Hauchsvej 7
4180 Sorø
Denmark

T: +45 – 22 94 66 00
anjaholm@centralvetpharma.com
www.CentralVetPharma.com

Anja E. H. Holm

Independent consultant in authorisation of veterinary medicines, Central VetPharma Consultancy

- CEO and chief consultant www.CentralVetPharma.com

Chair of the Committee for medicinal products for veterinary use (CVMP) for 6 years, June 2010 – June 2016

2010 - 2016
European Medicines Agency (EMA)
London

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- Responsible for leading the meetings of the Committee, for ensuring discussion of the most important topics, for taking **robust scientific decisions** in all cases by consensus or voting, **leading the strategic progress** in the projects surrounding the applications, select and motivate working groups and represent the Committee in meetings and conferences. CVMP consists of delegates from all EU-member states and is responsible for scientific advice to the EU-commission related to all EU-applied or -authorised veterinary medicines and scientific opinions on any topic referred to EMA from national authorities or other bodies.

- **EU's member in the Steering Committee of V-ICH** (**V**eterinary **I**nternational **C**ooperation for **H**armonisation of registration requirements for veterinary medicinal products): International harmonisation of guidelines and Outreach to non-VICH countries and regions. 2010- 2016.
  Negotiation and coordination of EU's opinion and mandate in projects related to harmonisation of study requirements for authorisations.
  VICH is an **international cooperation** between authorities and industry in USA, Japan, Canada, Australia, New Zealand and South Africa. The Steering Committee decides the work programme for the scientific groups and **negotiate solutions** when a topic is stuck. VICH has a Global Outreach Forum to involve the rest of the world, in particular Brazil, Russia, India, and China together with the rest of Asia and South America. For this Forum, I have described and presented a basic pharmacovigilance scheme, for implementation in new countries. The meetings take place around the globe and cultural respect and understanding is essential.

- **Scientific Coordination Board, EMA,** member 2010 - 2016.
  Representing CVMP, I participated together with the seven other committee chairs and EMA's top management in the Board meetings where cross-committee topics and strategic developments were handled. Contributions to EMA's **policy and prioritisations** and developing EMA's scientific projects.

- **Chair of CVMP's Strategic Planning Group** (SPG), 2006-2010.
  Structuring and progressing CVMP's work-plan, initiation of new guidelines, handling of cooperation, **coordination** of working groups with overlapping projects, **development** of the committee members and working party

chairpersons, relations to the group for national competent authorities, planning of EU strategic meetings, etc.

1998 – July 2016
Danish Medicines Agency

Chief scientific veterinary advisor, 1998 - 2016
Danish representative in the EU, 2004 - 2010
Head of Unit for Clinical Trials with human and vet medicinal products, 2016
Authorisation and surveillance of medicines.

- **Head of Unit for Clinical Trials,** 1/3 – 31/7 2016. Personnel management, recruitment, coordination of the doctors, pharmacists, biologists, and office clerks, development of priorities for the unit, planning of daily work, adherence to time tables, patient safety assessments, management board representation, etc.
- **Danish Medicines Agency's delegate in EU for veterinary medicinal products**
  From 2004 to 2010 member of CVMP for Denmark, and from 2006-2010 also elected as Vice-chair of CVMP. Authorised by the Health Ministry to vote on behalf of Denmark in all cases handled by the Committee.
    - **Rapporteur for several EU-applications of new medicinal products, both pharmaceuticals and immunologicals, including genetically modified organisms (GMO) vaccines**

  A team of scientific experts led by a Rapporteur assesses the medicines that are to be authorised in EU prior to the discussion in the Committee. The Rapporteur contributes to the assessment, collects the outstanding issues, leads the discussion process and proposes solutions.
    - **Assessor for safety and efficacy assessments** 1998 - 2004

  Drafting of the scientific assessment report in applications for authorisation on veterinary medicines, etc., including vaccines, pharmaceuticals, GMOs, MRL-applications (Maximum Residue Limits in animal-derived food products), clinical trial protocols, periodic safety update reports (PSUR), adverse reactions etc.
    - **Member of CVMP working parties**

  Scientific advice working party, study protocol advice to the industry, 2004 – 2010, subsequently observer as CVMP-Chair, 2010 – 2016.
  Pharmacovigilance working party, 1998 - 2006
  Immunological working party, 2004 – 2006.

- **Pharmacovigilance scheme** 1998 – 2004
  Responsible for the development of the Danish veterinary pharmacovigilance scheme and handling of adverse event reports, assessment of PSURs, contribution to the EU pharmacovigilance system, including guidelines and database.

