



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, **Fabiola Micheletti**

Organisation/Company: Istituto Superiore di Sanità

Country: Italy

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

Classified as public by the European Medicines Agency

2

## 2.7 Grant / Funding to organisation /institution

No interest declared

## 2.8 Close family member interest

No interest declared

## 2.9 Repurposing of a medicinal product

No interest declared

## 2.10 Any other interests or facts

I work at the National Centre for the Control and Evaluation of Medicines (CNCF)- Istituto Superiore di Sanità, (Rome, Italy). CNCF is part of the OMCL/ISS in Italy. People working within CNCF are covered by DoI at the Quality Assurance Level within the frame of ISO 17025 and ISO 9001. Therefore colleagues within CNCF have the same level of control which is applied by EMA, independently from being EMA experts or not. I cannot exclude that other colleagues outside CNCF/OMCL, but within ISS, may comply with dot n. 3 as described above. However, no interaction takes place between CNCF personnel and other colleagues outside CNCF but belonging to ISS on EMA topics as well as in terms of consultancy advice to pharmaceutical companies.

## 2.11 Committee for Advanced Therapies (CAT) member or alternate

Not a CAT member or alternate

## 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 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 clearly indicate that the views are my own if acting in my own capacity or those of

Classified as public by the European Medicines Agency

the EMA, Committee, Working Party, Expert Group or other group if acting on behalf 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 to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

Full Name:	Fabiola Micheletti
Date:	2021-11-17

*For Definitions of activities etc, refer to Policy on Handling of competing interests / Electronic DOI template*