Veterinary
Medicines
Directorate

VMD Open Meeting

2 October 2015

Veterinary
Medicines
Directorate

General Updates

Marie Hendrickx
Director of Authorisations

Overview

- People and teams
- Processes and continual improvement
- Reduction of regulatory burden
- Industry choice of RMS
- Communication
- 3Rs and fish vaccines
- On the horizon

People and Teams

- Staff – Approx 150 Full time Equivalents
- Reductions in some teams due to
  - more IT processes
  - improved processes
- New appointments in 2015
  - Head of AMR team
  - Head of Pharmaceutical and Feed Additives team
  - Director of Authorisations Division
- 5 training day a year continues
- Investor-in-People Silver Award renewed

Processes and Improvements

- Simplifications of our guidance
- Digital by default allows
  - cost savings
  - simplification of processes for our customers (import certificates, E-submissions)
- Robust processes confirmed by external audits
  - ISO 27001 IT security certification
  - ISO 9001 Quality Management System certification

Electronic Working

- E- Submissions
- Historical dossiers scanned
- Electronic Filing
- Electronic Invoicing
- Automated data transfer (e.g. to EudraPharm and EudraVigilance)
- On-line systems:
  - Adverse event reporting
  - Import certificates
  - Export certificates
  - Product information database

Reduction of regulatory burden -1

In place

- Export certificates and allergen imports requirements streamlined
- Fee reductions for national variations
- Risk based approach for inspections reduces numbers of inspections and site visits

