



सत्यमेव जयते

Government of India
Ministry of Agriculture and Farmers Welfare
Department of Animal Husbandry, Dairying & Fisheries
CCS National Institute of Animal Health
Baghpat, Uttar Pradesh-250 609

One Day Brainstorming Workshop

on

Harmonization of Production and Quality Control of Veterinary Biologicals in India

(NASC Complex, New Delhi; Friday, the 24th June 2016)

Proceedings

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A one-day brainstorming workshop was organized by CCS National Institute of Animal Health at NASC Complex, New Delhi to discuss the roadmap of “Harmonization of Production and Quality Control of Veterinary Biologicals in India”. Vaccine manufacturers in public (14) and private (8) sectors represented by personnel from R&D, production and quality control, experts in animal health from ICAR and IVRI, policy makers from the department (DAHDF), IPC and DCGI participated in the event. A list of participants is annexed at Appendix-1.

The inaugural session was presided over by Shri Devendra Chaudhary, IAS, Secretary (ADF), Govt of India. Dr. Suresh S. Honnappagol, Animal Husbandry Commissioner, Govt of India; Dr. R. K. Singh, Director, IVRI; Dr A. Ramkrishan, Deputy Drug Controller (India), and Dr. Ashok Kumar, ADG (Animal Health) ICAR graced the function. The function started with the formal welcome address by Dr. Sandeep Kumar Singh, Joint Director, CCS NIAH, Baghpat. Followed by this, Dr. Praveen Malik, Director, CCS NIAH gave a brief overview of the workshop indicating that the workshop will be conducted in a participatory mode with the aim to develop a dynamic roadmap for harmonization of veterinary biologicals. After this, Dr. Ashok Kumar spoke a few words regarding the requirement of harmonization of the protocols. Dr. R. K. Singh addressed the gathering and briefed about the importance of goods manufacturing practices and the quality requirement of vaccines. Followed by this, Dr. A. Ramkishan described about the drugs and their quality and the requirement of documentation. He also explained about the regulatory requirements, the various parameters and good manufacturing practices. The AHC, Dr. Suresh S. Honnappagol mentioned about the the current status of veterinary vaccines in India in his opening remarks.

Subsequently, Shri Devendra Choudhary, IAS, Secretary (Animal Husbandry, Dairying & Fisheries) Govt of India delivered his inaugural address. In his remarks, he instructed to draw an action plan for the harmonization of production and quality control of veterinary biological in India. The Secretary (ADF) has desired to prepare a deliverable action plan in three months for

harmonization of production and quality control of veterinary biologicals in India. This may include listing of discrepancies in the protocols given in IP, Drugs and Cosmetic Act *vis a vis* OIE and other international pharmacopoeias like BP, EP, 9CFR etc. The action plan should delineate the clear role and responsibility of each partner *i.e.* CCSNIAH, IVRI, Public and private vaccine manufacturers etc. He has emphasized on the need of networking of labs for quality control testing of veterinary biological to share the work load and supplement each other.

The Secretary (ADF) has asked the institute to include CSIR and DBT in this mammoth job (especially for coordination on research facet of the issue) and instructed the institute to invite them in next meetings on this issue. He has entrusted the responsibility of identifying and engaging all national and international resources on this issue to CCSNIAH, Baghpat. He desires that CCSNIAH should prioritize the issues and network with other agencies for providing solutions to this major issue. He added that the disease prioritization, networking of labs and harmonization of production and quality control of veterinary biological should be taken up in a stipulated timeframe.

The Secretary has announced an additional budget of Rs 100 lakhs to CCS NIAH during 2016-17 for developmental activities so as to strengthen itself to work as national nodal agency for quality control of veterinary biologicals in India.

The inaugural session was ended with the vote of thanks by Dr. Sweta Raghuvanshi, Assistant Director, CCSNIAH, the organizing secretary of the workshop.

In the first technical session Dr. Suresh S. Honnappagol, AHC has described about the need for harmonization to set the pace of the meeting. In continuation to this, Dr. S.M Byregowda, Director, Institute of Animal Health and Veterinary Biologicals, Hebbel, Bengaluru explained about their experience as state veterinary biological unit, the various vaccines they produce and the exhaustive documentation for GMP followed by them. The experience in the private sector was shared by Dr. S.N. Singh, Managing Director, Biovet Pvt. Ltd; he spoke about various international guidelines and the lacunae they have observed. Dr. A.K Tiwari HOD, standardization division IVRI, shared his experience in quality control testing from the perspective of CDL.

