Welcome
Establishing and Growing Animal Health Business in China: It’s Easier Than You Think
November 12, 2014
Presented by Husch Blackwell Partner Fang Shen and Kansas State University Professor and President of VaxiAm LLC Dr. Jishu Shi

Dr. Jishu Shi
A native of China
DVM Degree from Beijing/China Agricultural University
PhD in Veterinary Immunology - K-State, 1995
Professor @ K-State College of Veterinary Medicine
Director of U.S. – China Center for Animal Health, K-State Olathe
Special Assistant to the Provost for China Affairs, K-State
President, VaxiAm Group, LLC, Manhattan, Kansas
Presentation Outline

Introduction to the Chinese animal health industry
- Overview of Chinese economy, the Chinese animal agriculture, and animal health industry

Opportunities and Challenges of Chinese animal health markets
- Regulatory agencies
- Current practice and policies on animal disease control
- Challenges
- Opportunities

Top 5 largest economies by GDP in PPP terms in 2020

<table>
<thead>
<tr>
<th>Rank</th>
<th>Country</th>
<th>GDP in PPP: 2020 ($ billion)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>China</td>
<td>26,117</td>
</tr>
<tr>
<td>2</td>
<td>USA</td>
<td>22,482</td>
</tr>
<tr>
<td>3</td>
<td>India</td>
<td>9,297</td>
</tr>
<tr>
<td>4</td>
<td>Japan</td>
<td>5,620</td>
</tr>
<tr>
<td>5</td>
<td>Russia</td>
<td>4,410</td>
</tr>
</tbody>
</table>

Euromonitor International
May 2013

Year Over Year Growth (%)

U.S. China World

IMF 2014

2012 2013 2014 2015

0 2 4 6 8 10

U.S. vs. China: GDP and Populations

Population (millions)

2012 2013 2014 2015

IMF 2014

9.63 x10^6 sq. km

9.60 x10^6 sq. km

Population density

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**Worldwide and Chinese Animal Health Market by Sector**

2012 = $22.5 billion (World)
Excluding nutritional feed additives

- 57% Companion Animal
- 43% Food Animal

2012 = $6.5 billion (China)
Excluding nutritional feed additives

- 91.5% Companion Animal
- 8.5% Food Animal

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**Chinese Animal Health Regulatory Agencies**

1. Ministry of Agriculture (MOA)
2. Bureau of Veterinary Services (Approval)
3. Center for Veterinary Drug Evaluation (Evaluation)
4. China Animal Disease Control Center (AI, FMD, PRRS, and CSF vaccine purchase)
5. China Institute of Veterinary Drug Control (Quality control)
6. Provinical Animal Disease Control Centers (Purchase: 4 + commercial vaccines)

Ministry of Commerce
State General Administration for Quality Supervision, Inspection and Quarantine

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Chinese Animal Health Market

**Veterinary pharmaceuticals, antibiotics, herbal medicines, disinfectants**

**Veterinary biologics including vaccines, antisera, and diagnostics**

**Vet medical devices**

**Entities**

- Active Ingredients: 1650
- Manufacturers: 1791
- Product Registrations: 11000
- Drug sellers: 33000

**MOA 2014**

**Chinese Animal Health Market (2012)**

- Biologics: $1,433 million
- Pharma: $2,709 million
- Herb: $694 million
- API: $1,613 million

$6.449 billion
Chinese Animal Health Market

Many small sized companies

<table>
<thead>
<tr>
<th>Sales (RMB Million)</th>
<th># of Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
</tr>
<tr>
<td>&lt;0.5</td>
<td>95 (6.32%)</td>
</tr>
<tr>
<td>&gt;0.5-&lt;5</td>
<td>557 (36.64%)</td>
</tr>
<tr>
<td>5-200</td>
<td>823 (54.15%)</td>
</tr>
<tr>
<td>&gt;200</td>
<td>44 (2.89%)</td>
</tr>
</tbody>
</table>

2013 Data

Imported Veterinary Drugs

2012

<table>
<thead>
<tr>
<th>Category</th>
<th>x 100 million RMB</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologics</td>
<td>57.6%</td>
<td>10.3%</td>
</tr>
<tr>
<td>Feed Additives</td>
<td>27.4%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>10.3%</td>
<td>3.3%</td>
</tr>
<tr>
<td>Anti-parasitic</td>
<td>5.1%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Others</td>
<td>3%</td>
<td>0.9%</td>
</tr>
<tr>
<td>SCS</td>
<td>29%</td>
<td>5.1%</td>
</tr>
<tr>
<td>Poultry</td>
<td>26.2%</td>
<td>44.6%</td>
</tr>
<tr>
<td>Pets</td>
<td>10% in 2011</td>
<td>0.3%</td>
</tr>
</tbody>
</table>
Top 6 Provinces with the Highest # of Animal Health Products Manufacturers

How commercial veterinary drugs are distributed in China?

