Report

Webinar for Focal Points on Veterinary Medicinal Products (6th cycle)

7-9 December 2020

Introduction:

The OIE has launched a global capacity building programme for OIE Delegates and National Focal Points (FP). Among other aspects, this programme aims to present good governance concepts to OIE Members, to explain and clarify the role and responsibilities of the OIE FP for Veterinary Products, and to facilitate consistency and harmonisation amongst OIE Members when assigning duties to these officials. OIE FP are an important means of enabling countries to fulfill their OIE obligations and to strengthen communication and collaboration between the OIE and its Members.

A webinar for the FP for Veterinary Products as part of the 6th Cycle Training Seminars was organised by the OIE Regional Representation for the ME in close collaboration with the OIE Headquarters Antimicrobial Resistance and Veterinary Products (AMR & VP) Department. The webinar took place from the 7th - 9th December 2020.

Nine out of 13 invited countries attended the webinar and many engaged actively with the experts. Simultaneous interpretation to Arabic, as well as the translation of important documents such as the "How to set up a pharmacovigilance system for veterinary medicinal products" which was prepared in the framework of a public-private partnership, were provided.

Participating countries: Bahrain, Egypt, Iraq, Jordan, Kuwait, Oman, Saudi Arabia, United Arab Emirates.

Participants from OIE: Elisabeth Erlacher-Vindel, Maria Szabo, Rebecca Hibbard, Morgan Jeannin, Delfy Gochez, Mduduzi Welcome Magongo.

Summary:

The proceedings of the three-day webinar were as follows:

Day 1:

The webinar started with an **introduction by Elisabeth Erlacher-Vindel (Head of the AMR & VP Department),** summarising the objectives of the 6th Cycle of Focal Point Training Seminars including key issues such as:

- Antimicrobial use and resistance including the Global Action Plan developed by WHO with the support of the OIE and FAO and other Tripartite activities;

- The OIE database on the use of antimicrobial agents.

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- Antiparasitic resistance and associated challenges;

- The quality of veterinary products, including the issue of substandard and falsified veterinary products;

- General principles and implementation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines, and an update on VICH Outreach Forum activities.

After an introduction of the participants, facilitated by Dr Ghazi Yehia, the webinar sessions proceeded as follows:

A- AMR Session: Introduction to the AMU data collection.

The presentations of the AMU team (Morgan Jeannin, Delfy Gochez, and Mduduzi Welcome Magongo) focused on the OIE questionnaire on antimicrobial use and the calculation of quantities in kilograms of active ingredients, as well as the transition to the future OIE AMU database.

In order to consider Members' needs for the development of the future AMU IT system, an online questionnaire was circulated among the participants.

The points of focus of the discussions were:

• The need for a stronger commitment from the region to participate in the OIE AMU data collection to ensure the inclusion of regional data in the OIE AMU Annual Report.

• Encouragement for countries to use the calculation tool to assist and ease the transmission of reliable information.

• The emphasis placed by the OIE on strict confidentiality of country-level data transmitted to the AMU team.

• Improving awareness of the future AMU IT system and involving countries in the Middle East during the testing phase.

Day 2:

B- Quality of veterinary products session

Dr Jean-Pierre Orand gave a presentation on how to ensure **the quality of veterinary products**. Veterinary medicinal products are essential to ensuring animal health and welfare and to improving public health in general. The availability and use of reliable, effective veterinary products of good quality are pivotal to ensure animal health and welfare, play an important role in supporting food security and protecting livelihoods, and are a key part of the work to prevent the development of AMR. Use of non-good quality VMPs presents risks :

- for animal health as they might be inefficient medicines;

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- for human health due to risk of residues in food or zoonotic outbreaks;
- for environment as the might be source of pollution.

A good quality VMP is a VMP that has been authorised or registered by the national competent authority after the assessment of a dossier describing the composition and all the specificities requested to ensure that the VMP is safe and efficient.

To prevent any problem of quality, it is important to observe compliance with international (or national) standards at all steps of a VMP's life: from the research and development phase, through manufacturing and distribution, to use at farm level. OIE, VICH, and PICs are international bodies who have adopted such standards: guidelines, requirements, or good practices.

At national level, the competent authority in charge of control of good governance should have a very good knowledge of all the actors involved in the distribution chain of VMPs in their countries: importer, manufacturer, wholesaler, retailer, and users. These actors should be registered and inspected to confirm that they respect all needed measures to ensure the maintenance of VMP quality: conditions of storage (temperature, hygrometry), traceability (record of sellers and suppliers), and that the VMPs are legally authorised or registered.

