



## Case Study

# Our Approach to Anti-Microbial Resistance

## What is Anti-Microbial Resistance (AMR)?

The term ‘microbes’ encompasses a number of different microscopic organisms such as bacteria, viruses and parasites. Some of these are important for our health whilst others cause disease. Anti-microbials, such as antibiotics, prevent and treat infections caused by microbes in humans and animals. Anti-microbial resistance (AMR) is the evolutionary process by which microbes evolve over time and develop resistance to these treatments, meaning medicines become less effective against them. This makes infections harder to treat, easier to spread and more likely to cause severe illness and death. Inappropriate and/or excessive use of anti-microbials creates a risk that it contributes to the development of AMR over time.

Historically, there have been three areas of concern regarding the overuse of antibiotics:

1. for growth promotion in animals, where an antibiotic is administered in low doses purely to change the bacterial population in the gut to enhance the growth of the animal, rather than to treat a disease;
2. to reduce the likelihood of transmission across an entire herd when just a few animals have fallen ill; and
3. as a substitute for good animal husbandry/welfare relating to poor infection prevention and control (such as lack of hygiene).

AMR in livestock resulting from practices such as those above can contribute to the potential spread of antibiotic resistant pathogens, and there has been growing recognition regarding the importance of prudent and responsible use of anti-microbials.

## Regulatory Backdrop

In seeking to address 1) above, in 2006 the European Union banned the use of antibiotics for growth promotion. Then, in January 2022, the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) became effective and updated the rules on the authorisation and use of veterinary medicines in the European Union (EU). In particular, the Regulation sought to strengthen EU action to fight antimicrobial resistance through specific measures ensuring prudent and responsible use of antimicrobials in animals.

In effect, this regulation banned prophylactic and routine use of antibiotics in farming across the EU such that antibiotics can no longer be applied to compensate for poor hygiene and animal husbandry practices, thereby targeting the practices highlighted in 2) and 3) above.

This ban does not apply to the UK, although products exported to the EU must comply with its requirements. Although equivalent regulation does not currently exist in the United States, there is growing momentum.

## WHO guidelines on use of medically important antimicrobials in food producing animals

### Non-therapeutic use

#### Growth promotion

Animals are routinely given low doses of antibiotics for extended periods to increase feed efficiency and/or stimulate growth. May also prevent disease.

#### Prophylaxis

Routine group treatment of animals for extended periods of time where there is a high risk of infection, but no illness currently present.

### Therapeutic use

#### Metaphylaxis

Non-routine treatment of a group of animals that are in close contact with clinically infected animal(s).

#### Therapy

Non-routine treatment of animals with clinical evidence of infectious disease.

## The declining use of antibiotics in Europe

Governmental regulations and consumer preferences, such as a rising demand for antibiotic-free meat, have led to a decline in the desire to use antibiotics over recent years. This has contributed to the overall use of antibiotics in the EU declining significantly with this trend likely to continue, albeit at a slower pace.

In all large European food producing animal markets, there have been considerable improvements in the prudent use of antibiotics and overall antibiotic

consumption decreased by almost 50% between 2011 and 2020.

In the UK, use of antibiotics in farm animals decreased to the lowest recorded in 2021, with a 55% reduction since 2014. The UK is now one of the lowest users of antibiotics in Europe, and lower than any EU country with a significant livestock farming industry.

Sources:

European Medicines Agency ESVAC report

<https://commonslibrary.parliament.uk>



## Case Study

### Our Approach to Anti-Microbial Resistance continued

#### Overview of Dechra FAP Revenue

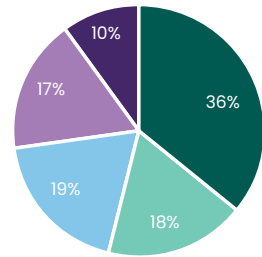
In the 2023 financial year, total Group net revenue was £761.5 million of which £89.0 million related to Food producing Animal Products (FAP).

Within our FAP revenue, the main product categories are as follows:

- **Water soluble antibiotics** mostly sold under our Solustab® range;
- **Other products containing antimicrobials**, largely relating to anti-infectives and locomotion;
- **Vaccines** for cattle, poultry and swine;
- **Anti-infectives and internal medicine** consisting of a number of different products, but which do not contain any antimicrobials; and
- **Other product categories** such as anaesthesia & analgesia and parasitology.

Against this context, whilst we accept that regulations restricting the use of antibiotics in food producing animals and shifting consumer preference towards plant based foods or animal products raised without antibiotics do represent risks, we do not believe that the risks arising from antimicrobial resistance will have a material impact on our business.

## FAP antimicrobials account for approximately 52% of all FAP sales and only 6% of total Group sales



- Water soluble antibiotics
- Other products containing antimicrobials
- Vaccines
- Anti-infectives & internal medicines that do not contain antimicrobials
- Other product categories

#### The Dechra FAP Portfolio

##### Current Make-up

The FAP antibiotics that we sell are used for treatment only, rather than prevention.

The European Medicines Agency's (EMA) Antimicrobial Advice Ad Hoc Expert Group (AMEG) has categorised antibiotics based on the potential consequences to public health of increased antimicrobial resistance when used in animals and the need for their use in veterinary medicine.

