

# Animal health around the globe



**Overview of Association Activities in 2015**

# Asia

AAHA (South East Asia) - [INFAH](#) (India) - [JVPA](#) (Japan) – [AHPA](#) (Thailand)

- **JVPA** organised the 5th VICH Conference (VICH5), “Reaching out to the world” in Tokyo from 27-29 October, with 189 participants from 23 countries.
- **AAHA** prioritised 5 key issues in 2015: Joint Venture ownership in China, shaping India regulation, Thai FSC requirements, Japan QA/QC requirement impacts and the VICH outreach connection to Asia.
- **INFAH** organised a National Seminar on ‘Contribution of Indian Animal Health Industry towards Healthy Animals and Healthier India’ on 13 February in New Delhi. Over 125 delegates from regulatory authorities and related institutes as well as embassy diplomats attended alongside INFAH members and the press.

## Regulatory affairs

- Throughout the year **AAHA** has been working on several country-based actions, identifying the priority issues through local team meetings and working with the local industry associations in Thailand and Indonesia. Next step: improve relationships between AAHA and local authorities.
- **AAHA** worked on various market access issues to avoid supply problems through clarification of regulations in Thailand and started a review of issues for Indonesia to support product supply and increase availability of animal health solutions.
- The Division of Standardisation of the Indian Veterinary Research Institute (IVRI), in collaboration with **INFAH**, organised a 2nd Regulators-Animal Vaccine Manufacturers meeting on 4 December 2015 under the leadership of Dr R K Singh, Director, IVRI.
- **INFAH**'s 4th Annual General Meeting in Mumbai on 10 August was attended by more than 75 delegates and addressed various issues affecting the industry including how to stimulate the animal health industry's growth.
- **JVPA** organised a marketing authorisation-holders workshop in February, prior to the publication in April of a collection of laws, regulations and notices related to the revision of the veterinary aspects of the PMD Act (Pharmaceutical Affairs Law).
- **JVPA** played a role in speeding up the approval processes for veterinary medicines supporting simultaneous examination by three government bodies involved.
- **AHPA** played important roles with the Thai FDA (Food and Drug Administration), DLD (Department of Livestock Development), ACFS (National Bureau of Agricultural Commodity and Food Standards) in the coordination of the implementation of AMR strategies and the provision of data on antibiotics (import statistics, species usage)

## Value to Society

- **INFAH** helped create awareness of egg protein on ‘World Egg Day’ (9 October) through communicating the nutritional values of eggs and distributing boiled eggs to primary school children and an orphanage. INFAH also facilitated slogan competitions and an egg shell art competition in the Bombay Veterinary College in Mumbai.
- **INFAH** in association with Tamil Nadu Veterinary and Animal Sciences University (TANUVAS) organised free health camps for animals in flood-affected areas of Tamil Nadu state in December.
- **INFAH**'s contribution towards the growth and success of the Indian poultry industry was recognised at the Golden Jubilee of Indian Poultry Industry organised by the Indian Poultry Journalist Association, and an award was presented to INFAH by the Minister for Finance, Government of Telangana state, India.
- **JVPA** promoted World Antibiotic Awareness Week (16-22 November) with enhanced incorporation by the Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF).
- **JVPA** submitted a report to JMAFF for review by the Japan Food Safety Commission on the impact of the use of veterinary antibiotics through foods on human health, based on the collection of recent information regarding antibiotic resistance.
- **AHPA** finalised the Good Business Practice Manual and will distribute to members March 2016.



