

# ***Authorising Antimicrobials based on Fluoroquinolones***

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# Overview

- Antimicrobial resistance is regarded as a serious issue by UK Government for both animal and human medicines.
- VMD works closely with vets and farming industry to produce responsible use guidelines - RUMA.
- Fluoroquinolone products are regarded as an animal treatment of last resort in recognition of importance in human medicine.
- All therapeutic antimicrobials are prescription only medicines and can only be prescribed by veterinary surgeons.
- Annual sales data report monitors trends in sales of antimicrobials. Fluoroquinolones represent approximately 1% of total volume sales (i.e. 1-2 tonnes pa)



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# Assessment of FQ based products

- Fluoroquinolone applications are assessed in the same way as other products.
- FSA, HPA, EA and for fish products CEFAS contribute to the assessment process as necessary.
- For fluoroquinolones and all other antimicrobial applications for use in food producing animals, the HPA's antimicrobial resistance team advise on the possible impact on human health.
- Recent increase in applications for generic fluoroquinolones as products reach the end of the 10 year data protection period. Don't expect to see an increase in total Fluoroquinolone sales.



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# Regulatory assessment

- Studies on effects on gut flora
- Conclusions on induction of resistance genes
- Selection for resistance
- MIC and PK/PD data
- Transfer of resistant genes
- Risk-Benefit assessment



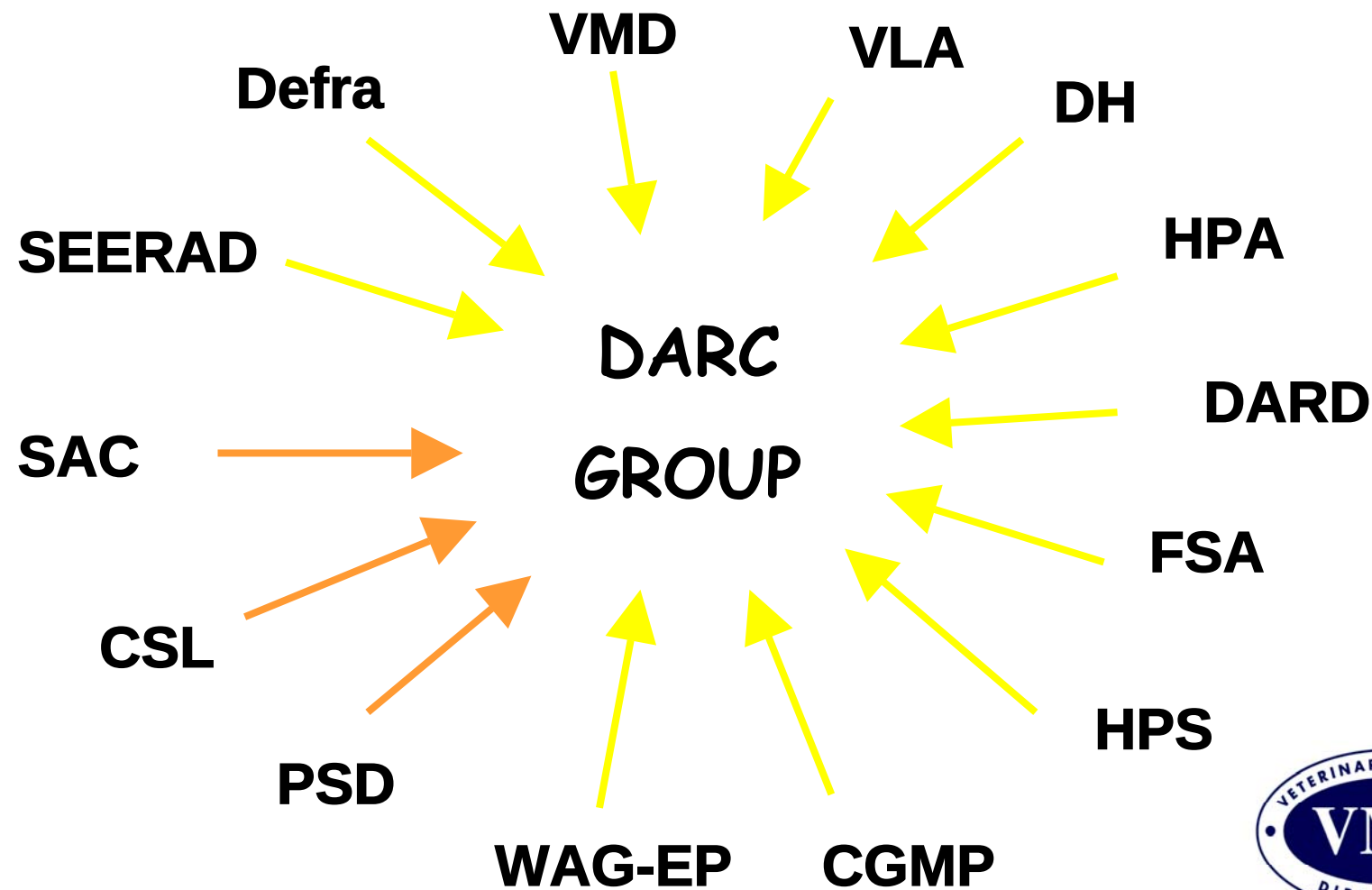
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# **Defra Antimicrobial Resistance Co-ordination (DARC) group**

