

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:

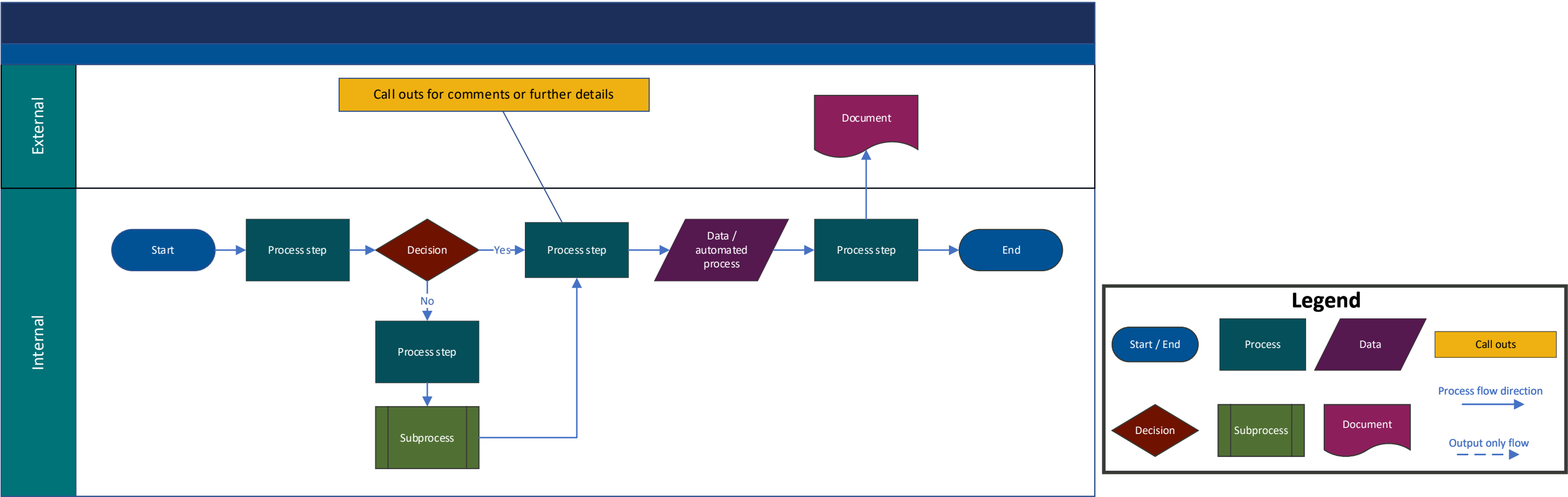
- Pre Application Assistance (PAA), Application Submission and Preliminary Assessment which covers the submission process, and the scope and approach of the application.
- Triage and Planning, Application & Technical Risk Assessment and Application recommendation are more technical in nature.
- Finalisation,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

How to read these process maps?

Each process map:

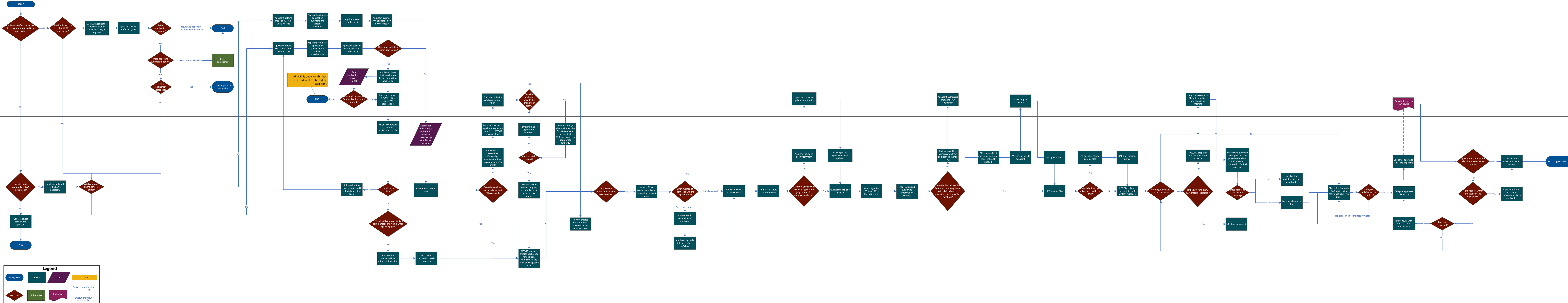
- consists of two swimlanes representing external and internal processes.
 - the external swimlane captures stakeholder inputs or processes,
 - the internal swimlane represents APVMA's internal inputs or processes,
- has a start, next step (GOTO) and / or end,
- consists of a number of process steps 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



