ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

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Presentation Paper
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EUROPEAN INITIATIVES TO MONITOR ANTIBIOTIC RESISTANCE AND USAGE AND INDUSTRY PERSPECTIVES FOR THE FUTURE

Secretariat
April 2014
European initiatives to monitor antibiotic resistance and usage and industry perspectives for the future

Phil Sketchley
Chief executive, NOAH
NOAH

- The National Office of Animal Health (NOAH) represents the UK animal medicines industry
- Represents UK industry with the regulatory agencies and at IFAH Europe
- Aim is to promote the benefits of safe, effective, quality medicines for the treatment and welfare of all animals.
- 23 Corporate Members, approximately 90% of UK vet medicines industry
- Member of RUMA (Responsible Use of Medicines in Agriculture Alliance)
Industry Perspective on Antimicrobial Resistance

- General points on Antimicrobial Resistance and the UK perspective
- European perspective-actions taken to date in different Member States
- European Legislative review
- Industry perspective on antimicrobial resistance and the future legislation changes
General Points on Antimicrobial resistance

- Industry wants for its products to remain effective for as long as possible - best achieved by the promotion of and adherence to responsible use by vets and farmers
- Appropriate regulatory climate is needed to encourage industry to continue to invest in R and D in animal health
- High costs to market- c. 150 million euros to develop a livestock medicine- need confidence that ROI achievable
General Points on Antimicrobial resistance

- Measurement of resistance across EU Member States and in different reports - little consensus - different countries/institutions gather data and measure resistance in different ways
- Makes comparisons between reports and between Member States’ data difficult - Clinical Resistance vs Epidemiological Cut-off Values
- ECV- reduced susceptibility, true clinical resistance is the clinical break points
- Lab detected ‘reduced susceptibility ’- often referred to as ‘resistance’ in some reports
Clinical breakpoints vs epidemiological cut-off values

- “Epidemiological resistance” not necessarily clinically relevant!
Antibiotic resistance - UK

- UK Department of Health 5 year strategy on AMR published Sept 2013
- UK Parliament Science and Technology Committee inquiry into AMR - awaiting report
- International dimension of resistance acknowledged - people and foodstuffs moving all over world - little control in developing world
- Strategy acknowledges human use the main driver of human resistance problems;
- ‘Increasing scientific evidence suggests that the clinical issues with antimicrobial resistance that we face in human medicine are primarily the result of antibiotic use in people, rather than antibiotics in animals’.
Antibiotic resistance - UK

- Recent scientific papers from Mather et al (2013) on Salmonella, Wu et al (2013) on ESBLs in poultry support the DoH view
- Resistance in vet pathogens rare - unusual for a sick animal with bacterial infection to fail to respond to treatment where the appropriate antibiotic is used
- More research is needed on resistance surveillance and transmission pathways (likely to be included in new EU Vetmed legislation)

References:


Implementation of the UK 5 year strategy

- RUMA action plan to implement launched and published – will be reviewed quarterly

UK 5 YEAR ANTIMICROBIAL RESISTANCE (AMR) STRATEGY

ACTION PLAN FOR THE RESPONSIBLE USE OF MEDICINES IN AGRICULTURE ALLIANCE (RUMA) AND ITS INDIVIDUAL MEMBERS

1. The UK 5 year AMR Strategy was launched on 10 September 2013. RUMA, a unique alliance of 23 organisations across the whole UK livestock sector, was among the groups that welcomed and supported the strategy.

2. The Alliance has discussed the actions that will be required to implement the strategy and has developed this action plan, based on the detailed actions in Annex B of the Strategy, to set out the actions that RUMA and/or its members will take. Inevitably, the plan is still at an early stage. RUMA members have agreed to review and record progress against the plan at RUMA’s quarterly meetings and to publish the plan and its subsequent revisions to provide an open report on how this work is developing. During these reviews new actions will be added to the plan including any identified by the high level steering group made up of DARC, ARHAI and ACSMF members who the strategy says will agree an action plan to implement the strategy.

3. A list of RUMA members and the acronyms used in this plan are at Annex A.

4. If you have any comments on the plan please send them to RUMA’s Secretary General, John FitzGerald, at rumasec@btinternet.com.

