



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

SCIENTIFIC COMMITTEE MEMBERS AND EXPERTS

I, **Barbara Bonamassa**

Organisation/Company: Italian Medicines Agency

Country: Italy

Declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical companies and in medical device companies are those listed below:

Pharmaceutical company interests

1.1 Employment

No interest declared

1.2 Consultancy

| Time Period | Start Date | End Date | Name of pharmaceutical company | Type | Product name | Therapeutic indication | General role / Area of activity |
|-------------|------------|------------|--------------------------------|----------------------------|--|------------------------|---------------------------------|
| Past | 01-01-2021 | 01-01-2021 | Oloker Therapeutics S.r.l. | Individual product related | CPCplus (Cardiac Progenitor Cells) (01/0 | Refractory angina | |

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 hereby declare to be/have been:

_ quality assessor (consultant) at Oloker Therapeutics S.r.l., advising the quality aspect development of CPCplus, i.e., a somatic cell therapy medicinal product under development for the treatment of refractory angina (from 01/01/2021 to 15/01/2021),

_ quality assessor (consultant) for Biotherapeutic Products (BTPs) at the Prequalification Unit of the World Health Organization (WHO) _ Medicines Assessment Team (PQT/MED) (from 26/10/2020 to 31/12/2020 & 04/05/2021 _ present),

_ member of the Editorial Advisory Board for the journal "Cell & Gene Therapy Insights",

_ member of the CASSS Cell & Gene Therapy Meeting Committee,

_ member of The European Society of Gene and Cell Therapy (ESGCT) (Membership number: 136149),

_ member of The European Hematology Association (EHA) (Membership number: 042953).

I do not have or had direct or indirect interests in medical device companies or notified bodies.

1.11 Committee for Advanced Therapies (CAT) member or alternate

1.11.1 Employment

No interest declared

1.11.2 Consultancy

No interest declared

1.11.3 Strategic advisory role

No interest declared

1.11.4 Financial interest

No interest declared

1.11.5 Clinical investigator

No interest declared

1.11.6 Grant / Funding to organisation/institution

No interest declared

1.11.7 Close family member interest

No interest declared

1.11.8 Any other interests or facts

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I do not have or had direct or indirect interests in medical device companies or notified bodies.

Medical device company interests

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

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_ quality assessor (consultant) at Oloker Therapeutics S.r.l., advising the quality aspect development of CPCplus, i.e., a somatic cell therapy medicinal product under development for the treatment of refractory angina (from 01/01/2021 to 15/01/2021),
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_ member of The European Hematology Association (EHA) (Membership number: 042953).
I do not have or had direct or indirect interests in medical device companies or notified bodies.

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.

Full Name: Barbara Bonamassa

Date: 2024-03-25

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