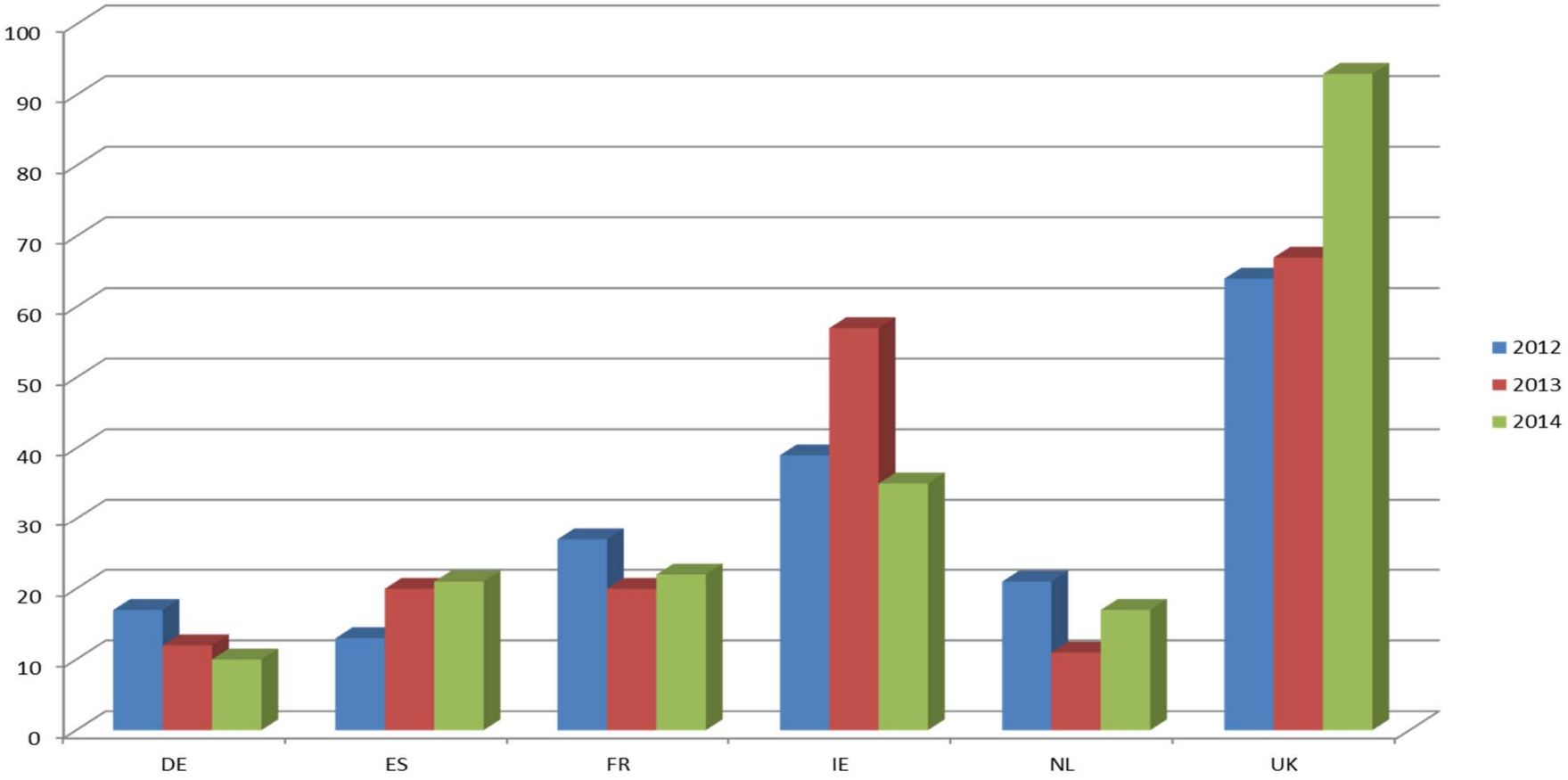
Reduction of regulatory burden - 2

In progress

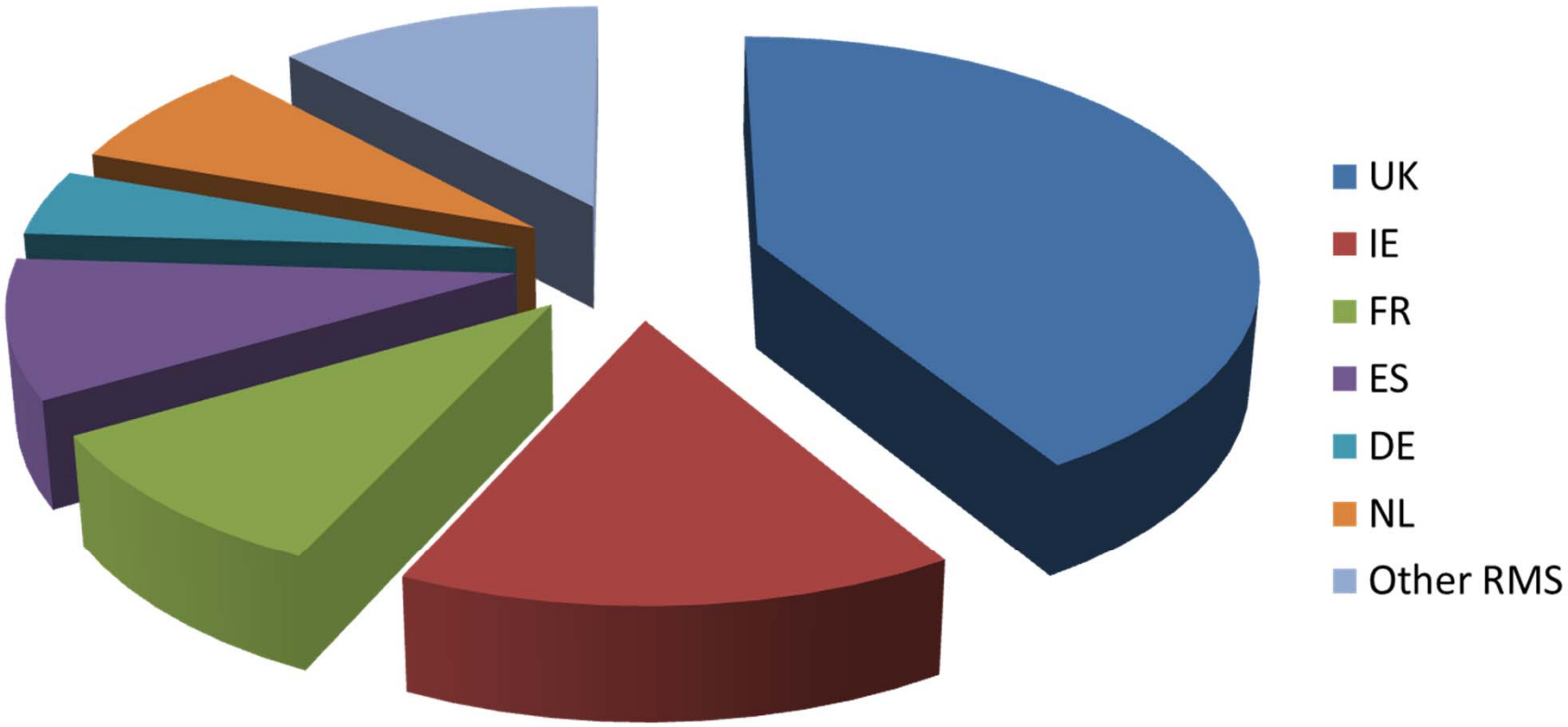
- Animal Test Certificates application process review
- Inspection of fish farms into be carried out by Marine Scotland
- Using earned recognition scheme to extend inspection intervals (egg producers and medicated feed manufacturers)