The conlcusions of this presentation were:

- Ensuring the quality of veterinary medicinal products is essential.
- Appropriate legislation and staff (trained inspectors, laboratory capacities) are needed: Efficient systems of authorisation or registration (for VMPs and companies), transparency and communication, an efficient inspectorate body with appropriate power, and a national surveillance program run by an accredited laboratory are essential, as are the capacity to prosecute and recall products.

Dr Rebecca Hibbard presented on **substandard and falsified (SF) veterinary products.** Her presentation provided background information on this topic, and the OIE's proposed future work in this area, in particular, the potential for developing an OIE information and alert system for SF veterinary products. The Focal Points' feedback was requested on the proposed system outlined during the presentation.

The presentations were followed by a discussion session on the quality of veterinary products. Participants had been sent a short questionnaire in advance of the webinar, and these questions were expanded on during the discussion session. From the answers received in advance of the webinar, and the discussion that took place during the webinar, it was found that:

- At least half of the countries in the Middle East reported having some form of surveillance system or network to follow up issues of veterinary product quality. Among those that did not, it was mentioned that testing could be possible in cooperation with the Food and Drug Administration of Saudi Arabia via the Gulf Cooperation Council (GCC) network.

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- The main point of contact/authority with the responsibility for the quality of veterinary products varied between countries, in most cases belonging to the relevant government Ministry/department for agriculture or animal health, to local forms of government, or to the Ministry/department responsible for human health.

- The majority of countries have a legal basis for sampling the market for veterinary products, and for recall of those products. Less than half of the countries reported having a national or regional laboratory, or a database of the veterinary products registered in their country.

Discussion including the questionnaire on the quality of veterinary products was facilitated by **Rebecca Hibbard and Mária Szabó**.

C- Antiparasitic session: Dr Christo Hilan, professor at Kaslik University, presented the outcome of the questionnaire on antiparasitic resistance (APR), which was conducted in the Middle East Region in June and July 2021.

Responses to the the questionnaire, which was developed by the OIE Electronic Expert Group on Antiparasitic Resistance (EEG APR), were received from nine Members. The results included the following findings:

- The majority of respondents felt that the status of anthelmintic resistance (AHR) in their country was mostly unknown at the national level. This situation could be due to a lack of communication on the topic, as compared to antimicrobial resistance and the absence of official control of veterinary drug residues.

- Regarding the diagnosis of AHR, the faecal egg count reduction test (FECRT) seems to be unknown or very rarely used. This suggests that in general, treatment with anthelmintics is made without confirmation of a parasitic infection via laboratory diagnosis.

- Very little awareness or information on anthelmintic resistance was reported for countries in the ME.

- Regarding the regulatory environment for anthelmintics, the majority of respondants indicated that registration practices do exist and are comprehensive, and that labels on anthelmintic are comprehensive, but that the use of anthelmintics in farms is neither restricted nor recorded.

- Of five proposals for information that could assist in improving the control of AHR listed in the questionnaire, the **'List of available anthelmintics and their indications for use' and 'Methods of prudent and responsible use of anthelmintics'** were the most frequently selected. Regarding the options presented in the questionnaire for knowledge gaps with respect to parasite control, '**diagnosis of resistance'** was the most frequently selected,

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followed by '**extension service**'.

The detailed outcomes and conclusions of this questionnaire in the Middle East can be found in an article published in the OIE Bulletin December issue: OIE News-December 2020

oiebulletin.com/wp-content/uploads/2020/12/OIE-News-December-2020-Results-of-the-survey-on-antiparasitics-and-resistance-in-the-Middle-East.pdf

Comments of the speaker:

During his presentation, Dr Hilan provided some important contextual informationabout the Middle East region relevant for APR including the climate (90% of the region is classified as an arid and semi-arid zone, while 10% of the region consists of humid zones), and the local livestock production systems. Sheep and goats are reared in an extensive pastoral system and the main feed source for these animals are rangeland pastures for grazing. Cattle are mostly reared in intensive systems and fed with concentrates and crop residues. Poultry production is an exclusively intensive system. These factors could have an impact on the presence and the spread of internal and external parasites.

