

CONNECT

Volume - 6, July 2018



Editor's Note

Dear Members,

Welcome to yet another edition of Infah Connect. It gives us immense pride to share with you all one of our greatest achievements – the creation of an exclusive Veterinary Cell at CDSCO. After years spent in relentless pursuit of this objective, we can now finally look forward to more focused developments in the Animal Healthcare sector from a regulatory perspective with this exclusive cell creation.

The past couple of months have been very eventful. One of the major events organised in recent months was the "One Health Conference" featuring multidisciplinary approach towards the broader dynamics of inter connected animal and human healthcare, food and environment and the collective efforts required to create a healthy planet. Continuing its collaboration on the global stage, INFAH participated in the 2nd VIV MEA Conference representing the Indian Animal Healthcare industry and highlighted the potential of Indian companies in animal healthcare sector. We have also covered the highlights of the IPC addendum meeting attended by INFAH members to incorporate new monographs and upgrade the existing ones via errata .

Supporting the Indian Government to raise the bar of Indian animal husbandry practices, INFAH met the PVS-OIE evaluation team as representatives of the industry. With an aim to enrich its relationships with animal health stakeholders, INFAH participated in the Annual Conference of IAAVR and Indian Poultry Review Biosecurity Summit.

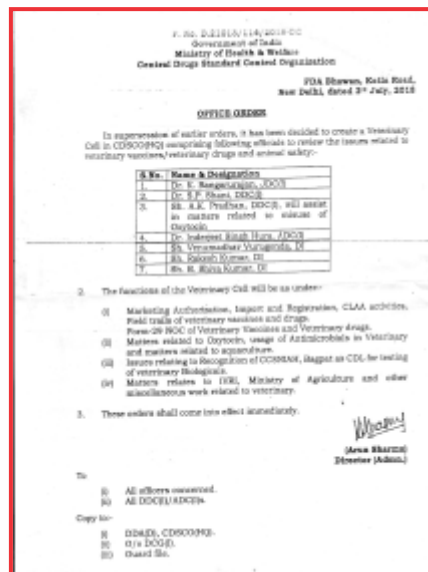
Every subcommittee of INFAH is operating flawlessly owing to their regular analysis and strategic actions plans. The issue covers meetings of Subcommittees of Import- Export, Human Resource and Feed Supplement & Feed Additive.

Glimpses of some of the interesting news from Global front and Indian arena are featured in the news section of the issue. Our market update section features an interesting article on the Top 20 Animal Health companies of World in 2017. Finally, our last section showcases the critical circulars that are set to make an impact on the industry and calendar of events to save our dates for important happenings across the Industry.

We hope you enjoy this exciting edition of INFAH Connect and provide your valuable feedback to help us better this platform on every front through i-Connect. Until, we meet next time, stay healthy and happy.

With Regards,

Vijay Teng
Editor
INFAH CONNECT



The Central Drugs Standard Control Organisation (CDSCO) has been the national regulatory body of Ministry of Health and Family Welfare for approval of pharmaceuticals, biologicals and medical devices for both human and veterinary use. As the dynamics and requirements of the Animal healthcare sector differ on many fronts from the human sector,

INFAH has always been a strong advocate for the creation of a more specialised and dedicated team at CDSCO for the regulatory needs of Veterinary products. INFAH has been aggressively representing the matter before CDSCO since its inception. Finally, our years of collective efforts have borne fruit. It is an occasion of pride for us that CDSCO office has created a dedicated Veterinary Cell. The cell would be headed by Dr. K. Bangarurajan, JDC and Dr. S. P. Saini, DDC. This development is a historic milestone in INFAH's journey and a testament to our resolute collective efforts. With this exclusive cell creation, we now have a window to put forward our views and expressions pertaining to animal healthcare sector, and we can now expect better co-ordinated approach and more progressive developments in years to come.

INFAH attends Indian Poultry Review Biosecurity Summit



INFAH actively participated in the Indian Poultry Review Biosecurity Summit held at Kolkata on 11th May 2018. Over 85 delegates participated in this summit. Eminent Avian Pathologist Dr. J. L. Vegad, Prof. Pankaj Shukla and representatives of Industry were invited as speakers. Mr. Amit Saraogi, MD- Anmol feeds and Mr. Madan Mohan Maity of West Bengal Poultry Federation shared their views on the need of Biosecurity measures to curtail spread of poultry diseases.

Dr. Vijay Makhija, General Secretary- INFAH, represented INFAH in the event and highlighted the role of INFAH in ensuring Healthier Animals and Healthier India. Dr. Makhija shared his views on significance of Biosecurity in poultry farms.

One Health Summit at New Delhi



The Cornell Sathguru Foundation for Development (CSFD), Indian Federation for Animal Health Companies (INFAH) and University of Hyderabad jointly organised the One Health India Summit on 3rd-4th May' 2018 at Hyatt Regency, New Delhi. The event was inaugurated by Dr. Eshwar Reddy, DCGI and Dr. S. R. Rao, DBT.

The conference brought together some of the best academicians world over and participants from the Government of India and industry to discuss the future of "One Health" and how minor changes in, can affect all concerned. The attendees gained a deeper and broader understanding on how inter connected healthcare, food and environment is and the need to encourage collaborative efforts of multiple disciplines working locally, nationally, and globally to achieve the best health for people, animals, and our environment.

The participants were drawn from CDSCO, FSSAI, FAO, INFAH, WHO India Office, NCDC, DBT, Welcome Trust, CDC India Office, Ministry of Agriculture and Farmers Welfare, Cornell University, ICAR-CIRG, NDDB, IVRI, TANUVAS, GADVASU, KVASU, University of Hyderabad, National Institute of Nutrition, Human Pharmaceutical industry and Animal health industry.