UK Popularity as RMS

RMS : Procedures Ending 2012 -2014



RMS : Procedures Ending in 2014



Communication

- GOV.UK – VMD's website material moved over in November 2014
- VMD branding change – old logo replaced by new Government insignia
- Veterinary medicines guidance - streamlined to meet users' needs making it easier to read, digest and access on GOV.UK
- Attended events for vets, animal owners and industry
- Pro-active comms – want to reach more people with our messages using others' communications channels. You can help us.

3Rs Update for 2014

- UK Official Batch Release for IVMPs is operated by the VMD
  - Access to data on all batches released via the UK.
  - Access to data regarding the in process and finished product testing of all UK authorised products
- By collating the two sets of data we have been able to analyse how the use of animals for these tests has changed over time
- VMD reviewed the use of animals in the quality control testing of all batches of IVMP from 2007 to 2014 for fish

3Rs and Fish

Fish vaccine batch release data 2007-2014

- 159 batches of 14 authorised vaccines for use in trout and salmon were released via the UK
- All inactivated vaccines, many multi-valent, requiring the use of relatively large numbers of fish to assess potency

3Rs and Fish

Fish vaccine batch release data 2007-2014

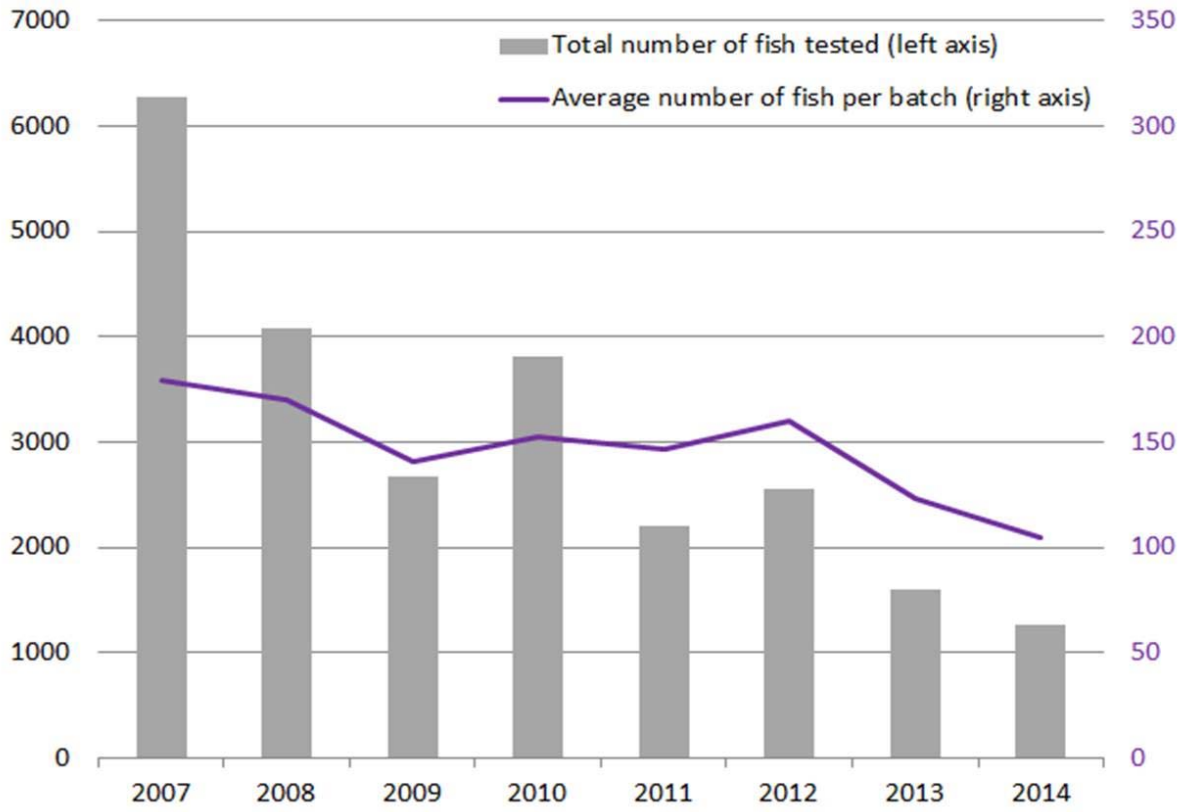
- Included vaccines against
  - ✓ *Aeromonas salmonicida*,
  - ✓ Infectious pancreatic necrosis virus,
  - ✓ *Yersinia ruckeri*,
  - ✓ Salmon pancreas disease virus,
  - ✓ *Listonella anguillarum*,
  - ✓ *Moritella viscosa*
  - ✓ Salmonid alphavirus

