

OIE Conference on Veterinary Medicinal Products in the Middle East Damascus (Syria) 2-4 December 2009



Results of the Questionnaire on the present situation of veterinary medicinal products in the Middle East Summary

OIE Regional Representation for the Middle-East

Veterinary medicinal products (VMP) are essential to animal health, animal welfare and public health. Animal health professionals in the field and livestock producers need fast access to quality, safe and effective veterinary medicinal products, at a reasonable price.

Public policies for veterinary medicinal products are a constant concern of the OIE, and one of the main components of animal health policies. This concern is reflected in the OIE global strategy, enshrined in the 4th strategic plan for 2006-2010.

Under this strategic plan, OIE Members have expressed their desire to pursue the historic policy of animal disease control and prevention by extending it to all aspects of animal health policies, based on structured and competent national Veterinary Services.

Veterinary Services are indisputably accepted and acknowledged as a global public good and should take primary responsibility for the good governance and service delivery in accordance with international standards and public expectations.

The registration and marketing authorization of veterinary medicinal products are an integral and essential component of veterinary service delivery and must therefore be included and mandated in national legislation to be within the primary responsibility of the public Veterinary Services.

The OIE organized in Dakar from 25 to 27 March 2008, a Conference on improving the registration, distribution and quality control of veterinary medicinal products in Africa, which recommended that the OIE should organise similar Conferences in each of the other four regions in the world to help alleviate poverty and reduce animal health and public health risks, in particular those arising from the marketing of poor quality veterinary medicinal products and their distribution by inadequately trained persons.

In this framework the OIE will organize from 2 to 4 December 2009 a regional conference for the Middle East in Damascus Syria.

In order to provide preliminary information on veterinary medicinal products in the Middle East, to facilitate exchange and discussion during this specific Conference, the OIE Regional Representation for the Middle East has undertaken the assessment of country situation regarding legislation, registration and control procedures for veterinary medicinal products, using a detailed questionnaire.

The questionnaire took into consideration the following items:

- Regulatory Authority for veterinary medicinal products
- National production of veterinary medicinal products
- Registration and Marketing authorization
- Quality control
- Distribution
- Veterinary medicinal products' importation
- Surveillance and control
- Commercial veterinary diagnostic tests

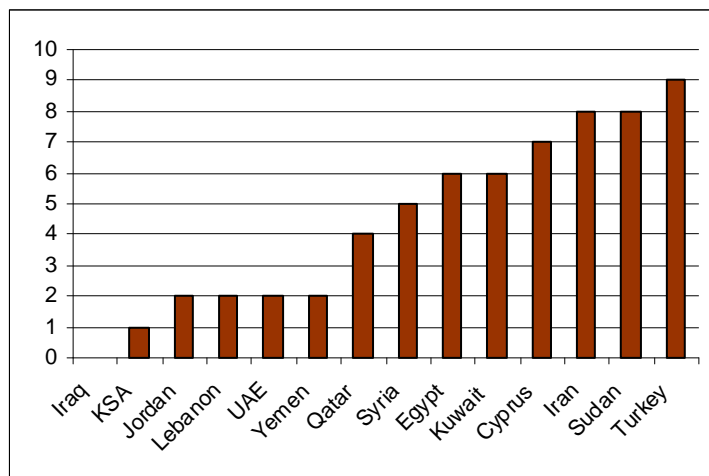
14 countries answered to the questionnaire, this represents about 66 % of Regional Members: Cyprus, Egypt, Iran, Iraq, Jordan, KSA, Kuwait, Lebanon, Qatar, Sudan, Syria, Turkey, UAE and Yemen.

1. Regulatory Authority for veterinary medicinal products

All countries have regulations on VMP. Nevertheless the Regulatory Authority is different country by country, but generally it is the Ministry in charge of Veterinary Services (mainly the Ministry of Agriculture), except for Egypt, Kuwait and UAE where the Ministry of Health and the Ministry of Agriculture (Ministry of Environment in UAE) share this authority (the MoA is responsible for vaccines and the MoH for other drugs) and in Cyprus and KSA where the Regulatory Authority is an other governmental agency.

The number of specific texts regulating VMP is different country by country (graph 1).

Except for Iraq where regulation of VMP is integrated in other texts, every country has specific texts on VMP.



In some countries (KSA, Jordan, Lebanon, UAE and Yemen), 1 or 2 texts compiled all the regulations.

