



Editor's Note

Dear Members,

It gives us immense pleasure in bringing forth yet another exciting edition of INFAH Connect. As you know, this initiative is born with the idea of progressing together by sharing vital information, inviting suggestions and reform measures, which will help us to take the animal health industry forward into a glorious future.

This edition of INFAH Connect disseminates light on various tasks undertaken by INFAH in the past few months. On the regulatory front, representation of GST matter and co-organising round table on guidelines for antimicrobial standards in Livestock healthcare in association with IAAVR were the major initiatives. Under the CSR initiatives, INFAH extended help to the farmer's affected in Chennai floods.

One of the major attraction is INFAH participation at HealthforAnimals for attending the 26th General Assembly and 4th Members' Association Forum at Brussels, Belgium. On the reform side, we have initiated various measures to reach out to the college students with a view to create more awareness of the animal health industry. This is also opening gateway for young and enthusiastic professionals to join us and take our industry to the next level. The edition also covers topics such as subcommittee reports, market update, industry news and many more.

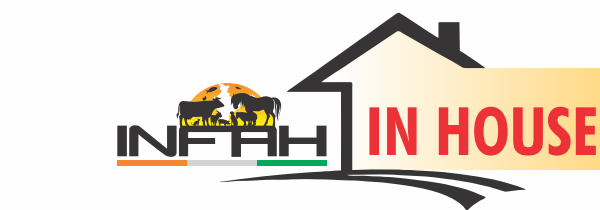
On the concluding note, I urge you to share your feedback and suggestions to improve this platform. With your ideas and participation, we can make INFAH Connect more engaging and enriching expression. You can reach out to us on infahconnect@infah.org; infahconnect@gmail.com Looking forward to hearing from you.

Happy reading!



We invite interested members to be part of INFAH Connect team as Zonal Coordinators.

Interested members are requested to write back to us at: infahconnect@infah.org; infahconnect@gmail.com



GST Representation

Animal health industry manufactures feed supplements to optimize the nutritional value of animal feeds and support animal productivity. Feed supplement/ Feed additive products are currently exempted from Central Excise Duty and also VAT across majority of states in India. However, now with a view to simplify and integrate the current diverse indirect tax structure in India, the government of India seeks to introduce 'Goods & Service Tax' (GST). Under GST regimen certain essential goods and services are proposed to be exempted from levy of GST. Therefore, INFAH wishes to extend the currently available Indirect Tax exemption on Feed Supplement in the GST regimen as well. To realize this INFAH has appointed KPMG for representation before various stakeholders with a view to cover animal feed supplements in the list of 'exempted goods'. Following work has been done in this direction until March' 2016.

- A representation document on behalf of INFAH has been prepared which has been reviewed and validated by the managing committee.
- Representation has been already submitted to Empowered Committee of State Finance with copies to Ministry of Finance (Joint Sec. Revenue) and Department of Animal Husbandry, Dairy and Fisheries (Secretary). We have accordingly represented to the Empowered Committee of State Finance Ministers that animal feed supplements should continue to be categorically exempt from GST even under the proposed GST regime so as to avoid any negative impact of additional tax burden on feed supplements which are an essential ingredient of animal feeds.

Followup Meetings

A meeting with key officials in Department of Animal Husbandry, Dairying & Fisheries (Animal Health Commissioner, Secretary and Joint Secretary) was undertaken to solicit action on the INFAH representation for GST. INFAH team comprising of Dr. Atrey, Mr. Teng, Dr. Phalke and KPMG representative Mr. Dalvi met all key officials.



In coming days a similar meeting with Central Board of Excise & Custom and Ministry of Finance is planned by KPMG to further take this representation and try to convince these authorities considering inclusion of feed supplement in the list of products exempted from levy of GST.

Round Table on Guidelines for Antimicrobial Standards in Livestock Healthcare

Indian Association for the Advancement of Veterinary Research (IAAVR) during its 16th Indian Veterinary Congress, 23rd Annual Conference of IAAVR and National Symposium on 'Strengthening of Governance in Animal Health and Production Activities for the benefit of Farmers and Livestock owners' organized a Round Table on 'Guidelines for Antimicrobial Standards in Livestock Healthcare' with the aegis of Indian Federation of Animal Health Companies (INFAH) in College of Veterinary Science and Animal Husbandry, Orissa University of Agriculture and Technology (OUAT), Bhubaneswar on 27-28th February' 2016.

The round table was attended by more than 120 Veterinarians associated with academic and research field and policy makers from Indian Council of Agricultural



Eminent speakers presenting their views during the round table conference



Research and its associated institutes and also from State and Central Universities. The objective was to deliberate over the concerns of Antibiotic usage in animal healthcare and its impact on human health. The round table was co-chaired by Dr. Sitangsu Mohan Deb, Director, ICAR-National Research Centre on Yak; Mr. Vijay Teng, General Secretary, INFAH and Dr. Rishendra Verma, Founder Secretary, IAAVR.



The round table was participated by eminent speakers, Dr. Sumanth Gandra, Centre for Disease Dynamics, Economics and Policy (CDDEP, Washington) ; Dr. G. Sarath Chandra, Professor and Head, Pharmacovigilance Laboratory for Animal Feed and Food Security, Tamil Nadu Veterinary and Animal Sciences University (TANUVAS); Mr. Somu Ambat, Access Consultancy; Dr. S. K. Mody, Professor and Head, Department of Pharmacology and Toxicology, S.D.A.U, Sadarkrushinagar and Industry professionals, Dr. Nitin Bhatia and Dr. D. J. Kalita.

The scientific deliberations highlight that antibiotics are essential part of therapeutics management of infectious disease in both livestock and pet animals, insuring better animal health and life. India currently contributes 3% of the world livestock antibiotic consumption and harbours 10% of the world food animal production. By 2030, this consumption would go upto 4% considering the animal population and need of antibiotics for a healthy and secure life of animals and also human. The need is to strike a balance between the benefits and risk of using antimicrobials in the food supply chain. The discussions even highlighted that the recent CSE study suggests that concentration of antibiotics isolated from specimens are within the MRL outlined by European Union and United States. The concern is to ensure responsible and prudent use of antibiotics for animal welfare and protection as well as management of infectious diseases ensuring food from these animals is safe and healthy for humans.



INFAH stands for farmers affected with Chennai floods

INFAH in collaboration with TANUVAS organized three animal health camps for the farmers who got affected by Chennai floods. On 16th December' 2015 at Nolambur in Chennai, 19th December' 2015 at Karai Village in Kancheepuram district and 23rd December' 2015 at Vadalur in Cuddalore district. In Chennai, it was a mobile health camp covering various places of Nolambur and Vanagaram villages.