- Between 80 and 260 fish were tested for safety and potency per batch released

3Rs and Fish -2

80% decrease in the total number of fish used over an 8 year period

The average number of fish used per batch released decreased by 42%



Batch safety testing in fish

- Batch safety testing of fish vaccines was responsible for around 40% of all fish used in batch testing between 2007 and 2012
- The requirement of batch safety test was removed from April 2013
- **Removal of the requirement for the batch safety test by the Ph. Eur. resulted in a decrease of 1,000 fish per year based on 2012 figure**

On the Horizon

- Spending review underway in DEFRA
- Antibiotic resistance strategy implementation
- Continue input into the EU legislation revision
- Inspection fees review
- Pharmaceutical Industry survey for 2016

Veterinary
Medicines
Directorate

Proposals for new EU regulations on veterinary medicines

Dr Nick Renn
Head of Legislation

Proposals for new EU Regulations:

Adopted September 2015:

1. Veterinary medicines
2. Amendments to Council Regulation 726/2004
3. Medicated feed

Council of EU MS meets monthly

European Parliament Committees:

Environment, Public Health and Food Safety

Agriculture and Rural Development

Today

Some key changes

– including those aimed at reducing the risk of antimicrobial resistance

How discussion in Council has been “progressing”

Highlights for veterinary medicines

PROPOSAL FOR VETERINARY MEDICINES

THE COMMISSION'S OBJECTIVES FOR VETERINARY MEDICINES:

Address the public health risk of antimicrobial resistance

Reduce administrative burdens

Improve the functioning of the internal market

Stimulate competitiveness and innovation

Increase the availability of veterinary medicinal products

Antimicrobial resistance

"Action plan against the rising threats of antimicrobial resistance" Commission paper of 2011.

Actions:

2. Strengthen the regulatory framework for veterinary medicines and medicated feed
7. Promote efforts to analyse the need for new antibiotics into veterinary medicine
10. Strengthen surveillance systems on AMR and antibiotic consumption

AMR: Impact Assessment Options

1. Provisions to minimise risks to public health arising from the authorisation and use of antimicrobials
2. Harmonise the collection of data
3. Incentives for the development of antimicrobials for veterinary medicine
4. Clarify rules on advertising of prescription medicines

Marketing Authorisations

1. National – unaffected
2. Mutual recognition – Reference member state assessment considered by concerned member states
3. Decentralised – one member state's assessment considered by concerned member states
4. Centralised – scope widened

- Streamlining - removes administrative burden
- Unclear of full impact on funding – NCAs reduced to core number?