Almost all of our antibiotics are classified as C (Caution) and D (Prudence) using the

AMEG categorisation, meaning they are to be preferred if antibiotic treatment is necessary.

Dechra first entered the European FAP market with the acquisition of Eurovet in May 2012. Although FAP sales have grown in absolute value since then, they represented only 11.7% of Group sales this year compared to 19.6% when we acquired Eurovet.

Gross sales of FAP antimicrobials, both as a proportion of all FAP sales and total Group sales, have decreased between financial years 2015 and 2023, from 69% to 52% and 10% to 6% respectively.

In particular, we voluntarily discontinued sales of the antibiotic colistine even before the regulations banned its usage, as this was not seen as prudent with regards to AMR.

In the 2023 financial year, we entered the US FAP market for the first time via the acquisition of Med-Pharmex Holdings, Inc which has a small FAP portfolio containing antimicrobials.

#### Products Containing Antimicrobials

Our market leading *Solustab* range of water soluble antibiotics provide a reliable and stable product when added to drinking water and reduces the need for additional enhancing agents.

Within this range, the main brands are:

- Octacillin®, a powder containing amoxicillin for the treatment of diseases in swine and poultry;
- Soludox®, a powder containing doxycycline for swine and chickens; and

- Methoxasol®, a ready to use liquid medication containing the proven synergistic combination of sulfamethoxazole and trimethoprim to treat swine and poultry.

#### Other FAP Categories

Elsewhere in our FAP portfolio, Tri-Solfen® is a topical anaesthesia which multiple applications that helps to improve animal welfare when performing procedures such as piglet castration and tail docking, amongst others.

The main driver of FAP revenue growth over recent years has been our vaccines portfolio which, by its very nature, indirectly helps to reduce the use of antimicrobials. Moreover, our R&D pipeline has a number of potential new vaccine projects that, if successful, will diversify our portfolio further and help to prevent AMR moving forwards.

#### Looking Ahead

We do anticipate that the absolute sales of FAP, including those containing antimicrobials, will continue growing. However, we have an increasing focus on Companion Animal Products (CAP), including the major pipeline projects expected to launch over the coming years. As such, we expect the proportion of FAP sales, including those containing antimicrobials, as a proportion of total Group revenue to gradually decrease over time.



## Case Study

### Our Approach to Anti-Microbial Resistance continued

#### Responsible Manufacturing, Promotion and Use of Antibiotics

The Dechra business model operates across the entire value chain including manufacturing, selling and ongoing technical support given to veterinarians who use our pharmaceuticals. This means we are uniquely placed to have a positive impact within the animal healthcare industry.

#### Manufacturing

All of our FAP water soluble antibiotics are manufactured in house at either our Bladel or Zagreb facilities. Within the very limited injectable antibiotics that we sell, the vast majority are also manufactured in house, with a small proportion manufactured at a third party Contract Manufacturing Organisations (CMO).

All sites perform local monitoring of the process effluent to remain compliant with any permits or licences and we have started a Pharmaceuticals in the Environment project to help us gain greater visibility over our manufacturing discharges.

#### Promotion

Our products have never been registered for the purposes of growth promotion and we have never marketed antibiotic usage for this objective anywhere in the world.

Therefore, such indications have never been on the labels of any antibacterial products sold by Dechra, including in territories where these practices are still legal.

When promoting the *Solustab* range, we proactively highlight the product benefits in terms of ease of administration and consistency of result.

We do not incentivise sales representatives or third party distributors specifically on sales of antibiotic products.

As an alternative to antibiotics, we also offer an anti-inflammatory treatment, Solacyl®, to support the self-healing capabilities of animals. Where appropriate, this can be administered by the veterinarian to reduce the need to use antibiotics.

#### Use by Veterinarians and Farmers

We regard the responsible use of antibiotics as treating the right animals with the right antimicrobial at the right time and in the right dose.

To encourage the responsible use of antibiotics, we provide a range of training and support to employees and veterinarian customers including a:

- *Solustab* Support Tool that our sales team use when visiting customers;
- *Solustab* training module for employees on the internal education platform, Delta;
- solustab.eu website for use by veterinarians and farmers; and
- Dechra Academy module for veterinarians promoting an integrated approach to mastitis (herd management, early detection and targeted treatment). This includes the importance of proper diagnosis and sensitivity testing.

We have developed a dosing application for use by veterinarians in clinics and on farms to help minimise under and overdosing and spillage. We also offer sensitivity testing support via an antibiotic paper ring test for mastitis pathogens.

#### Our Statement Regarding AMR in Food producing Animals

Despite all efforts by veterinarians and farmers to prevent disease, sometimes animals do get sick. Dechra believes these animals deserve to be treated, respecting the principles of prudent use of antibiotics.

Our products and services are designed to support responsible use. We do not have in-feed additives for blanket treatment, we offer water soluble products for the treatment of targeted groups and injectables for individual treatment, thereby minimising use. We offer diagnostics to identify the most targeted treatment protocol and to support veterinarians in calculating the correct dose.

Approximately 95% of our European FAP antibiotic sales are class D, which are first choice treatments according to the EMAs AMEG categorisation, as they pose the lowest risk to human health when being used in animals and are the lowest risk category of antibiotics with regards to the development of AMR.

The rest are in class C, which are products that can be used in case there is no effective treatment in class D. We do not sell products from class A, which should not be used in food producing animals.

