Animal Health: R&D Functions & Externalisation Opportunities

PEER REVIEWED

Introduction

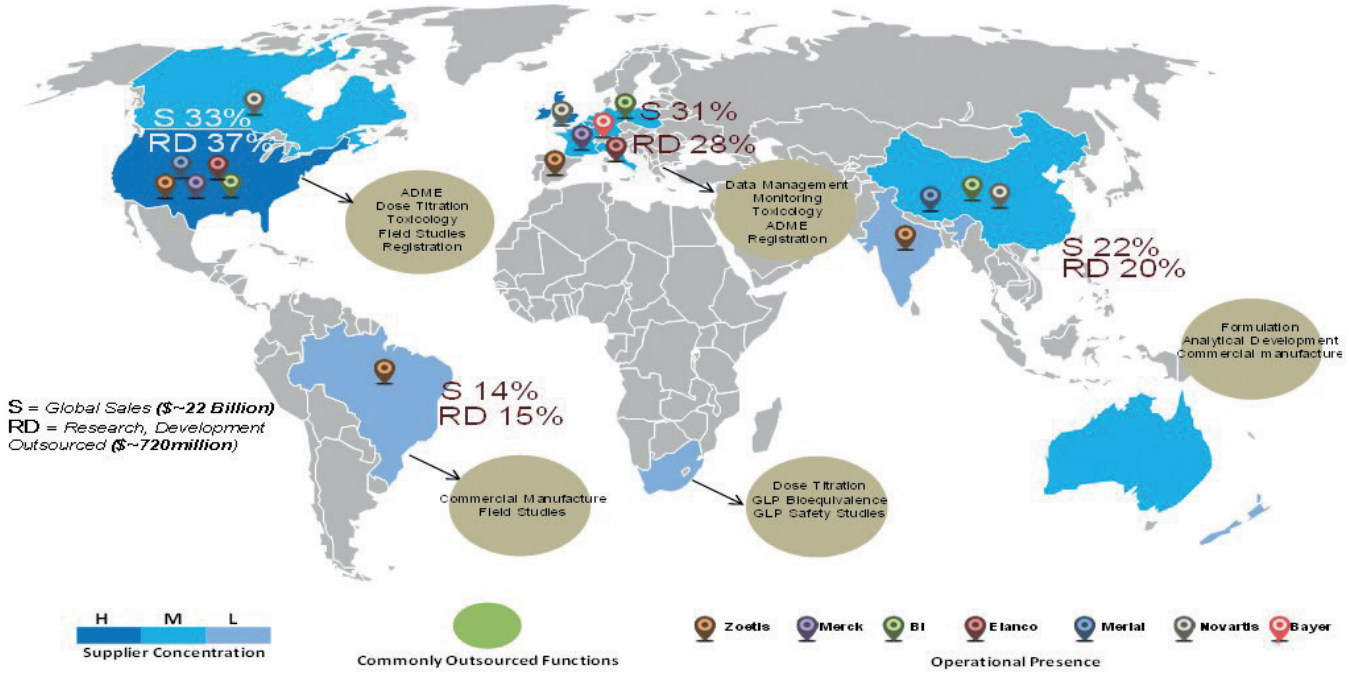
Over the last two decades the costs and time of developing an animal health product have both increased by >100 % and six years, respectively. R&D investment across the top manufacturers, which account for 10 -12 % of sales, is slated to reach the $3 billion mark in next 2-3 years. Outsourcing in key regions such as the EU has increased from the average 25 % to 40 % and the last decade has witnessed a surge in the number of dedicated animal health CROs, labs & consulting organisations, pan-US and EU. Given such market developments, it is in the best interest of category/sourcing managers to have actionable insights, in order to grasp cost savings opportunities and streamline their R&D functions via taking informed decisions concerning externalising functions. This paper attempts to provide a cursory glance at the global animal health market, its chief constituents, R&D trends, outsourcing practices incorporated by large manufacturers and best sourcing approaches, across shared functions of human and animal health R&D divisions, such as toxicology and process-oriented functions such as data and project management, to name but a few.

Recommendations

Leverage outsourcing, for the cost and time benefits that accrue to a manufacturer, by virtue of externalising functions based on an objective assessment of each spend category/ micro-market/function. Revisit existing sourcing practices and seek to consolidate spend among a preferred list of suppliers for two-pronged benefits of A. vendor management through reduced number of transactions and B. cost benefits through volume bundling and qualifying for discounts.