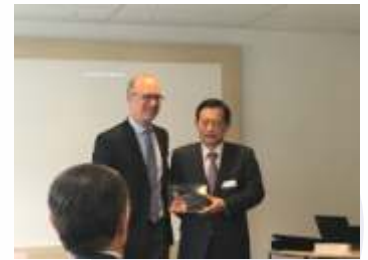
Inputs like Fodder seeds, feed, mineral mixtures, salt bricks were distributed. Veterinary Aid like medications, vaccinations, pregnancy diagnosis, general health checkup was provided to bovines of beneficiaries. Awareness on Azolla as economical and efficient livestock feed and water sanitation were also demonstrated.

Vice Chancellor, TANUVAS; Dean, Madras veterinary college; Director Clinics, TANUVAS; Technical Staff, Non-Technical Staff and students of TANUVAS actively supported this initiative. Most of INFAH member companies participated in these camps.



INFAH @ HFA - Brussels

Animal Health associations across the globe had come under one roof at office of HealthforAnimals in Brussels, Belgium on 8th and 9th March for 26th General Assembly and 4th Members' Association Forum.



The event was attended by member associations, AAHA (South East Asia), AMA (Australia), AHI (USA), AISA (Italy), APIFARMA (Portugal), BfT (Germany), CAHI (Canada), FIDIN, IFAH-Europe (Europe), INFAH (India), JVPA (Japan), LIF (Sweden), NOAH (U.K.), Pharma.be (Belgium), SAAHA (South Africa), SIMV (France), SINDAN (Brazil), Science Industries (Switzerland), THAI AHPA (Thailand), VETERINDUSTRIA (Spain) and VIF (Denmark).

Ms. Kim Hardie, Communications Director from HealthforAnimals shared various information, documents and tools developed by HFA for general public and Animal health stakeholders. She also talked about the plans of HFA to organize 'World Vaccination Day' on 20th April.

Joseph Harvey, the guest invitee from Animal Pharm described the animal health industry to be healthy and performing well. He explained that the challenge of the industry is to communicate clear messages that make sense and relate to target audience. He stated that communicating about diseases and their impact on trade, economic growth, food safety and security should to be a collaborative effort.

Major topics covered during discussion were global regulatory convergence, responsible use of antibiotics, pharmaceuticals in the environment etc.

In the General Assembly, George Heidgerken, President HealthforAnimals presented the report of activities of the association for the last twelve months. He recalled the priorities agreed for the federation which includes Global regulatory convergence and harmonization, pathways for

access to market and for innovative new products, key developing markets: China, Brazil, Russia, India and networking among the association members and communicate value animal health (companies) brings to society. He also presented financial report of 2015-16.

Carel du Marchie Sarvaas, Executive Director HealthforAnimals presented the proposed programme of activities for 2016-2017.



INFAH was represented by Mr. Vijay Teng, General Secretary, INFAH. He presented the regulatory status in India and shared best practices that are applied. He also elaborated the Animal welfare efforts going on in India. Mr. Teng shared with all the member associations about the initiatives taken by INFAH towards streamlining various regulatory issues, addressing the concerns of animal health companies and contributing towards the society by conducting CSR activities. He also highlighted the areas where both associations can collaborate and it was agreed to organize the "Global Animal Health Conference: 2016" at New Delhi on 17th November.

World Tuberculosis Day 2016

World Tuberculosis day on 24th March of each year is designed to build public awareness about the global epidemic of tuberculosis (TB) and efforts to eliminate the disease. On 24th March 1882, Dr. Robert Koch discovered the cause of tuberculosis, the TB bacillus. This year the theme for World TB Day was 'Unite to End TB'.

INFAH in association with Madras Veterinary College, TANUVAS organized "World Tuberculosis Day" on 24th March 2016 at Department of Veterinary Public Health and Epidemiology. Under this event quiz competition on "Zoonotic Importance of Tuberculosis" was conducted for undergraduate students. This function was presided over by Dr. M. Sekar, Professor and Head. The Dean of Madras Veterinary College, Dr. C. Balachandran distributed the prizes to winners.



Attracting Talent for Animal Health Industry

To increase awareness among the college students about the career prospects in Animal Health Industry various initiatives have been taken up by INFAH in the past few months.



As a pilot study, a team of INFAH members conducted session on 'Opportunities in Animal Health Industry' at 3 colleges. One was suburban government college, one suburban private college and one city-based college. In comparison to city-based college, the colleges situated in suburban areas had shown a very positive response towards a career in AH industry.

A team led by Chairman of HR subcommittee, Dr. B. P. Manjunatha had approached the College of poultry Production and Management at Hosur in Tamil Nadu which offers B Tech in poultry production and technology for the session. The students and staff were overwhelmed to know about the job opportunities offered by the AH industry. Such poultry institutes can be a very good source of talent for the poultry health industry.



The College of Avian Sciences and Management, formed under the aegis of Kerala Veterinary and Animal Sciences University, offers 3 years poultry integrated course. They have invited us to speak to the students on personality management, while doing so we will expose them to Animal Health Industry too.



SUBCOMMITTEE REPORTS

1. Biologicals Subcommittee

The major discussion within the subcommittee are Industry Interactive Meet with Regulators; Validity period of Import Registrations; Target Animal batch testing on safety and efficacy; Companion Animal Vaccines Approvals; Avian influenza documentation for exports etc.

- Industry Interactive Meet between the industry and Regulators is scheduled on 4th December every year at IVRI, Izatnagar.
- The current validity period of Registration certificates and Import licenses of 3 years requires to be at parity with licenses issued by state and Central FDA. The members felt that it would be relevant to represent this matter to CDSCO for increasing the same to 5 years, as existing for local manufacturing license periods.
- Target Animal batch testing on Safety and Efficacy waiver was proposed and would be discussed further with Dr.

Ashok Kumar Tiwari, Head, Division of Biological Standardization, IVRI

- The animal health industry is facing concerns of approvals from MOA for Canine biologicals. It was discussed to refer the matter to the regulators with the facts and discuss the way forward.
- Avian Influenza free documentation for exports is a need and should be represented to MOA for their support.

– Contributed by Dr. D. K. Dey

2. Drugs and Therapeutics Subcommittee

- The subcommittee has decided that 'New Veterinary Monographs' of both API and Finished formulations (FF) for addition/ inclusion in IP- Vet' 2018 will be submitted to IPC through INFAH
- As FSSAI is in the process of establishing MRL in milk and meat for Veterinary drugs, therapeutic subcommittee is of the view that INFAH needs to develop meaningful linkages with FSSAI so as to stay updated with the developments.
- Due to rising debate on AMR related to use of antibiotics in food animals, it was decided that INFAH members need to pursue (and assist) IAAVR committee for submission of the proceeding of the recent round table conference on AMR at IAAVR Conference (Bhubaneswar) to regulatory authorities.
- It was also felt that representation of INFAH is required with GEAC committee to resolve the ambiguity in the process of approval for recombinant veterinary products.