Deputy Drug Controller (India) Dr. A Ramkishan welcomed the idea of networking of labs and he expressed support of CDSCO in giving them guidance for completing the GMP standards by visiting and inspecting the labs. He assured full cooperation and support to CCSNIAH for carrying out the quality control and harmonization requirements for veterinary biologicals.

In the afternoon, group discussions session was organized by forming four groups of participants to discuss and come up with their recommendations on following four agenda:

- Identification of priority diseases
- Identification of experts for development/validation of SOPs
- Identification of expert labs for undertaking QC testing
- Problems associated with vaccination failure & Training of vaccinators

Recommendations of each group were presented by the representatives of the respective groups on each question during round table discussion session. Thorough discussion ensued on each recommendation with lots of input from the participants. Recommendations emerged out during this session were summed up and finalized during plenary session. These draft recommendations have been circulated to all participants for comments which were included to formulate final recommendations.

The participants agreed unanimously to a dynamic roadmap which has the scope of continuous improvement through monitoring and reviewing which will act as a benchmark for the future. It was also agreed that the QC laboratories of vaccine manufacturers in public and private sectors and national quality control laboratories should work in close collaboration and develop a functional relationship with each other. The CCSNIAH has been envisaged to co-ordinate between manufacturers and other agencies for harmonization of veterinary biologicals in India.

Recommendations

Major recommendations which emerged out of the deliberations and discussion are summarized hereunder:

1. A database of animal diseases including companion animals may be developed by DAHDF through NADRS and make it available in public domain.
2. An agenda on surveillance of diseases may be included in the forthcoming RDDDL meeting. Private manufacturers may also consider funding some projects on emerging diseases which may be implemented through various national institutes in NARS.
3. A Committee comprising (i) the Head, Division of Biological Standardization, IVRI, Izatnagar or any other scientist nominated by Director, IVRI; (ii) Director, CCSNIAH, Baghpat; and (iii) Deputy Drug Controller of India, CDSCO, Delhi representing the office of the DCGI to advise State BP units for implementation of GMP may be constituted and communicated to the State BP Units by AHC.
4. Following priority diseases have been identified for the development and validation of SOPs and expert labs in the first phase:

Large ruminants	Small ruminants	Swine	Poultry	Canine
FMD	PPR	CSF	RD	Rabies
Brucellosis	Sheep pox		MD	Parvo virus infection
HS	Goat pox		IBD	CD
BQ				

Other diseases may be taken up in second phase as per the need of the country and directions of the department by CCSNIAH.

5. It has been recommended after thorough discussion that identification of experts for development of SOPs and their validation may be proposed by CCSNIAH with the following broad structure comprising members from:
 - i. IVRI, Izatnagar/ICAR institutes/NARS
 - ii. CCSNIAH, Baghpat
 - iii. IPC, Ghaziabad
 - iv. State Biological Production Units/Private manufacturing Unit
 - v. Any other subject matter specialist, if required

Draft SOPs developed by CCSNIAH may be taken as backbone.

6. The identification of experts and expert laboratories (from the above list) will be carried out by CCSNIAH considering their expertise, capacity and willingness, with the approval from AHC, DAHDF.
7. The procedure and modalities for recognition/approval of expert labs in the network will be chalked out by CCSNIAH along with a mechanism of annual reviewing.
8. On the agenda related to the problems associated with vaccine failure, it was emphasized that due care should be taken on the following points during any vaccination programme:
 - i. Proper vaccination regimen (not to carry out vaccination on the face of outbreak);
 - ii. Marking system for vaccinated animals;
 - iii. Post vaccination sero-monitoring;
 - iv. Maintenance of cold chain from production to the use;
 - v. Required antigenic mass;
 - vi. Proper nutritional and genetic make-up status of animals;
 - vii. Deworming of animals before vaccination;
 - viii. Issues related to non-vaccination of pregnant animals may be researched upon;
 - ix. Proper reporting system of vaccination and vigilance of vaccination program; National and state level technical teams to monitor vaccination process working independently to bring seriousness to the on-going control programs
 - x. Vaccine Adverse Reaction (VAR) reporting system; a project on this issue may be formulated by CCSNIAH;
 - xi. Bio security measures at farm;
 - xii. Awareness program to adopt vaccination program by farmers and its effectiveness to be evaluated;
 - xiii. Training of vaccinators: both public and private sector should impart trainings; CCSNIAH has already initiated in this direction by proposing a trainers' training programme.
9. Besides these issues, it has been discussed and recommended that QC labs of state BP units should adhere to the compliance GLP. Strengthening of CDLs under DCGI has been recommended.
10. Data pertaining to potency testing of vaccines along with serum samples from such animals may to be submitted by manufacturers/IVRI, Bengaluru to Division of

Standardization, IVRI and CCSNIAH for correlation in search of alternative testing methods.