- Manufacturers
- Regional Distributors
- Veterinary Clinics
- Pet Stores
- Pet Owners
- Individual Farmers
- Animal Agriculture Companies
Important Questions

How many companion animal clinics are in China?
\[ \approx 2000^* (350+ \text{ in Beijing}) \quad ^*1500 \text{ in 2012} \]

What types of drugs do they use?
Drugs used for humans and food animals {drugs for pets?}

Where do they get the drugs from?
Distributors for human drugs and food animal drugs, no distributors only for companion animal products

Chinese Companion Animal Health Market

- Biologicals $250 million 17%
- Pharmaceuticals $400 million 21%

\[ \text{Yearly average (2007-2012)} \]

- Beijing: 7.5
- Shanghai: 4.5
- China: 1.7
- U.S.: 36.5
Important Questions

What types of veterinary equipment do they use?
- Domestic (X-ray machines)
- U.S. and Japan

How many dogs are in China?
- (100 m vs. 70 m in the U.S.)
- (8-15 m vs. 63 m as actual patients)

How many cats are in China?
- (80 m vs. 74 m in the U.S.)
- (5 m vs. 47 m as actual patients)
### Hot Products in Chinese Companion Animal Health Markets

**Top 8 product categories:**
- Dog food
- Cat food
- Canned food
- Nutritional gel
- Hair beauty product
- Calcium supplement
- Snacks
- Mineral supplement

**Most needed products:**
- Joint health products
- Cardiac disease medicine
- Cancer therapeutics
- Kidney health products
- APD, hemodialyzers, & supplies
- Diagnostic equipment

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### Chinese Animal Health Market:

**Challenge and Opportunities**

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large market, no large companies</td>
<td>Work force: low educational background and industry experience</td>
</tr>
<tr>
<td>Most companies make and sell generic and similar products</td>
<td>Sales people work for more than one company: loyalty?</td>
</tr>
<tr>
<td>Most companies have little or no research and development</td>
<td>Many companies do not have core business practices</td>
</tr>
<tr>
<td>High operational costs: sales force, high energy cost, low technology</td>
<td>Few consumers (farmers) have brand concept/loyalty</td>
</tr>
</tbody>
</table>
What your company should be evaluating

Old Program, Big market
AI, FMD, CSF, PRRS

New Areas
- Brucellosis vaccine and diagnostic reagents
- Vet diagnostic reagents and equipment for pets
- Pet food and medicine
- Companion animal care equipment

Key to business success:
Working with a good local business partner

VaxiAm Group Network in China includes:

China Ministry of Agriculture
Chinese Veterinary Medical Association
Chinese Veterinary Drug Association
China Animal Disease Control Center
China Institute of Veterinary Drug Control
What types of information we can provide

How animal health products are distributed in China?
What are the leading product categories in China?
What are the products most needed in the Chinese market?
What major changes will occur in the Chinese animal health market in the next 3 to 5 year?
How to find a Chinese partner to manufacture your products locally and not lose your formulations, know-how, and technology?
Assistance in registering animal health products in China?
Assistance in finding sales agents or distributors in China?

What can VaxiAm Group do for you?

Animal health market analysis
Regulatory affairs consultation
Product registration
Selection of business partners:
  Sales agents
  Distributors
  Manufacturers

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Legal Issues in Establishing Animal Health Business in China

Fang Shen, Partner, Husch Blackwell LLP
November 12, 2014

Forms of Market Entry

- Employee?
- Independent contractor?
- Sales Representative?
- Distribution Agreement
- Licensing Agreement
- Manufacturing Contract
- FDI: Setting up your own operation (representative office, WFOE, or JV)
- Etc., etc., etc.
Forms of Market Entry

- What are your goals and resources?
- What is the most effective method in achieving your goal?
- What tax issues are created?
- What liability issues are out there?

