

# Public Declaration of Interests and Confidentiality Undertaking of European Medicines Agency (EMA), Scientific Committee members and experts

# **Public declaration of interests**

I,	Alan Boobis	
Organisation/Company: Country:		Imperial College London
		United Kingdom
do pha	hereby declare on my hono armaceutical industry are the	our that, to the best of my knowledge, the only direct or indirect interests I have in the ose listed below:
2.1	Employment	
No	interest declared	
2.2	Consultancy	
	interest declared	
2.3	Strategic advisory role	
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

I consulted for and served as an expert witness in the USA for a group of attorneys, which originally included Arent Fox LLP (Par Pharmaceuticals Inc & Par Pharmaceutical Companies Inc); DuaneMorris LLP (Wockhardt); Vinson & Elkins LLP (Impax Laboratories Inc); Winston & Strawn LLP (Actavis South Atlantic LLC & Actavis Inc); Brinks Hofer Gilson & Lione (Watson Pharmaceuticals Inc, Watson Laboratories Incs, Watson Pharam Inc) in a patent dispute involving Nuedexta (dextromethorphan/quindine combination), used for dermatitis, emotional lability and a number of neurological orders in human patients. This consultancy was from July 2011 - Sept 2013. The issue related to a beneficial drug-drug interaction between the two components of the preparation.

I am currently a member of the Board of Trustees of the Health and Environment Sciences Institute Branch (HESI) of the International Life Sciences Institute (ILSI); chair of the Board of Trustees of ILSI; vice-president of the European Branch of ILSI. These organizations are not for profit. They are funded in part by unrestricted funds from pharmaceutical companies. I was a member of the Scientific Advisory Board of the EU-Framework funded projects HEROIC and PEDICT-IV until 2014. I was chair the Scientific Advisory Board Innovative Medicines Initiative (IMI) project Mechanism-Based Integrated Systems for the Prediction of Drug-Induced Liver Injury until 2016. These projects included some pharmaceutical companies as partners. I received no remuneration. I am a member of the Scientific Advisory Board (non-remunerated) of the Swiss Centre for Applied Human Toxicology and of the Long Range Research Strategy (LRSS) Scientific Advisory Board, Cosmetics Europe (2017-date) (non-remunerated).

I was academic supervisor for a PhD student supported by an MRC-CASE studentship with GSK, from Oct 2011 to Oct 2015. The project was on the mitochondrial toxicity of drugs.

I was a member of the Phase I Protocol Review Board of the NIHR/Wellcome Trust Imperial Clinical Research Facility, where I provide input on toxicological issues, until June 2017.

Members of the Department of Medicine, Imperial College London, where I am employed, provide advice to and conduct research supported by pharmaceutical companies. None of these staff is under my management.

I a member of the British Pharmacology Society, the British Toxicology Society, the Royal Society of Biology, the European Society of Toxicologists (EUROTOX) and the US Society of Toxicology.

I chair the UK Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (COT). I am regularly a member/chair of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) dealing with residues of veterinary drugs and of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR).

## 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.
- 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.

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:	Alan Raymond Boobis	03/12/17
Date:	2017-12-03	

For Definitions of activities etc, refer to Policy on Handling of Conflicts of Interest / Electronic DOI template