

Report

Webinar for Focal Points for Veterinary Products (6th cycle) 17-19 February 2021

Introduction:

OIE Focal Points (FP), nominated by OIE Delegates and acting under their supervision, are an important mechanism for countries to satisfy their OIE obligations and to strengthen communication and collaboration between Members and the OIE. Regional Workshops for OIE National Focal Points for Veterinary Products are regularly held. The webinar for the Focal Points (FP) for Veterinary Products in Europe as part of the 6th Cycle Training Seminars was organised by the OIE Regional Representations for Europe in close collaboration with the OIE Headquarters Antimicrobial Resistance and Veterinary Products (AMR & VP) Department. The webinar took place from the 17th - 19th February 2021. The seminar provided the FP with information on rights, commitments, and responsibilities of the OIE National FP in the standard-setting process, and compliance of their countries with OIE international standards. It also provided a more in-depth understanding of key issues such as antimicrobial resistance (AMR) including Tripartite activities, the OIE database on the use of antimicrobial agents, and the OIE Strategy on AMR, as well as raising awareness of antiparasitic resistance and the quality of veterinary products, including the challenge of substandard and falsified veterinary products and harmonisation/convergence of regulatory systems for registration of veterinary products. A full day of the webinar was dedicated to data collection (antimicrobial use) and to the OIE system used for this purpose. Three questionnaires completed by the FP helped in the discussion during the webinar: a survey on antiparasitic agents and resistance in terrestrial and aquatic animals, a survey on substandard and falsified veterinary products, and a survey on pharmacovigilance.

Forty-four of 53 invited countries attended the webinar. Some countries attended the meeting with more than one representative, such that 61 members were eventually registered.

Simultaneous interpretation in Russian, as well as the translation of important documents such as the document on “How to set up a pharmacovigilance system for veterinary medicinal products” were provided.

Participating countries: Armenia, Austria, Azerbaijan, Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Malta, Moldova, Montenegro, The Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, San Marino, Serbia, Slovakia, Spain, Sweden, Switzerland, Tajikistan, Turkey, Turkmenistan, Ukraine, United Kingdom.

Participants from OIE Headquarters: Elisabeth Erlacher-Vindel, Maria Szabo, Rebecca Hibbard, Morgan Jeannin, Delfy Gochez, Mduduzi Welcome Magongo. From the OIE Regional Representation (RR) for Europe: Marina Sokolova, Jean Perchet, Ekaterina Panina. From the OIE Subregional Representation (SRR) for Central Asia: Mario Latini and Mereke Taitubayev. From the OIE Subregional Representation (SRR) in Brussels: Tomasz Grudnik and Roberto A. Balbo.

The webinar had three sections (the agenda is attached), one per day, which were led by Mereke Taitubayev (SRR in Nur-Sultan), Roberto A. Balbo (SRR in Brussels), and Mario Latini (SRR in Nur-Sultan).

The webinar proceeded as follows:

The webinar started with the opening speech **by Mereke Taitubayev of the OIE SRR**. On behalf of the OIE Director General Dr Monique Eloit and the Regional Representations of OIE for Europe, Mereke Taitubayev welcomed everyone to the “Regional Seminar for OIE National Focal Points for Veterinary Products (6th Cycle)” He explained that the seminar was built on the feedback received from previous seminars and would focus on different aspects of quality of veterinary medicines, taking into account the recommendation of the 2nd OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents in Animals Putting Standards into Practice (Marrakesh, Morocco 29th-31st October 2018). Five previous Regional Workshops for OIE National Focal Points for Veterinary Products held to date.

This online training was an additional opportunity to make progress with the main subjects related to quality of veterinary products: falsified and substandard veterinary products, pharmacovigilance, raising awareness of antiparasitic resistance, and assisting OIE Members to provide data for the sixth round of the data collection on antimicrobial agents intended for use in animals.

Experts from the OIE Collaborating Centres (OIE CCs) provided technical support for the webinar as they have done for previous seminars.

The objectives of the meeting were:

- 1) An overview of ongoing activities related to AMR.
- 2) Follow up of recommendations from the OIE 2nd OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents in Animals: Putting Standards into Practice.
- 3) Introduction of new topics such as improving access to quality of veterinary medicinal products worldwide.