In order to better control APR, the following potential solutions could be considered:

- Awareness and training sessions to better understand the life cycle of helminths;
- Training sessions held on the application of methods for diagnosis of APR such as FECRT;
- Antiparasitics of good quality should be sold and administered only by animal health professionals.

Day 3: Pharmacovigilance session

D- Elisabeth Bégon, from Anses-ANMV (OIE collaborating center for VMP) gave a presentation on pharmacovigilance (PHV), stressing that post-marketing surveillance of Veterinary Medicinal Products (VMPs) consists of PHV, together with quality controls. Information gathered from the field, once a VMP is marketed and used on a large scale, is crucial for the knowledge of the safety profile of the product. This is because preapproval clinical trials are conducted on a low number of animals, and therefore cannot provide a complete picture of the product's safety profile.

The scope of PHV includes spontaneous reports of safety issues or lack of efficacy issues, mostly observed by veterinarians or animal owners. These can be reported directly to Regulatory Authorities, or through Marketing Authorisation Holders.

It also includes non-spontaneous reports collected through post-authorisation studies and literature reviews, information on residues/violation of withdrawal periods, environmental issues, and issues arising after off-label use, or human reactions after exposure to a VMP.

Spontaneous reporting is the main source of pharmacovigilance data. Underreporting and reporting biases are recognised limitations of this passive surveillance system. However, this

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system allows continuous monitoring of the benefit/risk balance of VMPs, and subsequent actions that may be necessary to maintain a favorable benefit/risk balance, such as variation or suspension of a Marketing Authorisation, and communication on safety issues directed towards users of VMPs.

International harmonisation in the field of veterinary pharmacovigilance is an ongoing initiative of the VICH, and the five guidelines in pharmacovigilance that have been developed so far provide helpful information to authorities willing to set up a pharmacovigilance system, although these guidelines do not cover all aspects of pharmacovigilance.

E- Dr Ghazi Yehia, OIE Regional Representative for the ME, presented the results of the questionnaire on the quality of veterinary products and pharmacovigilance, which are summarised below:

1- Most of the countries have or are in the progress of developing a designated governmental body for the registration of veterinary products, and a publically accessible database.

2- Most of the countries have PHV legislation and a functioning system with guidelines used in post-marketing activities. The key elements of this system include strict control and reporting of sales in clinics, pharmacies, and wholesalers.

3- Countries in the region are in favor of the OIE preparing a relevant chapter in the Terresrial and Aquatic Codes/Manuals on the minimum requirements for setting standards for a basic PHV system. This could be set at a regional/sub-regional level.

F- A basic phamacovigilance system for veterinary medicinal products was presented by **Rondeep Bhui, Health for Animals industry representative and Head of Global Pharmacovigilance at Boehringer Ingelheim Vetmedica GmbH.**

The presentation aimed to highlight the main areas of concern when trying to build a basic pharmacovigilance system in a country of jurisdiction via the OIE Focal Point of the respective OIE Members. Health for Animals' PHV experts group prepared a document on "How to set up a pharmacovigilance system for veterinary medicinal products" in collaboration with all relevant OIE Collaborating Centers and the OIE Headquarters, via the AMU & VP Department .

Importance is placed on international harmonisation and standardisation of reporting using VICH guidance and "pooling" or sharing data internationally. Key reasons for this include:

- International cooperation
- Removes duplication
- Worksharing
- Cost effectiveness
- Efficient use of resources
- Promotes global trade.

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The roles and responsibilities of the National Competent Authority (NCA), Market Authorisation Holder (MAH), veterinarians, and animal owners were described when it comes to creation of a pharmacovigilance system.

It was noted that it is important to establish the scope of the PHV system, especially related to the ambition of the NCA compared to the resources available. Imporant aspects to consider include:

- Form of IT/People
- Budget (funding)
- Number of anticipated adverse event reports
- Number of products on the market
- Local culture of reporting (education at the grass roots is important to build this culture of reporting)

Additionally, focus needs to be given to the types of products to be included and the adverse events that should be included in the scope of the PHV system.

Care must be taken in the creation of legislation and guidance. The legal basisof PHV is important to provide clarity on the roles and responsibilities of the NCA, MAH and veterinarians. The communication of the content of legislation at all levels is required to promote PHV.

Other details on the basic PHV system such as the reporting format, timelines for reporting, causality assessment, signal and risk management, archiving, communicating PHV outcomes, and PHV inspections was covered in the presentation (available in English and Arabic) and further details are described in the document/manual: How to set up a pharmacovigilance system for veterinary medicinal products.

