



Regional Seminar for
OIE National Focal Points for
Veterinary Products (6th Cycle)
Kuala Lumpur, Malaysia
14-16 January 2020

EXTERNAL CONCEPT NOTE

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1. Background

During the 76th General Session in May 2008, the importance of the Focal Points (FPs) for information on animal diseases was re-iterated, and Delegates were also requested to nominate additional focal points for wildlife, veterinary products, animal production food safety, animal welfare and aquatic animals. OIE FPs, nominated by OIE Delegates and acting under their supervision, is an important mechanism for countries to satisfy their OIE obligations and to strengthen communication and collaboration between Member Countries (MCs) and the OIE.

The OIE Sub-Regional Representation (SRR) for South East Asia was established in 2010 and has been entrusted with the organisation of several training courses for OIE FPs including wildlife, animal disease notification, animal welfare, communication, aquatic animal diseases and veterinary products.

Under the technical supervision of the OIE Scientific and Technical Department, now renamed the OIE Antimicrobial Resistance and Veterinary Products Department, the training of Focal Points for Veterinary Products in Asia and the Pacific commenced in 2011 with a first (cycle) seminar organised for all Focal Points in Siem Reap, Cambodia : <https://rr-asia.oie.int/about-us/focal-points/veterinary-products/> and was followed by second, third, fourth and fifth cycle seminars in Bangkok, Thailand and Tokyo, Japan in 2012-2018 (see table below).

Cycle	Venue	Year
I	Siem Reap, Cambodia	2011
II	Bangkok, Thailand	2012
III	Tokyo, Japan	2014
IV	Tokyo, Japan	2016
V	Bangkok, Thailand	2018
Tot.		5

These seminars provided the FPs with knowledge on rights, commitments, and responsibilities of the OIE National Focal Points in the standard-setting process and compliance of their countries with the OIE international standards. It also provided the more in-depth understanding of key issues such as antimicrobial resistance (AMR) including the Global Action Plan developed by WHO with the support of the OIE and FAO, Tripartite activities, the OIE database on the use of antimicrobial agents, and the OIE strategy on AMR, raise awareness on anti-parasitic resistance, and quality of veterinary products including the challenge of falsified medicines, possibility on harmonisation/convergence of regulatory systems for registration of veterinary products.

The new cycle (VI) will build on the feedback received from previous seminars, focus on different aspects of quality of veterinary medicines and revisit the recommendations of the 2nd OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents in Animals “Putting Standards into Practice” (Marrakesh, Morocco, 29 - 31 October 2018).

The experts from OIE Collaborating Centres (OIE CCs) will technically support the seminar like previous times.

The proposed organisation is as indicated below:

Cycle	Venue	Mo/Year
VI	Kuala Lumpur, Malaysia	01.2020

2. Objectives

The 3-day seminar will provide participants with:

- 2.1. An overview of ongoing activities related to the AMR.
- 2.2. Follow up on recommendations coming from the OIE 2nd OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents in Animals: “Putting Standards into Practice”
- 2.3. An introduction of new topics such as to improve access to quality concerning veterinary medicinal products worldwide:
 - 2.3.1. OIE is engaging with relevant WHO experts to draw on their experience and expertise to scope opportunities for developing an alert and response mechanism for substandard and falsified veterinary medicines;
 - 2.3.2. OIE will further explore options how it can support countries to establish or strengthen an active surveillance system to tackle substandard and falsified drugs and address pharmacovigilance using VICH Guidelines;
 - 2.3.3. In line with recommendation nr. 8 from the OIE Global Conference (Marrakesh, 2018), the OIE will gather available information to explore the opportunity to develop standards or guidelines related to autogenous vaccines and other alternatives to antimicrobials, including guidance for quality, safety and efficacy, as tools to reduce the need to use antimicrobials.