Submission of all dossiers will have to be done electronically

Dossier and antibiotics

Antibiotics

- Cannot be critical for human health: Rules and list planned
- Data for to show risk to public or animal health and risk mitigation measures
- Right to refuse application for an antibiotic:

  poor benefit:risk assessment

  growth enhancer

- SPC to include strategic use of antibiotic
- Antibiotics only on vet prescription

Labelling

- Defined for immediate and outer packaging “shall contain only..”
- Reduced for smaller packages
- Pictograms to be introduced – reduced need for translation

SPC Harmonisation

- Summary of product characteristics will to be harmonised: groups of similar products
- Products with **national marketing authorisations**

  - issued before 1 January 2004
- Limited to species, therapeutic indication, shortest withdrawal period

  - the quality part of the dossier is missing
- Favourable opinion by Committee for Mutual Recognition
- Unfavourable then groups of products have to go for reassessment
- Before July 2000 – environmental risk assessment

Post-authorisation

Variations

– list of variations requiring scientific assessment

- risk to public
- animal health
- environment

- others will be “do and tell”

No renewals

No sunset clause

Pharmacovigilance

Risk-based approach

PSURs no longer required

EU database

Electronic reporting and signal detection

Data Protection

- 10 years (cattle, sheep, pigs, chickens, dogs, cats)
- extended by one year for each additional species

- 14 years for all other species and for antibiotics if the active is new to the EU
- extended by four years for a minor species

- 18 years for bees

- Maximum of 18 years data protection

Antibiotic consumption

- Member States to collect and report data on the volume of **sales and the use** of veterinary antibiotics

- Commission may establish rules on method of data gathering

Advertising

Prescription medicines, psychotropics and narcotics may not be advertised

Does not apply to persons permitted to prescribe or supply

Prescribing

- Vets will only be able to supply antibiotics to animals under their care
- Cascade prescribing: restrictions of critical antibiotics:

  Commission may establish a list of antibiotics which cannot be used under the cascade

  Risk to human health considered
- Cascade decision tree flattened:

  human medicines can be used as an alternative first choice if an authorised veterinary medicine is not available
- Withdrawal periods for cascade prescribing revised

Other changes

- Clinical trials
- Internet sales
- Veterinary prescriptions recognised throughout EU
- Wholesale distribution authorisation valid throughout the EU
- Competent authority to provide help desk for SMEs

<u>Bee medicines:</u>

Vets will be ale to import from third countries if there is no suitable medicine available in Europe

Reduced authorisation requirements

So far..

Council of EU working parties

- Meeting every month
- 1st technical read through at article 116 (of 149 and annexes)

Luxembourg aiming to complete by December

European Parliament

Debated in Committees: ENVI

MEPs have a critical role –

VMD providing briefing

UK Stakeholders lobbying

Highlights for medicated feed

Medicated feeds

Commission's objectives for medicated feed

Make medicated feed available to farmers and pet owners at a competitive price

Improve animal health by precise dosage of oral VMPs

Remove barriers for innovative, "novel" medicated feed – pet products

Over-come the zero-tolerance for unavoidable carry-over of VMPs

Curb AMR-risk from residual and sub-therapeutic administration of antibiotics

Proposal for Medicated Feed

- Carry-over

  antibiotics: 0.1mg kg^{-1}

  Commission argues this will reduce risk of AMR

- Prescribed medicated feed only to be used for animals examined by the vet

- Antibiotics shall not be used to prevent disease

So far..

Council of EU MS

- First technical read through completed in Feb

  4 Council Working Parties

- "Annotated text" release 9 June
- Second technical read through at article 12

- Presidency concerned about read-across with vet medicines

European Parliament

Debated in Committees: Agri

MEPs have key role - VMD briefing

- Stakeholder have also been lobbying

Next steps

- Annotated text for veterinary medicines to become available during The Netherlands presidency
- Developments with medicated feed adjusted to ensure read across
- Lobbying MEPs when appropriate
- Trilogue
- Adoption in 2017?