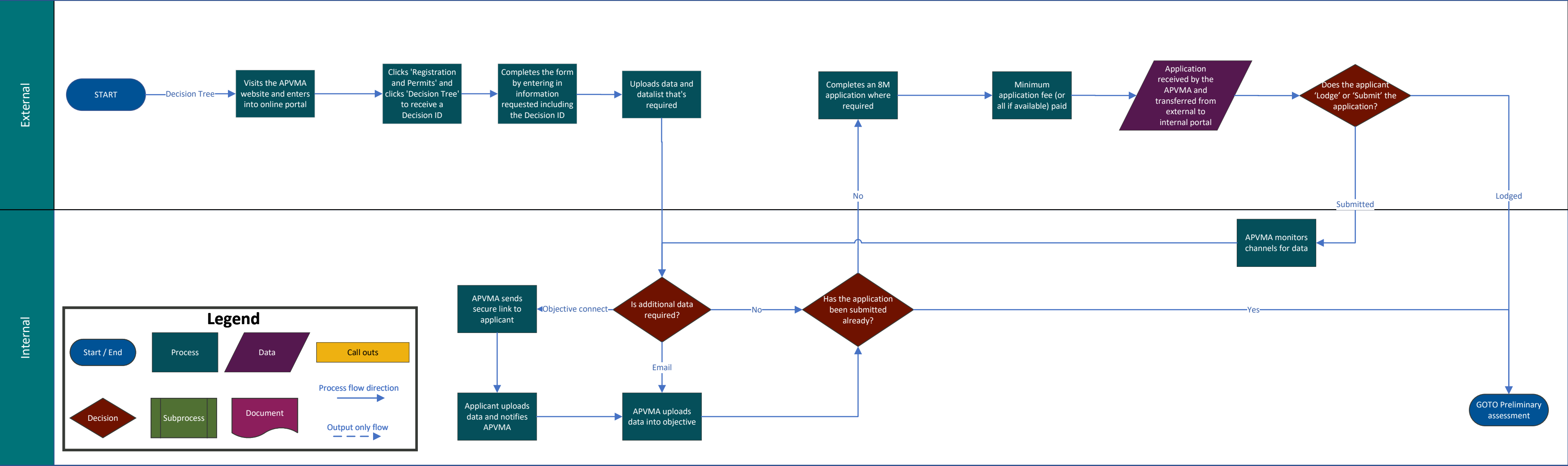
External

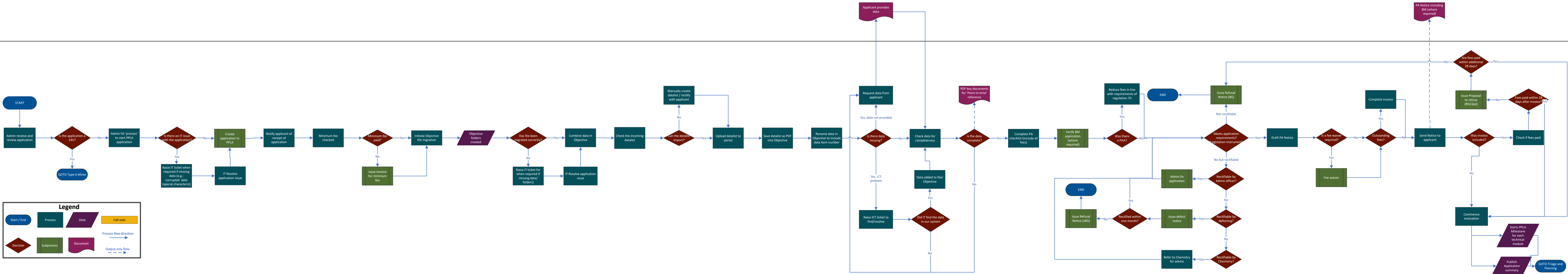
Internal

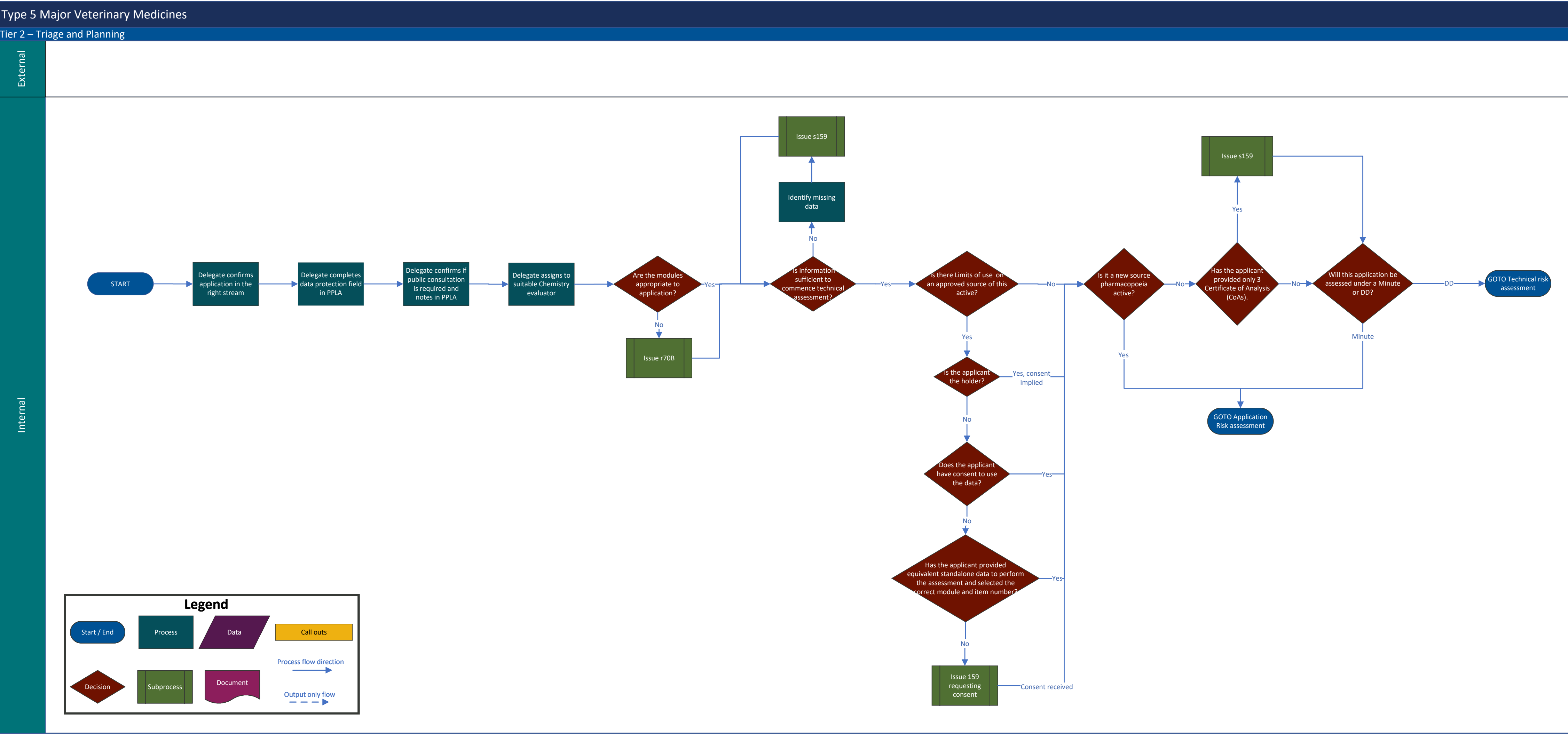