Eminent professionals viz Dr. P. Reddana, University of Hyderabad; Mr. K. Vijayraghan, CSFD; Dr. Rajesh Bhatia, FAO; Dr. Alexandra Traviz, Cornell University; Dr. Ashok Tiwari, IVRI; Dr. Samar Mahendran, CGS Hospital; Dr. Shoor Vir Singh, ICAR-CIRG; Dr. J.P.S. Gill, GADVASU; Dr. G. Ravi Kumar, TANUVAS; Dr. Criag Altier, Cornell University; Dr. S.K. Rana, NDDB and many renowned experts graced their presence for the summit. INFAH was represented by Dr. D. K. Dey, President; Mr Vijay Teng, Vice President; Mr. Satish Pasrija, Former President ; Dr. Arun Atrey, Past President; Dr. P. G. Phalke, Treasurer and Dr. Vijay Makhija, General Secretary as well as members of INFAH sub-committees, Dr. K. Anand Kumar, Managing Director, IIL and professionals from Animal welfare associations.

The two days summit had eight sessions including presentations on Food Safety, Infectious Diseases & One Health, Current & Emerging Zoonotic threats and Prevention to Management of One Health. The session on 'Resisting the microbial resistance' had deliberations on myths and truth of antimicrobial resistance with the human health, animal healthcare and environment perspective. The panelists for session included Mr Jaideep Gogtay, Cipla; Mr Rajesh Bhatia, FAO; Chand Wattal, Sri Ganga Ram Hospital; Dr Criag Alter, Cornell University; Dr V.K. Shankar, Bayer ; Dr Nitin Bhatia, Intas; Dr. D. J. Kalita, Zydus and Dr D K Dey, President, INFAH.

Ms. Pushpa Vijayaraghavan, Director Sathguru Management Consultants, and Summit emphasised that the Interconnections of human health, animal health, food and environment can no longer be ignored and the idea of the "One Health Concept" is in essence, to appreciate the wealth of opportunity that lies in the interface area of this triad, which could be capitalised on, to protect the health of our planet as a whole.

Dr. D. K. Dey from INFAH chaired the inaugural session and highlighted the role of Animal Health Industry in maintaining healthy animals and healthier humans and thereby contributing towards healthy environment and healthy globe. As the first multi-stakeholder "One Health Summit" in India provided a strong foundation for an India centric discussion and conceptualisation of actionable solutions. The summit focused on the following key themes that were identified as critical in the Indian context were the rising alarm from Antimicrobial Resistance, emerging zoonotic diseases and food safety. The position paper on "acknowledging challenges and paving the way forward" was also released. The summit has laid the foundation for more sectorial alliances and multiple disciplinary approach to address the national concerns.



INFAH meets the PVS- OIE Evaluation Team



As a part of OIE-PVS evaluation, OIE representatives have been undertaking visits of the major establishments of Animal Healthcare sector of India to evaluate the country's animal husbandry infrastructure, policies, manpower and talent. In the second round of discussions, OIE team requested Department of Animal Husbandry, Dairying and Fisheries (DADF) to arrange a round of discussion with the pharmaceutical and animal feed private sector of India.

Dr Suresh Honnappagol, Animal Husbandry Commissioner, DADF invited private stakeholders and associations for an interactions with OIE team on 13th April 2018 at Krishi Bhavan, New Delhi . Dr Shrish Nigam and Dr Shyam Morada represented INFAH as the Veterinary Pharmaceutical Association along with representatives of CLFMA.

OIE discussed the best practices performed from breeding to feeding and retailing of animal protein with perspective of disease control and food safety. INFAH team highlighted their vision, mission, activities, affiliation and the journey travelled so far. The meeting was chaired by Animal Husbandry Commissioner and the discussions were oriented towards zoning across the country, biosecurity, surveillance programs for infectious diseases for livestock and farm animals, Antimicrobial resistance and its concerns, availability of spurious drugs and the standards of animal feed and feed additives as well as animal welfare issues. INFAH and CLFMA jointly and actively participated in the discussions on behalf of the animal healthcare industry.

IPC Addendum Meeting at IPC, Ghaziabad



The Drugs & Therapeutics and the Biological & Biosecurity sub-committees of INFAH has been working consistently with Indian Pharmacopoeia commission (IPC) for upgrading the Veterinary monographs in the fourth volume of Indian Pharmacopoeia (IP). The committee had prepared the list and monographs of pharmaceutical formulations, biologicals and active pharmaceutical ingredients which was submitted to IPC. With the effort of INFAH members, 14 new Veterinary monographs have been included in IP 2018 and many monographs have had improvements and refinements.

In order to review and upgrade the Veterinary monographs for forthcoming IP addendum 2019, IP veterinary working group meeting was held on 9th April 2018 at Indian Pharmacopoeia commission, Ghaziabad.

INFAH sub-committee members participated in the meeting and provided scientific inputs on various Veterinary monographs that need modification or upgrading. Based on the inputs of the members, errata was published on 25th May 2018 for 11 Veterinary monographs. Few modifications on some existing drug monographs and addition of new monographs are considered for incorporation in the IP addendum 2019."

INFAH @ Annual Conference of IAAVR



The Indian Association for the Advancement of Veterinary Research (IAAVR) organised 18th Indian Veterinary Congress and XXVth Annual Conference of IAAVR and National Symposium on “Indian Veterinary Leadership to Promote National and International Collaboration, Coalitions and Linkages for Global Competitiveness in Animal Health and Production, Research and Education” on 23-24th February 2018 at SVU, Tirupati, Andhra Pradesh.

