



Public Declaration of Interests and Confidentiality Undertaking of European Medicines Agency (EMA)

SCIENTIFIC COMMITTEE MEMBERS AND EXPERTS

I, **Jens Bate**

Organisation/Company: Federal Institute For Drugs And Medical Devices

Country: Germany

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:

1.1 Employment

No interest declared

1.2 Consultancy

No interest declared

1.3 Strategic advisory role

No interest declared

1.4 Financial interests

No interest declared

1.5 Principal investigator

No interest declared

1.6 Investigator

No interest declared

1.7 Grant / Funding to organisation /institution

No interest declared

1.8 Close family member interest

No interest declared

1.9 Repurposing of a medicinal product

No interest declared

1.10 Any other interests or facts

I work for the Federal Institute for Drugs and Medical Devices (BfArM) in Germany (part time, 80 %). Wide range of regulatory work there, in the field of clinical trials with medicinal products, as my employer is one of two German regulatory agencies (NCA: "National Competent Authority").

The institution, with me contributing to this, also provides so-called "Scientific Advice", "Protocol Assistance", "Kick-off Meeting" and the like to industry, investigators, research societies, clinical/contract research organisations (CROs). The applicant usually has to pay a fee to the agency for this. Answering to patients and trial sponsors requests.

I now and then contribute to my employer's research projects, e.g. regarding adverse drug reactions, to lectures to master students and to physicians in training for specialisation in clinical pharmacology; formerly: Revisions of pharmaceutical textbooks.

Results of my secondary employments (fee for service) in skin cancer and veins' diseases screenings in occupational medicine contribute to academic healthcare research. Vaccination services physician (SARS_CoV_2, influenza). Blood Donation services physician (part time, 20%).

Member of: Cologne Association of Dermatologists e. V. (VKH), European Academy of Dermatology and Venereology (EADV)

1.11 Committee for Advanced Therapies (CAT) member or alternate

Not a CAT member or alternate

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

No interest declared

2.9 Any other interests or facts

With my current five current employers (see below) several hundred people work. It may well be possible that some fulfil criteria of the third bullet point "work in an organisation/institution where your colleagues provide consultancy advice to medical device companies, but you are not directly involved in the provision of such advice. Examples include employees of Official Medicines Control Laboratories, staff members of academic departments, etc."

I am member in professional organisations (see below). It may well be possible that some fulfil criteria of the third bullet point "Participation in European societies/research foundations/strategy boards/treatment groups/focus groups, which may be funded in full or in part from unrestricted grants from medical device companies."

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 as long as the information or document has not been made public/is not in the public domain.
- Not to disclose (or authorise any other person to disclose) in any way to any third party ¹ 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.
- When expressing views to indicate clearly that the views are my own if acting in my own capacity or those of the EMA, Management Board, Committee, Working Party, Expert Group or other group if acting on behalf of that group.
- Not to disclose any commercially confidential information.

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 and complete to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

1. Third party does not include employees of the National Competent Authorities who either have employment contracts that provide confidentiality obligations or are encompassed by confidentiality obligations under national legislation on professional secrecy.

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| Full Name: | Jens Bate |
| Date: | 2023-03-30 |

For definitions of activities etc, refer to the policy on handling of competing interests.