In stark contrast to the competitive dynamics witnessed in the human health pharmaceutical market, which is close to 40x the market size of animal health products and pegged at a massive $ 856 billion, the fragmented and intricate animal health industry faces its own set of challenges. The two major product segments, namely, companion animal and farm animal products, albeit having shorter, less expensive R&D cycles, are taxed with stringent regulatory demands, formulation and medicine administration complexities and competition for resources with the human health divisions. Furthermore, insofar as the market potential is concerned, it is critical that manufacturers target significant unmet needs across product types (anti-microbial, vaccines and parasiticides) and species segments, whilst challenges relating to compound scouting and escalating costs are efficiently managed. The aforementioned phenomena are expected to prompt newer business models to emerge alongside a hitherto unobserved greater reliance on the third-party R&D partners.

Current Industry Trends:



Source: Primary Interviews and secondary document http://www.ifaheurope.org/about/about-the-industry/facts-and-figures.html, (http://www.ifahsec.org/ifah-reveals-outcome-of-global-benchmarking-survey-on-animal- health-industry/)

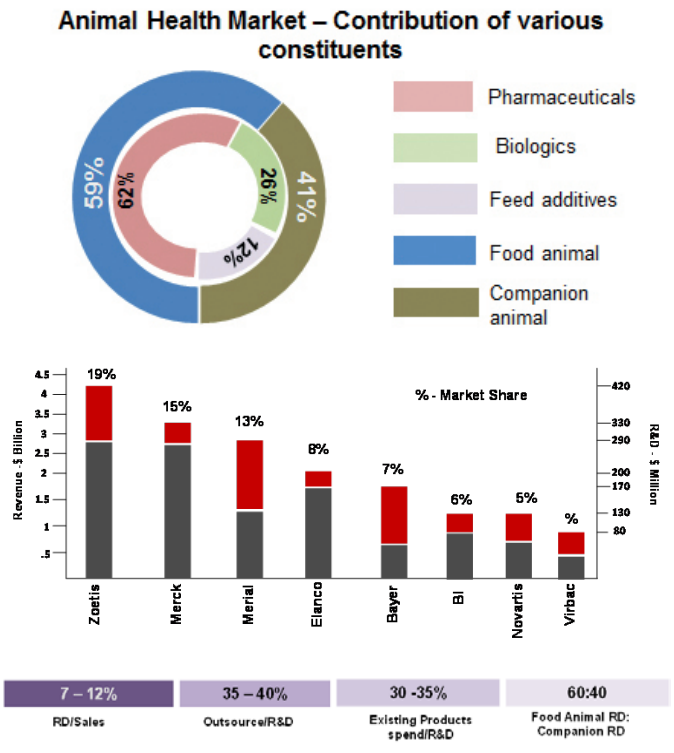
"Considering the significant increase in costs of diseases and the rise in ownership of companion animals, R&D focus in the next few years would be 'NextGen' parasiticides and anti-virals, across livestock and companion animals"

Global Sales Set to Grow at a CAGR of 6%

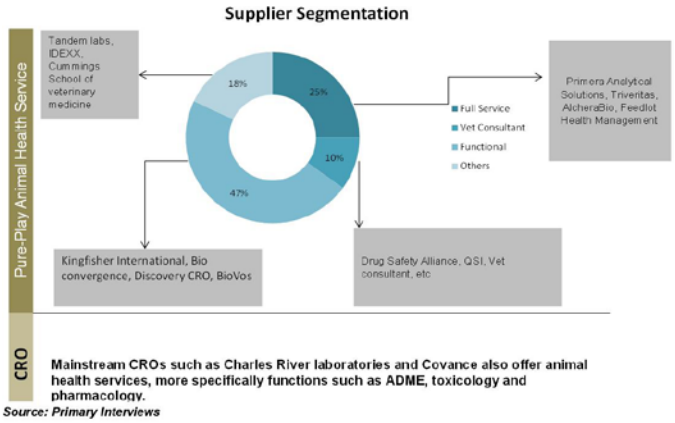
The US and EU currently account for close to three-quarters of the $22 billion global animal market. In the EU, France, Germany, Italy, Spain, and the United Kingdom are the markets expected to drive sales in the product segments companion and livestock. The top-selling animal health products are anti-parasitic for companion animals, and generate annual sales of almost $1 billion a year. Zoetis is the leading firm, with sales close to $4.2 billion and a healthy pipeline of products. The emerging markets, including India and China, have been predominantly farm-animal-driven markets as opposed to companion animals. However, this trend is likely to change, as the overall economic outlook in these regions will drive adoption of pets, especially among the growing middle classes.

