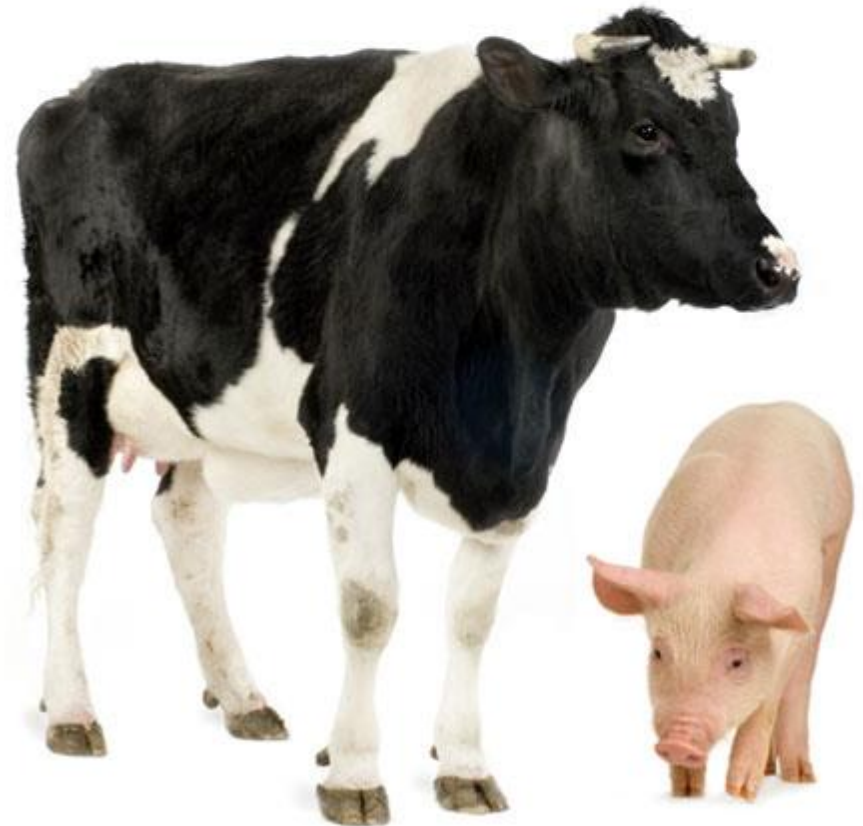


Farm Animal Antibiotics Market 2020-2035

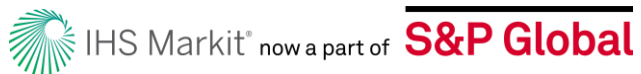
Animal Health Market Analysis



Animal Health | Special Report

Farm Animal Antibiotics Market 2020-2035

Animal Health Market Analysis



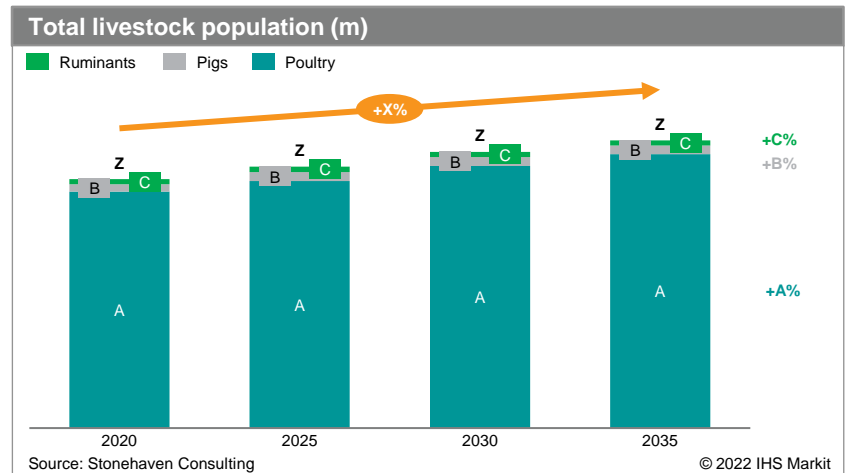
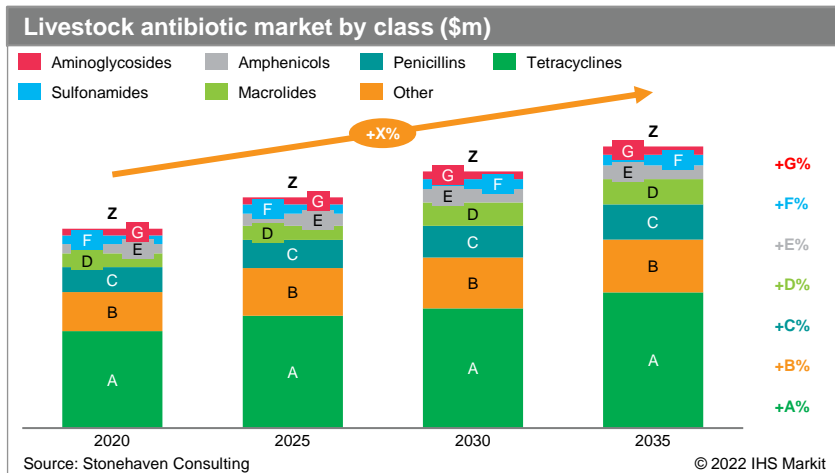
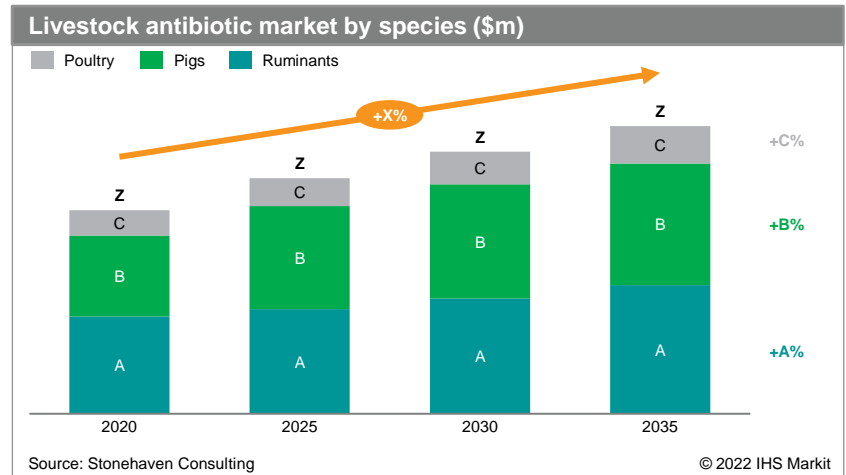
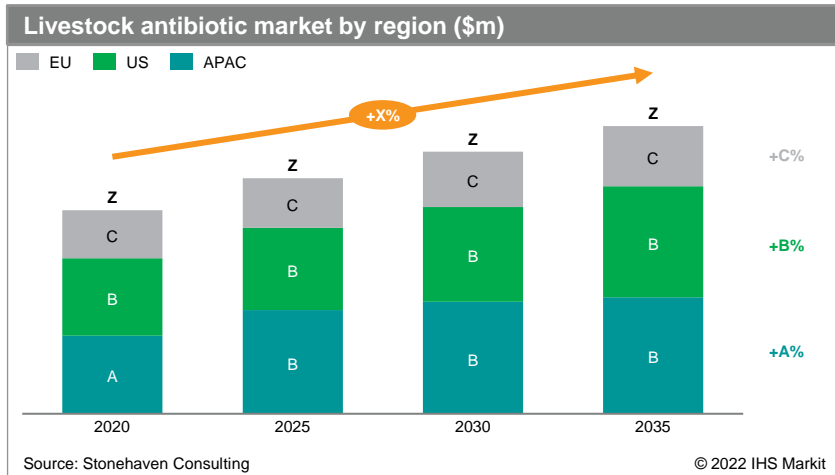
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Chapter 1: Executive Summary