Over 175 delegates from all over the country participated in the two-day congress. The Congress was inaugurated by Prof. Purnendu Biswas, Vice Chancellor, West Bengal University of Animal and Fisheries Sciences (WBUAFS); Prof. Suresh S Honnappagol, Animal Husbandry Commissioner, DADF, Ministry of Agriculture along with Padam Shree Dr. G.C. Mishra and Dr. Y. Hari Babu, Hon'ble Vice Chancellor, Sri Venkateswara Veterinary University (SVU). Other eminent Veterinarians present to grace the occasion and participate in the scientific deliberations were Dr. T.S. Chandrasekhara Rao, Dean, CVSc, SVU; Dr. K. Nalini Kumari, Associate Dean, CVSc, SVU; Dr. S. N. Singh, President and Dr. Rishendra Verma, Founder Secretary, and Dr. A. Ravi, Organizing Secretary, IAAVR. The congress was also attended by eminent Veterinarians from Food Safety and Security Authority of India (FSSAI); National Institute of Animal Health (NIAH); Indian Pharmacopoeia Commission (IPC); Central Military Veterinary Laboratory, Remount Veterinary Corps; Border Security Force (BSF); Indo-Tibetan Border Police Force (I.T.B.P.); Seema Suraksha Bal (SSB) and many university professors, faculty and students.

On behalf INFAH, Dr. D.K. Dey (President), Dr Arun Atrey (Past President) and Dr. P. Karunanidhi (Member), Alembic participated in the conference. During the plenary session, Dr D K Dey made a presentation on the animal health industry of India, its potential and challenges. Since the session was chaired by Dr Honnappagol, the deliberations on the possible collaborations and regulatory framework were also

discussed. Dr Arun Atrey highlighted the activities of INFAH and its global affiliations through his presentation. The conference also witnessed deliberations on the concerns of Antimicrobial Resistance (AMR) in humans with presentations from Dr Manoj Sood, Elanco. Dr. Nitin Bhatia (Intas) and Dr. D. J Kalita (Zydus) focussed on the status of animal health industry and its responsibilities towards managing AMR. They also emphasised on myths and facts related to AMR in human and animals, and discussed the way forward for effective management of AMR. Dr. Ram Prakash (Virbac), Dr. Sanjay Gavkare (Venkys) and many other animal health industry professionals participated wholeheartedly in the event.



INFAH @ VIV-MEA2018



VIV MEA second edition was held at Abu Dhabi National Exhibition Centre on 5th to 7th February 2018. There were total of 368 direct and indirect exhibitors from 46 countries. Conference themes included respiratory viruses in poultry, modern ways to market eggs, how dairies thrive in hot and dry climates, extruding feeds for aquaculture, fly control on farms and actions against mould toxins in feed grains.

Almost 300 top level professionals from Middle East and Africa region were invited and hosted by the organizer via dedicated Industry Leader program.

VIV-MEA 2018 has provided the international platform for INFAH to represent Indian Animal Health sector. The objective of the participation was to give a realistic perspective of Animal Health sector in India and to focus on “Made in India, Made for the World” concept. From INFAH, the event was attended by Dr. D. K. Dey (President), Dr. P. G. Phalke (Treasurer), Dr. Jeetendra Verma (Executive Member) and Mr. Divya Gulati (Executive Member).

Dr. D. K. Dey made a presentation on “Indian Animal Health Industry- Fast emerging preferred choice” to the august gathering. The presentation gave insight into Indian AH sector, INFAH and its subcommittees, the stringent regulations prevalent in India and what Indian Animal Health Industry offers to the World to become a Veterinary Pharmaceutical Hub of the World. The details of all INFAH members, their core product categories and what they offer were shared with the delegates who attended the presentation. Dr. Dey also emphasised on the fact that the Indian companies hold 47% of the market of generic animal health products in Africa and the Middle East. The presentation was followed by the query session and interactions with the audience.

Feed Supplement & Feed Additive Subcommittee Meeting



The meeting of Feed Supplements and Feed Additives subcommittee was held on 9th July 2018 in Mumbai. The meeting was organised under the chairmanship of Mr. Satish Pasrija and was attended by Dr P G Phalke, Mr Raja Mukherjee, Mr Tanweer Alam, Dr. Jeetendra Verma and Dr. Ram Prakash. The agenda discussed included GST impact on cost of feed supplements, Anti-microbial resistance in humans and animals, Antibiotic residue issue on feed supplements / feed additives- Current development and future ahead, Issue faced with import of animal feed additives- HSN classification and publication of white paper on Feed Supplements / Feed Additives in India. The meeting started with review of last subcommittee meeting held on 7th December 2017. The following topics were discussed in length:

Impact of GST on cost of Feed Supplement Products

The concerns were also discussed in the last meeting and it was planned to study whole supply chain with the help of outside agency. Since post implementation, all GST related issues are now stabilized. Therefore, it was agreed that there won't be any action required for this.

Nevertheless, sometimes categorization of feed supplements under different tax slab is creating issues for many

companies. Ideally feed supplements are exempted from GST. Members feel that this misplacement is happening due to lack of precise status of feed supplement given by competent authority. It is resulting in misinterpretation and categorization in higher tax brackets.

In order to solve this issue, it was agreed by all members to perform 360 degree analysis with the help of KPMG. It will help to precisely define the status of feed supplements from all angle and prepare a complete document that will be useful to represent this matter at various platforms. Scope of work to KPMG also include to suggest way forward in order to address various issues.