Conclusion:

In the end, the webinar was very instructive and appropriately managed. Dr Erlacher-Vindelassured the participants that a follow-up and exchange of information will continue to be provided, and asked the relevant authorities to be vigilant in the control of veterinary products, in regards to their impact on animal health and also potentially on human health.

Comments and follow up:

It was found that the webinar format, as compared to in-person training, presented major challenges to engaging participants and generating discussion. Although most of the Focal Points completed the questionnaires in advance of the webinar, only a small number of Focal Points were actively engaged in the group discussion during the webinar itself.

There are many possible reasons for this, including potential problems with internet connections, a reluctance to speak on camera, or the difficulties in building a rapport with participants in brief, online interactions. Consideration should be given as to how to adapt the discussions in future

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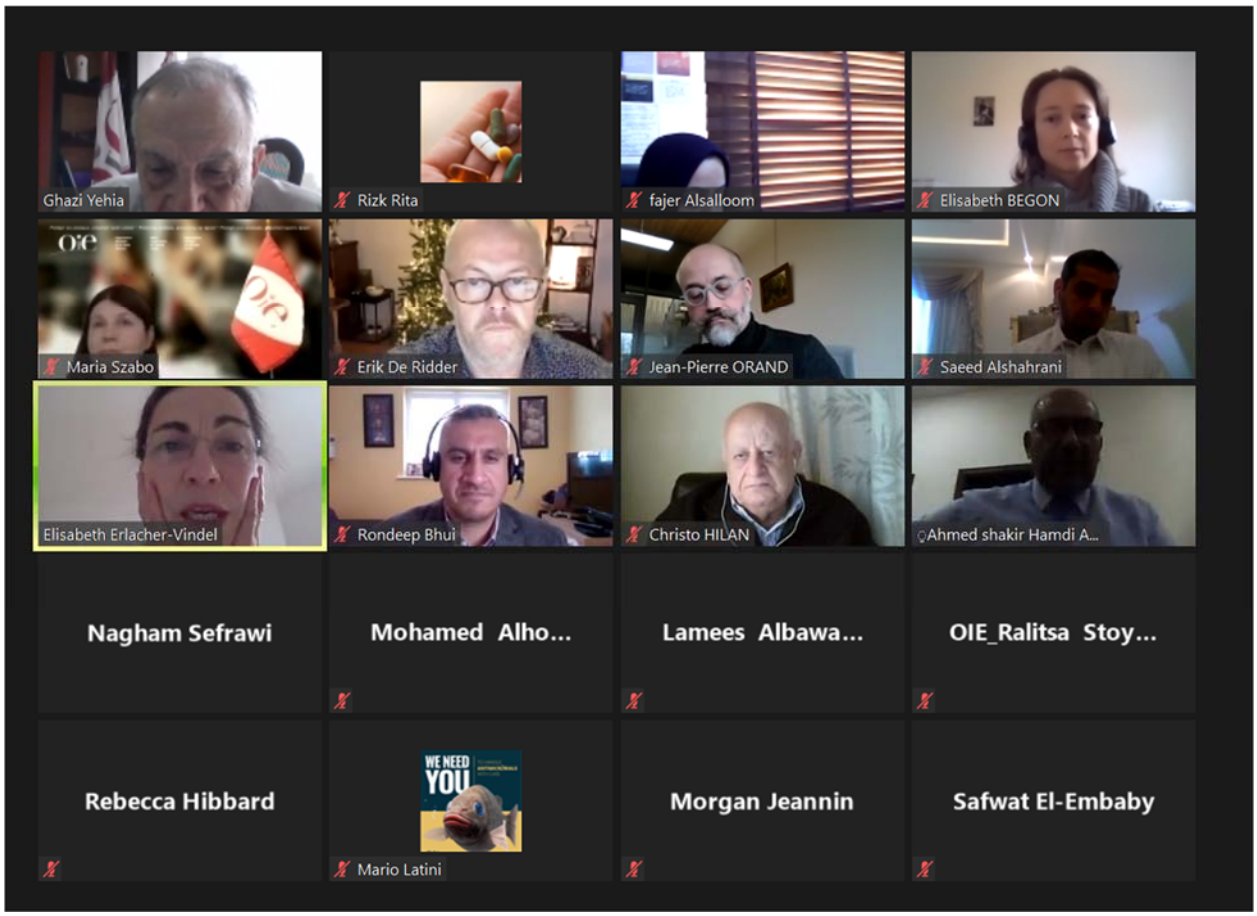
webinars to encourage more active participation from Focal Points. It is hoped that a future in-person meeting will facilitate greater participation and engagement.