Livestock Antibiotic Market (1/2)

Modest growth in populations and shifting treatment regimes hold off decline in a genericized market



Livestock Antibiotic Market (2/2)

Market 'status quo' belies the challenge ahead on coordinated modeling and treatment resilience

Tightening regulatory landscape

- The increasing concern of cross-species antimicrobial resistance has led to concerted global action towards tightening regulations, also for veterinary antibiotics
- Europe is the region with the earliest adoption of new antibiotic categorizations. The region has now defined the first list of drug classes reserved strictly for human use, among other restrictions
- While approved veterinary drug classes have been listed in the reserved class so far, the stricter regulations will continue to have an impact in antibiotic usage, also in other geographic regions over the outlook period

Improvements to standard of care rely on 'smarter' data and more rapid diagnostic results

- There are three established global players with one clear leader (XXX), many generic players and limited investment
- Signs of waning efficacy, tighter regulations and limited investments increase the need for alternative treatment technologies, prevention and improvements in animal nutrition
- More rapid diagnostic results, as well as higher global collaboration for consistent data capture and drug resistance modeling, could bring substantial benefits to today's standard of care

Livestock production under price (and other) pressure

- The livestock market faces increasing costs through inflationary pressure, health management and eventually environmental change. Populations remain stable, with declining trends in parts of Europe balancing a slight rebound in Asia
- The growth of antibiotic-free animal protein production will be constrained by erosion of the consumer's purchasing power at the beginning of the outlook period
- The antibiotic market remains flat in real terms, with volume declines offset by increased dose efficacy requirements and pricing opportunities from drug class substitutions

Interdependency with human health could increase urgency for the category

- The rate of pathogen emergence could be faster than ever before in the decades ahead, through reduced biodiversity and an increasing likelihood of animal-human transmissions
- Antibiotic usage decline is a short-term symptom of a longer-term challenge. The need for new antibiotics or alternative treatment technologies could become more urgent than ever before, but the topic seems to be 'below the radar' for now

Chapter 2: Regulatory Landscape

Regulations for Antibiotics Use (1/2)

A tightening landscape driven by the concern for cross-species antimicrobial resistance

Overall

The registration of antibiotics for veterinary use is generally overseen by a country's animal health pharmaceutical regulatory authority and, in some cases, only by a supra-regional regulatory authority.

« *More information on regulations for antibiotics use* »

« *More information on regulations for antibiotics use* »

Regulations for Antibiotics Use (2/2)

A tightening landscape driven by the concern for cross-species antimicrobial resistance

Harmonization of use requirements through international trade

As a general rule, livestock products are a global trade commodity. In a highly simplified view, the animal is often raised and slaughtered in one country, then shipped to another geography for human consumption.

« **More information on regulations for antibiotics use** »

Increasingly, producers in exporting countries align their medicine usage to the regulatory requirements of their final destination.

« **More information on regulations for antibiotics use** »

Antimicrobial Resistance Management (1/4)

A global priority

Global institutions led by the World Health Organization (WHO), alongside the Food and Agriculture Organization of the United Nations (FAO) and the World Organization for Animal Health (WOAH) focus on the concept of One Health.

« *More information on antimicrobial resistance management* »

« *More information on antimicrobial resistance management* »

Antimicrobial Resistance Management (2/4)

The EU case

Stricter, narrower use labels due to the AMR cascade

Regulatory agencies have gone on to adopt the WHO categorization and made their own categorization recommendations and legislation.

« **More information on antimicrobial resistance management** »

Important terms in EU regulations 2019/06 and 2019/04

The four European antibiotics categories listed:

Category A – xxx

Category B – xxx

Category C – xxx

Category D – xxx

« **More information on important terms** »

Antimicrobial Resistance Management (3/4)

Global implications of tighter regulations

« **Information on global implications of tighter regulations** »

New product development considerations

The antibiotics that are most likely to receive regulatory approval in the future are those from classes considered to be of low importance in human medicine, or that are unrelated to any medically important antibiotic.

« **More information on new product development consideration** »

Existing product lifecycle management

For licensed veterinary antibiotics where field and pharmacovigilance data demonstrate waning levels of efficacy, pharmaceutical companies might be asked to review the amount of active pharmaceutical ingredient (API) in their current product formulations upwards, with relevant supportive data.

« **More information on existing product lifecycle management** »

Antimicrobial Resistance Management (4/4)

Opportunities and open questions

The opportunity to improve antibiotic treatment record systems

« **Information on opportunity to improve treatment record systems** »

Reserved class veterinary antibiotics

With no new significant veterinary antibiotic launches in sight, the concept of 'reserve' antibiotics specific for use in veterinary medicine seems limited.

« **More information on reserved class veterinary antibiotics** »

Proactive veterinary antibiotic resistance modeling would benefit all

The question of resistance management in veterinary medicine is not exclusive to antibiotics.

« **More information on proactive veterinary antibiotic modelling** »

Regulatory Landscape by Region (1/2)

US

The CVM, under the US FDA, provides regulatory approval for veterinary medicines. The Minor Use /Minor Species act (2004) qualifies veterinary candidates for development incentives.

« ***More information on regulatory landscape in the US*** »

Europe

The Committee for Medical Products for Veterinary Use (CVMP), operating under the European Medicines Agency (EMA), regulates veterinary pharmaceuticals.

« ***More information on regulatory landscape in Europe*** »

Regulatory Landscape by Region (2/2)

Asia Pacific | Latin America

In China, the development and marketing approval of veterinary pharmaceuticals is governed by China's NMPA. NMPA regulations are highly stringent when compared against other Asia Pacific countries.

