

Product Development



Product Development

It is our mission to develop products to improve animal welfare, and as such animal health and wellbeing is always a top priority in our drug development efforts. In line with that commitment, we carefully consider the responsible use and humane treatment of animals in all of our required 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 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 in development of our products as dictated by specific country requirements. Dechra's Animal Welfare Committee is made up of Dechra employees and Community Members and reviews all studies conducted in the field.

We are committed to the following principles:

- animals must be treated humanely with greatest consideration given to their health and welfare and consistent with meeting the necessary scientific objectives; and
- all 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 Animal Welfare Committee ensures that a minimal number of animals are used and that their treatment is humane, and Dechra inspects all facilities which perform testing to confirm proper care and treatment of animals is evident. Dechra consistently oversees that all studies conducted by or on behalf of Dechra have been reviewed by an animal welfare committee. Additionally, any clinical trials will only be conducted in animals with the disease the product is intended to treat and owner consent for inclusion in the study will be obtained.

The difference between Novel, Generic and Generic Plus product

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

- Novel: for new animal drugs three key sections, known as the dossier, for the registration process:
 1. **Safety:** includes a study in healthy animals that evaluates the effects of multiples of the intended dose;
 2. **Efficacy:** includes the study(ies) in which the effectiveness of the drug is demonstrated in animals with the targeted disease; and
 3. **Manufacturing:** the quality and purity of the drug product are demonstrated along with proof that the drug product can be manufactured consistently through the production of several independent large scale batches.
- Generic: a generic is a pharmaceutical product that contains the same chemical substance as the novel drug. Approvals for a generic drug 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 injection. The manufacturing section for a generic drug may require fewer pilot batches than for a pioneer drug, but the emphasis on quality and purity is identical.
- Generic Plus: is a product which is approved as a generic but improves on it through the development of a better formulation, dosage form, delivery system or packaging.

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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, when requested, for best practices and appropriate ethical treatment;
- promotes awareness of animal welfare and subscribes to the guiding principles of 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 Community 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 Community 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-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; 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 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 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 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 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 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.

