

Antimicrobial resistance: Public policy implications

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Antimicrobial Resistance and One Health



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Legislation

21st Century Cures Act (2016)

- Expedites approval and use of new antibiotics

Generating Antibiotic Incentives Now (GAIN) Act (2012)

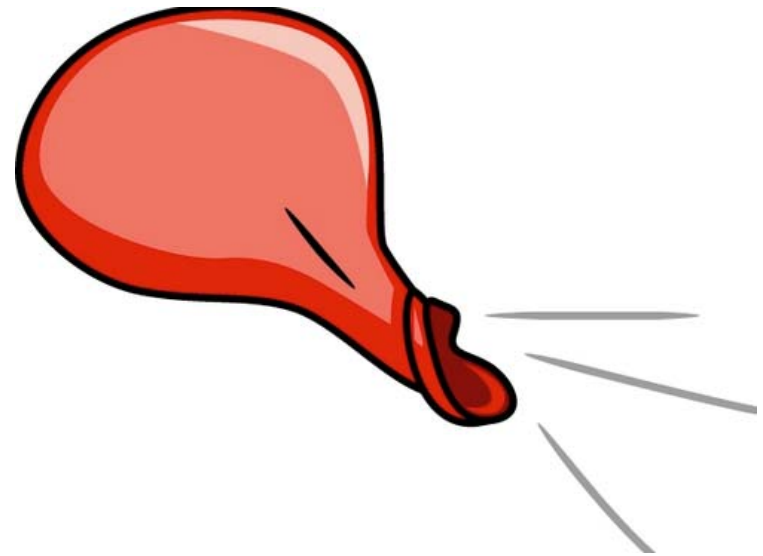
- Extends exclusivity for antibiotics for serious/life-threatening infections by 5 years
- fast track, priority review and expedited regulatory approval process for included drugs

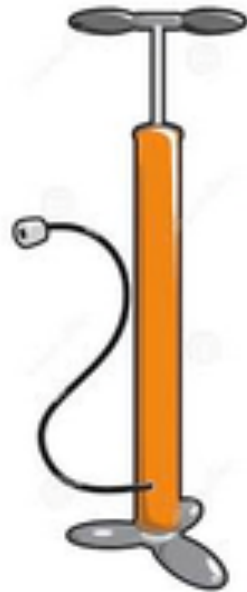
Pending AMR legislation

- Reinventing 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

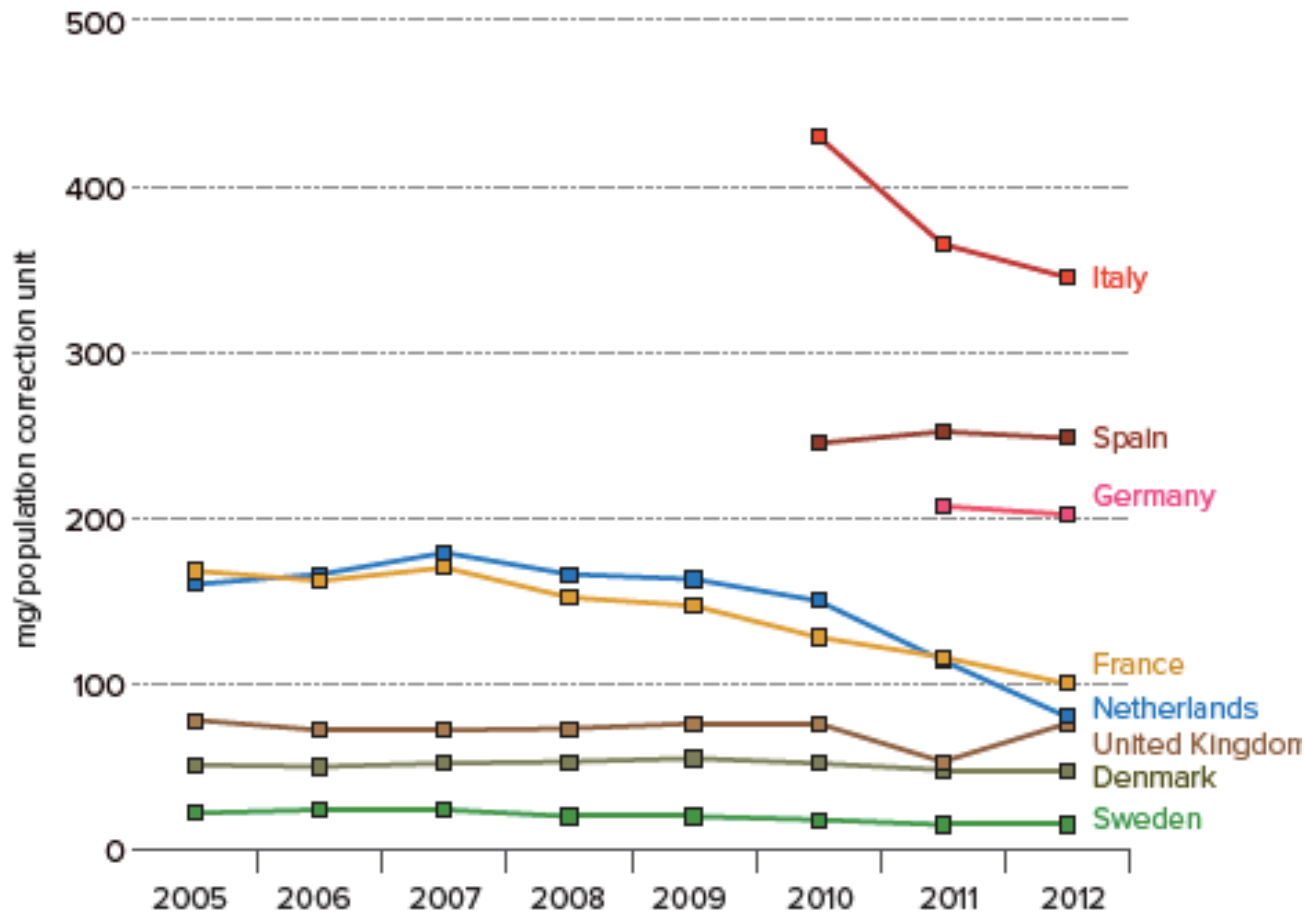


FIGURE 3-3: Sales of active ingredients of antibiotics for food animals in selected European countries, 2005–2012

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?

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Thank you!



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