« ***More information on regulatory landscape in Asia Pacific / Latin America*** »

Top Antibiotics by Class and Regulatory Classification

Class	Company	Molecule Name	Brand Names ¹	Species			AMEG Category ²	Shared with Humans
				Cattle	Swine	Poultry		
Aminoglycoside	Company 1	Molecule 1	Brand 1	Y/N	Y/N	Y/N	X	Y/N
	Company 2	Molecule 2	Brand 2	Y/N	Y/N	Y/N	X	Y/N
Cephalosporin	Company 1	Molecule 3	Brand 3	Y/N	Y/N	Y/N	X	Y/N
	Company 2	Molecule 4	Brand 4	Y/N	Y/N	Y/N	X	Y/N
Fluoroquinolone	Company 1	Molecule 5	Brand 5	Y/N	Y/N	Y/N	X	Y/N
	Company 2	Molecule 6	Brand 6	Y/N	Y/N	Y/N	X	Y/N
	Company 3	Molecule 7	Brand 7	Y/N	Y/N	Y/N	X	Y/N
Lincosamide	Company 1	Molecule 8	Brand 8	Y/N	Y/N	Y/N	X	Y/N
Macrolide	Company 1	Molecule 9	Brand 9	Y/N	Y/N	Y/N	X	Y/N
	Company 2	Molecule 10	Brand 10	Y/N	Y/N	Y/N	X	Y/N
	Company 3	Molecule 11	Brand 11	Y/N	Y/N	Y/N	X	Y/N
Penicillin	Company 1	Molecule 12	Brand 12	Y/N	Y/N	Y/N	X	Y/N
	Company 2	Molecule 13	Brand 13	Y/N	Y/N	Y/N	X	Y/N
	Company 3	Molecule 14	Brand 14	Y/N	Y/N	Y/N	X	Y/N
Pleuromutilin	Company 1	Molecule 15	Brand 15	Y/N	Y/N	Y/N	X	Y/N
Tetracycline	Company 1	Molecule 16	Brand 16	Y/N	Y/N	Y/N	X	Y/N
	Company 2	Molecule 17	Brand 17	Y/N	Y/N	Y/N	X	Y/N
	Company 3	Molecule 18	Brand 18	Y/N	Y/N	Y/N	X	Y/N

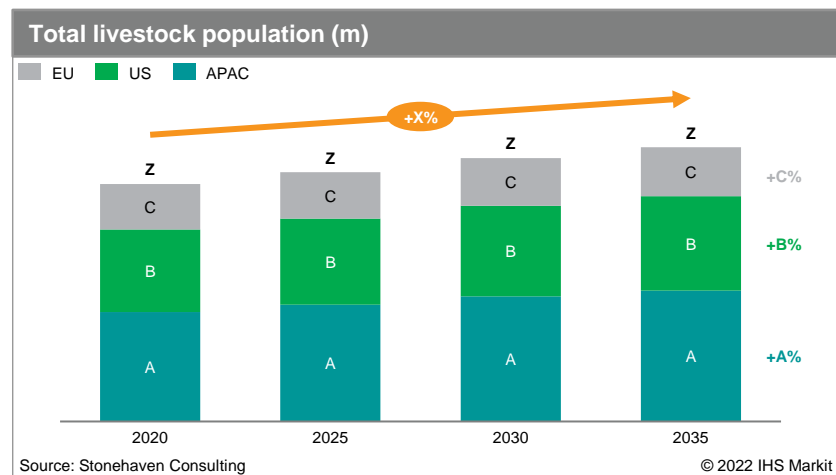
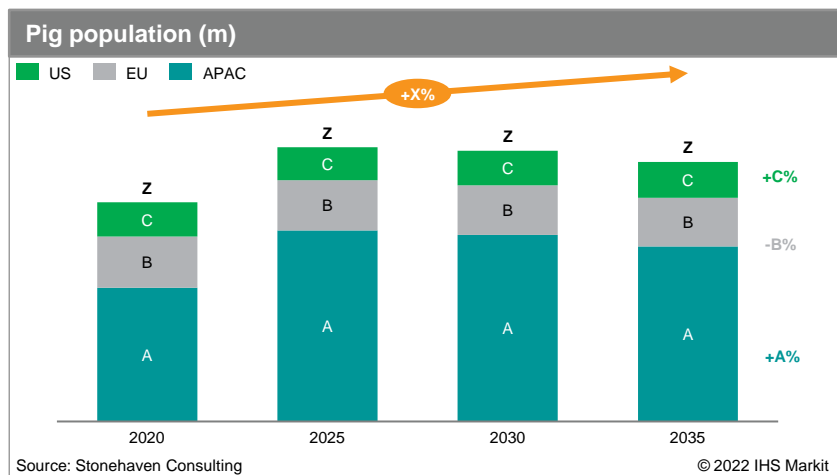
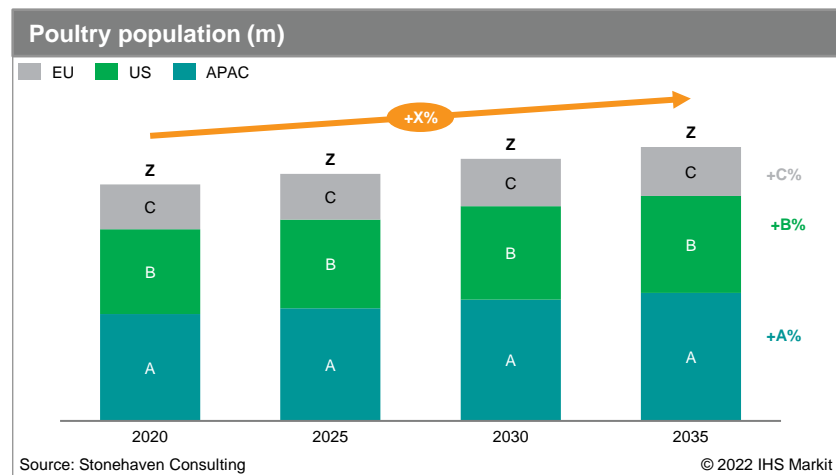
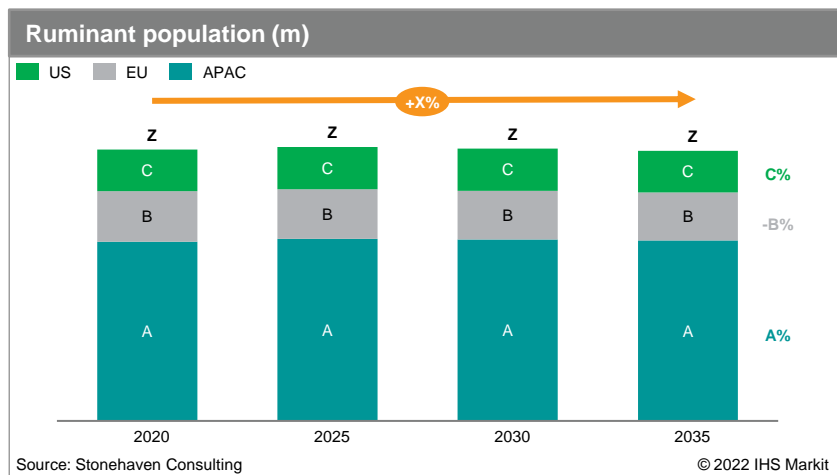
1. Reference products, generic versions not listed

2. AMEG: Antimicrobial Expert Group; composed of representatives and experts from various European Commission groups

Chapter 3: Market

Livestock Populations (1/2)

Flat to low single-digit population growth over the outlook period



Livestock Populations (2/2)

A stable industry with potentially rising production costs

Ruminants

The ruminant population is expected to remain flat globally in the outlook period.

« **More information on ruminant population** »

Pigs and poultry

The swine and poultry populations will experience low single-digit growth until 2035.

« **More information on pig and poultry population** »

Growth drivers

« **Information on growth drivers** »

Key inhibitors

Production input constraints will drive higher production costs.

