Veterinary
Medicines
Directorate

VMD Pharmaceutical Industry Day

Welcome and Introduction

Presented by: Marie-Odile Hendrickx

Date: Friday 23rd June 2017

Fire Alarm Sounding

- Leave the building by the nearest available safe exit route

- Proceed to the Assembly Point **situated in the visitor car park behind the Gatehouse/Security Building**

- Remain at the assembly point with teams until you receive instructions from VMD officials or site security

Staff update

- Head of EU Exit Co-ordination : Abi Seager
- Team merger: Licensing Administration and General assessment under Gavin Hall
- Head of the P&FA team: Rutendo Manyarara (TARA)

Morning Schedule:

Time	Topic	Speaker
9:30 - 10:00	**Registration - Including Tea & Coffees**	All
10:00 - 10:05	Meeting start – Introduction from Marie	Marie Hendrickx
10:05 - 10:40	Update on EU Exit (35mins)	Abi Seager
10:40 – 11:00	Update on the new Regulations and the Great Repeal Bill (20mins)	Lea Reynolds
11:00 – 11:20	Industry perspective on the Cascade (20mins)	Donal Murphy – National Office of Animal Health
11:20 – 11:40	Reduction of regulatory burden (CMDv/VMD) (20mins)	Gavin Hall
11:40 – 12:05	The Nagoya Protocol on Access and Benefit Sharing: Implementation in the UK (25mins)	Katie Beckett -Department for Business, Energy and Industrial Strategy
12:05 - 13:00	**Buffet Lunch Provided**	

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EU Exit

Presented by: Abi Seager, Head of EU Exit Co-ordination
Date: 23 June 2017

The next half hour

- What I know and what I don’t know
- The EU Exit programme of work
- Day 1 issues
- Communications
- IT
- Workshops
- The future

What we know

- Article 50 was triggered on 29 March 2017
- There is a 2 year negotiation period
- Negotiations have started!
- The actual date of withdrawal will form part of any negotiated withdrawal agreement and could be later than March 2019 but plan for March 2019.

What we don't know

- If it will be as a hard an exit as originally thought.
- If it will be 'deal or no deal'
- How the negotiations will end up
- Exactly what the 'New State' will look like
- How we might end up working with the EU and EMA

So…

There’s lots we don’t know

but

we can’t sit back and wait for the answers,

so we are planning for a range of negotiated and a non-negotiated outcome.

The EU Exit Programme

- Workstreams:
  - Great Repeal Bill
  - Market Access and Customs Union
  - Withdrawal Agreement and negotiations
  - Contingency planning and building
  - Stakeholder Engagement

Great Repeal Bill

- Lea Reynolds

Market Access and Customs Union

- Trade is a top priority
- Identifying barriers to trade
- Need to ensure continued trade on Day 1
- Different trade models
- Residues surveillance programme
- MRLs
- Border control issues
- Imports and Exports

Withdrawal Agreement & negotiations

- Aim for a smooth transition
- Aim to ensure business continuity
- Aim to ensure continued availability of veterinary medicines
- Aim to ensure UK is attractive and viable for MAHs

Contingency planning & building

- Addressing Day 1 issues and longer term ‘slow burn’ issues

- Planning for a range of potential outcomes
  - Scenario A - sliding scale of EMA interaction
  - Scenario B - no relationship with EU

- Opportunities may come to be realised after transition state

Working with others in government

- Defra
- DExEU
- MHRA
- FSA
- HSE

Stakeholder engagement

- Original plans for UK wide engagement

- Now local level
- Consultation on legislation
- Workshops on issues and process changes

Day 1 & high priority issues

- Centralised MAs
- Maintenance of mutually recognised MAs
- Locations - MAH, QP, batch release
- Joint labelling
- On-going applications
- On-going referrals
- Pharmacovigilance and Rapid Alerts
- MAPIs
- Access to IT
- Special Imports Scheme
- GMP inspections
- MRLs
- Generics

IT

34 databases, systems, data exchanges with EMA

Considered priority IT systems:

- Submission portal
- Pharmacovigilance systems
- Rapid Alerts
- Secure correspondence system

Scoping build/buy options

Development, integration, user testing and decision points

Workshops

- In the Autumn
- Invitation to register interest
    - Gov.uk
    - Mavis
    - Vet record
- Indication of topic preferences
- On the day
    - Work through scenarios or step through processes
    - Aim to gather views, record issues and identify opportunities

Recent communications from EMA

- Everyone is planning for EU Exit
- Legislation permits business as usual
- UK still fully committed to EU network
- Critical decision dates for own business planning
- Q&A will be published soon

Current work

- Great Repeal Bill
- More detailed contingency planning
- Day 1 issues, step by step through processes
- Identifying opportunities and risks
- Stakeholder engagement planning

The future

A thriving UK animal health industry

Any questions?

- Thank you
- Contact me

a.seager@vmd.defra.gsi.gov.uk

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EU Review of Veterinary Medicines
&
Great Repeal Bill

Presented by: Lea Reynolds
Date: 23 June 2017

Overview

- Update you on what's happened so far with the EU Council Negotiations
  - Recap some of key issues and explain how the text has evolved in these areas
  - Give a view on how we see things progressing

- Give an overview of our work on the Great Repeal Bill

Story so far…

- Commission proposal(s) released 10 September 2014

- Council Working group
  - Monthly meetings
  - All articles discussed and redrafted at least twice

- European Parliament
  - agreed list of 289 consolidated amendments
  - voted to open negotiations with council - not started

Story so far…

- Maltese Presidency coming to an end
  - Pace of discussion increased
  - Moved to a topic approach
  - Last working group to be held 28-29 June

- Estonian Presidency starts 1 July
  - Council working groups dates already set for July and September
  - We are hopeful that the quicker pace will continue
  - The UK will continue to take part in the negotiations for the foreseeable future

The Commission's Objectives for Veterinary Medicines

- Address the public health risk of antimicrobial resistance
- Stimulate competitiveness and innovation
- Reduce administrative burdens
- Improve the functioning of the internal market
- Increase the availability of veterinary medicinal products

Antimicrobial Resistance

- Original proposal
  - Restrictions on antibiotics critical for human health
  - MS must report data describing antibiotic consumption
  - Restrictions on cascade prescribing of critical antibiotics
  - Vets can only dispense antibiotics to animals under their care
- Latest text*
  - Restrictions on Prophylaxis and Metaphylaxis
  - Definitions of Prophylaxis, Metaphylaxis, Antimicrobial and Antibiotic

Cascade

- Original proposal
  - Decision tree flattened
  - Implementing act to establish list products that can be used in fish (animal, human and environmental safety)
- Latest text*
  - 3 step tier
    a) EU authorised VMP
    b) Then a human product from the MS concerned
    c) Then a extemporaneous preparation
  - New derogation to allow a product authorised in a third country to be used if it authorised for the same species and indication (does not apply to Immunological products)

Variations to MAs

- Original proposal
  - list of variations requiring scientific assessment
  - All others will be “do and tell”
- Latest text*
  - list of variations requiring No scientific assessment
    - “do and tell” – within 30 days of implementation
  - All others will require assessment

Internet Sales

- Original proposal
  - Common logo scheme
  - All veterinary medicines permitted to be supplied online
- Latest text*
  - Only veterinary medicines not subject to a veterinary prescription may be sold online
  - Small group of MS have argued for a derogation to allow MS to permit all medicines if they choose to

Manufacturing

- Original proposal
  - Active substances, intermediate products and excipients subject to full manufacturing/GMP requirements

- Latest text*
  - Manufacturing Authorisations no longer required for above
  - GMP Certificates can be issued for API Sites
  - Registration scheme for importers, manufacturers and wholesale distributors of active substances (based in EU)
  - Principles of GMP/GDP to be adopted into implementing acts

Pharmacovigilance

- Original proposal
  - risk-based approach
  - PSURs no longer required
  - EU database
  - electronic reporting and signal detection

- Latest text*
  - Presidency has tried to clarify responsibilities
  - Further detail on how signal management process will work
  - Sales figures to be recorded annually in database

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Great Repeal Bill

Great Repeal Bill

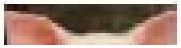
- Purpose
  - Repeal European Communities Act 1972
    - Save all secondary legislation made using section 2(2) ECA 1972 and equivalent powers
    - Save all directly applicable EU law (i.e. Regulations and Decisions) – with some modifications
    - Give a power to make consequential amendments to remove legal inoperability

- Veterinary Medicines Regulations 2013
  - Made under Section 2(2) of the European Communities Act
  - Considered “mostly operable”
  - inoperable areas will need be amended:
    - Most obvious change will be removal of references to “Member State”

Great Repeal Bill – Next Steps

- VMD working to identify inoperable areas of the VMR
- Intending to hold stakeholder workshops in the Autumn to discuss details with Industry
- Working with Defra lawyers to prepare an amending statutory instrument (SI) for the VMR
  - SI will coincide with the Great Repeal Bill (Day 0)
  - SI will be subject to full formal consultation process

Thank you!



NOAH
‘Industry perspective on the cascade’

Donal Murphy, Head of Technical and Regulatory Affairs,
NOAH

National Office of Animal Health

About NOAH

- The National Office of Animal Health (NOAH) represents the UK animal medicines industry and promotes and defends the responsible, promotion, sale, distribution and use of animal medicines.
- 26 Corporate Member Companies- to be a NOAH member company must have a full Marketing Authorisation for a veterinary medicine (a licensed veterinary medicine)
- Aim is to promote the benefits of safe, effective, quality medicines for the health and welfare of animals.
- Acts as a consultative body to the industry, Government, the media and the general public.

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National Office of Animal Health

The cascade

- Ideally, industry would be able to develop and license products for each and every indication and species
- In practice-not possible
- The cascade is needed as flexibility to allow vets to treat the wide range of species and conditions that they encounter
- It is essential for animal health and welfare

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National Office of Animal Health

The cascade

- Likely to remain in a similar form in new EU Veterinary Medicines Regulations once finalised
- BREXIT???
- Industry view is that retention of a broadly similar UK prescribing cascade to the proposals in the new EU Veterinary Medicines Regulations is the preferred option

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National Office of Animal Health

The cascade-current wording- VMR 2013

- *(2) If there is no authorised veterinary medicinal product in the United Kingdom for a condition the veterinary surgeon responsible for the animal may, in particular to avoid unacceptable suffering, treat the animal concerned with the following ("the cascade"), cascaded in the following order—*

  (a)a veterinary medicinal product authorised in the United Kingdom for use with another animal species, or for another condition in the same species; or

  (b)if there is no such product that is suitable, either—

  (i)a human medicinal product authorised in the United Kingdom; or

  (ii)a veterinary medicinal product not authorised in the United Kingdom but authorised in another member State for use with any animal species (in the case of a food-producing animal, it must be a food-producing species); or

  (c)if there is no such product that is suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation authorising the manufacture of that type of product

1st option-vet medicine

2nd option-choice between human product or an SIC vet med

3rd option-'vet specials'

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The cascade

- NOAH members agree that if the prescriber has real concerns about lack of efficacy for the licensed product, based on genuine past experience when used in that animal, it is appropriate to use the cascade to treat the animal (such concerns should also be handled via PV reports)
- NOAH members also agree that if the animal has had a suspected adverse event to the licensed product in the past, it is appropriate to use the cascade to treat the animal
- NOAH members do not believe that cost or convenience are appropriate justifications to use imported products/human products/veterinary specials ahead of vet licensed products

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The cascade- examples

- *A veterinary surgeon wishes to prescribe an antibiotic injection to a horse. There are two veterinary medicinal products (VMPs) available with the same active substance and concentration, one is licensed for horses, one is licensed for cattle.*
- NOAH view- even though the cattle product is cheaper the licensed equine product should be used.

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The cascade- examples

- *A veterinary surgeon wishes to treat a cat for a dermatological condition. There is no VMP licenced for that indication in cats. There is a VMP licensed for this indication in dogs, and a VMP containing the same active substance licensed in cats but for a different indication.*
- NOAH view- the vet can choose which product she wishes to prescribe as they are equally weighted on the cascade.

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The cascade- examples

- *A veterinary surgeon has been made aware of an injectable product produced by a 'specials' manufacturer (therefore product will be unauthorised) that they would like to try. There is an oral preparation containing the same active substance on the market licensed for use in the target species already.*
- NOAH view- in order to comply with the cascade, the licensed VMP should be used first.

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The cascade- examples

- *The patient did not respond well to the licensed treatment (for that indication and species) and the veterinary surgeon wanted to move on by using the injectable 'specials' product. However, on further investigation, the vet discovered that there was a human pharmaceutical product licensed with the same active substance on the UK market and therefore prescribed this treatment to his patient*
- NOAH view-unauthorised products (specials) fall below human pharmaceutical products and EU VMPs imported under an SIC on the cascade, therefore the human product should be used first, if suitable

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The cascade- ‘specials’

- ‘Specials’ are bottom of the cascade options- why is this?
  - Niche products
  - Animal welfare- best for animals to have licensed products where possible
  - No safety and efficacy data
    - Although there can be publications made available giving that impression to prescribers
  - No PV monitoring for ‘specials’
    - Lack of awareness exists amongst vets that there is no PV system for ‘specials’

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The cascade- some questions?

- Who at the VMD should vets and MAHs go to for advice on the cascade? The VMD legislation team?
- How is the cascade regulated and ‘policed’ and by whom?
- NOAH understanding is that this is by the VMD inspection team and by the Practice Standards Scheme inspectors of the RCVS
- More information on what is assessed in these inspections would be useful
  - E.g.- should records be kept for inspection by the RCVS PSS/VMD of owner consent to the use of an unlicensed product? and are such records inspected?)

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The cascade- some questions?

- NOAH aware of some product categories where the sales of the human licensed version are greater than the sales of the veterinary licensed product
- Other issues (e.g. PV) could explain some use of the human version but unusual that sales of the human product are greater
- NOAH does not wish to prevent vets being able to use products within the spirit of the cascade, but such disparities suggest extensive non-compliance
- Cost does seem to be used as a reason to use the cascade by some prescribers leading to quite significant market share for some unlicensed products in therapeutic areas where a vet product is available

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The cascade- some questions?

