An Intro
Origin of the perceived risk

- Increasing population and disposal income
- Intensive farming system increasing pressure on natural resources
- Competing uses of feed ingredients and increasing resource scarcity
- Using antimicrobials to enhance nutrient utilization by animals
- Conflicting demands of food safety vs human health concerns
- More pertinent in Asia Pacific region, as we have 60 percent of world population and high levels of undernutrition and malnutrition

Strategies to address risk

- Regulated use of medically important antimicrobials based on
  - Risk assessment:
    - Establishment of MRLs
    - Microbial resistance (to specific shared class antibiotics)
  - Marketing status
  - Route and extent of usage
  - Monitoring and review mechanism
  - Supporting efficacy and safety data

- Limitations for specific non-therapeutic use
- Phased elimination of non-therapeutic use

## A Framework for Regulations

<table>
<thead>
<tr>
<th>Approval conditions</th>
<th>High risk</th>
<th>Medium risk</th>
<th>Low risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marketing Status</td>
<td>Prescription</td>
<td>Prescription/ Veterinary Feed Directive</td>
<td>Prescription/ Veterinary Feed Directive/ Over-the-counter</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extra-label use (&quot;ELU&quot;)</td>
<td>ELU Restrictions</td>
<td>Restricted in some cases</td>
<td>ELU permitted</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extent of use</td>
<td>Low</td>
<td>Low, medium</td>
<td>Low, medium, high</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-approval monitoring</td>
<td>Yes</td>
<td>Yes</td>
<td>In certain cases</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advisory committee review considered</td>
<td>Yes</td>
<td>In certain cases</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Route of administration</td>
<td>i. Injection</td>
<td>i. Injection</td>
<td>i. Injection</td>
</tr>
<tr>
<td></td>
<td>ii. Oral (feed/water)</td>
<td>ii. Oral (feed/water)</td>
<td>ii. Oral (feed/water)</td>
</tr>
</tbody>
</table>

---

*5th Global Animal Health Conference and Workshop 2016*
Limited approval for non-routine usage, only in cases where

(a) There is significant risk of transmission of disease or infection to food-producing animals;

(b) It is necessary to prevent or reduce the risk of transmission of the disease or infection described in (a);

(c) It is administered for the shortest duration possible to prevent or reduce risk of transmission of the disease or infection described to the animal;

(d) the medically important antimicrobial is administered—
   I. at a scale no greater than the barn, house, or pen level; and
   II. to the fewest animals possible; and
   III. by the Department or registered medical practitioner for the bona fide purpose of his profession shall have in his possession any such medically important antimicrobial or shall vaccinate any animal with such medically important antimicrobial unless licensed in that behalf.

In-feed usage guidelines

1) Feed business operators shall establish, implement and maintain permanent written procedures based on HACCP system.

2) Carry-over limits for antimicrobial actives in medicated feed or intermediate in the last batch/stage before non-target feed shall be pre determined by the regulatory authority.

3) Feed business operators supplying medicated feed shall ensure that quantities supplied or mixed do not exceed:
   a) the quantities provided in the prescription; and
   b) the quantities required for one month's treatment or two weeks in case of medicated feed containing antimicrobial veterinary medicinal products.
   c) Medicated feed containing antimicrobial veterinary medicinal products shall not be used to prevent diseases in food-producing animals or to enhance their performance.

Elimination of non-therapeutic use

- ‘Non-therapeutic use’ has been defined to include growth promotion and continuous use of medically important antimicrobials for purposes other than therapeutic use or non-routine disease control
- Time bound plan for withdrawal of non-therapeutic use of medically-important antimicrobial in food-producing animals

Approval is withdrawn automatically (in 2 years) unless a decision is taken to continue, when it is established there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable in whole or in part to the non-therapeutic use of the drug

(a) By the holder of approved application
(b) By a risk analysis conducted by the regulator and other relevant information

Way forward …

- Uniform regulatory process for animal medicines
- Common disease control programs
- Leading to free trade for food, a step closer to removing world hunger – what we at Access Consulting Group believe in doing
Thank You!