Thank you

Veterinary Medicines Directorate

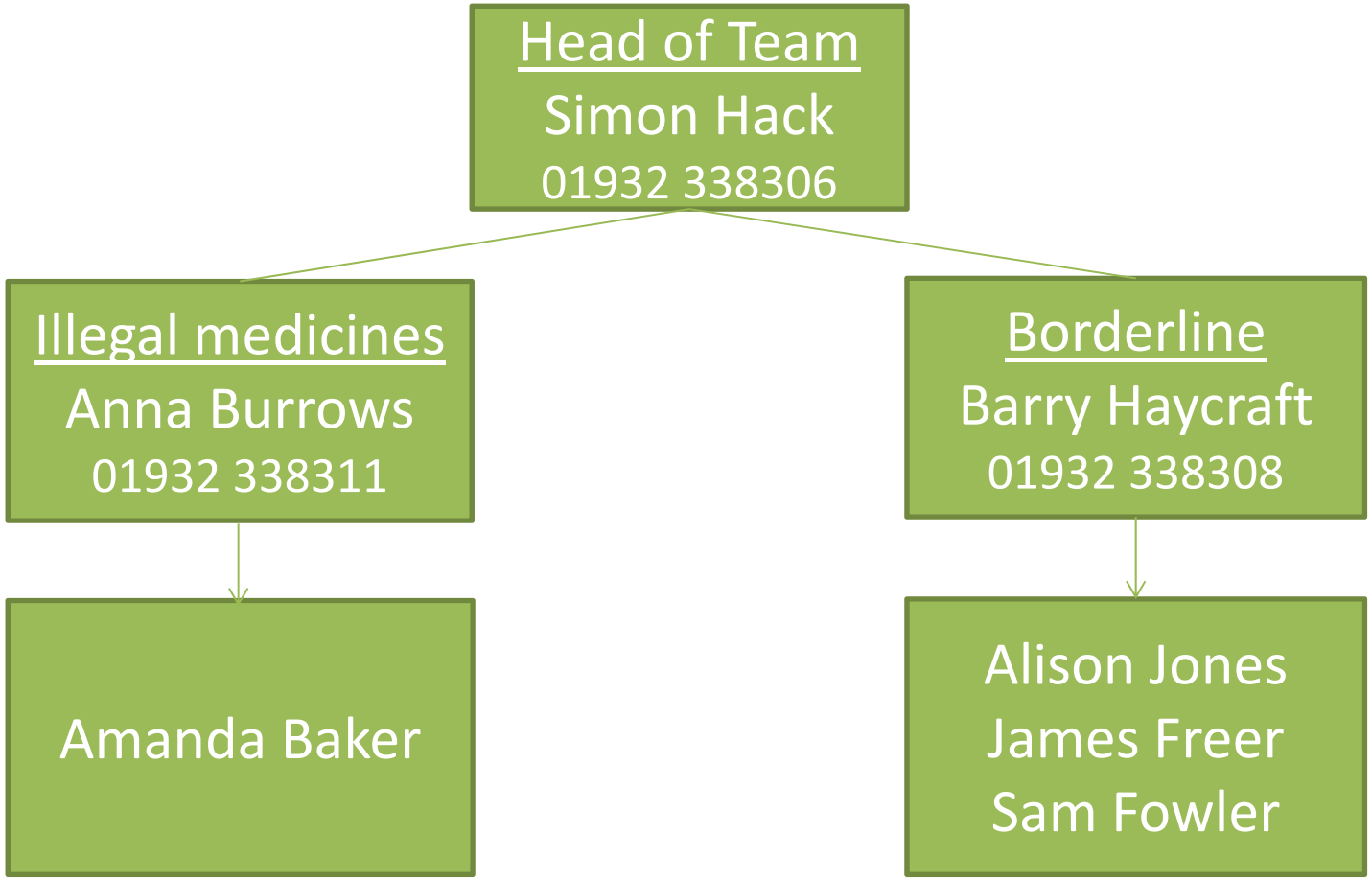
Enforcement

"It's about time law enforcement got as organised as organised crime"

Rudolph Giuliani

Presented by: Simon Hack
Date: 2 October 2015

Team structure



What we do

- Enforce the Veterinary Medicines Regulations
- Aim to eliminate the use of illegal veterinary medicines by reducing marketing, sale, supply and administration of such products
  - Borderline products: Unauthorised products marketed for sale that may be considered to be medicinal by presentation or by function
  - Illegal medicines: possession, administration and sale of these medicines. Includes the sales of medicines online.

