

Product Development

Although some products may have a slightly different path, most novel and generic products follow a fairly standard process containing six phases, defined as: Evaluation, Feasibility, Research, 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 speed to market relative to the competition.

In addition to developing new products, Dechra also is looking continuously to improve existing commercial products to retain and grow market share. Lifecycle activities are varied but may include changing primary packaging or dose form for improving convenience for the user or adding claims or species to widen the addressable market. These activities are generally called lifecycle management and can lead to substantial growth, even for established products.

Dechra's current development pipeline is a mixture of short, medium and long term new opportunities and lifecycle projects.

Generating and Prioritising Ideas

Ideas are usually generated by Marketing and Business Development, but Dechra encourages all employees to share ideas for new or existing products. Ideas will be prioritised by Marketing and the most attractive ones will be evaluated by a small cross functional Evaluation team. During the **Evaluation** phase, the team defines the scope of the project and assesses if the cost benefit ratio is favourable considering market need, market value, therapeutic indications, strategic fit and the probability of technical and regulatory success. The team also define the work required in the Feasibility phase.

Making the Chemistry Work

The second phase of the process is **Feasibility**, which involves the collection of a range of preliminary data to identify early stop points.

In this phase proof of concept level data for pharmaceutical development (formulation and manufacturing process), efficacy and safety is created and a regulatory pathway is identified. The purpose of this phase is to eliminate projects with low probability of success as early as possible.

All the necessary pilot data is generated in the **Research** phase to:

- understand the efficacy and safety profile (innovation) or the likelihood of establishing bioequivalence (generics);
- ensure high quality pharmaceutical development; and
- establish the best strategy to maximise the probability of technical and regulatory success.

The main purpose of the Research phase is to de-risk the expensive, long and resource intensive Development phase. In addition, during the Research phase the formulation and manufacturing process are finalised, and the dose that is both safe and effective is determined. For some projects, this phase can be relatively straight forward, while for others it can be iterative, for example finding a formulation that gives the desired safety and efficacy profile.

