Veterinary Medicines Directorate

Pharmaceutical Industry Day

2015

Welcome and Introduction

Presented by: Marie-Odile Hendrickx

Date: 25 June 2015

Fire Alarm Sounding

- Leave the building by the nearest available safe exit route

- Proceed to the Assembly Point **situated on the grassed area south of building 97 (far side of main car park)**

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

Morning Schedule

Time All times include Q&A	Item	Speaker
10:00 – 10:30	Registration (including tea and coffee)	
10:30 – 10:35	Welcome and introduction	Marie-Odile Hendrickx
10:35 - 11:05	Update on the revision of the EU legislation on veterinary medicines	Nick Renn
11:05 - 11.20	Product Literature Standards (mock-up assessments)	Emma Thompson
11.20 - 11:50	. GOV update Revision of VMGNS for plain English.	Matthew Isted
11:50 - 12:20	Inspections & Enforcement	John Millward
12:30 – 14:00	**Lunch** **(buffet lunch provided)**	

Please Note: All presentations shown today will be available on Gov.uk on the VMD news page

Veterinary
Medicines
Directorate

Proposals for new EU regulations on veterinary medicines

the state of play

Dr Nick Renn
Head of Legislation

Today

Scene setting

Veterinary medicines proposal

Medicated feed proposal

The state of play

Proposals released September 2014

- Package of three
  - Veterinary medicines
  - Medicated feed
  - Amendments to Council Regulation 726/2004

VMD workshops

2 for veterinary medicines: 8 Oct and 24 Nov

1 for medicated feed: 16 Dec

1:1 Meeting with individual stakeholders

Highlights from the veterinary medicines proposal

Aims

The Commission's Objectives

- 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

Specific measures to address AMR

- Identify and reserve certain antimicrobials for human use only (detail for tertiary legislation)
- Establish a list of antimicrobial products that are restricted for use under the cascade (tertiary legislation)
- Veterinary Surgeons can only retail supply antimicrobials to animals under their care

Antimicrobial resistance (ii)

- New data requirements for antimicrobial products
  - Information on the risk to public and animal health in relation to use of the product
  - Information on risk mitigation measures taken to limit resistance developing
- MS can require post-authorisation studies
- Obligation on MS to collect data on volume of sales and use of products

Marketing authorisations

Database of products

Approval processes streamlined

- Scope of Centralised route widened
- Mutual Recognition/Decentralised (MRP/DCP) routes changed
- Subsequent Recognition of MRP/DCP products (within 30 days)
- National route remains the same

Marketing authorisation (ii)

Variations

List of variations requiring scientific assessment

Others “do and tell”

Detail to be agreed in tertiary legislation:

- risk to public health
- animal health
- environment

No renewals

No sunset clause

Marketing authorisations (iii)

Proposed Harmonisation of SPCs

- Administrative harmonisation
- Scientific re-evaluation

Reduced labelling requirements

- Pictograms

Data protection periods extended

- 14 years for antimicrobial products and products for minor species
- 18 years for bee products
- For each new major species added extend by 1 year
- For each new minor species added extend by 4 years
- Maximum of 18 years

Pharmacovigilance

Risk-based approach

PSURs no longer required

EU database

Electronic reporting and signal detection

Prescribing cascade

- Cascade
  - 2 tiers
    - UK authorised product in another species or condition; Product from another MS; UK authorised human product
    - If no product in 1, an extemporaneous preparation
  - Additional restrictions for food-producing aquatic species
  - Withdrawal periods
    - Statutory minimum; or
    - The longest withdrawal period on the SPC multiplied by 1.5 (if there is one)
    - Derogation for bees

Other draft changes

- Provisions for online Supply
  - EU Common logo
  - Register of sites maintained by each MS
- Restrict advertising of Prescription Only Medicines to those who can supply them
- Clinical trials
  - Harmonised procedures for authorisation - 60 day
  - Definition and purpose
  - Food-producing animals - authorised products
    - or don’t enter the food chain

Medicated feed

Medicated feed

Commission's objectives

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 medicated feed – pets

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

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

Medicated feed (ii)

Carry over (cross-contamination)

First draft:

1% for antibiotics

3% for other medicines

New draft

0.1 mg kg^{-1} for antibiotics

1 mg kg^{-1} for other medicines

Medicated feed (iii)

Prescription of medicated feeds

Prescribed feed may only be used for animals ***examined*** by the person who issued the prescription and only for diagnosed disease.

Validity: 6 months for non-food species

3 weeks for food species (3 months in 90/167)

1 week for antibiotics (in revised text)

Stipulation on who keeps what record.

Records kept for 3 years.

Medicated feed (iv)

*"Medicated feed containing antimicrobial products shall **not be used to prevent diseases** in food-producing animals or to enhance their performance"*

Commission has confirmed that this refers to prophylaxis and not metaphylaxis – definitions are still to be agreed.

Quantities supplied do not exceed the quantities in the prescription

- One month's treatment
- Two weeks treatment for antibiotics

Where are we now?

Negotiations in Europe

In Council of EU working parties:

Veterinary medicines:

First technical read-through: 9 working parties

51 articles and 3 annexes

First revision due in early 2016?

Medicated feed:

"Annotated text" for second read-through

Luxembourg presidency has one other meeting

European Parliament

Veterinary medicines:

Committee on the Environment, Public Health and Food safety

Medicated Feed:

Committee on Agriculture and Rural Development

The domestic front

Parliament:

Scrutiny Committees

European Affairs Committee

Stakeholders:

Open invitation for 1:1 meetings with individual companies

Will be setting up a focus group for medicines

Veterinary Medicines Directorate

Thank you

Any Questions?