- **Member of EU's strategic group for veterinary pharmacovigilance (ESS – European Surveillance Strategy), an HMA-group.** 2005 – 2016.
  Active participant since the start as Danish representative or CVMP chair. Developed steering tools, drafted guidelines, and organised courses in

pharmacovigilance, acknowledging that EU's member states have pharmacovigilance schemes with different levels and resources.

- **The National Antibiotics Council under the Ministry of Health**, 2010 - 2016.
  Member of the Council and working groups regarding veterinary and human medicinal initiatives to reduce development of **antimicrobial resistance**. Contributed to the organisation of a high-level EU-conference about antibiotic resistance during the Danish Presidency of EU. The Council is a cross-sectorial coordinating body and aims to promote prudent use of antibiotics in Denmark.

- **National Training Champion for Denmark in the EU-Network Training Centre** (EU-NTC)**,** 2014 – 2016.
  EU-NTC is a cooperation between EU's authorities with one National Training Champion in each country, who provides information about **competence development**, courses, meetings, webinars, etc. to the relevant unit-heads and represents the Danish Medicines Agency in the European Network training centre. This is for the benefit of the scientific assessors (pharmacists, medical doctors, veterinarians), who must develop through continuous education.

- **Contribution and negotiation of new legislation** for medicines regulation.
  When new legislation is drafted in my areas of expertise, I have contributed with thorough experience, creating **overview and coherence** in the comments to the legal proposals and through negotiation meetings for the legal text to become adequate and constructive.

- **Preparatory and explanatory notes to the Danish Parliament**, 1998 - 2010
  Drafted **comprehensive and complete texts** about the content and procedure of the scientific proposals for EU-authorisations prior to formal decisions.

- **Presentation of scientific, strategic and policy topics** at Danish as well as international meetings. Profound experience as presenter on more than 50 conferences, symposia and meetings, with good feedback that my communication is **clear and engaging**.

- **Chapter in textbook on fish vaccines**, 2013
  Main author on a chapter in an international textbook on fish diseases: Anja Holm, Byron Rippke, Ken Noda: Textbook "Fish Vaccination" (2013), "Authorisation of fish vaccines".

2001 – 2002
Denmark's Veterinary Institute, Dept. of Virology

Research project at the Danish Virus Institute, Lindholm
Took educational leave to participate in a large EU-financed research project on **DNA-vaccines**, where I drafted a public **risk assessment**:
"DNA-vaccines for food-producing animals, technology and safety aspects", 2004.
I presented the project and the risk assessment on conferences in UK (NIBSC, 2002), Denmark (EU-fish, 2005), Norway (Bioteknologinævn, 2008) and Ireland (TOPRA, 2012).

I was selected by **WHO** for the working group for DNA-vaccines (2004-2006) that drafted “WHO’s Technical guidance document for testing of DNA-vaccines”.

1994 – 1998
Veterinary practice

Veterinary practitioner at the clinics of Birgit Poulsen, Slagelse, and Bjarne Rasmussen, Hårlev
Veterinary surgeon/practitioner in small animal practice (Birgit Poulsen, Slagelse) and in mixed large and small animal practice (Bjarne Rasmussen, Hårlev). Responsible for medicinal and surgical treatment of animals in the clinics and at the premises of the clients. In addition, I made vaccination campaigns for homing pigeons, and managed the work of the nurses, including administration of salary, contracts, courses, etc.

1991 – 1993
Lundbeck Pharma

Assistant (student’s job) in the toxicological department
Handling and medication of **laboratory animals**, including study observations, euthanasia, autopsy and documentation in **GLP**-studies.

Elected exam censor at Copenhagen University, Veterinary **Pharmacology and Toxicology**, incl. Pharmacy and Clinical pharmacology, 2016-2019.

Personal skills

Enthusiastic, well-prepared, ambitious, straightforward, looking for solutions, motivating, responsible, fast and with broad overview. I enjoy working with people, presenting difficult topics and help others make the best decisions for them. I respect professional competence in any field and I have a clear-cut analytical view on problems. I can prioritise my work, and I can cut through to a decision in discussions. The complexity of a task motivates me and I investigate, plan, and cooperate for optimal outcome.

Languages

Danish – Native speaker
English – Fluent, in writing as well as verbally
German – (worked in Switzerland) Good verbal and reading skills, average in writing
Swedish and Norwegian – understands and reads well.
French and Dutch – understands and reads some.