- Implications on prescribing vets if they do not follow the cascade- understand that this is a breach of the RCVS Code
- Many vets seem unaware that specials are not licensed veterinary medicines and only for use via the cascade
- Some vets appear to have the impression that they are equivalent to a licensed vet medicine
- How to report breaches of the cascade? Should this be to the RCVS or the VMD or both?
- Who is responsible for ensuring vets understand the cascade and where products rank within it? Is more publicity and explanation to vets needed?

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The cascade-final thoughts

- Veterinary medicines industry supportive of the retention of the cascade- essential for animal health and welfare to retain the cascade
- Important that it used appropriately and enforced
- Vet medicines industry is circa 2.5% of the human medicines industry- a small sector
- Need incentive of knowing that what are often niche products will be used to treat animals where they are available, if companies are to be encouraged to license and register vet medicines

NOAH
National Office of Animal Health

Questions?

Email:

d.murphy@noah.co.uk

Telephone: 0208 367 3131

National Office of Animal Health

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REDUCTION IN REGULATORY BURDEN

Presented by: Gavin Hall
Date: June 2017

“YOUR PAST EXPERIENCE WILL SHAPE YOUR FUTURE EXPECTATION”

We will be looking at what the VMD and CMDv have done to reduce regulatory burdens.

We Will Cover

- Fees
- Mock Ups
- Variations

Money

- Jan12 – Reduction in CMS fees by 40%

- Apr 14 – Reduction in Fees for national Type IA, IB and Type II Variations

- Apr 16 – 50% reduction in fee charged for national workshare :UK role is other

Mock Ups

- Changed the way we deal with mock-ups. Changes apply to national (MRP/DCP) MAs.
- Previously asked to provide revised mock-ups for assessment for **all** applications that affect them.
- Now, only have to provide revised mock-ups in **some** cases.

We will not routinely request mock ups for:

- Renewals
- Type IA variations
- Selected type IB and II variations
- Where mock-ups are not requested, we will annotate the agreed changes onto the latest authorised versions and issue these to you.

Summary

- Live since 1st April 2016.
- Requests for revised mock ups have reduced from 27% to 19% since implementation.
- We did not require any MAH to submit mock ups more than 2 times per application.

Variations

- Work sharing is encouraged.

- Changes in active substance specifications occurring as a consequence of a change in CEP / ASMF to be submitted as a single variation.

- Change in name and / or address of MAH – to RMS and affected CMS only.

Variations

- MRP / DCP - Where product names are different and want to change, a single variation is to be submitted. Not grouped.
- RMS will decide on classification if a CMS has a different view.
- Active participation on Joint Variations task Force

Variations

- CMDv agreed pilot on Part II harmonisation with single Type II variation.
- CMDv agreed to have unofficial work sharing with extension application that applies to a product range.
- Reviewed variations Q&A published by CMDh for continued relevance to CMDv

Bonus Slide

- Conversion of Article 34 referrals to MRP status.
- Shortened timetable for MRP / Repeat Use
- Adopted ASMF work share procedure
- Agreed the principle of biowaivers applies to hybrids in case of identicality

Bonus Slide

- Removal of nearly 40 national requirements across the Member States.
- Notification inbox – We confirm if specific minor changes to mock ups require a variation
- Sun Set Clause - Proportionate approach

THANK YOU

Any Questions?

Department for Business, Energy & Industrial Strategy

Regulatory Delivery

The Nagoya Protocol on Access and Benefit Sharing: Implementation in the UK

VMD Pharmaceutical Industry Day 2017

Friday 23rd June 2017

katie.beckett@beis.gov.uk

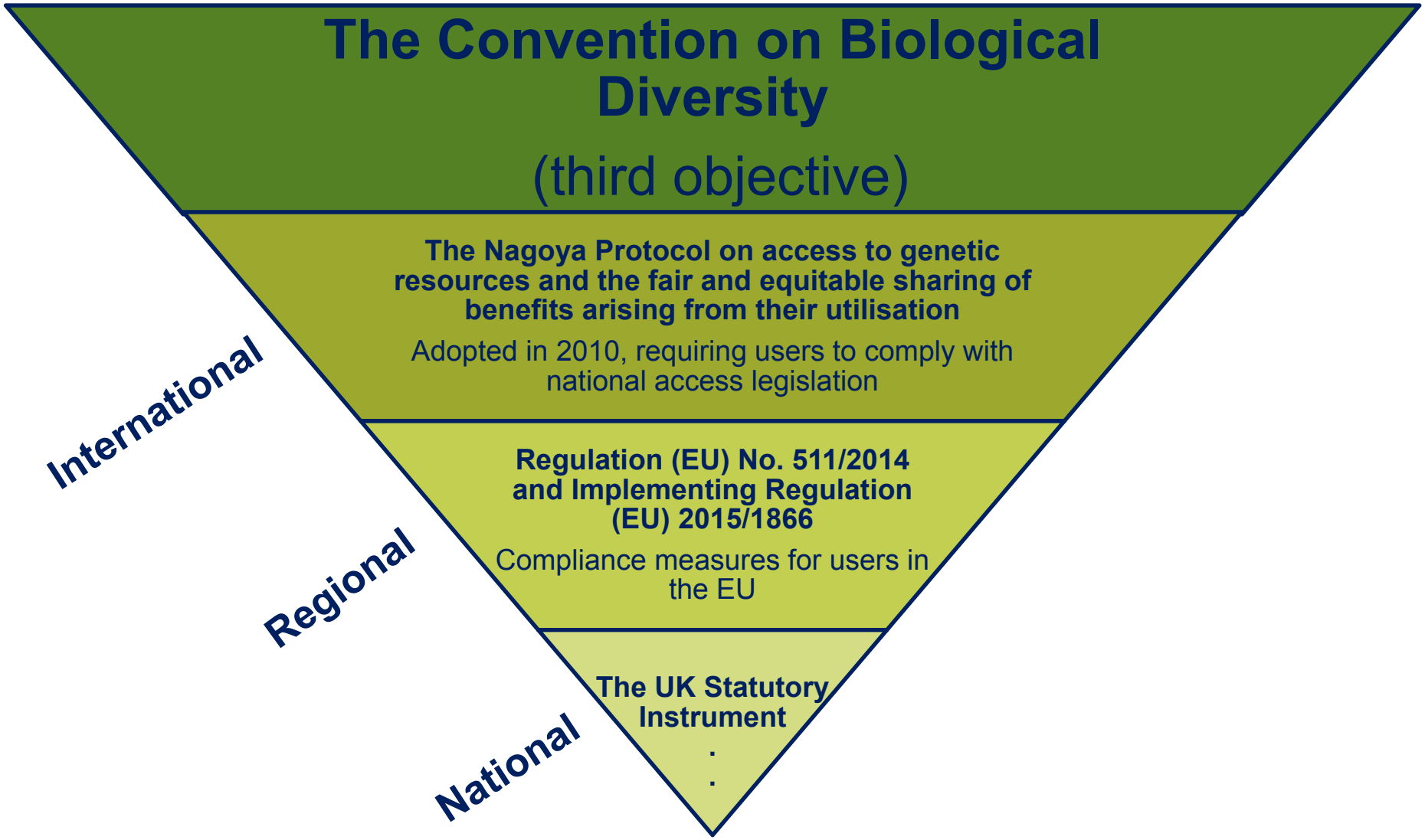
Who we are

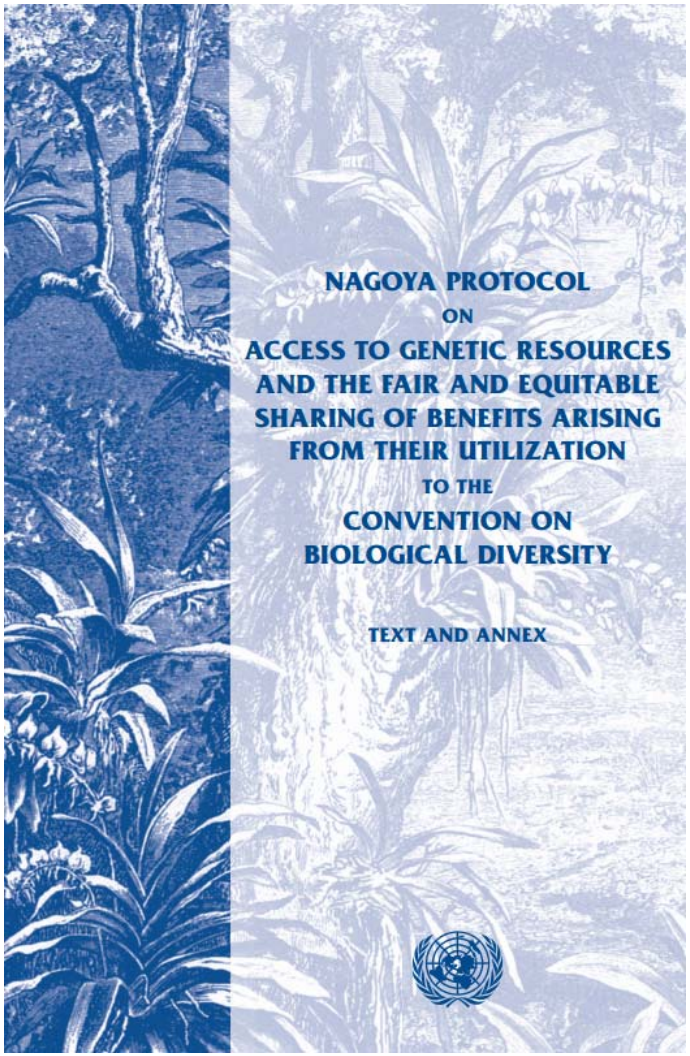
Regulatory Delivery (RD)

- Enforcement authority for Access and Benefit Sharing (ABS) in the UK
- Technical and product-based Regulations with environmental focus
- Expertise in risk-based market surveillance, supporting compliance and addressing non-compliance in a proportionate and pragmatic manner

Defra

- Policy lead on Access and Benefit Sharing
- National Focal Point (NFP)

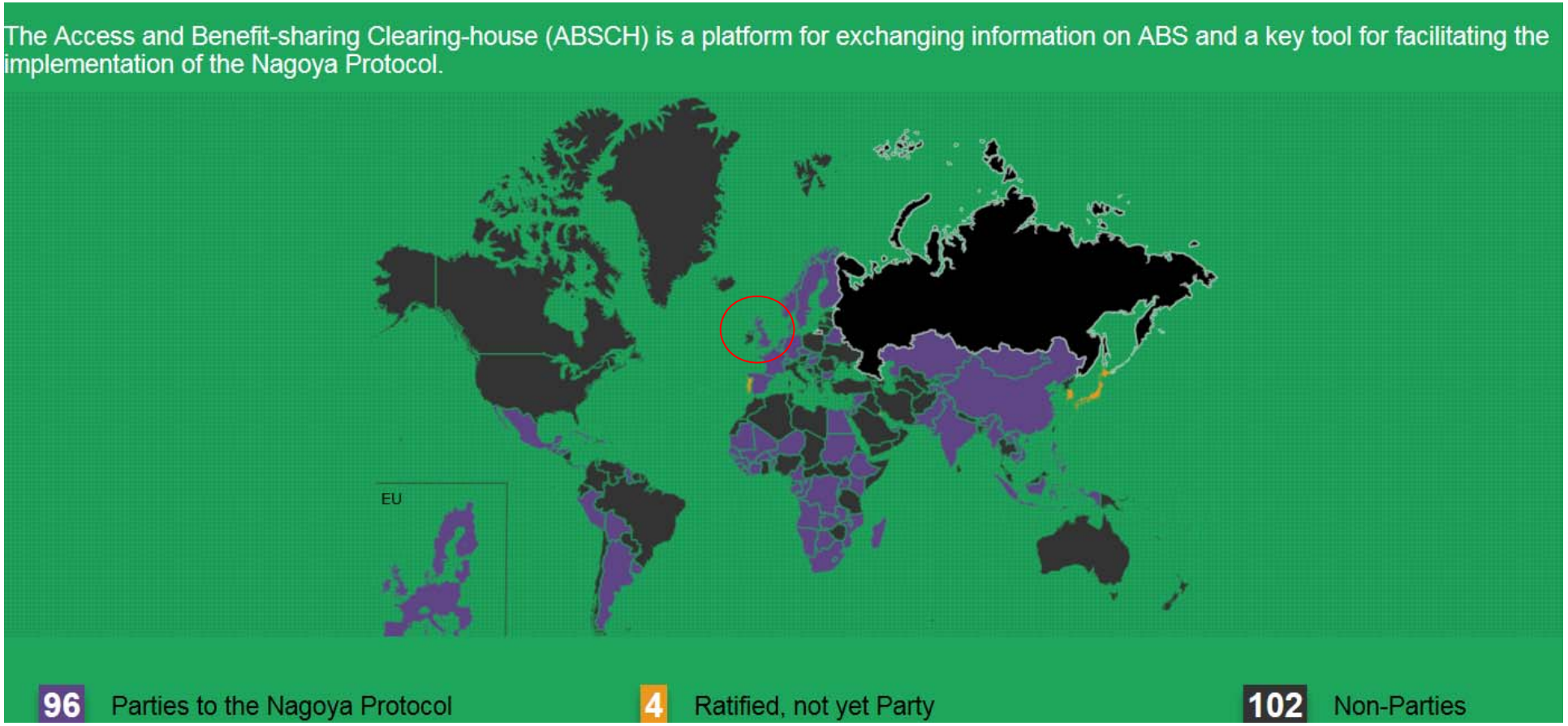

The Convention on Biological Diversity
(third objective)
The Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation
Adopted in 2010, requiring users to comply with national access legislation
Regulation (EU) No. 511/2014 and Implementing Regulation (EU) 2015/1866
Compliance measures for users in the EU
The UK Statutory Instrument
.
.
International
Regional
National



NAGOYA PROTOCOL

- Supplementary to CBD
- Legal framework for implementation of the fair and equitable sharing of benefits arising from utilisation of genetic resources
- More predictable conditions for access to GRs
- Help ensure benefit-sharing when GRs leave the country of origin
- Traditional knowledge associated with GRs
- Tools: Access and Benefit Sharing Clearing House

Access and Benefit Sharing Clearing House (ABS-CH)