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Product Literature Standard (Mock-Up Assessment)

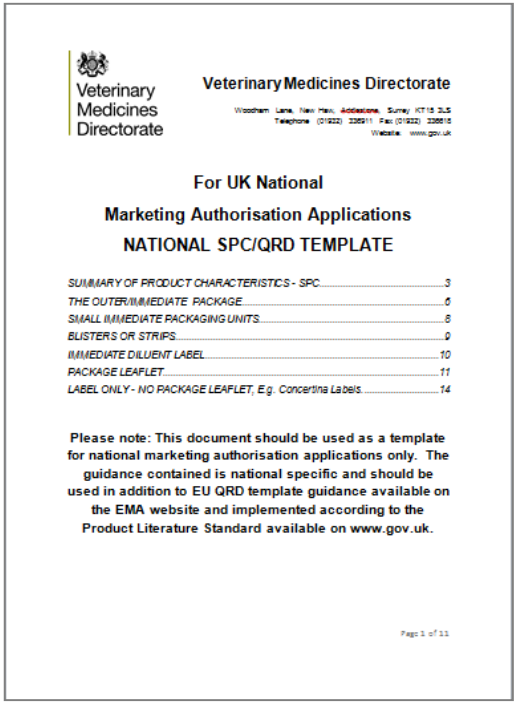
Presented by: ~~Renee Sheehan~~ Emma Thompson
Date: 25 June 2015

What information should I include on my medicine box, label and SPC?

- EU Directive 2001/82/EC (as amended)
  - Available from www.hma.eu
- Veterinary Medicine Regulations 2013
  - Available from www.legislation.gov.uk

What information should I include on my medicine box, label and SPC?

- The approved ‘what’ is documented as:
  - EUROPEAN AUTHORISATIONS:
    - A QRD - Quality Requirements Document
    - EU QRD template, available from www.ema.europa.eu
  - NATIONAL AUTHORISATIONS:
    - A QRD or SPC only – Summary of Product Characteristics
    - National QRD template, available from www.gov.uk (search terms: apply to market a medicine)



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For UK National

Marketing Authorisation Applications

NATIONAL SPC/QRD TEMPLATE

SUMMARY OF PRODUCT CHARACTERISTICS - SPC 3
THE OUTER/IMMEDIATE PACKAGE 6
SMALL IMMEDIATE PACKAGING UNITS 8
BLISTERS OR STRIPS 9
IMMEDIATE DILUENT LABEL 10
PACKAGE LEAFLET 11
LABEL ONLY - NO PACKAGE LEAFLET, E.g. Concertina Labels 14

Please note: This document should be used as a template for national marketing authorisation applications only. The guidance contained is national specific and should be used in addition to EU QRD template guidance available on the EMA website and implemented according to the Product Literature Standard available on www.gov.uk.

How should I present the approved information?

- Product Literature Standard (PLS)
  - Guidance for industry on the production of mock-ups for use on the UK and Irish markets
  - Recent review changes, to include:
    - Complete review of the format = easier to navigate and user friendly
    - Further detail on specific areas in response to your enquiries and feedback
  - Available from www.gov.uk (search terms: product literature mock-ups for an animal medicine license)

How should I present the approved information?

Can you read this easily?

Can you read this easily?

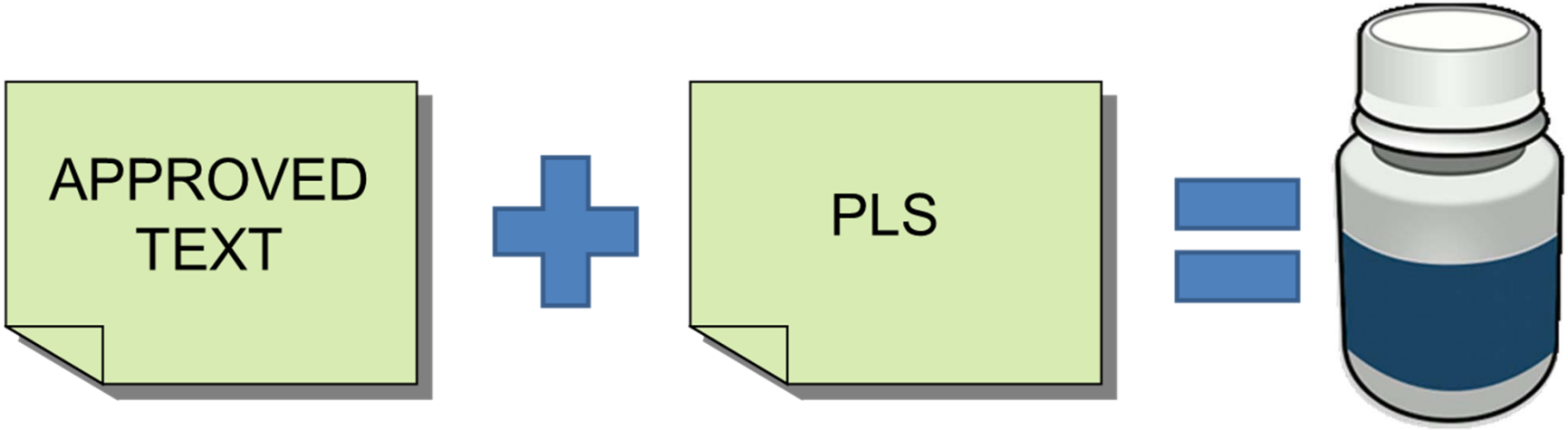
Or this?

Can you read this easily?

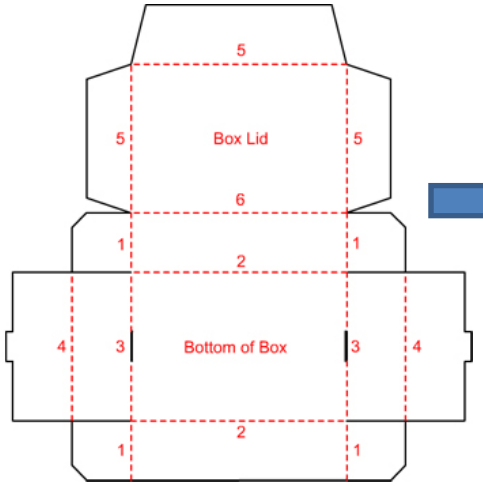
How about this?