11. Promotion of research activities for development of alternative tests/*in vitro* tests for potency and safety testing of vaccines in target animals has been strongly recommended to be carried out at CCSNIAH and IVRI. It was informed to the house that CCSNIAH would soon initiate outsourcing and funding few selected projects on these lines.
12. It was strongly recommended to create a separate specialized cadre of officers/scientists in the States exclusively for biological production and quality control of BP. A letter may be written by the Department of AHDF on this issue to the Secretaries/Directors of Animal Husbandry of the various States. A voice was also raised by participants regarding autonomy to BP units in the States.
13. On the issue of harmonization and supply of reference cultures, sera etc., it was suggested and agreed upon that the task may be taken up by IVRI, Izatnagar and VTCC Hisar in conjunction with private manufacturers.
14. Creation of an expert institute on companion animals was emphasized viewing the lack of knowledge base on the diseases of the non-food-producing animals. Considering the importance of such diseases especially zoonotic ones, it was recommended that such institution may be created by ICAR.
15. There needs to be an expert committee to review an emerging and re-emerging diseases situation in the country for all the species.

Appendix-1

List of Participants:

1. Shri Devendra Chaudhary, IAS, Secretary (ADF) , Govt of India, Krishi Bhawan, New Delhi (on Chair)
2. Dr Suresh S Honnappagol, AHC, Govt of India, Krishi Bhawan, New Delhi
3. Dr. R K Singh, Director, ICAR – IVRI, Izatnagar (UP)
4. Dr. Ashok Kumar ADG (AH) ICAR, Krishi Bhawan, New Delhi
5. Dr. Praveen Malik, Director, CCS NIAH, Baghpat (UP)
6. Dr. A Ramkishan , Deputy Drug Controller , CDSCO, New Delhi
7. Dr. Robin Kumar, Senior Scientist , Indian Pharmacopeia Commission , Ghaziabad
8. Dr. M. Kalaivani, Indian Pharmacopeia Commission , Ghaziabad
9. Dr Meenakshi Dahiya, Indian Pharmacopeia commission , Ghaziabad
10. Dr. A K Tiwari, Head, Biological Standardization, ICAR- IVRI, Izatnagar (UP)
11. Dr. Aniket Sanyal , JD, ICAR-IVRI, Bangalore (Karnataka)
12. Dr. H. K Muniyellappa , Joint Commisioner (LH), DADF, GOI, Krishi Bhawan, New Delhi
13. Dr. H. R. Khanna, Asssitant Commissioner, DADF, GOI, Krishi Bhawan, New Delhi
14. Dr. Sujit Kumar Dutta, Assistant Commissioner, DADF, GOI, Krishi Bhawan, New Delhi
15. Dr. Vinay Kumar Gupta, CDSCO, New Delhi
16. Dr. Shiv Kumar, CDSCO, New Delhi
17. Dr. P. Balarajeswara Reddy, Deputy Director, VBRI, Samalkot, Andhra Pradesh
18. Dr. T Srinivasulu, Asst Director, VBRI, Samalkot, Andhra Pradesh
19. Dr. Hanumantha Reddy , Joint Director, VBRI, Hyderabad, Andhra Pradesh
20. Dr. Taran Singh, Institute of Animal Health and Production, Ranchi, Jharkhand
21. Dr S. M. Byregowda, IAHVB, Hebbal, Bangalore, Karnataka
22. Dr. Asha Mayanna, IAHVB, Hebbal, Bangalore, Karnataka
23. Dr. G. K. Chandrakala, IAHVB, Hebbal, Bangalore, Karnataka
24. Dr Renu Mishra, Vety Assistant Surgeon, IAHVB, Rasalpara, Mhow, M P
25. Dr. Naheed Perveen Sheikh, Vety Assistant Surgeon, IAHVB, Rasalpara, Mhow, M P
26. Dr. Bhagwan Singh Karada, IAHVB, Rasalpara, Mhow, M P
27. Dr. Ravindra Gangadhar Firke, IVBP, Aundh, Pune, Maharashtra
28. Dr. Sadashiv Gopalrao Kale, IVBP, Aundh, Pune, Maharashtra
29. Dr. Johnsi Koruth, IVP, Ranipet, Vellore, Tamil Nadu
30. Dr. K. Ravikumar, IVP, Ranipet, Vellore, Tamil Nadu
31. Dr. Kulwant Singh , PVVI, P.A.U. Campus, Ludhiana, Punjab
32. Dr. Pritpal Singh, PVVI, P.A.U. Campus, Ludhiana, Punjab
33. Dr. CK Shukla, (Joint Director, QC), IVB, Badshah Bag, Lucknow, UP
34. Dr. Rajesh Kumar Singh, VO, (Prod.), IVB, Badshah Bag, Lucknow, UP
35. Dr Amal Kumar Dey, IAHVB, Kolkata, West Bengal
36. Dr. Aranya Kumar Sarkar, IAHVB, Kolkata, West Bengal
37. Dr. Atish , Antirabies Vaccine Lab, R S Pura, Jammu, (J&K)
38. Dr. Yasir , Antirabies Vaccine Lab, R S Pura, Jammu (J&K)
39. Dr. R.K. Verma, Haryana Veterinary Vaccine Institute, Hisar, Haryana
40. Dr. Shivankur Dutta, Haryana Veterinary Vaccine Institute, Hisar, Haryana
41. Ms Samridhi Mishra, SPIL, Dewas (MP)
42. Dr. TVS Rao, Brilliant Biopharma Pvt limited, Hyderabad, Telangana.

