

## Managing the Threat of Antimicrobial Resistance in Animal Health

Antimicrobial resistance (AMR) is a growing threat to public health across the globe, with detrimental implications for human and animal health.

Pressure has been mounting, led by regulators in Europe and the U.S., to promote more responsible use of antimicrobials. Specifically, there is pressure to limit the use of antimicrobials in animal health, putting at risk a foundational segment of today's animal health market.

In this *Executive Insights*, L.E.K. Consulting explores the evolving industry dynamics, draws out implications for the animal health industry and highlights opportunities for the industry to turn a trend primarily seen as a threat into a driver for growth.

Since their discovery in the first half of the 20th century, antimicrobial drugs have saved countless lives and transformed human and animal health. Antimicrobials (or more specifically antibiotics targeting bacterial infections) have turned deadly infections such as pneumonia or streptococcal meningitis into manageable illnesses, and have enabled major advances in surgery and the medical management of cancer — advances that would be unthinkable if we did not have the ability to protect patients from bacterial infections. The use of antimicrobial drugs improves

the health and welfare of humans and animals alike, driving an approximately \$47 billion<sup>1</sup> global market<sup>2,3</sup> — but their widespread use contributes to the growing threat of antimicrobial resistance.

A confluence of factors associated with antimicrobial resistance in the food chain is creating significant headwinds for pharmaceutical players in the animal health industry. These companies generate more than \$3 billion annually from antimicrobial sales, representing approximately 15% of global animal health drug sales.<sup>1</sup>

### Antimicrobial Resistance: A Growing Threat

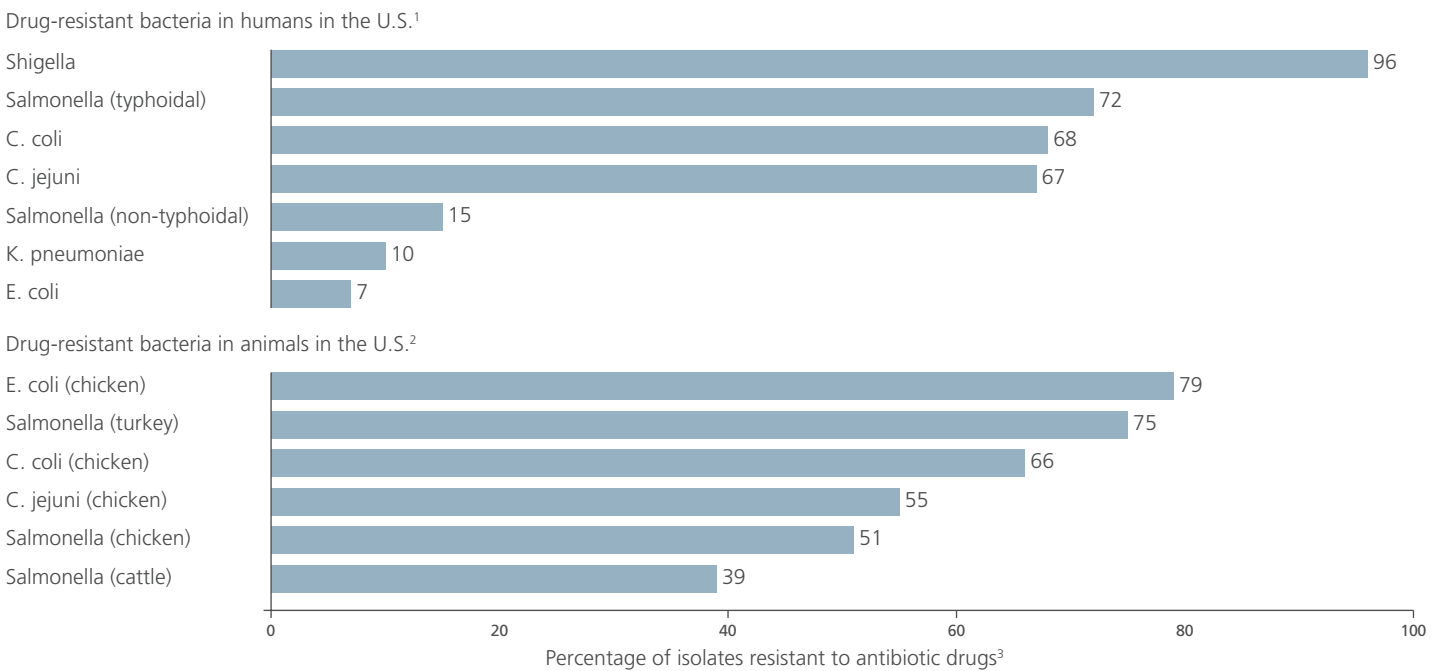
The widespread use of antimicrobial drugs has contributed to bacterial strain selection and the evolution of an increasing number of drug-resistant bacteria species (see Figure 1), creating such global challenges as:

- Approximately 700,000 human deaths are caused globally each year by antimicrobial-resistant microorganisms<sup>4</sup>
- Complications associated with the use of antibiotics, such as the 250,000 cases of *Clostridium difficile* observed in U.S. hospitalized patients, drive incremental healthcare costs of approximately \$20 billion to \$35 billion in economic losses<sup>5</sup>
- In animal health and agriculture, a documented trend toward greater resistance suggests that the benefit of using antibiotics for therapeutic and preventive purposes is increasingly offset by the gradual loss of efficacy

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Figure 1  
Levels of Antimicrobial Resistance in Humans and Animals



Note: <sup>1</sup>2011; <sup>2</sup>2010; <sup>3</sup>Resistant to at least one antibiotic  
Source: MMWR, NARMS, L.E.K analysis

## AMR in Humans and Animals: One Health

Although the extent and causes of AMR are increasingly understood, the solutions required to stem the tide of AMR are complex, and a concerted effort among all users of antimicrobial drugs will be needed.

- Risks associated with the concurrent use of many antibiotics in animals and humans (see Figure 2) are driving public expectations for animal health to help stem the tide of AMR
- A “One Health” approach, which has been successful in managing the threat from zoonotic diseases, is viewed as critical in solving the AMR problem
- Antimicrobial stewardship has emerged as a unifying approach to fight AMR in animal and human health and is focused on:
  - Reducing the incidence of bacterial infections through preventative measures
  - Averting and monitoring the spread of resistant bacteria

- Improving the use of antibiotics by leveraging information that can enable more effective and responsible use of antibiotics
- Promoting the development of innovative diagnostic tests and antibiotics to improve the management of bacterial infections

Key pharmaceutical players in animal health are already supporting the cause through changes in product labels, voluntary product withdrawals and responsible use programs. However, driven by public concerns, the pressure to further restrict the use of antimicrobials in animal and human health is expected to increase.

## Policy response and market pressures

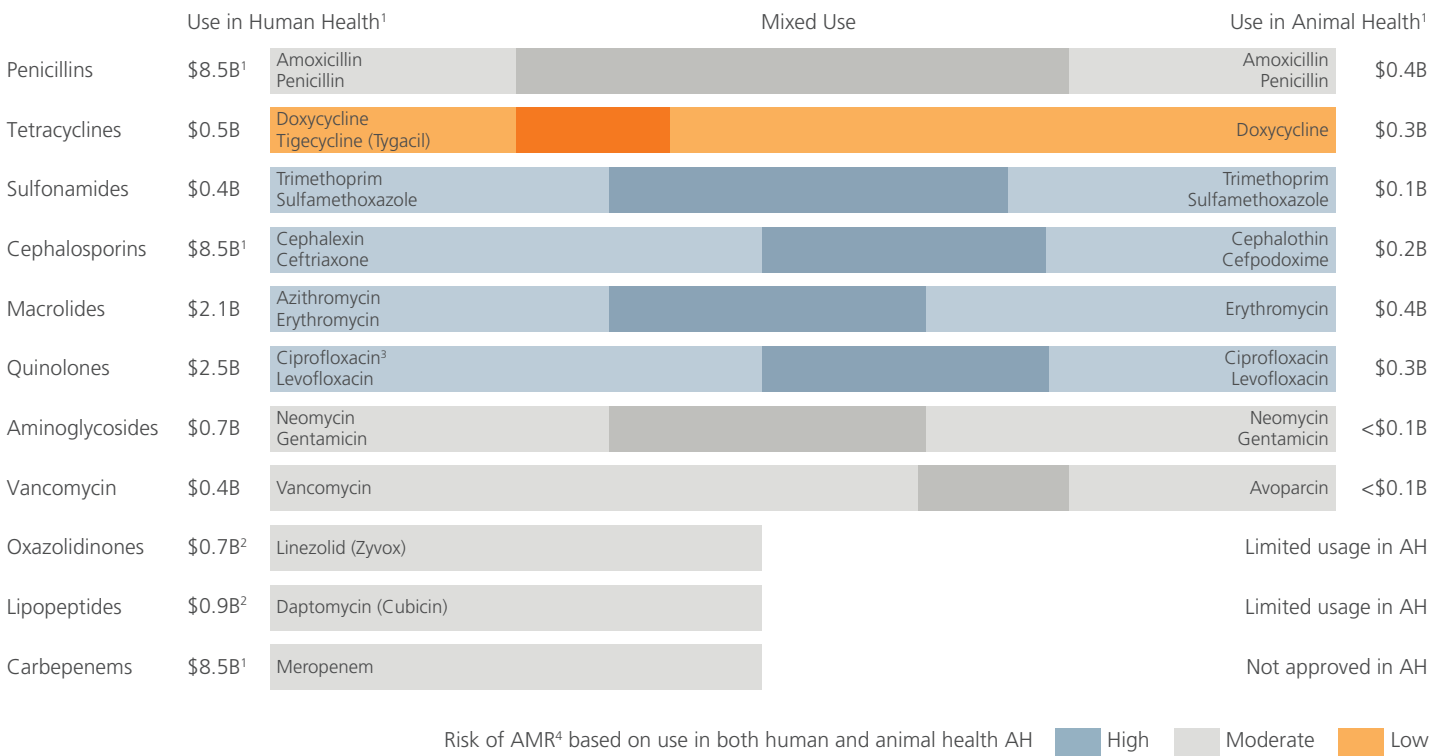
The global dimensions of AMR prompted the World Health Organization, in a 2014 surveillance report, to label AMR a global health security threat,<sup>6</sup> further supporting global policy pressure on the use of antimicrobial drugs. Related policy initiatives include an EU ban on the use of antimicrobial growth promoters in livestock, broad policy recommendations from the Review on