« **More information on key inhibitors** »

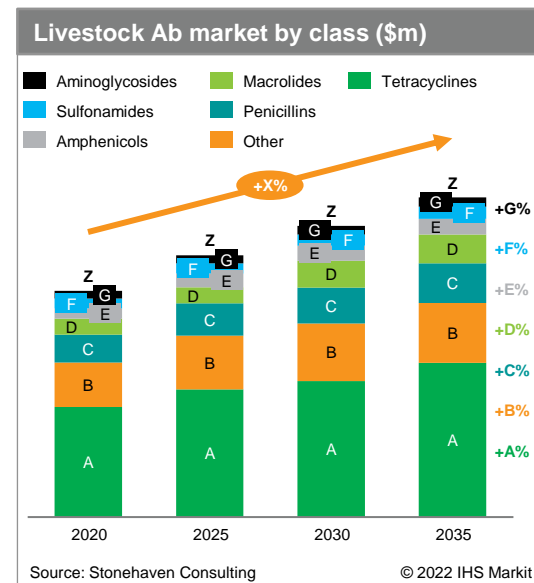
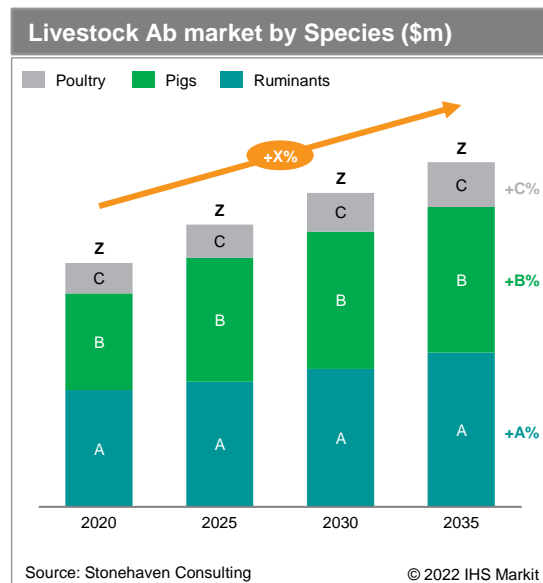
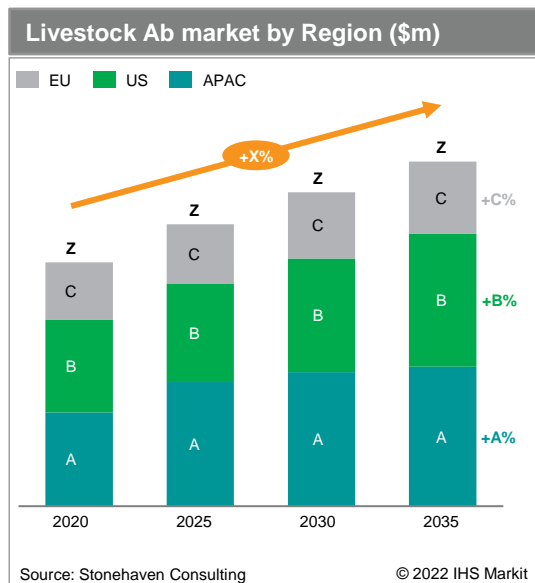
Livestock Antibiotics Market

Low nominal growth reflects stable populations and inflationary pressure

Overall

The livestock antibiotics (Ab) market will experience low single-digit nominal growth in outlook period.

« **More information on overall livestock antibiotics market** »



Estimated Volume of Active Ingredient Sold

Minor treatment cost increases expected despite high genericization

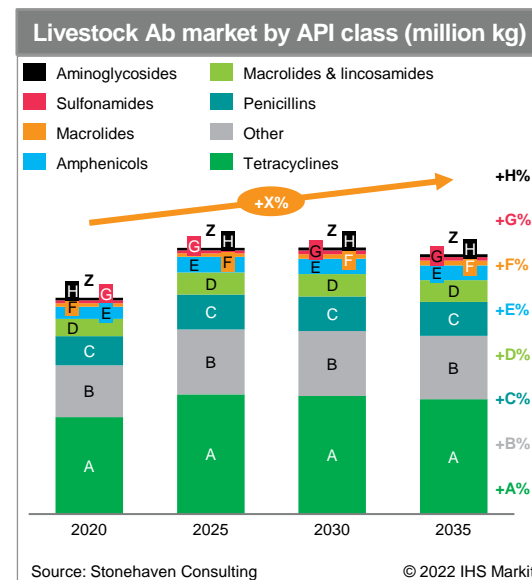
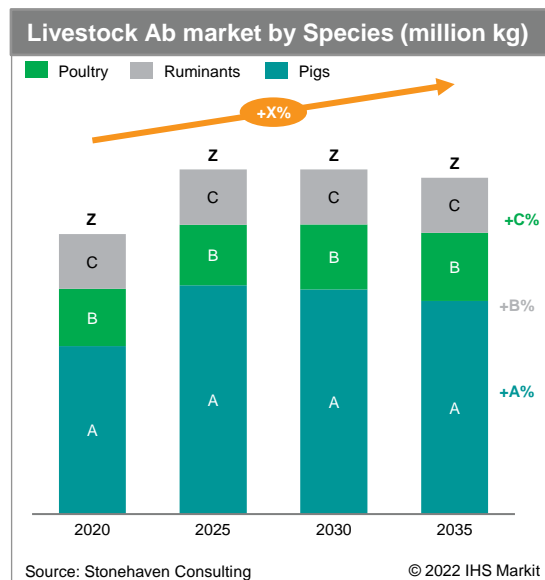
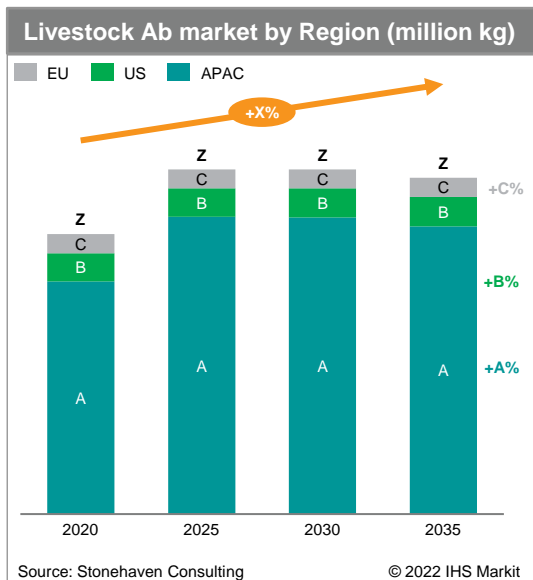
Volume drivers

Estimated change in volume of active ingredient sold primarily driven by livestock population growth.