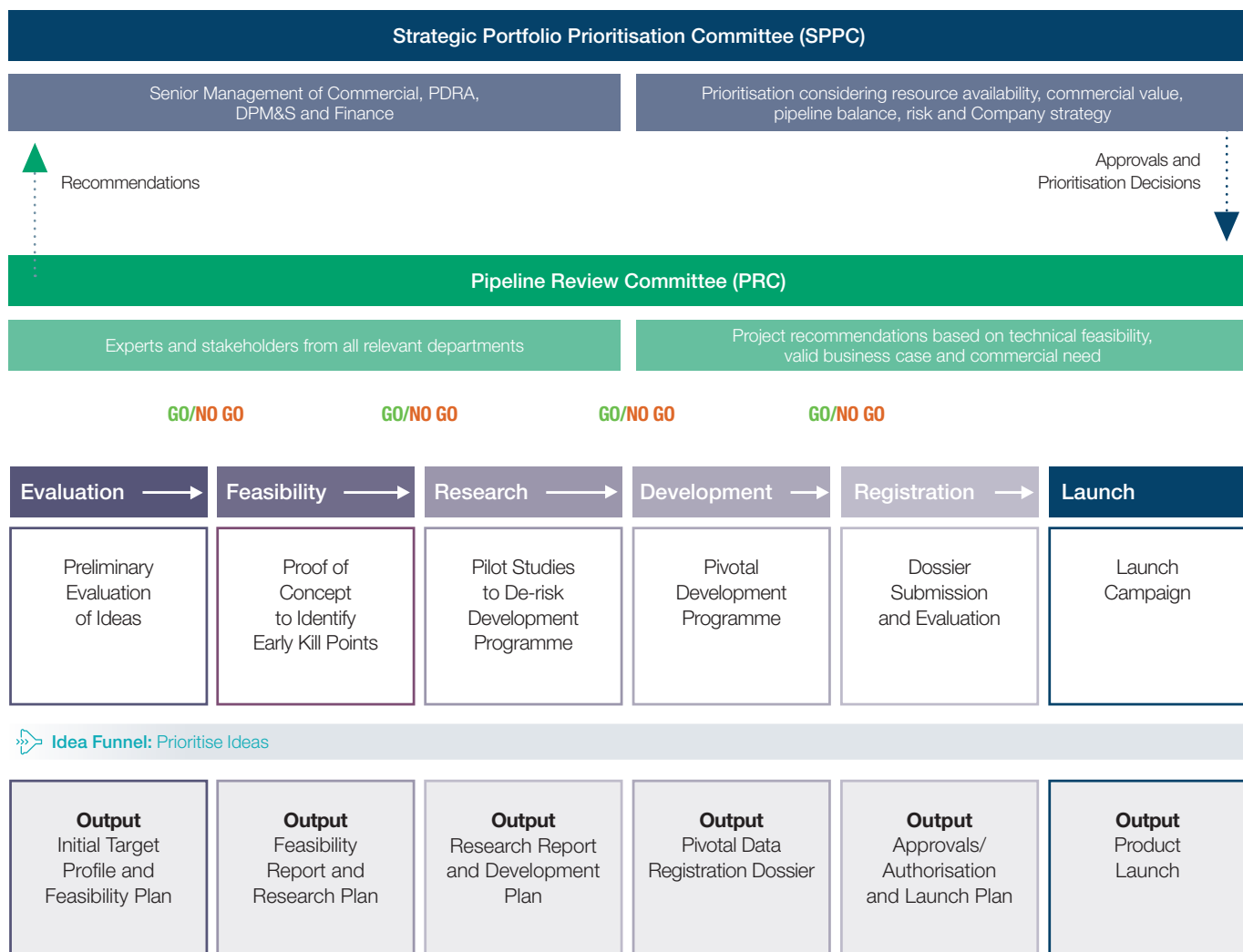
Stage Gate Process

The Pipeline 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 Pipeline Delivery on page 30