Based on the report submitted by KPMG, a representation would be made to commerce ministry in consultation with DADF, MOA.

Members also feel that it is time to consider registration of feed supplement through MOA. This would validate the status of feed supplement and there won't be any misrepresentation. However, this is delicate issue and there should be good level of preparation by INFAH members to take its representation to MOA.

Impact of AMR / Antibiotic Residue

This issue is currently more pertinent in poultry and aquaculture, however it is likely to spill over other species. It is also likely that the issue may lead to more regulation for manufacturing and sale of feed supplements.

Issue faced with import of feed additive products for animal use - HSN classification. Way forward.

There is multiple issue where feed additives are categorized in chapter other than 23.09 leading to higher import tariff. Although there is list of feed additive given by MOA, however ADC at custom do not follow it and they classify the goods as per their understanding.

It was agreed to represent this matter at MOA and Ministry of Commerce. The representation can be prepared by taking the inputs from KPMG study reports.



HR Subcommittee Meeting



INFAH HR subcommittee met on 30th May 2018 at Varsha Office, Bengaluru to discuss and deliberate on Priority HR issues, challenges and solutions to structure the proposed HR Conclave. The meeting was attended by Dr. Manjunatha BP, Dr. Tanweer Alam, Dr. Joydeep Sarkar, Mr. Baskar Varadhan, Mr. Sudhir Shetty, Mr. Vinay Tiwari, Mr. Umesh Kulkarni and Mr. Sripad N.

The following major points were discussed during the meeting:

1. Standardizing the entry level parameters like age, salary band etc. for the new recruits
2. Understanding the aspirations of new generation and accordingly modifying the recruitment processes
3. Forecasting the manpower requirements for next three years
4. Methods to structure career progression plan and career development program
5. Proposal for streamlining and standardizing relieving process across INFAH member companies
6. Practices to be emphasized by the member companies:
 - a. Completion of notice period in previous company
 - b. Relieving letter and No-dues report submission during joining at new company
 - c. Employment benefits viz. Social Security benefits like Group Medclaim Policy, Group Insurance Policy, Group Gratuity Policy & other Employee Engagement benefits to be included to attract the new hires
 - d. Learning & Development for Field Staff
 - e. Infusion of Fresher's in the system
7. HR Conclave is proposed to be held on 20th July at Mumbai with an agenda to streamline and standardize HR practices across the INFAH member companies.



Imports and Exports Subcommittee Meeting



The meeting of INFAH subcommittee on Imports and Exports was held on 22nd January 2018 at Zoetis Office, Mumbai. A total of 13 members attended the meeting. A very fruitful discussion happened on all the burning issues of industry and simultaneously action plan was designed to take up the issues at various levels.

Major issue of product classification under different chapters were discussed at length. Committee members discussed on increasing the validity of current registration certificates from 3 years to 5 years. A committee was formed to study the duty structure of other countries so that INFAH can pursue to the Indian Government to make a similar structure for Indian Animal Health Industry for imported products. Issues related to Aqua hatchery feed import, export of AH products and import of Nicarbazine as feed supplement were also discussed. For all the points discussed, a relevant action plan was made to resolve the issue and take it forward.

Meeting ended with thanks to all the members and special gratitude were extended to Mr Ketan Dhamanaskar and Dr Smita Mahajan, Zoetis for hosting the meeting at Mumbai.

GLOBAL NEWS

World Zoonosis Day

World Zoonosis Day is observed on 6th July every year to emphasize and bring the awareness about zoonosis amongst people, and teach them to take right action.

Approximately 150 zoonotic diseases are known to exist. Wildlife serves as a reservoir for many diseases common to domestic animals and humans. Persons working with wildlife should be alert to the potential for disease transmission from

animals. Neither animal handlers nor the general public have reason to be alarmed or frightened but everyone should respect the potential for disease transmission and use sound preventive measures.

Source: <https://keepincalendar.com/July-6/World-Zoonoses-Day/640>

College of Veterinarians of British Columbia bans onychectomy

The College of Veterinarians of British Columbia (CVBC) has banned the practice of partial digital amputation, also known as onychectomy or declawing, of domestic cats from June 2018. The province is the second in Canada to ban declawing, following the procedure's condemnation from the Canadian Veterinary Medical Association (CVMA). "Elective and nontherapeutic declawing is ethically problematic and not an appropriate means of dealing with feline behavior issues," reads CVBC's statement. The college acknowledges there are medical conditions that may necessitate partial or full digital amputation as an appropriate medical therapy, such as biopsy for diagnosis, severe trauma, or medical conditions affecting the health of the nail (i.e. onychodystrophy, paronychia, neoplasia of the nail bed/phalanges), but adds there is no medical condition or environmental circumstance of the cat's owner that would justify declawing. The practice is banned in the U.K., Europe, Australia, and several California cities.

Source: <https://www.veterinarypracticenews.com/college-of-veterinarians-of-british-columbia-bans-onychectomy/>

Animal Welfare Foundation marks 35 years

Animal Welfare Foundation marks its 35 years of existence on 12th June 2018. AWF was established in 1983 by eight members of the British Veterinary Association (BVA) with the proceeds of a legacy from Colleen Macleod left to BVA. The members agreed that the funds would be better placed in a charity which could operate with the sole aim of improving animal welfare. The charity has since functioned as an independent entity, while maintaining a close relationship with the BVA.