After the meeting, the document on "How to set up a pharmacovigilance system" was recirculated in Arabic and English to the Focal Points for Veterinary Products for comments, with a deadline of 15 days. The aim, which was communicated during the webinar, is to publish a consolidated document including all of the OIE Regions' feedback on this document by the end of the 6th Cycle Training Seminars for OIE National Focal Points for Veterinary Products in 2021.

This document was prepared and circulated in advance of the seminar in English and Arabic, along with the other questionnaires and presentations which were prepared in advance. These documents were made available to Focal Points on the e-learning training website to facilitate the Focal Points' preparation for the webinar. As this tool was only used by a minority of participants, it could be promoted in the future .



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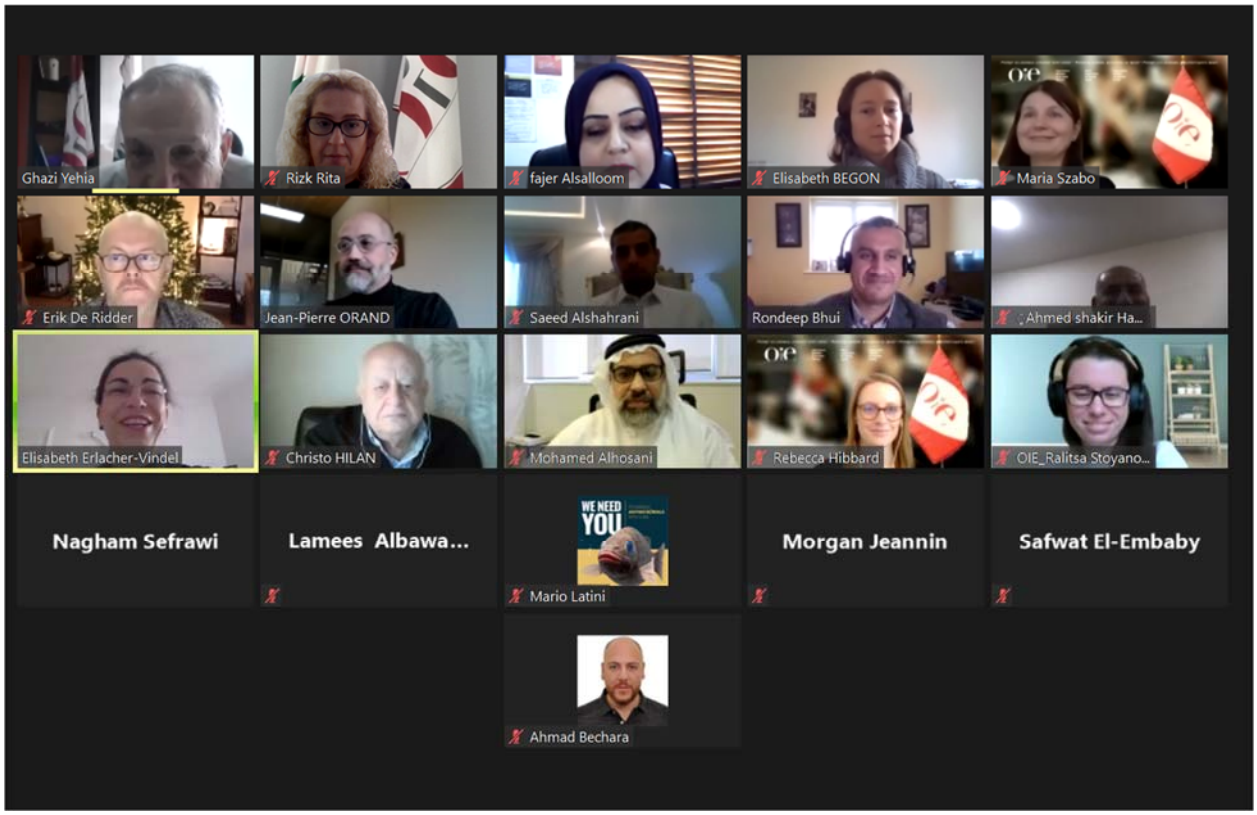

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