The 6th Cycle seminar aimed to provide the following information to the FP:

- Knowledge on pharmacovigilance, including how to set up and run a basic pharmacovigilance system/the minimum requirements for a pharmacovigilance system, good practice guide for competent authorities, good practice guide for industry, introduction of supporting documents (e.g., Adverse Reaction reporting template), and VICH guideline(s).
- Discussion on what the OIE’s role could be in setting up possible minimum requirements for a pharmacovigilance system.
- Global surveillance and monitoring of falsified and substandard veterinary products.
- Current activities such as antimicrobial resistance and antiparasitic resistance sessions.

The event aimed to increase the role of FP at the national level to implement or create National Plans for AMR and to put activities of veterinary services on the path of the Global Vision aligned with the OIE Standards.

FP were encouraged to actively participate in any sections of the event and to share their experiences.

General Information on the roles and responsibilities of OIE National Focal Points for Veterinary Products was provided by an e-learning platform accessible to Focal Points to allow to ^prepare the training in advance.

Dr. Jean-Pierre Orand from ANSES – the French agency for veterinary medicinal products, an OIE Collaborating Center - gave a presentation on “**How to assure 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;
- for human health due to risk of residues in food or zoonotic outbreaks;
- for environment as they might be a 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 would be safe and efficient.

To prevent any problem of quality, it is important to observe compliance with international (or national) standards at all the steps of VMPs life: from the research and development phase, through manufacturing, distribution, to use at farm level. OIE, VICH, and Pharmaceutical Inspection Co-operation Scheme (PIC/S) are international bodies who have adopted such standards, guidelines, requirements, or good practices.

At national level, the competent authority in charge of the control of good governance should have a very good knowledge of all the actors involved in the distribution chain of VMPs in their countries: importers, manufacturers, wholesalers, retailers and users. These actors should be registered and inspected to ensure that they respect all needed measures to for 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.

In addition to inspection, a national surveillance program of VMP quality can contribute to ensuring that the VMPs used are of good quality. The surveillance program should be based on a risk analysis to identify what the priorities are and to adapt the number of analyses to the available resources (human and financial resources). The OMCL (official medicines control laboratories) network of the Council of Europe was presented as a good example of regional cooperation and could be useful to help the OIE Members.

The conclusions 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 (VMP 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 is the capacity to prosecute and recall products.

Dr Rebecca Hibbard from the OIE's AMR&VP Department presented on the topic of substandard and falsified (SF) veterinary products. Her presentation provided background information on this subject, 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 received a short questionnaire in advance of the webinar, and some of the responses were presented to the participants to facilitate further discussion. From the answers provided in advance and the discussion that took place during the webinar, it was found that:

- Almost all countries in Europe that responded reported having some form of surveillance system or network to follow up issues of veterinary product quality (34 out of 35 responses). A smaller majority of countries had a formalised surveillance system in place (24 out of 35 responses) and access to a national or regional laboratory for monitoring the quality of veterinary products (29 of 35 responses).
- The main point of contact/authority with the responsibility for the quality of veterinary products varied between countries, though in almost all cases this was either the

veterinary services or the Ministry of Health, and in some cases the responsibility was shared between the two. The importance of intersectoral collaboration was noted during the group discussion, with several countries providing examples of how effective collaboration is ensured between the human and animal health sector for managing veterinary product quality. In several countries, the responsibility for authorisation of veterinary products, and for surveillance of veterinary product quality, was managed by different authorities.

- Almost all countries that responded reported having a legal basis for sampling the market for veterinary products (33 or 34 responses), a legal basis for recall of those products (33 of 34 responses), and a database of the veterinary products registered in their country (31 of 34 responses), although this database was not always publicly available, and did not always include imported veterinary products.
- During the discussion several Focal Points indicated that they thought the proposed OIE global surveillance and alert system for SF veterinary products would be useful for their country.

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

Pharmacovigilance session

Dr. Mario Latini from the OIE SRR for Central Asia presented the “**Outcomes of the online questionnaire on the quality of veterinary products and pharmacovigilance**”. Thirty-seven countries answered the questionnaire. Thirty-five of these countries have a designated governmental body for registration of veterinary products and each of these countries has a database or list for all authorised/registered veterinary medicinal products, of which 34 have the list of registered products publicly accessible. Thirty-three countries have pharmacovigilance (PHV) legislation and 32 declared that this system is implemented and functioning. Not all countries have PHV guidelines that are used in post-marketing activities, although guidelines are present in 32 countries. In most countries, the pharmacovigilance system is based on the obligation to register adverse effects in a database. The registration of products, the awareness and communication system, and the action by regional or central government (like suspension or revoking or modifying authorisations in case of adverse effects) are other main points declared by countries as part of a definition of a pharmacovigilance system. Regarding the OIE’s role in pharmacovigilance, 18 countries declared that the OIE should coordinate among different stakeholders to avoid too many disharmonised systems being developed worldwide, and 29 respondents indicated that the OIE should prepare a chapter in the OIE Manual or Code on the minimum requirements for how to set up a basic pharmacovigilance system, to provide a standard for OIE Members. Twenty-four countries stated that a pharmacovigilance system could be set up at a Regional -Sub-Regional level, especially for small countries.