Over 200 delegates from the veterinary, animal welfare and academic fields gathered in London on 12th June to take part in a day of thought-provoking and inspiring discussions on some of the most pressing issues impacting animal welfare. As with previous years, the 2018 Animal Welfare Foundation (AWF) Discussion Forum aimed to pose challenging questions to the veterinary profession to encourage it to re-evaluate current thinking and practice, and to discuss possible solutions to enhance animal welfare for generations to come. Topics at this year's event included the role of insurance in impacting pets' quality of life, human behaviour change to improve animal welfare, and pre-purchase consultations for prospective pet owners.

Source: <https://www.bva.co.uk/news-campaigns-and-policy/newsroom/news-releases/animal-welfare-charity-marks-35-years-with-exceptional-day-of-thought-provoking-debates/>

Australia's chief vet to lead World Organisation for Animal Health (OIE)

Dr Mark Schipp, Australia's Chief Veterinary Officer (ACVO) has been elected as the new President of the World Organisation for Animal Health (OIE) World Assembly. The announcement was made at the OIE's annual meeting in Paris in May 2018. The OIE is instrumental in developing worldwide animal health and welfare standards that inform the international guidelines of the safe trade of animals across 182 OIE member countries. The World Organisation for Animal Health was founded in 1924. The objective of the OIE is to improve animal health and welfare worldwide and one of its key missions is to ensure transparency of the global animal health situation including zoonoses.

<https://www.vetvoice.com.au/media-releases/australias-chief-vet-to-lead-world-organisation-for-animal-health-oie/>



HC declares animals to be 'Legal Persons'

Uttarakhand High Court on 4th July 2018 made a unique ruling by according the status of "legal person or entity" to animals in the state, saying "they have a distinct persona with corresponding rights, duties and liabilities of a living person".

The entire animal kingdom, including avian and aquatic ones, are declared as legal entities. The court also declared all the Uttarakhand natives as guardians of animals and endowed them with the duty to ensure the welfare and protection of animals.

The division bench also gave directions ranging from the amount of load allowed to be pulled by various animals in accordance with the kind of carriage being pulled to the amount of riders per carriage. Further banning the use of spike or other sharp tackle or equipment on the animal, the court also directed the state government to ensure that if temperature exceeds 37 degree C or drops below 5 degree C, no person be permitted to keep harness any animal used for purpose of drawing vehicles. The court also went into the aspect of animal safety, highlighting the need for fluorescent reflectors in carriages and animal certificates of unladen weight of vehicles, compulsory shelter of sustainable size for

horses, bullocks and stray cattle and a direction to veterinary doctors of Uttarakhand to treat any stray animals brought to them or visiting them. The court directed that the animal driven carriages have to be given "Right of Way" over other vehicles.

Source: PTI, Nainital, July 4, 2018

Kidwai to soon treat dogs with cancer

The Kidwai Memorial Institute of Oncology, Bengaluru, will soon offer radiation therapy for pets. To begin with the treatment will be offered to dogs. The Karnataka state cancer institute is in the process of starting a separate section that will deal with pets with cancers, a facility that is not available in veterinary hospitals across the state. This section will be entirely dedicated to canine patients. Experts from Tata Memorial Hospital, Mumbai, are being roped in to help initiate the process. A team of doctors from radiation therapy department of Kidwai is working in collaboration with experts from Mumbai, who have previously worked on setting up such centres in the country.

Source: Deccan Herald, July 5th, 2018 - <https://www.deccanherald.com/city/kidwai-soon-treat-dogs-cancer-679083.html>

New Immunotherapy for Brucellosis developed by GADVASU

A Novel immunotherapy for bovine brucellosis showing cure in adult cows in three months has been developed by the scientists at Guru Angad Dev Veterinary and Animal Sciences University (GADVASU), Ludhiana.

The therapy is developed by combining Brucella abortus vaccine strains of S19 and RB51 upon killed by bacteriophage and used as therapeutic vaccine.

In the experimental study the cows were treated with a single injection of 2ml of lysate prepared from above strains. The cows were monitored fortnightly over a period of three months employing Brucella specific molecular biomarker. The therapy eliminated live virulent Brucella abortus organisms from cows as indicated by progressive reduction and ultimately complete absence of the biomarker in blood by 90th day of treatment.

The breakthrough is the brainchild of Dr. Hari Mohan Saxena, Professor of Immunology, Department of Veterinary Microbiology meticulously executed by Dr. Sugandha Raj, MVSc student under his supervision.

Source: Internal

Dr S Eswara Reddy appointed as new DCGI



Joint Drugs Controller Dr S Eswara Reddy has been appointed as the new Drugs Controller General of India (DCGI) in February 2018 after Dr GN Singh has completed his term.

Dr. Reddy has obtained his Masters Degree in Pharmacy from College of Pharmaceuticals Sciences Manipal in 1994 and a PhD from JNTU, Hyderabad in 2009. He has

experience in pharmaceutical manufacturing, academics and regulations.

He started his career as a Drugs Inspector in CDSCO, West Zone, Mumbai in 1998 and has good experience in GMP, GCP and GLP audits. He was promoted as Assistant Drugs Controller of India in 2009. He has participated in many national and international seminars, workshops and meetings on various areas of drugs regulations and undergone training from USFDA, KFDA, South Korea and WHO, Geneva.

He was invited to make presentations at various seminars and workshops. He got Best Drugs Inspector award in 2005 and Distinguished Alumni Award from Manipal Academy of Higher Education, Manipal.

