Product Development

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It is our mission to improve animal health and welfare globally, and as such the wellbeing of animals used in the development of our products is always a top priority. In line with that commitment, we carefully consider the responsible use and humane treatment of animals in all of our studies. When we are required to conduct studies to achieve product registrations, we minimise the number of animals to achieve the necessary outcomes. Whenever possible, we will use information that can be derived from in vitro systems, computer models or existing publications in an effort to limit the number of studies needed.

Regulatory agencies, governmental bodies, or animal welfare review boards approve the scientific purpose for involving animals as dictated by country specific requirements.

We are committed to the following principles:

- We will comply with all relevant regulations.
- Any animal studies should only be performed after considering whether the numbers of animals can be Reduced, Replaced by in vitro methods, or the procedures Refined to minimise distress, the 3"R's".
- Animals will be treated humanely with greatest consideration given to their health and welfare and consistent with meeting the necessary scientific objectives.
- All studies conducted by or on behalf of Dechra will be reviewed by an Animal Welfare Committee or similar oversight committee.
- For clinical trials involving client owned animals an owner consent will be obtained and the study will be reviewed by Dechra's Animal Welfare Committee.

The Difference Between Novel, Generic and Generic Plus Products

Novel and Generic products are the main types of new animal drug applications that Dechra applies for:

- **Novel:** are products registered for the first time and require the submission of a dossier containing three key sections for the registration process:
    - Safety: examines risks to the environment, the human administrator of the product, as well as the safety of the product in the target animal at multiples of the intended dose
    - Efficacy: includes the study(ies) in which the best dose is identified, and the effectiveness of the drug is demonstrated in animals with the targeted disease
    - Manufacturing: the quality and purity of the product are demonstrated along with proof that the product can be manufactured consistently through the production of several independent large scale batches
- **Generic:** are products that are near identical to an already registered pioneer product and contain the same chemical substance(s). Approvals for a generic require demonstration of in vivo bioequivalence of the proposed product to the novel (reference) product. There are exceptions for some classes of drugs, primarily those intended for intravenous injection or those not absorbed from the digestive system. The manufacturing section for a generic may require fewer pilot batches than for a pioneer drug, but the emphasis on quality and purity is identical.
- **Generic Plus:** are products which are approved as a generic but improve on it through the development of a better formulation, dosage form, delivery system or packaging. It may include use in additional species or for additional indications.

Animal Welfare Committee

As a veterinary pharmaceutical company, we work diligently to maintain the highest standards of putting animal health and welfare as a priority in everything we do. When we run clinical trials we have the study protocols reviewed by our Animal Welfare Committee to ensure that all aspects of the study that affect the animal have been robustly evaluated for proper ethical treatment and that, if applicable, owner interests have been addressed in the owner consent form. To achieve this, Dechra's Animal Welfare Committee:

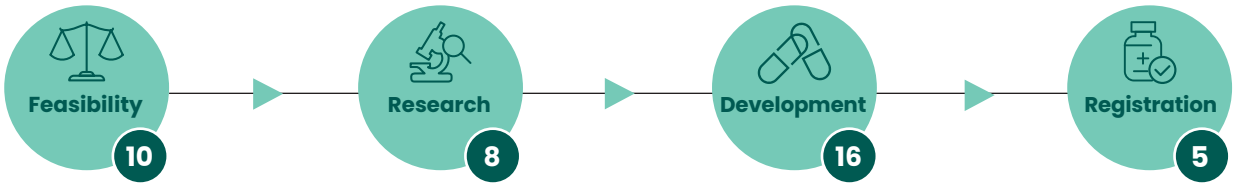
- protects animal welfare by providing ethical review of studies for best practices and appropriate ethical treatment;
- promotes awareness of animal welfare and subscribes to the guiding principles of 3R's (reduction, replacement, and refinement) whenever possible;
- assesses that animal risks are minimised and outweighed by the potential benefits of the study;
- reviews informed consent documents ensuring that the information provided fully outlines the nature, purpose and risks to the animal and is comprehensive and understandable to the owner;
- provides critical feedback by asking questions and freely communicating with the researchers; and
- is comprised of veterinary professionals, members educated in science and regulations, and member(s) that represent the public-at-large who ensure the research follows the Company's position on animal welfare.