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Figure 2

## Risks Associated With Concurrent Use of Antibiotics in Animals and Humans

Overlapping use of antimicrobial classes in human and animal health can add to the potential risk of antimicrobial resistance



Note: Sales reflects 2013 U.S. only. Antibiotic examples are representative and not exhaustive. <sup>1</sup>Reflects usage of B-lactams, which includes penicillin, cephalosporins and carbapenems; <sup>2</sup>Reflects sales of branded; <sup>3</sup>Nalidixic acid is considered low risk, while ciprofloxacin is considered high risk; <sup>4</sup>Risk reflects drug is associated with food-borne disease and key therapy for human disease (High=Both, Moderate=Either). Low are those drugs for non-food-borne disease, no cross-resistance within class or limited transmission across species.

Source: FDA, EvaluatePharma, Global Markets, WHO, L.E.K. analysis

Antimicrobial Resistance in the EU, a presidential executive order in the U.S., and select U.S. states (including California) considering or passing legislation banning antimicrobials for growth promotion in livestock.

Adding to the policy issues, consumers are increasingly exerting pressure to curb the use of antibiotics both through direct lobbying and the growing trend toward antibiotic-free organic meat, poultry and dairy products.

- Organic foods and beverages, which typically ban the use of antibiotics, now make up 5%-10% of the \$750 billion U.S. market for nutrition, and that market is growing much faster than is the market for conventional foods.
- The same trend toward organic foods is unfolding in other Western markets, where controls on antimicrobial use for

organic foods may be even stricter. Growing consumer awareness in an increasingly global food-supply chain is likely to raise public concern and pressure beyond the EU and U.S. as well.

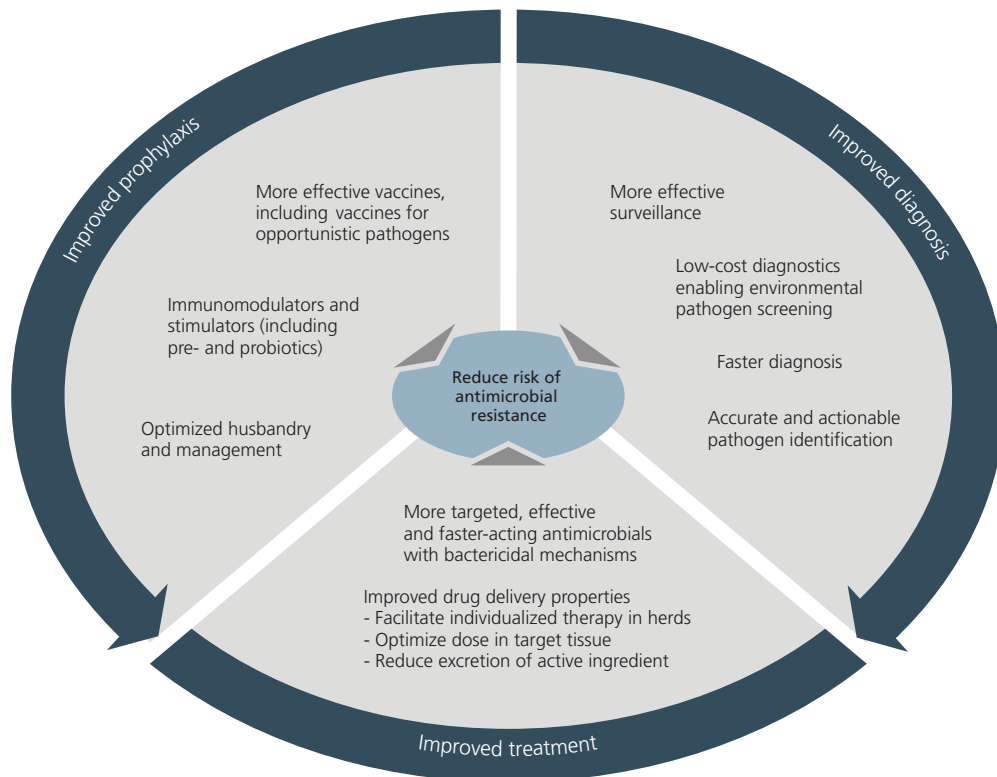
A case in point: Some of the largest global restaurant chains, including McDonald's and Subway, are planning in the near future to stop selling meats produced using antibiotics.