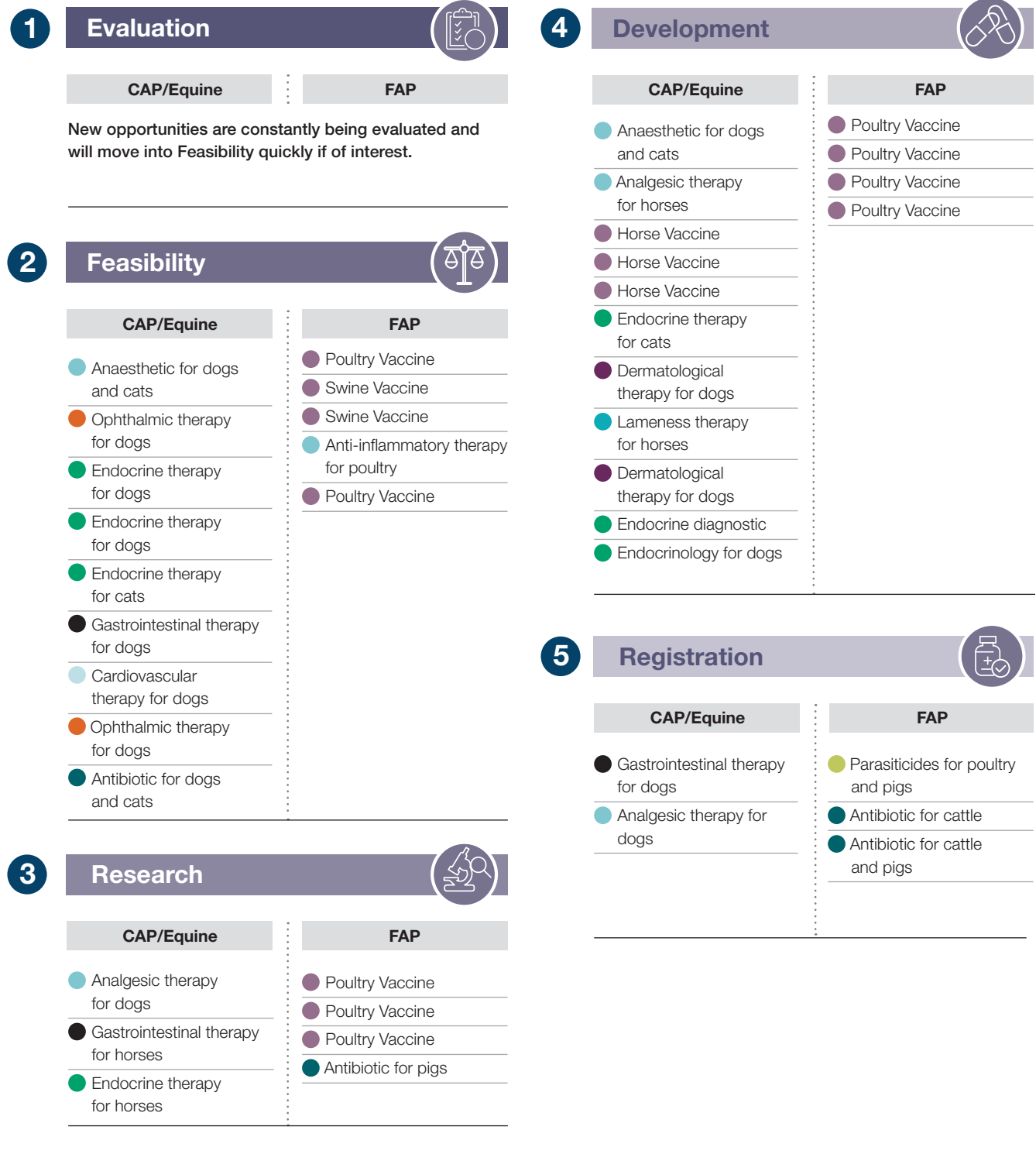


Product Development



Product Pipeline

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.



Key to Product Pipeline

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

Global Product Offering

		COUNTRY																				INTERNATIONAL*								
Key Product	Animal	Australia	Austria	Belgium	B&H	Brazil	Canada	Croatia	Denmark	Finland	France	Germany	Ireland	Italy	Mexico	N'lans	NZ	Norway	Poland	Portugal	Serbia	Slovenia	Spain	Sweden	UK	US	Africa	Asia	Europe	Americas
<i>Atipam/Sedastop</i>	Cats, Dogs		●	●	●		●	●	●	●	●	●	●	●	●	●		●	●	●	●	●	●	●	●	●	1	5	4	
<i>Carprofren/Carprovet</i>	Dogs	●	●	●				●	●	●	●	●	●	●	●	●	●		●	●	●	●	●	●	●		1			
<i>Comfortan</i>	Cats, Dogs		●	●	●		●	●	●	●	●	●	●	●	●	●						●	●	●	●	●				
<i>Dexmedesed</i>	Cats, Dogs		●	●				●	●	●	●	●	●	●	●	●						●	●	●	●	●				
<i>Domidine</i>	Cattle, Horses		●	●			●			●	●	●	●	●	●	●						●	●	●	●	●	1	3	2	
<i>Euthasal</i>	Cats, Dogs, Rabbits, Cattle, Horses																												2	
<i>Melexoral/Meloxicam</i>	Cats, Dogs	●	●	●	●		●	●	●	●	●	●		●			●	●	●	●		●	●	●				3	8	
<i>Pardale V</i>	Dogs																													
<i>Sedator/Sedastart</i>	Cats, Dogs		●	●	●			●	●	●	●	●	●	●	●	●			●	●	●	●	●	●	●	●	1	8	8	
<i>Tilzolan</i>	Cats, Dogs																									1	6	6		
<i>Tralieve/Tramadol</i>	Cats, Dogs		●	●	●			●	●	●	●	●	●	●	●	●			●	●	●	●	●	●	●					1

Other products: Anesketin, Bupredine, Fentadon, Intubeaze, Ketamine, Meloxidolor, Myorelax, Nerfasin, Relaquine, Rominervin, Sedalex, Sympagesic, Tranquinervin