RUMA
April 2014

<table>
<thead>
<tr>
<th>Strategy actions – Annex B</th>
<th>Section 5.6 Actions for Animal Health (Bold added by RUMA)</th>
<th>RUMA/members’ action</th>
<th>Progress</th>
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</thead>
<tbody>
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<td>Key area 1: improving infection prevention and control practices</td>
<td>considering the use of farm assurance schemes as a mechanism to increase adherence to best husbandry including isolation of sick animals, testing of new stock and responsible use of antibiotic principles, while ensuring animal health and welfare, NFU, Species Groups, Red Tractor - encouraging retailers to review their standards for meat and animal products and to set clear specifications, concerning biosecurity, antimicrobial stewardship and good</td>
<td>RUMA will need to help develop improved infection prevention and control practices and to disseminate advice on them through RUMA Guidelines or advice notes. RUMA to develop protocols for members’ advisory staff to ensure they are able to provide up to date advice on antibiotic resistance and responsible use when they interact with farmers.</td>
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Antibiotic resistance - restriction of classes

- Class related restrictions - comments from human sector, submission from Public Health England to UK Parliament Science and Technology Committee inquiry;
- One major uncertainty, despite the agreed need for antimicrobial stewardship to prevent and slow resistance, is exactly what good stewardship looks like. There is a tendency in the UK to equate stewardship with simply minimising use of antibiotics such as cephalosporins and fluoroquinolones. Consequently, there have been major increases in the use of a very narrow range of alternative antibiotics, especially an antibiotic called piperacillin-tazobactam. This can be equated to 'squeezing the balloon' by potentially creating a resistance problem elsewhere. Rather than ‘swinging the pendulum’ away from use of what might be the most effective antibiotic for the patient (e.g. use of cephalosporins), improving knowledge about appropriate prescribing is required.

Source-
http://data.parliament.uk/writtenevidence/WrittenEvidence.svc/EvidenceHtml/3415
Antibiotic resistance- regulatory climate

- Antibiotic resistance one of the issues under consideration as part of EU revision of the Veterinary Medicines legislation
- Animal health industry- great concern that a new veterinary antibiotic would be unlikely to be licensed by regulators or would have requirements in authorisation that would severely limit the use
- Regulatory uncertainty around antibiotic resistance acts as major disincentive for companies considering research pipeline
- Precautionary approach rather than evidence based
Antibiotic resistance- regulatory climate

- Veterinary bodies and industry- all wish to retain use of Critically Important Antibiotics (CIA) for veterinary use
- What is classed as CIA varies depending on what body you consult with and also changes over time - ban on CIAs could really limit future vet antibiotics
- Ban on CIAs can lead to overuse of remaining classes - lead to resistance to remaining products
- Necessary to retain all classes for animal health and welfare reasons
European Legislative Review

- Review of the EU regulatory framework for veterinary medicines underway
- Antimicrobial resistance and the implications for human and animal health one of the matters under consideration
- The regulatory “package”;
  - 2001/82 – veterinary medicines
  - 1990/167 – medicated feeding-stuffs
European Legislative Review

- Impact assessment and draft legislation for new Veterinary Medicines Regulation/Directive and Medicated Feed Directive expected in late Summer or early Autumn 2014
- Process will then be delayed because of EP elections
- Co – decision process follows, amendments etc.
- Will take effect ‘on the ground’ in late 2017/early 2018
European Legislative review

- Current European legislation is a Directive
- Transposed into national legislation through the Veterinary Medicines Regulations (VMR)
- If new legislation were to be a directive – would be transposed into national legislation through new VMR
- BUT understand new legislation will be a Regulation to be applied directly across EU - means no national ‘tweaking’
- Will remain in place for approx. 10 -15 years
Proposals from different sources

- Proposals to ban prophylactic use from NGOs, UK based MPs, MEPs from Nordics
- RUMA view (supported by NOAH)- Therapy, control and preventive tx needed in vet sector
- Preventive treatment (sometimes referred to as Prophylaxis)
  - Treatment of an animal or a group of animals, before clinical signs of disease, in order to prevent the occurrence of disease or infection.
  - Preventive treatment with antibiotics should:
    - only be applied to animals diagnosed at high risk of bacterial disease, and
    - only occur under prescription by a veterinarian on the basis of epidemiological and clinical knowledge, and not be applied routinely, and
    - not be used to compensate for poor hygiene or for inadequate husbandry conditions.
Proposals from different sources

- Decoupling dispensing by the vet from prescribing - latest information NOAH has is this will **not** be in draft legislation
- However- highly likely that will be proposed as amendments by MEPs, or Member States
- Currently, Nordics, Spain, Italy have decoupled prescribing and dispensing- still large variations in volumes used
- Many Member States oppose splitting prescribing and dispensing as does the OIE
NOAH and IFAH Europe proposals

- Use existing legislation to counter inappropriate use
- Minimise preventative use (not prohibit!) - justifiable under some circumstances – **but never to prop up bad husbandry**
- Biosecurity, husbandry, to prevent disease
- RUMA guidelines on responsible use an example
- Increased communication and training – increase activity and budget for RUMA and EPRUMA
- Need to retain all available classes for vet use i.e. hope to avoid any bans on critically important antibiotics
- Necessary for animal health and welfare that vets retain access to existing authorised medicines
NOAH and IFAH Europe proposals