For the others, VMP regulation consists of few texts, with a maximum of 9 texts in Turkey.

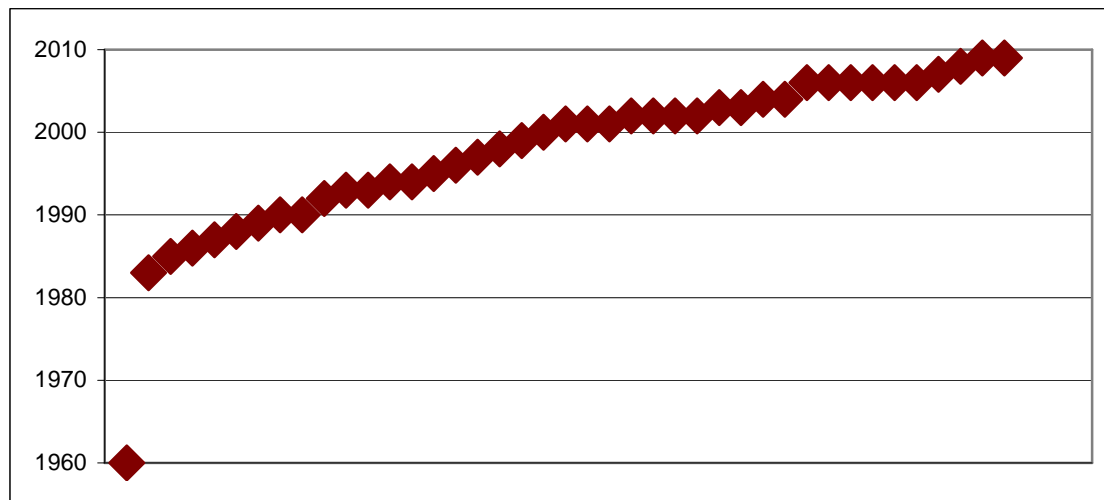
Graph 1: Number of Texts concerning VMP in each country

The legislation is generally quite complete in most of the countries and all the steps are usually covered: definition of Maximum Limit Residues, Authorization, Manufacture, Importation, Distribution, Use, Control, Pharmacovigilance and Inspection.

Nevertheless, Pharmacovigilance and the definition of Maximum Residue Limits are not covered everywhere.

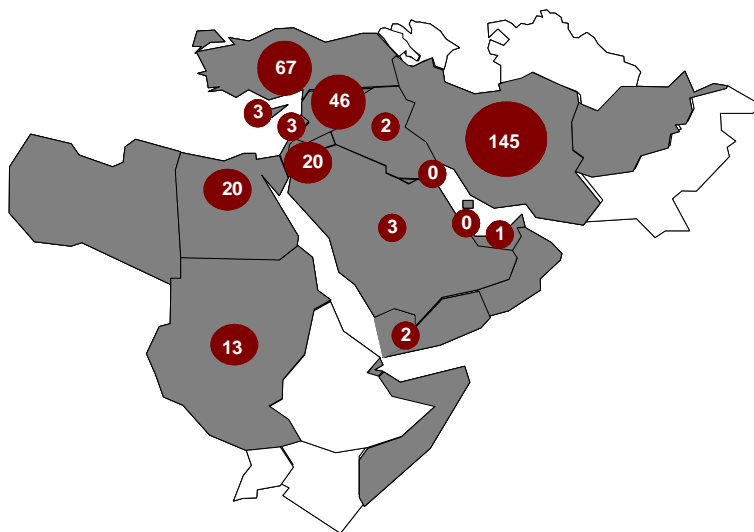
In some countries without Veterinary Medicinal Products manufactures, regulation on this activity is de facto unnecessary.

The legislation is quite recent in the region (graph 2). Most of the texts were adopted after 1980 and a large part after 2000.



Graph 2: Dates of text adoption in the Region

2. National production of veterinary medicinal products



Except Kuwait and Qatar, every country has VMP manufactures. The number of manufacture is very different country by country. About half of countries have less than 3 manufactures in their territory (Cyprus, Iraq, KSA, Lebanon, UAE and Yemen)

Iran, Turkey and Syria hosted the main part of manufactures in the region.

Map 1: VMP Manufactures in the Middle East

All manufactures are registered in every country and National Manufacture Good Practices (NMGP) are established in all countries.

