



## Surveillance & Monitoring of Veterinary Medicines – Current & Future Needs

**J. Gabriel Beechinor**  
Director of Veterinary Sciences

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APHA Animal Health Conference – Safe Food, Role of Animal Health Industry



## Agenda/Topics to Be Covered

- General role
- Role in surveillance and monitoring
- Future developments

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## Our Role

The role of the Health Products Regulatory Authority (HPRA) is to protect and enhance public and animal health by regulating medicines, medical devices and other health products.



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## Department Responsibilities

Deputy Chief Executive	Compliance	Human Products Authorisation and Registration	Human Products Monitoring	Human Resources and Change	ICT and Business Services	Quality, Scientific Affairs and Communications	Veterinary Sciences
International Finance Corporate affairs Legal	Inspections Audits Site licensing Market compliance Enforcement	Clinical trials and investigations Medicines licensing CHMP, CMDh Reclassification Device registration & notified body oversight	Pharmacovigilance PRAC Device vigilance	Recruitment and selection Learning and development Change management	ICT CESP Project management Business services	Communications Classification Knowledge management Quality management	Clinical field trials Medicines Licensing CVMP, CMDv Pharmacovigilance Scientific animal protection

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Glossary | As Gaeilge

**HPRA**  An tÚdarás Rialála Táirgí Sláinte  
Health Products Regulatory Authority

My HPRA: [Login](#) [Register](#)

ABOUT US MEDICINES **VETERINARY** MEDICAL DEVICES BLOOD, TISSUES, ORGANS COSMETICS CONTROLLED SUBSTANCES

Veterinary

- > Our Role
- > Veterinary Medicines Information
- > Safety Information
- > Regulatory Information
- > Veterinary News & Events
- > Special Topics
- > Contact details
- > Scientific Animal Protection

## Veterinary

Welcome to the veterinary section of our website. This area includes our veterinary medicines product database, safety and quality updates, and industry regulatory news.

I want to:

[Report an issue](#)
[Get fees info](#)
[See all Guides & forms](#)
[Contact the HPRA](#)

Find a Veterinary Medicine

For centrally authorised product information click here


Enter a Trade Name, Active Substance or Licence Number...

[View all Veterinary Medicines](#)
[Advanced Search](#)


The HPRA for:

- [Patients & Public](#)
- [Healthcare Professionals](#)
- [Industry](#)


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## The regulatory standards



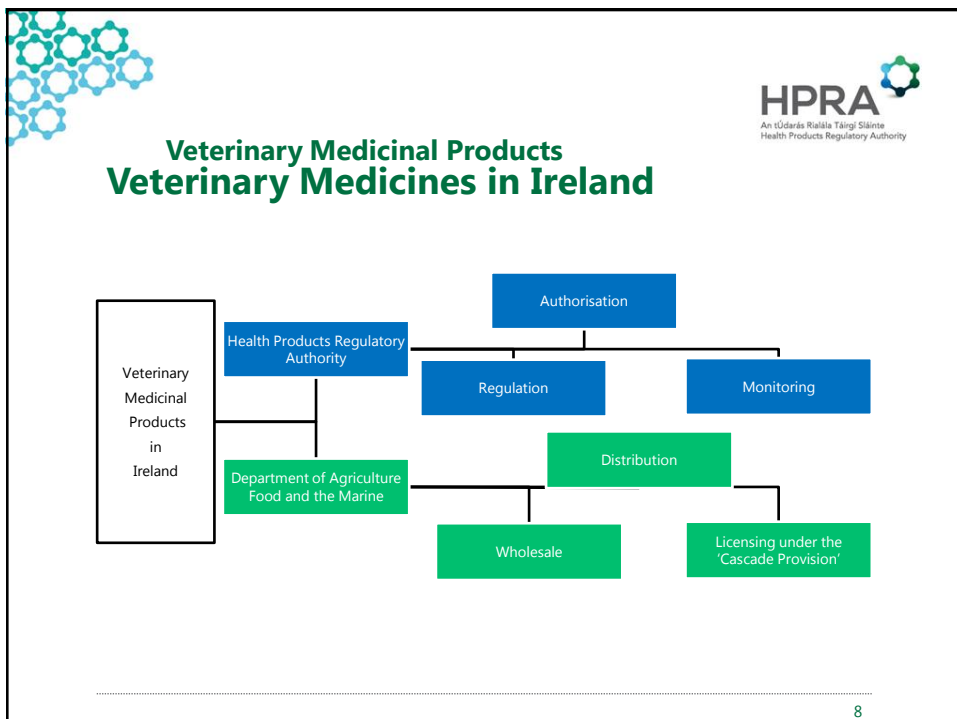
- Quality
- Safety
- Efficacy
  
- On-going benefit/risk evaluation
- Applications must be kept up to state-of-the-art