Source:

<http://www.pharmabiz.com/NewsDetails.aspx?aid=107388&sid=2>

Shri. Tarun Sridhar takes charge as Secretary, DADF



The 1984 batch IAS from Himachal Pradesh, Shri. Tarun Sridhar has taken the charge as Secretary at Department of Animal Husbandry, Dairying and Fisheries (DADF) in March 2018. Mr. Sridhar has earlier worked as Additional Chief Secretary, Department of Animal Husbandry and Fisheries in the Government of Himachal Pradesh.

Source: <http://pashusandesh.com/Tarun-sridhar>

Dr. Swadesh Kumar Chaudhary appointed as the new Director at AH, Himachal Pradesh



Dr. Swadesh Kumar Chaudhary resumed his charge as the new Director of Animal Husbandry Department, Himachal Pradesh. Prior to this, he was working as the Joint Director in the Animal Husbandry Department.

Dr. Swadesh is a graduate and post-graduate from Bikaner Veterinary College. He joined the

Himachal Pradesh Government in 1984 as a Veterinary Surgeon. Dr. Swadesh has risen to the highest rank through sheer hard work, determination, passion and commitment.

Source: <http://pashusandesh.com/dr-swadesh-kumar>

Dr. C. Balachandran appointed as Vice Chancellor, TANUVAS



C. Balachandran, an eminent veterinary pathologist, has been appointed as the Vice-Chancellor of the Tamil Nadu Veterinary and Animal Sciences University (TANUVAS). He will hold the post for three years from the date of his assumption of office in April 2018.

Dr. Balachandran was instrumental in obtaining accreditation from the

Indian Council of Agricultural Research for the Madras Veterinary College. He has authored six books and guided nine Ph.D., research scholars.

A former Registrar of the TANUVAS between 2010 and 2013 and Dean of the Madras Veterinary College between 2015 and 2017, Dr. Balachandran has 21 years experience as professor and has specialised in Avian Mycotoxicoses/ Pathology, Clinical Pathology, Cancer Biology-Clinical, Experimental Pathology.

He started his career as an assistant professor at the Poultry Research and Development Centre, Namakkal, in 1980 and rose to the level of the Dean of the Madras Veterinary College.

Source: <https://www.thehindu.com/news/national/tamil-nadu/balachandran-new-v-c-of-tanuvas/article23409372.ece>

Dr. Ashish Paturkar - The New Vice Chancellor of MAFASU, Nagpur



Dr Ashish Paturkar was previously serving as Associate Dean and Head of Department, Microbiology Pathology, Parasitology, Veterinary Public Health and Livestock Products Technology at the Bombay Veterinary College, Parel, Mumbai. He has been appointed for a term of five years. He succeeds Prof Aditya Kumar Misra whose term ended on

7th September 2017.

Dr. Paturkar has graduated from Nagpur Veterinary College and obtained his Masters and Doctoral degrees in Veterinary Public Health from Bombay Veterinary College, Mumbai.

He has more than 26 years' experience of Teaching, Research and Extension in Veterinary Public Health. After starting his career as Assistant Professor, he worked as Professor and Head and Associate Dean of Bombay Veterinary College, Mumbai from June 2011. He has 57 research articles at his credit and has guided 33 postgraduate and 5 doctorate students for research and has handled 29 research projects funded by national and international agencies. He has been nominated as expert member on various scientific committees of national and international organizations. He has till date authored 11 books, 3 International Compendiums, 8 booklets and has 3 patents to his credit.

Source: <https://www.nagpurtoday.in/dr-ashish-paturkar-is-the-new-vice-chancellor-of-mafsu/01221200>

Market Update

Animal Health Top 20 Companies in 2017

The average growth rate across the animal health sector's top 20 companies saw a significant jump in 2017 to 18%. In the previous fiscal year, this figure was 9%. The average growth rate is an indicator of the general health of the industry's leading companies, who are largely experiencing growth through M&A, the companion animal market and a broader geographic base for food animal products.

The combined revenues of the top 20 firms took a major leap in 2017. This figure came to around \$27bn, compared to the \$25bn recorded in 2016.

Animal health top 20 for fiscal 2017

Company	Local currency sales (million) 2016	Local currency sales (million) 2017	Change	Sales in 2017 (\$ million)
1. Zoetis	\$4,888	\$5,307	9%	\$5,307
2. Boehringer Ingelheim Animal Health	€ 1,460	€3,901	167%	\$4,408
3. Merck/MSD Animal Health	\$3,478	\$3,875	11%	\$3,875
4. Elanco	\$3,158	\$3,086	2%	\$3,086
5. IDEXX Laboratories	\$1,649	\$1,832	11%	\$1,832
6. Bayer Animal Health	€1,523	€1,571	3%	\$1,775
7. Ceva Santé Animale	€912	€1,100	21%	\$1,243
8. Virbac	€871.80	€861.90	1%	\$974.0
9. Phibro Animal Health	\$751.5	\$764.3*	2%	\$764.3
10. Dechra Pharmaceuticals	£247.60*	£359.30*	45%	\$455.8
11. Huvepharma	€360.43	€395.30*	10%	\$446.7
12. Kyoritsu Seiyaku	¥44,700**	¥48,600**	9%	\$439.8
13. Vetoquinol	€350.40	€352.20	1%	\$398.0
14. Norbrook Laboratories	£239***	£272***	14%	\$344.7
15. Nippon Zenyaku Kogyo	¥32,700****	¥34,200****	5%	\$307.8
16. CAHIC	CNY2,047	CNY2,020	1%	\$299.0
17. Hipra	€225.90	€251.60	11%	\$284.3
18. Jinyu Group	CNY1,448	CNY1,855	28%	\$274.5
19. Bimeda	\$200	\$220	10%	\$220
20. Abaxis	\$177.7	\$186.7	5%	\$186.7

The coming together of Boehringer Ingelheim Animal Health and Merial has naturally had a major impact on the animal health industry and the top 20 rankings.