In addition, the seminar will provide the FPs with:

- Information on the roles and responsibilities of OIE National Focal Points for Veterinary Products and the update on OIE standards and guidelines related to the veterinary medicinal products including update on VICH activities;
- Knowledge and examples of good governance of veterinary medicinal products (VMPs) that may assist MCs to improve their regulatory authorisation/registration framework; including convergence/harmonisation of regulatory systems;
- Knowledge on pharmacovigilance, how to set up and run a basic pharmacovigilance system/ the minimum requirements for the pharmacovigilance system, good practice guide for competent authorities, good practice guide for industry, introduction of supporting documents (e.g. adverse reaction reporting template) VICH guideline(s);
- Discussions on what could be the OIE’s role to set up the possible minimum requirements for the worldwide pharmacovigilance system;
- Global Surveillance and Monitoring System for rapid alert regarding falsified and substandard products how to fight against with illegal veterinary drugs; present OIE findings so far inviting WHO, FAO, WCO, etc.;
- Explore the current status of using autogenous vaccine in animals.

Finally, the seminar will address recent initiatives of interest to the FPs, i.e. feedback from the World Bank Project (“Enabling the Business of Agriculture” Project Livestock Topic <http://eba.worldbank.org>) and the Pharmaceutical Inspection Co-operation Scheme (PICS)

As in previous seminars, this seminar too will foster opportunities to learn and share information, strengthen the network within the Asia and the Pacific region through dedicating as much time as possible to interactive sessions, forum discussions.

This activity contributes to all six strategic objectives/cross-cutting areas of the OIE 6th Strategic plan (2016-2020), but is specifically geared towards attaining SO 1 (AMR) and SO 3 and CC A.

- Strategic objective 1: Securing animal health and welfare by appropriate risk management
- Strategic objective 2: Establishing trust through transparency and communication
- Strategic objective 3: Ensuring the capacity and sustainability of veterinary services
- Cross-cutting area A: Scientific excellence

Cross-cutting area B: Diversity, Inclusiveness, Engagement, Transparency

Cross-cutting area C: Governance

3. Outcomes and follow-up activities

After the 3-day training seminar, the FPs will:

- have developed a better understanding of the pharmacovigilance, assist Member Countries to use the existing VICH guidelines related to pharmacovigilance. To develop minimum requirements for a pharmacovigilance guideline in collaboration with Health for Animals (an active member of VICH, holding the VICH secretariat) OIE Collaborating Centres and the relevant partners. Better understanding of the VICH Quality Guidelines;
- have been updated on the situation of prudent and responsible use of antimicrobial resistance and anti-parasitic resistance;
- be able to set up or improve their legislation, regulations, technical standards or guidelines to have a practical regulatory framework for the management of veterinary medicinal products from registration to post authorisation surveillance; and strengthen the capacity to the veterinary services;
- have gathered country experiences and explored proposals on how various stakeholders could contribute to the fight against falsified, substandard and illegal veterinary medicinal products. Provide feedback, inputs of feasibility on set up a functioning Veterinary Global Surveillance and Monitoring System for rapid alert regarding falsified and substandard veterinary medicinal products;
- be aware of the technical standards of manufacturing, quality control and prudent use of autogenous vaccines;
- have strengthened the network of Focal Points for Veterinary Products and within the countries and with other stakeholders, and National Competent Authorities.

4. Target group (35)

The target group consists of 32 OIE Subject Matter Focal Points on Veterinary Products from Asia and the Pacific (including the host country, Malaysia).

List of countries

Australia	Malaysia (Host)
Bangladesh	Papua New Guinea
Bhutan	Pakistan
Brunei	Sri Lanka
Cambodia	Thailand
China PR	Micronesia
Chinese Taipei	Mongolia
Fiji	Myanmar
India	Nepal
Indonesia	New Zealand
Iran	New Caledonia
Japan	Philippines
Korea DPR	Singapore
Korea RO	Timor-Leste
Lao PDR	Vanuatu
Maldives	Vietnam

