal processes.
  - the external swimlane captures stakeholder inputs or processes,
  - the internal swimlane represents APVMA's internal inputs or processes,
- has a start, next step (GOTO) and / or end,
- consists of a number of process steps and can include decision points, subprocess, automated steps, comments / call outs or documents,
- has components on separate pages where distinct stages of the application are detailed.

An example map and legend is provided below









## Type 5 Major Veterinary Medicines Tier 2 – End-of-Llfe START START Applicant requests States and cancellation of territories draft Letter received response and send completing form or to chem review the APVMA website review Minute drafted to Active is involuntary send to states and Cancellation cancelled by the Gazette notice territories giving Delegate approves Gazette notice Active cancelled in drafted and sent to Gazette END APVMA under approved by them 10 days notice approved by received? final cancellation drafted the PPLA holder saying the if there is a reason division 5 of the delegate active is cancelled AgVet Code active should not be cancelled Legend Start / End Call outs Process **Process flow direction** Document Output only flow