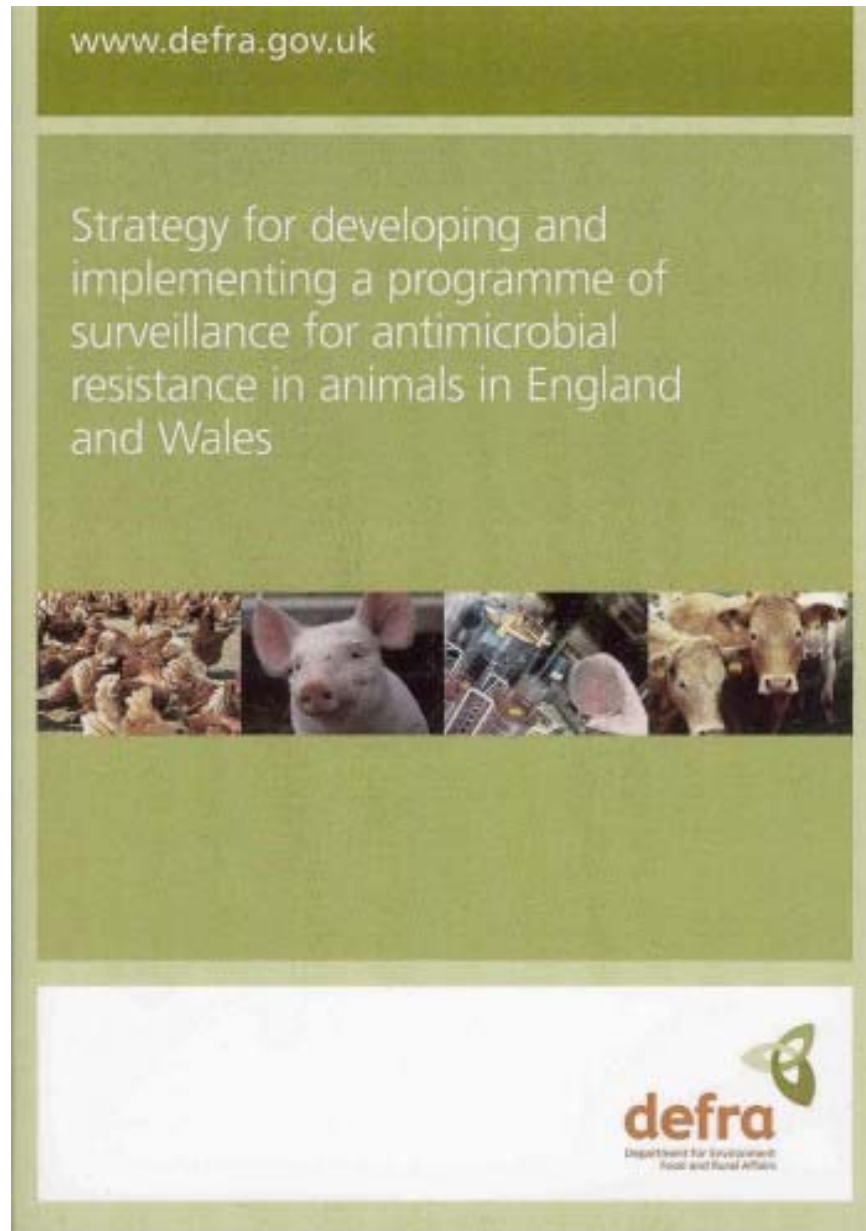


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# DARC Group



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Report available from:

★ VMD website