What happens during mock-up assessment?

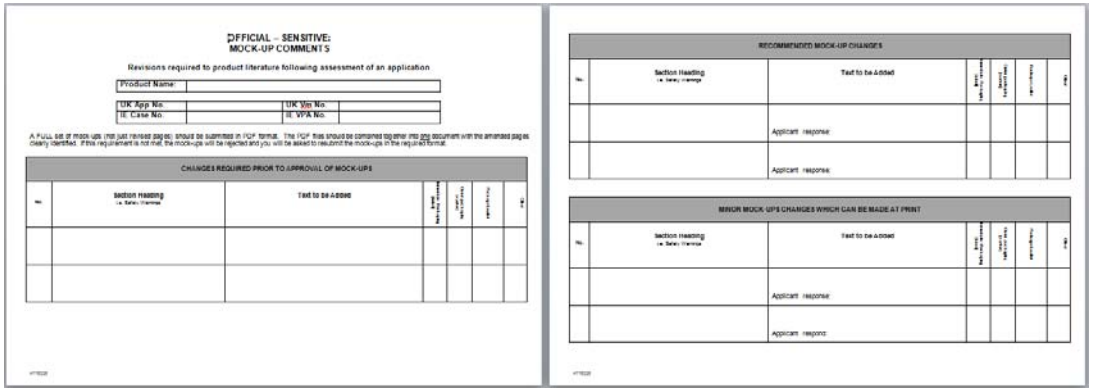
- Mock-ups are assessed during a national mock-up period, following completion of the assessment phase



What happens during mock-up assessment?



Up to 20 days to assess



Up to 20 days to submit amended mock-ups

How long does mock up assessment take?

- Mock-ups are assessed during a National mock-up phase at the end of the procedure
- General Assessment Team
- Line by line assessment against QRD and PLS
- 20 days to assess mock ups
- Revised mock-ups requested
- 20 days to re-assess

Common Issues

- Analysis of issues identified since 1 April 2015
  - 55 mock-ups assessed
  - **100%** mock-ups contained errors!!
  - 63% contained serious issues!
  - 27% required mock-ups to be submitted up to 4 times (new unauthorised changes added and/or applicant failed to address issued raised during assessment)

Common Issues

- Serious errors include:
  - incorrect withdrawal period
  - wrong indication
  - wrong species
  - wrong contraindications
  - missing or incorrect warnings
  - illegible text
  - pictures or pictograms where the species could be misunderstood
  - wrong product name
  - wrong legal category
  - incorrect dosing information

Some had more than one serious error

Top Tips

- Use the PLS
- Tell us font size at the outset
- Do not deviate from the approved QRD or the approved SPC (if no QRD) text
- Address any labelling space limitations on your mock-ups during the assessment phase
- Do not make changes to your mock-ups that are outside the scope of the variation you have applied for

Conclusion

- We want you to get your mock ups right first time!

Thanks for listening
Any Questions?

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GOV.UK
Finding what you need

Presented by Matthew Isted and Viv Saville
25 June 2015

GOV.UK

- November 2014 – VMD moved to GOV.UK (VMD's website closed down)
- GOV.UK has all the information users **need** to comply with the law, access Government services etc
- Search-based
- You can find everything you need about veterinary medicines by keyword searches
- Our new-look guidance is shorter, clearer and more succinct

GOV.UK

- Viv and I will:
  - show you the VMD information on GOV.UK
  - help you with anything you're having difficulty finding or that is not on there that you need
- So let's go into GOV.UK (www.gov.uk)

Thank you

Any questions?

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Inspections & Enforcement

Presented by John Millward
Pharmaceutical Open Day: 25 June 2015

Overview

- Three inspection teams:
  - who they are
  - what they do
- Inspection Schedules
- Main inspection findings
- Enforcement activities

GMDP Inspections

Good Manufacturing Practice Inspection team (GMP IT)

- Three inspectors
- Responsible for inspecting:
  - Manufacturing (GMP) sites in UK and 3rd countries, including:
    - Non-Food Animal Blood Banks, Equine Stem Cell Centres, Autogenous Vaccine sites, 'Specials ' and 'Schedule 6' manufacturing sites
  - Wholesale dealer (GDP) sites in UK
- Inspect against EudraLex Vol 4* – GMP guidelines

* http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm

Inspection Plan

- Risk-based inspections – two parts:

1) inherent risk
    - for GMP sites – at least every 33 months
    - for GDP sites – at least every 60 months for ‘low-risk’ products, otherwise 48 months
2) number and types of deficiencies observed at previous inspection
    - maximum interval reduced to 12 months in ‘worst case’

Inspection Schedule

	Number of sites	2015-16	2014-15
GDP	170	60	31
GMP	118	46	39
Combined GMP/GDP	14	10	2

Findings

GMP generally improving (except Schedule 6):

- Main issues:
  - Quality Risk Management
  - Change control
  - Standard Operating Procedures (SOPs)
  - Verification of new suppliers
  - Staff training
  - Maintenance of building & equipment

GDP – generally improving:

- Main issues:
  - SOPs – particularly self-audits
  - Recall procedures

Retailer & Feedingstuffs Inspections

Inspections & Investigations team (IIT)

- Six inspectors
- Responsible for inspecting:
  - Veterinary Practice Premises (VPPs) in UK
  - Suitably qualified person (SQP) retailer premises in UK
  - Medicated feed businesses' premises in GB
  - 'Low level' investigations
- Risk-based inspections
- All premises inspected against published criteria*