Intelligence

- Complaints
- Information received
- Inspections
- Other regulators/enforcement bodies

Enforcement Tools

- Risk based enforcement strategy:
  - Advisory letters, warning letters
  - Improvement/Seizure notices
  - Investigations
  - Police cautions, prosecutions
  - Website take down

Partners

- Police
- National Crime Agency (NCA)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- Border Force (BF)
- Local Authorities (LAs)
- Working Group of Enforcement Officers (WGEO)
- Royal College of Veterinary Surgeons (RCVS)

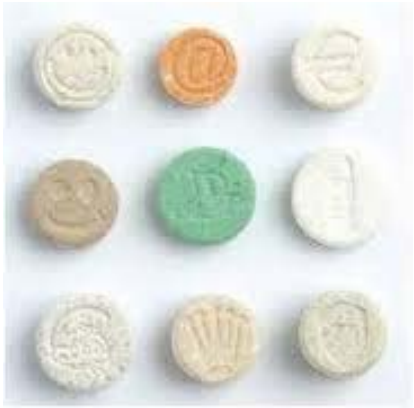
Illegal medicine sales via the internet

- **Proactive not reactive**
- eBay
- Discountpetcare
- Nominet
- Border Force

Operation Pangea

Recreational Drug Use

Ketamine



Cocaine

Recreational Drug Use

Drug-Cutting Agents – new powers

- **Serious Crime Act 2015 Part 4: The seizure and forfeiture of drug-cutting agents**

  - Part 4 of the Act provides new civil powers for UK law enforcement to seize, retain and destroy substances reasonably suspected of being intended for use as cutting agents for drugs controlled under the ***Misuse of Drugs Act 1971***, in order to restrict their supply into the illicit drugs trade. These powers are intended to target substances rather than individuals.

Enforcement Newsletters

Veterinary Medicines Directorate

ENFORCEMENT NEWSLETTER

ISSUE 3

- The Veterinary Medicines Directorate is an Executive agency of the Department for Environment, Food and Rural Affairs (Defra)
- We authorise and regulate veterinary medicines in the UK
- We aim to ensure the responsible, safe and effective use of veterinary medicines

Illegal Activity on the Internet

We deal with a number of regulatory issues concerning sales of veterinary medicines via the internet. As with other channels, internet sales can fall foul of the Veterinary Medicines Regulations.

Our concerns include:

- Overseas companies targeting the **UK** market
- Sales of unauthorised veterinary medicines, including antibiotics
- Sales of products claiming to **treat** or **prevent** disease
- Supply of authorised products
  - by non-qualified persons
  - from unauthorised premises
  - without correct procedures in place
- Product marketing
  - e.g. advertising of **POM** (Prescription Only Medicine) products

WHAT WE DO

We treat the illegal sale of veterinary medicines seriously and take robust enforcement action as appropriate. Our activities include:

- Gathering information/intelligence
- Sending advisory letters/guidance raising awareness of the veterinary medicines legislation
- Sending warning letters
- Issuing improvement notices
- Removal of products from internet platforms
- Closing down **.co.uk** websites

Contact: enforcement@vmd.defra.gsi.gov.uk

Enforcement Cases Year to Date	Quarter 1 2015/16	Quarter 2 2015/16
Borderline products: illegal marketing of non-medicinal products (medicinal by presentation or by function) Cases reported Cases completed (including carry over)	 50 73	 **37** **39**
Internet product listings removed (Illegal sale of veterinary medicinal products via the Internet)	308 including 85 antimicrobials	**532** **including** **41 antimicrobials**
Letters sent following breaches of the VMR	162	**88**
Prescription tampering/fraud cases reported	31	**8**
Seizure notices (Issued whenever illegal medicines are seized)	3	**0**
Improvement notices (Issued when improvements are required to comply with the Veterinary Medicines Regulations)	1	**1**
Cases referred to Defra Investigation Services with a view to prosecution	10 1	**4** **0**

“INTELLIGENCE IS THE ABILITY TO ADAPT”

Stephen Hawking