Dr. Sandrine Rougier from ANSES made a presentation with the title “**Veterinary Pharmacovigilance: Introduction**”. Pharmacovigilance (PhV) is defined by the World Health Organization as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. Pharmacovigilance is essential because, despite the rigor of the pre-approval drug development process, it is impossible to have complete information about the safety of a drug at the time of approval. The safety profile of a product can evolve over time. An ongoing collection and evaluation of post-market adverse event reports and other safety information is essential to ensure safe and effective use of a product over its lifetime. Assessment of spontaneously reported

adverse events is the primary post market surveillance method for veterinary medicinal products. Analysis of individual case reports can be challenging, and training is necessary. With small numbers of reports, individual case review and assessment may be feasible. Large volumes of adverse event reports may necessitate implementing signal detection and management tools; however, assessment of individual cases contributing to a “signal” remains necessary. Spontaneous adverse event reporting is a form of passive surveillance and has limitations: underreporting of adverse events is considered significant, incidence of adverse events cannot be reliably determined, the data is observational (reporting biases), a causal link between a product and an adverse event cannot be definitively determined, it is highly dependent on the quality of data, and incomplete or inconsistent data prevent conclusions being drawn. The VICH (International cooperation on Harmonization of Technical requirements for registration of veterinary medicinal products) Pharmacovigilance Guidelines (GLs) were developed to facilitate information exchange of any type of adverse event report between manufacturers and regulatory authorities. An effective pharmacovigilance system is a key component of drug regulation systems; it promotes public health through early identification; gives an assessment and risk mitigation of drug safety issues not identified pre-approval; gives information (labels, product information sheets, safety alerts) that help ensure approved products remain safe and effective and promotes public trust and confidence.

Dr. Rondeep Bhui, HealthforAnimals industry representative gave a presentation on the document/operating manual “How to set up a basic pharmacovigilance system for veterinary medicinal products”. The presentation aimed to highlight the main areas of concern when trying to build a basic pharmacovigilance system in a country of jurisdiction for the OIE Focal Points for Veterinary Products. HealthforAnimals have created a manual on “How to set-up a pharmacovigilance system for veterinary medicinal products” in the framework of Public Private Partnership in consultation with OIE Collaborating Centres and the OIE Headquarters. Importance is placed on international harmonisation and standardisation of reporting to 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.

Roles and responsibilities of the National Competent Authority (NCA), Market Authorisation Holder (MAH), veterinarians, and animal owners were described in connection to setting up a pharmacovigilance (PhV) system. It was underlined that is important to establish the scope of the PhV system, especially related to the ambition of the NCA compared to the resources available. The pivotal 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, the focus needs to be on the types of products to be included, and the adverse events that need to be in scope of the PhV system.

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

Other details of a basic PhV system such as the reporting format, timelines for reporting, causality assessment, signal and risk management, archiving, communicating PhV outcomes, and PhV inspections were covered in the presentation, and further details are described in the document “How to set up a basic pharmacovigilance system” which is available in English and Russian.

Antiparasitic session

Dr. Nathalie Bridoux from ANSES (OIE Collaborating Center) presented the results of the **“Survey on antiparasitic agents and resistance in terrestrial and aquatic animals in European region”** The questionnaire was developed by the OIE’s Electronic Expert Group on Antiparasitic Resistance (EEG APR), and the aim of the survey was to have a better understanding of the situation regarding anthelmintic resistance. The results of this survey will be used as an input for the OIE document on “prudent and responsible use of antiparasitics” being prepared by the EEG APR.