[www.vmd.gov.uk](http://www.vmd.gov.uk)

under publications  
and general tabs



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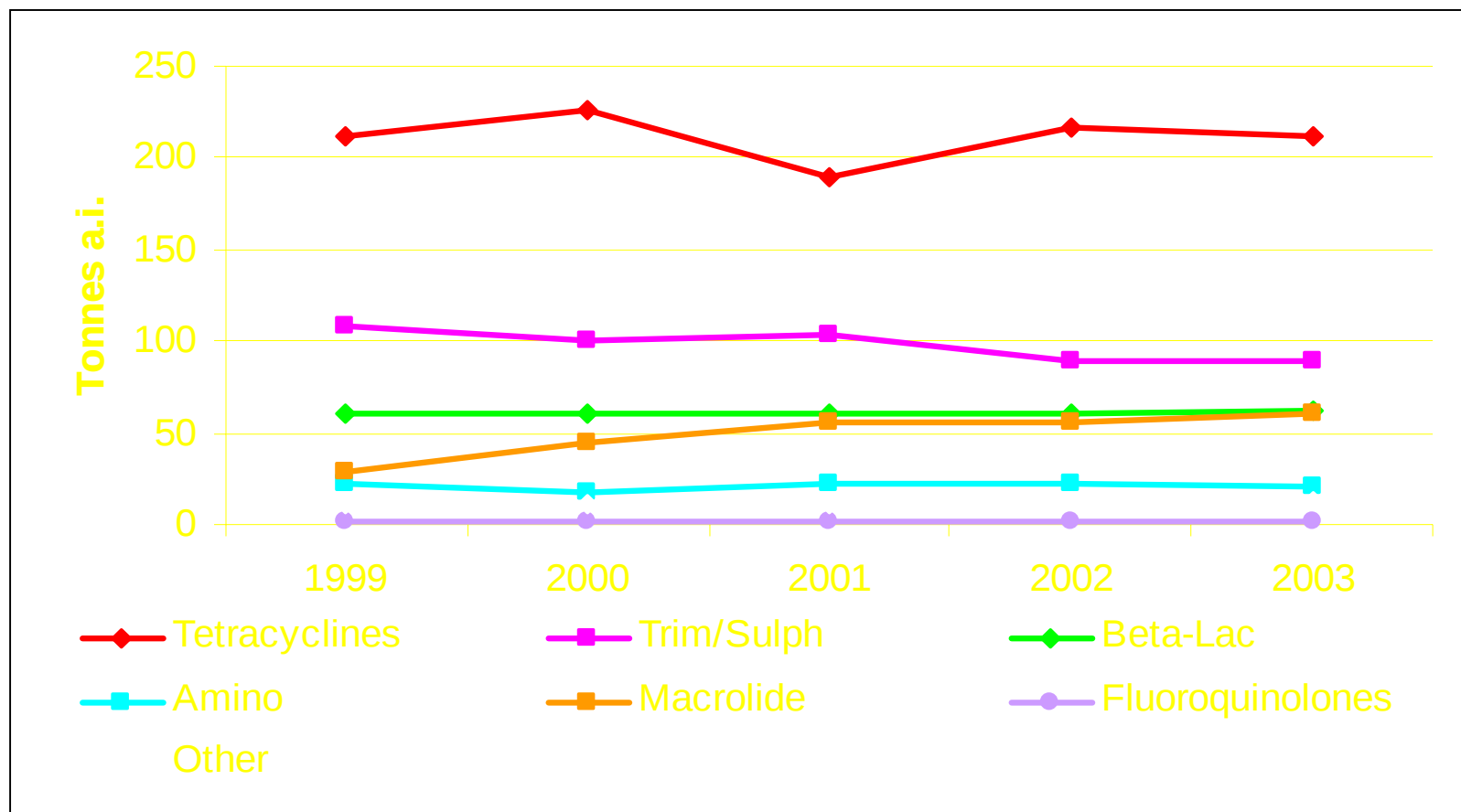
# AM Sales Data Report