Treatment cost drivers

In addition to the inflationary pressure previously mentioned, and with most antibiotics facing high genericization already, treatment cost increases are driven primarily by:

« **More information on treatment cost drivers** »

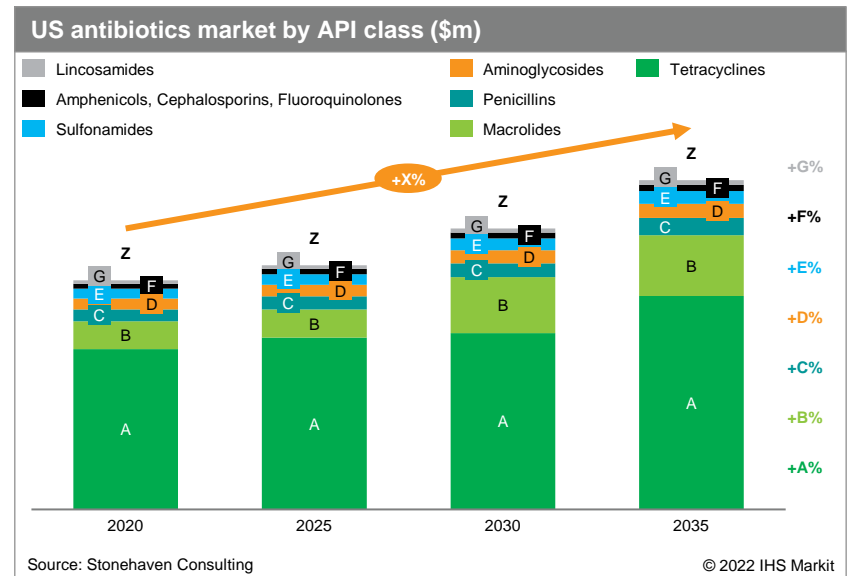
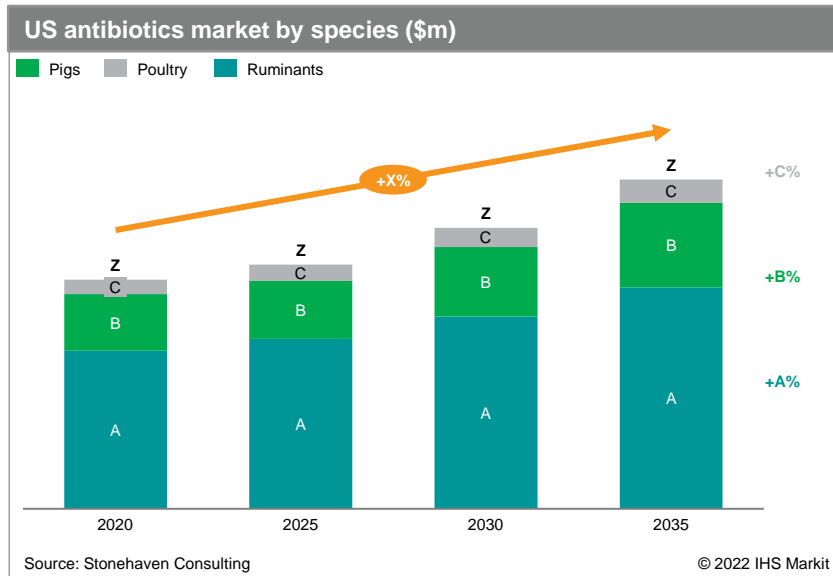


Chapter 4: Market by Region

US Market Size and Growth

The US livestock antibiotics market is expected to reach approximately \$X billion by 2035, with poultry as the only species with a nominal growth rate above X%.

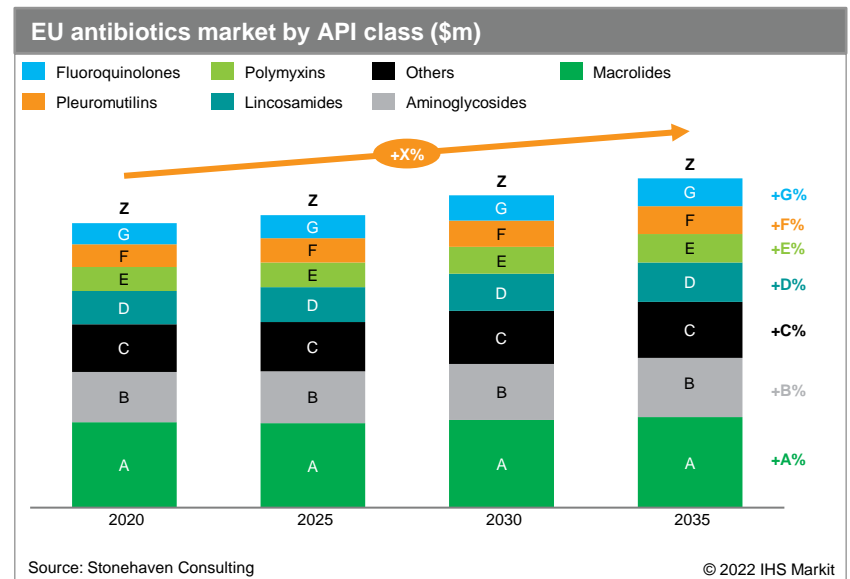
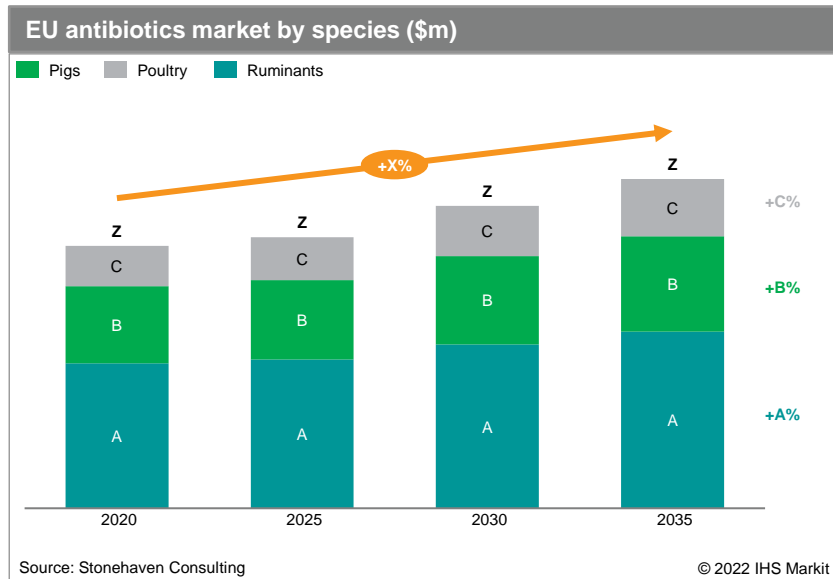
« **More information on the US market size and growth** »



EU Market Size and Growth

The EU livestock antibiotics market is expected to reach approximately \$X billion by 2035, with poultry as the only species with real growth.

« *More information on the EU market size and growth* »



APAC Market Size and Growth

Overall

The livestock antibiotics (Ab) market is expected to grow approximately \$XX million over the outlook period.