Research & Development

The average R&D spending among mid-size pharmaceutical firms (revenue of $200-800 million) and large animal health companies (>$800million), is 7-8% and 10-12% of sales, respectively. R&D facilities of large pharmaceuticals are primarily concentrated in the major markets the US and EU. A marked difference in spending within various functions of the value chain is the fact that ~35% of the R&D budget is directed towards existing brands' life-cycle management. Key product segments and species of spend include parasiticides, vaccines for cats, dogs and cattle. R&D would also seek to tap opportunities in ectoparasitic, osteoarthritis, cardiac, renal, cancer, analgesia, anaesthesia and reproductive area.



Source: Primary Interviews and secondary documents http://www.ifahsec.org/ifah-reveals-outcome-of-global-benchmarking-survey-on-animal-health-industry/, please refer to the research methodology)



Source: Primary Interviews

Animal Health - Outsourced Services Market

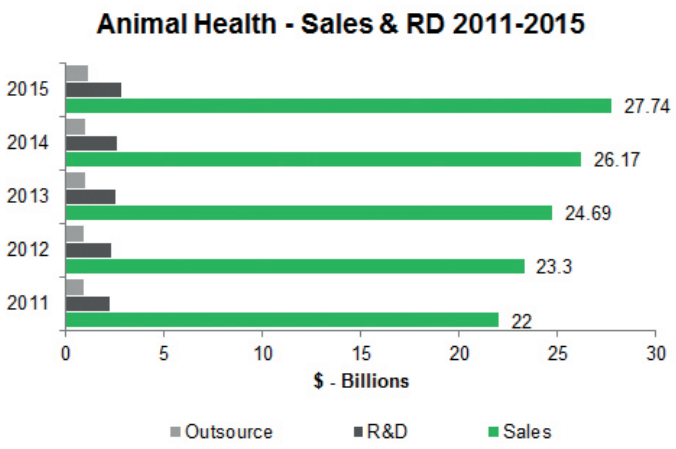
The average outsourcing rate hovers at 40% of the R&D budget. A large portion of the functions are outsourced to functional CROs, who specialise in various phases such as field studies and discovery R&D.

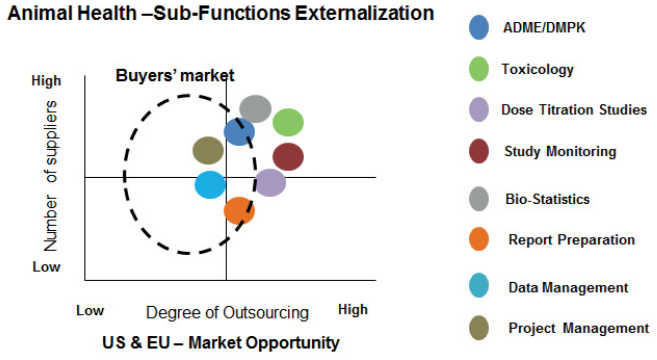
Off-shoring to emerging markets, unlike human health R&D, is restricted, owing to that fact that field studies ought to be done in the target commercial markets and the poor track record of discovery/innovation in developing markets. Hence, the US and EU would be the leading destinations for contracted work and are likely to account for over 50% of the animal health CRO market.

"The CROs offering animal health services are well poised to address greater volumes of contracted work, partly owing to consolidations, competition for finite resources and an inherent dearth of expertise in the animal health sector. Large pharmaceuticals including Zoetis, Merck, Elanco, and Bayer engage with multiple service providers. Outsourcing in silos as opposed to an integrated approach is largely due to higher process & cost efficiencies gained through functional engagements especially in functions such as regulatory submissions and project management."

Companion Animal Development: Toxicology Advantage

There are virtually no toxicology tests required for companion animals, and therefore the chief driver for TOX is the livestock segment, for which studies are conducted on rodents to determine safety factors and continue till the development phase. Toxicology is also done in conjunction with residue testing for human food safety in the development phase. Three- and six-month toxicology programmes are mandated by the regulatory agencies and usually overlap between discovery and development phases. **Therefore, the low requirement of the toxicology for companion animals allows slashing significant amount of development time and the associated costs**. Furthermore, DMPK is optional for companion animals; however, in the case of livestock the same is mandatory.