- ★ Annually publish data on sales of veterinary antimicrobials
- ★ Seven reports published to date and available on web site
- ★ Enhancing the report year on year to make it more meaningful to stakeholders
- ★ 2005 data collection is underway and will be published this year (2006)
- ★ UK one of five EU countries that prepare an annual report of AM sales/consumption.



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## Sample Results - Therapeutic Antimicrobials



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# ruma

## GUIDELINES

### Responsible use of antimicrobials in dairy and beef cattle production

The guidelines assume that the antimicrobial substances available are officially authorised for the purpose for which they are used and that they are lawfully obtained.

Produced by the Cattle Working Group of the RUMA Alliance.

September 2004

This booklet summarises the RUMA guidelines on the responsible use of antimicrobials in dairy and beef cattle production. They are lawfully obtained.

The emergence of human medical crossover of resistance and the associated medical antimicrobials.

The Responsible Use of Medicines in Agriculture Alliance (RUMA) has reviewed the use of antimicrobials in dairy and beef cattle production.

To this end, RUMA has produced this booklet to give advice to farmers and vets on the use of antimicrobials in dairy and beef cattle production.

### For Farmers

The use of animal medicines carries with it responsibilities. Under UK legislation, all antimicrobials are licensed for specific species and uses.

A product will not be authorised unless very

### THE GUIDELINES

There is a the farmer the right to ensure the effective use of antimicrobials in dairy and beef cattle production.

Farmers have a responsibility to ensure the effective use of antimicrobials in dairy and beef cattle production.

<http://www.ruma.org.uk/guidelines/cattle.html>

# ruma

## GUIDELINES

### Responsible use of antimicrobials in pig production

In order for medicines to be used responsibly they must be lawfully obtained and used in accordance with the label directions or veterinary advice.

Produced by the Pig Working Group of the RUMA Alliance.

June 1999  
Updated October 2004

RUMA guidelines farmers have principles that

Antimicrobials and welfare of the treatment

The emergence of human medical bacteria could (and vice versa) treatments in

The Responsible Use of Medicines in Agriculture Alliance (RUMA) has reviewed the use of antimicrobials in pig production.

To communicate the use of antimicrobials in pig production, RUMA has produced this booklet to give advice to farmers and vets on the use of antimicrobials in pig production.

### For Farmers

The use of animal medicines carries with it responsibilities. Under UK legislation, all antimicrobials are licensed for specific species and uses.

### THE GUIDELINES

All farmers have a responsibility to ensure the effective use of antimicrobials in pig production.

<http://www.ruma.org.uk/guidelines/pigs.html>

### Cattle

# ruma

## GUIDELINES

### Responsible use of antimicrobials in poultry production

In order for medicines to be used responsibly they must be lawfully obtained and used in accordance with the label directions or veterinary advice.

Produced by the Poultry Working Group of the RUMA Alliance.

June 1999  
Updated October 2004

This booklet summarises the RUMA guidelines on the responsible use of antimicrobials in poultry production. They are lawfully obtained.

