

## Presentations by Anja Holm

Over the years, I have presented in meetings and conferences on many topics that I am very familiar with.

You can see some *front pages* here:

[Authorisation of medicines](#)

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[Pharmacovigilance](#)

[Availability of medicines](#)

[Referrals](#)

[CVMP and working parties](#)

[VICH](#) – (International Cooperation on Harmonisation of technical requirements for registration of Veterinary medicinal products)

[DNA-vaccines and GMO's](#) (Genetically Modified Organisms)

[Antimicrobial resistance](#)

Slides with updated information

Clear messages

A lively and engaging presentation

It will be a pleasure for me to participate in a meeting at your premises or elsewhere and present on the topic that you are interested in. Please contact me for further information and exchange:

[info@CentralVetPharma.com](mailto:info@CentralVetPharma.com)

## Authorisation of medicines



# Mutual Recognition Procedure in Europe

## Vaccines

Dr. Anja Holm  
Chair of CVMP

Committee for Medicinal  
Products for Veterinary Use,  
European Medicines Agency

Danish Medicines Agency  
Copenhagen, Denmark  
anh@dkma.dk

**Workshop for OIE national Focal Points for  
Veterinary Products**  
23 – 26 November 2010, Johannesburg, South Africa




Dr. Anja Holm  
Chair of CVMP, EMA

Danish Medicines Agency  
Copenhagen, DK - Denmark  
anh@dkma.dk

### Overview of existing structures relevant for Veterinary Products

**Regional Structures: Europe  
European Medicine Agency (EMA)**

Workshop for OIE national Focal Points for Veterinary Products  
23 – 26 November 2010, Johannesburg, South Africa



### Den nye MRL-forordning 470/2009

Møde VIF – LMS  
30. September 2009  
Anja Holm



## Benefit-risk assessment

### Benefit-risk assessment and risk management in our procedures and legislation

Precidency meeting of CVMP –  
Budapest 30-31 May 2011  
Anja Holm



### Risk management discussions in the context of CVMP

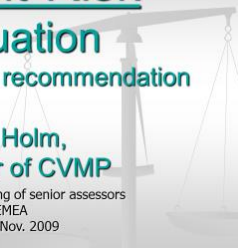
Anja Holm  
Informal CVMP meeting  
Antwerp, Belgium  
27. Sept 2010

## Benefit-Risk evaluation

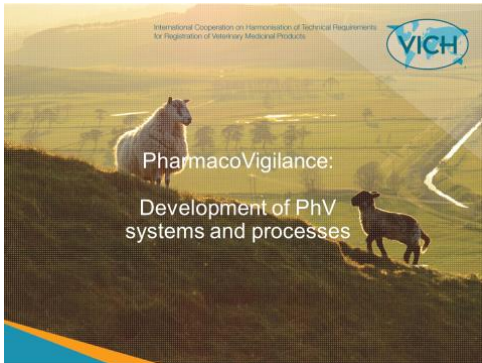
### Overview of the recommendation

Anja Holm,  
Vicechair of CVMP

Benefit-risk training of senior assessors  
EMA  
12-13 Nov. 2009



# Pharmacovigilance



## Pharmacovigilance:

Experience with development of PV systems and processes.

## Government perspective

VICH Outreach Forum  
Auckland NZ, 2013  
Anja Holm, EU

## PSUR Conclusions & recommendations

Assessor training in EMEA  
November 26-27, 2008.  
Anja Holm  
Danish Medicines Agency



## Post Marketing Safety Surveillance, present and future

Medicademy module 8  
Veterinary Pharmacovigilance  
Anja Holm

Sundhedsstyrelsen  
Danish Health and Medicines Authority

## ESS European Surveillance Strategy

Informal CVMP/CMD(v) meeting in Helsinki, Finland  
5. September 2006

Anja Holm



## Assessment of ADRs



- Expedited reporting -  
Centralised products

Informal CVMP 20-09-2005,  
Windsor, UK.  
Anja Holm

**The Informal CVMP/VMRFG meeting**  
**Hillerød, Denmark**

**Pharmacovigilance reports**  
**- getting them, using them, trusting them**

Anja Holm  
 26 November 2002

The informal CVMP/VMRFG meeting - 26 November 2002

## Availability of medicines

**Availability & Harmonisation**  
**Friends or Enemies?**



Anja Holm - CVMP chair

HMA – Poland. 5.th July 2011

**Regulation appropriate for needs Europe**

Anja Holm  
 CVMP- chair

Committee for Medicinal Products for Veterinary Use  
 European Medicines Agency

**Global availability conference**

London 23-24 March 2011



## Referrals

### Outcome of referrals at CVMP



Anja Holm  
 CVMP Chair

TOPRA - 5 October 2010

## CVMP and working parties



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

**CVMP work plan for 2016:  
Highlights and potential implications  
for new applications and developments**

EMA/FAH-Europe Info Day 2016




Presented by Anja Holm on 17 March 2016  
Chair of the Committee for Medicinal Products for Veterinary Use (CVMP)