Working with a Chinese Partner

- Due Diligence
  - Existence and operation
  - Business Scope
  - Financial strength
  - Trustworthiness/Integrity
Working with a Chinese Partner

Have a good written contract

- Specify the geographic area, market, segment or scope of distribution
- Include specific performance requirement
- What else do you want to control (e.g., limit on resale price mark up)?
- Term and termination
- U.S. form contract probably won’t work

Working with a Chinese Partner

Have a good structure

- KansasCo is a Kansas company with headquarters in Overland Park. KansasCo manufactures a range of devices that deliver drugs to cats and dogs. It started selling its products in China three years ago through a distributor. Since then KansasCo has seen the overall demand for its products increase in China, but at the same time local competition has also grown.

- To produce more products quickly to supply the China market and bring down the cost, KansasCo started discussion with a Chinese company called ShanghaiCo. ShanghaiCo currently manufactures similar products under its own brand names.

- KansasCo would like to have ShanghaiCo manufacture the products under KansasCo’s design and brand name. The products will then be shipped to KansasCo’s existing distributor in China for sale to customers
Have a Good Structure

Option One

Shanghai Co.

Payment: $1000

Manufacturing and sale contract

KansasCo

Payment: $2000

Distribution agreement

Distributor

$3000

Customers

Option Two

KansasCo

License agreement

Shanghai Co.

Manufacturing and Sale Agreement

Distributor

$1000

Payment

Customers

$3000

Issues

- Any import duty applicable?
- What local taxes are due?
- Control?
- Intellectual Property?
### Structure

**Option One**
- Shanghai Co.
  - Distribution agreement
  - $3000 Payment
  - $1000 Imports duty and VAT
  - $3000 Customers

**Option Two**
- Kansas Co.
  - License agreement
  - $1000 Payment
  - $3000 Customers
  - VAT

### Foreign Direct Investment

- Governmental approval required for Foreign Invested Enterprise (“FIE”)
- Typical approval process:
  - Preliminary proposal to local people’s government (30 days)
  - Examination and approval by MOFCOM (or local branch) (3 months)
  - Business Registration with State Administration of Industries and Commerce (within 30 days of approval)
  - Other Registrations (other registration within 1 month after the business registration: tax, foreign exchange, customs, etc.)
A Few Points…

- Feasibility Study Report/business plan required
- Location of FIE, legal representative and general manager need to be decided
- Lease agreement required

Foreign Direct Investment – Entity Choices

- Wholly Foreign Owned Enterprise ("WFOE")
- Equity Joint Venture ("EJV")
- Contract Joint Venture ("CJV")
Foreign Direct Investment Regime

Four categories of investment:

- Encouraged
- Permitted
- Restricted
- Prohibited

Encouraged

Easily granted and sometimes preferential treatment available; examples:

- Projects using new technology
- Development and production of animal feed
- Development and production of veterinary vaccines (except those that are included in national plan)
- Pharmaceutical formulations: production of new formulations and new products employing new technologies
- New products and new formulations of antibacterial drugs, anthelmintics, insecticides and anti-coccidiosis drugs for veterinary use
- Most manufacturing (especially pharmaceuticals, new materials, industrial equipment, electronic equipment)
- Projects that can develop central and western China
Restricted

More stringent scrutiny, and maybe ownership restriction; examples:

- Wholesales and retail trade
- Securities and investment management
- Freight, warehousing and logistics
- Professional service

Prohibited

- Projects that endanger state security or public interest
- Projects that occupy large tracts of farmland
- Projects that involve precious species protected in China
- Projects that utilize manufacturing techniques or technologies unique to China (e.g., Chinese traditional medicine, weapons and ammunitions)
Dispute Resolution

- Court v. arbitration
- Where?

