



VICH OUTREACH FORUM
14th Meeting (held virtually)
16 November 2021

SUMMARY REPORT

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr Jean-Pierre Orand, Director of the French agency for veterinary medicinal products - OIE collaborating centre, on behalf of the OIE.

Dr Orand opened the meeting by welcoming the participants to the 14th VICH Outreach Forum (VOF), regretting that for the second time this meeting could be held virtually only.

Dr Ivo Claassen, Head of the Veterinary Medicines Department at the European Medicines Agency and chairman of the VICH Steering Committee (SC), regretted also that once more he was not able to welcome the participants in the EMA's facilities in Amsterdam. He hoped that it will be possible when the meetings will be scheduled again in Europe in 2024.

Dr Orand indicated that the topic "EuFMD/FAO project for a pre-qualification system for veterinary medicines" has been added to agenda item 7. AOB.

2. Report by the SC on issues raised by Outreach Forum members during the 13th VICH Outreach Forum virtual meeting in November 2020

The VICH Secretariat briefly summarised the report from the SC ([link](#)) that was circulated prior to the meeting and addressing the follow up from the SC to the discussions held at the 13th VOF meeting.

The main features are:

- As requested, the VOF meeting agenda was circulated in January 2021
- The proposed agenda for the 15th VOF was also provided in advance of this meeting
- Specific topic for discussion – AnimalhealthEurope will present the result of survey on approaches taken by VICH countries on regulatory control of autogenous vaccines
- Brief summary on the activities of the 9 VICH Expert Working Groups
- Start of a reflection in the SC on the update of the VICH structures, one of the aims being to improve and facilitate further involvement of VOF members in the VICH activities
- Confirmation that VICH 7 Public Conference will take place in 2024 in conjunction with the 17th VOF and 43rd SC meetings – date & location to be confirmed.

3. Report by OIE on their activities concerning Veterinary Medicinal Products (VMPs) since the last Forum

The OIE briefly summarised the report ([link](#)) focussing on the activities of OIE on VMPs since the last VOF meeting.

The presentation details:

- The regular dissemination of information on VICH to OIE Member Countries
- The ongoing support provided by the OIE to the VOF, including the brief summary with the key items to OIE Delegates and the Focal Points of Veterinary Products, parallel invitation letters (in addition to the invitation letter sent by the VICH Secretariat) for this meeting to the Delegates and Focal points of the VOF countries as well as and the 3 Organisations, ASEAN, CAMEVET and UEMOA
- An update on the OIE Specialist Commission (Biological Standards Commission), although this year the Commission did not have time to address the VICH related issues due to the time constraints caused by the virtual meeting format
- The 6th Cycle of Training Seminars for Focal Points (FP) for Veterinary Products has been completed in all OIE Regions, with the promotion of VICH related information such as VICH general principles, VICH Quality and Pharmacovigilance GLs, the benefits of being a VICH Outreach Forum (VOF) member
- The OIE also listed meetings with OIE involvement that took place in 2021 and might also be of interest to VICH

The OIE also forwarded the greetings of the new head of the OIE Veterinary Products Department, Dr. Javier Yugueros-Marcos, who could not take part this meeting.

4. VOF Topics – Autogenous vaccines

AnimalhealthEurope recalled that at the last meeting the VOF members had asked to receive information on the regulation of Autogenous Vaccines in the VICH countries/regions.

Although this is not a VICH topic, AnimalhealthEurope has agreed to provide an overview ([link](#)) on how these products are handled in the different VICH regions.

AnimalhealthEurope explained the background and pointed out that the local definition of an Autogenous Vaccine differs between VICH countries/regions.

The participants received a summary of the data submission requirements and noted that in general the use of Autogenous Vaccines is restricted to the herd or flock from which the microorganism(s) was isolated.

A more detailed overview of the regulatory control of autogenous vaccines in the VICH regions is also available in a Word document ([link](#)).

OIE mentioned that at the last OIE global conference on antimicrobial resistance and prudent use of antimicrobial agents, it was recommended to explore the opportunity to develop standards or guidelines related to Autogenous Vaccines to reduce AMR. This reflects the high activity at international level where the PIC/S Vet subgroup has developed a Concept Paper on GMPs for veterinary biological products including Autogenous Vaccines whilst OIE is currently evaluating the possibility to develop an OIE GL on Autogenous Vaccines.

Thailand thanked AnimalhealthEurope for having addressed this topic, which is out of the scope of VICH, within the VOF.

ASEAN has developed a standard GL on the use and the manufacturing of Autogenous Vaccines, which is being used by Thailand and Singapore.

Thailand suggested to provide more details at the 15th VOF meeting.

Act: Thailand

Morocco asked for clarification on the Safety requirements for Autogenous Vaccines in the USA.