### Strategic implications for animal health

The trends outlined above are challenging the animal health industry to provide solutions that support animal health and welfare and also create attractive shareholder returns in an increasingly uncertain environment.

Figure 3  
Antimicrobial Innovation

Themes and trends in antimicrobial innovation with the potential to reduce the risk of antimicrobial resistance in humans and animals



Source: L.E.K. analysis

As a result, animal health companies will need to critically evaluate their product portfolios and business models and adjust to adopt strategies that prepare their franchises for the new realities in infectious diseases. Based on our experience, we see two key strategic imperatives:

**Understand the opportunities.** For animal health companies willing to adapt, opportunities abound to provide new solutions that get to the heart of the AMR issue. Those opportunities range from rapid diagnostic tools (to ensure more targeted use of existing antibiotics) to greater use of non-antibiotic strategies to control infectious diseases (e.g., targeted vaccines, immunostimulators and non-antibiotic growth promoters) and continued investment in new antibiotics that can treat the most serious infections and that have the potential to drive material growth and competitive differentiation. The required technology to develop these innovative solutions is becoming more available,

as illustrated by the emerging themes in Figure 3. However, their current use in animal health is still limited, highlighting significant opportunities for players willing to take the first steps. The relevant technologies have the potential to drive significant value for end users through better disease control and improved animal welfare and productivity, plus the potential to command value-based pricing, de-risk the business in the face of regulatory changes, and ultimately achieve solid sustainable returns for animal health companies willing to make the required investments.

**Shape the thinking.** Another important strategic imperative is shaping the environment through demonstrated leadership in antimicrobial stewardship and a broader implementation of more appropriate use. Such strategies may include proactively engaging the public, actively participating in the industrywide discourse in order to shape policy, collaborating with all other relevant

# Executive Insights

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stakeholders (e.g., regulators) and everything in between. These partnerships should focus on creating better tools to effectively monitor the use of antimicrobials and the prevalence of antibiotic resistance (e.g., enhanced reporting), resulting in valuable insights for the industry as a whole with the goal of improving surveillance, disease management strategies and animal health outcomes.

## Conclusion

Creating superior value in a rapidly changing market will require a strong understanding of the evolving landscape, allowing players to focus on the best value-creation opportunities for their specific business context and needs.

The optimal path to success will look different for each company. However, all manufacturers with animal health businesses need to consider the dynamics discussed above in the context of the relevant antimicrobials business/franchise (e.g., product, technology, species and regional focus), their evolving capabilities (e.g., commercial, technical and R&D) and the overall strategic goals of the business.

In our experience, a systematic approach consisting of three key steps can help define the optimal path forward for animal health companies and create superior value. Those steps are:

- Fully understand the critical trends that define the quickly evolving antimicrobials landscape specific to their business, and the expected impact of these trends over time
- Map out and prioritize potential strategic opportunities across key antimicrobial market segments
- Define an integrated strategy focused on building sustainable leadership positions

This proactive approach can turn the threat of AMR within animal health into an opportunity to positively impact a major, growing public health threat, as well as an opportunity to drive sustainable growth and competitive advantage.

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<sup>1</sup>\$3.3B for animal health and \$43.6B for human health.

<sup>2</sup>Markets and Markets, "Animal Antimicrobials and Antibiotics Market Forecast to 2018," 2014.

<sup>3</sup>Transparency market research, 2014 in 2013.

<sup>4</sup>OECD, "Antimicrobial Resistance in G7 Countries and Beyond," 2015.

<sup>5</sup>CDC, "Antimicrobial Resistance Threats in the U.S.," 2013.

<sup>6</sup>WHO, "Antimicrobial Resistance — Global Report on Surveillance," 2014.

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## About the Authors



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