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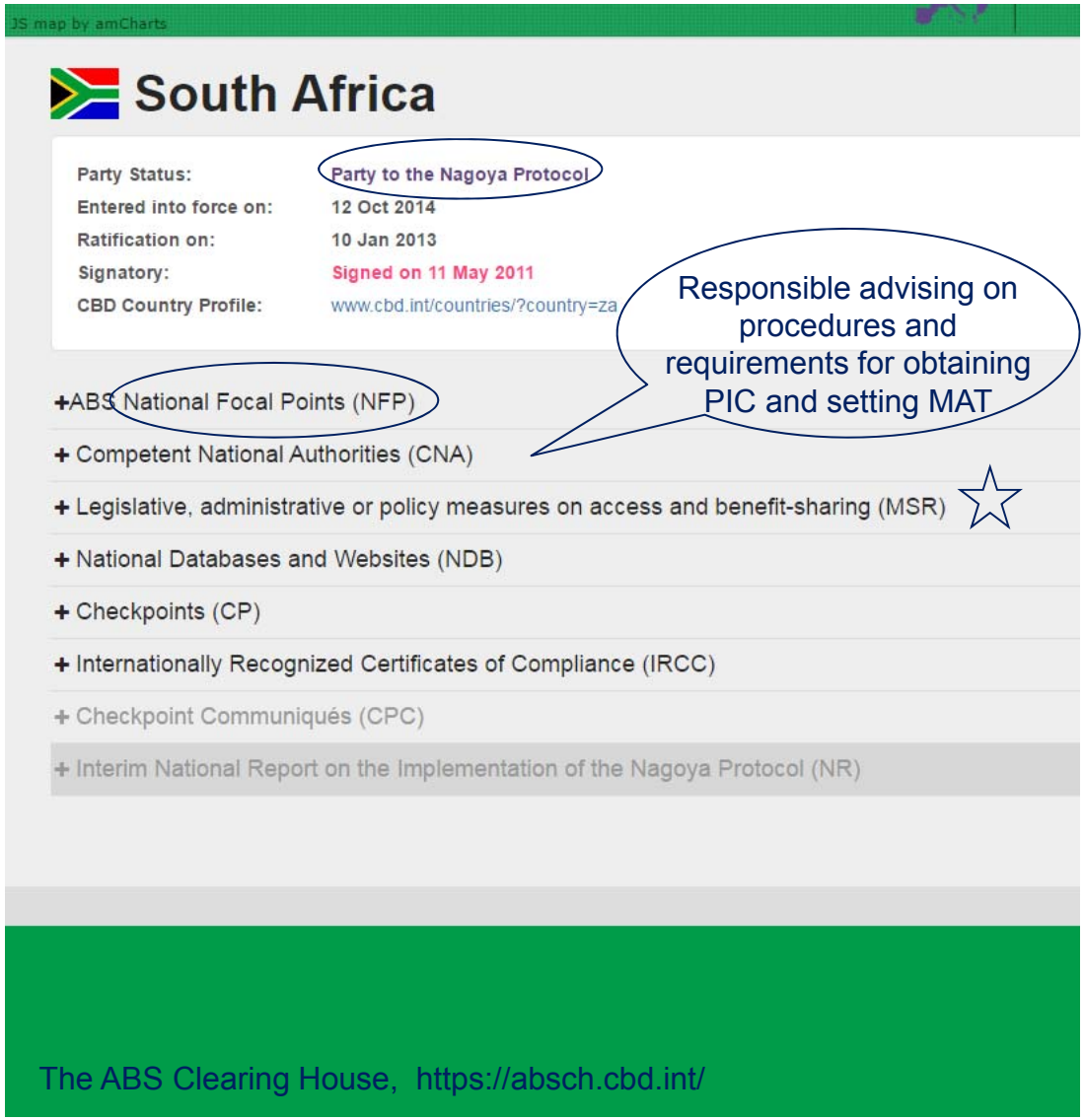


ABS Clearing-House

- Platform to exchange info
- Connecting users and providers
- Country profiles and summaries
- Helps countries monitor utilisation of genetic resources
- Publically available
-

https://absch.cbd.int/

Regulation (EU) No 511/2014 on compliance measures for users

- Entered into force on 12th October 2014
- Access in accordance with applicable legislation of the provider country
- Research and development
- Genetic material (plant, animal, microbial, other) and traditional knowledge
- Due diligence
- Does not address access to genetic resources in Europe

Assessing scope (EU Legislation)

The EU Regulation applies to genetic resources that meet all of the following conditions:

I. from countries that **exercise sovereign rights**

II. where countries have **established applicable access measures and ratified the Nagoya Protocol**

III. if **accessed after 12 October 2014**

IV. those that are not already **governed by specialised international instruments**

Activities considered to be in scope (EU Regulation)

- Research on a genetic resource leading to the isolation of a biochemical compound used as a new ingredient incorporated into a pharmaceutical product

- Creation or improvement of yeasts, resulting from human action through an R&D process, to be used in manufacturing process

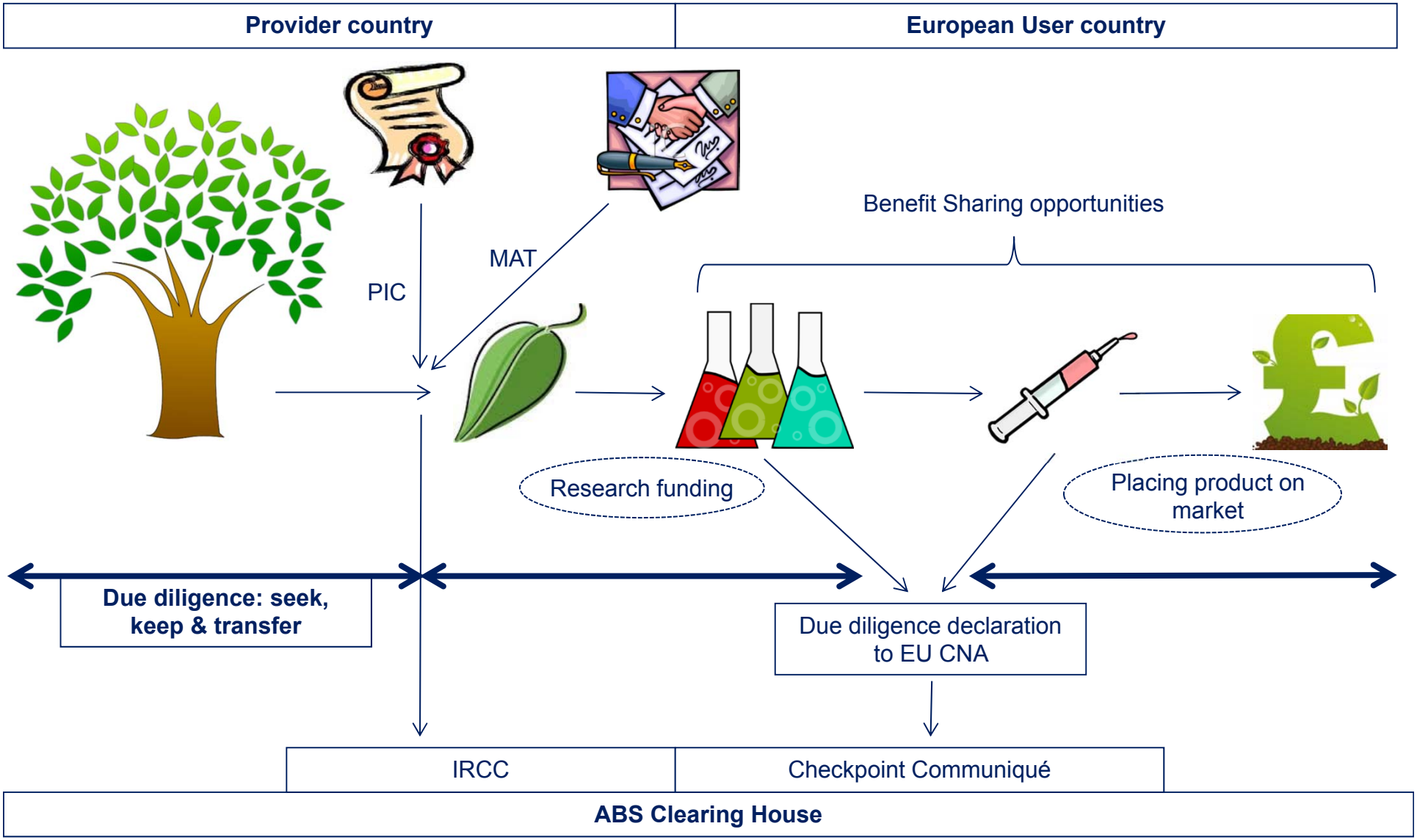
- Genetic modification – creation of a genetically modified plant containing a gene from another species

Activities considered to be out of scope (EU Regulation)

- Handling and storing of biological material and describing its phenotype

- Genetic resources as testing tools (GR is not the object of the research)

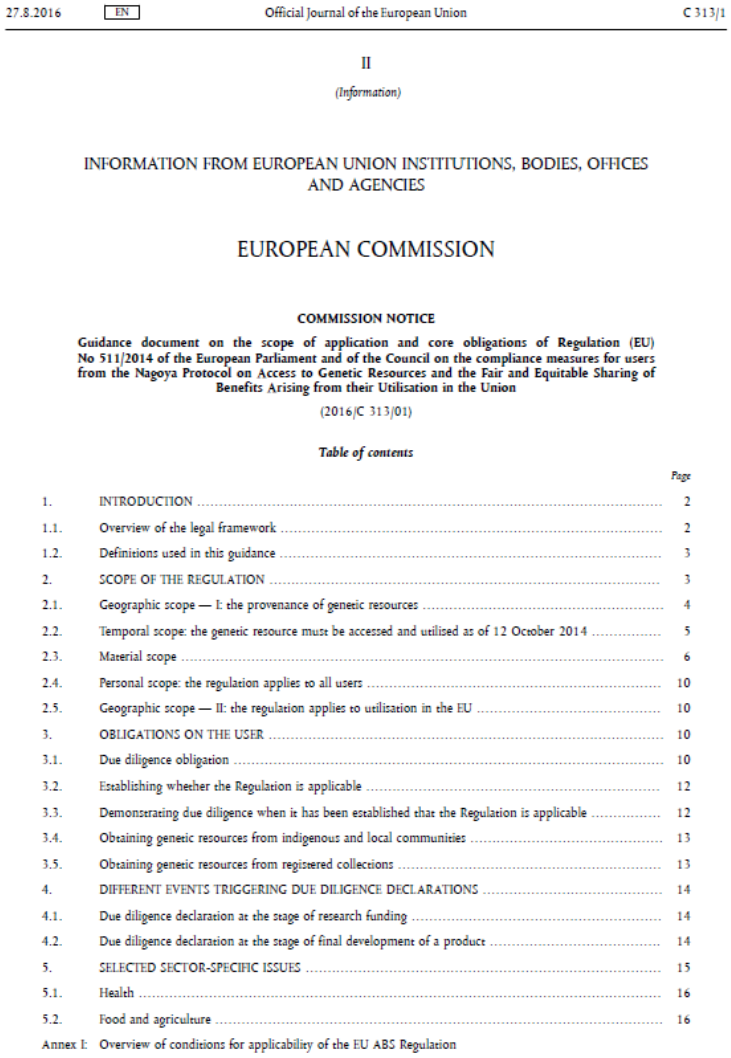
- Supply and processing of relevant raw materials for incorporation into a product (no new research)



Regulatory Delivery

Support for users

- Best practices
- Horizontal – published cross-sector guidance
- Sector specific – in preparation
  - Cosmetic
  - Pharmaceutical
  - Bio-control
  - Plant breeding
  - Animal breeding
  - Food & feed
  - Biotechnology
  - Collections and research institutions



27.8.2016 EN Official Journal of the European Union C 313/1

II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

COMMISSION NOTICE

Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union

(2016/C 313/01)

Table of contents

Approach to enforcement

Credit: Cartoonsy

- *Veterinary medicine and human medicine?*
- *Trends towards increasing use of natural products in product development?*

Lunch will now be provided at the back of the conference room.

12:05 – 13:00

Enjoy!

Afternoon Schedule:

13:00 – 13:20	CMDv guidance on autogenous vaccines (20mins)	Noemi Garcia del Blanco
13:20 – 13:40	Products Quality Defects trends and GMP related issues (20mins)	Gill Clarke
13:40 – 14:00	Environmental Risk Assessment (PBTs) update (20mins)	Hannah Reeves
14:00 – 14:20	Latest development in AMR activities (20mins)	Elizabeth Marier/Kitty Healey
14:20	Wrap-up - closing session	Marie Hendrickx

Veterinary Medicines Directorate

Recommendations for the manufacture, control and use of inactivated autogenous veterinary vaccines within the EEA

Presented by: Dr Noemi Garcia del Blanco

Head of Biologicals and UK alternate CVMP

Outline

- Background behind the new guidance document
- CMDv Working Group on autogenous vaccines
- Summary of the guidance contents
- Implications to the existing requirements in the UK

Background

- Directive 2001/82/EU Article 3 (1) b) excludes : “Inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of the holding in the same locality.”
  - ➢ Consequence : national regulation applies
- Two surveys completed in the past on this topic (2004 and 2013).
- The need for harmonised requirements was pointed out by the majority of Member States.
- One of the major questions was whether specific requirements for autogenous vaccines should be developed and introduced.
  - – The majority of replying MSs were supporting a possible harmonised set of requirements for autogenous vaccines.
  - – Member States would have to harmonise their approach amongst themselves.

Background

HMA meeting in September 2013 identified the need for clarification of the definition of autogenous vaccines as well the consideration of the need to develop a harmonized approach within the European Union.

- The HMA TFIL (Task Force on Improvement of Vet Legislation) was asked to prepare a paper for HMA consideration on these topics.
- HMA endorsed the proposals prepared by the TFIL in February 2014:
  - Keep the definition of the directive as it is
  - Clarify in a concept paper the interpretation of « in the same locality » and the concept of epidemiological links between farms
  - Deletion of article 4 (possibility to Member States to have live autogenous vaccines)
  - Premises requirements
  - Necessity to have good practices regarding the manufacture of autogenous vaccines and to define minimum requirements
  - Pharmacovigilance obligations

Background

An additional survey was prepared in 2014 for circulation in order to have a better vision of the practices in Member States.