Different Veterinary Medicinal Products are manufactured in the region. Antimicrobials, anti-inflammatory and parasiticides are commonly produced. But biological products, hormones and vaccines, which required more specialized manufacturing process are not produced everywhere. Some countries mentioned also the manufacture of vitamins and minerals (Turkey), feed supplements and additives (UAE).

The situation concerning vaccine production is very interesting and could have some impact on the control of certain diseases, for example FMD.

Vaccination is the main strategy adopted in the region for FMD control. The situation of FMD in the Middle East is characterized by regular changes in circulating serotypes, which are

very specific to the region, such as the A Iran 05, now largely spread all over the Middle East. The lack of local vaccine producers could have a negative impact on the control of the disease by delaying response to new serotypes due to insufficient supply in adapted vaccines.

3. Registration – Marketing authorization

National Marketing Authorizations (NMA) are delivered everywhere and generally by the Regulatory Authority of each country. In Egypt the registration is only delivered by the Ministry of Health, while the Ministry of Agriculture is also part of the Regulatory Authority.

In the region all VMP are registered, except Biological products in Jordan and Hormones in Iraq and KSA.

Marketing Authorizations are always delivered based on dossier submission. Quality control of the products and assessment of their efficacy and safety, particularly concerning residues, are applied almost everywhere.

Some countries have also other requirements such as:

- Stability studies, in Egypt, Lebanon and UAE,
- Toxicity studies, in KSA and Lebanon
- Clinical studies, in KSA, Egypt and Lebanon
- Risk – Benefit studies in Qatar
- Commercial information, in Turkey,
- And certificate of origin and free sale, in Syria, Turkey and Yemen.

4. Quality control

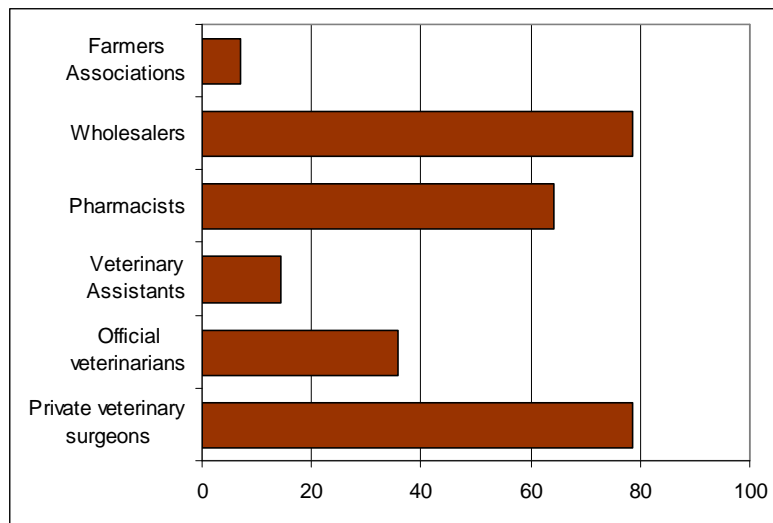
Except Lebanon, Qatar, Turkey and Yemen, all countries have in place a quality control programme. Turkey will start this kind of programme in 2010.

To implement quality control programmes, countries generally use laboratories from the public sector. Iran resorts also to private laboratories.

While every country has also dedicated staff and documented quality control procedures, most of them have records on control results and two third of them information on adverse events and action they took.

5. Distribution

The distribution of VMP is mainly made by private veterinary surgeons, pharmacists and wholesalers.



In certain countries (Cyprus), wholesalers are only authorized to distribute VMP to private veterinarians and pharmacists.

In Cyprus, Egypt, Iraq, Kuwait and Sudan the distribution is also made by Official Veterinarians, in Egypt and Yemen by Veterinary Assistants and only in Egypt by Farmer associations.

Graph 3: Distributors

Some countries have also specific way of distribution, such as in Iran, where there is official national and provincial companies distributing those products.

Except Lebanon and Yemen, all countries register the distributors.

Most of countries have also restrictions on the distribution way of certain products. The restrictions concern either the product itself, such as Narcotics, Anaesthetics, Hormones, some ATB, and Poisons, for which the distribution is restricted on veterinary prescription; or its use in national official programmes implemented by countries: this concerns essentially vaccines, such as in Yemen, Jordan, Iraq and Iran, or other products such as trypanocids in Sudan.

In the region the price of VMP is controlled in about half of countries.