## What we do in the field of veterinary medicines.....

- Evaluate and authorise:
  - Circa 100 new veterinary products/year
  - Circa 2000 variations to marketing authorisations/year
  - Circa 100 transfer of marketing authorisations/year
  - Circa 800 periodic safety update reports/year
- Competent authority for decision on what is a veterinary medicinal product (animal remedy)
- Publish pertinent information on veterinary medicinal products on [www.HPRA.ie](http://www.HPRA.ie)

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## Our Regulatory Functions by Product

HPRA regulation	Pre-market studies	Pre-market authorisation	Product manufacture	Product wholesale / distribution	Product advertising	Post-market monitoring
Human medicines	HPRA Function	HPRA Function	HPRA Function	HPRA Function	HPRA Function	HPRA Function
Medical devices	HPRA Function	Part HPRA Function	HPRA Function	Non-HPRA Function / Non Applicable	Non-HPRA Function / Non Applicable	HPRA Function
Blood and tissues	Non-HPRA Function / Non Applicable	Non-HPRA Function / Non Applicable	HPRA Function	HPRA Function	Non-HPRA Function / Non Applicable	HPRA Function
Veterinary medicines	HPRA Function	HPRA Function	HPRA Function	Non-HPRA Function / Non Applicable	Non-HPRA Function / Non Applicable	HPRA Function
Scientific animal protection	HPRA Function	HPRA Function	Non-HPRA Function / Non Applicable	Non-HPRA Function / Non Applicable	Non-HPRA Function / Non Applicable	HPRA Function
Controlled substances	Non-HPRA Function / Non Applicable	Non-HPRA Function / Non Applicable	HPRA Function	HPRA Function	Non-HPRA Function / Non Applicable	Non-HPRA Function / Non Applicable
Cosmetics	Non-HPRA Function / Non Applicable	Non-HPRA Function / Non Applicable	HPRA Function	HPRA Function	Non-HPRA Function / Non Applicable	Part HPRA Function


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## HPRA in practice

- Customer service oriented
- Financially independent
- Supporting innovation
- Networked with EU medicines agencies

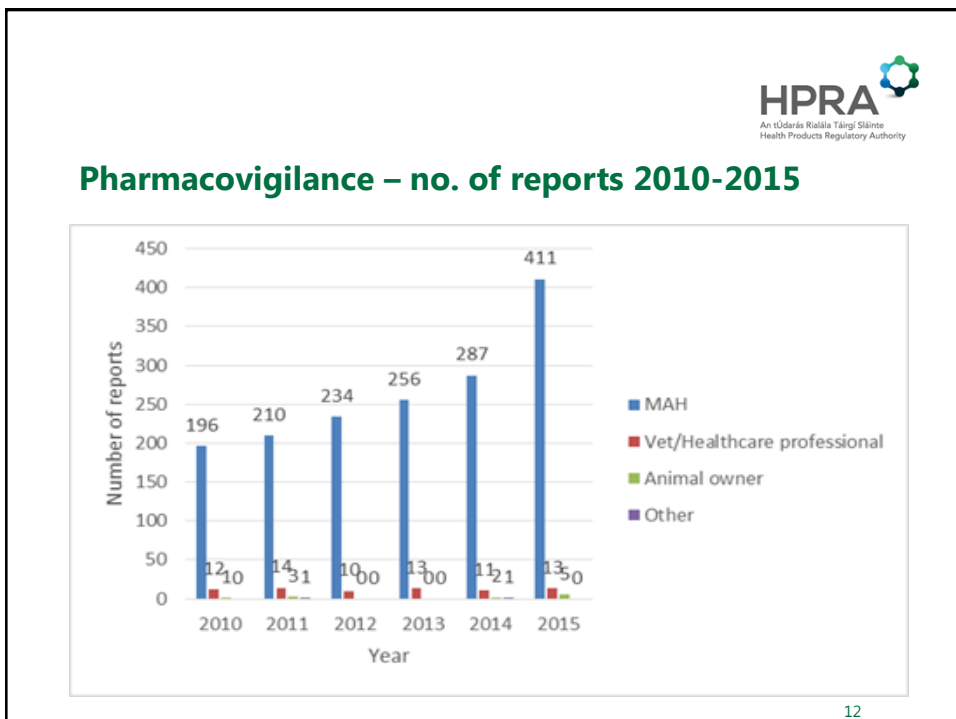
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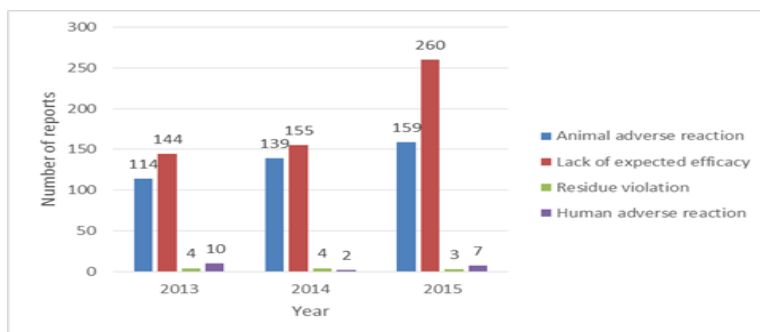
## HPRA supervision and monitoring