USDA agreed to provide more information to Morocco after the meeting.

Act: USDA

5. Information about training recording and follow-up webinar

The EU confirmed that a new presentation on the [VICH guidelines on Environmental Risk Assessment of Veterinary Medicines - VICH GL6 and GL38](#) has been placed on the VICH website training section in Module 4 - Safety.

3 additional presentations explaining how these VICH GLs are implemented in the EU, Japan and the USA have also been made available.

These presentations are all enhanced with an audio track explanation in order to facilitate their understanding.

The EU encouraged all VOF delegations to widely share these presentations in their organisations in order to enable as many colleagues as possible to view them.

As was done last year, this training session will be completed by a Q&A 1.5 hours follow-up webinar with the VICH experts from the different regions. This session will take place on **Wednesday 2 February 2022** and will offer the opportunity for all VOF members to receive further explanations and clarifications.

Questions and comments should be provided to the VICH Secretariat in advance of the webinar in order to ensure that the experts can prepare their inputs.

Act: All

The OIE pointed out that last year's session on the application of VICH GL 27 had been very successful

The OIE asked the VOF members for further topics for training webinars, but none was suggested.

6. Discussion on the draft agenda for the 15th VOF

The OIE took the participants through the draft agenda that was circulated prior to the meeting.

The OIE expected that a face-to-face meeting will be possible again for the 15th VOF, to take place in the USA (Washington DC area) on 15th November 2022.

The pre-meeting initially planned for this year, will be organised in the afternoon of the first day for exchanges between VOF members only, with a representative of the OIE.

The specific topics currently planned with VICH experts will cover the stability of vaccines as well as the stability of medicated premixes (VICH GL 8).

India, which had provided several proposals for topics prior to the meeting, suggested discussing the topic of alternatives to antimicrobials, but this proposal was not retained by the members.

India also proposed to discuss the "digitalisation of the data and internationally approved protocols for harmonisation of drugs which will create and ease in accessing the Internationally approved protocol for harmonization of drugs".

It was however pointed out that digitalisation of the data is not a VICH topic, although VICH does discuss the format of dossier submissions (e.g. GL53 Electronic Exchange of Documents: Electronic File Format, and a new discussion document on Global Regulatory Dossier Framework).

India indicated that it would provide a presentation for further discussion – to be confirmed.

Act: India

Thailand mentioned again that the topic of Autogenous Vaccines is important in the ASEAN region. A questionnaire on the current legislation and usage of Autogenous Vaccines has been recently circulated to the ASEAN member countries.

Singapore indicated that the country has a requirement for a GMP like approach for the manufacturing of AVs.

Thailand & Singapore will update the VOF at the next meeting.

Act: Thailand/Singapore

Ukraine suggested receiving more information on the determination of withdrawal periods for generic products in order to clarify the value of bioequivalence data for supporting withdrawal periods and whether additional residue studies are needed.

OIE asked all members to provide further suggestions for the agenda of the next meeting by mid-January 2022.

Act: All

A final draft agenda will be circulated at the end of January.

7. AOB

➤ *EuFMD/FAO project for a pre-qualification system for veterinary medicines*

The OIE reported that the FAO had contacted VICH to introduce a project that the FAO European Commission for the control of Foot-and-Mouth Disease has recently launched for the development of a feasibility study for a pre-qualification system for veterinary medicines, similar to the existing WHO pre-qualification system.

The FAO has explained that it is seeking volunteers within the VOF members from different countries/regions who would accept to join a Technical Stakeholder Advisory Group that would support the EuFMD in developing prioritization criteria.

The Secretariat confirmed that the VOF members will be contacted by the FAO in the near future.

8. Confirmation date and venue of the next VICH Outreach Forum meeting

The **15th VICH Outreach Forum** meeting will be held on 15 November 2022 in the Washington DC area - USA.

9. Conclusion

The Secretariat thanked all participants throughout the different regions for their participation in this virtual meeting, which, for some people, took place at a very late or very early hour of the day.

Dr Orand thanked all VOF participants for their participation and inputs and hoped to meet everybody in person again in November next year.