Type 5 Major Veterinary Medicines

Tier 2 – Application Submission

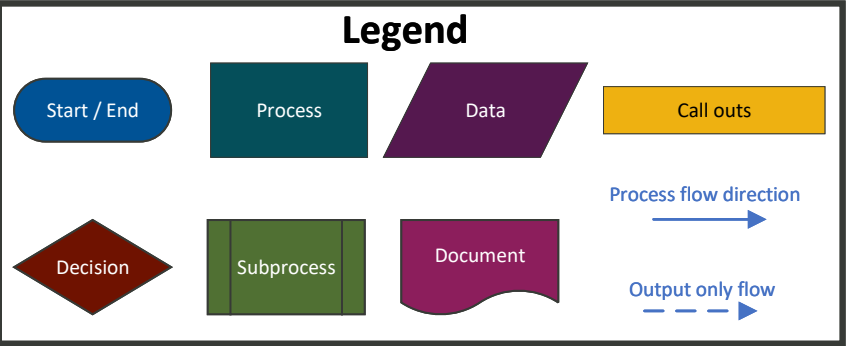
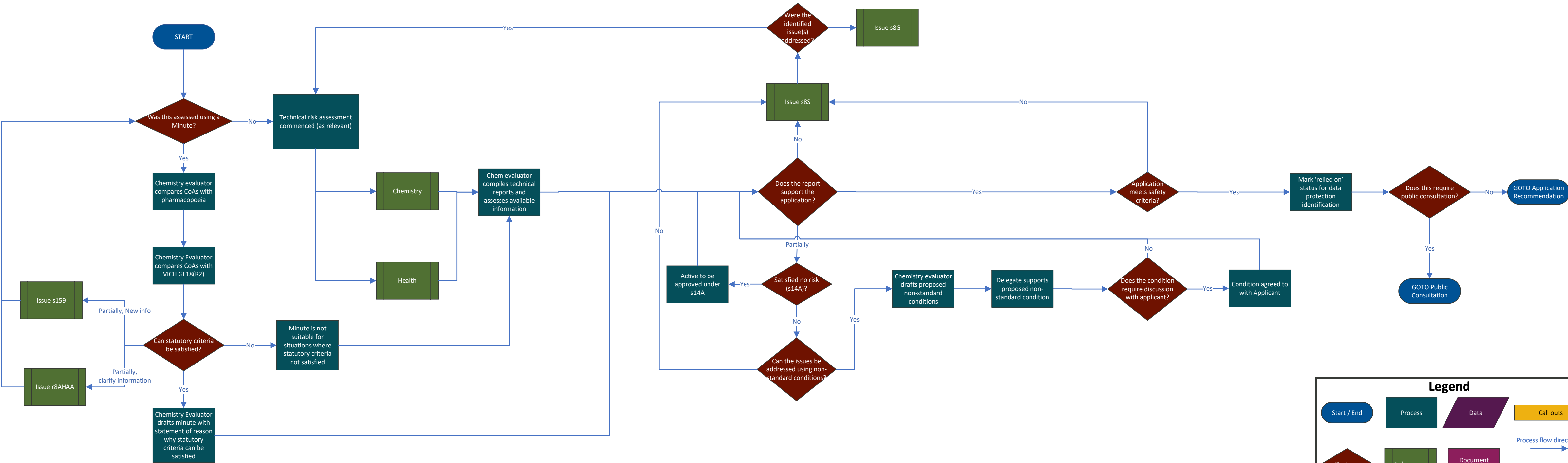