- Pharmacovigilance
- Consumption of veterinary antibiotics in Ireland
- Monitoring the quality of veterinary medicines
- Intelligence from other actors in the global network
- Availability of veterinary medicines

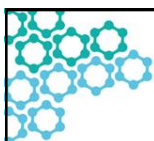
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## Pharmacovigilance – no. of SAE reports 2013-2015





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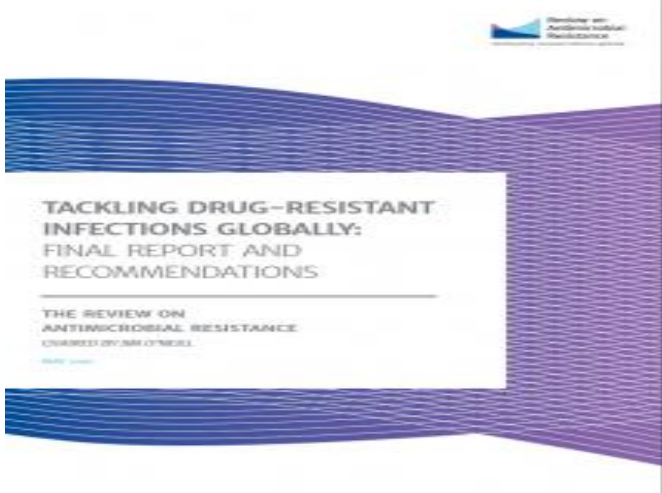
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## Antimicrobial resistance



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## O'Neill, OIE, FSAI and others -

- We must **reduce the extensive and unnecessary use of antibiotics** in agriculture.
- Antibiotics are a precious resource that cannot be taken for granted..... There needs to be a worldwide **change in behaviour** if their effectiveness is to be preserved.
- Acquired AMR occurs in response to antimicrobial use; therefore, **measures to reduce antimicrobial use are central** to responding to this challenge.

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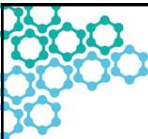


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## Sampling & Analysis programme

- Testing of products – Target is to check 40 veterinary medicines for 2016
- Packaging and labelling checks
- Coordinated with EU surveillance programmes
- HPRA uses different labs, in Ireland and EEA

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## Manufacturing trends

- The manufacturing chain is increasing complex and fragile:
  - There is a concentration of production of active substances for veterinary medicines in few countries (e.g. China)
  - Opportunities for trade and brokering increase chances for counterfeits

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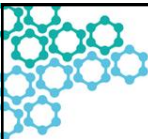


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## HPRA

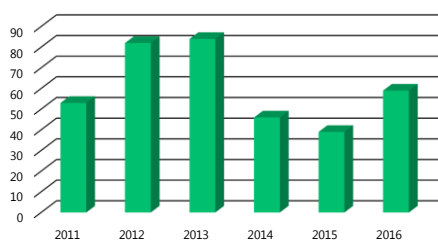
- Monitors AR16/18 DAFM licences on a regular basis
- Participates in the EU network of agencies to identify problems of availability and to find solutions
- Conducted a survey of animal health companies on their policies towards availability of veterinary medicines in Ireland during 2016
- Has in place various incentives to address the national position

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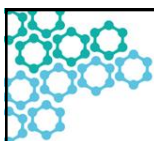
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## Company trends – consolidation?

Number of transfers of product authorisations 2011 - 2015





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## The Future

- 2014 Proposal for new EU regulation on veterinary medicines
  - Reduction of administrative burden
  - Simplified pharmacovigilance reporting
  - New regulatory tools to address Antimicrobial Resistance
  - EU wide harmonisation of 'legacy' products
  - Increased decision-making powers to the centre

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## Thank you

- [www.hpra.ie](http://www.hpra.ie)
- Questions?

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## Strategic Plan 2016 – 2020

HPRA Strategic Goals				
1. Optimised Regulatory Systems	2. Better Informed Users	3. Access to Health Products	4. Supporting Innovation	5. Internal Capabilities

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