- Highlighted the different approach in different member states:
  - Bacteria, parasites, virus
  - Adjuvants allowed
  - Pharmacovigilance
  - Data requirements
  - Manufacturing standards
  - Species
  - Authorisation and renewal process (or not specific regulation existing)
  - Interpretation of the same locality
  - Importation

- BUT all agreed that Autogenous vaccines are important
- HMA supported the creation of a working group held by CMDv to work on autogenous vaccines

CMDv Working group on autogenous vaccines

The mandate of the CMDv autogenous vaccine working group was:

- To analyse the results of the survey adopted at the CMDv meeting in April 2014 in order to have a better vision of the practices in Member States and to benchmark the practices in these.

- To discuss the consequences of the deletion of the article 4(1) which gives the possibility to Member States not to apply to live autogenous vaccines the marketing authorisation process as described in the directive.

- To clarify the words “same locality” and to explain the concept of epidemiological links between farms.

- To define good practices regarding manufacture, control and distribution of autogenous vaccines (to elaborate on minimal requirements) and to make proposals regarding pharmacovigilance of autogenous vaccines.

CMDv Working group on autogenous vaccines

Between 2015 and 2017 the autogenous vaccines working group worked on the preparation of recommendations paper for use, manufacture and control of autogenous vaccines.

- In order to harmonise practices over EEA, the autogenous vaccines working group has put into the document some keys requirements.

- The following representatives participated: FR, BE, CZ, DE, ES, HU, IS, LV, NO, SK and UK.

CMDv Guidance on autogenous vaccines

<date>
EMA/CMDv/452656/2017

Recommendations for the manufacture, control and use of inactivated autogenous veterinary vaccines within the EEA

This guidance describes the scope and the recommendations for the use of inactivated autogenous vaccines as well as the prerequisites for manufacturing and testing. Those should ensure a similar level of “obligations of means” throughout EEA. However additional national requirements may apply, and anyone planning to manufacture or use autogenous vaccines should check the relevant requirements with the responsible authority.

CMDv
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

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SPECIAL TOPICS

Lessons learned from the CMDv's pilot voluntary SPC harmonisation procedure 2009-2012
CMDv communication on Japan monitoring - 25 July 2013

CMDv recommendations for the manufacture, control and use of inactivated autogenous veterinary vaccines within the EEA – March 2017

CMDv Guidance on autogenous vaccines

- Introduction
- Scope
- Definition
- Principles/Preconditions applicable for manufacture and use of veterinary autogenous vaccines
- Obligations of the responsible veterinarian depending on national provisions
- Requirements for manufacturers
- Isolation of the antigen used thereafter as starting material
- Procedure for manufacture and formulation of inactivated autogenous vaccines
- Stability
- Labelling
- Annex 1 :
  - Member States within EEA in which the production and the use of viral inactivated autogenous vaccines are/are not authorised

CMDv Guidance on autogenous vaccines

Scope

- Scientific advice for the production, control, use and the monitoring (pharmacovigilance) of inactivated autogenous vaccines.
- Define a minimal level of manufacturing process and control practices to ensure the quality of these products.
- Do not include the various technical and administrative obligations which need to be respected by manufacturers and veterinarians in the different EEA MS.
- The use of live autogenous vaccines is not allowed in most of the EEA MS and should be currently discouraged within the EEA.
- Requirements with respect to import of inactivated autogenous vaccines have to be set by responsible authority.

CMDv Guidance on autogenous vaccines

Definition

- Directive 2001/82/EU Article 3 (1) b): “Inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of the holding in the same locality.”

- The wording of the directive does not reflect the recent situation of integrated concepts of breeding/rearing/production of animals within the EEA.

- To reflect the current situation in husbandry within the EEA the current regulation is interpreted in the guidance document.

CMDv Guidance on autogenous vaccines

Same locality: should be understood as “same and single rearing site and/or same farm where the pathogen(s) is/are present or multiple rearing sites and/or farms having an epidemiological link.”

The terms “same locality” cover the concept of an epidemiological unit in which animals share the same epidemiological status i.e. the same pathogen (identical isolate).

Same rearing site/same farm: means “a place where several rearing building(s) are located with only short distance between them. On these places animals are regularly raised.”

CMDv Guidance on autogenous vaccines

Epidemiological link:

"Groups of animals have an epidemiological link when one of them is to be put in contact with pathogens it has never met before, but which are present in the other group of animals raised in another rearing site/farm.

The movement of animals between rearing sites/farms should be considered when establishing the epidemiological link. As a consequence, animals raised on rearing sites/farms geographically distinct, that have an epidemiological link, are belonging to the same locality.

- It is mainly applicable for poultry or pigs when considering parental lines raised in production chain systems.
- For aquatic animals, an epidemiological link also exists between different farms/sites within one geographic area; where an identical pathogen is circulating and spread e.g. by wild aquatic species."

CMDv Guidance on autogenous vaccines

Principles/Preconditions applicable for manufacture and use of veterinary autogenous vaccines

- The use of inactivated autogenous vaccines should be considered if there is no other IVMP suitable to be used under the cascade prescriptions (articles 10 and 11 of Directive 2001/82/EC) for the same species.

- Conditions to use an autogenous vaccine: no appropriate vaccine is licensed in the EEA or lack of efficacy of licenced vaccines on the farm/site in question has been experienced and reported to the responsible authority.

CMDv Guidance on autogenous vaccines

That means :

- No licenced vaccine related to the pathogen and target species is available in the EEA

  or

- Lack of efficacy of the licenced vaccine for the indication and relevant farm/site has been reported to the Pharmacovigilance system by the responsible veterinarian

  or

- The licenced vaccines do not contain the same antigens type (e.g. serotype/serovar, capsular antigen type, fimbria type, etc.) or the authorised conditions of use of the vaccine does not fit with the field situation

  and

➢ The specific pathogen was isolated from the concerned/same locality/animal during an outbreak of the disease.

CMDv Guidance on autogenous vaccines

- Inactivated autogenous vaccines must be manufactured solely from the pathogens or antigens which were obtained in the concerned locality; and they are only allowed to be used in this same locality.

To renew the manufacturing authorisation if required, it should be proven that pathogens or antigens obtained in the previous sampling are still relevant with respect of the epidemiological situation present in the locality concerned. Reuse of isolates may be authorized if it has been verified that they are still relevant for the locality.

CMDv Guidance on autogenous vaccines

Obligations of the responsible veterinarian depending on national provisions

- The veterinarian who has made the initial diagnosis of the involved infectious agent and ordered the prescription is responsible for the administration of the inactivated autogenous vaccine in the field.

- Before the inactivated autogenous vaccine is used in a large number of animals in the clinical practice, it may be recommended to the responsible veterinarian to administer the vaccine first in a small number of animals in the concerned locality.

- The responsible veterinarian and/or the owner should report to the responsible authority and to the inactivated autogenous vaccine manufacturer after observation of any suspected quality defects and any suspected adverse reactions related to the use of the vaccine.

CMDv Guidance on autogenous vaccines

Requirements for manufacturers:

- **General**
  - The manufacturer must hold a specific manufacturing authorisation for inactivated autogenous vaccines.
  - The manufacture of autogenous vaccines should be performed in accordance with the conditions provided in the manufacturing authorisation.
  - A manufacturer should have a designated person ensuring the quality of each individual batch of vaccine and the compliance with legislation.
  - The manufacturer should follow the principles and guidelines of Good Manufacturing Practices (GMP) or at least the requirements of production and product testing conditions as described in these recommendations.
    - e. g. name of veterinarian, list of antigens and adjuvants, TSE compliance, appropriate documentation, manufacturing records, reference samples…

CMDv Guidance on autogenous vaccines

❑ **Facilities**

At least the below requirements should be met :

- Adequate construction and hygienic conditions of the rooms.
- Suitable storage rooms.
- Cleaning and disinfection management for rooms, materials and personnel.
- The different steps of production should be performed separately (in particular inactivation procedures).
- Main equipment such as fermenters, incubators, laminar flow hoods, autoclaves or ovens appropriately qualified and/or validated.
- Incubators, freezers and refrigerators should be monitored.

CMDv Guidance on autogenous vaccines

❑ Personnel

At least the below requirements should be met :

- The manufacturer has permanently and continuously the services of at least one qualified person.
- An organisation chart indicating the duties and responsibilities of all personnel is laid down in writing.
- A qualified person should be designated as responsible for release of vaccine batches.
- The key personnel should attend trainings focusing on hygiene, microbiology vaccine production and testing.
- Training program for all personnel to cover the principles and the guidelines of the GMP.
- Hygienic management should be established, documented and trained annually.
- Production has to be performed under aseptic conditions where necessary (e.g. antigen production, filling).

CMDv Guidance on autogenous vaccines

Isolation of the antigen used thereafter as starting material

- **Collection of samples, tissues of the infected animals**

- Proper diagnosis of the infectious disease in an animal/in the locality, including differential diagnosis.

- Samples should always be taken in the respective locality or the epidemiological link where the inactivated autogenous vaccine should be used.

- Sampling shall be conducted by the responsible veterinarian.

- Active substances used for the inactivated autogenous vaccines production should not be come out of notifiable diseases agents in EEA and the isolates must not have been biotechnologically modified from the isolation onwards.

- Traceability of the samples taken to obtain the microorganisms used to manufacture the active substances.

CMDv Guidance on autogenous vaccines

❑ **Isolation and identification**

- Isolation and identification of the antigen shall be conducted by a competent authorised contract site according to validated method and SOP (e.g. a diagnostic laboratory or a licensed manufacturer).

- For viral inactivated autogenous vaccines, isolation and purification should be done in accordance with the principles laid down in European Pharmacopoeia (Ph. Eur.).

- A time span for the use of the isolates for the production of an autogenous vaccine may be required by responsible authority.

CMDv Guidance on autogenous vaccines

Procedure for manufacture and formulation of inactivated autogenous vaccines

❑ Starting materials

- Should comply with the provisions laid down in the Ph. Eur. or national pharmacopoeias.
- If animal origin (including cells for production of viral vaccines): comply with the relevant specific and general monographs of the Ph. Eur.
- Any materials originating from animals which might transmit TSE should comply with the provisions of the "Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" and the relevant Ph.Eur. monographs.
- A system of seed lot should be in place.
- Adequate measures should be in place to avoid mix-up and/or contamination with other antigens.
- Seed material must be pure. Minimum requirements are testing for purity including extraneous agents and identity testing.
- Starting materials must be sterile according to Ph. Eur. 2.6.1.

CMDv Guidance on autogenous vaccines

❑ Production

- At least should be performed in line with GMP principles.
- Not be performed in the same facilities and with the same equipment used for the production of licensed IVMPs in order to avoid cross-contamination.
- Production should be done on a batch basis only.
- The whole manufacturing process must be conducted under conditions ensuring the required quality of the product.
- Antibiotics should not be added during the production of an inactivated autogenous vaccine.
- Production method should be described and documented in detail.
- Live virus titre/number of viable bacteria of the bulk must be determined before inactivation and maximum pre-inactivation titre/count established.
- Critical manufacturing operations shall be validated.
- The maximum residue limits for ingredients defined by food regulations shall be met for autogenous vaccines intended for food-producing species.
- If preservatives are used, the efficacy should be tested as required by Ph. Eur.

CMDv Guidance on autogenous vaccines

❑ Inactivation

- Products should be inactivated by the addition of an inactivation agent accompanied by sufficient agitation. The mixture should then be transferred to a second sterile vessel, unless the container is of such a size and shape as to be easily inverted and shaken to wet all internal surfaces with the final culture/inactivation mixture. Suitable temperature has to be maintained through the whole inactivation process.

- Data on inactivation must be collected and inactivation should be validated. The validation of the inactivation including all test systems can be carried out exemplarily on a strain of one group of pathogens. Inactivation validation shall be performed in line with Ph. Eur. requirements.

- For viral autogenous vaccines, requirements for inactivation validation set in European guidelines regarding viral vaccines should be met.

CMDv Guidance on autogenous vaccines

❑ **Controls on the finished product**

The vaccine has to be subject to the following tests at minimum:

- Sterility: according to the Ph. Eur. monograph 2.6.1.
- Complete inactivation: with at least two passages in the production medium. The test for inactivation must be validated and the detection limits must be defined. Control testing of residual levels of inactivating agents is required.

Bacterial vaccines:

- Endotoxin content: should be tested as required by Ph. Eur.

Viral vaccines:

- Absence of extraneous agents: should be ensured according to requirements of the Ph. Eur. and European guidelines (regarding extraneous agents in viral vaccines). Validation of any test used should be provided.

CMDv Guidance on autogenous vaccines

Stability

Tests on the stability of the finished product are not expected for inactivated autogenous vaccines. Storage in appropriate conditions for 6-12 months starting from final filling is considered acceptable.

- As no studies on in-use-stability in general are available for these vaccines, the filling size has to be chosen in such a way that the content of one container can be used up within one working day (8 hours). It is up to the responsible veterinarian to order the correct filling size.

CMDv Guidance on autogenous vaccines

Labelling

- Manufacturer
- Batch number
- Expiry date
- Composition : Inactivated antigen(s) and adjuvant/(s)
- Name and address of the responsible veterinarian
- Dosing and method of administration
- Target species and subcategory of animals for which the inactivated autogenous vaccine is intended
- Locality where the antigens or pathogens used for manufacture of the inactivated autogenous vaccine were sampled
- Storage conditions
- The words “For animal treatment only”
- Any further precautions given in the prescription issued by the responsible veterinarian
- Precaution regarding handling of the unconsumed or unused inactivated autogenous vaccine
- Withdrawal period if relevant

Implications to existing requirements in UK

Not that many!

Guidance

Veterinary Medicines Regulations

From: Veterinary Medicines Directorate
Part of: Animal and plant health
Published: 14 April 2014

Sets out legal text on the manufacture, authorisation, marketing, distribution and post-authorisation surveillance of veterinary medicines.

- Authorisation/Types of authorisation
- Labelling
- Records
- Adverse reactions
- Inspection of premises

Implications to existing requirements in UK

The manufacturing premises and the method of production must be the subject of a valid AVA for autogenous vaccines manufactured from pathogens or antigens obtained from an animal/s and used for the treatment of that animal and/or other animals within the same epidemiological unit or in the same rearing chain.

