



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, Nevenka Trsinar Brodt

Organisation/Company: Agency for medicinal products and medical devices of the Republic of Slovenia

Country: Slovenia

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

Period	Company	Products	Therapeutic Indication
12/2006-08/2007	Billev Pharma aps, Denmark	Advising companies (Pfizer Animal Health, Merck Animal Health, Actavis and Gedeon Richter) on the regulatory aspects and requirements for quality documentations	
12/2006-08/2007	Billev Pharma aps, Denmark	Noriram tablets (Gedeon Richter)	Arterial hypertension

2.3 Strategic advisory role

No interest declared

2.4 Financial interests

No interest declared

2.5 Principal investigator

2

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

No interest declared

2.9 Any other interests or facts

I do not own a patent relating to a medicinal product neither participate in the above mentioned activities.

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:

Nevenka Trsinar Brodt

Date:	2018-10-30
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For Definitions of activities etc, refer to Policy on Handling of Conflicts of Interest / Electronic DOI template