* Search 'GOV.UK' for VMGNs 3 and 17

Inspection Schedule

	Number of premises	2015-16	2014-2015
VPPs	2556	608	553
SQP Retailer premises	1679	414	610
Feed Mills	137	53	42
On-Farm mixers	536	115	188
Medicated Feed Distributors	276	67	71

Findings

SQP retailers good compliance

VPPs, generally improving

- Main issues:
  - Temperature monitoring of medicines' storage areas
  - Broach dates not recorded/exceeded
  - SOPs
  - Not segregating out of date/unusable medicines (cars!)
  - Controlled Drug (CD) register format (inc ketamine)
  - CDs not stored securely
  - Requisition orders for Schedule 2 & 3 CDs

PhV Inspections

Pharmacovigilance (PhV) inspections

- One inspector (cross training with other PhV staff)
- National inspection programme re-launched this year, combining with relevant CVMP inspections
- Focus on education, as well as compliance
- Inspect against Eudralex Volume 9B* and VMR

* http://ec.europa.eu/health/documents/eudralex/vol-9/index_en.htm

Inspection Plan

- Most MAHs can expect a national inspection in the next 2-3 years
- MAHs with centrally authorised products can expect a CVMP requested inspection at some point
- Aim to move to a risk based system with a planned maximum inspection frequency of 5 years
- Currently maximum interval between CVMP requested inspections is 3 years

Inspection Schedule

	Number of MAHs	2015-16	2014-15
National PhV inspections	90 (70+)	20	0
CVMP requested PhV inspections		5	4

Findings

- Generally positive
- All inspections have identified some areas of minor/major non-compliance
- Findings depend on MAH factors e.g. number of Mas held, company size, staff experience
- Main findings:
  - training
  - under reporting (recognising cases/causality)
  - no access to a vet for QPPV
  - poor documentation of procedures

Hints and Tips for Inspections

- Provide requested documents prior to the inspection
- Maintain communication before and after the inspection
- If an area of non-compliance is identified during the inspection, be forthcoming with relevant information
- Provide required evidence of corrective and preventative actions within specified time

Enforcement

- Aim to achieve compliance through advice and/or enforcement
- Enforcement Strategy – ‘escalator’ approach:
  - Risk-based inspections – written reports
  - Advisory letters
  - Warning letters
  - Improvement and seizure notices
  - Suspension or revocation of authorisation
  - Referral to Defra Investigation Services (DIS)
  - Prosecution
  - Referral of personnel to professional bodies

Enforcement Activities

Dealing with:

- Internet sales – both in the UK and overseas sites
- Advertising prescription medicines
- Making medicinal claims for non-medicinal products
- Prescription misuse
- Matters referred by the Inspection teams

Enforcement Activities

Enforcement cases	2014/2015 Year total	Q1 2015/2016
Unauthorised products/medicinal claims Cases reported Cases completed	 337 302	 34 33
On-line marketplace product listings removed	1224 (inc 212 antimicrobials)	228 (inc 24 antimicrobials)
Advisory/Warning Letters (includes prescription letters)	262	119
Prescription tampering/fraud reported	183	20
Seizure notices	7	3
Improvement notices	7	1
Referral to DIS for formal investigation (of which prescription fraud)	38 (17)	7 (7)

Enforcement Activities

The Future

- Continue to identify ways to reduce regulatory burden
  - Joined-up inspections within the VMD
  - Delegated inspections
  - Extend ‘Earned Recognition’
- On-going review of fees
  - Simplification

In Summary

Comprehensive risk-based inspection programme in place – from medicines' manufacture to retail

Comprehensive post-authorisation surveillance inspection programme in place

When things go wrong, effective enforcement strategy in place

Talk to us

Contact details

- General enquiries: postmaster@vmd.defra.gsi.gov.uk
- GMPIT and IIT: inspections@vmd.defra.gsi.gov.uk
- PhV IT: v.warnock@vmd.defra.gsi.gov.uk
- Enforcement: enforcement@vmd.defra.gsi.gov.uk

Abbreviations

- CD – Controlled Drug
- CVMP – Committee for Medicinal Products for Veterinary Use
- GMP – Good Manufacturing Practice (manufacturing)
- GDP – Good Distribution Practice (wholesale dealing)
- MAH – Marketing Authorisation Holder
- PhV - Pharmacovigilance
- QPPV – Qualified Person for Pharmacovigilance
- SOP – Standard Operating Procedure
- SQP – Suitably Qualified Person
- VMR – Veterinary Medicines Regulations
- VPP – Veterinary Practice Premises

Thank you

Any questions?

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

12:30 – 14:00

Enjoy!

Afternoon Schedule

VMD PHARMACEUTICAL INDUSTRY INFORMATION DAY

Time All times include Q&A	Item	Speaker
14:00 - 14:15	Legal Category Changes	Suzanne Eckford
14:15 – 14:35	AMR- Prescription data collection	Paul Green
14:35 – 14:55	Biopharmaceutical products	Anna-Maria Brady
14:55 - 15:00	Closing statements	Marie-Odile Hendrickx

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VMP Distribution Categories: which should I apply for – and how do I change it?

