Anja Holm
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31 March 1965

Married to Hans Hoogland
Children; 23, 20, 12 years

Education

- 2014 – 2018: **Diploma education in Management**, bachelor level 3-years part time, University College Sjælland
  Modules: Personal leadership 1+2, Management and employees 1+2, Management and organisation 1+2, Economical management, Management, communication and organisation, Management and coaching. Final project: Management across distances and cultures.

- 2011 – 2011: **Veterinary Regulatory Affairs**, Medicademy exam Module 14, Copenhagen

- 2009 – 2010: Business Practitioner in **NLP Communication and negotiation**, Metropol, Copenhagen

- 1987 – 1994: Veterinary surgeon (**Doctor of Veterinary Medicine**, DVM), KVL, Copenhagen University, Veterinary faculty.
  - Post-graduate education in diseases of horses, birds, gastroenterology, endocrinology, nephrology dog and cat, behavioural therapy, surgery and laboratory technique.

- 1981 – 1984: Baccalaureate - mathematics-biology, Støvring gymnasium, A-level certificate: 10,5

Professional experience

Aug 2016 - now

Consultant in authorisation of veterinary medicines, Central VetPharma Consultancy – Founder, CEO, consultant www.CentralVetPharma.com

- Independent consultant providing advice and assistance for the Animal Health Industry in relation to authorisation of veterinary medicinal products and other legal, regulatory, or scientific topics.
  Broad overview of the **EU regulation of Veterinary Medicines.**
  Unique knowledge about the Committee for Medicinal Products for Veterinary use (**CVMP**) and the **European Medicines Agency (EMA)**.
  Long experience with centralised procedures, **referrals**, **scientific advice**, **Oral Hearings** in front of CVMP, Maximum Residue Limits (**MRLs**), **Out-of-Scope** applications, legislation.
  Scientific and regulatory knowledge for **Innovative products**, Minor-Use-Minor-Species (**MUMS**), expert reports, Periodic Safety Update Reports (PSURs), pharmacovigilance, **Answers to List-of-Questions**, **clinical trial protocols**.
  Experience in **due diligence** for veterinary products, input to **development plans** and **dossier content**.
  Conference reports, meeting preparation and conduct.
  Good communication skills and experienced trainer / presenter.

Dedicated **courses** and **workshops** on location, in cooperation with Cyton Biosciences.
Participation in **Investment Forum** events, chair of **TOPRA**'s veterinary symposium working group 2018, 2019, 2020.

CEO - Chief Executive Officer - Panion Animal Health, Sweden (part-time)

Oct 2016 - now

- Panion Animal Health develops a **gene therapy** treatment of drug refractory epilepsy in dogs. Panion was registered on the Swedish stock market, Spotlight **stock market** Stockholm, from July 2017 to October 2019. As CEO, the preparation for stock market entrance, IPO, and **investor contacts** were fundamental tasks.
  Panion was acquired by CombiGene AB in autumn 2019.

Tasks and responsibilities:

Daily business operations, **budgets**, **business plan**, **development plans**, scientific and regulatory input to board and consultants, quarterly and annual public reports, **annual general meeting for shareholders**, controlling consultants in EU and USA, handling **FDA and EMA contacts and pre-submission meetings**, planning and commissioning scientific studies and clinical trials, **due-diligence** work on in-licensing projects, planning and conduct of **board meetings**, service of board chair and members, trademark protection, press releases, and lots more.

Chair of the Committee for medicinal products for veterinary use (CVMP)

2010 - 2016
European Medicines Agency (EMA)
London

Tasks and responsibilities:

- **Chair of the Committee for medicinal products for veterinary use (CVMP) in the European Medicines Agency (EMA, London) 2010-2016.**
  Responsible for planning and leading the monthly 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 since **2010-2016**. **Negotiates and coordinates 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 SC 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 occurs around the globe and cultural respect and understanding is essential.

- **Scientific Coordination Board, EMA,** member **2010-2016**.
  Contribute to EMA's **policy and prioritisations** and develop EMA's scientific projects. Representing CVMP, I participate together with the other committee chairs and EMA's top management in meetings where we handle cross-committee topics and strategic developments.

