

Overview of activities in 2014



Summary of animal health associations' achievements around the world

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Europe

IFAH-Europe

Regulatory affairs

- The joint European Medicines Agency-EMA/IFAH-Europe info-day on the theme '<u>The latest</u> developments scientific review, marketing authorisation procedures and legislation' took place at the EMA in London with a record attendance.
- IFAH-Europe published a set of pictograms for use on the immediate labels of veterinary medicines, as well as a best practice guide for the use of pictograms. See the pictograms and the guide
- IFAH-Europe organised a conference on 'Better regulation for veterinary medicines: Road to a
 <u>European marketing authorisation</u>' in Brussels, where it called on decision-makers to complete
 the journey to a true single market and develop one single EU-wide marketing authorisation
 process for veterinary medicines.
- IFAH-Europe actively participated in the meeting of the 30th VICH Steering Committee and the 4th Outreach Forum held in Brussels.
- Throughout the year IFAH-Europe held regulatory outreach activities to improve the mutual recognition, the decentralised and centralised procedure for veterinary medicines, as well as other regulatory topics. These included meetings with key EU and national authorities, as well as other stakeholders.
- IFAH-Europe welcomed the European Commission's proposals package for revised legislation for veterinary medicines and medicated feed, and firmly supported the Commission's aim of improving the availability of veterinary medicines throughout Europe. See press release
- IFAH-Europe spoke at the 9th TOPRA annual veterinary medicines symposium. Key topics included the European Commission's proposals for revised veterinary legislation, immunologicals and new technologies, global regulatory strategies, regulatory approaches for small and medium sized enterprises, as well as antimicrobial resistance.

Antibiotics

- IFAH-Europe welcomed the European Medicine Agency's 4th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report and expressed support for the concept of transparency of antibiotic use in animals. See press statement
- On European Antibiotic Awareness Day (18 November) IFAH-Europe called for the safeguarding
 of antibiotics for veterinary use for the future under the banner 'as little as possible, as much as
 necessary' to ensure animal health and welfare. <u>See statement</u>

- IFAH-Europe and partners celebrated the Brussels. Hosted by MEP Julie Girling, the guest speakers from the Dogs for the Disabled charity presented their work to help children with physical disabilities in the Netherlands and the United Kingdom.
- IFAH-Europe joined a broad coalition of partner organisations representing Europe's agricultural
 and food business interests and co-signed their <u>'Food for Thought' vision paper</u> calling for better
 and smarter policy-making that fosters innovation and creates jobs, ensuring that the EU
 agrifood-chain becomes more productive and resource-efficient.
- The European Platform for the Responsible Use of Medicines in Animals <u>EPRUMA</u>, which includes IFAH-Europe, welcomed the Belgian and Spanish stakeholder platforms for the Responsible Use of veterinary medicines, AMCRA and VETRESPONSABLE, as associate members.
- IFAH-Europe published <u>an infographic</u> explaining how veterinary medicines are made and brought to the market.
- IFAH-Europe produced fact sheets highlighting the contribution of veterinary medicines to sustainability in terms of animal health, animal welfare, food safety and food security. See the fact sheets

North America

AHI (USA) - CAHI (Canada) - INFARVET (Mexico)

Regulatory affairs

- AHI's work resulted in improvements in the regulatory efficiency of the US Department of Agriculture's Center for Veterinary Biologicals (CVB), including facilitating faster release of vaccines for marketing, and proving input into the selection of the new Director of CVB.
- AHI scored another victory in the fight to protect the current economic structure for pets with a
 favourable court decision in a case briefed by AHI. The decision will help preclude the expansion
 of legal damages available in litigation involving animals, which, if allowed, would ultimately
 harm animals.
- CAHI continued to advocate for veterinary medicines regulation that will support proper use of
 medications by having control over importation and use of non-Canadian approved
 antimicrobials in Canada. A <u>new federal framework on antimicrobial resistance and use</u> has
 called for strengthened regulatory controls in this area.

