Animale

STRATEGY

In recent years UK veterinary practices have consolidated; be it by corporate acquisition or joint-venture partnership, joining buying groups and growth of the charitable sector.

The veterinary pharmaceutical sector has seen increased competition through numbers of suppliers and generic products.

Conversely, in part through M & A activity, there are now fewer high quality routes to market for those pharmaceutical licence holders without domestic sales channels.



We have developed our internal capability, expertise and cash position to take advantage of these market conditions and opportunities to focus our strategy in the following areas.

Our strategy for 2015 to 2018 is to:

- 1 Identify product candidates to maintain flow into and through development pipeline
- Increase efforts to license in new pharmaceutical products
- 3 Assess opportunities to innovate and strengthen Companion Animal Identification group
- 4 Increase the sales of our current products outside the UK

NEW PRODUCT DEVELOPMENT (NPD) PROCESS



Identification

Candidate identification and selection

28 Candidates

Identification

Animalcare draws on many areas to identify products to be considered for the pipeline. Our experienced staff use their market and practical knowledge as a great source of ideas and innovation along with market research with veterinary customers. Each project is assessed against criteria to determine its suitability.

The main criteria include:

- size of market
- technical and regulatory feasibility
- number of competitors
- competitor profile
- fit to existing and future range

Feasibility

Investment case prepared based on development, contract manufacturing, active ingredient source and market intelligence

9 Projects

Feasibility

If an opportunity satisfies these criteria the team assemble a project file that will include the regulatory strategy and a shortlist of facilities able to develop and manufacture the product. Early stage feasibility work may be undertaken. The investment proposal is submitted to the Board to gain their approval.

NPD Pipeline Monitoring

Regular project meetings are held with in-house teams and external partners, with progress monitored against the project timeline and budget using project management software. The development pipeline is reviewed by the Board at all Board meetings.





The varied nature of product development dictates that the exact process can be different for each project; however the diagram below explains some of the key steps in the Animalcare process.



Development

Data generated from manufacturing and clinical trials

7 Projects

Development

In most cases the product will be developed at the Contract Manufacturing Organisation (CMO) which will ultimately manufacture the product. Work will start immediately to source the Active Pharmaceutical Ingredient (API) and develop analytical methods. Small scale development batches will be manufactured for setting aside on stability and for use in any clinical studies.

Regulatory

Licence application dossier prepared and submitted

4 NPD + 4 EPD Projects

Regulatory

The dossier is assembled and submitted to the regulatory authorities and is monitored through the process by the Animalcare team. The regulatory assessment process is controlled by a strict timetable; for most of our projects this is 210 days. In our experience it takes 12 months from submitting the dossier to launching the product on the UK market.

Commercial

New product launched First Product Launches Planned H2 FY16



2-3 years to maturity

Launch

Once the marketing authorisation is received, and packaging layouts have been approved by the authorities, launch batches can be manufactured and packed ready for commercial launch. In all, the process outlined above may take between three and five years depending on the project's complexity and the development and clinical trials required.

Existing Product Development

Whilst the model and stages outlined above are followed for new product development, from time to time we identify an opportunity to modify an existing pharmaceutical product in our range, which would provide additional features to increase sales or prolong the product life cycle. These types of projects are termed Existing Product Development (EPD) and necessitate trials, studies and regulatory fees, therefore an investment proposal would still be considered by the Board as with the NPD process.