- **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 – 2016
Danish Medicines Agency

Chief advisor, veterinarian, Danish representative in the EU
Head of Unit for Clinical Trials with human and vet medicinal products.
Authorisation and surveillance of medicines.

Tasks and responsibilities:

- **Head of section for Clinical Trials** 1/3 – 31/7 2016. Comprises personnel management, recruitment, coordination of the doctors, pharmacists, biologists, and office clerks, development of priorities for the section, planning of daily work, adherence to time tables, patient safety assessments, 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 elected as Vice-chair. Authorised 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 vaccines, including genetically modified organisms (GMO)**

  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 Levels 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-now
  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 so the legal text becomes 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 **Research project at the Danish Virus Institute, Lindholm**

Denmark's Veterinary Institute, Dept. of Virology

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.

Other assignments

Advisory board member, Sorø pain clinic and acupuncture by Anja Funder**,** June 2019 – now.

Reviewer for Science Magazine for manuscript: "One health approach to the use of veterinary pharmaceuticals: Diclofenac in vultures as a wake-up call ", Oct. **2014**

TOPRA editorial board member, "The Regulatory Rapporteur", 2016 – now.

Chair of the TOPRA annual symposium veterinary working group, 2018, 2019, 2020.

Fellow of TOPRA, FTOPRA.

Member of the **Association of Veterinary Consultants**, AVC, 2016 – now.

External appointed exam censor at Copenhagen University, **Veterinary clinical Pharmacology and Toxicology**, incl. Pharmacy, 2016-2023

Selected publications - complete list can be provided.

- "**Diagnostics** in the veterinary field: The role in health surveillance and disease identification". Anja Holm, Richard Hill, Attila Farsang, Carman Jungbäck. Biologicals, 2019 Sep;61:80-84. doi: 10.1016/j.biologicals.2019.07.002. Epub **2019** Aug 13.
- ***"Stem cell** breakthrough in Europe".* Anja Holm. International Animal Health Journal, vol. 6, issue 2. July **2019**.
- *"The **evolving regulation** of veterinary medicines in Europe: Progress or bureaucracy?"* Anja Holm. Animal Pharm, Informa, Jan **2019**.
- ***"MUMS Medicinal products**; Availability and Market Share Expansion."* Anja Holm. International Animal Health Journal, vol. 5, Issue 4, Nov **2018**.
- *"At the **Frontiers of Animal Health**: A European Perspective"*. Anja Holm and Pascale Canning. International Animal Health Journal, vol. 4, Issue 4, Dec **2017**.
- "*Use of **colistin**-containing products within the European Union and European Economic Area (EU/EEA): development of resistance in animals and possible impact on human and animal health"*. International Journal of Antimicrobial Agents (**2015**). B. Catry, M. Cavaleri, K. Babtiste, K. Grave, K. Grein, **A. Holm**, H. Jukes, E. Liebana, A L Navas, D. Mackay, A. Magiorakos, M A M Romo, G Moulin, C M Munoz, MCMF Pomba, M Powell, S Pyorälä, M Rantala, M Ruzauskas, P Sanders, C Teale, EJ Threlfall, K Törneke, Ev Duijkeren, JT Edo.
- *"Authorisation of fish vaccines".* Textbook "**Fish vaccination**" (**2013**), kap. 11. Anja Holm, Byron Rippke, Ken Noda.
- *"**DNA-vaccines** for food-producing animals, technology and safety aspects"*, a public risk assessment with focus on animal, environmental and consumer safety. **2004**. Anja Holm. Danish Veterinary Institute.
- *"Ny lovgivning for veterinærmedicin".* Dansk Veterinær Tidsskrift, DVT **2007**, 1. Jan., 90,1. Anja Holm
- *"Sommerfuglelarver giver mundhulenekroser".* Dansk Veterinær Tidsskrift. DVT **2008**,1. May, 91, 9. Anja Holm & Jytte Lyngvig
- *"Bivirkningsregistrering 2002".* Dansk Veterinær Tidsskrift, DVT **2003**, 1. Sept., 86,17. Anja Holm & Lotte Winther

