EXPERIENCE WITH ANTIMICROBIAL DATA COLLECTION IN ANIMALS

NEED FOR HARMONISATION

JAPAN EXPERIENCE
Today’s Topics

1. Regulation of Vet. Medicinal Products (VMPs) In Japan
2. Japanese Veterinary Antimicrobial Resistance Monitoring System (JVARM)
3. An overview of veterinary antimicrobial products in Japan
Reasonable and Safe Use of VMPs in Japan

**Before Licensing**
Marketing Approval System
- Prohibits distribution of unapproved drugs

**Distribution**
Restrictions on the distribution of vet. drugs
- Prohibits distribution without authorization

**Usage**
Restrictions on the usage of vet. drugs
- Establishes usage standards for vet. drugs

**At the retail level**
Veterinarian
- Must not prescribe without consultation
Prescription system
- Prohibits selling drugs without direction or prescription of vet.
VMP Distribution

Marketing Authorization Holder

Distributor

wholesaler

Distributor

Retailer

Veterinarian

Animal Owner

Animal
**Prescription**

- **Name of medicine**
- **Quantity**

Information about treated animal
- e.g., sex, age, identification number

Information about animal owner

**Indications**

Dosage, administration, treatment period, withdrawal period others (public health concerns, technological concerns)

- **Date of issue**
- **Information about veterinarian in charge**

a set of 4 identical documents
1. For the veterinarian
2. For the regulating authority
3. For the distributor
4. For the animal owner
1) Regulation of Vet. Medicinal Products (VMPs) In Japan

2) JVARM

3) An overview of the availability of veterinary antimicrobial products in Japan used for therapy
1. Objective
   - Nationwide monitoring of antimicrobial resistance
   - Monitoring of veterinary antimicrobial use

2. Established in 1999

3. National Veterinary Assay Laboratory (NVAL)

4. Targeted bacterial species
   - Indicator bacteria (E.coli & Enterococcus)
   - Food-borne pathogen (Salmonella & Campylobacter)
Monitoring of Antimicrobial Consumption

VMP Distribution

NVAL report data annually

Pharmaceutical Affairs Law

Marketing Authorization Holder (MAH)

Distributor wholesaler

Veterinarian

Animal

Animal Owner

Retailer pharmacy
<table>
<thead>
<tr>
<th>~2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name</td>
<td>Trade Name</td>
</tr>
<tr>
<td>Sales amount (¥ 1,000)</td>
<td>Sales amount (¥ 1,000)</td>
</tr>
<tr>
<td>Volume of sales (kg, L)</td>
<td>Volume of sales (kg, L)</td>
</tr>
<tr>
<td>the names of antimicrobials</td>
<td>the names of antimicrobials</td>
</tr>
<tr>
<td>Contents of the antimicrobials</td>
<td>weight of the active ingredients</td>
</tr>
<tr>
<td>The routes of administration</td>
<td>The routes of administration</td>
</tr>
<tr>
<td>Target animal species</td>
<td>Target animal species</td>
</tr>
<tr>
<td>Estimated Percentages of Sales for Each Animals Species</td>
<td>Estimated Percentages of Sales for Each Animals Species</td>
</tr>
</tbody>
</table>
Collates analyses and evaluates the data
Publishes the data in a yearly report and posts it on the Web

### Sales Amount and Sales Volume of Antibiotics (2005)

<table>
<thead>
<tr>
<th>Class</th>
<th>Active substance</th>
<th>route of administration</th>
<th>Sales amount (¥1000)</th>
<th>Amount of active substance (kg)</th>
<th>Estimated Percentages of Sales for Each Animal Species</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Beef Cattle</td>
<td>Dairy cow</td>
<td>Pig</td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>Oxytetracycline</td>
<td>oral</td>
<td>383,157</td>
<td>204,154</td>
<td>1.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>injection</td>
<td>158,791</td>
<td>1162.7</td>
<td>11.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>total</td>
<td>541,948</td>
<td>205316.7</td>
<td></td>
</tr>
<tr>
<td>Doxycyclin HCl</td>
<td>oral</td>
<td>520,321</td>
<td>23713.5</td>
<td>84.3</td>
<td>15.6</td>
</tr>
</tbody>
</table>

1) Regulation of Vet. Medicinal Products (VMPs) In Japan

2) JVARM

3) An overview of the availability of veterinary antimicrobial products in Japan.
Trends in veterinary antimicrobials sold in tonnes of active substance
Sales of antimicrobial agents by target species, in tonnes of active substance, during 2006-11
Sales of antimicrobial agents, in tonnes of active substance, during 2006-11
Trends in number of animals slaughtered in slaughterhouses and poultry slaughtering plants (1,000 heads/birds).
Conclusion

• JVARM is to monitor the consumption of veterinary antimicrobials from data released by Marketing Authorization Holder
• The data include weight in kilograms of the active ingredients
• Antimicrobials were most frequently used in pigs.
• Tetracycline had the highest sales volume.
Thank you very much for your attention.

JVARM REPORT

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