		COUNTRY																				INTERNATIONAL*									
Key Product	Animal	Australia	Austria	Belgium	B&H	Brazil	Canada	Croatia	Denmark	Finland	France	Germany	Ireland	Italy	Mexico	N'lans	NZ	Norway	Poland	Portugal	Serbia	Slovenia	Spain	Sweden	UK	US	Africa	Asia	Europe	Americas	
<i>Amoxi-Clav/Clavubactin/Clavacillin</i>	Cats, Dogs	●	●	●					●	●	●		●	●		●	●		●	●			●		●	●		2			
<i>Cefpodoxime Proxetil/Cefppoderm</i>	Dogs																									●	4	7			
<i>Diatrim</i>	Cats, Dogs, Cattle, Pigs		●	●							●	●	●	●		●				●	●		●		●		1	1			
<i>Doxybactin</i>	Cats, Dogs	●	●	●		●		●	●	●	●	●	●	●	●	●	●			●	●		●		●		1	7			
<i>Equibactin</i>	Horses		●	●				●	●	●	●	●	●	●	●	●				●			●		●		1	2			
<i>Enroquin</i>	Cats, Dogs	●		●		●			●	●	●	●	●	●	●	●	●			●			●		●		2				
<i>Marboquin</i>	Cats, Dogs																														
<i>Metrobactin</i>	Cats, Dogs		●	●				●	●	●	●	●	●	●	●	●				●	●	●	●	●	●	●	5	8			
<i>Animax</i>	Cats, Dogs																									●					

Other products: GentaCalm, Muricin

		COUNTRY																				INTERNATIONAL*									
Key Product	Animal	Australia	Austria	Belgium	B&H	Brazil	Canada	Croatia	Denmark	Finland	France	Germany	Ireland	Italy	Mexico	N'lans	NZ	Norway	Poland	Portugal	Serbia	Slovenia	Spain	Sweden	UK	US	Africa	Asia	Europe	Americas	
<i>Canaural</i>	Cats, Dogs	●	●	●			●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●	●	●	●		7	8		
<i>Isaderm</i>	Dogs	●	●	●	●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●	●	●	●		5	8		
<i>Malaseb/Miconahex</i>	Cats, Dogs		●	●	●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●	●	●	●		2	9		
<i>Malacetic</i>	Cats, Dogs						●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●	●	●	●		8	12	1	
<i>Osurmia</i>	Dogs	●	●	●		●		●	●	●	●	●	●	●	●	●	●	●	●	●	●		●	●	●	●		7	10	6	
<i>Triz Range</i>	Cats, Dogs		●	●	●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●	●	●	●		9	10		

Other products: Recicort, CerumAural, CleanAural, Dermanolon, Sporimune, Anti-Sept, DermAllay, DermBenSS, DermLyte, EpiKlean, KlearOtic

		COUNTRY																				INTERNATIONAL*									
Key Product	Animal	Australia	Austria	Belgium	B&H	Brazil	Canada	Croatia	Denmark	Finland	France	Germany	Ireland	Italy	Mexico	N'lans	NZ	Norway	Poland	Portugal	Serbia	Slovenia	Spain	Sweden	UK	US	Africa	Asia	Europe	Americas	
<i>Felimazole</i>	Cats	●	●	●			●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	6	6			
<i>Forthyron/ Thyroxine/ Thyroxanil</i>	Dogs	●	●	●					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		5	8		
<i>Vetoryl</i>	Dogs	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		9	12		
<i>Zycortal</i>	Dogs	●	●	●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		5	9		

Other products: Cosacthen

Lameness		COUNTRY																				INTERNATIONAL*								
Key Product	Animal	Australia	Austria	Belgium	B&H	Brazil	Canada	Croatia	Denmark	Finland	France	Germany	Ireland	Italy	Mexico	N'lans	NZ	Norway	Poland	Portugal	Serbia	Slovenia	Spain	Sweden	UK	US	Africa	Asia	Europe	Americas
<i>Cyclopray</i>	Cattle, Pigs, Sheep		●	●	●		●	●	●		●	●	●	●	●	●	●		●	●	●	●	●	●	●		1	4	11	
<i>Equipalazone</i>	Horses	●	●	●					●		●	●	●	●	●	●	●		●	●	●	●	●	●	●			5	3	
<i>HY-50</i>	Horses			●			●		●	●	●	●		●	●	●	●		●	●	●	●	●	●	●			5	2	
<i>Osphos</i>	Horses	●	●	●		●	●		●	●	●	●	●	●	●	●	●		●	●	●	●	●	●	●			2	3	
<i>Phycox</i>	Dogs, Horses						●								●										●			1		