Presented by: Suzanne Eckford
25 June 2015

Distribution Categories - reminder

- **POM-V**
  - Require Prescription issued by Vet
  - Supplied by Vet or Pharmacist
- **POM-VPS**
  - Require Prescription issued by Vet, Pharmacist or SQP
  - Supplied by Vet, Pharmacist or SQP
- **NFA-VPS** [Non food producing animals]
  - **No Prescription required**
  - Supplied by Vet, Pharmacist or SQP
- **AVM-GSL**
  - **No Prescription required**
  - Over the counter sale

Distribution Categories – legal base

Vet Medicines Regulations 2013: Schedule 3: Part 1

The following MUST be classed as POM-V

- Narcotic or psychotrophic substance
- Products intended for administration following a diagnosis or clinical assessment by a vet

The following MUST be classed as POM-V or POM-VPS

- Products for food producing species
- Products for which special precautions must be taken to avoid unnecessary risk to target species/ user/ environment
- Products which may cause effects that impede/interfere with subsequent diagnostic/therapeutic measures
- Products containing an active substance that has not been included in an authorised VMP for 5 years

Distribution Categories – legal base

Exception from POM-V/POM-VPS category for food producing species VMPs when:

- Formulation that require no particular skill or knowledge to administer
- Do not present risk to target animal/ user/ environment – even if used incorrectly
- SPC contains no warnings of potential serious side effects associated with correct use
- Product (or any other containing same active) not been subject to frequent AE reports
- Not contraindicated for use with other non- prescription VMPs

Distribution Categories – legal base

.....continued

- Not subject to special storage conditions
- No risk for consumer safety as regards residues in food obtained from treated animals, even when product used incorrectly
- No risk to animal or human health as regards development of resistance to antimicrobials or anthelmintics, even when product used incorrectly

Distribution Categories – New MAs

What categories are assigned to new products?

- Full MA (article 12, 13a) - Product containing a new active substance
  - **POM-V or POM-VPS**
- Generic MA (article 13(1)(3))
  - **Same DC as the reference product**

Distribution Categories – New MAs

- Full MA (article 12, 13a, 13b) - Product containing an active substance present in a VMP >5 years
  - Can request **same distribution category** as other products containing same active (or higher)*
  - National application – can request **lower DC** as part of MA application**

* *New fixed combination product containing 2+ actives already present individually in VMPs will be authorised as POM-V*

** *extension of procedure necessary to allow VPC referral*

Changing Distribution Category

How do I change the DC of my product?

- **UK National Type II variation**
- Need to submit data to support requested change
  - **Expert report** which provides a critical analysis of the B:R of proposed supply/use of product
  - Assessment of **PSUR data** and any post authorisation surveillance studies
  - Changes to **SPC/QRD*** ** appropriate to target category

*** *Products with EU MA must submit EU Type II variation to amend SPC/QRD before UK DC change can be completed.*

Changing Distribution Category

What should I include in the B:R assessment?

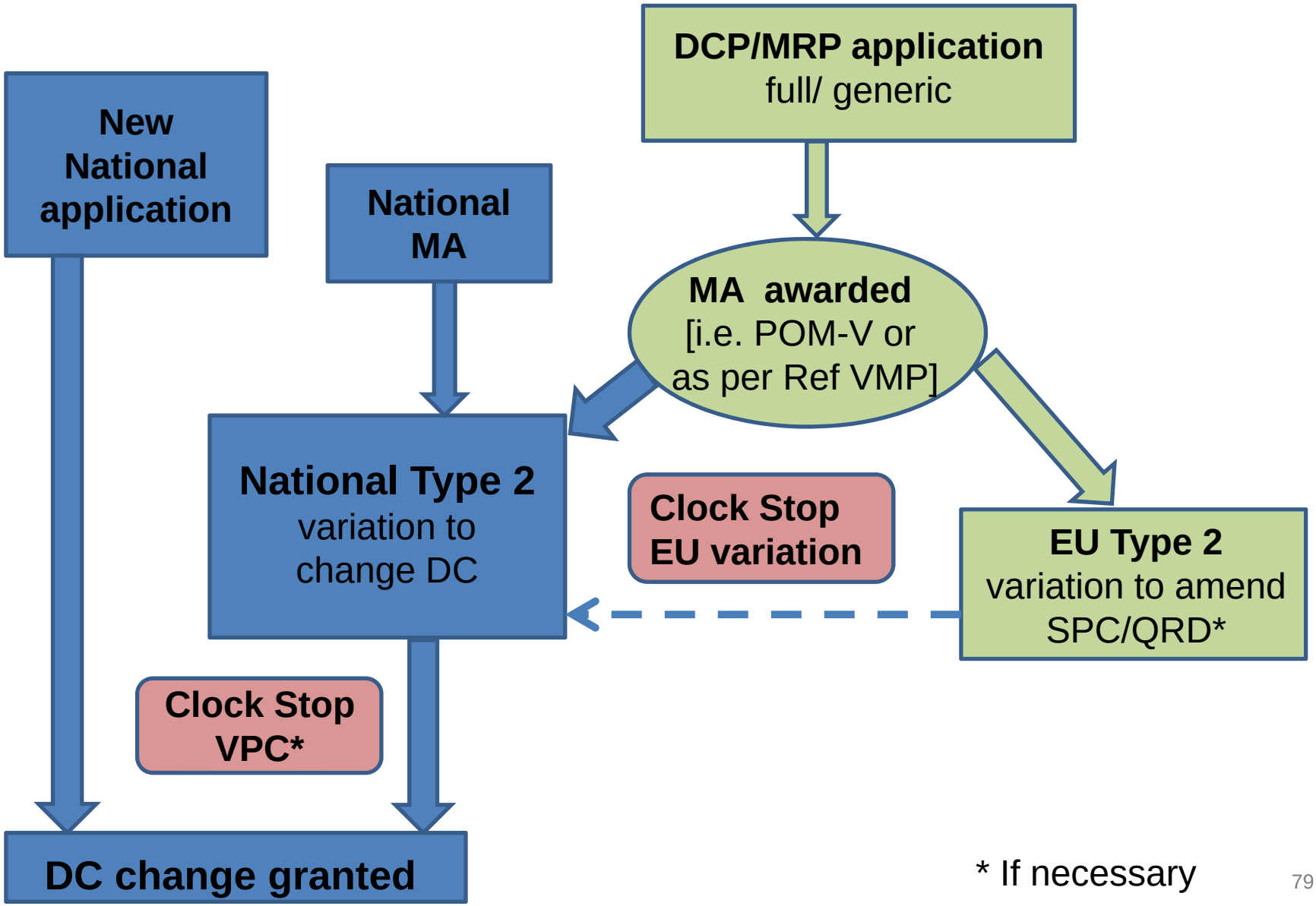
- Level of risk to user/ target animal/ non target animals/ the environment/ the consumer (food producing species only) AND how these can be mitigated
  - Safety margins
  - Any likely interactions with other non prescription medicines
  - Ease of administration
  - Provision of user warnings
- Benefits to user/ target animals, e.g. greater availability