– Contributed by Dr. Arun Atrey

3. Feed Additives and Feed Supplements Subcommittee

- **GST representation**
Subcommittee has appointed KPMG to discuss the matter of considering inclusion of feed supplement in the list of products exempted from levy of GST. Representation has been already submitted to Empowered Committee of State Finance with copies to Ministry of Finance (Joint Sec. Revenue) and Department of Animal Husbandry, Dairy and Fisheries (Secretary). [For more details, please refer INFAH In-house section]
- **Harmonization of understanding and interpretation of feed supplement**
One of key issues which we are continuously addressing is to harmonize understanding of feed supplement among all stakeholders. In this direction, subcommittee has proposed to create a working group to prepare a comprehensive list of ingredients and its usage that can be basis for identification of these as feed supplement or feed additives. Same list could be validated by government authority.
- **Misbranded Products in the feed supplement category**
There is established guideline for labeling feed supplement products. However still there is concern due to some misbranded / mislabeled products sold in the market in feed supplement category; eg. Dewormer sold

as feed pellets, Nutritional Supplements claimed for prevention of mastitis, Injection sold as feed supplement and may more...

Such products further add to confusion among various authority about identity of feed supplement. Therefore, subcommittee has realized need to raise more awareness to the companies where such mislabeled / misbranded products are detected. Objective is that there should be uniformity among the industry to ensure that feed supplement products are labeled as per specified guideline.

– Contributed by Mr. Satish Pasrija

4. Herbal Subcommittee

- **Organising a Round Table conference with key regulators including Ayush:** The subcommittee is planning to have a round table conference with the regulators. The committee agreed that we need to deal in descending order of priority with National & Local Regulators respectively. A meeting was held with Dr DC Katoch, Advisor-Ayurveda, Ministry of Ayush on 18th April' 2016. Two dates, 3rd June & 10th June' 2016 were proposed to Dr Katoch for Round table conference.
- **Dealing with counterfeit:** INFAH would release guidelines on this regard. There was a proposal for a separate committee to counter counterfeits.
- **Ayurvedic Pharmacopeia:** Ayurvedic Pharmacopeia revision is in progress under the chairmanship of Dr Joshi of BHU. Dr. Katoch from Ministry of Ayush has invited the Veterinary industry to submit the list of herbs used in AH industry for inclusion in Veterinary Ayurvedic Pharmacopeia.

Dr Katoch also advised that Veterinary Ayurvedic companies should submit list of Herbs used along with their specifications for review, ratifications and practically expediting the process of Ayurvedic Veterinary Pharmacopeia.

Challenges facing Herbal Products Sector

Committee Members outlined the following challenges:

- (a) Herbal products are excluded from Institutional purchase lists.
- (b) This subject is of utmost importance and needs elaborate representation in similar platforms including Ministry of AYUSH and Ministry of Animal Husbandry.
- (c) Further to enhance the credibility of Herbal formulations, the suggestion was made to have AYUSH Mark of quality which is currently known as AYUSH Standard, issued to the producer by the Ministry of AYUSH.

– Contributed by Dr. Shirish Nigam

5. Imports and Exports Subcommittee

- INFAH subcommittee would formulate a comprehensive list of feed additives to get it included in the approved list for implementing at ports. The matter would be represented to MOA.
- Newly implemented single window system (Sugam) is

now in process for all imports. As per new regulations, the system requires approval of ADC port/Animal Quarantine/Plant Quarantine.

- Import duty for products like Vitamins and Amino acids of various Asian countries would be reviewed to evaluate that the duties on Indian port are not higher.
- During the subcommittee meeting, EICI guidelines were discussed. It was concluded that same are required to maintain the quality for European exports.
- INFAH to make representation for procuring Avian Influenza Free Certificate from Director, NIHSAD and DDG (Animal Sciences)

– Contributed by Dr. Jeetendra Verma

6. GMP & CSR Initiative Subcommittee

- The subcommittee has been very active in organizing various activities under corporate social responsibility.
- INFAH subcommittee in collaboration with TANUVAS had organized 3 animal health camps for farmers affected by Chennai floods. [Please refer INFAH in-house for more details].
- To highlight the Zoonotic importance of Tuberculosis, INFAH organised a quiz competition for undergraduate students at public health department of Madras Veterinary college. [Please refer INFAH in-house for more details].

– Contributed by Dr. Vijay Makhija

7. HR Initiatives Subcommittee

Entry of fresh and competent talent in our industry is one the most effective way to look for aggressive business growth. We realize that awareness of Animal Health Industry is quite low amongst students of most of the colleges. Even if they are aware of the industry, still most of the time, they are not able to see a clear road map of career progression in this industry. And that's the reason, why they give low priority to AH industry as a career option.

To draw the awareness of students towards our industry, we on behalf of INFAH carried out few pilot projects under which we visited few Science degree colleges and got very encouraging response from the students and faculty. [Please refer INFAH in-house for more details].

The subcommittee has invited companies to take up the task of participating in at least one educational institute every quarter. A activity format is circulated to all the member companies. The SOP and detailed presentation will be also be shared.

Having done this activity, we will be creating Web portal on INFAH website so that interested candidates can post the CVs. We also need to create a poster to depict Career opportunities in Animal health, which can be pasted in college notice boards.

– Contributed by Dr. B. P. Manjunatha

Market Update

Trends impacting the AH industry's- Current Business Strategic Model

AH business models to date have largely relied on lifecycle strategies and industry consolidation that result in commercial economies of scale. Here, we will analyze some of the recent trends which call into question reliance on these models.

We will organize these trends by the value-driver categories they impact. Understanding these trends will help to reveal why AH companies may need to consider new growth strategies and business models.

1. Innovation

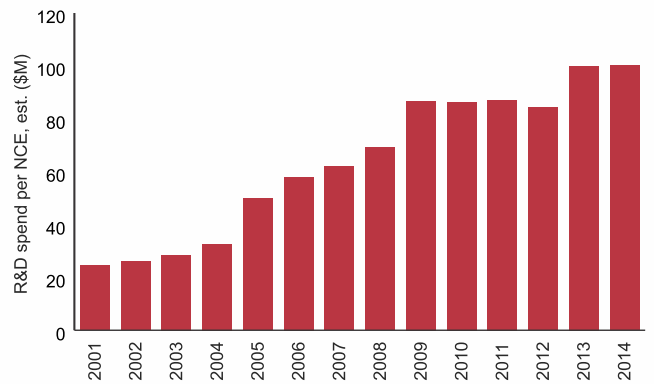
Declining R & D productivity has led to highly mature product portfolios

The AH industry has seen a significant decline in R&D productivity. This decline can be seen in the reduction of NCE approvals over the last decade, combined with increased R&D spending.