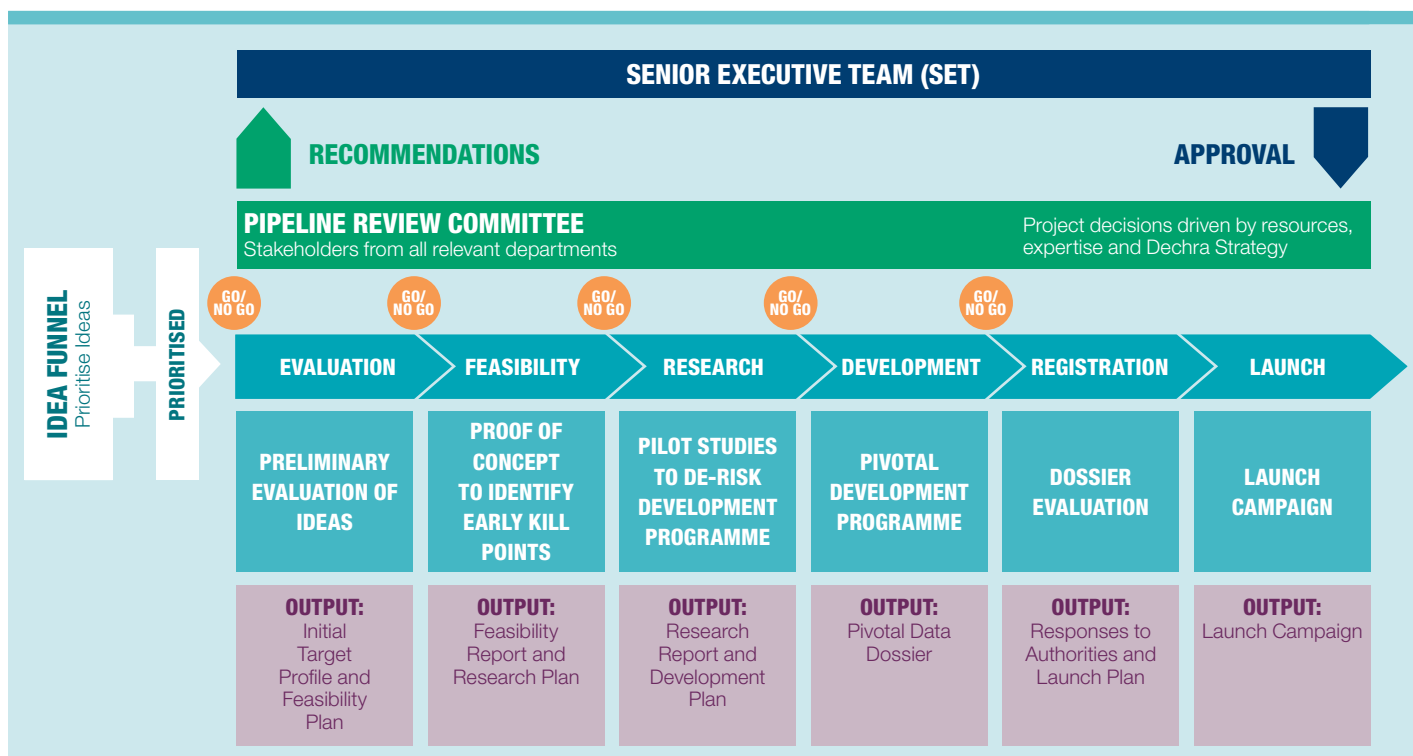
Entering the Development Phase

The **Development** phase is the longest part of the process, potentially taking two or four years. After the formulation has been demonstrated to be stable, up to three registration 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**.

The whole process from beginning to end can take between three and ten years before **Launch** depending on complexity and nature of the product.

Stage Gate Process

The Pipeline Review Committee analyses each project after each phase for any technical or regulatory risks and issues and any changes in the business case. Projects are prioritised based on their overall commercial and strategic value.





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 market or as projects are terminated. For competitive reasons, exact project details are not disclosed.

Evaluation		Feasibility		Research		Development		Registration	
CAP/Equine	FAP	CAP/Equine	FAP	CAP/Equine	FAP	CAP/Equine	FAP	CAP/Equine	FAP
<p>New opportunities are constantly being evaluated and will move into Feasibility quickly if of interest</p>	Analgesic therapy for cats	Antibiotic for cattle and pigs	Paracetamide for cats	Antibiotic for pigs	Paracetamide for dogs	Antibiotic for cattle	Antibiotic for dogs and cats	Fluid therapy for cattle	
	Anti-inflammatory for horses	Antibiotic for pigs and poultry	Paracetamide for dogs	Paracetamide for poultry	Endocrine diagnostic	Poultry vaccines	Dermatological therapy for dogs	Poultry vaccines	
	Gastrointestinal therapy for dogs	Anti-inflammatory for Poultry	Dermatological therapy for dogs	Antibiotic for pigs	Dermatological therapy for dogs	Poultry vaccines	Antibiotic for dogs and cats		
		Swine vaccines	Analgesic therapy for dogs	Antibiotic for cattle, pigs and poultry	Lameness therapy for horses	Antibiotic for cattle, dogs, cats, horses	Analgesic therapy for dogs		
			Dermatological therapy for dogs	Poultry vaccines	Lameness therapy for horses		Analgesic /anti-inflammatory for horses		
			Dermatological therapy for dogs	Poultry vaccines	Lameness therapy for horses		Antibiotic for dogs and cats		
			Endocrine therapy for horses		Analgesic therapy for horses		Anaesthetic for dogs and cats		
			Endocrine therapy for cats		Endocrine therapy for dogs		Gastrointestinal therapy for dogs and cats		
			Ocular anti-inflammatory for dogs		Cardiovascular therapy for cats		Anaesthetic for horses		
			Gastrointestinal therapy for dogs		Gastrointestinal therapy for dogs		Anaesthetic for dogs and cats		
			Anti-inflammatory for horses		Gastrointestinal therapy for dogs		Anaesthetic for horses		
			Dermatological therapy for dogs		Dermatological therapy for dogs		Antibiotic for horses		
			Antibiotic for rabbits		Antibiotic for dogs and cats		Gastrointestinal therapy for dogs		
			Antibiotic for dogs		Anti-inflammatory for dogs and cats				
					Gastrointestinal therapy for dogs				
				Urological therapy for dogs					
				Anti-inflammatory for horses					

Key

- Analgesic, Anaesthesia, Anti-inflammatory ●
- Antimicrobial ●
- Antiparasitic ●
- Cardiology ●
- Dermatology ●
- Endocrinology ●
- Fluid therapy ●
- Gastrointestinal ●
- Vaccines ●
- Locomotion ●
- Urology ●