



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

**Public Declaration of Interests and Confidentiality Undertaking of
European Medicines Agency (EMA),
Scientific Committee members and experts**

Public declaration of interests

I, **Nanna Aaby Kruse**

Organisation/Company: Danish Medicines Agency

Country: Denmark

do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical industry are those listed below:

2.1 Employment

No interest declared

2.2 Consultancy

No interest declared

2.3 Strategic advisory role

No interest declared

2.4 Financial interests

No interest declared

2.5 Principal investigator

No interest declared

2.6 Investigator

No Interest Declared

2.7 Grant / Funding to organisation /institution

No interest declared

2.8 Close family member interest

Company	Type of Interest Declared
NDA Regulatory Service	As of 1/3-2013 my husband works, at NDA Regulatory Service, a regulatory affairs consultancy. Current position: Director, NDA Regulatory Advisory Board

2.9 Any other interests or facts

In May 2016, I gave a talk (ICH Q12 Established Conditions ? concepts and updates from Expert Working Group) at the Paris CASSS meeting.*

In April 2017, I gave a talk (Regulation for biosimilars) to a delegation from the Bangladesh Medicines Agency at the Ministry of Foreign Affairs of Denmark

In September 2017, I gave a talk (An insight to the latest regulatory activities) at BioTalk 2017 Conference, Berlin*

In September 2017, I gave a talk (ICHQ12: status of the lifecycle management guideline) at PDA Monoclonal Antibody Workshop in Berlin*

*Travel and accommodation for the meetings in Paris and Berlin were paid by the organizers. I have NOT received any fees, grant or funding for any of the talks given.

CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

"EMA Activities" encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the European Medicines Agency's Management Board, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on assessments; work as an expert on guidance development.

"Confidential Information" means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EMA Activities.

"Confidential Documents" mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

I understand that I may be invited to participate either directly or indirectly in certain EMA activities and hereby undertake:

- To treat all Confidential Information and Confidential Documents under conditions of strict confidentiality.
- Not to disclose (or authorise any other person to disclose) in any way to any third party any Confidential Information or Confidential Document.
- Not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EMA activities.
- To dispose of Confidential Documents as confidential material as soon as I have no further use for them.

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm the information declared on this form is accurate to the best of my knowledge and I acknowledge that my

information will be stored electronically and published on the EMA website.

Full Name:	Nanna Aaby Kruse
Date:	2018-09-28

For Definitions of activities etc, refer to Policy on Handling of Conflicts of Interest / Electronic DOI template