# Australia and New Zealand

[Animal Medicines Australia](#) (Australia) - [Agcarm](#) (New Zealand)

- **Animal Medicines Australia (AMA)** completed a strategic review of the Australian agricultural and veterinary chemicals regulatory system, in collaboration with Ernst & Young, and a project commissioned to the leading Australian agricultural think-tank, the Australian Farm Institute, titled, "The economic importance of Australia's livestock industries and the role of animal medicines and productivity-enhancing technologies". Both projects involved extensive engagement across the political, governmental, and industry realms, including the Federal Agriculture Minister.
- **Agcarm** has been working alongside the New Zealand Veterinary Association and Ministry for Primary Industries (MPI) to be proactive in management of AMR. MPI released an antimicrobial resistance direction statement in December 2015. Agcarm will be monitoring progress of the implementation of the goals set out in the document.
- **AMA - Future of Animal Health** project: Engaging with student animal and agricultural scientists in Australia, and student veterinarians to showcase the animal health industry, to promote the career opportunities and develop the domestic skill base.

## Regulatory affairs

- **AMA:** The Australian Government announced an independent review into the merits of a proposal to relocate the APVMA (Australian Pesticides and Veterinary Medicines Authority) away from Canberra which may have led to staff cuts. AMA will continue to work cooperatively with all stakeholders to ensure that actions in relation to the APVMA do not hurt the veterinary pharmaceuticals industry.
- **AMA:** The APVMA spent the year dealing with implementation issues from the previous round of legislative and operational reforms while pursuing several important initiatives in partnership with industry.
- **AMA:** the 2016 focus for Australia will be on reducing the burden of upfront technical intervention for products of low regulatory concern, navigating the implementation of Globally Harmonised System of Classification and Labelling requirements (which must feature on labels of relevant products by 1 January 2017), and continuing to play a leading role in the development of the Government's legislative agenda during 2016 – both before and after the federal election.
- **Agcarm:** A positive result was achieved by lobbying of government ministers and discussions with officials about our concerns regarding the level of resourcing within the Ministry for Primary Industries (MPI) ACVM Group. Agcarm negotiated a small registration fee increase which resulted in ACVM employing two extra people to help with backlog of veterinary medicines authorisations. Secondly Agcarm negotiated some performance indicators which cover time ACVM takes to process non-regulated applications such as label changes, responding to communications and publishing annual reports on time. Agcarm will be monitoring the achievement of these KPIs.
- **Agcarm:** Submissions to the parliamentary Primary Production Select Committee close January 2016 and Agcarm will be lobbying to have the current five years data protection for innovative products extended to ten. Agcarm has support of other New Zealand primary sector industries.

## Value to Society

- **AMA:** Leading the establishment of the Animal Registries Working Group with state and territory governments and other like-minded industry organisations to provide a national registry system for pets, in the process providing valuable activity data for member companies.
- **AMA:** Development of Antibiotic Prescribing Guidelines with AVA (Australian Veterinary Association) to ensure the continued use of antibiotics in a sustainable & safe manner/environment.
- **AMA** has a new President: Mr Andrew Mason. Andrew is the Country Division Head Animal Health at Bayer Australia – Animal Health.
- **Agcarm** hosted an antimicrobial resistance seminar in October 2015. Agcarm members and representatives from the Ministry for Primary Industries, NZ Veterinary Association and primary sector industry representatives attended.





# Europe

## IFAH-Europe

- New Secretary General and new President for **IFAH-Europe** - Roxane Feller – former Director of the Economic Department in FoodDrinkEurope - became Secretary General for IFAH-Europe in February. Christian Behm of Bayer Animal HealthCare GmbH took up the reigns as Chairman for the association in June. Under the new leadership **IFAH-Europe** developed a strategy 'more visibility for more impact' to further the voice of the industry in Europe on a range of policy areas affecting animal health, such as the veterinary medicines and medicated feed regulations, pharmaceuticals in the environment, trade, animal welfare and innovation in disease prevention and control.
- Healthy animals, healthy food, a healthy future - Animal Health industry presented its contribution to a sustainable agricultural production at the **IFAH-Europe** conference in Brussels with Head of Cabinet for European Commissioner Health & Food Safety Vytenis Andriukaitis as keynote speaker.
- Speaking at the ECDC launch event of the 8th European Antibiotic Awareness Day, **IFAH-Europe** Secretary General, Roxane Feller called for collaborative action from policymakers, scientists, industry, veterinarians, farmers, medical professionals, as well as the general public to address the issue of antibiotic resistance.