- Technical framework for viral autogenous vaccines

Guidance

Autogenous Vaccine, Non-Food Animal Blood Bank, Equine Stem Cell Centre Authorisation

Thank you for your attention

Veterinary
Medicines
Directorate

Product Quality Defects

Trends and GMP related issues

Presented by: Gill Clarke
Date: 23 June 2017

Overview

Product Quality Defects

- Reporting procedure
- VMD's assessment
  - Rapid Alerts and product recalls
- Trends
  - Numbers and types of defects

GMP Non-Compliance of Active Substance Manufacturers

- Trends
  - Types of deficiencies
- VMD's process
  - Issues
  - Case study

Product Quality Defects

All concerned competent authorities should be informed in a timely manner in the case of a confirmed quality defect, e.g.

- manufacturing issues
- product deterioration
- detection of falsification
- non-compliance with the marketing authorisation, or
- any other serious quality problem

Article 13 of Directive 91/412/EEC

GMP Guide Chapter 8.8

Sources of Suspected Quality Defect Reports

- Marketing Authorisation holder
- Other national competent authorities
  - via Rapid Alert notification
- Health professionals (veterinarians)
- General public
- Official Medicines Control Laboratories
- Pharmacovigilance reports

Identification of Product Defect - Procedure

Guidance

Report a product defect: veterinary medicine

GOV.UK

- MAH submit *Product defect report form* to rapidalert@vmd.defra.gsi.gov.uk
  - Product name and marketing authorisation (Vm) number
  - MAH or distributor
  - Details of the manufacturing site(s)
    - including the batch certification/release/importation sites
  - Batch number and expiry date
  - Nature of the defect
  - Distribution details – UK and rest of Europe
  - The action taken or being taken by the MAH

Identification of Product Defect - Procedure

- VMD Inspections Administration Team log defect
- Assessment Group provide comments (within 48 hours)
  - Quality, Safety & Efficacy assessors
  - GMP inspectors
  - Pharmacovigilance vet
  - other experts
- Comments and requests for additional information are communicated to the MAH (5-7 days to respond)
- Cycle continues until a satisfactory resolution
  - product or batch recall
  - corrective actions

Classification of Defects

- Class 1 (Critical): the defect presents a life threatening or serious risk to health
  - Product/pack mix-ups
  - Microbial contamination of sterile product
- Class 2 (Major): the defect may cause mistreatment or harm to the animal, but is not critical
  - Missing or incorrect information – leaflets
  - Non-compliance with specification (e.g. assay)
- Class 3 (Minor): the defect is unlikely to cause harm
  - Faulty packaging (wrong or missing batch number)
  - Faulty closure
  - Unclassified

Product Recalls

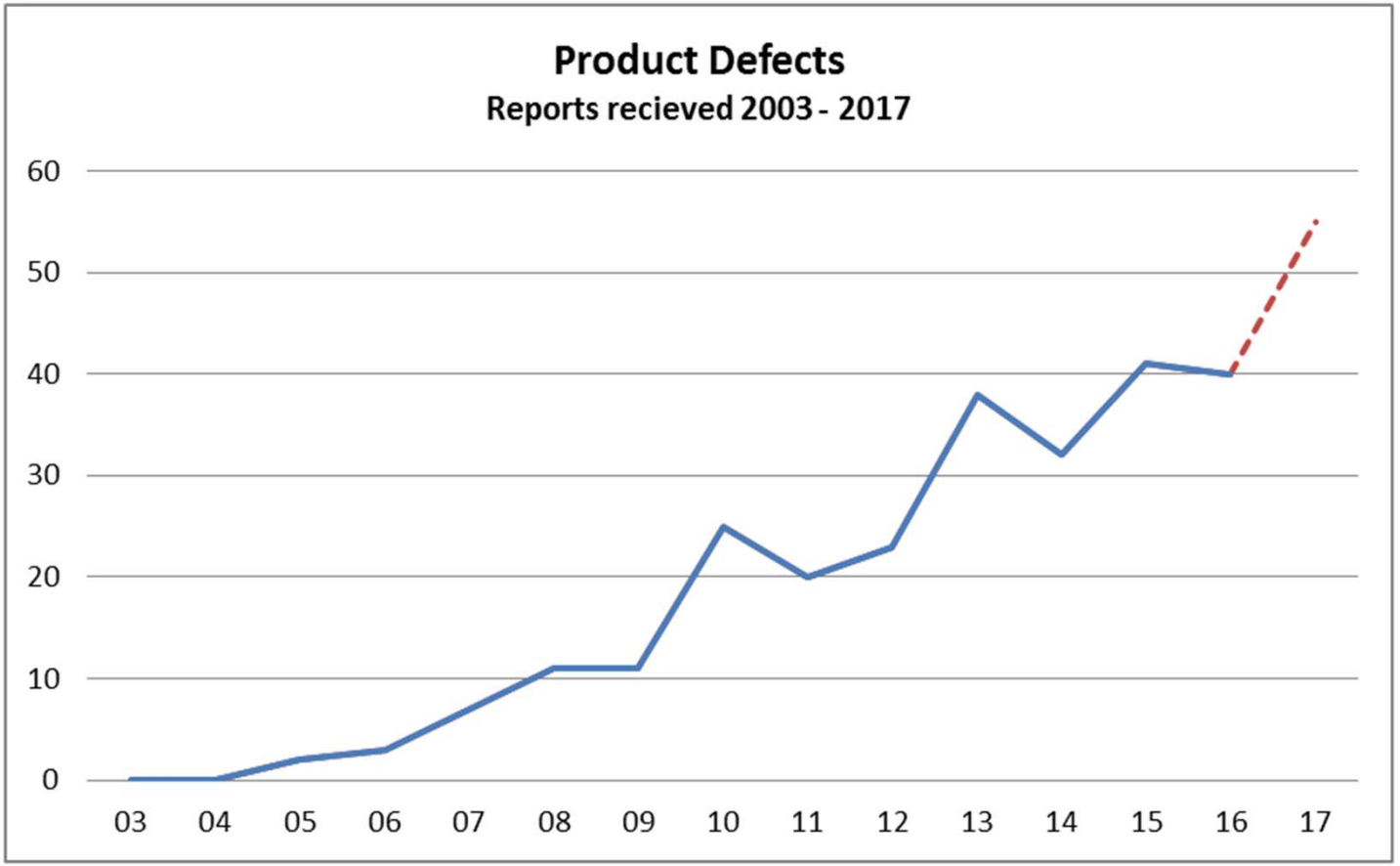
- The level of any recall depends on the seriousness of the risk
  - Class 1 (Critical)
    - product recall to end-user (farmer/pet owner)
  - Class 2 (Major)
    - product recall to retailer (vet / pharmacist / SQP)
  - Class 3 (Minor)
    - product recall to wholesale dealer, or
    - may not require a recall
      - Letter to vets

- All product recalls published on VMD homepage on GOV.UK

Rapid Alert

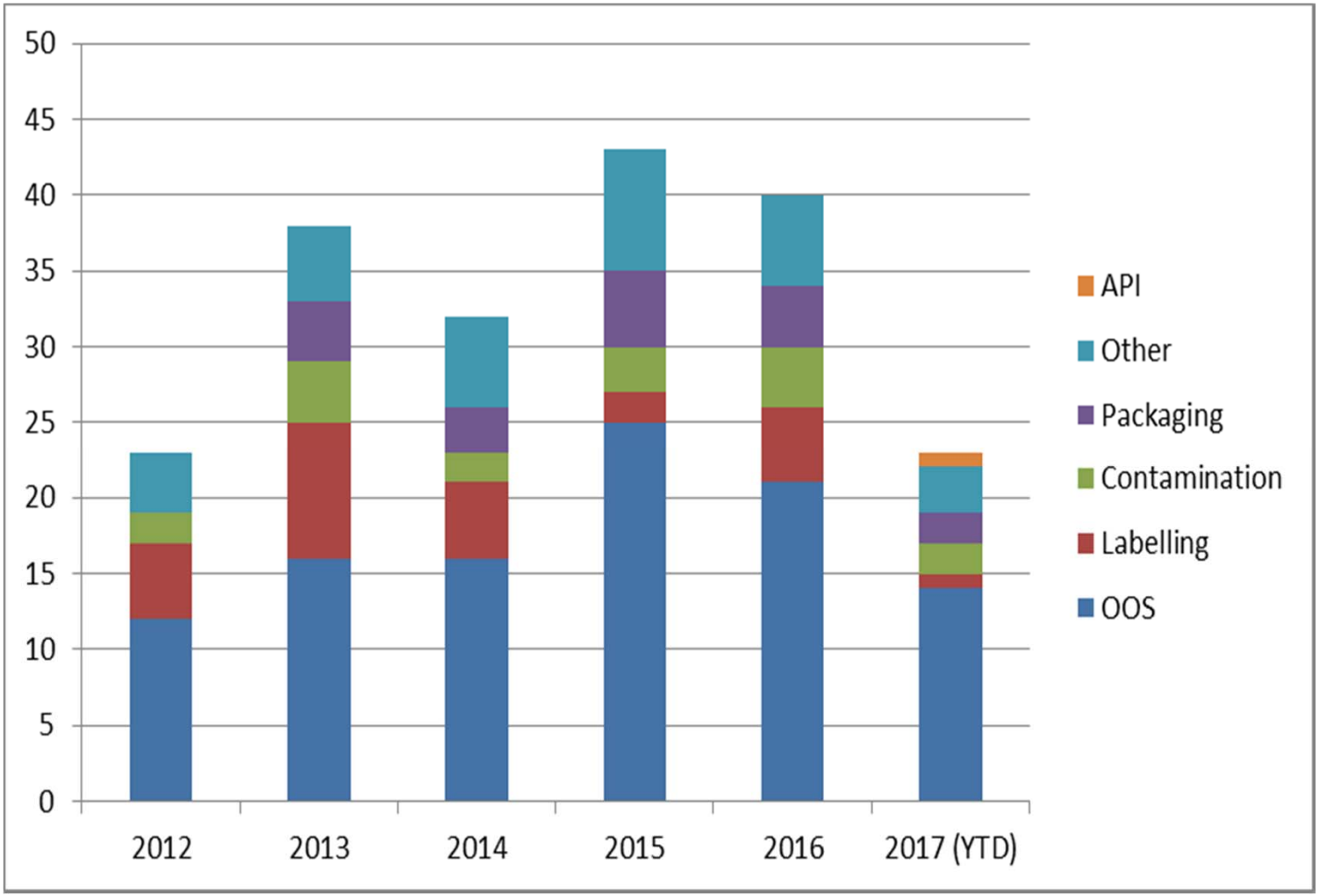
- An urgent notification from one competent authority to other authorities that a batch recall has been initiated
  - only used when urgency and seriousness dictates
- Class 1 defect
  - to other national competent authorities including EEA member states, PIC/S, EDQM, WHO, FDA and mutual recognition partners, irrespective of whether or not product/batch was exported to that country
- Class 2 defect
  - only to those national competent authorities where we know the batch has been distributed
- Class 3 defect
  - out of scope - not circulated as a Rapid Alert

VMD Product Defect Reports (2003 – 2017)



2016 40 defect reports 12 recalls

Types of Product Defects



GMP Non-Compliance

Active substances used in VMPs must be manufactured in accordance with GMP for starting materials

Regulatory inspections of API sites

Inspection triggers

- sterile substances
- suspicions of non-compliance
  - national authorities, warning letters from the FDA, whistle blowers
- routine risk-based selection (EU member states, EDQM)
  - location of the site
  - number and nature of APIs manufactured
  - history of inspections by other authorities
- re-inspection (routine or after suspension)

Falsified Medicines Directive (for human medicines)

- tougher rules on the controls and inspections of producers of active pharmaceutical ingredients

As a result, there are increasing reports of GMP non-compliance

Procedure following serious GMP Non-compliance

- There is a **consolidated procedure** [1] for dealing with all circumstances of **serious GMP non-compliance**
  - requires the **inspectorate** discovering serious GMP non-compliance **to recommend appropriate action**, involving other authorities and **to communicate the recommendations**
  - **National competent authorities** should follow the recommendations unless they can justify alternative action based on specific national considerations

[1] In Compilation of Community Procedures on Inspections and Exchange of Information EMA/INS/GMP/321252/2012 Rev 15

VMD Process

- Identify UK VMPs affected

one site → many APIs → many, many VMPs

- Are there alternative, unaffected VMPs on UK market?
- Define criticality of API

API not critical site	→	Suspend use of API from affected
	→	Inform MAH

VMD Process

API is critical

- Inform MAH
- Risk assessment (MAH with VMD), considering:
  - nature of the findings during inspection
  - alternative sources of active substance
    - may have alternatives authorised but are they viable - can they meet global demand?
    - what measures are being taken to identify alternative source
  - criticality of products in terms of animal welfare
    - non-critical products can become critical if the whole class of products is implicated
  - potential risk mitigation measures
- May allow continued use (with specific controls)

Case Study – Zhejiang Hisun

- FDA alert issued (affecting 3 Zhejiang Hisun sites)
  - November 2015
- EMA facilitated meeting of EU response team
  - Obtained FDA inspection report
  - Agreed action plan
- EU Member State inspection (Spain)
  - June 2016
- EU Statement of Non-compliance issued
  - September 2016
- VMD communicated decision to MAHs
  - October 2016
- CEPs suspended
  - October 2016

Case Study – Zhejiang Hisun

- Impact on UK VMPs

1 ASM

↓

10 APIs

↓

239 VMPs

- 6 APIs considered not to be critical
  - API cannot be used
- 4 APIs considered critical
  - risk assessment/mitigation measures on product by product basis

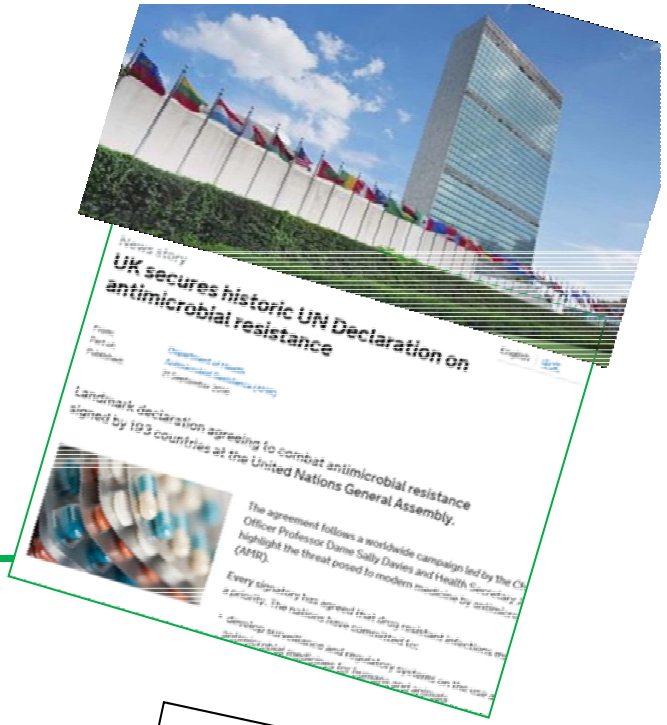
Thank you

Any questions?