In summary: Thirty-six out of 54 countries answered the questionnaire. The survey had eight multiple-choice questions: ranking of the most economically important animal species, anthelmintic resistance status, use of diagnostic methods, availability of information on anthelmintic resistance, rating of the country’s regulatory environment for anthelmintics, quality of anthelmintics for sale, the nature of information needed to improve control of resistance, and the biggest knowledge gaps for parasite control. The survey’s results indicated that most respondents selected cattle, pigs, and broilers as the most economically important species, followed by sheep and layers. Aquaculture was indicated as being of high economic importance for some countries, but of lower economic importance for others. Most of the respondents stated that information about anthelmintic resistance in their countries is mostly unknown (56% at national level and 63% at local level). It was indicated that there was very little awareness or information available on anthelmintic resistance by 37% of respondents. The results also suggest that methods of diagnosis are not widely used (33% of FP answering that there is very low use of methods of diagnosis, and 28% of FP responding that methods of diagnosis are only used on research facilities). Regarding the regulatory environment for anthelmintics, 92% of respondents thought that the registration practices in their country are comprehensive, 81% that the labels on anthelmintics are comprehensive, and 86% indicated that anthelmintics are sold in their original containers. When considering the quality of anthelmintic preparations for sale, 22 % of respondents thought that the majority of anthelmintics in their country are of good quality, and 44% that anthelmintics are of good quality if purchased from known providers, while 69 % of respondents thought that the quality of anthelmintics is highly reliable. When asked about the biggest knowledge gaps in their country with regards to parasite control, 72% of respondents indicated diagnosis of resistance. Respondents were also asked to select information that they believe would assist in improving the control of anthelmintic resistance in their country, and 97% of respondents selected “Methods of prudent and responsible use of anthelmintics”.

The conclusions are that there is a need to increase knowledge of anthelmintic resistance (research on resistance mechanisms, control and treatment, diagnostic tools), to raise awareness of anthelmintic resistance, to communicate and develop the use of diagnostic tools and control methods for resistance, and to encourage targeted selective treatment and treatment upon

diagnosis. There is a need for defining methods for prudent and responsible use of anthelmintics. The final recommendations provided by Nathalie Bridoux during her presentation were to base treatment on the confirmation of worm infestation pressure using appropriate diagnostic measures, promote targeted selective treatment at farm level, ideally with a post-treatment check-up, harmonise prudent use warnings, provide guidance on resistance data to be included in marketing authorisation applications, promote increased availability of anthelmintics for minor species, restrict use of combination products, and make a sufficient number of pack sizes available.

Dr Mária Szabó, on behalf of the Electronic Expert Group on OIE AMR & Veterinary Products Department, presented on “**Antiparasitic Resistance: Update on the current OIE activities**”.

The Concept Note to create an Electronic Expert Group on Antiparasitic Resistance (EEG APR) was prepared based on feedback received during the 4th and 5th Cycle Training Seminars for Focal Points for Veterinary Products. The EEG is working on preparation of a document on Responsible and Prudent Use of Antiparasitics which is limited to food animal/grazing species. The survey on antiparasitic agents and resistance in terrestrial and aquatic animals was conducted in Asia, Africa, and the Middle East and ongoing in Europe. The current status of knowledge concerning anthelmintic resistance is limited. More research is needed on the development of quick and efficient diagnostic kits with affordable prices or also research on the epidemiology of antiparasitics. In general, treatments with anthelmintics are made without confirmation of a laboratory diagnosis of parasitic infection. There is a need to increase awareness of antiparasitic resistance at veterinary schools and among farmers and the public (training, media).

Dr Smaro Sotiraki from the Vet Res Institute HAO-DEMETER (Greece) contributed with the presentation: “**Prevalence and Economic Impact of Antiparasitic Resistance in Europe**”. Helminth infections are ubiquitous in grazing ruminant production systems and are responsible for significant costs and production losses. Anthelmintic resistance (AR) is now widespread throughout Europe (although there are still gaps in our knowledge in some regions) and represents a growing concern in ruminant livestock farming worldwide. Data from a recently created European database including published and unpublished AR research on gastrointestinal nematodes (GIN) and liver fluke (*Fasciola hepatica*) (Rose Vineer et al., 2020) has shown that regional (country) prevalence is highly heterogeneous, ranging between 0% and 100% depending on livestock sector and anthelmintic class, and generally increased with increasing research effort in a country. Aggregated results in sheep and goats since 2010 reveal an average prevalence of resistance to benzimidazoles (BZ) of 86%, macrocyclic lactones except moxidectin (ML) 52%, levamisole (LEV) 48%, and moxidectin (MOX) 21%. All major GIN genera survived treatment in various studies. In cattle, prevalence of AR varied between anthelmintic classes from 0–100% (BZ and ML), 0–17% (LEV) and 0–73% (MOX), and both *Cooperia* and *Ostertagia* survived treatment. Suspected AR in *F. hepatica* was reported in 21 studies spanning 6 countries. For GIN and particularly *F. hepatica*, there was a bias towards preferential sampling of individual farms with suspected AR, and research effort was biased towards Western Europe and particularly the United Kingdom.