### Regulatory affairs

- Throughout the year **IFAH-Europe** engaged with key EU and national authorities to discuss the European Commission's proposals for revised legislation for veterinary medicines and medicated feed amongst other topics.
- Hosted in the European Medicines Agency's new headquarters in London, the joint EMA/**IFAH-Europe** info-day saw industry and regulators discuss '[The latest developments – scientific review, marketing authorisation procedures and legislation](#)'.
- During the [10th TOPRA Annual Veterinary Medicines Symposium](#) **IFAH-Europe**'s Technical Director, Rick Clayton highlighted the need for new veterinary legislation pending in Europe to stimulate innovation while cutting the animal health industry's over-sized administrative burden.

### Value to Society

- European Pet Night was hosted by MEPs Julie Girling and Norbert Lins who spoke about the benefits of pets alongside 12-year old Gemma who talked about life with diabetes and her medical alert assistance dog, Polo.
- **IFAH-Europe** continued promoting its antibiotics strategy throughout 2015. During the [conference](#) 'Farmers and veterinarians together to tackle antimicrobial resistance', held under the Luxembourg Presidency of the Council of the European Union, **IFAH-Europe**'s Chairman called for policies on the use of antibiotics in animals to be based on science and for the focus to be on Responsible Use of antibiotics.
- The European Platform for the Responsible Use of Medicines in Animals - [EPRUMA](#), of which **IFAH-Europe** is a founding member, celebrated its 10<sup>th</sup> anniversary and published a new booklet: [EPRUMA best-practice framework for the use of antibiotics in food-producing animals](#) outlining a 'next level' approach for implementing responsible use of antibiotics on the farm for further optimisation of animal health, following on from the 2008 brochure.
- **IFAH-Europe** published [an infographic](#) explaining the differences between the human medicines and veterinary medicines sectors.
- **IFAH-Europe** produced a [leaflet](#) outlining the role of IFAH-Europe with information on the European animal health industry.



# North America

[AHI \(USA\)](#) - [CAHI \(Canada\)](#)

- **AHI** participated in a White House Forum on Antibiotic Stewardship. In conjunction with the forum, AHI hosted a “Meeting of the Minds” dinner bringing together experts in human and animal health to share information on tackling the issue of antibiotic resistance. This was one of three such learning opportunities hosted by AHI in an effort to increase communication and understanding between the human and animal health communities.
- **CAHI-AHI:** Canada’s Veterinary Drugs Directorate and the U.S. Center for Veterinary Medicine are part of a joint Canada/U.S. programme to review certain new veterinary medicine submissions. It has resulted so far in 2 approvals for companion animal products at the same time in both countries. A number of food animal submissions are now being reviewed using the regulatory cooperation initiative as a base. This will lead to greater alignment in product labels and improved availability in both Canada and the U.S.
- **AHI’s** annual Pet Night on Capitol Hill featured the dog Jagger who starred in the moving “Max” and Frosty, the cat from the award-winning television show “Modern Family.” AHI also used the event to sponsor the “Cutest Pets on Capitol Hill” contest.

## Regulatory affairs

- **AHI** drove a stakeholder workshop on potency specifications for biological products, and continues discussion with the USDA to align its policy with international norms
- **AHI** is working with the USDA to smooth the implementation of comprehensive labelling changes that impact all biological products and to establish the ability to make electronic submissions of key regulatory documents.
- **AHI** led a coalition of member companies and those from the Generic Animal Drug Association to work with FDA on implementation of the Judicious Use Policy to eliminate growth promotion on labels of medically important antibiotics. An AHI member company team led a move to develop a standardised VFD format for veterinarians to write orders for antibiotics mixed in feed, which will assist producers and veterinarians in complying with the new guidelines.
- **AHI** formed a new International Trade and Standards Committee to deal with Codex and OIE and to identify issues affecting trade of animal health products and foods.
- **CAHI** has been advocating harmonisation of veterinary medicine regulation throughout 2015. Controls over Own Use Importation and importation and use of active pharmaceutical ingredients will help harmonise Canada’s regulatory programme with other developed countries. Lost opportunity sales of animal pharmaceuticals in Canada due to importation and use of non-approved pharmaceuticals is estimated to have a value of \$50 - 75M (Canadian).