Public CVMP workplan

Luxembourg presidency CVMP meeting 2015  
Anja Holm



STATUS ON FUNCTIONING OF  
**AD-HOC EXPERT GROUPS  
AND SCIENTIFIC  
ADVISORY GROUPS**

Presidency meeting - CVMP  
Copenhagen, 31 May 2012

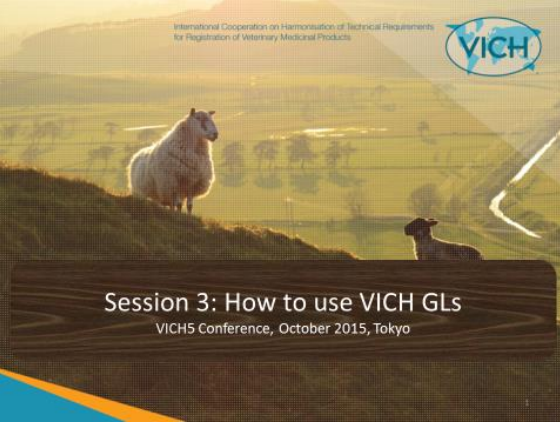



Peer-review  
Rapporteurs view

Informal CVMP - April 2009  
Brno  
Anja Holm

## VICH

International Cooperation on Harmonisation of Technical Requirements  
for Registration of Veterinary Medicinal Products



**Session 3: How to use VICH GLs**  
VICH5 Conference, October 2015, Tokyo

# DNA-vaccines and GMOs



**Advanced Veterinary Vaccines in EU:  
GMO - Vector - DNA**

**Legislation, guidance and challenges**

Anja Holm  
Veterinary Vaccines, Brussels 5-6  
December 2012

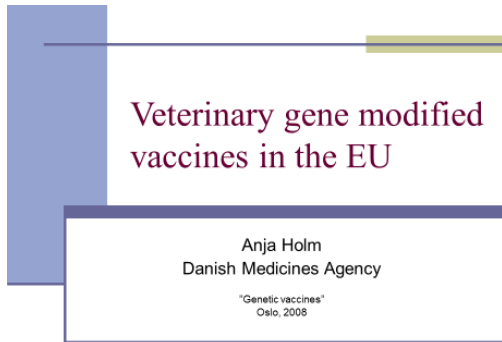
Sundhedsstyrelsen  
Danish Health and Medicines Authority

# DNA-vaccines

Anja Holm

Danish Health and Medicines Authority

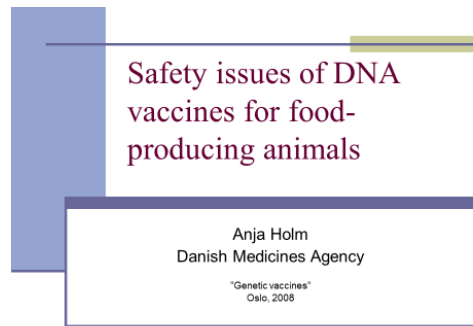
TOPRA-VET  
2-3 OCTOBER 2012, DUBLIN



**Veterinary gene modified  
vaccines in the EU**

Anja Holm  
Danish Medicines Agency

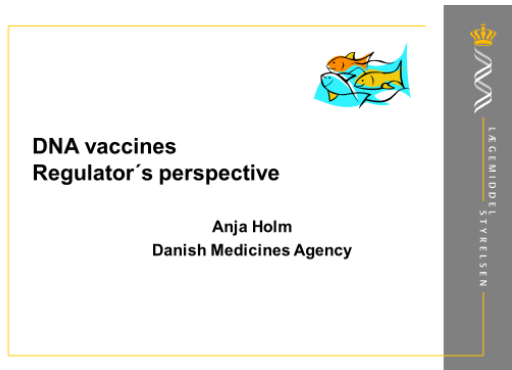
"Genetic vaccines"  
Oslo, 2008



**Safety issues of DNA  
vaccines for food-  
producing animals**

Anja Holm  
Danish Medicines Agency

"Genetic vaccines"  
Oslo, 2008



**DNA vaccines  
Regulator's perspective**

Anja Holm  
Danish Medicines Agency

LÆGEMIDDELSTYRELSEN



**Safety of DNA-vaccines**

- Consumer safety + animal safety
- Public risk assessment report

Dr. Anja Holm  
Danish Veterinary Institute  
NIBSC-meeting 2002

## Antimicrobial resistance

### Treatment alternatives CVMP's AMR strategy

Presidency meeting of CVMP and CMDv  
Vilnius, Lithuania  
2013

Anja Holm



### Principles for the assessment and authorisation of antimicrobials in the EU

VICH Outreach Forum, October 2015

Presented by Dr Anja Holm  
Chair of the EMA Committee For Medicinal Products for Veterinary Use (CVMP)



### ANTIMICROBIAL RESISTANCE

VET Journal club 30/4 2012

FORMANDSSKABSKONFERENCE  
14-15 MARTS 2012



### Progress in the area of antimicrobial resistance

## CVMP

EMA-HMA conference 15-16 Sept 2011

Presented by Anja Holm, Chair of CVMP

## Guidelines and assessor training

EU Network Training Centre (EU-NTC)

<http://euntc.eudra.org>

Kvalificeret kompetenceudvikling for EU's lægemiddelmmyndigheder



3 MARTS 2014

Anja Holm

LÆGEMIDDELSTYRELSEN  
DANISH MEDICINE AGENCY



### What are the overall benefits of guidelines

EMA / IFAH-Europe Info-day  
6-7 October, 2005.

Anja Holm, CVMP