- Review seen as an opportunity to help improve availability of veterinary medicines across EU
- Increased data protection to promote innovation in the veterinary medicines sector (animal pharma only c. 2% of human pharma market), only 10 years for ROI currently
- Data protection also needed for new claims as well as new molecules e.g. new species
- Many pioneer companies also involved in human pharma
- Regulatory uncertainty and negative climate for vet use likely to encourage even more focus on human medicines
NOAH and IFAH Europe proposals

- On the whole - UK vets prescribe responsibly - transparency at use phase needed
- Gather more data at vet and farm level - identify high users and the reasons for high use compared to their peers
- Are the reasons for the high use valid? If not, advice and guidance on measures to reduce use?
- Likely that vets and farmers will need to submit data on antibiotic use to a central point where it will be collated and analysed
NOAH and IFAH Europe proposals

- Unexpected treatment failures in veterinary medicine - not widespread
- Industry sponsored research CEESA survey backs this view (1)
- Data needs to be gathered across EU in a harmonised manner, harmonised methodology etc.
- More surveillance needed across EU on both target pathogen resistance and resistance transmission pathways
- Proposals for EU surveillance now being developed by Heads of Medicines Agency Veterinary (HMAv) as per Commission paper

http://ac.elscdn.com/S0924857912004372/dx.doi.org/10.1016/j.ijantimicag.2012.11.004
NOAH and IFAH Europe proposals

- Use new and existing classes strategically
- Treatment choices - guided by diagnostics, to minimise resistance development but mandatory use of diagnostics prior to use of Abs - may cause welfare issues – development of pen side tests needed
- Prevention better than cure - farm biosecurity, building design and the use of vaccines
- Ongoing importance of Responsible Use of Medicines in Agriculture Alliance (RUMA) - actively involved in responsible use initiatives and implementation of the UK AMR strategy (EPRUMA in EU)
NOAH and IFAH Europe proposals

- Strict interpretation of ‘the cascade’ required, but critical to retain ‘the cascade’ for welfare reasons
- Without cascade, minor use and minor species (MUMs) treatment needs unlikely to be met
- Improved regulatory framework - more licensed authorisations will lead to less cascade use
- IFAH Europe proposal for a true single market for veterinary medicines - may reduce need to resort to the cascade
- Need to retain in feed as a route - a solution, not a problem - improves welfare, practicalities need to be considered
Conclusions

- The use of antimicrobials in veterinary medicine will change following legislative review
- Need a full range of antimicrobials to remain available for use in veterinary medicine (responsible use)
- Essential that a range of routes of administration remain available e.g. in-feed
- Need to encourage innovation and investment in vet med sector
- Over zealous use of the ‘precautionary principle’ has potential to negatively impact innovation and animal health and welfare
- International dimension must be remembered - avoid ‘exporting food production’
Communicating on animal medicines
Excerpt from NOAH launch brochure, 1986

NOAH and its task

SCIENCE AND TECHNOLOGY make massive contributions to everyday life and nowhere more so than in the production of the food we eat.

Modern livestock farming is now more efficient and safe than at any time in history, thanks to the use of vaccines and antibiotics. Huge investment in animal health research and development in the past thirty years has developed controls for all the most serious livestock diseases and stock can now be raised in a healthy and more productive way to the benefit of all.

The companies which make up the National Office of Animal Health (NOAH) are at the forefront of all these improvements for animals and not least in the important pets sector where owners can be confident that their pet can look forward to a healthy, disease-free life.

It is NOAH’s chief task to inform and educate the public about animal health and the part played by the companies which produce the products that ensure freedom from disease. NOAH’s role is all the more vital given the rise in consumer interest in how our food is produced.

Misunderstanding can occur among the public about the need for animal health products. NOAH welcomes informed and rational debate, but it will at all times support that which has been scientifically tested and approved against ill informed comment.

The main concern of animal health companies is to produce safe products for livestock and consumers. The development of new products requires huge financial investment, and many years’ work. This investment could be lost at a stroke if the product fails to come to market because of political expediency or the manipulation of consumer fears. If this threat grew too great, companies could be deterred from entering into long term research and animals, farmers and consumers would suffer.

Through liaison with opinion formers, decision makers, government officials, the veterinary profession, distributors and farmers, NOAH will work to convince the public that animal health matters and that the wise use of modern aids actually assists consumer safety.
What do we know about consumer concerns?

- NOAH commissioned studies through the IGD in 2006 and 2009 which helped us to understand what consumers understood, or perceived about animal medicines in the food chain,

- Following these surveys we updated briefing notes and produced our ‘myth busting’ document:  
  - ‘Animal Medicines- What you should know’

- In March 2013, following a further study, again commissioned by IGD, we held a further food chain conference, on working together to dispel the myths of livestock production
What did we learn?