Source: Primary Interview

In-licensing Compounds

Most animal health companies, especially the mid- and small-sized, do not have their own discovery organisations. Some firms like Aratama and Kinread Biosciences outsource 100 % of the development work. "Seekers" zero in on potential compounds to be in-licensed from the human health parent organisation, and the same are developed for various target species. This is seen as a highly pragmatic approach as products suitable for cats can be suitable for dogs, and extension to other species is possible.

Commonly Outsourced Functions and Preferred Regions

Formulation: Heavily outsourced to vendors like **ARGENTA, CEBIPHAR, PIEDMONT**

Regulatory: Regulatory dossier preparation, submission and support are outsourced often to specialist animal health regulatory CROs or consultants. In the EU, each technical section requires a "Detailed and Critical Summary" (also called an expert report) that is highly outsourced. Outsourcing of the DACS is always within the EU. Outsourcing of regulatory dossiers is in the US for US submissions and the EU for EU submissions.

Pharmacovigilance: Clinical trial PV is largely outsourced; however, pharmacovigilance for post-marketed drugs has been retained. Zoetis and Bayer have invested in training PV resources for managing post-marketed drugs' PV.

Contract Management: Cursory Adoption Trends

Model	Developed Markets	Emerging Markets
FTE based pricing		
FFS based pricing		
Project based pricing		
Project based engagement		
Preferred partnership		
Strategic partnership		

Outsourced Functions and Preferred Regions

Functions	Regions
Clinical trial material storage and distribution	US and EU
Electronic data capture systems for studies	US
Clinical pathology and chemistry	US and EU
GLP Bioequivalence Studies	US, EU, Canada, South Africa
GLP target animal; safety studies	US, EU, Canada, South Africa
Formulation/Analytical Development	US, EU, New Zealand, India
Commercial Manufacture	US, EU, Eastern Europe and Asia

Conclusion

In conclusion, the supply market for outsourced animal health services will likely witness consolidations at functional levels in different regions. Academic institutions would also play an integral part in early innovation and discovery. The US and EU, which adhere to the VICH guidelines, will continue to remain major markets in terms of sales and R&D spending. Investments would also be directed at diseases for which there haven't been treatments, like the feline viral diseases; however, they will remain at moderate levels as incidences have been low. Time and costs to gain registrations have increased significantly and therefore sponsors/manufacturers are expected to rely on third-party specialised regulatory consultants. Competitive positions of the leading animal health manufacturers such as Zoetis, Merck and Merial will be closely monitored, and one could expect stern competition from the likes of Elanco and Novartis, adding to the dynamism of the animal health market.

Research Methodology and References

The contents of this paper were derived from secondary literature and primary interviews with suppliers based in the US and EU (sample size - 21). Comments of key opinion leader with animal health experience of over 25 years in R&D management and outsourcing auditing have also been captured.

Secondary Sources

1. "IFAH reveals outcome of Global Benchmarking Survey on Animal Health Industry" -PDF
2. "Facts & Figures of the European animal health industry"
3. "Animal Health: Market & Opportunities: Companion animal landscape" by Linda J.I. Horspool
4. "Facts and Figures About the Animal Health Industry - NOAH"
5. "Promoting a positive environment for veterinary medicines: A case for separate regulation for the animal medicine sector
6. Financial statements of companies and other press releases

Working Notes:

Company	Sales - Year 2012	R&D % of 8.1%/10%	Sales ratio Livestock : Companion animal	R&D split $ million	% total R&D	Market Share
Zoetis	$4.2billion	420 million	65:35	273:147	23.3	24%
Merck	$3.3billion	330 million	80:20	264:66	18.3	19%
Merial	$2.9billion	290 million	40:60	116:174	16.1	16.5%
Elanco	$2billion	200 million	85:15	170:30	11.1	11.5%
Bayer	$1.7billion	170 million	30:70	51:119	9.5	10%
BH	$1.3billion	130 million	70:30	91:39	7.2	7.1%
Novartis	$1.3billion	130 million	50:50	65:65	7.2	7.1%
Virbac	$.8billion	80 million	50:50	65:65	7.2	4.6%
		Sum:1750				

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Sales Growth :6% CAGR

	Sales	RD 10%	RD 8%	RD 12%
2011	$22	2200m	1760m	2640m
2012	$23.3	2330m	1864m	2796m
2013	$24.69	2469m	1975m	2962m
2014	$26.17	2617m	2093m	3140m
2015	$27.74	2774m	2219m	3328m

Outsourcing @ 40% : 10% RD level

		OS
2011	2200m	880m
2012	2330m	932m
2013	2469m	988m
2014	2617m	1047m
2015	2774m	1110m

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