Mongolia, current situation of veterinary products and it’s quality assurance methods

Regional Seminar for OIE National Focal points for Veterinary Products
Tokyo, 3-5 December, 2014
Mongolia

- Mongolia is a landlocked country, bordered by Russia and China
- With land of 1,564,116 square kilometers, Mongolia is the 19th largest country in the world.
- Population 2.94 million in 2014
- The capital city is Ulaanbaatar. It is home to 45% of the population.
- With extreme weather, very hot in the summer around 35°C and extremely cold in the winter, in January averages as low as −40°C
Livestock population is 45 mln, in addition pig, duck and poultry farms are enlarged due to increasing demand of the urban consumers.

Due to market demand, Mongolia imports veterinary products such as animal feed supplements, and Veterinary drugs.

Recent years increased number of dairy and beef farms.

Mongolians horse lovers and number of racehorses increased in Mongolia, at the same time increased imports of equine supplements to Mongolia.
Veterinary medicine production in Mongolia

- 8 veterinary pharmaceutical companies operate in Mongolia.
- The largest and State owned manufacturer is the Biokombinat.
- Biokombinat operates 17 departments, 4 services with 300 employees.
- It is producing 110-120 thousand liters per year, or 25-30 million doses of the liquid preparations, 13-25 million doses of the dried preparations.

Mongolia locally produces 80% of vaccines and 20% of veterinary drugs.
Veterinary medicine production in Mongolia

- Biokombinat established early 1923, updated and equipped by the Hungarian technology in 1973.
- While the introduction of modern technology the Mongolian researchers were developing more than 60 different kinds of veterinary products for the prevention, diagnosis, and treatment of infectious diseases.
Our lab confirms quality of veterinary vaccines and diagnostics and other products by using of national and international standards.
Imports of the veterinary products

More than 80 companies importing veterinary products from many different countries to Mongolia.

- Port Dodge, USA
- Norbrook laboratories Limited LTD Northern Ireland
- Eco animal health from UK
- Merial, COOPHAVET of France
- Cipla, Vetnex, Brilliant bio pharma from INDIA
- Kalbe animal health from INDONESIA
- Invesa from SPAIN
- The Arab pesticides & veterinary drugs Mfg.Co
Importation of the veterinary products

- Vilsan from Turkey
- DONG BANG Co. LTD, Green Cross from Korea
- Venedim corporation from Vietnam
- Hebei Yuanzheng Pharmaceutical Co.LTD from China
- “Vetpreparaty” from RUSSIA
- “Rubikon” from BELARUS
- “Ukrzoovetprompostach” from UKRAIN
Certificate of analysis for finished product

**Certificate of Analysis**

**Norbrook Laboratories Ltd**

**Name of Product:** Norcollin LA Norbrook Equestrian

**Batch Number:** 1231-03

**Quantity:** N/A

**Manufacturing Date:** June 2011

**Expiry Date:** June 2014

**Packaging:** 100ml Clear Glass

**Active Ingredients:**
- Procaine Penicillin (150 mg/mL)
- Benzathine Penicillin (112.5 mg/mL)

<table>
<thead>
<tr>
<th>Analytical</th>
<th>Results</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Conforms</td>
<td>An off-white, light suprasuspension is clear; N/A should not adhere to the surface of the bottle. Any deposit should redissolve on gentle shaking.</td>
</tr>
<tr>
<td>Fill Volume</td>
<td>100% (102 ml)</td>
<td>Not less than the declared amount.</td>
</tr>
<tr>
<td>pH</td>
<td>7.0</td>
<td>7.0 to 7.4.</td>
</tr>
<tr>
<td>Syringability</td>
<td>Conforms to ISO 11604 test.</td>
<td></td>
</tr>
</tbody>
</table>

**Assay:**
- Procaine Penicillin: 15.29 ± 0.086 % (24 samples)
- Benzathine Penicillin: 11.17 ± 0.017 % (24 samples)
- Total Penicillin: 16.40 ± 0.16 % (24 samples)
- Methyl-p-hydroxybenzoate: 0.10 ± 0.01 % (24 samples)

I hereby certify that the above information is authentic and accurate in so far that the specification information is available to us and we confirm that our scientific findings are true. This batch of product has been formulated/Manufactured, including packaging and quality control at the above mentioned site (Manufacturing Authorization Number: March 2005) in full compliance with GMP requirements and in accordance with the specification provided to us. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Prepared By: Lindsay Andrews

Date of Issue: 16-02-2011

APPROVED FOR THE HEAD OF QUALITY CONTROL
Certificate of analysis for finished product
Testing veterinary products

The veterinary drugs in accordance with its related certificates and by the international methodology. For instance, content of the active substances by HPLC

- HPLC testing for drugs
- virology, bacteriology testing for vaccines
- virus neutralization
- toxin neutralization
# HOW WE TEST DRUGS AND VACCINES

<table>
<thead>
<tr>
<th>Category</th>
<th>Tests</th>
</tr>
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<tbody>
<tr>
<td><strong>PURITY TEST</strong></td>
<td>• BACTERIAL TEST&lt;br&gt;• FUNGY TEST</td>
</tr>
<tr>
<td><strong>SAFETY TEST</strong></td>
<td>• INACTIVATION&lt;br&gt;• SAFETY</td>
</tr>
<tr>
<td><strong>TEST</strong></td>
<td>• BIO TEST&lt;br&gt;• SEROLOGICAL TEST</td>
</tr>
<tr>
<td><strong>OTHER CHEMICAL TEST</strong></td>
<td>pH, Inactivation chemical compounds, adjuvant....</td>
</tr>
</tbody>
</table>
Standard Database

- USA Pharmacopeia
- British Pharmacopeia
- Chinese Pharmacopeia
- Korean Pharmacopeia
- Russian Pharmacopeia
SPECIFICATION AND CONTROL METHODS OF THE FINISHED PRODUCT

OXYTETRACYCLINE 10% INJECTABLE SOLUTION
VDQCL is the national quality assurance and certification authority for all types of veterinary drugs, vaccines and bio-preparations that locally manufactured, imported and the newly designed for animal infectious and parasitic disease, for its prevention and diagnosis.
Veterinary Drug Quality Control Laboratory

The laboratory consists of three units
1. Certification department
2. Testing lab
3. Pharmacopoeia Committee

Testing laboratory
Veterinary Drug Quality Control Laboratory

• accredited by the Standardization and Metrology Authority (SMA national)
• methodology is based upon NTBB and MNS, Russian Federation, China, USA, South Korea and British Pharmacopeias
• Mongolia locally produces 80% of veterinary vaccines and imports rest of 20% of vaccines mostly for FMD, and vaccines for small animals
• Mongolia locally produces 20% of veterinary drugs and imports rest of 80% of drugs which includes antibiotics, vitamins, and anti-parasitic drugs
Tested veterinary products in 2009-2012 /type, name/
The Challenges

PERCENTAGE

- Equipments
- Methodology
- Standard substances
- Reagents
- Animals

47.6%
19%
14.3%
9.5%
9.5%
THANK YOU FOR YOUR ATTENTION