« **More information on APAC market size and growth** »

China

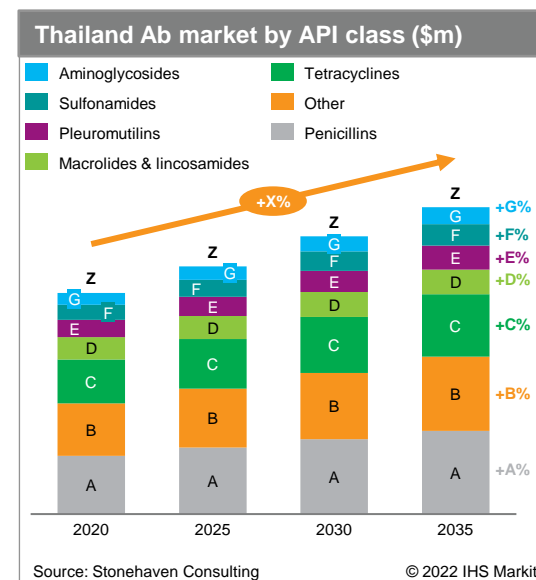
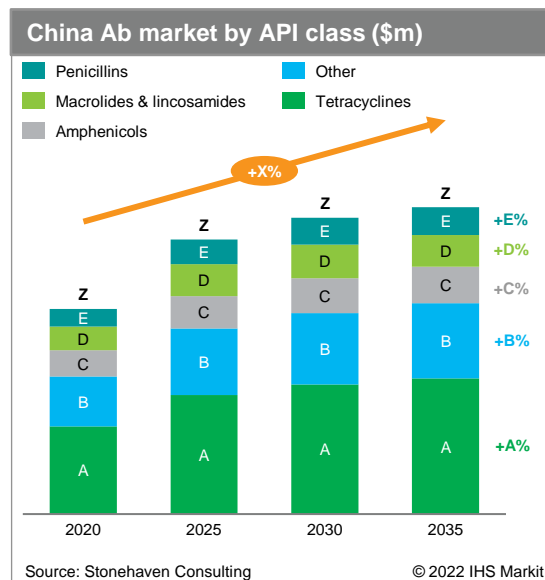
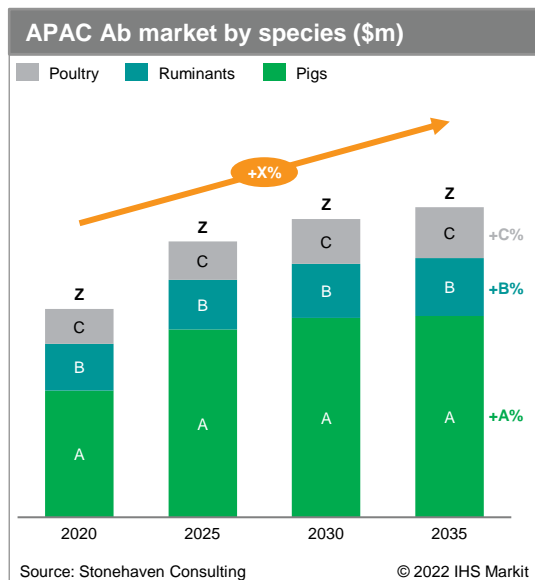
The leading market by value in the region, China, continues to experience price erosion across all drug classes.

« **More information on China market size and growth** »

Thailand

The Thai livestock antibiotics market grows just ahead of inflation by \$XX million between 2020 and 2035.

« **More information on Thailand market size and growth** »



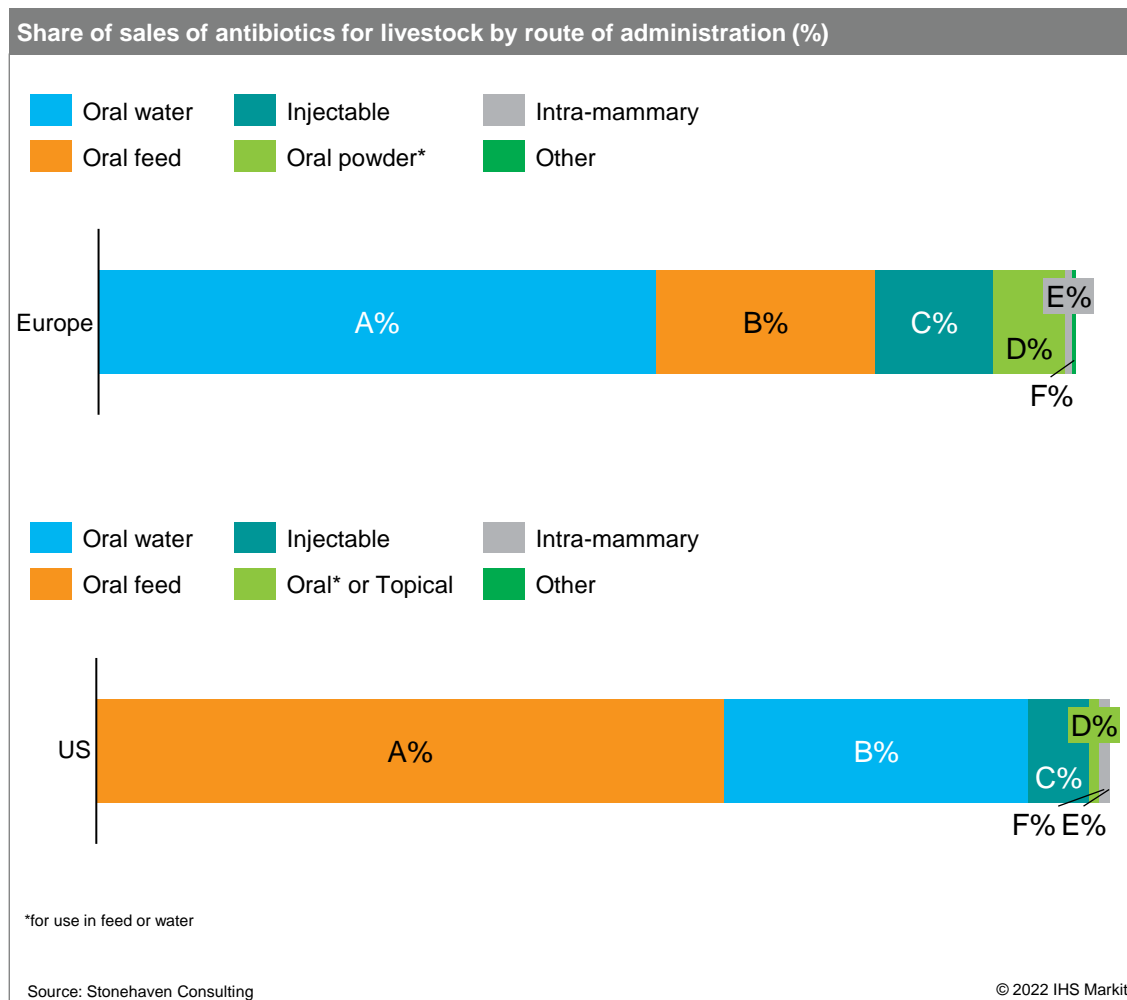
Chapter 5: Standard of Care

Antibiotics Current Standard of Care (1/3)

Traditionally split into two core needs

The current standard of care encompasses three main product categories: oral formulations for in-feed use, water-soluble formulations and injectables.

« **More information on core needs** »



Antibiotics Current Standard of Care (2/3)

Experts reported that in China, oral formulations make up the largest share of the prescriptions, except where certain combinations of drug classes and species are best served by injectables. For example, cephalosporins in swine or penicillins and macrolides in cattle.

« *More information on veterinarian point of view* »

From the veterinarian's point of view (customer voice)

« *Information on veterinarian point of view* »



Due to reporting differences, obtaining a consistent global overview of antibiotic usage per species, indication and route of administration remains a challenge in the livestock sector.

