

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

Scientific committee members and experts

I, **Karel Allegaert**

Organisation/Company: European Academy Of Paediatrics

Country: Belgium

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	25-04-2023	24-04-2024	Aspire Pharm Ltd	Product-related (one or more products)	vitamin A formulation, parenteral	Bronchopulmonary dysplasia, prevention	
Past	01-11-2021	31-12-2022	Piaon	Product-related (one or more products)	Giapreza (angiotensin II)	refractory hypotension in children, PIP related advice	
Past	01-10-2018	31-08-2022	Biotest	Product-related (one or more products)	immunoglobulines	prevention of neonatal infections	
Past	01-10-2021	31-12-2023	Johnson and Johnson Consumer Inc	Product-related (one or more products)	paracetamol	pregnancy related safety	
Past	01-06-2021	01-06-2024	Mythra	Product-related (one or more products)	Estetrol (E4)	perinatal asphyxia, drug development advice	
Past	30-11-2022	01-03-2023	Ferrer	Product-related (one or more products)	Treprostinil	neonatal pulmonary hypertension	
Past	03-07-2023	24-07-2023	Organon	Product-related (one or more products)	Ebopripant	tocolysis, preterm	
Past	01-02-2023	28-02-2023	Almirall	General matters (i.e. non-product specific)			single online lecture on pediatric clinical pharmacology

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
Current	01-08-2019		Shionogi	Cefiderocol	DSMB member, pediatric and neonatal gram negative infections
Past	01-01-2019	01-05-2022	Johnson and Johnson	Rilematovir	DSMB member, RSV treatment in infants
Current	01-09-2021		Merck	Cladribine	pregnancy registry, case adjudication, phase 4 trial
Current	01-02-2024		Aspire	vitamin A	DSMB member, prevention bronchopulmonary dysplasia
Current	01-01-2018		01-04-2024	remimazolam	DSMB member, pediatric sedation
Current	01-08-2022		Premier Research, Realta	RLS0071 (lead dual-target peptide)	DSMB member, perinatal asphyxia
Past	01-06-2014	01-06-2022	UCB	Breviracetam/radiprodil	DSMB, neonatal seizures
Current	22-06-2023		Neurophoxia	iminobiotine	DSMB member, perinatal asphyxia
Current	08-11-2022		ELGAN Pharma	insulin (oral)	DSMB member, intestinal malabsorption in preterm
Current	01-09-2020		Shionogi	Naldemedine	DSMB member, Opioid induced obstipation in children
Past	01-05-2020	30-04-2024	Novartis	Artemether/lumefantrine	DSMB member, malaria in neonates and young infants
Current	01-11-2021		Traverse	Sparsetan	DSMB member, proteinuric glomerular diseases in children
Current	20-04-2023		Shionogi	Orolofirm	DSMB member, fungal infections in children and neonates

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
KU Leuven	full professor
Erasmus MC Rotterdam	senior researcher, department of hospital pharmacy

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

No interest declared

Any other information

No interest declared

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:	Karel Allegaert
Date:	2025-04-21

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