Antibiotics

- AHI continued its work with US Food and Drugs Administration on an implementation plan to
 phase out growth promoting indications in medically important antibiotics approved for use in
 feed and water of food-producing animals and restricting those medicines to veterinary control.
 See AHI's video: 'Animal health industry commits to FDA guidance 213'.
- CAHI members voluntarily agreed to work with the Veterinary Drugs Directorate (VDD) of Health
 Canada to remove growth promotion claims from medically important antibiotics used in feed
 and water while also having veterinary oversight of the products. See press release

- AHI hosted a successful 'Pet Night on Capitol' along with the 'Cutest Pets on Capitol Hill' contest
 as part of the ongoing 'Healthy Animals. Healthy People. Healthy Planet' campaign. Read more
 about Pet Night.
- CAHI continued its work in the area of end-of-life stewardship for the products its members sell.
 Pet and food animal stewardship programmes developed by CAHI are helping to ensure that
 obsolete or unwanted product is safely and cost effectively disposed of. To build on existing
 industry-led stewardship initiatives already in place, CAHI worked with <u>CleanFarms</u> to expand
 their obsolete pesticide collection programme to include livestock and equine medicines.
- CAHI worked with stakeholder groups such as <a href="tel:the-tel:

South America

ALAVET (Chile) - CAPROVE (Argentina) - SINDAN (Brazil)

Regulatory affairs

- ALAVET participated in the activities of the Chilean Ministry of Agriculture's working group on agriculture and livestock. The group discussed topics such as externalising certain aspects of marketing authorisation dossiers, as well as modifying regulation on veterinary medicines.
- ALAVET held regular meetings with the national Chilean control authority for fishing and aquaculture (SERNAPESCA) on biologicals and pharmaceutical products for this sector. Topics included procedures to assess the efficacy of vaccines, especially those used to control Piscirickettsiosis and Caligus in salmon. The group discussed a proposal to establish a pharmacovigilance programme.
- SINDAN provided input to the Brazilian Ministry of Agriculture in relation to a new regulation on veterinary medicines. SINDAN supported proper antibiotic use in animals, and made proposals for a consolidated list of feed additives to be used by the Brazilian Department of Inspection of Animal Origin Products (DIPOA) for controlling proper use of feed additives and preventing nonlegal residues in food. Additionally, SINDAN submitted several proposals to the Ministry of Agriculture and other government agencies on the regulation of post-approval changes, prescription, pharmacovigilance, good clinical practice, etc.
- SINDAN also participated in the Brazilian delegation of the Codex Alimentarius Committee on Residues of Veterinary Drugs in Food (CCRVDF) and provided input in national and international meetings in support of the Brazilian positions in Codex.
- The Committee of the Americas for the Harmonisation and Control of Veterinary Medicines
 (CAMEVET) approved three guidelines on residues of veterinary medicines in animal tissue.
 These will be instrumental to ensure a proper design and implementation of residue trials and to
 have a well-established withdrawal period in CAMEVET countries. Representatives from ALAVET,
 CAPROVE and SINDAN contributed to the drafting of these guidelines together with academics
 and national regulatory authorities.

Communications and stakeholder dialogue

ALAVET carried out a study on the sales and use of veterinary medicines produced by the
association's members in 2013. Results revealed salmon breeding as the most important market
segment, followed by products for bovine, pigs, small animals and poultry.