In another study, the economic cost [low estimate – high estimate] of GIN, liver fluke, and lungworm infections to the European ruminant livestock industry was estimated, by a deterministic spreadsheet model as a function of the proportion of the ruminant population exposed to grazing, the infection frequency and intensity, the effect of the infection on animal productivity and mortality and anthelmintic treatment costs. The combined annual cost of the three helminth infections in 18 participating countries was estimated at € 1.8 billion. The cost of AR against macrocyclic lactones except moxidectin (ML) was estimated to be € 38 million annually. The annual estimated costs of helminth infections per sector were € 941 million [€ 488

– 1442 million] in dairy cattle, € 423 million [€ 205–663 million] in beef cattle, € 151 million [€ 90–213 million] in dairy sheep, € 206 million [€ 132–248 million] in meat sheep and € 86 million [€ 67–107 million] in dairy goats. Important data gaps were present in all phases of the calculations which lead to considerable uncertainties around the estimates. Accessibility of more granular animal population datasets, deeper knowledge of the effects of infection on production, levels of infection and livestock grazing exposure would make the largest contribution to improved burden assessments.

All the above data represent a joint effort, as part of the COST Action COMBAR (involving 199 researchers from 34 countries) and the Livestock Helminth Research Alliance (LiHRA). The main aim was to provide a baseline dataset which could be used to support decision making in research and policy to mitigate the negative impacts of helminth infections and anthelmintic resistance in Europe.

Tripartite sections

Dr Danilo Lo Fo Wong from WHO made the presentation “**WHO supporting activities on AMR in the European region**” The WHO European action plan on antibiotic resistance has been adopted by all 53 Member States. It was necessary because there is no systematic AMR surveillance in large parts of the Region and so there is a need for international standards and data sharing. The activities of this plan are focused on training, capacity building, data management, research/projects, and surveillance. Surveillance involves two different networks: the European Antimicrobial Resistance Surveillance Network (EARS-Net) and the Central Asian and European Surveillance of AMR (CAESAR). The target is by 2023 to have 60% of all antibiotics consumed coming from Access, the group of antibiotics at lowest risk of resistance. Evidence shows that to promote responsible use of antibiotics, Access antibiotics should make up at least 60% of national consumption. This will not only result in better use of antibiotics but also in reduced costs and increased access. Reaching this threshold by 2023 will contribute to countries achieving health-related targets of the Sustainable Development Goals. By using AWaRe as an index to measure antibiotic consumption in different health care settings, countries will gain an insight into the use of antibiotics at national level. Once these benchmarks have been established, policy makers will have the tools to adjust consumption to local needs and prescribers will have clear guidance on what to prescribe when. The Access group should be first and second-choice antibiotics and should be widely available in all countries. They should also be affordable and quality assured. The Watch group should be first and second-choice antibiotics used only for a specific, limited number of indications because they have a higher resistance potential. The Reserve group should be the last resort antibiotics when other antibiotics have failed or for infections of multi-resistant bacteria. The WHO organised an online course: “Antimicrobial Stewardship: A competency-based approach” where a guidance document is explained. These are the first international evidence-based guidelines on the core components of infection prevention and control (IPC) programmes. These new WHO guidelines are applicable for any country and suitable to local adaptations and take account of the strength of available scientific evidence, the cost and resource implications, and patient values and preferences. The guidelines describe what is necessary (that is, recommendations) to effectively improve infection prevention and control (IPC). This year, the European region focuses on the need for a One Health approach to tackle AMR as well as raising awareness of the alarming information we receive related to the inappropriate use of antibiotics during the ongoing COVID-19 pandemic. To support human and animal health colleagues throughout the region, advocacy materials that can be used to raise awareness among the public, patients, producers, and politicians was produced. These include social media tiles and posters. This suite of advocacy documents was created to explain how AMR

affects health in different contexts and how focusing on different sectors can contribute to managing AMR. One area in which it is particularly important to ensure a One Health approach is the issue of AMR in food safety.

