Characterizing US Animal Drug Consumption by Sales

Farm Foundation & USDA, Economic Research Service
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FDA, Center for Veterinary Medicine
Sales of Drugs for Food-Producing Animals

- **US Congress** - Section 105 of the Animal Drug User Fee Amendments of **2008**
- First summary on 2009 sales published on **December, 2010**
FDA-Approved Animal Drug Products

• Ingredient(s)
• Dispensing Status
• Route of Administration
• Species
• Indication(s)
• Dosing Information
• Duration of Use
Congressional Limitations to the Public

(E) The Secretary shall make summaries of the information reported under this paragraph publicly available, except that-

(i) the summary data shall be reported by antimicrobial class, and no class with fewer than 3 distinct sponsors of approved applications shall be independently reported; and

(ii) the data shall be reported in a manner consistent with protecting both national security and confidential business information.
2009 SUMMARY REPORT on Antimicrobials Sold or Distributed for Use in Food-Producing Animals

Table 1: Antimicrobial Drugs Approved for Use in Food-Producing Animals: 2009 Sales and Distribution Data Reported by Drug Classes

Table 2: Antimicrobial Drugs and Drug Classes Approved for Use in Food-Producing Animals
Table 1. Antimicrobial Drugs Approved for Use in Food-Producing Animals: 2009 Sales and Distribution Data Reported by Drug Class

<table>
<thead>
<tr>
<th>Antimicrobial Class</th>
<th>Annual Totals (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domestic</strong></td>
<td></td>
</tr>
<tr>
<td>Aminoglycosides</td>
<td>339,678</td>
</tr>
<tr>
<td>Cephalosporins</td>
<td>41,328</td>
</tr>
<tr>
<td>Ionophores</td>
<td>3,740,627</td>
</tr>
<tr>
<td>Lincosamides</td>
<td>115,837</td>
</tr>
<tr>
<td>Macrolides</td>
<td>861,985</td>
</tr>
<tr>
<td>Penicillins</td>
<td>610,514</td>
</tr>
<tr>
<td>Sulfas</td>
<td>517,873</td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>4,611,892</td>
</tr>
<tr>
<td>NIR(^2)</td>
<td>2,227,366</td>
</tr>
<tr>
<td><strong>Export</strong></td>
<td></td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>515,819</td>
</tr>
<tr>
<td>NIRE(^3)</td>
<td>1,115,728</td>
</tr>
</tbody>
</table>
2016 Sales Report

• 67 pages
• 18 tables
• 23 figures
ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS
ACTIVELY MARKETED 2009-2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE, ROUTE OF ADMINISTRATION, AND DRUG CLASS
Considerations

- Sales not indicative of how actually used in animals
- Sales in one year may result in use in another year
- Some sales may never result in use
- For non-feed drugs, vets might use in extralabel manner
- Some drug products approved:
  - for multiple species
  - for multiple indications
  - at multiple dosing regimens
<table>
<thead>
<tr>
<th>CATTLE (Beef cattle)</th>
<th>For the control of bacterial pneumonia associated with shipping fever complex caused by <em>Pasteurella</em> spp susceptible to chlortetracycline</th>
</tr>
</thead>
<tbody>
<tr>
<td>CATTLE (Beef cattle, over 700 pounds)</td>
<td>For the control of active infection of anaplasmosis caused by <em>Anaplasma marginale</em> susceptible to chlortetracycline</td>
</tr>
<tr>
<td>CATTLE (Beef cattle, under 600 pounds)</td>
<td>For the control of active infection of anaplasmosis caused by <em>Anaplasma marginale</em> susceptible to chlortetracycline</td>
</tr>
<tr>
<td>CATTLE (calves, beef, and non-lactating dairy)</td>
<td>For the treatment of bacterial enteritis caused by <em>Escherichia coli</em> and bacterial pneumonia caused by <em>Pasteurella multocida</em> organisms susceptible to chlortetracycline</td>
</tr>
<tr>
<td>CATTLE (growing cattle over 400 pounds)</td>
<td>Reduction of liver condemnation due to liver abscesses</td>
</tr>
</tbody>
</table>
NADA 046-699 (tetracycline in feed)

<table>
<thead>
<tr>
<th>CHICKENS (not laying eggs for human consumption)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>For the control of chronic respiratory disease and air sac infection caused by <em>Mycoplasma gallisepticum</em> and <em>Escherichia coli</em> susceptible to chlortetracycline</td>
<td></td>
</tr>
<tr>
<td>For the control of infectious synovitis caused by <em>Mycoplasma synoviae</em> susceptible to chlortetracycline</td>
<td></td>
</tr>
<tr>
<td>For the reduction of mortality due to <em>Escherichia coli</em> infections susceptible to chlortetracycline</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SHEEP (breeding)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>For reducing the incidence of (vibrionic) abortion caused by <em>Campylobacter fetus</em> infection susceptible to chlortetracycline.</td>
<td></td>
</tr>
</tbody>
</table>
For reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E *Streptococci* susceptible to chlortetracycline

