

Public declaration of interests and confidentiality undertaking of European Medicines Agency (EMA)

Scientific committee members and experts

I, Luca Massacesi

Organisation/Company: N/A

Country: Italy

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

Pharmaceutical company interests

1.1 Employment

No interest declared

1.2 Consultancy or strategic advisory role

Time period	Start date	End date	Name of pharmaceutical company	Type	Active substance name	Therapeutic indication	Role/area of activity
Past	12-05-2025	12-05-2025	Amgen	Product-related (one or more products)	anti CD20 Mabs	NMOSD, Myasthenia Gravis	member of an advisory board
Past	10-06-2025	10-06-2025	Merck-Serono	Product-related (one or more products)	cladribine	multiple sclerosis	
Past	05-06-2025	05-06-2025	Alexion	Product-related (one or more products)	Anti C' Mabs	NMOSD and Myasthenia Gravis	
Past	13-06-2024	13-06-2024	Novartis	Product-related (one or more products)	ofatumumab	multiple sclerosis	
Past	30-06-2023	30-06-2023	Roche	General matters (i.e. non-product specific)			Chairman and speaker in a one e day meeting on multiple sclerosis therapy
Past	31-03-2023	31-03-2023	Novartis	General matters (i.e. non-product specific)			Speaker and chairman in a one day scientific meeting on multiple sclerosis therapy
Past	30-06-2023	30-06-2023	Janssen	General matters (i.e. non-product specific)			Chairman and speaker in a one e day meeting on multiple sclerosis therapy
Past	05-10-2023	06-10-2023	Biogen	Product-related (one or more products)	Natalizumab	Multiple Sclerosis	

Past	24-11-2023	25-11-2023	Viartis	General matters (i.e. non-product specific)			Multiple Sclerosis
Past	01-05-2023	30-07-2023	Novartis	General matters (i.e. non-product specific)			Scientific committee member chairman and Speaker in a series of 3 one day scientific meetings on multiple sclerosis pathogenesis and clinic
Past	09-03-2023	09-03-2023	Alexion	Product-related (one or more products)	Eculizumab	NMOSD	
Past	01-02-2023	28-02-2023	Janssen	Product-related (one or more products)	Ponesimod	Multiple Sclerosis	
Past	19-07-2024	19-07-2024	Alexion	General matters (i.e. non-product specific)			NMOSD
Past	07-06-2024	07-06-2024	Roche	General matters (i.e. non-product specific)			Multiple Sclerosis
Past	31-05-2023	31-05-2023	Novartis	General matters (i.e. non-product specific)			Speaker and chairman in a one day scientific meeting on multiple sclerosis
Past	30-04-2023	30-04-2023	Alexion	General matters (i.e. non-product specific)			One day advisory board on eculizumab in optic neuromyelitis and in myasthenia gravis
Past	29-06-2023	30-06-2023	Merck-Serono	General matters (i.e. non-product specific)			Chairman and speaker in a two day meeting on multiple sclerosis therapy
Past	30-03-2023	31-03-2023	Alexion	General matters (i.e. non-product specific)			Speaker in a two day meeting on optic neuromyelitis and in myasthenia gravis
Past	01-01-2023	01-01-2023	Novartis	General matters (i.e. non-product specific)			Neuroimmunology course/ general

1.3 Financial interests

No interest declared

1.4 (Principal) investigator

Time period	Start date	End date	Name of pharmaceutical company	Active substance name	Therapeutic indication
Past	01-04-2024	30-04-2025	Cellerys	peptide coupled autologous red blood cel	multiple sclerosis
Past	01-06-2021	29-07-2024	Sanofi	tolebrutinib	multiple sclerosis
Current	19-01-2023		Merck-Serono	Cladribine	multiple sclerosis
Past	01-02-2023	01-06-2023	Biogen	natalizumab	multiple sclerosis

