Antimicrobial resistance: Public policy implications

Hellen Gelband

March 23, 2017

Antimicrobial Resistance and One Health
21st Century Cures Act (2016)
• Expedites approval and use of new antibiotics

Generating Antibiotic Incentives Now (GAIN) Act (2012)
• Extends exclusivity for antibiotics for serious/life-threatening infections by 5 years
• fast track, priority review and expedited regulatory approval process for included drugs
Pending AMR legislation

- Reinvigorating Antibiotic and Diagnostic Innovation (READI) Act (introduced 2015)
  - Tax credits for clinical testing of infectious disease products
Legislation [2]

• Reinvigorating Antibiotic and Diagnostic Innovation (READI) Act [pending re-introduction]
  • Tax credit for new antibiotics or antifungals for serious/life-threatening infection and rapid diagnostic tests
Animal bills

• Preventing Antibiotic Resistance Act of 2017 (S. 629)
  • Amend FDCA to preserve the effectiveness of medically important antimicrobials used to prevent, treat, control animal diseases

• Delivering Antimicrobial Transparency in Animals (DATA) Act (introduced 2015)
  • Increase reporting requirements for the use of antimicrobials in animals

• Preservation of Antibiotics for Medical Treatment Act (PAMTA) (introduced 2009, 11, 13, 15)
  • Require new animal drugs to demonstrate reasonable certainty of no harm to human health from AMR due to nontherapeutic use
FDA guidance on growth promoters

Guidance for Industry 213; Veterinary Feed Directive (Issued 2013; deadline for action, December 2016)

• Drug companies voluntarily commit to remove growth promotion on product labels
• Appropriate therapeutic use defined – for treatment, control and prevention
• Increased veterinary oversight
• Directives for medically important antibiotics in animal feeds
FDA guidance on growth promoters

• Progress (January 2017)
  • “All affected drug applications have either aligned with the recommendations outlined in GFI #213, or their approvals have been voluntarily withdrawn”
  • 93 applications intended for use in water converted from OTC to prescription
  • 115 applications intended for use in feed converted from OTC to veterinary feed directive
  • 31 (100%) growth promotion indications removed
  • Too soon to see impact on levels of use
Banning growth promoters: the European approach

• Sweden - first country to ban use of antibiotics as growth promoters in animal feed: 1986
• EU-wide ban: came into force in 2006 (passed in 2003)
• Results:
  • Some reductions in use (Netherlands, France, Italy)
  • Low-level use continues, masked as “prevention”/therapeutic use rather than growth promotion
FIGURE 3-3: Sales of active ingredients of antibiotics for food animals in selected European countries, 2005–2012

Source:
CDDEP 2015,
Elliot 2015
AMR: Local and Global

World Health Organization (2015)
• Every country to have NAP by May 2017

United Nations (2016)
• High-level GA session affirms WHO deadline

US Role?
For research, updates and tools on drug resistance and other global health topics, visit:

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Thank you!