Product Development

Dechra's pharmaceutical and vaccine development pipeline contains a mixture of short, medium and long term new opportunities and lifecycle products.

12
Projects in Feasibility

3
Projects in Research

13
Projects in Development

5
Projects in Registration

Whilst retaining an opportunistic and entrepreneurial approach, Dechra employs a structured development process consisting of six phases, defined as: Evaluation, Feasibility, Research, Development, Registration and Launch. Focus is given to the Group's key therapeutic sectors, and new development 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 medium to long term realisation with attractive high value returns, whilst generic developments generally have shorter timescales with returns dependent upon the number of other entrants and speed to market relative to competition.

In addition to developing new products, Dechra is also looking 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, treatment compliance for the patient or adding claims or species to widen the addressable market. These lifecycle projects can lead to substantial growth, even for established products.

Generating and Prioritising Ideas

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

Making the Chemistry Work

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

All the necessary pilot data are generated in the **RESEARCH** phase to:

- understand the efficacy and safety profile (innovation) or the likelihood of establishing bioequivalence (generics);
- enable 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 straightforward, while for others it can be iterative, for example finding a formulation that gives the desired safety and efficacy profile.

Entering the Development Phase

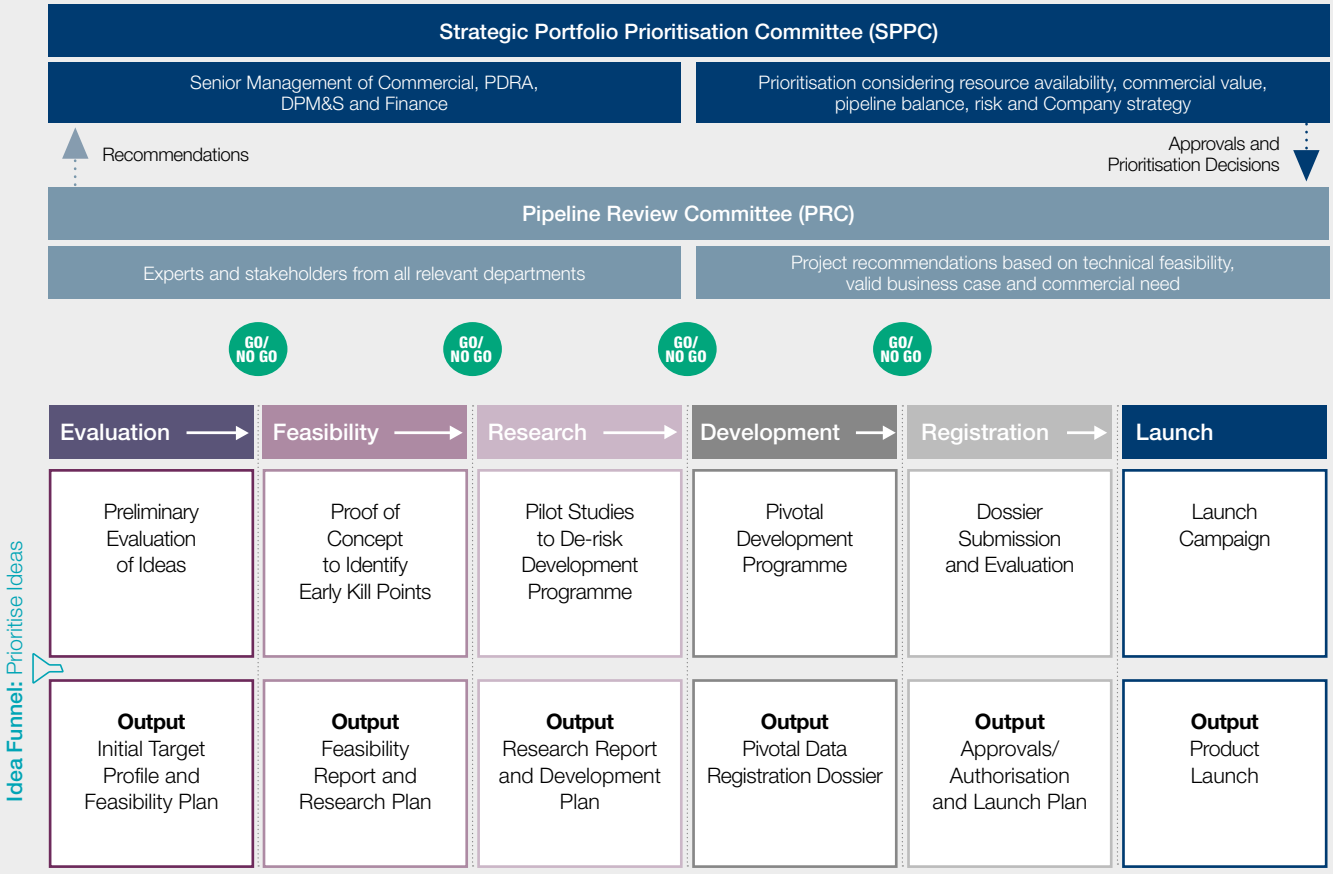
The **DEVELOPMENT** phase is the longest part of the process, potentially taking between two to four years. After the formulation has been demonstrated to be stable, up to three registration batches are manufactured for use in safety studies, efficacy studies and stability testing. For generic products,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

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

Stage Gate Process

The Pipeline Review Committee analyses each project after each phase for technical or regulatory risks and issues, and for any changes to the business case. Project decisions are endorsed by the Strategic Portfolio Prioritisation Committee which also prioritises projects based on their overall commercial and strategic value within resource constraints.