Boehringer's triple-digit growth enabled one of the most significant changes in Animal Pharm's top 20 in recent years. Aside from this acquisition-led improvement, several other companies posted double-digit increases in turnover – helped by both organic and acquisitional growth.

Years of sustained growth has seen top veterinary diagnostics player IDEXX Laboratories climb above Bayer Animal Health into fifth place. Merial's absence means there is a new top 10 company in the form of UK-based Dechra Pharmaceuticals, which has been building its global presence with a series of acquisitions. Dechra jumped four places to take 10th position ahead of Kyoritsu Seiyaku.

Along with Dechra, there was a continuation of the strength from the industry's mid-sized businesses. This specifically included firms specializing in generics, who – starting from a low base – have been able to expand rapidly into new geographies. This group includes Huvepharma, which climbed one spot to 11th.

While this highlights the strength of firms with large generic portfolios, companies such as Dechra and Huvepharma are bringing vaccines into their weaponry – diversifying their offerings and building on the growth their generics are already witnessing.

Outside the top 20

US animal safety diagnostics business Neogen saw animal safety revenues for 2017 increase by 8% to \$190.2m.

Ouro Fino Saúde Animal bounced back in 2017 and scored double-digit sales growth as Brazil's macroeconomic situation improved. The company's annual revenues came to around \$158m. This means it has now returned to the top of the Latin American rankings.

Argentine leader and veterinary vaccine specialist Biogénesis Bagó told Animal Pharm its annual sales grew 11% to

\$154m, as the company continues to globalize its business.

US generics Perrigo posted a 2% decline in animal health revenues to \$141.3m. US veterinary diagnostics firm Heska experienced a drop of 0.6% in sales to \$129.3m.

Sales from the third-largest Japanese veterinary medicines firm DS Pharma Animal Health dropped 1% to ¥12,700m (\$155m). The company suffered after its core companion animal business witnessed a decline in revenues.

UK generics business Animalcare has now moved closer to the top 20 after its merger with Belgian company Ecuphar – sales for 2017 reached £91.9m (\$118m).

India's Alivira Animal Health posted sales of around \$102m in 2017 after several years of transformative M&A. It is now the biggest animal health company based in India.

Vaccines still play an important role in generating sales growth in animal health. An example of this is Ceva Santé Animale's continuing growth. Additionally, Spanish veterinary vaccine expert Laboratorios Hipra also gained one place by moving to 17th.

Positivity for the majority

In the 2016 rankings, only four of the top 10 reported sales growth in excess of 5% and the majority of the double-digit performances were by mid-sized firms.

However, in fiscal 2017, some of the animal health majors came to the growth party. There were large increases in sales from Zoetis (the first animal health company to report over \$5 billion in annual revenues), Boehringer Ingelheim Animal Health, Merck Animal Health, IDEXX Laboratories, Ceva Santé Animale and Dechra Pharmaceuticals.

Other positive performances in the top 20 came from companies that are all working their way to the \$500m-per-year mark including Kyoritsu Seiyaku, Huvepharma, Norbrook Laboratories, Hipra, Bimeda (Animal Pharm estimated the sales of Irish generic specialist at \$220m) and Jinyu Group.

The next bracket of growth consists of firms that witnessed a solid 3-5% uplift in annual sales. This features Bayer Animal Health, Phibro Animal Health, Nippon Zenyaku Kogyo and Abaxis.

The companies that reported less than 3% growth experienced a mix of problems.

Vetoquinol reported 1% sales growth in 2017 as it continues to work on its antibiotics phase down, while Elanco reported an annual decline in sales as it goes through a portfolio re-organization. Virbac was impacted by ongoing destocking issues as it posted a dip in sales. China Animal Husbandry Industry Company (CAHIC) suffered as its vaccine revenues dipped. This was due to changes in the Chinese government's compulsory vaccination schemes.

Source: Animal Pharm:

<https://animalpharm.agribusinessintelligence.informa.com/AP014021/Animal-health-industry-rankings-2017-One-big-Boehringersized-change-masks-ongoing-vibrancy-across-bi>

CIRCULARS AND ANNOUNCEMENTS

RECORD NO. D. L. - 3300470

भारत का राजपत्र The Gazette of India

EXTRAORDINARY
PART II—Section 3—Sub-section (i)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

No. 443 नई दिल्ली, बुधवार, जुलाई 11, 2018/जुलै 26, 1948
NEW DELHI, WEDNESDAY, JULY 11, 2018/DECEMBER 26, 1948

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)
NOTIFICATION
New Delhi, the 11th July, 2018

G.S.R. 620(1)—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1954, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board is hereby published for intimation of all persons likely to be affected thereby, and notice is hereby given that all interested persons may file their objections or suggest any amendments in writing to the Secretary to the Ministry of Health and Family Welfare, Government of India, Room No. 444-A, D Wing, New Secretariat, New Delhi – 110011 or e-mail at drugs@mohtfw.gov.in.

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 444-A, D Wing, New Secretariat, New Delhi – 110011 or e-mail at drugs@mohtfw.gov.in.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (Amendment) Rules, 2018.
(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1954, after rule 64AA, the following rule shall be inserted, namely:—
“64AB. Information to be uploaded by the licensee on online portal SUGAM—
(1) The licensee licensed under this PART shall register with portal SUGAM (www.cdscopmohtfw.gov.in) and upload information as per the format provided in the portal pertaining to the licensee granted for manufacturing for sale or distribution of drugs and it shall be updated from time to time.
(2) The information uploaded by the licensee with SUGAM portal under sub-rule (1), shall be verified by the concerned Licensing Authority.”