Dr. Daniel Beltran-Alcrudo, and **Dr. Eran Raizman**, from FAO talked about “**FAO initiatives and activities on AMR in Europe and Central Asia**”, discussing activities that were made through Tripartite (FAO, WHO and OIE) initiatives. There were activities to raise awareness focused on the livestock sector, through associations, schools, universities, and other agricultural institutions.

Some initiatives were made through FAO’s tools, including the Progressive Management Pathway (PMP) for AMR and the FAO’s Assessment Tool for Laboratories and Antimicrobial Resistance Surveillance Systems (ATLASS). The first is a governance tool to help the food and agriculture production sectors – public or private – with developing and implementing multisector One-Health NAPs, identifying strengths, gaps, and action points, and to make a step-by-step improvements and track progress. This was conducted in Tajikistan and Kyrgyzstan, and Belarus and Armenia are in the pipeline. The second tool allows countries to assess and improve their national AMR surveillance systems, to generate a baseline and define a “stage” for laboratories, assess five main areas for effective surveillance, identify steps for improvement and priority actions, and monitor progress through the Progressive Improvement Pathway. A survey was made thorough interviewees: farmers (of priority production systems), field vets, vet pharmacies and feed mills, and through a mobile App – KoboCollect. These actions are combined with biosecurity assessment (Biocheck) of commercial poultry and dairy farms, and awareness efforts.

Based on the actions previously described, there is promotion of prudent use of antimicrobials and reduced AMU through good husbandry, biosecurity, and animal health practices in dairy & poultry commercial farms, with the participation of farmers and veterinarians. This involves demonstration at farms, farm visits and training materials. Other activities involve the baseline review and assessment of national legislation, and assisting countries in establishing intersectoral coordination mechanisms for National Action Plan (NAP) development and regional coordination.

AMR Session: Introduction to the AMU data collection.

Dr Morgan Jeannin, **Dr Delfy Góchez**, and **Dr. Mduduzi Magongo**’s presentations focused on the OIE questionnaire on antimicrobial use and the calculation of the quantities of active ingredients in kilograms as well as the transition to the future OIE AMU database. In order to take Members’ needs into consideration 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:

- Underline the increasing progress that was made in the region since the first round. Currently, for the 6th round there is a need for a stronger commitment of the Region to participate in the OIE AMU data collection to achieve the same level of participation as the 5th round.
- Encourage the countries to contact the Regional OIE colleagues or the AMU Team if there was any doubt or need for further assistance.
- The OIE Calculation Tool to assist in the data collection was introduced to the Region.

- Emphasize strict confidentiality of country level data transmitted to the Antimicrobial Use Team.
- Raise awareness of the future AMU IT system and involvement of certain countries in the Region for the testing phase.

Follow up of the Webinar:

After the meeting, the document “How to set up a pharmacovigilance system” was recirculated in English and Russian to the Focal Points for Veterinary Products for comments by 9th April 2021, alongside a survey on responsibilities for antiparasitic resistance by the different stakeholders. The aim, which was communicated during the webinar, is to publish a pharmacovigilance related document/manual, including all Regions’ consolidated feedback by the end of the 6th Cycle Training Seminars/Webinars. The aim of the survey on antiparasitic resistance is to collect answers from the Europe Region, in order to provide information for a global document on “prudent and responsible use of antiparasitics” intended for publication. All the presentations have been published on the OIE Europe website under the “OIE Focal Point Seminar: Regional Seminar for OIE National Focal Points for Veterinary Products”. The document “How to set up a pharmacovigilance system for veterinary medicinal products” in English has been published on the same website. The Russian version will be corrected and published thereafter.

Feedback on the Webinar

The webinar also provided the opportunity to have some feedback from the attendees. Some countries explained the difficulty in providing requested information to the OIE since the veterinary services are not under control of the Ministry of Health, but work under the Ministry of Agriculture and information might be split between Ministries. Even registration for veterinary products for the two different sectors may be made by different competent authorities. However, in many countries there is intersectoral collaboration between the parties. The sampling for control of veterinary products (including veterinary pharmaceuticals concerning antimicrobial agents) is often done through a surveillance plan and risk analysis. Suggestions come to address more the economic impact data of AMR. Many attendees stated their appreciation for the meeting, and that they would disseminate information and links to their collaborators.