Read more about Our Product Development on page 69.


Strategic Portfolio Prioritisation Committee (SPPC)
Senior Management of Commercial, PDRA, DPM&S and Finance
Prioritisation considering resource availability, commercial value, pipeline balance, risk and Company strategy
Recommendations
Approvals and Prioritisation Decisions
Pipeline Review Committee (PRC)
Experts and stakeholders from all relevant departments
Project recommendations based on technical feasibility, valid business case and commercial need
GO/ NO GO
GO/ NO GO
GO/ NO GO
GO/ NO GO
Evaluation
Feasibility
Research
Development
Registration
Launch
Idea Funnel: Prioritise Ideas
Preliminary Evaluation of Ideas
Proof of Concept to Identify Early Kill Points
Pilot Studies to De-risk Development Programme
Pivotal Development Programme
Dossier Submission and Evaluation
Launch Campaign
Output Initial Target Profile and Feasibility Plan
Output Feasibility Report and Research Plan
Output Research Report and Development Plan
Output Pivotal Data Registration Dossier
Output Approvals/ Authorisation and Launch Plan
Output Product Launch

Product Development continued

Product Pipeline

Delivering a strong and robust pipeline is one of the Group's strategic priorities. The 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 Launch or as projects are terminated. For competitive reasons, exact project details are not disclosed.

	CAP/Equine
1 Evaluation 	**New opportunities are constantly being evaluated and will move into Feasibility quickly if of interest.**
2 Feasibility 	Ophthalmic therapy for dogs Endocrine therapy for cats Endocrine therapy for dogs Endocrine therapy for dogs Gastrointestinal therapy for dogs Ophthalmic therapy for dogs Dermatological therapy for dogs
3 Research 	Gastrointestinal therapy for horses Endocrine therapy for horses
4 Development 	Analgesic therapy for horses Analgesic therapy for dogs Lameness therapy for horses Dermatological therapy for dogs Lameness therapy for horses Endocrine diagnostic Dermatological therapy for dogs Anaesthetic for dogs and cats Endocrine therapy for cats Endocrine for dogs
5 Registration 	Anaesthetic for dogs Antibiotic for dogs and cats Analgesic therapy for dogs Gastrointestinal therapy for dogs

Key to Product Pipeline

- Analgesic, Anaesthesia, Anti-inflammatory
- Antibiotic
- Antiparasitic
- Opthalmology
- Dermatology
- Endocrinology
- Gastrointestinal
- Vaccines
- Locomotion

FAP

Read more about The Evaluation Process on page 42.

FAP

- Poultry Vaccine
- Poultry Vaccine
- Antibiotic for pigs and poultry
- Swine Vaccine
- Anaesthetic for pigs

FAP

- Antibiotic for pigs

FAP

- Poultry Vaccine
- Paraciticide for poultry and pigs
- Antibiotic for cattle

FAP

- Antibiotic for cattle and pigs

Case Study

Clinical Studies during COVID-19: Creative solutions maintain product development progress

Members of the Product Development team recently presented to the European Medicines Agency and other pharmaceutical industry stakeholders on the challenges of conducting veterinary clinical studies during the pandemic. Attendees were fascinated to learn that the hurdles faced by animal health drug developers were almost identical to those experienced by teams developing human medicines.

When the pandemic struck in March 2020, Dechra had several studies in various stages of completion. It rapidly became apparent that COVID-19 was going to have a significant impact on the conduct of veterinary clinical field studies. Our immediate focus became how to adapt to the changing landscape to deliver on our timelines. For studies just starting, our relationship with sites willing to participate in studies was even more critical because a large list of study sites became unavailable for participation due to their stressed infrastructures as a result of illness, inability to identify critical study materials and/or closing their doors to pet owners. Inevitably, the participating clinics' first priority was to continue delivering veterinary services to sick animals in the face of lockdowns, while keeping staff and pet owners safe. Leveraging these long established relationships became imperative in asking our sites to take on more work.

As the veterinary world adjusted to new safe working practices, the Dechra teams had to act swiftly due to travel bans and quarantines, and create contingency plans. Study teams built new processes for training and monitoring, engaging in new ways to communicate and collect data effectively. Frequent and thorough communication was key in addition to accommodating individual study site challenges. Creative study marketing strategies at targeted clinics best able to continue study related activities and the identification of new study patients were required. Remote oversight and flexibility were important to ensure ongoing patients were not lost from the studies due to missed data or inability to comply with study demands. For critical data points requiring in person observation, study monitors local to the study location were hired to observe procedures for compliance to ensure good study conduct. Management of study drug and biological sample shipments required careful planning and oversight to overcome delays due to unreliable courier schedules.

Prior investment in a robust state of the art secure method to collect, store and review data allowed veterinarians to record patient data online and shift to a completely remote procedure for study oversight and closeout. This ensured that the extremely high level of data quality required for a clinical study was maintained. Paper study documents transitioned to more accessible electronic documents. Some novel process changes required advance discussions with the FDA.

Dechra was nimble enough to navigate through each of the hurdles that COVID-19 created and successfully adapted. Some of these alternative approaches will remain in our toolbox for future studies. Together with the ongoing excellent relationships with our participating veterinary clinics, Product Development delivered on its commitments.