Some countries provide also subsidies for the distribution. In Kuwait, Qatar and the UAE subsidies are total and VMP are provided free of charge to the farmers.

Products advertising is authorized everywhere and the cold chain is a critical point for a good distribution of VMP in the entire region.

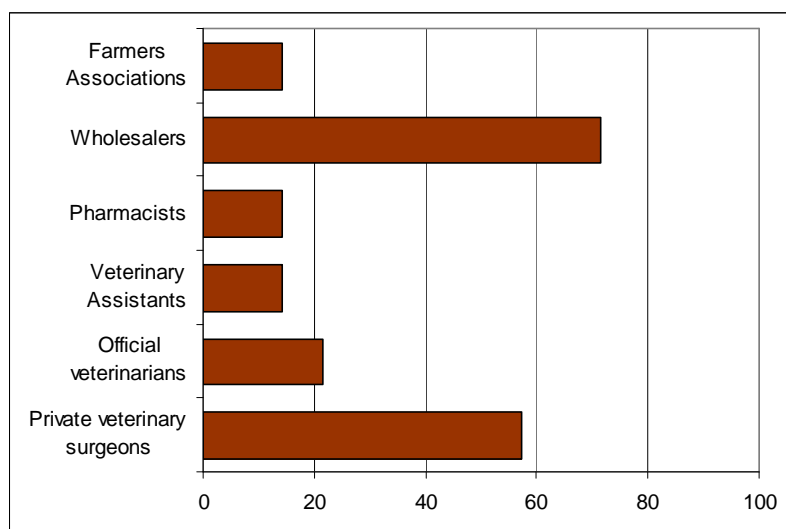
6. Veterinary medicinal products' importation

The Authority in charge of VMP imports is generally the same as the Regulatory Authority and in most of case is relevant of the Minister where the VS are located.

Except Kuwait, Lebanon and Sudan, every country accepts other NMA. Imports are generally made from EU or USA, or from any other countries, complying with specific national requirements.

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

Authorized importers are essentially wholesalers and private vets.



Official veterinarians are also authorized in Egypt, Iraq and Turkey, Veterinary assistants in Egypt and Yemen, pharmacists in Egypt and Lebanon and farmers association in Egypt and Iran.

Graph 4: Authorized Distributors

In few countries, illegal imports are a significant issue. This was mentioned by Iraq, Yemen and the UAE.

Egypt and Iran mentioned also this issue as moderate in their particular case and Turkey reported rare cases of illegal imports.

Concerned countries are generally those with the most important livestock population.

7. Surveillance and control

All countries have programmes for the control and the surveillance of VMP. It is generally the Ministry of Agriculture, or where the VS are located, that is in charge of these programmes.

In Kuwait and Turkey these programmes are conducted under the supervision of the MoH and the MoA and in Cyprus and KSA under the control of their official agency dedicated to VMP.

In most of the countries, surveillance and control of VMP are implemented along the general chain, from the manufactures to the use of these products.

But, few countries implement residue testing programmes, which consist generally on the search of heavy metals, aflatoxins, hormones and antibiotics.

The surveillance and control of antimicrobials is limited to some countries either concerning the monitoring of antimicrobial resistance (Cyprus, Egypt, Iraq, KSA, Lebanon, Sudan, Yemen) or the controls of sales (Cyprus, Egypt, Iraq, Kuwait, Sudan, Yemen).

When they are implemented, these programmes are conducted in collaboration with the MoH and/or the private sector.

8. Commercial veterinary diagnostic tests

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

For delivering authorizations of veterinary diagnostic tests, all countries take into account both OIE Standards and the OIE register of approved kits.

9. Countries' expectations

Countries' expectation can be summarized in two main areas:

- First the wish to harmonize VMP registration rules in the region,
- And also the improvement of the quality control of VMP in the region and an easy access to regional specialized laboratories.

10. Conclusions

This study is not a qualitative assessment, it is only based on country self evaluation by answering a questionnaire.

To summarize, in most of the region, the Authority involved in the control of VMP is generally located in the same Ministry than the VS.

All Middle Eastern countries have already adopted national legislation for the regulation of production and distribution of veterinary medicinal products, 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 Anti-Microbials.

Middle Eastern countries import substantial numbers of veterinary medicinal products and a regional harmonization for their registration is expected by most of the countries, which mentioned also their difficulties to have access to specialized laboratories for the quality control of VMP.