43. Dr.Sreenivas Reddy Guddeti , Indian Immunologicals Ltd., Hyderabad, Telangana.
44. Dr. Srinivas Kranti, Indian Immunologicals Ltd., Hyderabad, Telangana.
45. Dr. D K Dey (CEO), Globion India Pvt Ltd, Secundarabad, Telangana
46. Dr. Sanjay Gavkare, Venky's (India) Ltd, Pune , Maharashtra
47. Dr. S.M.Deshpande, GM, Venky's (India) Ltd, Pune , Maharashtra
48. Dr. S.D.Kubal, Venky's (India) Ltd, Pune, Maharashtra
49. Dr. D.B.Bhandari, Venky's (India) Ltd, Pune, Maharashtra
50. Dr Lalit M. Belwal, Indovax Pvt Ltd, Gurgaon, Harayana
51. Dr S.K. Batra, Indovax Pvt Ltd, Gurgaon, Harayana
52. Dr. Neeraj Agarwal Jt Dir , Biomed Pvt Ltd, Ghaziabad, UP.
53. Dr. Kiran Anklekar (Asso. Dir. QA&QC), MSD Intervet India Pvt Ltd, Pune, Maharashtra
54. Dr. Kiları (Asso. Dir, R&D), MSD Intervet India Pvt Ltd, Pune, Maharashtra
55. Dr. Shankaraiah Eggidi, MSD Intervet India Pvt Ltd, Pune, Maharashtra
56. Dr S. N. Singh , Biovet Pvt. Ltd, Karnataka
57. Dr. S. Krishnamachari , Sanvita Biotech, Medak District, Telangana
58. Dr. Nitin Bhatia , Intas Polivet, Ahmadabad (Gujarat)
59. Dr. Ranjit Ghadaqe, Ventri Biologicals , Pune
60. Dr. Hindustan Heel Azad, Biovet Pvt Ltd, Karnataka
61. Dr. Sandeep Kumar Singh, JD,CCSNIAH, Baghpat (UP)
62. Dr. Ashwini Kumar Singh ,AD, CCSNIAH, Baghpat (UP)
63. Dr. Sweta Raghuvanshi, AD,CCSNIAH, Baghpat (UP)
64. Dr. Mohd Reyaz , AD, CCSNIAH, Baghpat (UP)
65. Dr. Atulya M, AD,CCSNIAH, Baghpat (UP)
66. Dr. Sudam Bag, AD, CCSNIAH, Baghpat (UP)
67. Mrs Shipra Shrivastava, CCSNIAH, Baghpat (UP)
68. Km. Monika Srivastav, CCSNIAH, Baghpat (UP)
69. Shri Ranbir Singh, CCSNIAH, Baghpat (UP)