Role of the VPC

Role of Veterinary Products Committee

- Independent scientific committee – provides advice to VMD on specific issues
- EU applications not referred to VPC – timelines do not permit
- Type II DC applications usually referred to VPC when:
  - Applicant seeks DC lower than POM-V **and**
  - Active has not previously been marketed below POM-V

Changing Distribution Category



* If necessary

Changing Distribution Category

Example:

- Fipronil Generic:
  - Granted same DC as reference product
  - Subsequently submit national Type 2 variation to lower DC
  - Simultaneously submit EU type 2 variation to remove FAD claim from SPC/ amend QRD
  - No need to refer to VPC as precedent already set
  - National variation finalised once EU variation completed

Thank you for listening

More information on Distribution Categories can be found here:

VMGN 3: Guidance for retailers

VMGN 2: Marketing Authorisations for Veterinary Medicines

https://www.gov.uk/government/collections/veterinary-medicines-guidance-notes-vmgns

EMA CVMP: Guideline on the change of classification of VMPs authorised by the community (CVMP/430509/2009)

Thank you

Any questions?

Veterinary Medicines Directorate

Collecting data on the use of antimicrobials in animals

Presented by: Paul Green
Date: 25 June 2015

Why are data on antimicrobial use important?

UK 5-year AMR Strategy

One Health approach

- partnership between parts of government dealing with human and animal health

https://www.gov.uk/government/publications/uk-5-year-antimicrobial-resistance-strategy-2013-to-2018

European Processes

- Methods for surveillance of antimicrobial use
- Revision to European regulation

European Method

ESVAC =

European Surveillance of Veterinary Antimicrobial Consumption Group

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp

Developing EU methods for data collection on use of antimicrobials in priority species – pigs, poultry, cattle

European Regulation

- Draft Regulation on Veterinary Medicinal Products

- Article 54 - Requirement for collection of relevant and comparable data on the volume of sales and the use of veterinary antimicrobial medicinal products

What do we already know about antimicrobial use in animals in the UK?

Sales data pigs and poultry

- By weight of active ingredient
- Nearly ¾ of all sales of antibiotics authorised for use in animals are authorised for use in pigs, poultry or both
- More than half are authorised for use in both pigs and poultry

Antibiotic sales (tonnes active ingredient)

	2011	2012	2013
Cattle Only	12	14	14
Pig Only	**62**	**65**	**61**
Poultry Only	**23**	**22**	**19**
Sheep Only	<1	<1	<1
Fish Only	2	2	1
Pig and Poultry Only	**162**	**245**	**226**
Non Food species	35	35	36
Multi-species Food	29	33	34
Multi-species Food + Non Food	21	29	29
Total	**346**	**445**	**420**

Conclusions of scoping study

- Data on usage are already recorded but not readily accessible
- Not feasible to adopt other EU systems
- No single solution for all species or commodity sectors
- Central co-ordination needed and would encourage participation

Approach

- Focus on antibiotics
- Focus on pigs, poultry, cattle as priority
- Take a commodity sector-specific approach
- Incrementally building towards UK-wide all species data collection and capture system with benchmarking at farm level
- Minimum requirement of **annual aggregate data by product and commodity-sector group for the priority species**

Approach

- Develop central data capture system, defining essential data fields, and support private sector-led data collection initiatives
- Focus on facilitation of electronic data recording, collection and capture systems; join up with existing IT platforms / interfaces
- Private sector / industry led

Current activities

- VMD central data hub for sales and usage data, linked to VMD product databases
- Support and boost private sector led initiatives in priority livestock sectors
- Analysis of data on antibiotic use in companion animals – research projects

