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.

12 Projects in Feasibility
7 Projects in Research
10 Projects in Development
8 Projects in Registration

Dechra employs a structured process in its pharmaceutical and vaccine development pipeline while retaining an opportunistic and entrepreneurial approach. Focus is given to the Group’s 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, while 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.

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 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 will be 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 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);
- 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.

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