- **NCE approvals:** As per PwC analysis, New Animal Drug Application (NADA) approvals for NCEs have declined to an average of only seven approvals per year in the last decade, as compared to 12 per year in the prior decade (Fig. 1)
- **R&D spending:** We estimate that the whole AH industry spent a total of \$700 million on new product (NCE) innovation in 2014. This figure is almost twice the average annual spending level of the prior decade (Fig. 2).

We estimate that, on average, the AH industry currently spends \$100 million for every approved NCE, which is a

Fig. 2 – R&D Spend Per Approved NCE, 2001-2014



Source: PwC estimates based on data from FDA, Zoetis company filings, Vetnosis

significant increase in the industry's cost of innovation over the last decade (Fig. 2). One of the key reasons for this trend is that AH product manufacturers have been investing in therapy areas that are highly mature, with fewer opportunities for significant innovation

Lower R&D productivity means that AH product manufacturers' portfolios have matured. PwC estimates that the average age of the leading AH players' product portfolio is more than 15 years, with key drugs on the market for more than 20 years.

Mature product portfolios limit the potential of lifecycle strategies in driving growth

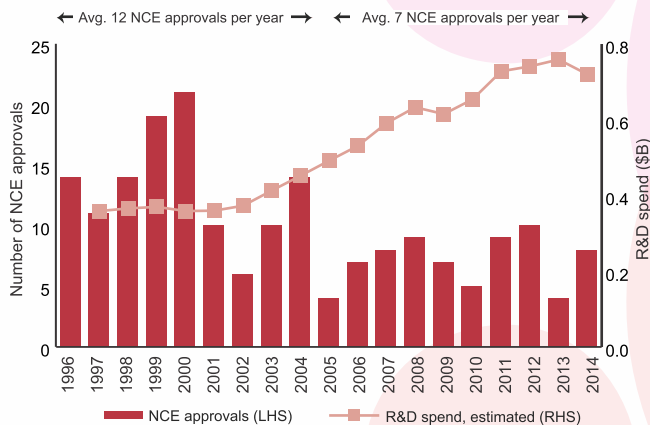
NCE approvals help to drive both sales and the launch of NADA approvals for product extensions (Fig. 3). In other words, NCE approvals set the stage for companies to formulate lifecycle strategies. With fewer NCE approvals in recent years, AH players are faced with limited opportunities to grow through lifecycle extension strategies in the near future

2. Portfolio Advantage & Commercial Excellence

Market share concentration limits the ability of leading AH players to grow through large acquisitions

Industry consolidation over the last decade has resulted in a consolidated competitive landscape.

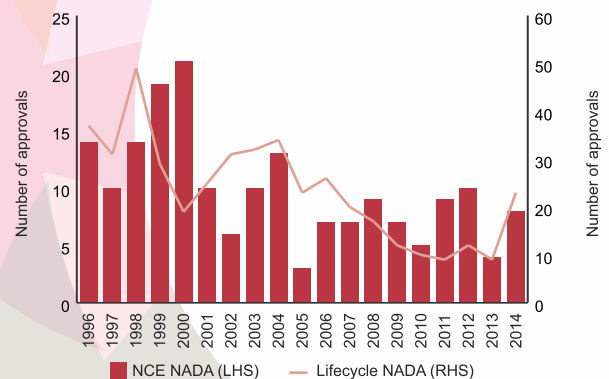
Fig. 1 – Decline of R&D Productivity: NCE Approvals vs. R&D Spending (estimated), 1996-2014



Note: 1996 R&D spending could not be estimated.

Source: PwC estimates based on data from FDA, Zoetis company filings, Vetnosis

Fig.3 – Lifecycle Launches' Relationship to NCE Approvals



Source: FDA/CVM, PwC analysis

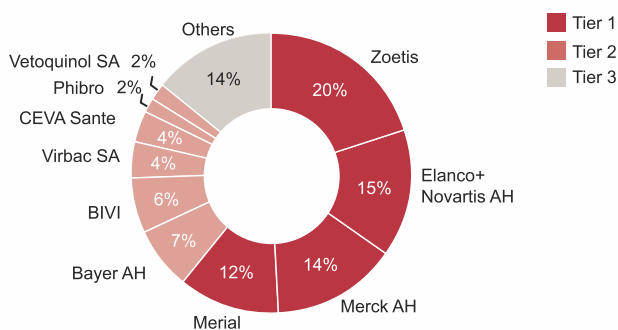
If we analyze the shares of each of the major AH players, we can see there are three tiers of competitors (Fig. 4).

- The top four players (“Tier 1”) represent 61% of the market. Tier 1 companies each have double-digit market share, and are at least twice as large as “Tier 2” players.
- The top ten players (Tier 1 and Tier 2 together) represent 86% of the market. Market share is even more concentrated at the level of product categories and species.
- The remaining market (“Tier 3”) comprises a large number of smaller players.

Given their market share, Tier 1 companies may have limited ability to pursue the traditional strategy of gaining commercial economies of scale via major/transformational deals, unless they work through antitrust concerns by divesting certain assets, or pursue targets whose portfolios are complementary to/distinctive from their own.

Large acquisitions for leading players could be challenging.

Fig. 4. – AH Product Manufacturer Tiers, by 2014 Market Share (Sales)



Note: Elanco acquired Novartis AH in January 2015.
Source: Company reports, Vetnosis, PwC analysis

Increased downstream consolidation in the Production Animal value chain has weakened AH players’ position

In addition to considering trends in the immediate AH product manufacturing industry, it is also important to understand trends in other parts of the AH value chain, particularly in the Production Animal segment. One key theme is the consolidation of downstream entities such as food retailers and food producers, which has weakened AH product manufacturers’ relative position in the value chain.

Consolidation among food retailers

In the U.S., one of the most mature food retail markets, the grocery industry has gone through several phases of consolidation over the last 20 years. Between 1993 and 2003, the share of the top four grocers almost doubled, and the top 20 players’ share grew by almost 50%. Now at \$450 billion in sales, the top 20 U.S. food retailers represent approximately 64% of U.S. grocery sales. Their

size gives them significant negotiating leverage in supplier contracting.

Other players have entered the food retail space, adding to AH product manufacturers’ challenges. Specifically, large global superstores and discount stores, such as Wal-Mart and Target, now have unprecedented influence: decisions by these large food retailers reverberate throughout the value chain. For example, several retailers have corporate social responsibility initiatives that pertain to suppliers, which AH product manufacturers need to consider. According to company Web sites:

- Wal-Mart is working towards sustainable food sourcing for key commodities such as beef. This shift may have implications for favored food producers, whose financial health helps drive AH product purchase decisions.
- Whole Foods does not sell meat from animals raised with antibiotics, and Chipotle aims to source 100% of its pork from naturally raised pigs that have never been given antibiotics. Recently, McDonald’s announced that new menu sourcing initiatives will include only “chicken raised without antibiotics that are important to human medicine.” Decisions such as these could constrain the potential market growth of these AH products, especially if more food retailers take similar positions.