The Committee holds twice yearly meetings in which the Committee Members are required to attend at least one meeting in a 12 month period. Protocols are reviewed on a continuous basis throughout the year and a Committee Member is required to participate in those reviews on a rotational basis.

All members of the Committee are required:

- to attend an orientation session with additional sessions offered as needed and as different circumstances arise;
- to participate in training on Dechra's Animal Welfare Statement, the Animal Welfare Committee Mission Statement and to review any other guidance/resources that are provided; and
- to participate in training on protocol review procedures.

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



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-licence opportunities are evaluated for strategic fit within these sectors. Therapies outside 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; innovative products 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.

Generating and Prioritising Ideas

Ideas are usually generated by our cross-functional Therapeutic Area Leadership (TALT) and Business Development (BD) Teams, 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 is 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 necessary pilot data is 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 processes 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 often the longest part of the process, potentially taking between two and 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 Governance Team (PGT) analyses each project after each phase for technical or regulatory risks and issues, and for any changes to the business case. Pipeline strategy and annual project resource allocations are endorsed by the Strategic Portfolio Prioritisation Committee (SPPC) based on their overall commercial and strategic value within resource constraints.

Read more about our **Pipeline Delivery** on pages to 40 and 41.

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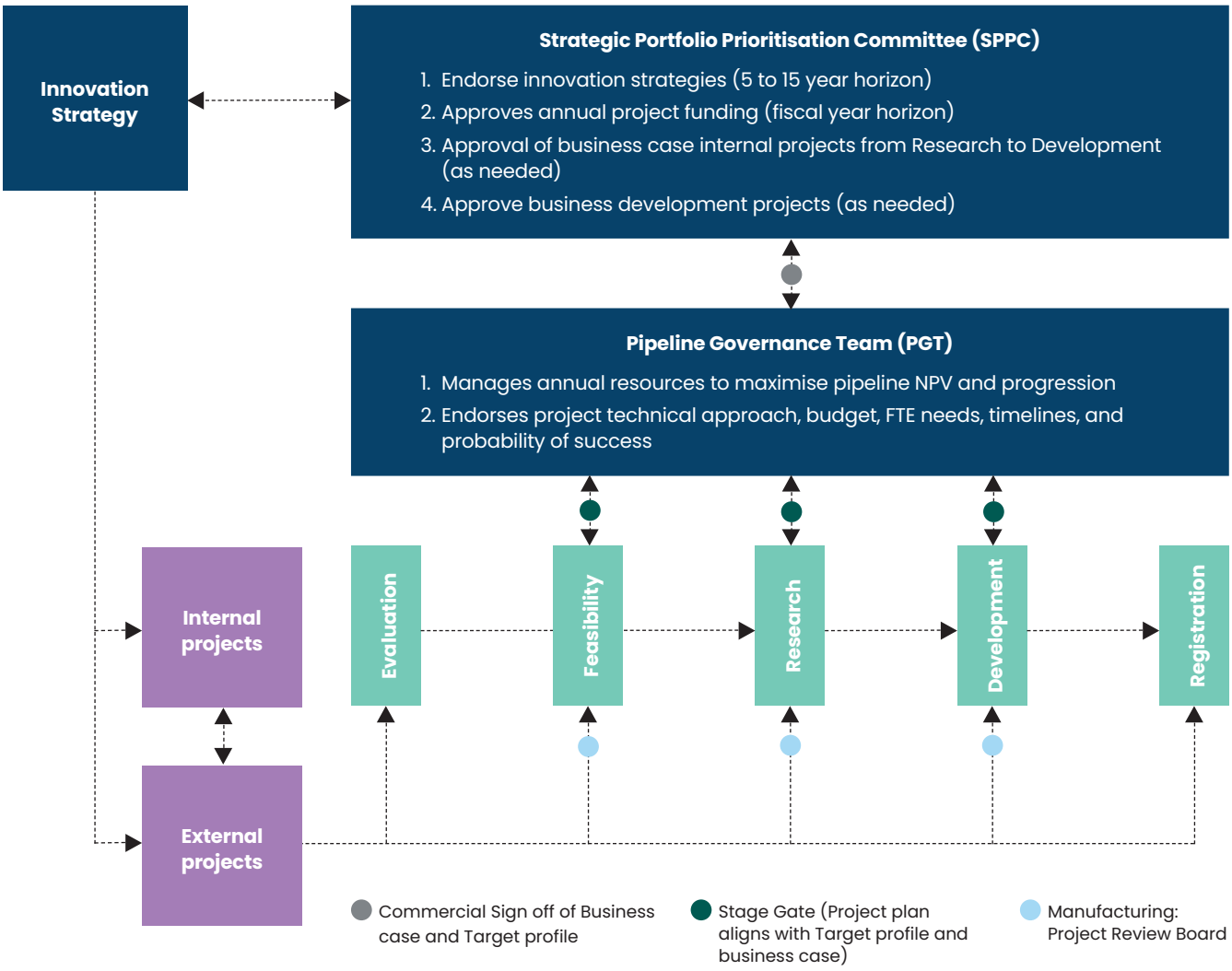
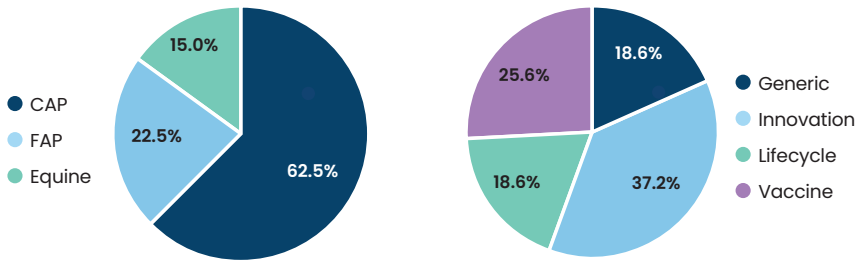