Poultry Sector

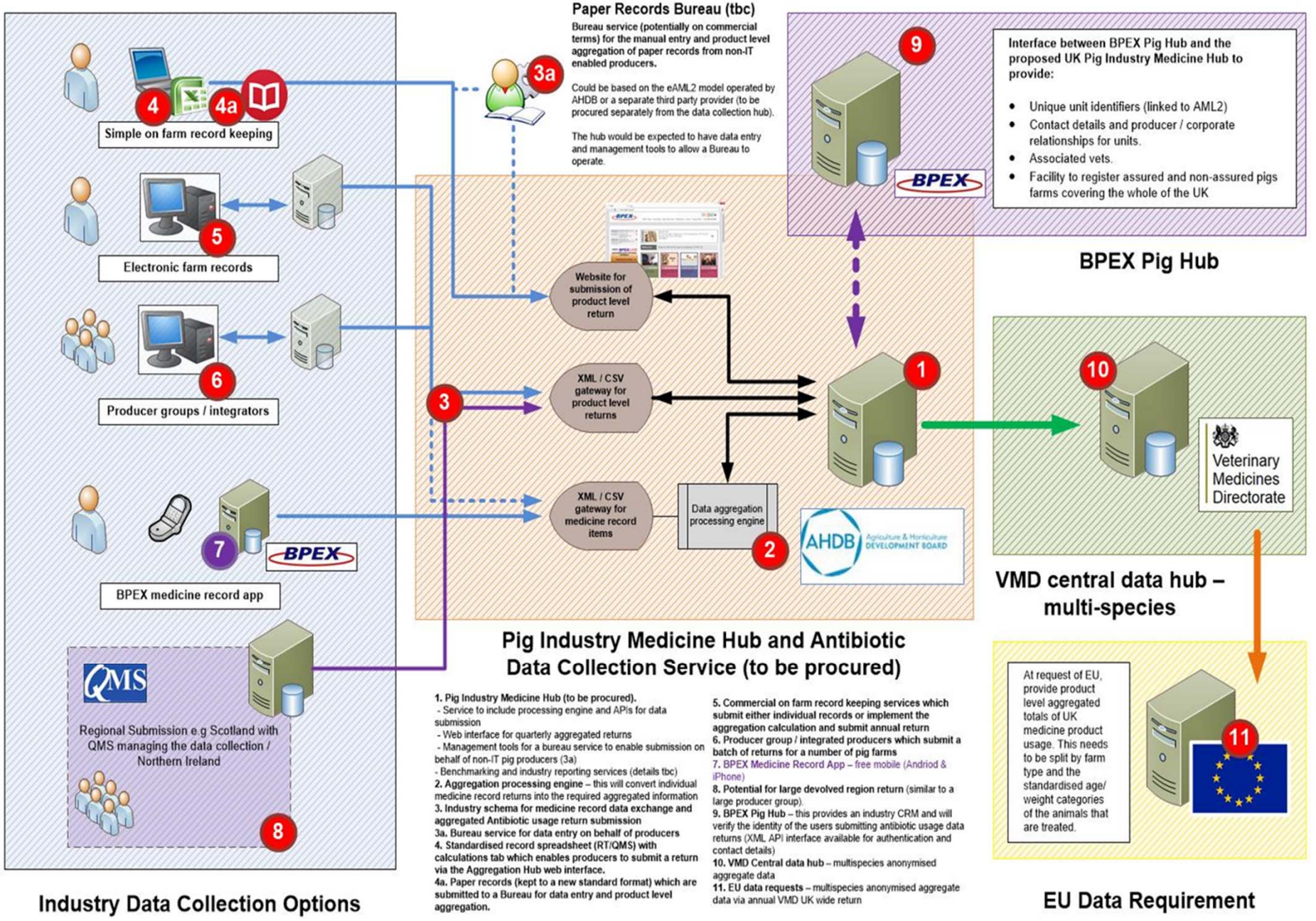
- British Poultry Council (BPC) leadership, data collection from producers for past 4 years
- Agreed template for data collection in meat poultry, egg layer and farmed game sectors
- Aim for voluntary sharing of aggregated annual usage data by commodity sector, by product

Pig Sector

- Pig Health and Welfare Council (PHWC) Antimicrobial Usage Subgroup
- Priority action to develop national UK data collection system
- Developed concept and design, industry led with VMD support

UK Pig Industry Medicine Hub

Pig Industry Medicine Hub



1. Pig Industry Medicine Hub (to be procured).
- Service to include processing engine and APIs for data submission
- Web interface for quarterly aggregated returns
- Management tools for a bureau service to enable submission on behalf of non-IT pig producers (3a)
- Benchmarking and industry reporting services (details tbc)

2. Aggregation processing engine – this will convert individual medicine record returns into the required aggregated information

3. Industry schema for medicine record data exchange and aggregated Antibiotic usage return submission

3a. Bureau service for data entry on behalf of producers

4. Standardised record spreadsheet (RT/QMS) with calculations tab which enables producers to submit a return via the Aggregation Hub web interface.

4a. Paper records (kept to a new standard format) which are submitted to a Bureau for data entry and product level aggregation.

5. Commercial on farm record keeping services which submit either individual records or implement the aggregation calculation and submit annual return

6. Producer group / integrated producers which submit a batch of returns for a number of pig farms

7. BPEX Medicine Record App – free mobile (Andriod & iPhone)

8. Potential for large devolved region return (similar to a large producer group).

9. BPEX Pig Hub – this provides an industry CRM and will verify the identity of the users submitting antibiotic usage data returns (XML API interface available for authentication and contact details)

10. VMD Central data hub – multispecies anonymised aggregate data

11. EU data requests – multispecies anonymised aggregate data via annual VMD UK wide return

Pig Sector

- Procurement by AHDB Pork (previously BPEX)
- Currently out to open tender
- Aim to start trialing early next year, with full roll-out mid-year 2016
- Industry steering group will oversee implementation

Cattle Sector

- Cattle Health and Welfare Group (CHAWG)
- Project to scope options across beef and dairy sectors, UK-wide systems
- Report being finalised
- Key recommendations around coordinated approach
- Veterinary practice management systems offer potential

Medicine Supply Chain

- Working with NOAH, veterinary wholesalers, practice management software providers and vet profession (VetXML Consortium)

- Key areas to facilitate data collection at vet practice level:
  - unique medicine identifiers (e.g. GTIN)
  - standardised data entry in practice management software

Thank you

Any questions?

Veterinary
Medicines
Directorate

Biopharmaceuticals

Presented by: Anna-Maria Brady
Date: 25 June 2015

What is a Biopharmaceutical?

- A drug created through bioengineering or biotechnological processes
- A biological macromolecule or cellular component, such as a blood product, used as a pharmaceutical
- Any medicinal product manufactured in, extracted from, or semisynthesised from biological sources

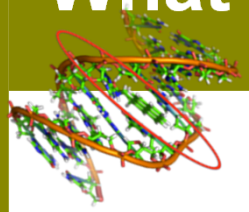
What is a Biopharmaceutical?