## Value to Society

- **CAHI’s** stewardship programme is in cooperation with the pesticide industry whereby unwanted animal health products are collected and safely destroyed. In 2015 approximately 4,500 kg of product was collected and destroyed (in 5 regions of Canada). This self-regulatory initiative is to demonstrate industry responsibility for the life of our products. It’s CAHI’s goal to have a uniform, cost-effective programme to manage unwanted animal health products across Canada.
- Under the umbrella of **AHI’s** “Healthy People. Healthy Animals. Healthy Planet” campaign, AHI produced a series of videos featuring veterinarians discussing the importance of animal health products in their practices.
- **AHI** built on its programme to improve understanding and collaboration between human and animal health experts. AHI contracted with a team from the Medical University of South Carolina to conduct and publish a literature review on animal use of antibiotics and its impact on public health, held a series of “Meeting of the Minds” to bring experts together to share experiences, and established an on-line learning community to extend discussion and collaboration between human and animal health experts.



# South America

[CAPROVE](#) (Argentina) - [SINDAN](#) (Brazil)

- **CAPROVE:** MOTIVATE Breakfast - Annual event bringing together over 200 national industry representatives, joined by national authorities and press. CAPROVE's President presented the main work streams for the association and the current state of animal health.
- **SINDAN** was a key player in the ban on long-acting avermectins production, sale and supply (Normative Instruction No 13 of May 2014) that was overturned and formally revoked in March 2015.
- **SINDAN:** Proposal sent to the Brazilian Ministry of Agriculture, Livestock and Supply (MAPA) to implement a fast track process for innovative products in order to reduce time to market.

## Regulatory affairs

- **SINDAN** was involved with the revision of a decree (5054) to incorporate the possibility to register generic products and other critical changes.
- **SINDAN:** MAPA has implemented the SIPEAGRO system (Integrated Electronic System for Products and Agricultural Establishments) and SINDAN prepared a list of questions with doubts, opportunities for improvement and suggestions on how to operate with the new system.
- **SINDAN** sent proposals for revision of various rules including: pilot batches for pharmaceutical products; registration of antiparasitics; variations regulations.
- **SINDAN** prepared a new proposal for a regulation specifically for avermectins and somatotropin and proposed to remove them from NI 25 law of 2012 (revoking NI 12 of 2014).
- Both **SINDAN** and **CAPROVE** participated throughout the year in a number of meetings with international and regional authorities including CODEX (CCRVDF), CAMEVET, OIE and VICH.
- **CAPROVE** held various meetings throughout the year to discuss different topics and coordinate work axes on animal disease, pets, biologicals, health campaign plans, and trade.
- **CAPROVE** continued to liaise with key players of the national agricultural sector, to exchange proposals and develop joint actions for greater animal productivity for Argentina.
- **CAPROVE** participated in a number of governmental subcommittees with SENASA, the national food and health service, and maintained ongoing dialogue on proposals for new regulations and the implementation of existing rules.
- **CAPROVE** also had several contacts with national bodies including the College of Veterinary Surgeons of the Province of Buenos Aires, CLAMEVET, the Chamber of Veterinary Distributors of Buenos Aires (CADISVET), the National Poultry Board, the Agrifood Strategic Program (PEA) and other agri-food chain partners to discuss ongoing strategies for the national livestock and food chain business.

## Value to Society

- **SINDAN** has been working with ABIEC/ABPA/SINDIRAÇÕES to influence the authorities to increase the sanitary level to maintain the protein supply.
- **CAPROVE** carried out sales surveys to compare both segments and products developed in different periods so that companies can identify performance in a given market. Findings showed the important role of the veterinarian in promoting the solutions provided by the industry.
- **CAPROVE** continued media campaigns on responsible pet ownership and applying health plans for increased livestock productivity.