Downstream consolidation weakens AH manufacturers’ position in the value chain.

Consolidation among food producers

In part due to the growing power of food retailers, food producers have pursued many consolidation deals in recent years. For example, in 2009, JBS entered the poultry market through its majority stake purchase of Pilgrim’s Pride. In 2013, Smithfield was acquired by Shuanghui International Holdings for \$4.8B. And in 2014, Tyson Foods (America’s largest chicken processor) acquired Hillshire Brands (branded meats). Deals that increase scale offer many benefits to the producer, including:

- Better pricing power versus food retailers and food service companies, and more influence in the AH value chain.
- More optimal cost structure and/or economies of scope.
- The ability to invest in advanced technology and equipment, thereby increasing productivity.

Food producers’ increased focus on sourcing costs is likely to be reflected in their purchase decision-making for AH products. Further, in parallel with food retailers, food producers such as Tyson Foods have said that they are “striving to eliminate the use of human antibiotics” from their livestock. Such concerns are also likely to impact their purchase decision-making for AH products.

Purchase decisions by the large food producers are likely

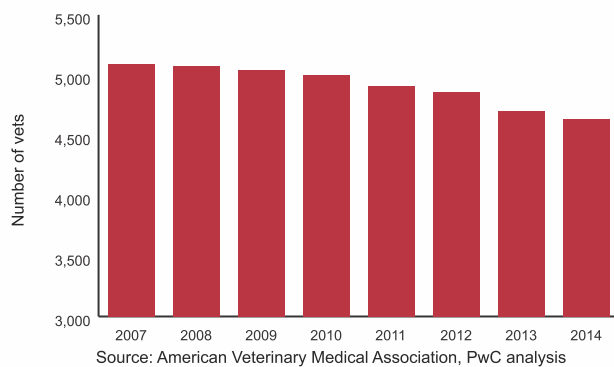
to decide winners and losers in AH product manufacturing, and could influence the choices that AH players should make in product development and sales.

Declining influence of vets in purchase decisions

Increased consolidation among food producers has created large, global corporations that increasingly make purchase decisions at the corporate level, thus reducing the influence of vets. The diminished role of vets has contributed to the consistent decline in the number of vets in the U.S. over the last eight years (Fig. 5). This trend means that Production AH players may need to rethink sales and targeting practices.

Fig. 5 – Number of U.S. Production Animal Veterinarians

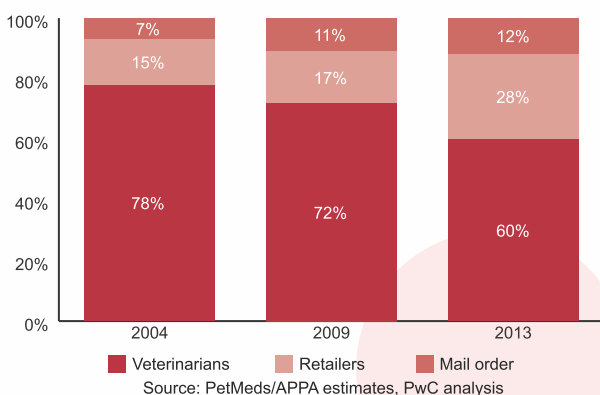
Note, y-axis starts at 3,000 vets.



In the Companion Animal segment, the influence of vets may also be declining, for two main reasons:

Channel shifts: Vets have traditionally disbursed the majority of Companion AH products, but their share of sales has declined in the U.S. over the last decade – from 78% of sales in 2004 to an estimated 60% in 2013 (Fig.6). This shift may be hastened if the Fairness to Pet Owners Act introduced in the U.S. Senate in May 2015 is passed. The bill calls for vets to write pet prescriptions, and could result in an increased ability for pet owners to buy AH products at pharmacies or retailers. This change could require Companion AH companies to rethink their strategies for targeting vets, because vets may become less important stakeholders (because their traditional revenue streams will be diverted) and there could be vet clinic consolidation.

Fig. 6 – AH Sales by Channel, 2004 - 2013



Growth of pet insurance: Currently, in the U.S., less than 1% of pets are covered by insurance, but enrollment is growing at 10% per year. According to Cowen and Company¹, some European countries already have high pet insurance penetration, such as Sweden (40%), U.K. (25%), and Norway (14%). Pet insurance introduces a new decision-maker to the AH value chain (i.e., third-party payers), which might further diminish the relationship AH product manufacturers have traditionally cultivated with vets. If third-party payers grow in influence, AH players may need to consider alternative sales and commercial model

¹ Cowen and Company. "Nexvet Biopharma Initiation- Barking up the Right Tree." Published 10th March 2015.

Technological innovation and new adjacencies are creating new opportunities

Adjacent sectors, such as diagnostics, genetics, devices, big data, predictive analytics, and mobile technologies, could help AH players improve their R&D productivity, operating efficiencies, and customer 'stickiness'.

Some examples of recent innovations from the Production Animal segment include:

- Bayer's free BCS Cowdication app, which allows users to take photos of dairy cows, expedites body condition scoring and obtainment of risk assessment for various diseases.
- Elanco acquired Ivy AH and added the AgSpan Benchmark Performance Program, which includes databases with live cattle and carcass performance data, plus nutritional, financial, and health information.
- Zoetis is participating in a U.K. research consortium to develop visual imaging methods and digital technologies focused on improving pig health. The company has opened a new Centre for Digital Innovation in London. Scientists at the new facility are working on apps and other technologies to improve both livestock production and Companion Animal health products. Zoetis has launched the initiative with an ambitious goal: to create an electronic health record for every farm animal in the U.K.

In the Companion Animal segment, innovative initiatives have also tended to focus on diagnostics and devices. For example:

- AliveCor's iPhone-based, FDA-cleared ECG device is perhaps more well-known in the human realm, but the company also has a Veterinary Heart Monitor for use with dogs, cats, and horses. Vets can screen pets' hearts quickly, without shaving the animal, and store ECGs in an app.
- A variety of pet activity monitors exist, with varying degrees of emphasis on health (versus overall wellness). Much of the innovation in this space is coming from new entrants. For example: FitBark has an activity monitor, collects data, and enables pet

owners and vets to track longitudinal trends as well as to make peer comparisons; Tailio is a sensor that rests under a cat's litter box and sends the cat's weight, waste, and litter box trends to an app that is viewable by vets; and Voyce tracks a variety of biometrics – heart rate, respiratory rate, activity trends, and calories burned – and is building algorithms to detect early 'red flags' in animal patients.

- Among AH product manufacturers, Parnell's Dog Monitor (also known as FETCH) is one example of innovation. The company's program captures data in real time to monitor dogs' responses to a prescribed course of Zydax.