1.5 Grant/funding to organisation/institution

No interest declared

1.6 Close family member interest

No interest declared

1.7 Committee for Advanced Therapies (CAT) member or alternate

Not a CAT member or alternate

Medical device company interests

2.1 Employment

No interest declared

2.2 Consultancy or strategic advisory role

No interest declared

2.3 Financial interests

No interest declared

2.4 (Principal) investigator

No interest declared

2.5 Grant/funding to organisation/institution

No interest declared

2.6 Close family member interest

No interest declared

Research organisation interests

3.1 Affiliation to a research organisation

Name of research organisation	Job title or role within the research organisation
Careggi University Hospital	Retired Professor of Neurology and retired Director Department Neurology 2

3.2 Involvement in a unit that manufactures medicinal products or medical devices

No interest declared

3.3 Involvement in a unit that acts as a marketing authorisation applicant or holder for a medicinal product

No interest declared

3.4 Involvement in the conduct of research and development subject to an agreement with a company

No interest declared

3.5 Regulatory engagement on academic research

Time period	Start date	End date	Name of research organisation	Active substance or medical device name	Therapeutic indication or intended purpose
Past	01-01-2023	30-06-2023	Department of Neurosciences, University of Florence	Tysabri, s.c. formulation	multiple sclerosis

Any other information

In the last three years I received educational grants for participation in scientific meetings/conferences from Biogen, Serono,

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 (EMA)'s Management Board, scientific committees, working parties and other groups (e.g., scientific advisory groups, ad hoc expert groups) as well as other bodies (i.e. Emergency Task Force, Medicines Shortages Steering Group and Medical Devices Shortages Steering Group); work as an expert on assessments; work as an expert on guidance development.

"Document" means any content whatever its medium (written on paper or stored in electronic form or as a sound, visual or audiovisual recording) held by the European Medicines Agency.

"Information" means any aggregation of data, which has a value and a meaning for the European Medicines Agency, and that is received, processed or published, for example, any news, written or oral communication, data in a file or the code in a program.

"Confidential Information" means all information of which I acquire knowledge, either directly or indirectly, as a result of my participation in EMA Activities, and that is not available to the public and whose unauthorised disclosure could seriously harm interests of the European Medicines Agency and/or of the natural or legal person who provided that information.

"Confidential Document" means any document that contains Confidential Information, and to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Any records or notes made by me relating to Confidential Information shall be treated as a Confidential Document. A Confidential Document might not necessarily contain a confidential marking.

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

- I am aware of and commit to observe the obligation not to disclose information of the kind covered by the obligation of professional secrecy, even after my duties have ceased, pursuant to Article 76 of Regulation (EC) No 726/2004, and similar provisions of professional secrecy laid down in relevant sectoral legislation.
- I must treat all Confidential Information and Confidential Documents that I acquire in the context of EMA Activities in which I participate, under conditions of strict confidentiality as long as the information or document has not been made public/is not in the public domain.
- I shall not disclose, or authorise any other person to disclose, in any way to any third party¹ any Confidential Information or Confidential Document.
- I shall not use, or authorise any other person to use, any Confidential Information or Confidential Document other than for the purposes for which it was made available to me in connection exclusively with EMA activities.
- I shall not retain the information for longer than needed for the completion of the EMA Activities, and I must dispose it securely as soon as I have no further use for it, e.g., by returning it to the EMA, or by destroying it using appropriate means that ensure that neither the Confidential Information contained in documents or the Confidential Document itself could be retrieved and/or reused by anyone.
- When expressing views, I shall indicate clearly whether the views are my own when acting in my own capacity or those of the EMA, Management Board, scientific committee, working party and other groups (e.g., scientific advisory groups, ad hoc expert groups) as well as other bodies (i.e. Emergency Task Force, Medicines Shortages Steering Group and Medical Devices Shortages Steering Group) when acting on behalf of that group.
- I am aware that the duty of professional secrecy, even after my duties in connection with EMA activities have

ceased, shall not apply to any document or information that I can reasonably prove was known to me before the start of my participation in EMA activities or which becomes public knowledge other than as a result of a breach of any of the above obligations on my part.

- I am aware that, should I breach the obligation of professional secrecy, the EMA may adopt appropriate measures, e.g., initiate a breach of trust procedure as per the applicable rules, and may inform the European Anti-Fraud Office (OLAF) in case of a suspected fraud.
- I shall process any personal data in compliance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725.

I confirm that the information declared on this public declaration of interests 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:	Luca Massacesi
Date:	2025-11-25

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