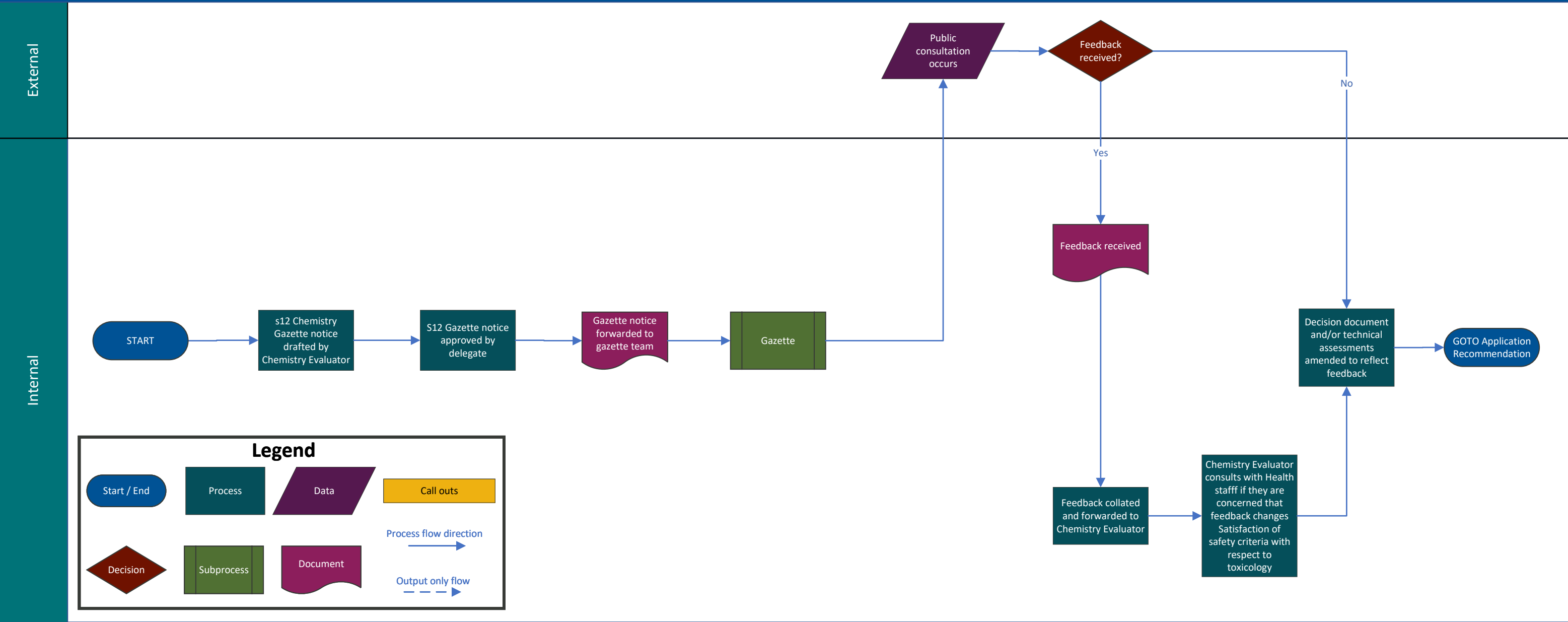
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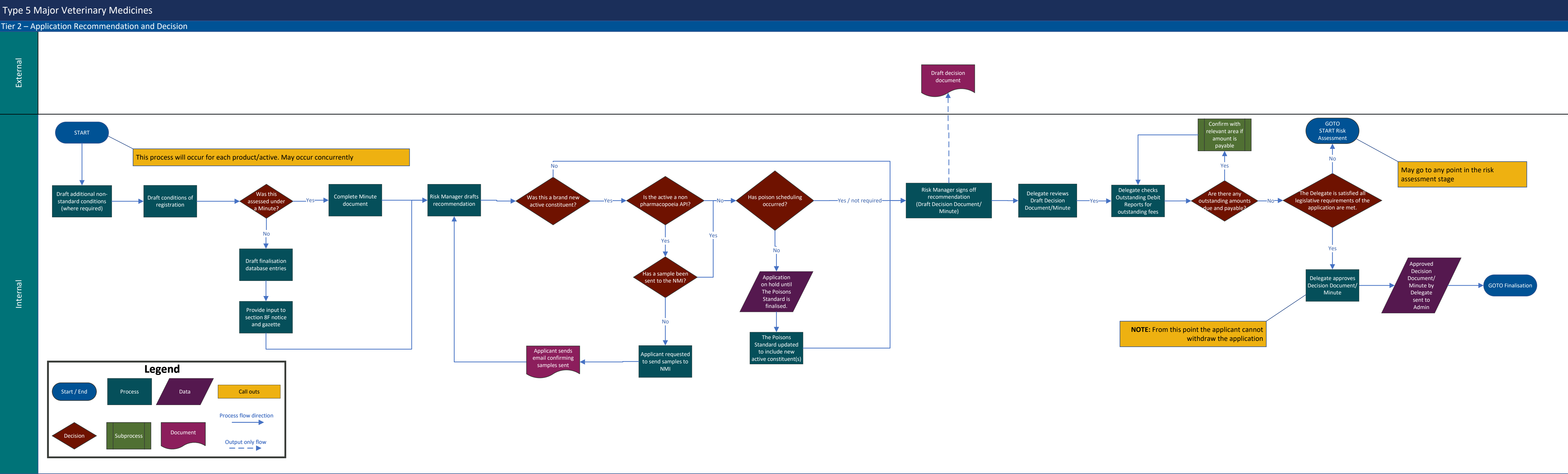
