Results of the questionnaire on Veterinary Medicinal Products in the Middle East
Damascus, Syria, 2-4 December 2009

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OIE Regional Representation for the Middle East

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Purpose of the Questionnaire

- Public policies for VMP are a constant concern of the OIE
- In March 2008 in Dakar, the OIE has started a programme of regional Conferences to improve the registration, distribution and quality control of VMP worldwide
- To favour exchange and discussion during the present conference, a questionnaire was set up by the OIE RR in order to provide preliminary information on VMP in the Middle East
Veterinary Medicinal Products

means any product with approved claims to having a protective, therapeutic or diagnostic effect or to affect physiological functions when administered to or applied to an animal. The term applies to therapeutics, biologicals, diagnostics and modifiers of physiological function (VICH guidelines - www.vichsec.org)
Questionnaire Answers

14 countries answered to the questionnaire (66 % of Regional Members):

Cyprus, Egypt, Iran, Iraq, Jordan, KSA, Kuwait, Lebanon, Qatar, Sudan, Syria, Turkey, UAE and Yemen

➢ General trends can be drawn
Questionnaire - Items

1. Regulatory Authority for veterinary medicinal products
2. National production of veterinary medicinal products
3. Registration and Marketing authorization
4. Quality control
5. Distribution
6. Veterinary medicinal products' importation
7. Surveillance and control
8. Commercial veterinary diagnostic tests
1. Regulatory Authority

- All countries have regulations on VMP
- The Regulatory Authority is different country by country

- Cyprus, KSA, Sudan: 21%
- Egypt, Kuwait, UAE: 21%
- MoA (VS): 58%
- MoH and MoA (VS): 21%
- Other Agency: 21%
1. Regulatory Authority – Legislation

- Specific Legislative texts by country
1. Regulatory Authority – Legislation

Area covered by the legislation

- Inspection
- Pharmacovigilance
- Control
- Use
- Distribution
- Importation
- Manufacturing
- Authorisation
- Definition of MRLs

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1. Regulatory Authority – Legislation

- Legislation quite recent
- Several legislative texts were adopted/amended after 2000
2. National Production of VMP - Location

- Except Kuwait and Qatar, every country has VMP Manufactures
2. National Production of VMP - Registration

- All Manufactures are registered in every country
- National Manufacture Good Practices are established in all countries (except actually in Turkey)
2. National Production of VMP

- Different VMP are Manufactured in the region

- Biological products
- Parasiticids
- Hormones
- Anti-inflammatories
- Vaccines
- Antimicrobials

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2. National Production of VMP

- Vaccination is the main strategy adopted in the region for FMD control
- Regular changes in circulating serotypes
- Serotypes very specific to the region (A Iran 05)
- Lack of local vaccine producers could delay response to new serotypes due to insufficient supply in adapted vaccines
3. Registration and Marketing Authorisation

- NMA are delivered everywhere
- Authority in charge of registration is different country by country
- Generally the same than the Regulatory Authority, except Egypt (MoH)

![Pie chart showing distribution of regulatory authorities: MoA 65%, MoH 7%, MoH and MoA 14%, Other Agency 14%]

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3. Registration and Marketing Authorisation

- All products are registered
- Except Biological products in Jordan and Hormones in Iraq and KSA

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3. Registration and Marketing Authorisation

- National requirements

- Safety Assessment (residue)
- Efficacy Assessment
- Quality Control
- Dossier submission

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3. Registration and Marketing Authorisation

- Few others requirements (countries' clarifications)

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability studies</td>
<td>Egypt, Lebanon, UAE</td>
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<tr>
<td>Toxicty studies</td>
<td>KSA, Lebanon</td>
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<tr>
<td>Clinical studies</td>
<td>KSA, Egypt, Lebanon</td>
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<td>Risk – Benefit studies</td>
<td>Qatar</td>
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<tr>
<td>Commercial information</td>
<td>Turkey</td>
</tr>
<tr>
<td>Certificate of origin and free sale</td>
<td>Syria, Turkey, Yemen</td>
</tr>
</tbody>
</table>
4. Quality Control

- Except Lebanon, Qatar, Turkey (in 2010) and Yemen, all countries have in place a quality control programme.