Asia and Africa

AAHA (South East Asia) - <u>AHPA</u> (Thailand) - <u>ASOHI</u> (Indonesia) - <u>INFAH</u> (India) - <u>JVPA</u> (Japan) - KAHPA (Korea) - <u>SAAHA</u> (South Africa)

Regulatory affairs

- AAHA's Thai members worked on the revision of regulation regarding the cold supply chain, good manufacturing practice accreditation, free sale certificate and the definition of new products.
- INFAH worked with all its members to ensure the implementation of withdrawal periods.
- INFAH provided quality inputs for the inclusion of veterinary items in monographs by the Indian Pharmacopoeia. Additionally, it contributed to Ayurvedic Pharmacopoeia by bringing consensus on the implementation of labelling guidelines for ayurvedic products.
- A new Japanese law on medicines, cosmetics and medical devices was enforced. The law makes
 a clear distinction between requirements relating to pharmaceuticals, medical devices and other
 products, which should help reduce the review period for medical devices and encourage
 innovation.
- SAAHA engaged with the Department of Agriculture, Forestry and Fisheries to improve consistency of registration requirements for veterinary medicines and address urgent matters. SAAHA and the regulatory body jointly reviewed the relevant guidelines.
- SAAHA participated in the meeting of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) as part of the South African delegation.

Antibiotics

- In coordination with the Indian Compound Manufacturers' Association, INFAH participated in the antibiotics working group which prepared a memorandum of associations regarding antibiotic residues together with the Animal Husbandry Commissioner and other senior officials. The group highlighted the safety factors adopted by the industry.
- AAHA's new Antibiotic Working Group reviewed issues relating to antibiotics in Indonesia,
 Vietnam and India. AAHA also engaged on the medicated feed additive issue in Indonesia.

- AAHA engaged with several organisations such as Asia-Pacific Economic Cooperation, the World
 Organisation for Animal Health (OIE) and the <u>US-ASEAN Business Council</u>, as well as local
 regulatory bodies to provide animal health industry support on target countries.
- AHPA worked on an awareness raising campaign to reduce the number of stray cats and dogs in Thailand.
- INFAH organised an industry/regulators interface at the Indian Veterinary Research Institute's
 Biological Standardisation Division. INFAH also organised a national seminar on the theme
 'Healthy Animals Healthier India', which gathered all key regulatory officials, academics as well
 as INFAH members. Additionally, INFAH participated in activities to promote animal protein to
 consumers, such as the World Egg Day event.
- JVPA promoted the appropriate and judicious use of antibacterial agents to key stakeholders.

Australia and New Zealand

Animal Medicines Australia (Australia) - Agcarm (New Zealand)

Regulatory affairs

- Animal Medicines Australia (AMA) worked with the Australian Pesticide and Veterinary
 Medicines Authority (APVMA) in ensuring collaborative and constructive implementation of
 regulatory reforms affecting the animal health sector. Additionally, AMA worked closely with the
 length of the supply chain to better understand the needs of the livestock and pet animal sectors
 through the challenges faced by the political realm. See press release
- Agcarm had several meetings with senior government official to express concerns about the level of resourcing within the Ministry for Primary Industries' (MPI) Agricultural Compounds and Veterinary Medicines Group. Staffing constraints resulted in a backlog of veterinary medicine applications waiting to be processed.
- Agcarm contributed to the New Zealand Environmental Protection Authority (EPA) hazardous substance compliance advisory group to help the authority with its new enforcement role, which includes packaging, labelling and safety data sheet compliance.

Antibiotics

Agcarm discussed the management and oversight of antimicrobial resistance issues in New
Zealand and worked to promote partnerships between industry and government on this topic.
Agcarm and the New Zealand Veterinary Association achieved unanimous support from the
National Antimicrobial Resistance Steering Committee (including regulators) for establishing an
effective and adequately resource governance group.

- Animal Medicine Australia's (AMA) annual dinner hosted the New South Wales Minister for Primary Industries, Katrina Hodgkinson MP, as the guest speaker. She spoke about the livestock sector and about the rapid growth in the pet sector in Australia.
- AMA undertook a pets advocacy initiative, researching the state and trends of pet ownership in Australia (see report), and engaging with the federal, state and local governments to work out a cohesive way of collating the information. Additionally, AMA commissioned the Australian Farm Institute, Australia's leading agricultural policy body, to undertake research and report on the economic, social and environmental values of the animal health sector in Australia.
- Representatives from EPA, MPI and WorkSafe New Zealand, the health and safety regulator, attended Agcarm's successful two-day field trip to inform regulators on the use of veterinary medicines and crop protection products in real situations. <u>See press release</u>
- Agcarm awarded two scholarships to support education and raise awareness about careers in Agcarm-related industries. An undergraduate veterinary medicine scholarship went to Hannah MacPherson to help her studies at Massey University. <u>See press release</u>

