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Common regulations for registration of Medicinal products in Middle East Region

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Introduction

Several animal pathogens were spread in different countries either due to:

- increased urbanization, with the accompanied animal movement
- the extension of international trade in livestock and livestock products.
Introduction

- The use of Veterinary Medicinal Products became a fundamental demand.

- The registration of these products assure the effectiveness and safety of the products for combating animal diseases; as well as the safety of consumers and environment.
Introduction

For the purpose of this presentation the Veterinary Medicinal Products are:

Vaccines, Anti-sera, Medicinal drugs, Disinfectants, Insecticides, Feed additives, and Diagnostic reagents.
This presentation will clarify the importance, concept and objectives of **registration** of veterinary medicinal products;

And in general the actual **situation** in the countries of the Middle East region,

As well the importance of **harmonization** of the registration procedures on the region level.
Situation in the countries of the Middle East region

- The first registration system started in the region was on 1955 in Egypt followed by Sudan in 1966.

- The reference System are mainly:
  - FDA regulations
  - EU regulations.
  - expertise of scientific committee
  - some countries has no reference system.
Situation in the countries of the Middle East region

- Some countries follow the international norms of OIE regarding the Registration of Veterinary Medicinal Products
- The regulations for imported products are not the same as the locally produced ones where there are some additional requirements for the imported one.
Situation in the countries of the Middle East region

- In some countries the VS approve the company itself (accept any product from the approved company accordingly).

- Few countries have system for registration of diagnostic reagents.

- In general, The majority of the current systems for registration doesn't approve directly the registered products in other countries of the region.
In case of rejection of imported veterinary medicinal products, the consignment are either re-exported to the country of origin or locally destroyed. in limited occasions the registration subjected to cancelling.

The documents required for submitting the registration dossier are somewhat different among member countries of the region subsequently the judgment on the product could be affected by different points of views among member countries.
Situation in the countries of the Middle East region

- Some countries enforcing ban on certain Veterinary Medicinal Products, it is worthy to refer that there were some differences between these products among the replied countries.

- The contents of the registration form are somewhat different.

- The validity period for registration differ from country to other.
<table>
<thead>
<tr>
<th>Item</th>
<th>Longest validity period/year</th>
<th>Shortest validity period/year</th>
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</thead>
<tbody>
<tr>
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<td>1</td>
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<tr>
<td>Anti-sera</td>
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<tr>
<td>Medicinal drugs</td>
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<td>3</td>
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<tr>
<td>Disinfectants</td>
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<tr>
<td>Insecticides</td>
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<td>3</td>
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<tr>
<td>Feed additives</td>
<td>10</td>
<td>3</td>
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<tr>
<td>Diagnostic reagents</td>
<td>5</td>
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Objectives of the registration

- Protecting animal health
- Protect human health
- Maintain the success of control and eradication programs for animal diseases
- Setting the obligations of the producers toward the competent authority and customers
Requirements for the success of a system for registration

- official legislation(s).
- efficient scientific and technical staff
- complete data on the animal diseases in the national territory.
- Production of vaccines under the regulations of the OIE manual for diagnostic tests and vaccine.
Requirements for the success of a system for registration (Cont.)

- listed specifications for the testing procedures and testing criteria.
- Good laboratory capacity.
- Registration of the establishments where veterinary medicinal products stored and sailed.
What are the specifications

- Specifications are critical quality standards that are proposed and justified by the manufacturer and approved by regulatory authorities as conditions of approval.

- “Conformance to the specifications” means that the drug substance and the medicinal product when tested according to the listed analytical procedures will meet the acceptance criteria.

- These are the list of references to analytical procedures and appropriate acceptance criteria to which the product should conform to be considered acceptable for its intended use.
Control of veterinary residues in animal and human feed.

- Veterinary medicine residues are the very small amounts of veterinary medicines that can remain in animal products such as meat, fish, eggs, honey and milk (after slaughter or collection), and so make their way into the food chain.
- When evaluating the residual effect for the purpose of registration, it must focus on three items:
  * the type(s) of animal for which the product is intended to be used
  * the residues in animal tissues (MRL and withdrawal period)
  * the residues in the environment.

Prevention of falsification.

The veterinary medicinal products could be subjected to fraud process as repackaging of expired products or packaging of any mixture or material(s) not belongs to the labeled active ingredient(s).
Why the registration of veterinary medicinal products (drugs)?

- Minimization the risk of toxicity and evolution of drug resistant pathogens.
  - important problems could arise from the dose either toxicity due to over dosage; or drug resistant pathogens due to under dosage.
  - Antimicrobial drug residues present in food from food-producing animals may cause adverse effects on the ecology of the intestinal micro flora of consumers.
Why the registration of veterinary medicinal products (drugs)?

- **Avoid the side effects and undesirable Interactions**.
  - Some drugs are immune suppressors or immune depressors this could lead to great problems when administrated with live vaccines.
  - Some medicinal products are teratogenic or abortogenic, others may impair the action of other medicinal products; i.e) use of bacteriostatics and bactericidal antibiotics.
Why the registration of veterinary medicinal products (vaccines)?

- A reliable supply of pure, safe, potent, and effective vaccines is essential for maintenance of animal health and the successful operation of animal health programmes.

- Immunization of animals with high quality vaccines is the primary means of control for many animal diseases.
Why the registration of veterinary medicinal products (vaccines)?

- Prevent the introduction of new strains.
- Maintain the condition of disease free. country or zone (without practicing vaccination).
- Assure the concentration of the standardized biological units per dose.
- Avoid the improperly produced vaccines.
- Avoid transmission of diseases via contamination with biological materials.
- Avoid impact of the surveillance programs.
Control of ecotoxicity

- The ability of each live vaccine to shed, to spread to contact target and non-target animals, and to persist in the environment must be evaluated to provide information for assessing the risk of the vaccine on the environment.
Why the registration of diagnostic reagents?

- Avoid the fallacy of laboratory results.
  - Many diseased animals will let free to transmit the infection to other animals within the country or to other countries during exportation.
  - Many negative animals will be culled in the course of eradication of positive reactors thus the cost of compensation of owners and restocking of the flock will be dispersed without benefits.

- Protect Animal and Human health:
  - Some diagnostic reagents are harmful to human being, for example; 2- Mercaptoethanol is carcinogenic so the registration of such products should take in consideration the availability of the protective measures during handling and use of such reagents.
Harmonization of the legislation for registration veterinary Medicinal products in ME
Harmonization of the legislation for registration veterinary Medicinal products in ME

Harmonization of the legislations and registration procedures among member countries of the ME region shall ensure:

- The mutual approval in all members countries of the registered medicinal product(s) in any member country.
- Rapid deployment of vaccines in case of emergency.
- Quality standards of veterinary medicinal products in all member countries.
- Reduce the risk of uncontrolled movement of animals within the region.
Harmonization of the legislation for registration veterinary Medicinal products in ME

- Harmonization of the legislations and registration procedures among member countries of the ME region shall ensure also harmonization of the animal disease control programs, with subsequently

  - Improvement of animal health and productivity
  - Safety of consumers
Thank You