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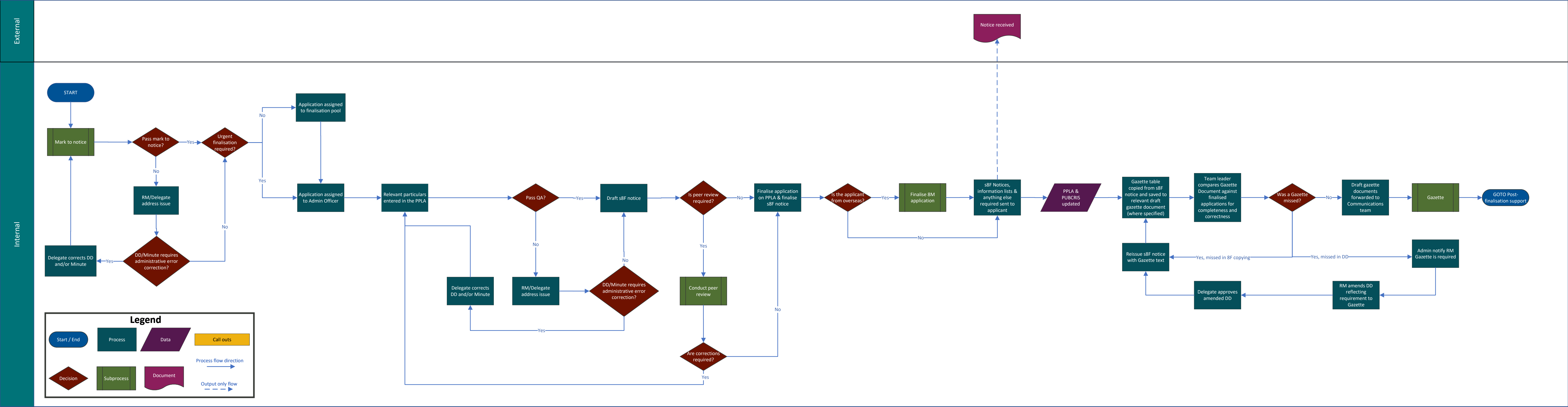