# Global

## HealthforAnimals

- IFAH renamed as **HealthforAnimals** in June 2015 and launched a microsite highlighting the animal health industry's contribution to society.
- The 4th Global Animal Health Conference held on 24-25 June in Dar es Salaam, Tanzania was organised with the support of an Organising Committee, facilitated by **HealthforAnimals** and funded by the Bill & Melinda Gates Foundation. The focus of the conference was on developing countries and on how to enable the widest availability of high quality, safe and efficacious products in these markets, with an emphasis on Africa, and East Africa in particular.
- **HealthforAnimals** communications efforts around World Zoonoses Day which included an infographic, a press release and a social media campaign, resulted in an interview with the BBC.

### Regulatory affairs

- **HealthforAnimals** finalised the 2015 benchmarking survey on best regulatory practice in Australia, Brazil, Canada, China, Europe, Japan and USA. The report will be launched early 2016.
- **HealthforAnimals** participated in the 5<sup>th</sup> VICH Conference (VICH5) and worked throughout the year to improve international harmonisation through [VICH](#), the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products, and its Outreach Forum.
- New position papers published: '[Global Principles and Perspectives on the Responsible Use of Medicines in Animals: \[GPPRUMA\]](#)', [The benefits of vaccines and vaccination](#), [Rabies eradication](#)
- **HealthforAnimals** continued to work very closely with the Codex Alimentarius Commission and member countries to adopt science-based standards in a timely manner. Global food safety standards for three veterinary products, Derquantel (sheep tissues), Emamectin Benzoate (salmon and trout tissues) and Monepantel (sheep tissues) were adopted in 2015.

### Value to Society

- As part of the rebranding as **HealthforAnimals**, a new [microsite was launched](#) outlining the animal health sector's contribution to society in areas like: emerging diseases, zoonoses, enough safe food in the future, new technologies, vaccines and innovation, pets and antibiotics.
- **HealthforAnimals** engaged with key international organisations and other stakeholders to advance animal health initiatives globally, namely through a think tank meeting in June and stakeholder roundtable in September.
- Short animation on [One Health](#) outlining the need for collaboration between human and animal health sectors, to achieve better health for people, animals and the environment. The video has been viewed around 50,000 times.
- On World Zoonoses Day (6 July) to help raise awareness of the growing risk zoonotic diseases pose to human life, animal health and welfare, **HealthforAnimals** created an [infographic](#) that highlights the economic impact and global threat.
- On 28 September – World Rabies Day – **HealthforAnimals** joined a number of global organisations calling for the eradication of rabies (see above-mentioned [Position paper](#))
- Published on International Dog Day in August, **HealthforAnimals** celebrated the age-old union between man and dog through the creation of an [interactive infographic](#), detailing the many valuable roles dogs perform in societies all around the world.
- 16-22 November saw healthcare organisations around the world take part in the first ever World Antibiotic Awareness Week. **HealthforAnimals** joined the call for global action against the growing resistance to antibiotics and other antimicrobial medicines in a [press statement](#) and through the publication of a [guide on antibiotics in veterinary science](#).



## About HealthforAnimals

HealthforAnimals is a non-profit, non-governmental organization representing companies and industry associations from both developed and developing countries. HealthforAnimals represents the animal health sector: manufacturers of veterinary pharmaceuticals, vaccines and other animal health products throughout the world, as well as the associations that represent companies at national and regional levels (referred to as Members).

The animal health industry provides value to society by protecting animals and as a consequence, humans, from diseases. Our products help keep pets and food-producing animals healthy. The public health benefits we bring include safer and more secure food supplies, more efficient production for increased food supply, improved sustainability, and prevention of the transmission of zoonotic diseases.

### North and South America



### Asia, Pacific and Africa



### Europe and Africa



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March 2016