The emergence of human medical bacteria could (and vice versa) treatments in

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To communicate the use of antimicrobials in poultry production, RUMA has produced this booklet to give advice to farmers and vets on the use of antimicrobials in poultry production.

### For Farmers

The use of animal medicines carries with it responsibilities. Under UK legislation, all antimicrobials are licensed for specific species and uses.

### THE GUIDELINES

Under the RUMA guidelines, all farmers have a responsibility to ensure the effective use of antimicrobials in poultry production.

<http://www.ruma.org.uk/guidelines/poultry.html>

### Pigs

# ruma

## GUIDELINES

### Responsible use of antimicrobials in sheep production

In order for medicines to be used responsibly they must be lawfully obtained and used in accordance with the label directions or veterinary advice.

Produced by the Sheep Working Group of the RUMA Alliance.

June 2000  
Updated October 2004

RUMA guidelines farmers have been used by

Antimicrobials have been used by

The emergence of human medical bacteria could (and vice versa) treatments in

The Responsible Use of Medicines in Agriculture Alliance (RUMA) has reviewed the use of antimicrobials in sheep production.

To communicate the use of antimicrobials in sheep production, RUMA has produced this booklet to give advice to farmers and vets on the use of antimicrobials in sheep production.

### For Farmers

The use of animal medicines carries with it responsibilities. Under UK legislation, all antimicrobials are licensed for specific species and uses.

### THE GUIDELINES

All farmers have a responsibility to ensure the effective use of antimicrobials in sheep production.

<http://www.ruma.org.uk/guidelines/sheep.html>

### Poultry

# ruma

## GUIDELINES

### Responsible use of antimicrobials in fish production

The guidelines assume that the antimicrobial substances available are officially authorised for the purpose for which they are used and that they are lawfully obtained.

Produced by the Fish Working Group of the RUMA Alliance.

June 2004

This booklet summarises the Farmer responsibilities section of the RUMA guidelines to provide quick and easy-to-read guiding principles for fish producers.

Antimicrobials have made a major contribution to fish health and welfare. They are vital medicines for the treatment of bacterial infections in fish.

The emergence of antimicrobial resistance as a serious problem in human medicine has prompted concerns about the potential for crossover of resistant bacteria from livestock to the human population and the associated possibility of this impacting on the effectiveness of medical antimicrobial treatments.

The Responsible Use of Medicines in Agriculture Alliance (RUMA), a coalition of organisations including agricultural, veterinary, pharmaceutical, retail and consumer interests, has been set up to address these concerns. It aims to review the use of antimicrobials and to establish practical strategies to enable farmers, including fish farmers, to reduce the need for their use.

To this end, RUMA has formulated comprehensive guidelines for the responsible use of antimicrobials in fish production. These give advice on all aspects from application and responsibilities of the farmer, feed manufacturer and veterinary surgeon, to strategies for reducing the need for use. This booklet summarises the Farmer Responsibilities section of the guidelines.

### For Farmers

The use of animal medicines carries with it responsibilities. Under UK legislation, all antimicrobials are licensed for specific species and uses.

A product will not be

### THE GUIDELINES

Regard therapeutic antimicrobial products as complementary to good management, vaccination and general site and farm hygiene. A site and farm health plan should be drawn up that outlines routine preventive treatments (for example vaccination, fungus control, salmon lice control etc.). Delay in initiating therapy causes welfare problems and may ultimately lead to increased medicine usage. Initiate treatment with an antimicrobial medicine, all of which are

# **Comparable list of veterinary and human AM's**

- ★ **Developed in conjunction with DH a list of all current veterinary and human AM's in the UK**
- ★ **Lists for antibacterials, antiprotozoals and antifungals**
- ★ **All available from DARC Group web site, hosted from VMD web site**
- ★ **Received positive feedback**



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# Recommendations

- Wide spectrum of activity across the EU in to inform professionals and public on AMR
- Local strategies are informed and guided by wider international debate
- Developing relationship between opinion leaders in human and veterinary fields
- A growing knowledge data-set to provide regulators, industry and interested parties with useful information



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