For the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline

For the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline

For the control of leptospirosis (reducing the instances of abortion and shedding of leptospiroae) caused by *Leptospira pomona* susceptible to chlortetracycline
NADA 046-699 (tetracycline in feed)

| TURKEYS (not laying eggs for human consumption) | For the control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline |
| For the control of hexamitiasis caused by *Hexamita meleagris* susceptible to chlortetracycline |
| For the control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline |

| TURKEYS (poults not over 4 weeks of age, not laying eggs for human consumption) | For reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline |
Inclusion of Estimated Species

• Proposed rule on May, 2015
• Public to provide comments by August, 2015
• Final rule published on July, 2016
• Revised summary first published on December, 2017
Public Comments on Proposed Species Estimates

• Species-specific sales estimates are beneficial to understand:
  – How antimicrobials are used in food animals
  – The relationship between sales/use and antimicrobial resistance (i.e. with NARMS data)
  – The impact of policies and practices to mitigate antimicrobial resistance (e.g. GFI #213 and the VFD rule)
Public Comments on Proposed Species Estimates

• Unclear how species-specific estimates will scientifically support USDA animal drug use surveys and NARMS resistance data

• Species-specific sales estimates are inappropriate to report because:
  – Can be inaccurate, especially due to the complications and inconsistencies of data collection
  – Do not constitute sound scientific data
  – Do not reflect actual usage
  – Are subject to misinterpretation due to lack of complete information
  – Do not constitute sufficient data to evaluate the impact of policies and trends in antimicrobial resistance
Public Comments on Proposed Species Estimates

• Antimicrobial use should be monitored at the farm-level

• FDA should collaborate with USDA (ARS and especially APHIS) and CDC to enhance existing collection efforts of on-farm antimicrobial use data that is:
  – Accurate, detailed, and quantitative
  – Used to understand the relationship between usage and resistance trends
  – Used to evaluate the impact of policies
  – Used to construct targeted interventions
2016 US Domestic Sales and Distribution
Medically Important Antimicrobials

- **Cattle**
- **Swine**
- **Chicken**
- **Turkey**
- **Other**

Annual Totals (kg):
- Medically Important
- Not Medically Important

Medical Importance
2016 US Domestic Sales and Distribution Medically Important Antimicrobials - **Estimated Cattle**

- **Aminoglycosides**: 95%
- **Macrolides**: 7%
- **Fluoroquinolones**: 5%
- **Cephalosporins**: 4%
- **Penicillins**: 3%
- **Sulfs**: 1%
- **Tetracyclines**: 1%
- **NIR1**: 0%
- **NIR2**: 0%
- **NIR3**: 0%
- **NIR4**: 0%

[Source: www.fda.gov]
2016 US Domestic Sales and Distribution
Medically Important Antimicrobials - Estimated Swine

www.fda.gov
2016 US Domestic Sales and Distribution
Medically Important Antimicrobials - **Estimated Swine**

![Pie chart showing the distribution of medically important antimicrobials used in swine. The chart is divided into several segments: Tetracyclines (80%), Aminoglycosides (11%), Sulfas (2%), Penicillins (1%), Lincosamides (1%), Macrolides (1%), NIR3, NIR2, NIR1, and other categories totaling 0%. The overall percentage of Tetracyclines is indicated as 95%.](www.fda.gov)
2016 US Domestic Sales and Distribution
Medically Important Antimicrobials - **Estimated Chickens**

- **56%**: Tetracyclines
- **29%**: Aminoglycosides
- **5%**: Sulfas
- **4%**: Macrolides
- **4%**: Lincosamides
- **2%**: NIR1
- **0%**: Other categories

[www.fda.gov](http://www.fda.gov)
2016 US Domestic Sales and Distribution Medically Important Antimicrobials - **Estimated Chickens**

- NIR1: 56%
- Lincosamides: 4%
- Macrolides: 4%
- Sulfas: 2%
- Aminoglycosides: 5%
- NIR2: 29%
- Tetracyclines: 0%

94%
2016 US Domestic Sales and Distribution
Medically Important Antimicrobials - **Estimated Turkeys**
2016 US Domestic Sales and Distribution
Medically Important Antimicrobials - **Estimated Turkeys**

- 70% Penicillins
- 21% NIR1
- 3% Aminoglycosides
- 1% Tetracyclines
- 0% Sulfas

96%