14th VICH Outreach Forum meeting Participants

1/ Forum members

ARGENTINA – CAPROVE	Patricia MILLARES
ARGENTINA – SENASA	Luisina GARCIA SAINZ
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	Isabela Maria ALVES DE AVILA
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	Marcos Vinicius DE SANTANA
BRAZIL – SINDAN	LEANDRO Jr.
BRAZIL – SINDAN	Luiz MONTEIRO
BRAZIL – SINDAN	Gabriela MURA
BRAZIL – SINDAN	Monica MARCUSO
CHINA (PR) – Institute of Vet. Drug Control	Natalia PIOVEZAN
CHINA (PR) – Institute of Vet. Drug Control	Shixin XU
CHINA (PR) – Institute of Vet. Drug Control	Su MA
CHINA (PR) – Institute of Vet. Drug Control	Xia WANG
CHINA (PR) – Institute of Vet. Drug Control	Xianming LIANG
CHINA (PR) – Institute of Vet. Drug Control	Jinglan YANG
CHINA (PR) – Institute of Vet. Drug Control	Ziyang LIU
CHINA (PR) – Institute of Vet. Drug Control	Xiaoping CHU
CHINA (PR) – Institute of Vet. Drug Control	Sifan GUO
INDIA – Ministry of Fisheries, Animal Husbandry & Dairying, Government of India	Adhiraj MISHRA
INDIA – Ministry of Fisheries, Animal Husbandry & Dairying, Government of India	Lipi SAIRIWAL
INDIA – Ministry of Fisheries, Animal Husbandry & Dairying, Government of India	Praveen MALIK
MEXICO – CANIFARMA	R. Alexandra LUNA ORTA
MEXICO – SENASICA	Maria Elena GONZALEZ RUIZ
MOROCCO – ONSSA	Sami DARKAOUI
MOROCCO – ONSSA	Hasnae BENALLA
MOROCCO – ONSSA	Younes WAHLI
NIGERIA – NAFDAC	Bukar USMAN
NIGERIA – NAFDAC	Sadiq YUNUS
SAUDI ARABIA – Saudi Food & Drug Authority	Taha M. RAMZI
SAUDI ARABIA – Saudi Food & Drug Authority	Walid A. AL-HOMAYIN
TAIWAN – Council of Agriculture Taipei	Ying-Kai CHANG
TAIWAN – Council of Agriculture Taipei	Cheng-Jou CHAN
THAILAND – Food and Drug Administration	Chaiporn PUMKAM
THAILAND – Food and Drug Administration	Supapitch SUPHAP
THAILAND – Food and Drug Administration	Arpasinee SANUPHA
THAILAND – Food and Drug Administration	Lertrob HONHANROB
THAILAND – Department of Livestock Development	Sasi JAROENPOJ
THAILAND – Department of Livestock Development	Julaporn SRINHA
THAILAND – Department of Livestock Development	Suchana SUKKLAD
THAILAND – Department of Livestock Development	Passawee PAKPONG
THAILAND – Department of Livestock Development	Thanawan NA THALANG
THAILAND – Department of Livestock Development	Porjai RATTANAPANADDA
UGANDA – National Drug Authority	Jeanne BUKEKA
UGANDA – National Drug Authority	Noel Mategyero AINEPLAN
UKRAINE – SCIVP	Yuriy KOSENKO
ZIMBABWE - Medicines Control Authority	Zivanai MAKONI
?????	Nicholas VITAL

2 / VICH Steering Committee

Members and (C) Coordinators

STEERING COMMITTEE (C) coordinators

AHI (ZOETIS)
AHI (BI)
AHI
EU (HEALTH PRODUCTS REGULATORY AUTH)
EU (EMA)
EU (EMA)
ANIMALHEALTHEUROPE (BI)
ANIMALHEALTHEUROPE (ELANCO)
ANIMALHEALTHEUROPE
JMAFF
JMAFF
JMAFF
JVPA (NIPPON ZENYAKU KOGYO CO.)
JVPA (Nisseiken Co.)
JVPA
US (FDA)
US (USDA APHIS)
US (FDA/CVM)

C. LOWNEY
E. NORTON
R. CUMBERBATCH (C)
D. MURPHY
N. JARRETT (C)
I. CLAASSEN - *Chairperson*
B. BOENISCH
E. DE RIDDER
R. CLAYTON (C)
K. EGUCHI
K. NODA
J. OHMORI (C)
I. ABE
K. TUCHIYA
K. OISHI (C)
M. LUCIA
M. PAGALA
B. ROBINSON (C)

OBSERVERS

Australia (APVMA)
Australia (AMA)
Australia (AMA)
Canada (Health Canada)
Canada (Health Canada)
Canada (CAHI)
New Zealand (MPI)
New Zealand (AGCARM)
South Africa (SAAHA)
South Africa (SAHPRA)
UK (NOAH)
UK (VMD)

D. SIBANDA
C. BENNETT
V. CLARK
M-J. IRELAND
M. BASSI
C. FILEJSKI
A. KINSELLA
J. HOWE
M. CHURCHILL
A. SIGOBODHLA
D. MURPHY
S. ECKFORD

INTERESTED PARTY

AVBC

G. DOWELL

OIE

OIE
OIE

J-P. ORAND
M. SZABO

VICH

HealthforAnimals

H. MARION (*Secretary*)

APOLOGIES

EU (EUROPEAN COMMISSION)
HealthforAnimals

J-N. PREUSS
C. DU MARCHIE SARVAAS