10 countries
71%
29%

Regular programme
No programme
4. Quality Control - Laboratories

- To implement quality control programmes, countries generally use laboratories from the public sector.
4. Quality Control – Control programmes

- Information on adverse events and actions taken
- Results of control
- Documented quality control procedures
- Dedicated staff and/or equipment

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5. Distribution of VMP - Distributors

- Farmers Associations
- Wholesalers
- Pharmacists
- Veterinary Assistants
- Official veterinarians
- Private veterinary surgeons

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5. Distribution of VMP - Registration

- Except in Lebanon and Yemen, distributors are registered everywhere
5. Distribution - Restrictions

- Most of countries have restrictions on the distribution of certain products

<table>
<thead>
<tr>
<th>Narcotics, Anaesthetics, Hormones, some ATB, Poisons</th>
<th>Veterinary prescription</th>
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<tbody>
<tr>
<td>National Programmes</td>
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<tr>
<td>Yemen (PPR – SP and GP)</td>
<td>Iraq (brucellosis)</td>
</tr>
<tr>
<td>Iran – Syria (vaccines)</td>
<td>Sudan (Trypanocides)</td>
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</tbody>
</table>

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5. Distribution – Other elements

- Advertizing
- Cold chain
- Distribution subsidy
- Price control

Free of charge in Kuwait, Qatar, UAE
6. Importation of VMP – Authorization

- Authority in charge of VMP importation

- Cyprus, KSA
- Kuwait
- Other Agency
- MoA - MoE (VS)
- MoH and MoA

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6. Importation of VMP - Authorization

- Except Kuwait, Lebanon and Sudan, every country accepts other NMA
- Imports from EU – USA or other countries complying with national requirements

79% NMA from other countries
21% Non acceptance
6. Importation of VMP - Procedure

- Every country has a specific import procedure and a list of authorized products is available everywhere, except in Qatar and UAE.
6. Importation of VMP - Importers

- Authorized importers are essentially wholesalers and private vets

- Egypt, Iran
- Egypt, Lebanon
- Egypt, Yemen
- Egypt, Iraq, Turkey
6. Importation of VMP – Illegal Imports

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6. Importation of VMP – Illegal Imports
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<th>Goats</th>
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7. Surveillance and control - Authority

- All countries have programmes for the control/surveillance of VMP

- 72% Authority
- 14% MoA
- 14% MoH and MoA
- 14% Other Agency

Cyprus, KSA
Kuwait, Turkey
7. Surveillance and control – Main Targets

- Use
- Prescription
- Retailing
- Wholesaling
- Manufactures
7. Surveillance and control - Residues

- Few countries implement residue testing
- Heavy metals, aflatoxins, hormones, ATB

9 countries

Control of residue: 64%
No programme: 36%

Iraq, Jordan, Kuwait, Qatar, Yemen
7. Surveillance and control - ATM

- Limited to some countries – in collaboration with the MoH and/or private sector

- Cyprus, Egypt, Iraq, Kuwait, Sudan, Yemen

- Cyprus, Egypt, Iraq, KSA, Lebanon, Sudan, Yemen
8. Commercial Veterinary Diagnostic tests

- Most of regional countries have a procedure to authorize Veterinary diagnostic tests

- Iraq, Jordan, Syria: 21%
- Others: 79%
8. Commercial Veterinary Diagnostic tests

For delivering authorizations, all countries take into account:

- OIE register of approved kits
- OIE standards
9. Countries particular expectations

- Harmonization of VMP registration rules in the region
  - Regional Marketing Authorization proposal

- Improvement of the quality control of VMP in the region
  - Access to regional specialized laboratory / ies
Conclusions

- This study is not a qualitative assessment, it is only based on country self evaluation to a questionnaire.
- It is a very general approach but the main trends can be identified.
- In most of the region, the Authority involved in the control of VMP is generally located in the same Ministry than the VS.
Conclusions

- All Middle Eastern countries have already adopted national legislation for the regulation of VMP production and distribution, but different strategies and policies are implemented in the region, particularly for their control, surveillance and importation.

- Particular efforts need to be done also in some countries in the control of residues and Antimicrobials.
Conclusions

- Middle Eastern countries import substantial numbers of veterinary medicinal products, a regional harmonization for their registration is needed.

- The main expectations brought out from this study is that regional collaboration should be improve, particularly in terms of registration and VMP quality control.
Acknowledgements

- To all focal points that answered this questionnaire for their collaboration and receptiveness to clarify some particular points of their specific national situation
Thank you for your attention