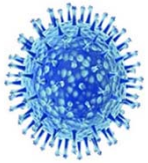
Industry survey mid 2000's showed that >85%, particularly in the U.S. considered that

- Biopharmaceuticals are a subset of pharmaceuticals which are inherently biological in nature and manufactured using biotechnology (involving use of live organisms)
- Drugs comprise the other major subset of pharmaceuticals, with their source and manufacture being chemical (non-biological) in nature
- Small molecules and other drugs are not biopharmaceuticals

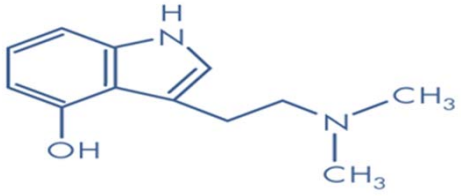
Ronald A. Rader, Biopharmaceuticals in the US and EU markets , Bioexecutive: March/May 2005

What types of products are Biopharmaceuticals?





- Vaccines, blood or blood components, allergens, somatic cells, gene therapies, tissues, recombinant therapeutic proteins, and cells used in cell therapy. View in US industry 2005
- Only those products based on newer platform technologies, such as recombinant proteins and monoclonal antibodies, leaving out non- recombinant cultured proteins, blood/plasma proteins, vaccines and other classes of products. This view/definition is more predominant in Europe



Regulation of Biopharmaceuticals US v EU

- The FDA regulates most biopharmaceuticals as biologicals. Some simpler biopharmaceuticals are regulated as drugs, such as recombinant hormones, for example, insulin and human growth hormone, and a few products are regulated as medical devices.

- The EU human medicine regulations define 'biological medicinal products' as "a protein or nucleic acid–based pharmaceutical substance used for therapeutic or in vivo diagnostic purposes, which is produced by means other than direct extraction from a native (non engineered) biological source"

What about Veterinary Biopharmaceuticals?

Rules Governing Veterinary Medicines in the European Union 2001/82/EC

- No definition of a biological product
- Technical annexes cover Pharmaceutical and Immunological products
- No explicit scope for cell products

Veterinary Biopharmaceuticals - the future?

Draft legislative proposal from the Commission

- Contains a definition of a veterinary biological product which includes scope of substance material
- Contains a definition and clear scope for a veterinary immunological product
- Applies to veterinary medicinal products prepared industrially or by a method involving an industrial process
- Does NOT apply to veterinary medicinal products containing autologous or allogeneic cells or tissues that have not been subjected to an industrial process

Veterinary Biopharmaceuticals - the future? Draft EU legislation definitions

‘Veterinary Medicinal Product’ means any substance or combination of substances which fulfils at least one of the following conditions:

‘Substance’ means any of the following matters:

- human
- animal
- vegetable
- chemical

Veterinary Biopharmaceuticals - the future? Draft EU legislation definitions

- ‘Biological veterinary medicinal product’ means a veterinary medicinal product an active substance of which is a biological substance
- ‘Biological substance’ means a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with knowledge of the production process and its control

Veterinary Biopharmaceuticals - the future? Draft EU legislation definitions

- ‘Immunological Veterinary Medicinal Product’ means a veterinary medicinal product consisting of vaccines, toxins, sera or allergen products and intended to be administered to an animal in order to produce active or passive immunity or to diagnose its state of immunity

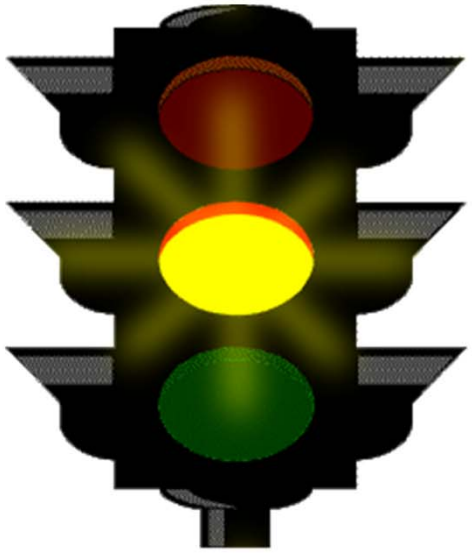
What happens now in practice?

What happens now in practice?

PAST

PRESENT

FUTURE



What happens now in practice?

We use existing technical frameworks and guidance in a tailored manner (mix and match) considering each novel product on a case by case basis

What happens now in practice? Mix and Match

Quality: Likely to be biological considerations and therefore relevant immunological requirements taken into account

Safety: Will depend on nature of product: may require toxicology

Efficacy: Will depend on the nature of the product: may require pharmacokinetics

Veterinary Biopharmaceuticals on the market –EU/UK

- Mid 90s – now: recombinant and GMO vaccines centrally authorised
- 2009 Immunological product for male pigs to reduce boar taint by biological castration containing a gonadotropin-releasing-factor (GnRF)-analogue-protein conjugate as the active substance
- 2013 anti cancer immunomodulator authorised centrally for treatment of fibrosarcoma containing interleukin-2 recombinant canarypox virus
- July 2014 centralised : anti cancer vaccine withdrawal day 180: company reason; additional investment in research and development required to answer the remaining issues not justified (EMA website withdrawal notices)

Veterinary Biopharmaceuticals on the market

- In the US:
- 2005 1st DNA mediated product licenced
- 2006 First plant cell-derived product licensed
- 2007 First veterinary cancer vaccine licensed
- 2012 First veterinary ribonucleic acid (RNA) vaccine licensed

Confused about where to go?

- **Innovation task force –**
  - *Multi disciplinary ad hoc from CVMP/EU experts*
- ***ADVENT*---*CVMP***
  - *Working Party--guidelines*
- ***CVMP Scientific Advice -***
  - *Formal written advice*

National authorities


Thank You
Mahalo
Kiitos
Tack
Toda
Grazie
Obrigado
Thanks
Takk
Merci
Gracias

Closing Statements

Marie-Odile Hendrickx

On the horizon

- Impact of the new legislation
  - How will it impact the VMD and industry activities
- AMR challenge
  - One Health report
- VMD continuous improvement activities
  - Continues….
- ATC consultation
  - Aiming to simplify process

We appreciate your feedback!