

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 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

Time Period	Start Date	End Date	Name of pharmaceutical company	Type	Product name	Therapeutic indication	General role / Area of activity
Past	01-10-2018	31-08-2022	Biotest	Individual product related	immunoglobuline formulations	prevention of neonatal infections, advice	
Past	01-02-2018	01-06-2020	Obseva	Individual product related	obe022	DSMB tocolysis study	null
Current	01-11-2021	22-03-2023	Travere	Individual product related	sparsentan	proteinuric glomerular diseases (pediatric)	null
Current	01-08-2022	22-03-2023	Premier Research	Individual product related	RLS_0071	perinatal asphyxia	
Past	01-02-2023	28-02-2023	Almirall	Cross product related/ general (non product related)			pediatric clinical trials
Current	01-08-2019	22-03-2023	Shionogi	Individual product related	Cefiderocol	pediatric infections (DSMB)	null
Past	01-03-2014	01-12-2015	Johnson and Johnson	Cross product related/ general (non product related)	null	null	advice on pediatric study design
Current	01-01-2018	22-03-2023	PAION	Individual product related	remimazolam	procedural sedation, PIP development, DSMB	
Past	30-11-2022	01-03-2023	Ferrer	Individual product related	treprostinil	neonatal pulmonary hypertension	
Current	01-05-2020	22-03-2023	Novartis	Individual product related	artemerther/lumefantrine	uncomplicated plasmodium	null

						falciparum malaria, DSMB	
Current	01-09-2021	22-03-2023	Merk	Individual product related	Cladribine	Pregnancy registry, advice	null
Current	25-04-2023		Aspire Pharm Ltd	Individual product related	vitamin A formulation	BPD prevention	
Past	01-02-2018	01-09-2019	heron	Individual product related	mixture local anesthetic and nsaid for	local anesthesia, postoperative pain management (advice)	null
Past	01-06-2014	01-06-2022	UCB	Cross product related/ general (non product related)	null	null	neonatal seizures (breviracetam, radiprodil), consultancy and DSMB
Past	01-07-2019	01-01-2022	GW Research Limited,	Individual product related	GWP42003_P (cannabinoid)	moderate or severe hypoxic ischemic encephalopathy, newborn (DSMB)	null
Current	01-06-2021	22-03-2023	Mythra	Individual product related	estetrol	perinatal asphyxia (PIP development advice)	null
Current	03-07-2023		Organon	Individual product related	ebopripant	tocolysis, preterm delivery prevention	
Current	01-09-2020	22-03-2023	Shionogi	Individual product related	Naldemedine	opioid induced constipation (DSMB)	null
Past	01-01-2015	01-01-2016	PAION	Individual product related	remidazolam	sedation in children, advice on the development of the PIP	null
Past	01-01-2019	01-05-2022	Johnson and Johnson	Individual product related	JNJ 53718678	RSV treatment, DSMB	null
Past	01-11-2021	31-12-2022	Paion	Individual product related	Giapreza	(refractory) hypotension (pediatrics) (PIP related advice)	
Current	01-10-2021	22-03-2023	Johnson and Johnson	Individual product related	paracetamol (OTC)	pregnancy related safety, fetal ductal closure	
Current	20-04-2023		Shionogi	Individual product related	olorofim	anti fungal	

1.3 Strategic advisory role

No interest declared

1.4 Financial interests

No interest declared

1.5 Principal investigator

Time Period	Start Date	End Date	Name of pharmaceutical company	Product Name	Therapeutic indication
Past	01-12-2014	01-09-2016	Obseva (DSMB)	OBE001	prevention preterm birth, tocolysis
Past	01-01-2014	01-10-2015	Pfizer	sildenafil	pulmonary hypertension of the newborn

Past	01-09-2014	01-12-2015	Basilea	ceftobiprole	bacterial infection (neonates)
Past	01-12-2014	01-09-2016	Obseva (DSMB)	OBE001	prevention preterm birth, tocolysis

1.6 Investigator

Time Period	Start Date	End Date	Name of pharmaceutical company	Product Name	Therapeutic indication
Past	01-05-2010	01-05-2011	Johnson and Johnson	rabeprazole	gastro_oesophageal reflux, neonates
Past	01-01-2007	01-12-2007	Wyeth	pantoprazole	reflux
Past	01-12-2011	01-02-2012	Bristol Myers Squibb	apixaban	anticoagulation
Past	01-09-2013	01-01-2014	Pfizer	sildenafil (iv) (switched to PI, cfr sup)	primary pulmonary hypertension of the newborn
Past	01-09-2009	01-06-2012	Johnson and Johnson/Janssen Cilag	doripenem	phase 1 study in neonates

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

as registered 16 October 2022

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

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'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:	Karel Allegaert
Date:	2023-07-03

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