Pipeline by Number of Projects



Product Pipeline

The table below 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.

Evaluation

CAP/Equine	FAP

New opportunities are constantly being evaluated and will move into Feasibility quickly if of interest.

Feasibility

CAP/Equine	FAP
Antibiotic for Dogs and Cats	Poultry Vaccine
Renal Therapy for Cats	Poultry Vaccine
Antibiotic for Dogs and Cats	
Dermatological Therapy for Dogs	
Dermatological Therapy for Dogs	
Anti-Viral Therapy for Cats	
Endocrine Therapy for Dogs	
Ophthalmic Therapy for Dogs	

Research

CAP/Equine	FAP
Ophthalmic Therapy for Dogs	Poultry Vaccine
Endocrine Therapy for Cats	
Endocrine Therapy for dogs	
Antibiotic for Dogs	
Analgesic Therapy for Dogs	
Analgesic Therapy for Dogs	
Gastrointestinal Therapy for Horses	

Development

CAP/Equine	FAP
Anaesthetic for Dogs and Cats	Poultry Vaccine
Dermatological Therapy for Dogs	Poultry Vaccine
Dermatological Therapy for Dogs	Poultry Vaccine
Cardiovascular Therapy for Dogs	Poultry Vaccine
Dermatological Therapy for Dogs	
Endocrine Therapy for Dogs	
Gastrointestinal Therapy for Cats	
Analgesic Therapy for Horses	
Horse Vaccine	
Horse Vaccine	
Horse Vaccine	
Endocrine Therapy for Horses	

Registration

CAP/Equine	FAP
Antibiotic for Cats	Antibiotic for Cattle and Pigs
Gastrointestinal Therapy for Dogs	
Endocrine Diagnostic	
Endocrine Therapy for Dogs	

Key to Product Pipeline

- Analgesic, Anaesthesia, Anti-inflammatory
- Antibiotic
- Anti-Viral
- Dermatology
- Endocrinology
- Gastrointestinal
- Renal
- Vaccines
- Ophthalmology
- Cardiovascular