Veterinary
Medicines
Directorate

Latest Developments in AMR Activities

Presented by: Elizabeth Marier
Date: 23 June 2017



Policy Update

Independent Review of AMR (O'Neill)

10 Recommendations

- Public awareness
- Hygiene, preventing infection spread
- Unnecessary use in agriculture; environment
- Surveillance in people and animals
- Rapid diagnostics
- Vaccines & alternatives
- Human capital (health, academia, commercial)
- Global Innovation Fund
- Investment in new drugs
- Global coalition

Government's response to O'Neill recommendations

Overall antibiotic reduction target

Overall target of 50 mg/kg across the animal sectors by 2018*.

2014 baseline (62 mg/kg). Represents 20% reduction in 4 years.

Sector specific targets

Evidence-based goals for each individual livestock species sector agreed by end of 2017.

Critically Important Antibiotics

Strict oversight of the use in animals of antibiotics critical for human health.

Supporting restrictions or even bans where necessary.

Transparency

Incorporation of standards into consumer-facing assurance schemes

- understand issues that matter to them
- help them take responsibility for informed food decisions

Source: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/553471/Gov_response_AMR_Review.pdf

* ESVAC methodology

European Union

- The 5 Year Action Plan 2011-2016:
- 12 actions, 5 Veterinary Related
  - Strengthen regulatory framework
  - Introduce recommendations for Prudent Use in Veterinary Medicine
  - Animal Health Law
  - Analyse the need for new antibiotics in veterinary medicine
  - Strengthen surveillance systems on AMR and antimicrobial consumption

European Union: looking ahead

1- Making the EU a best practice region on AMR

- Support member states developing action plans
- Strengthen One Health surveillance of AMR
- Increase professional and public awareness
- Expand action on AMR in the environment

2- Boosting research, development and innovation on AMR

- Early detection and improving surveillance
- Environment and transmission
- New therapeutics, alternatives/vaccines
- New diagnostics
- New business models
- Interventions in healthcare and agri/aquaculture practices

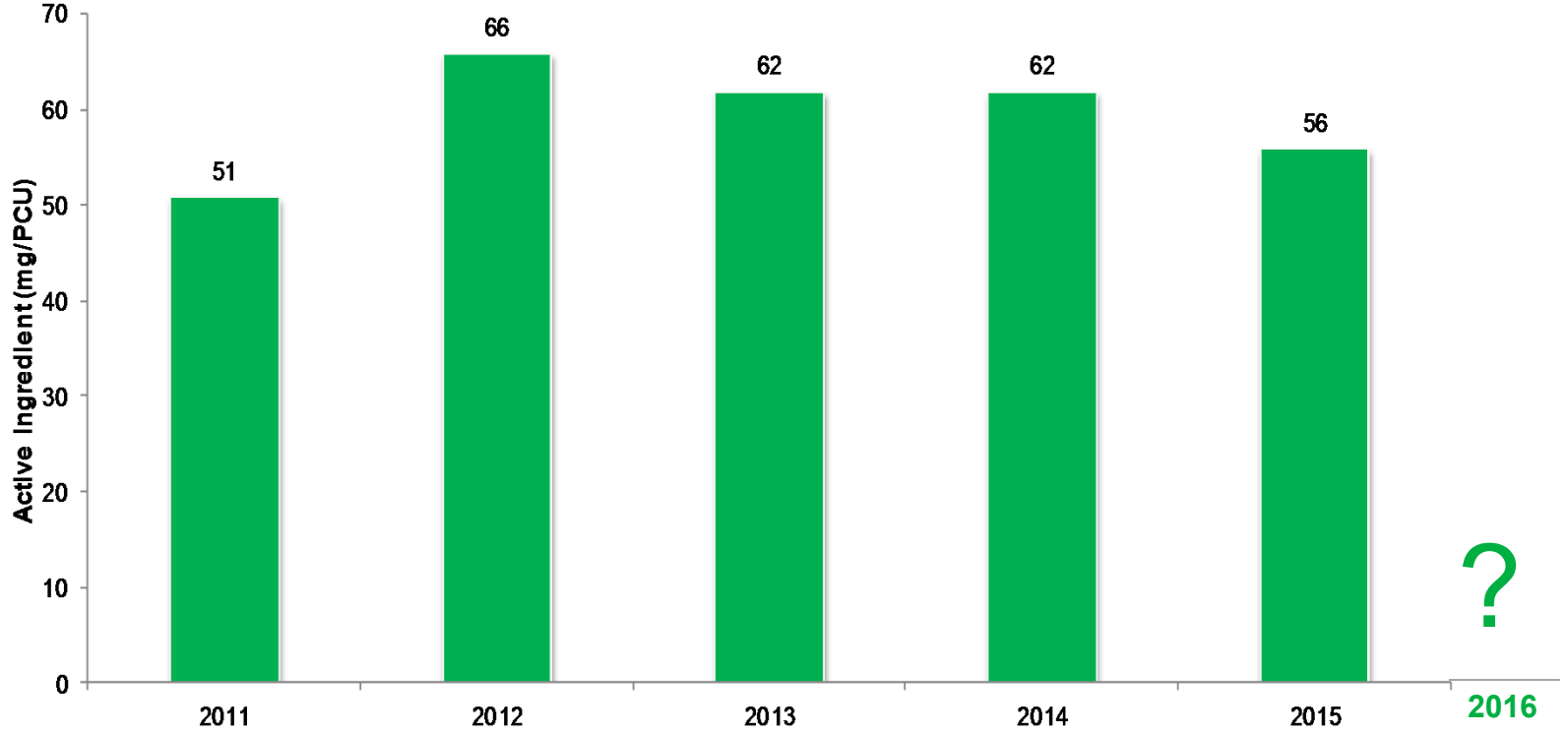
3- Shaping the global agenda on AMR

- Partner with WHO, OIE, FAO and relevant international organisations
- Support third countries, sharing expertise
- Keep AMR high on the international agenda
- Pursue high-level political commitments; UNGA, WHO, G7, G20

Surveillance Update

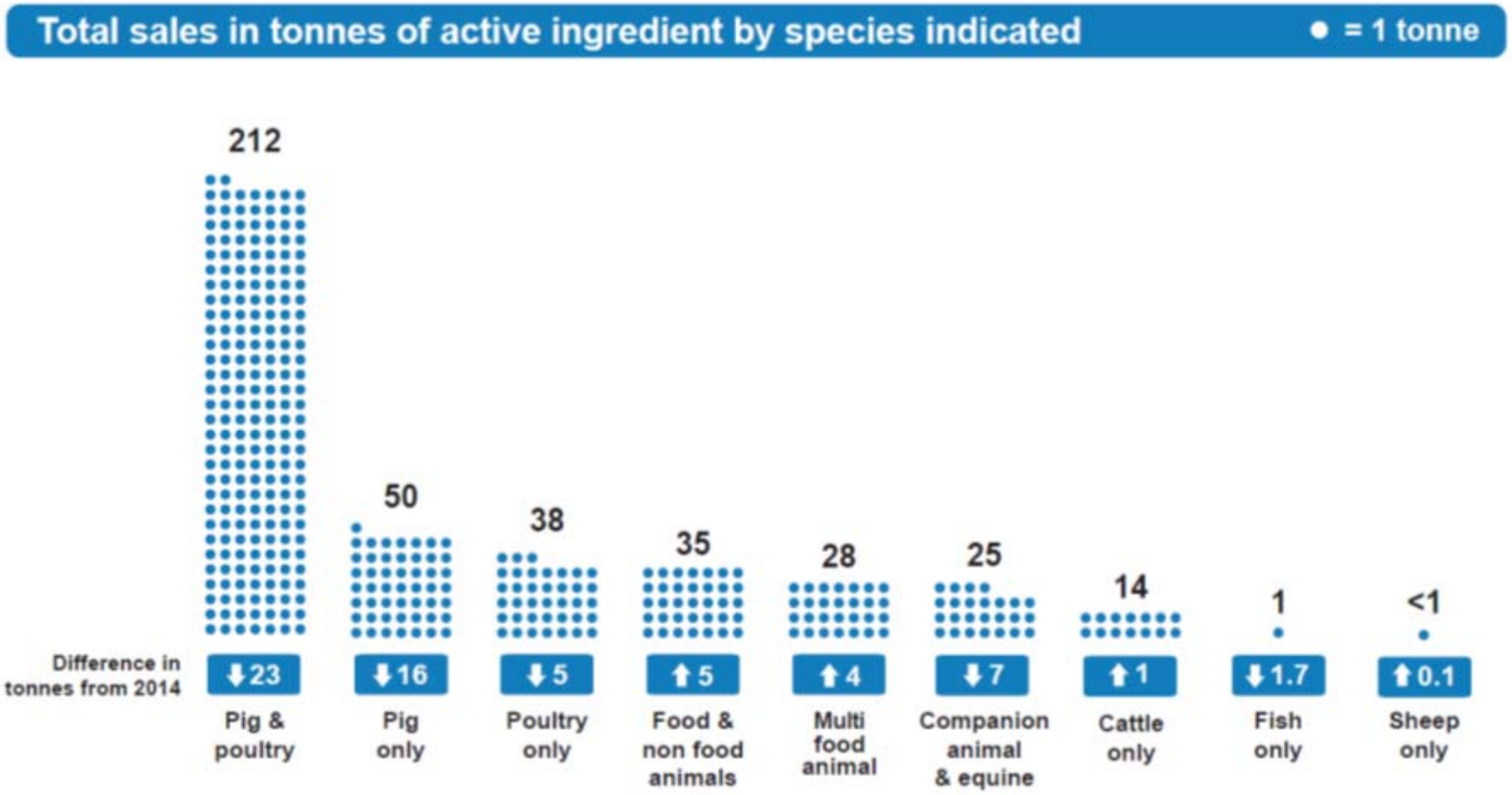
Antibiotic sales

- Total sales in 2015 = 404 tonnes; 56 mg/kg
- Reduction of 10% compared to 2014



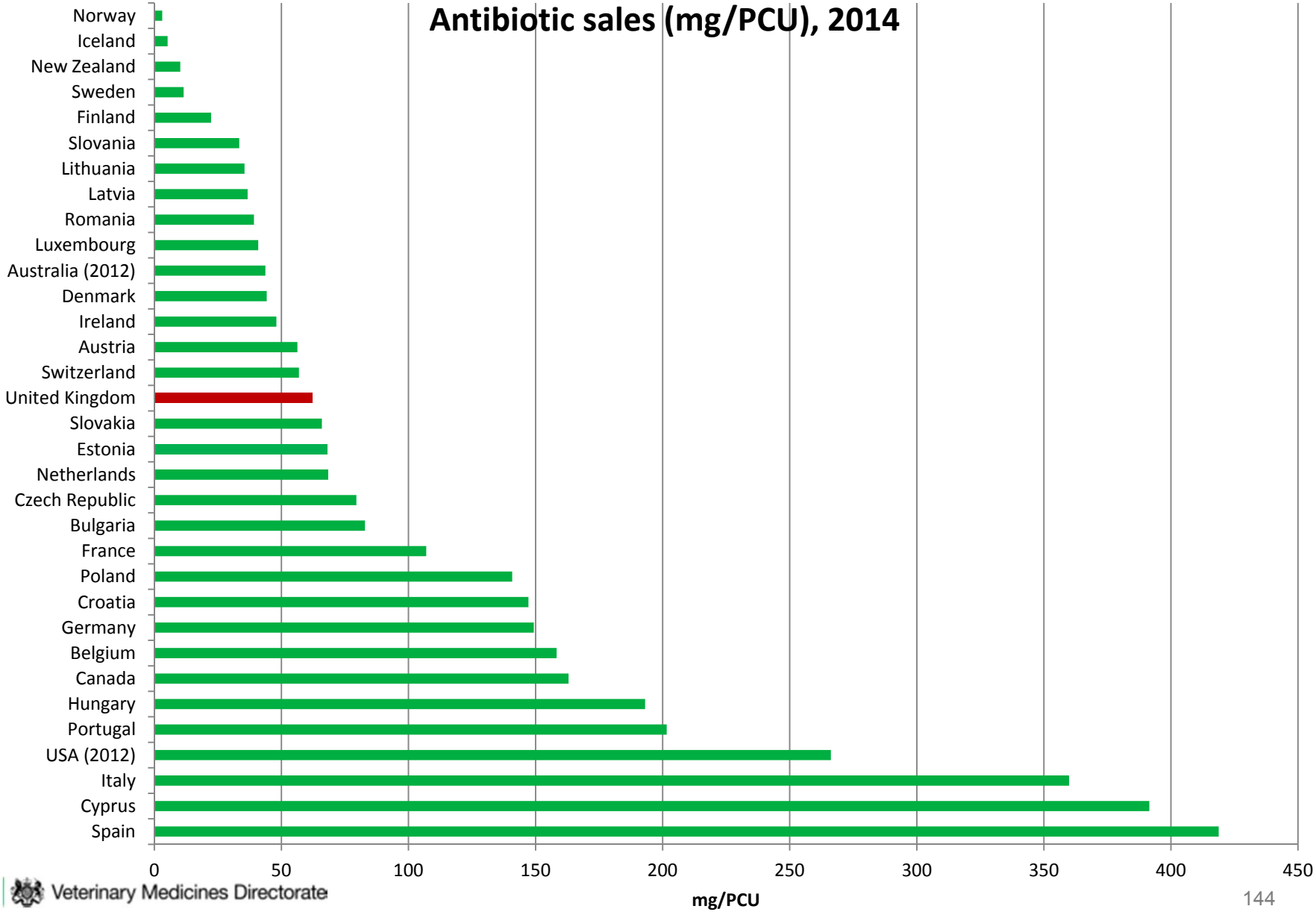
VARSS, 2015:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/582341/1051728-v53-UK-VARSS_2015.pdf

