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

MANAGEMENT BOARD

I, Virginie Hivert

Organisation/Company: N/A

Country: France

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

2.7 Grant / Funding to organisation/institution

Name of pharmaceutical company	Subject Matter
Alexion Services Europe; Alnylam Switzerland GmbH; Bayer AG; Biogen (Czech Republic) s.r.o; Boehring	ERTC UNRESTRICTED MEMBERSHIP 2022 - 35 c
Aeglea Biotherapeutics; Agios Pharmaceuticals	ERTC RESTRICTED MEMBERSHIP 2022 - 34 com

Inc.; Alira Health SAS; Amgen Inc., US.; Amicus Therap	
Bristol-Myers Squibb (BMS); Chiesi; Horizon Therapeutics; Kyowa Kirin International Plc.; NOVARTIS F	EURORDIS INTERNATIONAL INITIATIVES 2022
Aeglea Biotherapeutics; Alexion - AstraZeneca Rare Disease; Alnylam Switzerland GmbH; Amicus Therape	ERTC UNRESTRICTED 2023 - 38 companies
Adelphi; Charles River Microbial Solutions Germany GmbH; Ergomed PLC; Eversana; Istituto Comprensivo	UNSOLCITED 2023 - 6 companies
Boehringer Ingelheim International GmbH; PFIZER	KEY FUNDING 2022
Alexion Services Europe; Alnylam Switzerland GmbH; Biogen (Czech Republic) s.r.o; Chiesi; CSL BEHRIN	BLACK PEARL 2022 - 19 companies
Alexion - AstraZeneca Rare Disease; Alnylam Switzerland GmbH; Amylyx Pharmaceuticals EMEA B.V. ; Bio	Black Pearl 2023 - 20 companies
Bristol Myers Squibb (BMS); Chiesi; Horizon Therapeutics; NOVARTIS FARMA S.p.A.; PTC Therapeutics; R	EURORDIS International Intiatives 2023 -
CSL BEHRING; PFIZER; Roche; Swedish Orphan Biovitrum BVBA	PROJECT DEVELOPMENT 2022
Amicus Therapeutics UK Ltd; Chiesi; Horizon Therapeutics; Illumina Cambridge Ltd.; International Fed	Ukraine fund - 12 companies
Alexion Services Europe; Biogen (Czech Republic) s.r.o; BIOMARIN; Boehringer Ingelheim International	ECRD 2022 - 19 companies
Alexion - AstraZeneca Rare Disease; Biogen (Czech Republic)	EURORDIS MEMBERSHIP MEETING 2023 - 14 co

s.r.o; Chiesi; Clinigen Ltd; CSL BEHRING	
Amicus Therapeutics UK Ltd; BIOMARIN; Bristol Myers Squibb (BMS); CSL BEHRING; JANSSEN - a J&J compa	RARE BAROMETER 2023 - 6 companies
BioAgilytix Labs, LLC; Branding Science	Unsolicited
Alnylam Switzerland GmbH; Amicus Therapeutics UK Ltd; Boehringer Ingelheim International GmbH; Brist	RARE BAROMETER 2022 - 10 companies
Bayer AG; BioCryst Pharmaceuticals, INC.; Lundbeck A/S; Novo Nordisk HQ; Takeda Pharmaceuticals Inte	ERTC RESTRICTED 2023 - 8 companies
CSL BEHRING; NOVARTIS FARMA S.p.A.; Roche; Swedish Orphan Biovitrum BVBA	PROJECT DEVELOPMENT 2023 - 4 companies

2.8 Close family member interest

No interest declared

2.9 Personal interests, other than interests in a pharmaceutical company

No interest declared

2.10 Any other interests or facts

- International Rare Diseases Research Consortium (IRDiRC): Former vice-Chair of the Therapies Scientific Committee (until Feb 2021), and recently: co-lead of the Taskforce on 'Sustainable economic models in Repurposing', representative of EURORDIS in the Consortium Assembly and contributor to several activities, taskforces and working groups.

- IMI Project Conect4Children: EURORDIS is one of the Consortium member and nominatively I am a Member of the Educational Board. (current)

- CSA H2020 'European Rare dIsease research Coordination and support Action' (ERICA): EURORDIS is one of the Consortium member (current)

- In the context of the EU Pharmaceutical Strategy, the revision of the OMP & Paediatric Medicines EU regulation, and the persistent challenges in access, EURORDIS supports multi-stakeholders exchange to analyse the situation, elaborate new solutions and foster dialogue. Accordingly, EURORDIS has joined the 'European Expert Group on Orphan Product Incentives'. I joined discussions between March and May 2022.

- In the context of EURORDIS Round Table of Pharmaceutical Companies, I joined two one-hour meetings in 2022:
one with Pierre Fabre and Esperare foundation on 5th April 2022
one with Orchard Therapeutics on 7th April 2022

- EU-funded project REMEDI4ALL (started 1st September 2022) and responding to the call HORIZON-HLTH-2021-DISEASE-04-02 Building a European innovation platform for the repurposing of medicinal products: EURORDIS is one of the Consortium member and I am the representative of EURORDIS in the General Assembly. REMEDI4ALL is conducting 4 demonstrator projects (COVID-19, Pancreatic cancer, Multiple Sulfatase Deficiency, Osteogenesis Imperfecta) and will onboard additional projects during the duration of the EU funding. EURORDIS supports the identification and engagement of patients, including Patient Champions, within these projects.

- Contribution to the Global Conference on Advancing Social Pharmaceutical Innovation organized by Utrecht University in March

2023 (https://www.socialpharmaceuticalinnovation.org/)

- TOPRA Advisory Council (former commitment, not anymore)

- Speaker at the Medicines for Europe Annual Conference held in June 2023 (https://www.medicinesforeurope.com/events2023/ANNUAL23_Programme.pdf)

- Speaker at the conference organized by the french media Pharmaceutiques in July 2023 (https://pharmaceutiques.com/evenements/universite-pharmaceutiques/26emes-universites-de-pharmaceutiques/)

- Speaker at the TRANSFORM Alliance colloque (french) in July 2023 (https://transformalliance.eu/event/colloque-lunion-europeenne-un-espace-de-recherche-et-dinnovation-pour-les-therapies-geniques-et-cellulaires/)

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2.10 Any other interests or facts

All information related to GRANT / FUNDING TO ORGANISATION/INSTITUTION is provided in section 2A item 2.7 whether the company is developing only pharmaceutical and/or medical devices

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 clearly indicate that the views are my own if acting in my own capacity or those of the EMA, 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:	Virginie Hivert
Date:	2023-07-12

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