

Product Development

Although some products may have a slightly different path, most novel and generic products follow a fairly standard process containing five phases, defined as: Evaluation, Feasibility, Development, Registration and Launch.

Dechra employs a structured process in its development pipeline while retaining an opportunistic and entrepreneurial approach. Focus is given to the Group's therapeutic sectors. New development opportunities and in-license opportunities are evaluated for strategic fit within these sectors; therapies outside of the key areas are considered for inclusion in the pipeline if they are novel and address medical needs in the veterinary market.

A product's return on investment can vary: novel developments tend to have a medium to long term realisation with attractive high value returns; generic developments generally have shorter time scales with returns dependent upon the number of other entrants and our speed to market relative to the competition. Dechra's current development pipeline is a mix of short, medium and long term opportunities.

Generating Ideas

The **Evaluation** phase begins with identifying a novel molecule, an opportunity to develop a new formulation for an existing molecule, or an in-license opportunity. Before initiating a development programme, each opportunity is assessed by market need, market value, therapeutic indications, strategic fit and the likely complexity of the regulatory pathway.

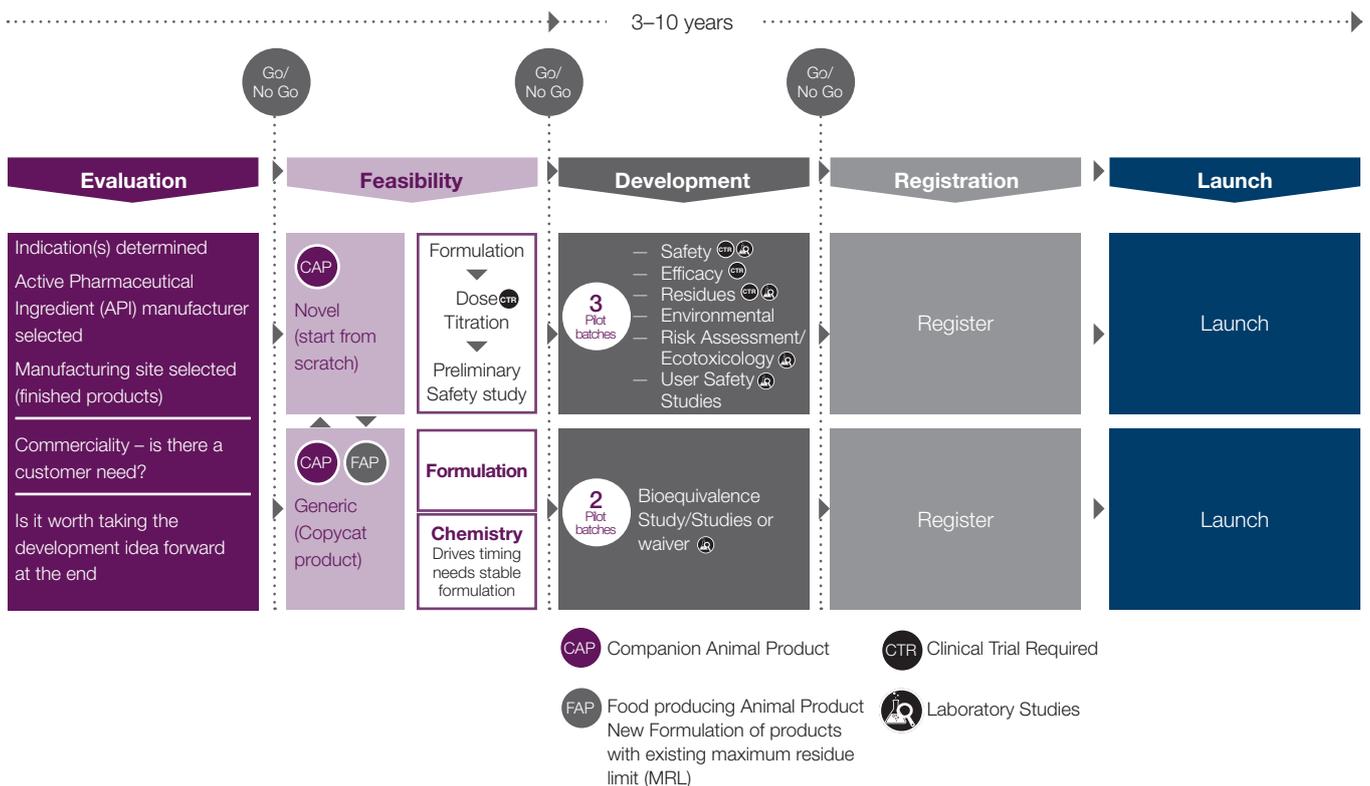
Making the Chemistry Work

The second phase of the process is **Feasibility**, which involves the collection of a range of preliminary data. When initiating development of a novel product, the correct dose has to be titrated and a stable formulation, that can be reliably and consistently manufactured, must be developed. For a generic product, the pioneer formulation may not meet the current regulatory requirements and may need to be reformulated. This phase is vital prior to initiating the development phase which involves expensive clinical trials or bioequivalence studies.

Entering the Development Phase

The **Development** phase is the longest part of the process, potentially taking two or three years. After the formulation has been demonstrated to be stable, two to three pilot batches are manufactured for use in safety studies, efficacy studies and stability testing. For generic products, the batches are used in one or more bioequivalence studies to demonstrate that activity will replicate the pioneer product. If the studies conducted during the Development phase demonstrate the required safety, efficacy and chemical stability of the product, regulatory dossiers are prepared for **Registration/Filing**.

From beginning to end, the development process can take between three and ten years before **Launch** depending on complexity and nature of the product.



Product Pipeline

A key strategic priority for the Group is the delivery and strength of the pipeline. The following chart outlines the status of the major projects. Owing to the nature of product development, the content of our pipeline will change over time as new projects progress from Evaluation to Development to market or as projects are terminated. For competitive reasons, exact project details are not disclosed.