- Early surveys showed us that consumers had faith in UK farmers.
- But some of the perceptions were disappointingly inaccurate – were they perpetuated by ill-informed media?
- Or mischievous lobby groups?
- Or was it because ‘we’ had not been proactive in our positive communications?
Positive about farmers and independent checks

73%

British farmers care for the health and welfare of their animals

60%

Animal medicines are assessed and checked by independent scientists to ensure they are as safe for people

n.b. some thought there were NO checks

Source: IGD Shopper Insight
Uncovering the myths

1. Medicines/vaccinations getting into **food chain**

2. **Growth hormones** used

3. Medicines more necessary in **intensive farming**

4. **Antibiotics** becoming **less effective** for people due to veterinary use

Source: IGD Shopper Insight
Myth: medicines and vaccinations get into food chain

Source: IGD Shopper Insight
Belief that growth hormones are used

- **Agree**: 37%
- **Neither agree nor disagree**: 34%
- **Disagree**: 29%

71% of respondents believe growth hormones are used. Source: IGD Shopper Insight
Increased demand for information on growth hormones

- Are animals feed or injected anything to make them **grow faster?**
  - 2012: 38%
  - 2008: 22%

- What are animals **fed?**
  - 2012: 30%
  - 2008: 32%

- Which **country** has the meat come from?
  - 2012: 28%
  - 2008: 21%

- What **difference** is there between animal rearing in the UK and overseas?
  - 2012: 17%
  - 2008: 7%

Source: IGD Shopper Insight
Medicines more necessary in intensive farming

90%

Source: IGD Shopper Insight
Antibiotics becoming less effective for people due to use in animals

76%

Source: IGD Shopper Insight
Are farm animals to blame for the rise of superbugs?

It’s normally pinned on doctors handing out antibiotics like sweeties. But there’s another, very unsettling theory...

The warnings that went ignored
corner was not the one they had just entered. This was the building where they had come to meet, the one they had been driven to in a large black SUV. They had just stepped out of the SUV, their presence announced by the sound of their footsteps on the driveway. The building was a large, imposing structure, its windows reflecting the sunlight that poured in from the sky above.

As they entered, they were greeted by a receptionist who showed them to a small office. Inside, two people sat at a desk. One of them was a man, the other a woman. The woman looked up as they walked in. “Good morning,” she said. “How can I help you today?”

The man introduced himself and explained the purpose of their visit. The woman nodded and said, “I’ll be glad to help. What can I do for you?”

The man explained that they had come to investigate a strange phenomenon that had been troubling them for some time. He described how, in recent years, there had been an increase in the number of cases of superbugs, bacteria that were resistant to antibiotics.

The woman listened carefully. “That’s interesting,” she said. “I’ve heard of that problem before. It’s getting worse all the time.”

The man continued, explaining that they believed the phenomenon might be linked to farm animals. “We think that the use of antibiotics in agriculture might be contributing to the development of superbugs,” he said. “But we need more evidence before we can be sure.”

The woman nodded again. “I see. Well, I’ll do some research and see what I can find. If I find anything that might help, I’ll let you know.”

The man thanked her and said goodbye. As they left the building, they couldn’t help but feel hopeful. If they could just find the evidence they needed, they might be able to prevent the spread of superbugs and protect the health of the people they served.
More consumers are demanding information

What sort of **living conditions** do animals have?

- 35% (2012)
- 32% (2008)

What hygiene standards exist?

- 30% (2012)
- 28% (2008)

For how long and in what conditions are animals **transported**?

- 19% (2012)
- 27% (2008)

**How** are animals killed?

- 18% (2012)
- 17% (2008)

**How long ago** was the animal killed?

- 11% (2012)
- 17% (2008)

**What legislation** exists to make sure animal meat is **safe**?

- 11% (2012)
- 21% (2008)

Who **checks** that everything is done right and how is this checked?

- 11% (2012)
- 20% (2008)

How can we be sure that the meat is what it says on the **label**?

- 10% (2012)
- 20% (2008)

Have the animals ever been **sick**?

- 14% (2012)
- 18% (2008)

Have the animals ever been **vaccinated** to prevent disease?

- 9% (2012)
- 15% (2008)

Have the animals ever been given **medicines** as a prevention?

- 8% (2012)
- 13% (2008)

Source: IGD Shopper Insight
Two new NOAH videos:

- **Consumer Film** - Animal Medicines in Food Production – Challenging Consumer Myths
  - [http://youtu.be/1qluroDR8Ak](http://youtu.be/1qluroDR8Ak)
- **Industry Film** - Animal Medicines in Food Production – The Food Industry Perspective
  - [http://youtu.be/UWihGoyJgBI](http://youtu.be/UWihGoyJgBI)
Questions?

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