



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Public declaration of interests

I, Nithyanandan Nagercoil

Organisation/Company: Medicines and Healthcare Products Regulatory Agency

Country: United Kingdom

do hereby 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

Period	Company	Category	Products	Therapeutic Indication
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	Cross product responsibility	CLINICAL RESEARCH PHYSICIAN INVOLVED IN CONDUCTING PHASE I/II/III TRIALS AND CLINICAL TRIAL RELATED ACTIVITIES LIKE MONITORING AND PHARMACOVIGILANCE THAT WAS OUTSOURCED TO CHILTERN INTERNATIONAL (CONTRACT RESEARCH ORGANIZATION). THIS INVOLVED DIFFERENT ACTIVITIES FOR DIFFERENT PRODUCTS. THE MAIN PRODUCTS, I WAS INVOLVED IN AS AN INVESTIGATOR ARE LISTED UNDER SECTION 2.7. MANY OF THE STUDIES WERE PHASE I, PHARMACOKINETICS AND SAFETY STUDIES, ALTHOUGH SOME WERE PHASE II/III.	
09/2004-01/2006	TORRENT PHARMACEUTICALS LIMITED, INDIA	Lead role	GENERIC ZOPICLONE	INSOMNIA
			GENERIC ZOLPIDEM	INSOMNIA
			GENERIC SERTRALINE	DEPRESSION
			GENERIC VENLAFAXINE	DEPRESSION
			GENERIC LAMOTRIGINE	SEIZURES
			GENERIC LEVETIRACETAM	SEIZURES
			GENERIC ROPINIROLE	PARKINSON'S DISEASE
			GENERIC SIBUTRAMINE	OBESITY
			GENERIC METFORMIN	DIABETES
			GENERIC PRAVASTATIN	HYPERCHOLESTEROLAEMIA
			GENERIC PERINDOPRIL	HYPERTENSION

2

			GENERIC LOSARTAN+AMLODIPINE	HYPERTENSION
			GENERIC INDAPAMIDE	HYPERTENSION
			GENERIC NEBIVOLOL	HYPERTENSION
			GENERIC AMLODIPINE	HYPERTENSION
			GENERIC ALFUZOSIN	BENIGN PROSTATE HYPERTROPHY

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

Period	Company	Products	Therapeutic Indication
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	AQW051 (NOVARTIS)	ALZHEIMER'S DISEASE
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	INFLUENZA VACCINE (CSL AND POWDERMED)	INFLUENZA
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	TOPICAL CICLOPIROX OLAMINE (STIEFEL)	SEBORRHEIC DERMATITIS
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	ICX-SKN (INTERCYTEX)	WOUND-HEALING/WOUND-REPAIR
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	INDACATEROL (NOVARTIS)	COPD
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	AZD5672 (ASTRAZENECA)	COPD
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	AZD9668 (ASTRAZENECA)	ASTHMA AND COPD
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	CAT-354 (MEDIMMUNE)	ASTHMA
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	PF-03491390 (PFIZER)	HEPATITIS-C
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	AZD5672 (ASTRAZENECA)	RHEUMATOID ARTHRITIS

02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	CHRONOCORT (PHOQUS)	CONGENITAL ADRENAL HYPERPLASIA
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	RO4597014 (ROCHE)	TYPE II DIABETES
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	MEFENAMIC ACID (PLETHORA)	PRIMARY DYSMENORRHOEA
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	VARENICLINE (PFIZER)	SMOKING CESSATION
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	BISACODYL (BOEHRINGER INGELHEIM)	CONSTIPATION
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	COARTEM (NOVARTIS)	MALARIA
02/2006-02/2008	CHILTERN INTERNATIONAL LIMITED, UK	UK-369 (PFIZER)	ERECTILE DYSFUNCTION

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

N/A

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:	Nithyanandan Nagercoil
Date:	2018-11-12

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