OIE Conference on Veterinary Medicinal Products in the Middle East, Towards harmonisation and improvement of registration, distribution and quality control

Damascus (Syria), 2–4 December 2009

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Final Recommendations

Harmonisation and improvement of registration, distribution and quality control of veterinary medicinal products in the Middle East

CONSIDERING

That good veterinary governance, which includes appropriate legislation and the compliance of Veterinary Services with OIE international standards on quality, is instrumental and an essential prerequisite for efficient enforcement of the registration, distribution and quality control of veterinary medicinal products,

That Middle East countries produce and import substantial numbers of veterinary medicinal products,

That Middle East countries have already adopted national legislation for the regulation of production and distribution of veterinary medicinal products, but they are not always in compliance with international standards,

That an effective regional authorisation system for veterinary medicinal products within and between countries can best be achieved through a harmonised regional approach and a regional network of laboratories for quality control,

The major economic advantages associated with the, safety, quality and efficacy of veterinary medicinal products for the development of livestock production, food security and food safety in the Middle East,

That intentional or unintentional misuse of veterinary medicinal products, particularly veterinary biologicals, represents a risk for animal and human health not only at local level but also at regional or global level,

The existence of international standards regulating the quality assurance, registration, distribution and use of veterinary medicinal products,

The importance of controlling residues from veterinary drugs in food products of animal origin,

The OIE-PVS Tool, including Gap Analysis and legislation guidelines for supporting quality of Veterinary Services,

That some groups of Middle East countries have already established collaboration mechanisms on regulation of veterinary medicine,

That relevant initial and continuing veterinary education programmes are essential for the appropriate use of veterinary medicinal products,

The recommendations adopted during the OIE conference on veterinary medicinal products in Africa, “Towards harmonisation and improvement of registration, distribution and quality control”, which took place in March 2008 in Dakar, Senegal,

The Resolution No. 25 on Veterinary products adopted by the World Assembly of Delegates during the 77th General Session of the OIE in May 2009,
THE OIE CONFERENCE ON VETERINARY MEDICINAL PRODUCTS IN THE MIDDLE EAST RECOMMENDS:

A. ALL THE RELEVANT STAKEHOLDERS, TO PARTICIPATE TO IMPROVE THE SAFETY, QUALITY AND EFFICACY OF THE VETERINARY MEDICINAL PRODUCTS USED IN THE MIDDLE EAST.

B. THAT OIE MEMBERS OF THE MIDDLE EAST REGION:

1. Promote and enhance in their respective countries good veterinary governance, which includes appropriate legislation and the compliance of Veterinary Services with OIE international standards, as an instrumental and essential prerequisite to effective implementation of legislation covering all aspects of products for veterinary use, including registration, quality control, transport, handling, distribution and final use.

2. Allocate appropriate human, physical and financial resources to Veterinary Services and laboratories to correctly implement the OIE standards and guidelines related to veterinary medicinal products and their control in the entire national territory in collaboration with the other relevant public authorities.

3. Promote national, regional and sub-regional testing laboratories to develop and implement quality management systems based on international recognised standards to enable harmonisation and standardisation of test methods.

4. Promote regional networking and appropriate training among laboratories and authorities responsible for the registration and quality control of veterinary medicinal products to improve capacity and reduce the cost of analysis.

5. With the guidance of the OIE Regional Representation, define within a regional coordination mechanism, the development and establishment of the harmonisation of registration requirements of veterinary medicinal products within the region based on international recognised standards.

6. Develop national institutional, administrative and financial mechanisms to increase the effectiveness of the quality control process starting from good manufacturing practices to the sale and use of those products under the supervision of Veterinary Services or of the authority responsible for veterinary medicinal products.

7. Improve communication and transparency with the private sector including private veterinarians, the pharmaceutical industry, supplier laboratories, pharmacists and livestock associations to help regulate and harmonise the marketing and distribution of safe and efficient veterinary medicinal products.

8. In collaboration with the OIE, monitor and align with developments and progress within VICH, and endeavour progressively to adopt and implement VICH guidelines as the technical requirements for registration established within their regulatory framework for veterinary medicinal products.

9. Strengthen the control of residues from veterinary medicinal products in food products of animal origin in agreement with standards developed on veterinary drugs by the Codex Alimentarius.

10. Encourage safe and effective vaccine production with priority given to diseases common in the region, in order to promote disease prevention and reduce costs to farmers.

11. To foster training in authorisation and use of veterinary medicinal products as part of the initial and continuing veterinary education programmes within the region (including principles of assessment, GMP, pharmacovigilance) with the participation of the “OIE national focal points for veterinary products”.

1 International Cooperation on Harmonization of Technical Requirements for the registration of veterinary medicinal products
THAT THE OIE:

12. Using the output of this conference, continue to develop and update guidelines and tools to enable OIE Members in the Middle East and worldwide to adopt and implement appropriate legislation and mechanisms for the registration, quality assurance and regulation of veterinary medicinal products, preferably using a regional or sub-regional basis, and encourage twinning of Laboratories and Collaborating Centres in the Middle East.

13. Organise regional workshops for the training of the “OIE national focal points for veterinary products” and provide them continuously with appropriate information.

14. Update and reinforce the OIE-PVS Tool, including Gap Analysis and legislation guidelines, in the field of veterinary medicinal products.

15. Continue to actively participate in and support the activities of the VICH and to share outcomes with OIE Members.