Antibiotic sales

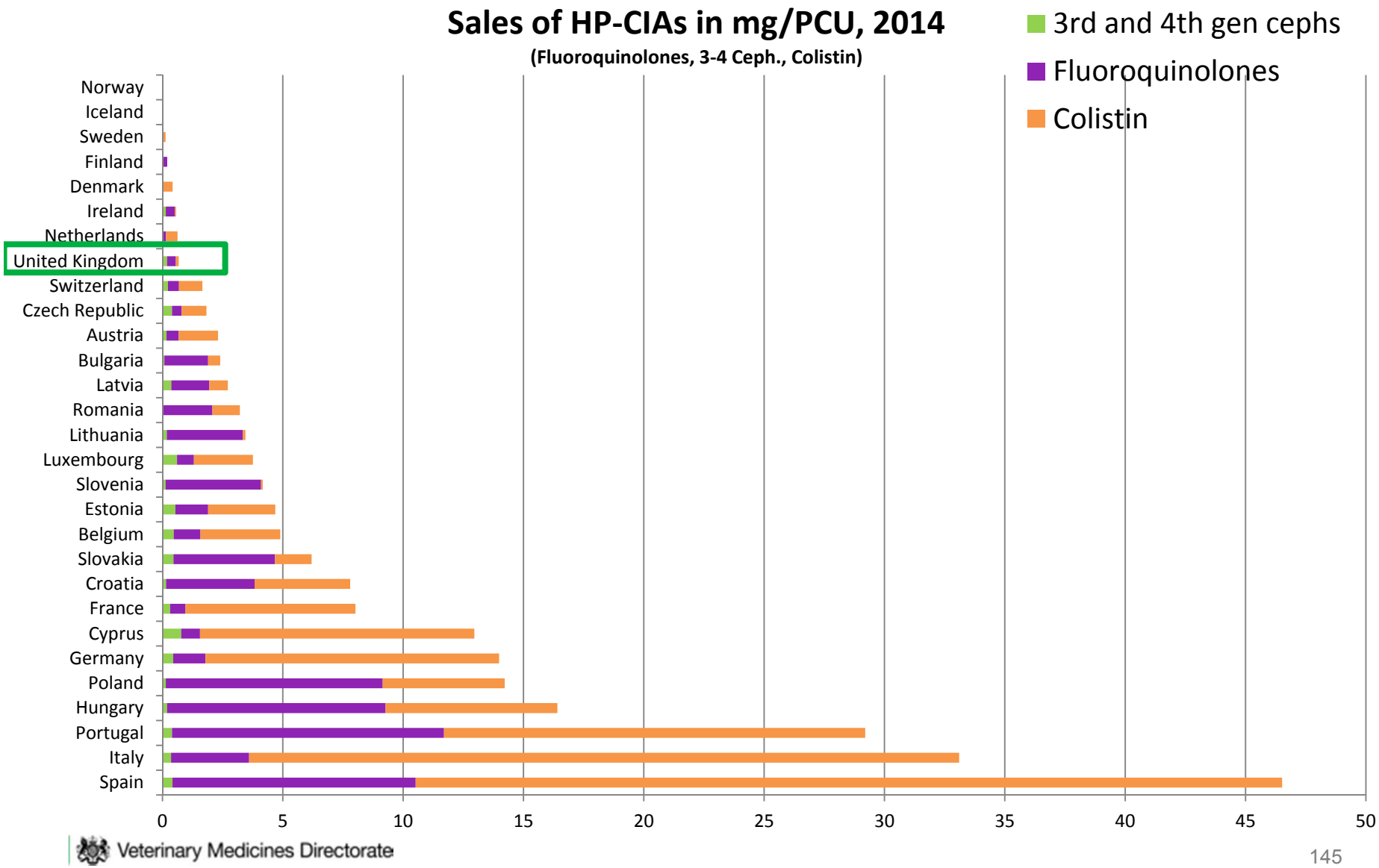


VARSS, 2015

ESVAC 2014 - Antimicrobial sales



Antibiotic sales



European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)

- Part of the European Medicines Agency
- Produced draft guidance on species level data collection:
  - Focus on pigs, poultry and cattle (split by dairy and beef)
  - Out for consultation until 24th September 2017

    http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/03/WC500224492.pdf

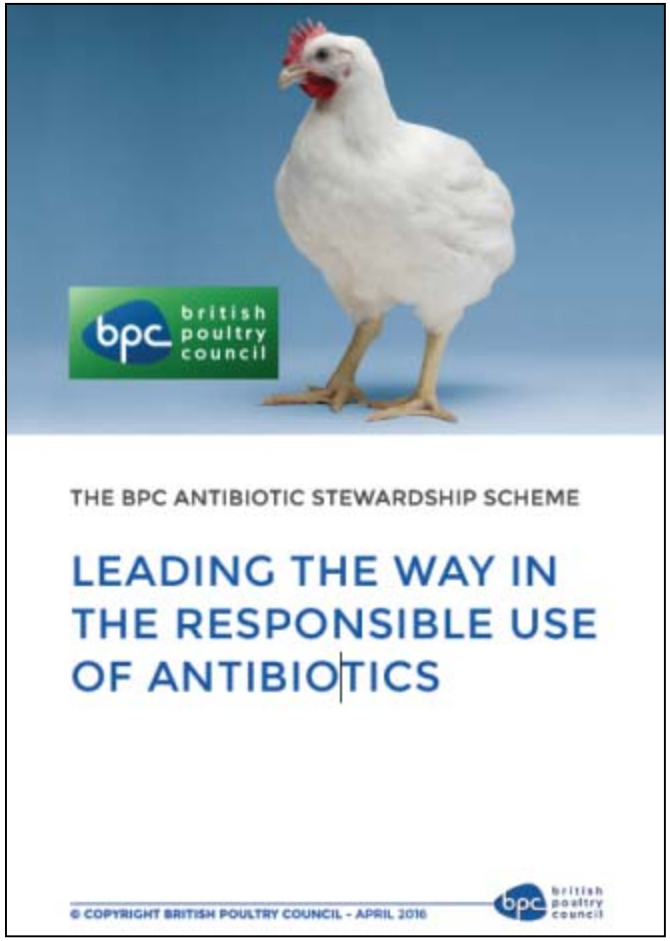
- Key benefits of species level data:
  - measure trends, identify risk factors, determine effect of reduction and control measures

Antibiotic usage project

CHAWG
Cattle Health & Welfare Group

SHAWG
Sheep Health & Welfare Group

PHWC
Pig Health and Welfare Council



eMB
e-medicine book

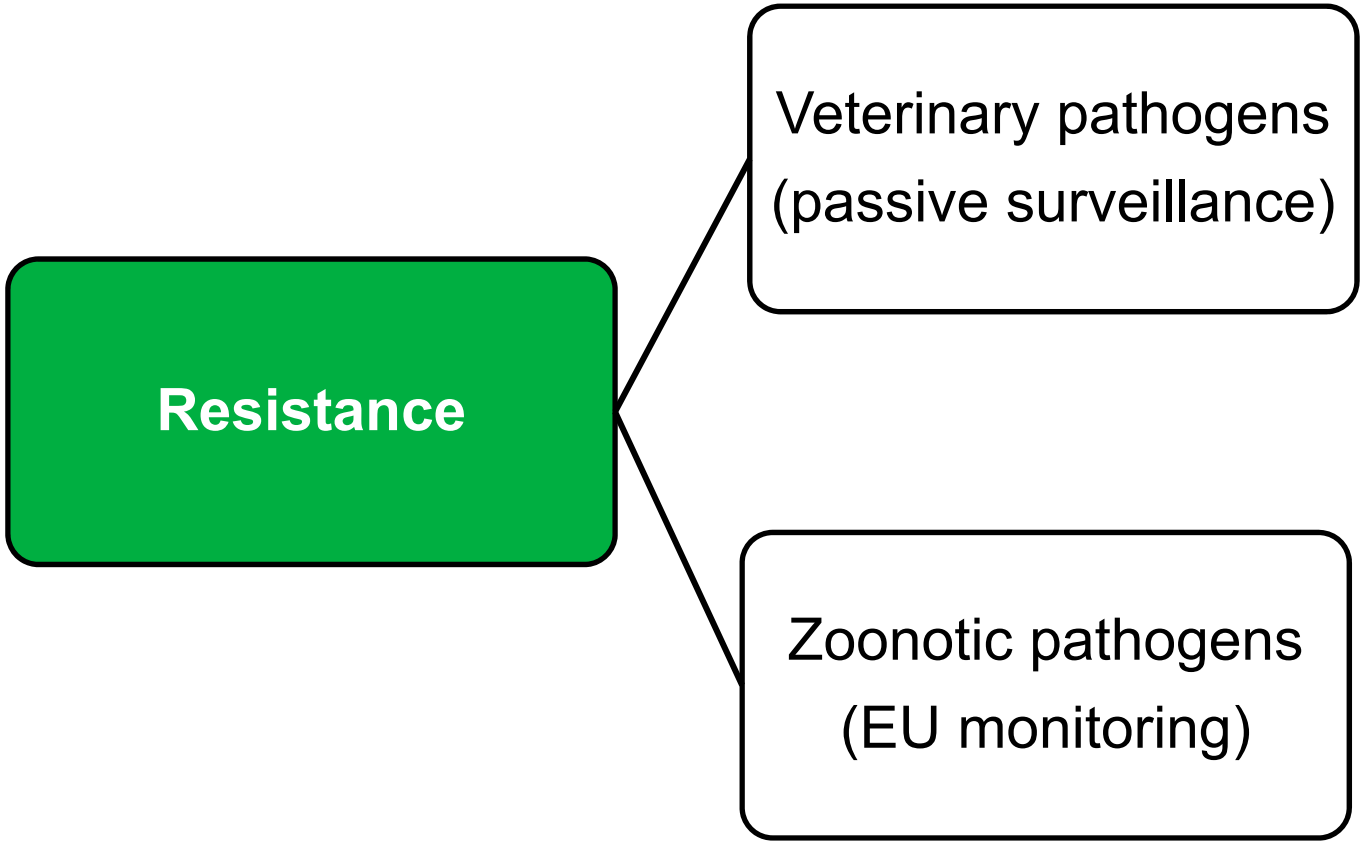
BEIC
British Egg Industry Council

RESPONSIBLE USE OF MEDICINES IN AGRICULTURE ALLIANCE
ruma

Sector Specific Targets

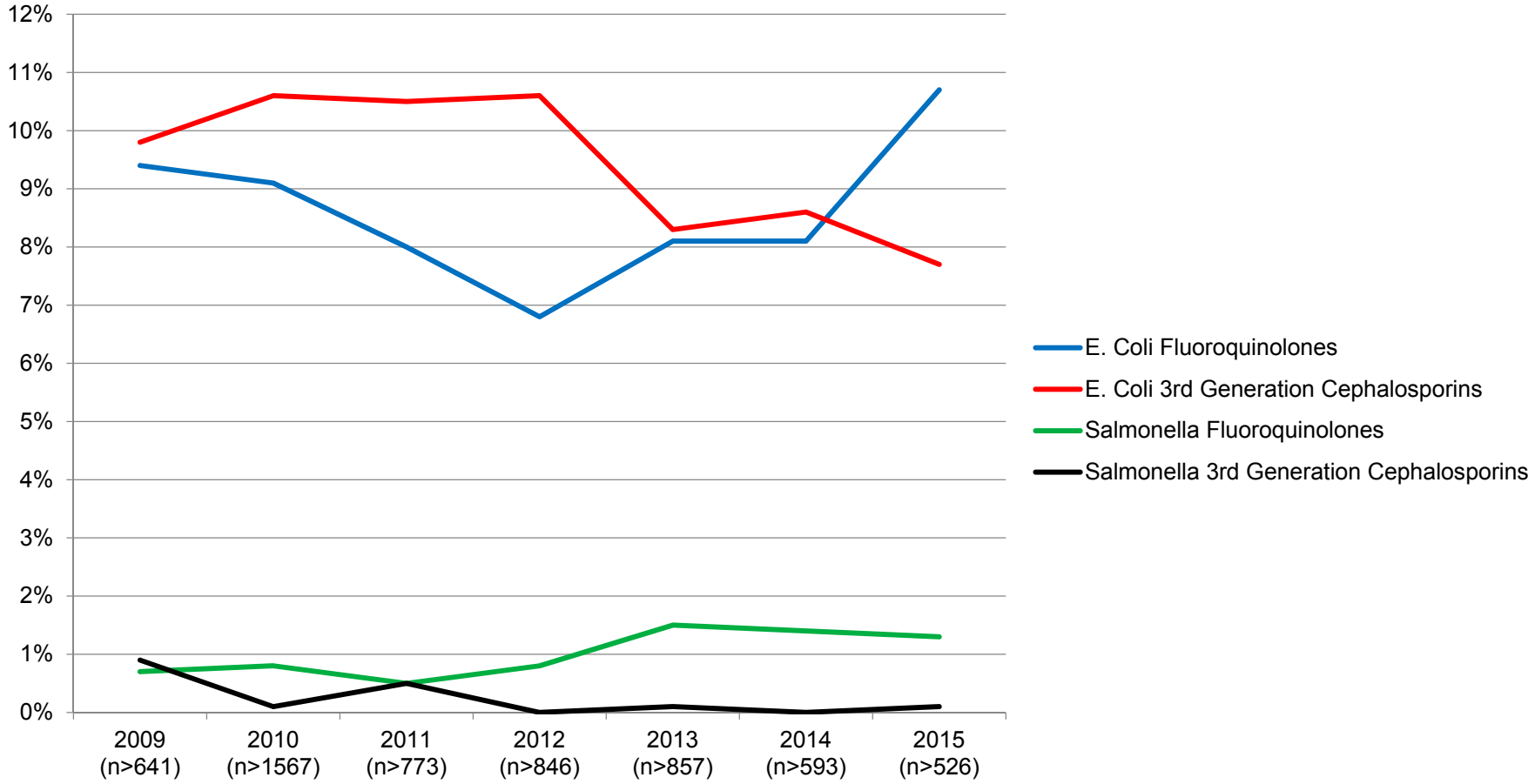
- Co-ordinated by RUMA via Targets Taskforce group
- Targets being produced by the sectors covering next 3-5 years
- Key principles for targets:
  - Ambitious, long term, sustainable and evidence based
  - Underpin responsible use and showcase best practice
  - Formulated in a way that is useful to the sector and maintains animal health and welfare
- Will not be the same across species due to the different levels of antibiotic use, different abilities to measure antibiotic use and different management systems