It is likely that initiatives such as these will continue to grow in importance as both food producers and pet owners recognize the value of real-time and/or longitudinal data in improving animals' health.

Vets' influence over purchase decisions is decreasing, but technologies and new adjacencies could create new opportunities.

3. Competitive Forces

In the past there were several barriers to entry for new entrants, including large commercial organizations with economies of scale, and a lack of regulations providing financial incentives for companies to enter the market. Some of these barriers are lowering, to some extent, resulting in new competitors entering the market: notably, generics and branded generics. This trend creates some risk to leading AH product manufacturers' branded sales.

Why do we think a change is happening? One signal is that some of the industry's top-selling products, which had sustained sales years past loss of exclusivity, are now facing increased generic competition. For example, Zoetis' carprofen (Rimadyl) withstood generic challenges – even growing sales – for many years after loss of exclusivity in 2001. Zoetis was able to achieve this outcome because of its proactive focus on lifecycle management. The company introduced a novel formulation of the drug (chewable), thereby dulling the impact of carprofen caplet launches by competitors including Impax, Norbrook and Piedmont.

However, the recent launch of Putney's chewable carprofen has resulted in pressure on Rimadyl sales, according to the company's earnings calls.

Another example of the AH industry's increased competitive intensity is sales declines after competitive launches, as seen in the case of Merial's fipronil (Frontline). Frontline was the industry's top-selling AH product – the first and only product to reach \$1 billion in sales – and one reason for recent declines was the entry of generic fipronil products.

So, what prompted these changes? There are two key factors: regulatory changes in the U.S. and E.U., and

channel shifts within the Companion Animal segment.

Regulatory changes in the U.S. and E.U. are facilitating generic entries

Certain regulatory changes in the U.S. and E.U. have facilitated approvals of generic drugs. In the U.S., we see evidence of this because following the passage of the Animal Generic Drug User Fee Act (AGDUFA) in 2008, there was an increase in original Abbreviated New Animal Drug Application (ANADA) approvals (Fig.7). The pace of original ANADA approvals during 2013-2014 was three times the pace during 2008-2012.

In the E.U., the European Commission adopted new measures on veterinary medicines and medicated feed in September 2014. According to an October 2014 press release by the European Medicines Agency, the Veterinary Medicines measures are intended to:

- simplify regulations and “reduce administrative burden for companies” by streamlining “marketing-authorization procedures and simplifying pharmacovigilance rules”
- “stimulate the development of new medicines, including products for small markets (minor use and minor species)”, and “better mechanisms to reward companies' investments in the development of innovative medicines” (e.g., extended data protection)
- “facilitate the circulation of veterinary medicines across the EU, through streamlined procedures and clear rules for internet retailing of veterinary medicines within the EU.”

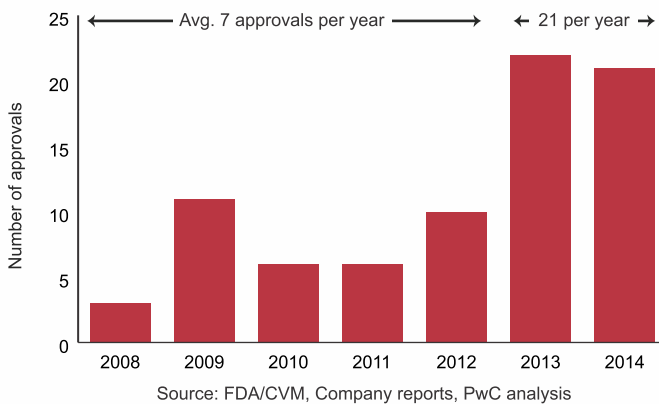
These measures and other regulatory changes could have wider-reaching consequences, beyond the growth of generics.

Channel shift in the Companion Animal segment is also facilitating generic entries

We have described how channel shifts in the Companion Animal segment have diminished vets' influence in purchase decisions. One other effect of the growth of alternative channels is increased points of entry for non-traditional competitors, specifically suppliers of OTC products and generics (both branded and non-branded). One early success story appears to be Putney, which has launched a chewable form of generic carprofen. Putney has relied on alternative channels and small distributors for its launch since exclusive distribution agreements of branded Animal Health companies have limited Putney's access to the large distributors.

Growth of alternative channels also creates opportunities for private label OTC products in certain AH sub-segments such as parasiticides. One example of a player that has been pursuing these opportunities is Perrigo, who traditionally played in the human consumer health industry, but entered AH with its acquisitions of Sergeant's

Fig. 7 – Original ANADA Approvals, 2008-2014



Petcare and Velcera. Perrigo's efforts are currently focused on the niche of OTC flea and tick products. Mylan, a leading generic player, has recently made a bid for Perrigo (at the time of writing, the acquisition is pending).

Competitive intensity has increased with entry of leading AH players into branded generics

Leading AH companies have in recent years launched competing branded generics for AH products going off-patent. For example, Novartis launched Parastar/Easyspot for Merial's Frontline (fipronil) in 2011, and Zoetis launched LA Combo for Merial's Frontline (fipronil) in 2014 and Engain/Actogain for Elanco's Paylean/Optaflexx (ractopamine) in 2013. Why might these launches represent a significant competitive threat and increase competitive intensity? Because leading AH product manufacturers possess the large commercial infrastructure needed to succeed in the context of a fragmented customer landscape. These launches could prompt other AH product manufacturers to follow suit, in turn increasing competitive intensity.

Generics seem to be gaining ground, due to regulatory changes and channel shifts in the companion animal segment.

4. Operational Effectiveness

Two key trends are increasing the importance of the operational effectiveness value-driver category.

- AH product manufacturers may face increased revenue pressure if traditional business models become less impactful or relevant. In light of this potential risk, AH players may need to re-examine operating effectiveness structures and/or processes to improve profitability.
- There is increasing prevalence of globalized food production corporations due to growing protein consumption in emerging markets and several cross-border deals. Production AH players may need to respond to this trend by creating operating structures (including manufacturing and supply chain) that reflect their customers' global needs. This topic will be discussed in greater detail in Section III.

Summary of Key Trends

A range of trends is impacting the AH industry's key value-drivers as well as creating new value-drivers. Key takeaways include: declining R&D productivity could prompt AH product manufacturers to diversify their strategies from simply lifecycle management alone; AH product manufacturer consolidation has created a tiered competitive landscape in which major acquisitions might not be feasible for all tiers; reduced influence of vets in purchase decisions could require rethinking targeting strategies; and AH product manufacturers may consider how to leverage new technologies and adjacencies in growth plans.

Times of change can represent opportunities to chart a new course. In the next section, we have assembled a playbook of strategic options.