Protection of Intellectual Property
Background

- Culturally, IP rights are not as well respected as in Western countries
- Good written laws and comprehensive legal framework
- Problem is weak and inconsistent enforcement system

Progress

Remarkable improvement has been made in recent years

CCP is taking it more seriously as more Chinese companies are spending on R&D and becoming technology intensive and CCP realizes that strong IP protection is integral to sustained economic growth
Example of Recent Improvements

- Comprehensive web portal: www.chinaipr.gov.cn providing guidance to foreign investors on government directives, programs and resources
- Increased judicial training and establishment of specialized IPR chambers
- Companies are seeking protection
- No. 1 in trademark filing in recent years

Progress

PATENT BOOM
Patent applications have grown rapidly in China, and last year surpassed those in the United States.

- United States
- China
- Japan
- South Korea
- European Patent Office

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Recent Victories by Foreign Companies in Patent Suits in China

- Ashland (U.S.)
- Strix (British)
- Neoplan (German)
- Anecdotal evidence suggests the recent win rate for foreign companies in IP suits in China is greater than 50%

Trademark

- Intellectual property rights are territorial
- Protected by the PRC Trademark Law and related rules and regulations
- Need to register both the English and Chinese versions, simplified and traditional Chinese, as well as Pinyin
- Trademark agreement required to be registered with the trademark office to be enforceable
Patent

- Protected by the PRC Patent Law and related rules and regulations
- Patents protected in the U.S. do not automatically have protection in China
- Follows a “first to file” system
- Applies “absolute novelty” standard:
  - A patent already issued by the U.S. Patent Office will not be able to meet the Chinese patentability standards;
  - Paris Convention: need to file within 12 months, or within 6 months for exterior design, from its first filing in the U.S. and claim the priority date.

Trade Secrets

- Protected by PRC Law Against Unfair Competition
- Use a written agreement to protect your know-how and trade secrets
- Try to avoid releasing the key information
- Treat the information as confidential: clearly mark as confidential all information, providing training to all personnel, include non-disclosure provisions in employment agreements
When Does IP Come Into Play?

- Sell products in China
- Manufacture products in China
- Licensing arrangements
- Setting up business operations in China
- Joint venture with Chinese partners
- Etc., etc.

Practical Advice

- Obtain registered protection for IP rights
- Seek professional help
- Have an IP strategy
  - What IP are important for your business?
  - How is your strategy in China different from (or similar to) our U.S. Strategy?
Practical Advice

- Think about China when you register patents in the U.S.
- Have you registered your marks in both English and Chinese?
- What about domain names?
- Do not solely rely on legal tactics to enforce your IP rights
- Record commercial arrangements in writing
- Control use of IP rights by local associates

Methods of Enforcement

Administrative Actions

- Raids; seizures; administrative restraining orders; fines
  - Intellectual Property Offices for patents
  - State Administration of Industry and Commerce or State Bureau of Quality and Technical Supervision for trademarks and trade secrets
  - National Copyright Administration for copyrights
Methods of Enforcement

Civil Actions

- Court injunctions; damages
  - Chinese People’s Court – refers to all levels

Methods of Enforcement

Criminal Actions

- Fines; imprisonment
  - Public Security Bureau

- Strengths and weaknesses depend on the complexity and severity of infringement
Protecting Intellectual Property

- Chinese IP system NOT perfect – but can be effective
  - Difficult to recover actual damages
  - Penalties are often weak
- Purpose of enforcement to protect IPR – not recover damages
- Effective enforcement requires strategy
  - Combine criminal, civil, admin or customs – PR campaign to send message
  - Influence public attitude – deter future infringement
  - End current infringement

FCPA Overview

- Prohibits bribery of foreign officials, foreign political parties or candidates to obtain or retain business
- Covers any U.S. person and any “domestic concern” organized under the laws of the United States or its agents
- Who is an official?
  - Any officer or employee of a government or of a government-owned entity, any foreign political party or official, any candidate for foreign political office, any official of a public international organization, and any other person while “knowing” that the payment or promise to pay will be passed on to one of the above.
Don’t Ignore the Facts!

- “Willful blindness,” “deliberate ignorance” and taking a “head-in-the-sand” attitude constitutes knowledge under the statute
- A company is not immune if the payment is made by a third party, such as an agent or consultant
- Liability may flow to a company if it:
  1. Authorizes an agent or third party to make improper payments to foreign officials; or
  2. Makes payments to an agent or third party with actual or constructive knowledge that all or a portion of money will be paid directly or indirectly to foreign officials.

China Specific

- Sponsorship of overseas children’s study/work
- Travel expenses
- Excessive “license fee”
Questions?

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