Type 5 Major Veterinary Medicines

Tier 2 – Public Consultation

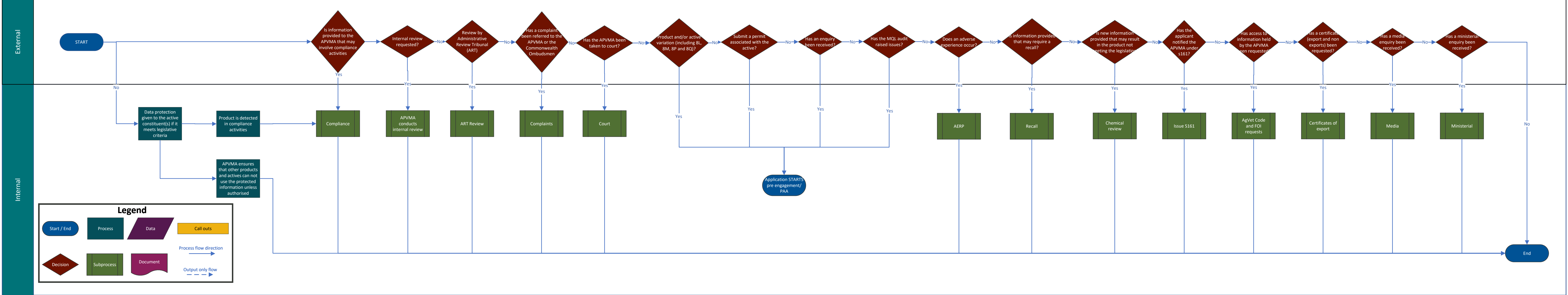






Type 5 Major Veterinary Medicines

Tier 2 – Post-finalisation Support



Type 5 Major Veterinary Medicines

Tier 2 – End-of-Life