Summary of Key Trends

Closing thoughts

The AH industry enjoys strong long-term demand-drivers,

Value-Driver Category

1. Innovation
2. Portfolio Advantage & Commercial Excellence
3. Competitive Forces
4. Operational Effectiveness

Key Trends

- Declining R&D productivity has led to highly mature product portfolios. There are limited opportunities for leading players to grow through further industry consolidation.
- Increased downstream consolidation in the Production Animal value chain has weakened AH's position.
- Vets are less influential in purchase decisions.
- Technological innovations and growth of new adjacencies may be considered in growth plans.
- Branded sales could be threatened by growth of generics and OTC/private label products, driven by regulatory changes in the U.S. and E.U., plus channel shift in Companion Animal segment.
- Profit pressure could be increasing.
- Increasingly global food producers require global operating structures. Source: PwC analysis.

particularly in emerging markets. However, a number of trends, including fewer NCE approvals, greater industry consolidation, reduced influence of vets, and new entrants, have started to diminish the potential of traditional strategies. AH companies may need to improve their growth potential by leveraging a broader range of value-drivers, including new ones that are emerging.

Source and Adapted from Animal Health Strategy Playbook for an Evolving Industry. PwC's Pharmaceuticals and Life Sciences Industry Group 2015.

GLOBAL NEWS

New guidance for pets exposed to rabies

Cats and dogs overdue for a vaccine can have a booster shot



New guidance in this issue of the JAVMA advises that cats and dogs that are exposed to rabies and are overdue for a vaccine can have a booster shot followed by an observation period rather than be subject to quarantine or euthanasia.

The recommendation appears in the 2016 edition of the Compendium of Animal Rabies Prevention and Control (J Am Vet Med Assoc 2016;248:505-517) from the National Association of State Public Health Veterinarians, along with other updates from the 2011 edition. Dr. Catherine M. Brown, co-chair of the compendium committee, described the compendium as a series of best practices that jurisdictions can choose to follow. According to the abstract, "Results indicated that dogs with out-of-date vaccination status were not inferior in their antibody response following booster rabies vaccination, compared with dogs with current vaccination status." The 2016 edition of the compendium also advises reducing the quarantine period from six months to four for unvaccinated cats and dogs exposed to rabies. The compendium committee based the guidance on unpublished data from various states.

Source: JAVMA News, AVMA- www.avma.org

Scientists cross-breed to improve head shape in toy dogs predisposed to a painful disorder

Scientists from the University of Surrey, working with an experienced breeder in the Netherlands, examined how the skull and brain of toy dogs change when a Brussels Griffon with Chiari-like malformation is crossed with an Australian Terrier. The succeeding hybrid puppy is then back crossed to a Brussels Griffon to give some of the

features of the Brussels Griffon, but keeping the longer skull of the Australian Terrier.

Short-nosed Brussels Griffon are at the risk of Chiari malformation, a debilitating condition found in toy dogs. The disease is characterized by premature fusion of skull bones forcing parts of the brain to push through the opening in the back of the skull causing fluid filled cavities to develop in the spinal cord. Chiari malformation causes headaches, problems with walking or even paralysis and has become prevalent in some toy breed dogs as a result of selective breeding.

Source: www.sciencedaily.com

Largest dog genetic study informs human diseases



Cornell researchers have completed the largest genetic study of dogs to date, comprising the genetic analysis of 4,200 dogs.

The study investigated 180,000 genetic markers, DNA sequences with a known physical location on a chromosome. Such markers can help link an inherited disease with the responsible gene.

The study, published Jan. 22 in Nature Communications, is a big step toward efficiently mapping genes responsible for complex diseases in dogs, most of which are very similar in humans, thereby accelerating our understanding of human genetic diseases. By identifying important genes and proteins in dogs for diseases and traits, researchers may then test those homologous genes in humans.

Source: Cornell Cronicle- <http://news.cornell.edu>

Federation of Independent Veterinary Practices formed Membership open to all UK-based veterinary practices



A new association that aims to represent the interests and promote values of independent veterinary practices has been launched.

Membership to The Federation of Independent Veterinary Practices (FIVP) is open to all UK-based practices meeting the essential criteria of independent ownership and high standards of veterinary service.

FIVP seeks to work with suppliers that wish to support this sector of the veterinary market and to develop services that support its development.

Source: <http://mrcvs.co.uk/en/news>

NEWS CORNER INDIA

Dr. Amrita Patel conferred with the Mahindra Lifetime Achievement Award



Dr Amrita Patel, the current Chairman of Charutar Arogya Mandal, Anand and former Chairman of National Dairy Development Board (NDDDB) was honored with Mahindra Samridhi India Agri Lifetime Achievement for her purposeful contribution that made a difference in the field of agriculture to increase productivity and rural prosperity. The award was conferred to her by Shri Radha Mohan Singh, Union Agriculture Minister on 4th March'2016 at New Delhi.

Dr Patel played a pivotal role in the implementation of Operation Flood, the largest developmental programme in the world. The programme helped to promote, finance and deliver a variety of supporting services to a national cooperative dairy structure that transformed the lives of millions of marginalised and small farmers and milk producers. The Mahindra Samridhi India Agriculture Awards were instituted by Mahindra & Mahindra Ltd to honor and recognize contributions of personnel's in the field of agriculture.

Receiving the award, Dr Patel said that true development involves creating institutional structures to enable rural producers to become a part of the economic mainstream. While dairy cooperatives have some remarkable achievements to their credit, new economic challenges and opportunities necessitate new institutional forms. One such form is that of a "Producer Company", an enterprise combining the institutional and ideological strengths of cooperatives with flexibility and autonomy available with a company.

Adulterated Milk Can Be Detected In Seconds, With This Paper Strip Invented by an IIT Student



Avishek Barla, final year B-Tech student, won the Gandhian Young Technical Innovation (GYTI) Award this year for developing a paper strip that reveals adulteration in milk in a few seconds. Avishek claims that the strip is divided into zones and it can detect as many as four adulterants in a single test. The paper contains reagents spread across the length of the strip. These change colour when it comes in contact with adulterated milk, as the adulterants react with the reagents, much like a litmus test. To make these strips, Avishek used a normal inkjet printer to "print" the chemicals in small amounts on the paper.

Source: www.betterindia.com

Presenting Delhi Police's Latest Weapon - The Adorable But Very Lethal Team Of Labrador Recruits



30 new Labrador Retriever dogs were added to the New Delhi Police Force on 4th April, in a ceremony that was held at the India Gate lawns. The new batch was procured by the Delhi Police from the Indian Army to add to its existing squad that's nearing retirement. The new recruits have already undergone preliminary training at Remount Veterinary Corp of the Indian Army. While twenty will be trained to sniff out explosives, others will be trained to nab criminals.