Level of Resistant Bacteria



Level of Resistant Bacteria

Percentage of resistance observed in E. coli and Salmonella from five species (Cattle, Pigs, Sheep, Chickens, Turkeys) between 2009 and 2015 from the clinical surveillance in England and Wales

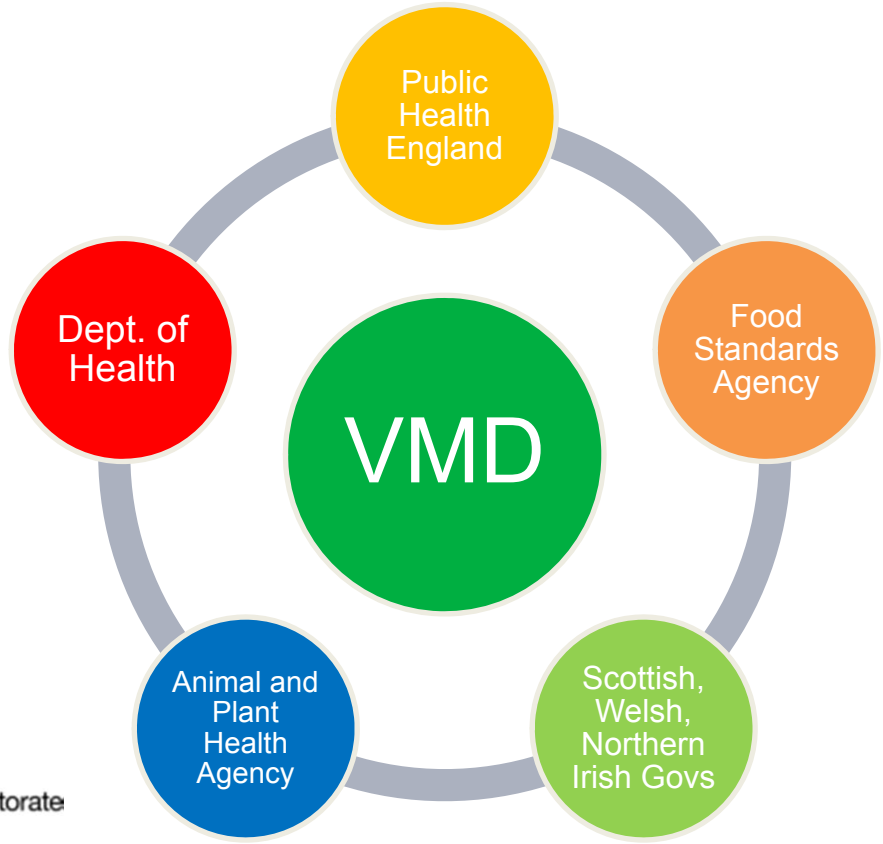


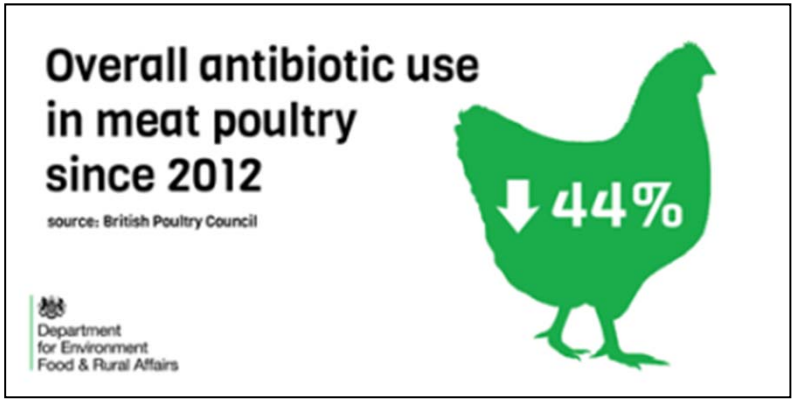
Resistant bacteria: ResAlert

Laboratory notifies VMD of finding

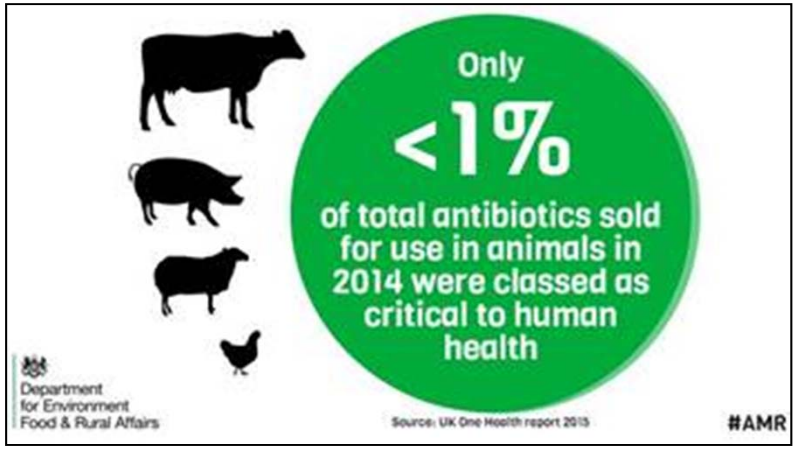
VMD sends ResAlert form to relevant departments

Teleconference to discuss finding and decide if further risk assessment is needed





Communication Update



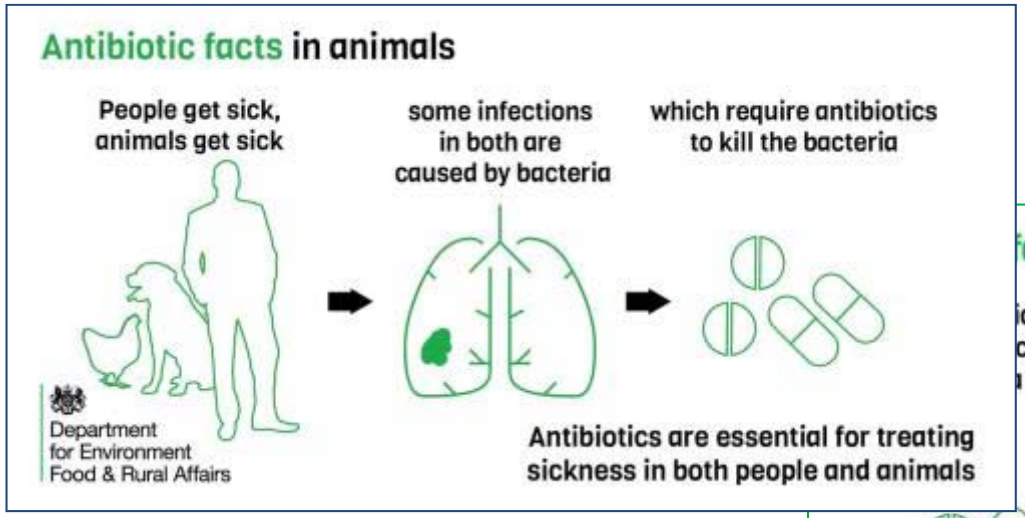
Engagement and EAAD/WAAW

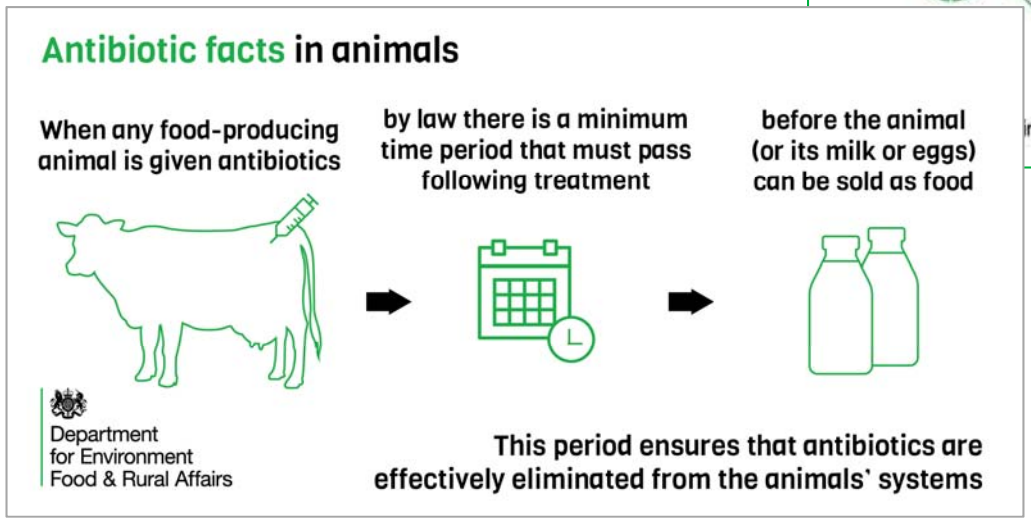
farm antibiotics

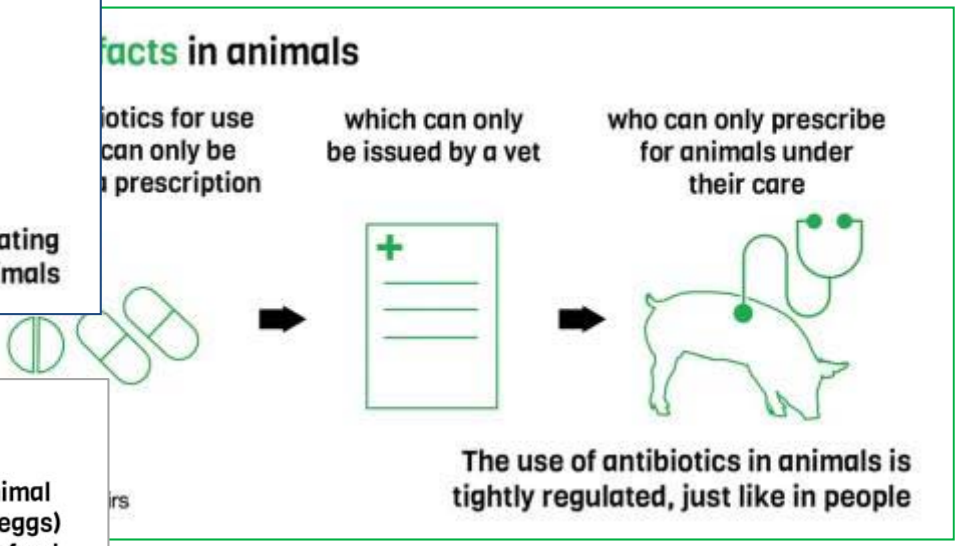
PRESENTING THE FACTS

www.farmantibiotics.org

Engagement and EAAD/WAAW

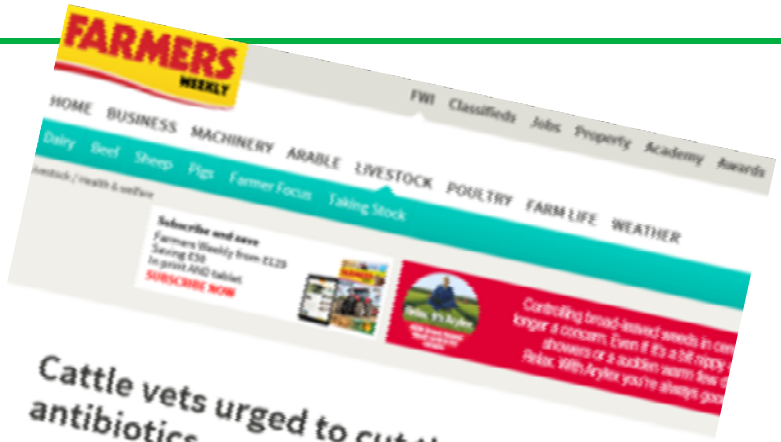






Veterinary Medicines Directorate

Industry's involvement



Future Actions

- Continue to improve our surveillance programmes
- Better linkage of AMR to antibiotic usage
- Improve harmonisation of surveillance
- Next One Health Report (Dec 2017): animal, human, food, environment resistance data, animal and human use data
- Implementing the commitment made following the AMR Independent Review recommendations
- Work on a new AMR Strategy
- Better engagement to inform public and animal health industry

Thankyou for listening!

Marie Closing Statements

VMD Novel Therapy Group

- Formed in response to increased regulatory activity in the area of advanced/novel therapies
  - AdVeNT and CVMP activities
  - VMD discussion with industry

- Rapid pace of change in natural and medical sciences
  - New classes of VMP on the horizon
  - Authorisation of first vet monoclonal Ab in 2017
  - Potential paradigm shifts in the approach to treatment of common veterinary conditions

VMD Novel Therapy Group

- Novel Therapy Group – Functions
  - Horizon scanning: identify future challenges
  - Develop guidance
    - Clarify regulatory requirements: a clearer path to market
    - Working with external partners (e.g. VICH)
  - Ensuring VMD continues to meet new challenges
    - Maintaining adequate in-house expertise
    - Ensure the Q/S/E of novel VMPs coming to market
    - VMD links with a network of UK experts (e.g. NIBSC / UK Stem Cell Bank
  - Cross team and multidisciplinary working in this challenging space

Over the horizon

- Keeping up with EU IT requirements
  - follow EMA approach to implementing ISO IDMP standards based on the four domains SPOR
  - to simplify data exchanges between all stakeholders, enhancing interoperability of systems at EU level and internationally
  - simplify: supply data once and re-use
  - industry to submit data on medicines to VMD in accordance with these formats and terminologies
- Workshops on EU exit in the fall
- Pharma industry survey next winter
  - we welcome your feedback

Thank you all for attending!