Nutrition		COUNTRY																				INTERNATIONAL*								
Key Product	Animal	Australia	Austria	Belgium	B&H	Brazil	Canada	Croatia	Denmark	Finland	France	Germany	Ireland	Italy	Mexico	N'lans	NZ	Norway	Poland	Portugal	Serbia	Slovenia	Spain	Sweden	UK	US	Africa	Asia	Europe	Americas
<i>Specific</i>	Cats, Dogs			●					●	●	●		●		●		●	●	●	●	●	●	●	●	●			3	11	

Water Solubles		COUNTRY																				INTERNATIONAL*								
Key Product	Animal	Australia	Austria	Belgium	B&H	Brazil	Canada	Croatia	Denmark	Finland	France	Germany	Ireland	Italy	Mexico	N'lans	NZ	Norway	Poland	Portugal	Serbia	Slovenia	Spain	Sweden	UK	US	Africa	Asia	Europe	Americas
<i>Altidox</i>	Pigs, Chickens, Turkeys		●	●							●	●							●	●			●							
<i>Centidox</i>	Pigs, Cattle		●	●								●		●		●							●							
<i>Otaccillin/Solamocta</i>	Pigs, Chickens, Turkeys		●	●				●	●		●	●	●	●		●			●	●	●	●	●	●	●			3	2	
<i>Soludox</i>	Pigs, Chickens, Turkeys		●	●	●			●	●		●	●	●	●		●			●		●	●	●	●	●		1	8	6	
<i>Tri-Solfen</i>	Cattle, Pigs, Sheep	●															●													

Other products: *Metaxol, Methoxasol, Phenocillin, Solacyl, Tialin*

Vaccines		COUNTRY																				INTERNATIONAL*								
Key Product	Animal	Australia	Austria	Belgium	B&H	Brazil	Canada	Croatia	Denmark	Finland	France	Germany	Ireland	Italy	Mexico	N'lans	NZ	Norway	Poland	Portugal	Serbia	Slovenia	Spain	Sweden	UK	US	Africa	Asia	Europe	Americas
<i>Avishield ND</i>	Chickens, Turkeys		●	●	●			●	●			●			●				●	●	●	●			●		5	7	5	
<i>Excell 10</i>	Cattle, Pigs, Sheep, Goats					●																							5	
<i>Vencomax</i>	Dogs					●																					1	1	7	

Other Brands		COUNTRY																				INTERNATIONAL*								
Key Product	Animal	Australia	Austria	Belgium	B&H	Brazil	Canada	Croatia	Denmark	Finland	France	Germany	Ireland	Italy	Mexico	N'lans	NZ	Norway	Poland	Portugal	Serbia	Slovenia	Spain	Sweden	UK	US	Africa	Asia	Europe	Americas
<i>Cardisure</i>	Dogs	●	●	●					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●			8	9	
<i>Isathal</i>	Cats, Dogs, Rabbits	●			●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●			5	6	
<i>Libromide</i>	Dogs		●	●				●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●				2	
<i>Mirataz</i>	Cats		●	●			●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●			5	7	
<i>Phenoleptil</i>	Dogs		●	●				●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●				3	
<i>Prednicortone</i>	Cats, Dogs		●	●	●			●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●			1	6	
<i>Prevomax</i>	Dogs		●	●	●			●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●			7	8	
<i>Vetivex</i>	Cat, Dogs, Cattle, Horses			●					●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●			1		

Other products: *Apovomin, Fruesdale, Hypertonic, Laxatract, Lubrithal, Ophtricycline, CleanOcular, Puralube, Vetropolycin*

* Not all products are sold in each country within a continent.