F. No. 2-17014-400019-D-049
SUKHDEV BHARGAVA, Jt. Secy.

Note: The principal rules were published in the Official Gazette with notification No. F.20-1095-H (I), dated 28th December, 1954 and last amended with notification number G.S.R. _____ (I), dated _____.

Notification on Information to be uploaded by the licensee on online portal SUGAM by CDSCO dated 11th July 2018

CDSCO / IT / 2018 - (09)
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organisation

FDA Bhawan, New Delhi
Dated: 27.04.18

Notice

The Central Drugs Standard Control Organization (CDSCO) in pursuance to implementation of e-Governance has launched an online portal 'SUGAM' (www.cdscopmohtfw.gov.in) on-14.11.2015. Various services rendered by CDSCO are being rolled out in phases.

In the latest phase, module for New Drugs, FDC and SND has been launched and all the stakeholders are requested to avail this facility which is intended to further reduce time and thereby the transaction cost.

The stakeholders, who have not registered, first need to register on SUGAM to avail this facility. The process of registration is provided on the homepage of SUGAM.


(Dr. S. Eswara Reddy)
Drugs Controller General (India)

To: All Pharmaceutical Associations

Copy to:

1. PS to DGHS
2. PS to JS (IT)
3. All Zonal offices of CDSCO
4. Guard File

Announcement of module for New Drugs, FDC and SND on SUGAM Website of CDSCO dated 27th April 2018

RECORD NO. D. L. - 3300470

भारत का राजपत्र The Gazette of India

EXTRAORDINARY
PART II—Section 3—Sub-section (i)
प्राधिकार से प्रकाशित
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No. 254 नई दिल्ली, बुधवार, अप्रैल 26, 2018/अप्रैल 6, 1948
NEW DELHI WEDNESDAY, APRIL 26, 2018/APRIL 6, 1948

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)
NOTIFICATION
New Delhi, the 26th April, 2018

G.S.R. 466(1)—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1954, was published, as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), with notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R. 136(1), dated the 3rd November, 2017, for inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Official Gazette were made available to the public on the 3rd November, 2017;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1954, namely:—

1. (1) These rules may be called the Drugs and Cosmetics (Sixth Amendment) Rules, 2018.
(2) They shall come into force on the 1st day of November, 2018.

Label of Scheduled drugs to bear "Caution or Warning" - Notification by CDSCO dated 26th April 2018

RECORD NO. D. L. - 3300470

भारत का राजपत्र The Gazette of India

EXTRAORDINARY
PART II—Section 3—Sub-section (i)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

No. 331 नई दिल्ली, बुधवार, मार्च 13, 2018/मार्च 22, 1948
NEW DELHI, WEDNESDAY, MARCH 13, 2018/MARCH 22, 1948

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)
NOTIFICATION
New Delhi, the 13th March, 2018

G.S.R. 322 (1)—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1954, was published, as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) with notification of the Government of India in the Ministry of Health and Family Welfare, Department of Health and Family Welfare, number G.S.R. 282(1), dated the 28th March, 2017, published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), for inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on 28th March, 2017;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by the section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1954, namely:—

1. (1) These rules may be called the Drugs and Cosmetics (Sixth Amendment) Rules, 2018.
(2) They shall come into force on the 1st day of September, 2018.

2. In the Drugs and Cosmetics Rules, 1954, in rule 96, in sub-rule (3), in clause (i), in sub-clause (A), for the words beginning with the words "For this purpose" and ending with the words "name and shall be", the words "For this purpose, the proper name of the drug or food shall show combination drug unless there shall show combination of vitamins and other food constituents containing same or cause drug, shall be placed or written in a conspicuous manner which shall be in the same font size as least size specified hereunder in the label on the base name, if any, and in other cases the label name or the trade name, if any, shall be written in brackets before or after the proper name and shall be" shall be substituted.

F. No. 2-1104308-2008
SUKHDEV BHARGAVA, Jt. Secy.

Note: The principal rules were published in the Official Gazette with notification No. F.20-1095-H (I), dated 28th December, 1954 and last amended with notification number G.S.R. 136(1), dated the 3rd November, 2017.

Updated by Div. of Printing & Communication, Govt. of India, New Delhi, India, under the Ministry of Health and Family Welfare, Government of India.

Amendment in Drug and Cosmetic Act by MOH&FW dated 13th March 2018



CALENDAR
Of Events

8th Dairy Tech India and International Exhibition on Poultry, Livestock & Technologies
31st Aug- 2nd Sep 2018
Bengaluru International Exhibition Centre, Bengaluru, Karnataka

AGRITEX India 2018
4th-6th October 2018
Hitex Exhibition Centre, Hyderabad, Telangana

Dairy Industry Expo 2018
12th-14th October 2018
Auto Cluster Exhibition Centre, Pune, Maharashtra

6th International Dairy and Poultry Tech Expo
20-22nd October 2018
Labh Ganga Convention Centre, Indore, Madhya Pradesh

7th Dairy and Poultry Fest 2018
24th-26th October 2018
Lucknow, Uttar Pradesh

VIV Leadership Conference India 2018
27th October 2018
Le Meridien, Kochi, Kerala

Poultry India Exhibition
28th -30th November 2018
Hitex Exhibition Centre, Hyderabad, Telangana



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Please feel free to share your opinions,
thoughts and suggestions at
infahconnect@infah.org



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