Antibiotics Current Standard of Care (3/3)

Important organisms for which antibiotic therapies required

Important organisms per disease area and livestock species					
	Ruminants		Pigs		Poultry
Respiratory	Organism 1 Organism 2 Organism 3	Respiratory	Organism 1 Organism 2 Organism 3 Organism 4	Respiratory	<i>Mycoplasma</i> <i>Escherichia coli</i>
Enteric	Organism 1 Organism 2	Enteric	Organism 1 Organism 2	Enteric	<i>Clostridium perfringens</i>
Mastitis	Organism 1 Organism 2	CNS	Organism 1		
Lameness	Organism 1 Organism 2				

Additional insights based on the expert interviews conducted for this report:

« **Information on antibiotics current standard of care – based on expert interviews** »

Standard of Care Outlook and Unmet Needs

A standard of care in a volatile transition period

It is possible to produce livestock virtually antibiotic-free. This could be one of the possible scenarios equated for the future standard of care.

« **More information on standard of care outlook and unmet needs** »

Traceability for all, not just the few

There is a need for more active research in the treatment space, including new drug class treatments, alternative treatment technologies with limited potential for resistance and more effective management of antibiotic classes available.

« **More information on standard of care outlook and unmet needs** »

Chapter 6: Competition and Innovation

Top Antibiotics by API Class

XXX is a leader across nearly every API class, followed by YYY

Rank ¹	Class	Company	Molecule Name	Brand Names
X	Aminoglycoside	Company 1	Molecule 1	Brand 1
X		Company 2	Molecule 2	Brand 2
X	Cephalosporin	Company 1	Molecule 3	Brand 3
X		Company 2	Molecule 4	Brand 4
X	Fluoroquinolone	Company 1	Molecule 5	Brand 5
X		Company 2	Molecule 6	Brand 6
X		Company 3	Molecule 7	Brand 7
X	Lincosamide	Company 1	Molecule 8	Brand 8
X	Macrolide	Company 1	Molecule 9	Brand 9
X		Company 2	Molecule 10	Brand 10
X		Company 3	Molecule 11	Brand 11
X	Penicillin	Company 1	Molecule 12	Brand 12
X		Company 2	Molecule 13	Brand 13
X		Company 3	Molecule 14	Brand 14
X	Pleuromutilin	Company 1	Molecule 15	Brand 15
X	Tetracycline	Company 1	Molecule 16	Brand 16
X		Company 2	Molecule 17	Brand 17
X		Company 3	Molecule 18	Brand 18

1. Top antibiotics in terms of sales per API class

Antibiotics Competitive Landscape

Global players defend mature brands in a highly competitive generic landscape

Global players

The antibiotic market measured by value is strongly led by XXX with a significant distance to the remaining top three players – YYY and ZZZ.

« **More information about global players** »

Generics companies

There are many local or regional generics companies providing cheaper alternatives to off-patent products. « **More information about generic companies** »

Companies	Geography	Portfolio
Company 1	XX XX	XX XX
Company 2	XX XX	XX XX
Company 3	XX XX	XX XX
Company 4	XX XX	XX XX
Company 5	XX XX	XX XX

Top Players and Their Portfolios

Steady revenue decline and limited innovation potential in category

XXX (category leader)

- Core products in this category include AAA injectable line, BBB, CCC and DDD. The total sales value of antibacterials and medical feed additives for livestock was \$X billion in 2021.

« **More information about category leader** »

YYY (#2 player)

- Core products in category include AAA, BBB, CCC and DDD. These are shared-class antibiotics in YYY's portfolio and have no outstanding patent protection

« **More information about #2 player** »

ZZZ (#3 player)

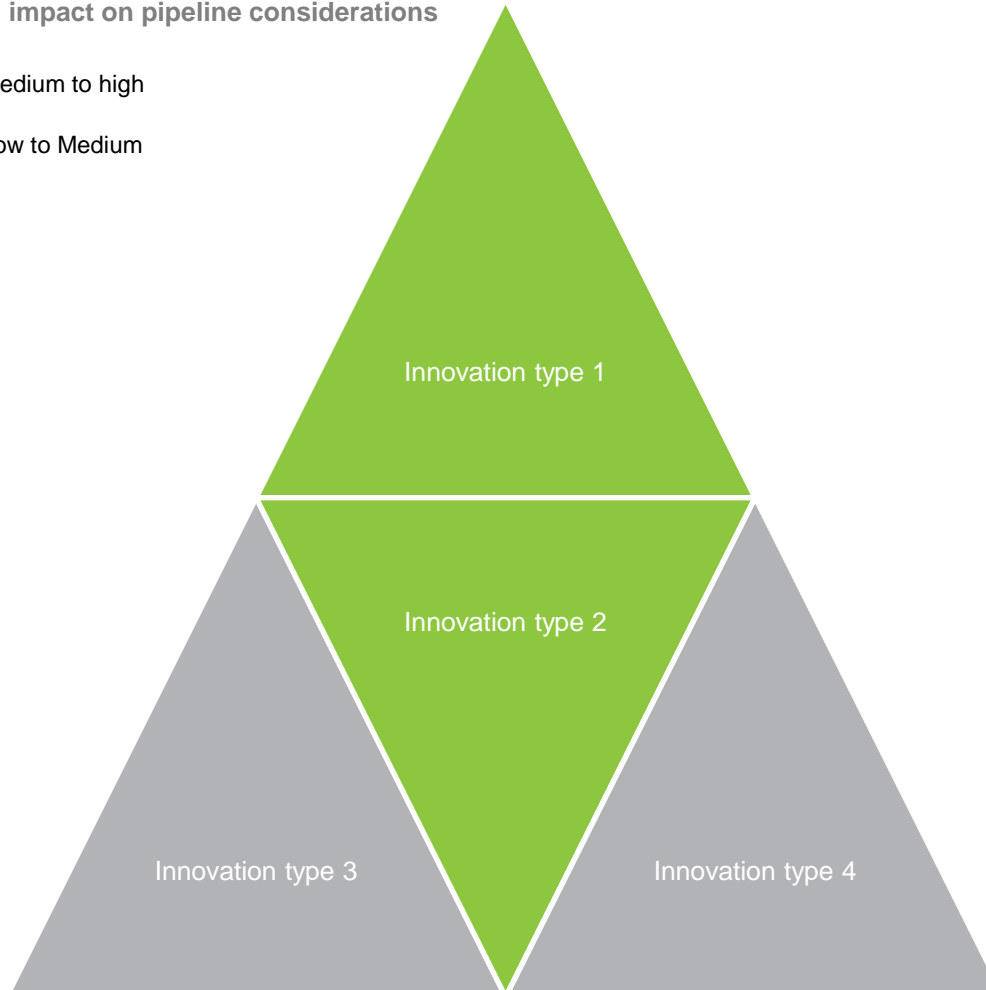
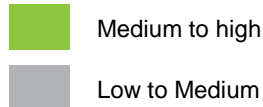
- Products in category include AAA, BBB, CCC and DDD

« **More information about #3 player** »

Innovation (1/2)

Conceptual overview of core unmet needs and pipeline impact in category

Estimated impact on pipeline considerations



Active companies in the unmet needs space

In the absence of significant treatment pipelines, we present a condensed overview of selected projects and companies active in the unmet needs space for the category in the next slide.