Source: www.indiatimes.com

New Office bearers in Veterinary Institutes



Dr. Trilochan Mohapatra took over as Secretary, Department of Agricultural Research and Education & Director General, Indian Council of Agricultural Research (ICAR)

Dr K M L Pathak
joins as Vice Chancellor,
DUVASU, Mathura



Dr H Rahman
joins as DDG (Animal Sciences),
ICAR



Dr Gaya Prasad
resumes charge as
Vice Chancellor, SVPDAT, Meerut



Dr Ashok Kumar
joins in as ADG (Animal Sciences),
ICAR

Dr P D Juyal
takes charge as Vice Chancellor,
NDVSU, Jabalpur



- a. HealthforAnimals has released a report on, 'Innovation in animal health' which discusses the future of the animal health industry and addresses common, global barriers to modern vaccine use including the regulatory process and market competition as well as existing scientific knowledge.

Other areas addressed in the report include, pet health, food safety and sustainability, and zoonotic diseases. The report was generated from discussions at a global stakeholder roundtable meeting in September 2015, hosted by HealthforAnimals and was independently authored by Oxford Analytica.

For more information: <http://healthforanimals.org/innovation-in-animal-health>

- b. Following the landmark resolution made at the World Economic Forum in Davos to tackle antibiotic resistance, HealthforAnimals has renewed its call to promote the responsible use of antibiotics, and

communicate the importance of veterinary medicine to global health for both animals and humans.

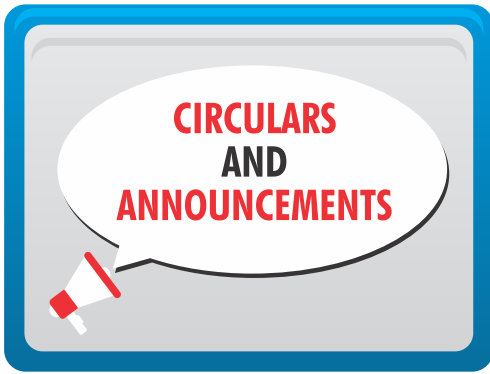
As part of its campaign to raise awareness of the role of antibiotics in animal health, HealthforAnimals, the global animal medicines association, has published a guide entitled: 'Antibiotics and antibiotic resistance in veterinary science'. The guide aims to dispel inaccurate or misleading information and can be freely accessed on the website: www.healthforanimals.org.

For more information: <http://healthforanimals.org/press-release-as-much-as-necessary-as-little-as-possible-healthforanimals-movie-on-antibiotics-and-safeguarding-animal-health-and-welfare>

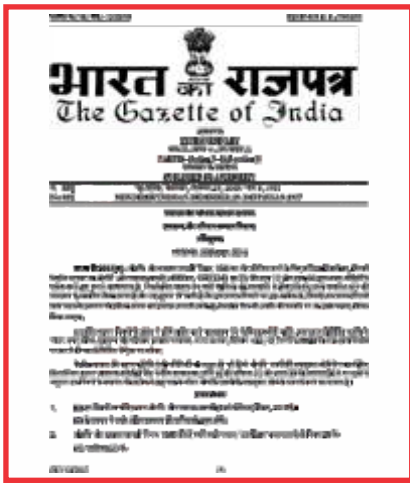
- c. HealthforAnimal has cautioned that inappropriate food, over-indulgence and poor exercise have all contributed to a 'humanisation' of pets' lifestyle and their environment, which has led to an increased prevalence of obesity. As in humans, obesity in pets is associated with chronic, and even life-threatening conditions such as diabetes, arthritis and liver disease.

Carel du Marchie Sarvaas, executive director of HealthforAnimals, commented on this worrying global trend: "It is wonderful that animals are playing such a central role in our family lives but it is essential that we do not over-indulge our pets.

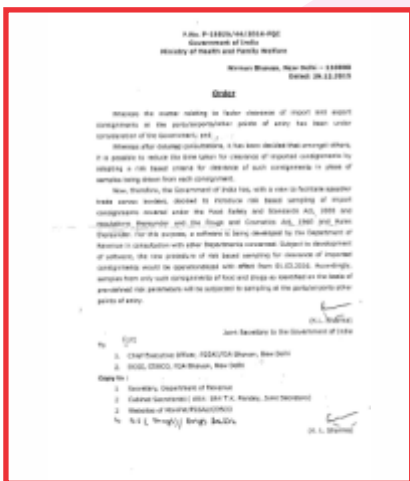
For more information:
<http://healthforanimals.org/are-we-slowly-killing-our-pets-with-kindness/>



Gazette Notification on Application fee revision dated 29th December 2015 from Ministry of Health



Representation: INFAH has represented the revision issue with MOH for amending the same for Veterinary Products



Ministry of Health and Welfare Order on Clearance of Import and Export Consignments dated 29th December 2015

Oscars for Veterinary Fraternity:

As we are well aware, without exception, all sectors come under one roof on an annual basis to award/recognize the best performances & contribution of the year gone by. Many of the veterinary companies also do it for their sales teams. But a common event for the entire industry eludes us.

To accelerate innovation and foster greater unity in our industry “Can we have something like the Oscars for the veterinary fraternity?”

I hope this thought strikes a chord with all of you as professionals working in such an important industry. Such an event would bolster the confidence of the industry & give much needed media publicity to the extraordinary work done by thousands of animal health professionals. Helping millions of farmers every year to obtain the best out of their farms is no mean feat & deserves a bigger pat on the back!

By: Dr. Vivek Unnikrishnan, Product Executive, Zydus Animal Health





Save the Date

5TH INFAH ANNUAL GENERAL MEETING

12th August' 2016
Mumbai | India



More information on how to apply will follow soon

Save the Date!

Global Animal Health Conference 2016

Improved Market Access for Authorised Veterinary Medicines – The Asian Perspective

17 November 2016 | New Delhi, India

BILL & MELINDA GATES foundation

OIE

INDIAN ASSOCIATION OF VETERINARY SURGEONS

FDA

DIA DEVELOP INNOVATE ADVANCE

GATVet

INFAH

Health for Animals



Agritic Africa 2016

15-17th June, Kenyatta International Conventional Centre, Nairobi, Kenya.

6th Agri Asia

2-4th September, Mahatma Mandir, Gandhinagar, Gujarat, India.

18th National Conference of Association for Prevention and Control of Rabies in India.

9-10th July, NIMHANS Convention Centre, Bengaluru, Karnataka, India.

40th Annual Congress of Indian Society of Veterinary Surgery

2-4th November, Madras Veterinary College, TANUVAS, Chennai, Tamilnadu, India.

Dairy Tech India 2016

26-28th August, Bangalore International Exhibition Centre, Bengaluru, Karnataka, India.

Eurotier 2016

15-18th November, Hanover Messe, Hanover, Germany.

5th International Poultry and Livestock 2016

26-28th August, Bangalore International Exhibition Centre, Bengaluru, Karnataka, India.

Kisan Samvaad

14-18th December, Pune, Maharashtra, India.



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