Global

IFAH

Governance and membership

- IFAH members reviewed the association's strategy to optimise impact and influence. Focus
 areas include increasing communication on societal value; greater focus on prioritised countries;
 a new name/brand, and a simpler and streamlined association; greater focus on pets, innovation
 and emerging diseases; and a stronger outcome-driven approach while enhancing relations with
 national associations.
- IFAH welcomed the Animal Health Federation of Paraguay (CEVEPA) as a new member.

Regulatory affairs

- IFAH advanced preparatory work to conduct a new and streamlined benchmarking survey on best regulatory practice in Australia, Brazil, Canada, China, Europe, Japan and USA in 2015.
- IFAH worked with representatives from various countries to improve international harmonisation through <u>VICH</u>, the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products, and its Outreach Forum. <u>See press release</u>
- IFAH provided input to Codex Alimentarius in establishing international food standards, e.g. maximum residue limits (MRLs), through participation at several Codex meetings.
- IFAH engaged with national associations in Latin America and BRIC countries to look into data protection and data exclusivity regulation with a view to boost research and innovation in those regions.
- Throughout the year, IFAH provided input to key international initiatives and discussion fora
 regarding antimicrobials in veterinary medicine and public health. This included participation in
 the OIE session on the global antimicrobial database and contributing to the World Health
 Organisation's (WHO) antimicrobial action plan. Additionally, IFAH called for transparency,
 monitoring and education on responsible use of antibiotics on the occasion of the international
 conference on the responsible use of medicines in animals. See press release

Communications and stakeholder relations

- IFAH engaged with key international organisations and other stakeholders to advance animal health initiatives globally. It strengthen relationships with organisations such as the World Organisation for Animal Health (OIE), the United Nations' Food and Agriculture Organisation, (FAO), the World Health Organisation (WHO), VICH, Codex Alimentarius and the World Bank, as well as the Bill and Melinda Gates Foundation (BMGF), the Global Alliance for Livestock Veterinary Medicines (GALVmed), the World Veterinary Association (WVA), and the International Agri-Food Network.
- IFAH produced a short animation on '<u>Healthier animals for a healthier world</u>' explaining IFAH's role in creating a healthier world through an innovative, responsible and sustainable animal health sector. The video has been viewed by more than 33,000 times.
- IFAH published an infographic titled '<u>The pathway to new veterinary medicines</u>' outlining how veterinary medicines are made and brought to the market.
- IFAH published a white paper on the growing threat of vector-borne diseases in humans and animals and an infographic with the support from BMGF. IFAH presented the paper to key international stakeholders at a roundtable event.
- On World Rabies Day, IFAH called for better coordination between governments, regulators, healthcare providers and the public to tackle the multidimensional impacts of rabies by ensuring that everyone has access to innovations available for its prevention and control. <u>See press</u> release
- IFAH highlighted the animal health industry's vital role in maintaining welfare on World Veterinary Day. <u>See press release</u>
- IFAH issued its 2013 annual report on the theme 'Overcoming barriers to animal disease prevention and control, a critical step towards One Health'.

About IFAH

The International Federation for Animal Health (IFAH) is the global representative body of companies engaged in research, development, manufacturing and commercialisation of veterinary medicines, vaccines and other animal health products in both developed and developing countries across the five continents.

IFAH represents both animal health companies (8) and national/regional animal health associations (29). These associations comprise both local small and medium-sized enterprises and international companies. Overall, these companies represent approximately 80% of the global market for animal health products.

IFAH International Federation for Animal Health AISBL

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