The availability of one or more of the following could yet lead to review of global players' decisions in the category:

« **More information on Innovation** »

Innovation (2/2)

Innovation happens mostly in the alternative spaces to antibiotics, with limited short-term impact

Non-antibiotic treatments	Gastrointestinal microflora (microbiome) improvement	Diagnostics
<p>Example 1 « <i>Explanation</i> »</p>	<p>Example « <i>Explanation</i> »</p>	<p>Example 1 « <i>Explanation</i> »</p>
<p>Example 2 « <i>Explanation</i> »</p>		<p>Example 2 « <i>Explanation</i> »</p>
<p>Example 3 « <i>Explanation</i> »</p>		<p>Example 3 « <i>Explanation</i> »</p>
<p>Example 4 « <i>Explanation</i> »</p>		<p>Example 4 « <i>Explanation</i> »</p>

Chapter 7: Definition and Methodology

Market Definition and Scope (1/2)

Definition of antibiotics and regional and species scope

Overview

The focus of the report is antibiotics used for livestock animals. Antibiotics are defined as any substance with a direct action on bacteria that is used for treatment or prevention of infections or infectious diseases. Some coccidiostats are anti-protozoal substances which also have an antibacterial effect. However, coccidiostats are excluded from the scope of this report. Certain antibiotics may be used for the purpose of growth promotion in some countries; these are also excluded from the scope of this report.

Regional scope

Countries included per region as follows:

- APAC includes China and Thailand
- EU includes UK, France, Italy, Spain, Germany and Poland, and
- US includes United States of America.

The countries chosen were based on whether data was available on the volume of sales of antibiotics. Data availability was particularly poor for countries in Latin America, hence the region was not included.

Species scope

- Ruminants includes cattle, sheep and goats
- Poultry includes broilers, layers and turkeys

Market Definition and Scope (2/2)

API class scope

API classes included in the report were based on how data was reported for the volume of sales of antibiotics. The following classes were covered for each region:

- Included
- Not included

	Tetracyclines	Penicillins	Other	Aminoglycosides	Amphenicols	Cephalosporins	Fluoroquinolones	Lincosamides	Macrolides	Macrolides & lincosamides	Sulfonamides	Pleuromutilins	Polymyxins	Trimethoprim	Quinolones
US	Included	Included	Not included	Included	Included	Included	Included	Included	Included	Not included	Included	Not included	Not included	Not included	Not included
Europe	Included	Included	Included	Included	Not included	Not included	Included	Included	Included	Not included	Included	Included	Included	Not included	Not included
China	Included	Included	Included	Not included	Included	Not included	Not included	Not included	Not included	Included	Not included	Not included	Not included	Not included	Not included
Thailand	Included	Included	Included	Included	Included	Included	Not included	Not included	Not included	Included	Included	Included	Included	Included	Included

Market Sizing Assumptions (1/2)

Volumes per API class were combined with estimates on price to model market size

Baseline volume data

« *Information on baseline volume data* »

Assumptions impacting volume

	Volume (kg) of antibiotics used per API class per species	Population growth	Changing consumer demands
Description	« <i>Information on assumption</i> »	« <i>Information on assumption</i> »	« <i>Information on assumption</i> »
Regional variation	« <i>Information on assumption</i> »	« <i>Information on assumption</i> »	« <i>Information on assumption</i> »
Species variation	« <i>Information on assumption</i> »	« <i>Information on assumption</i> »	

Market Sizing Assumptions (2/2)

Volumes per API class were combined with estimates on price to model market size

Baseline price data

Price per kg of API in 2020 was estimated based on expert input and Stonehaven Consulting estimates.

Market trends influencing change in price between 2020-2035

	Minimum inhibitory dose requirements	Genericization
Description	« <i>Information on assumption</i> »	« <i>Information on assumption</i> »
Regional variation	« <i>Information on assumption</i> »	« <i>Information on assumption</i> »

Additionally, X% p.a. inflation rate applied between 2020-2035. « *More information on assumption* »

Chapter 8: Report Authors and Expert Panel

Report Authors



Joseph Harvey

Head of Animal Health,
S&P Global

Joseph provides news and analysis regarding the global animal health market across a range of species and products. He conducts exclusive interviews with the sector's biggest companies and experts, as well as start-up firms. Having gained many years of experience in business journalism, Joseph started writing about animal health in 2012.

He previously built his experience by reporting on the human med-tech and diagnostics sector. Joseph is a well-known figure in the animal health sector through his articles, interviews, podcasts and webinars.



Arthur Redpath

Senior Global Marketing Expert,
Stonehaven Consulting AG

Arthur is a senior marketing executive with over 30 years of experience in the animal health, pharmaceuticals and agricultural industries, after graduating from Edinburgh University Royal Dick Veterinary College as a veterinary surgeon in 1987.

He joined Novartis Animal Health in 2000 where he progressed to global leadership roles. In 2015, he joined Elanco, where he assumed the leadership positions of EMEA Chief Marketing Officer and leader of the Global Marketing Excellence team.



Tamsin Saunders

Analyst,
Stonehaven Consulting AG

Tamsin holds a BSc in Biology from Imperial College London and an MSc in International Health Policy from the London School of Economics.

She has experience as a medical writer at Cherry and as a research analyst for McKinsey's pharmaceutical and medical products practice. At Stonehaven she has worked on Animal Health strategy projects in areas such as innovation strategy, commercial due diligence and market entry.

Expert Panel



Maria Sitjar
Senior Advisor

Maria graduated as DVM from the University of Barcelona in 1989, and after a 3-year internship in the School of Veterinary Medicine from the University of Minnesota, completed a MS degree in Swine Medicine in 1996. She has been part of the Animal Health Industry for more than 30 years. After serving in Upjohn and Pharmacia in technical services positions, she joined Novartis in 2005, where she moved to global marketing positions. In 2014 she joined Ceva where she was a key piece in the development of a global swine key customer team, which she led until 2020. Recently she joined the University of Minnesota Department of Studies in Justice, Cultural and Social Changes and she is interested in several projects involving cross cultural relationships and food in the business arena.



George Tice,
Senior Regulatory Advisor

George is a veterinarian with 28 years of broad business and corporate experience in Elanco Animal Health. He retired from Elanco at the end of April 2022 and his last role was Executive Director for Public Policy for Europe and International, in which capacity he led a Corporate Affairs team operating across the international affiliates outside the US. Before this, George was Director of Regulatory Affairs for Europe and was responsible for all regulatory submissions and compliance in Europe during that time. George has also had responsibilities in Elanco as Director for International Poultry Marketing and as General Manager responsible for Eastern Europe and the Arab world. George is a UK citizen and resides in Ireland with his wife, Scarlett.

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Chapter 9: Main Sources

Main Sources (1/2)

Chapter 1

1. Source 1

Chapter 2

1. Source 1
2. Source 2
3. Source 3
4. Source 4
5. Source 5
6. Source 6
7. Source 7
8. Source 8
9. Source 9
10. Source 10

Chapter 3 and 4

1. Source 1
2. Source 2
3. Source 3
4. Source 4
5. Source 5
6. Source 6

Main Sources (2/2)

Chapter 5

1. Source 1
2. Source 2
3. Source 3
4. Source 4
5. Source 5

Chapter 6

1. Source 1
2. Source 2
3. Source 3
4. Source 4
5. Source 5
6. Source 6
7. Source 7
8. Source 8

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