Selected courses/conferences – organiser, presenter or education:

- **Complete list including 50+ presentations (title, date and location) can be provided**

<u>Day courses for Industry conducted in collaboration with Cyton Biosciences (repeated at request)</u>
"Centralised Procedure", training course in cooperation with Cyton Biosciences, 20-21 Feb 2017
"Referrals" training course in cooperation with Cyton Biosciences, 15 March 2017
"Minor Use Minor species", training course in cooperation with Cyton Biosciences, 18 Nov 2017
"Novel therapies", training course in cooperation with Cyton Biosciences, 19 Feb 2018

<u>Medicines; regulatory science, legislation, authorisation, benefit-risk assessment:</u>
V-ICH 5 conference, "3R's principles", "Implementation of VICH guidelines", and "Assessment and authorization of antimicrobials in EU", Tokyo, Japan, Oct. 2015.
DIA-EMA-IFAH conf. on global medicines availability – Food security and sustainability, Washington DC, 2013.
Benefit-Risk Evaluation Workshop, CVMP, London. 12-13. Nov. 2009
Regulatory Science conference, EMA, London. 15. Dec. 2010.
EU Commission - Veterinary legislation, Paris, France. 14. March 2011.
OIE congress, Focal points for Veterinary Medicines, South Africa. 23-25. Nov. 2010.

<u>Vaccines:</u>

Modern vaccine adjuvants & delivery systems, MVADS congress, Dublin, Ireland. 4-6. June 2003.
European Association for Fish Pathologists, DNA-vaccines workshop, Copenhagen, 15. Sept, 2005.
Genetic vaccines congress, Oslo, Norway. 24-25. Nov. 2008.
Joint EMA/HMA workshop on requirements for the authorisation of vaccines within the EU, 25. May 2015.

Antibiotics:
EC-workshop: The impact on public health and animal health of the use of antibiotics in animals – analysis of the EMA scientific advice – 26 November 2015 (Session chair and rapporteur)
EAVPT congress on antibiotics, Prague, Czech R. 25-27 Aug. 2008
One Health conference, Nordic Council, Copenhagen. 15. May 2011
Combating antimicrobial resistance – time for joint action, Danish EU presidency Conference, in organising team and writer on Critically Important Antimicrobials. 14-15. March 2012.

Adverse events, pharmacovigilance:
Periodic Safety Update Report, assessor training, EMA, London. 26-27. Nov 2008.
Medicademy Veterinary pharmacovigilance module 8, Copenhagen, 28. November 2012.
Pharmacovigilance systems and processes, Global Outreach, New Zealand, Nov. 2013

Risk assessment and statistics
Risk Assessments - ethical, social and environmental aspects, IDA, Copenhagen, 2. Oct. 2000.
Statistical models in clinical trials, Danish Medicines Agency, 20-22. Jan ´99.
Quantitative Risk Modelling, David Vose consulting, Copenhagen 29. April -3. May, 2002.

Communication and media training:
Meeting facilitation and communication, Facilitators, Copenhagen, 2009
Media training, contact with the press, journalist Jette Sachs, 13. Nov. 2000.
Media training, Danish Medicines Agency, journalist Christian Howard-Jessen and M. Thorsen, 25-26. Jan. 2010

Organisation, public administration and Union representative:
Public administration, Danish school of public administration. 25. -26. Sept. 2000.
Union representative in negotiations. 3.-4. April 2000.
Liaison committee work, course. 6. –7. April 2000.
Handling of stress in your organisation, KVL, Copenhagen. 31. Jan. 2006
Management education in Legal affairs, Personnel and Salary, the Danish Central Administration, 2016.

Language

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.

Winner of the TOPRA Award for **Communication** in 2016 (TOPRA = The Organisation for Professionals in Regulatory Affairs, London).

Leisure time

I am active in the parent-school cooperation for my three children. I do trail riding on my own horse for 20+ years in the beautiful forest, close to where we live. I love travelling and experiencing new cultures and

nature. I often spend holidays and weekends with my family and friends, in the garden or the summer house on the west coast, walking, riding, or skiing, or with a good book.