European Medicines Agency

PUBLIC DECLARATION OF INTERESTS AND CONFIDENTIALITY UNDERTAKING OF EMEA MANAGEMENT BOARD AND SCIENTIFIC COMMITTEE MEMBERS AND EXPERTS

This document consists of two parts, the Public Declaration of Interests and the Confidentiality Undertaking. Both parts should be duly completed. **All pages have to be signed and dated**. If the document is completed by hand, please ensure that the information required is presented clearly.

PUBLIC DECLARATION OF INTERESTS

I, *(Title) DR* *(Name) JUNE* *(Surname) RAINE*

Nationality BRITISH

Organisation/Company MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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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:

(Please tick all boxes, and specify company and product name in case of a declared interest[1]. If necessary, use additional dated and signed sheets).

Table 1

Activity for a company in relation to a particular product / group of products	No	Currently or in the previous year	More than 1 year but less than 5 years ago	More than 5 years ago [2]
Employee	☒	☐	☐	☐
Consultant[3]	☒	☐	☐	☐
Principal investigator[4]	☒	☐	☐	☐
Member of a steering committee, member of an advisory board, or equivalent body	☒	☐	☐	☐
Investigator (not principal) for the development of a product[5]	☒	☐	☐	☐

SIGNATURE: [redacted]

DATE: 19 October 2009

1 If you tick any of the shaded boxes (declared interest), you must provide additional information regarding company and products involved on Page 2. If you declare an interest in Table 1 but do not provide the relevant information on Page 2, your form will be returned to you for completion.

2 You are invited to provide information on interests over 5 years ago. This information will not be used in the evaluation of declared interests but will be useful in the context of an increased transparency as regards previous interests.

3 A **consultant** is defined as an expert who charges a fee (personal, institutional or both) for providing advice or services in a particular field

4 A **Principal Investigator,** for the purposes of this document, is considered to be the (co-ordinating) investigator responsible for the co-ordination of investigators at different sites participating in a multicentre trial.

5 **An Investigator, for the purposes of this document, is considered to be an investigator involved in a clinical trial at a specific trial site. An investigator may be either the responsible leader of the clinical trial team (responsible for the conduct of the clinical trial at that site, including designation and supervision of the team) or a member of the team, who performs critical trial related procedures and makes important trial related decisions.**

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	Period of activity	Company	Products Please list any products for which you had primary responsibility	Therapeutic indication
Employee				

	Period of activity	Company	Products Please list any products for which you acted as a consultant with respect to their development.	Therapeutic indication
Consultant				

	Period of activity	Company	Area of activity / product	Therapeutic indication
Member of a steering committee, member of an advisory board, or equivalent body				

	Period of activity	Company	Products	Therapeutic indication
Principal investigator				

	Period of activity	Company	Products	Therapeutic indication
Investigator (not principal)				

SIGNATURE: [redacted]

DATE: 19 October 2009

I have a financial interest in a pharmaceutical company of:	NO	YES	Company
• **more than 50,000 Euro or equivalent** (Investment funds excluded)	☒	☐	
• **less than 50,000 Euro or equivalent** (Investment funds excluded)	☒	☐	

	NO	YES	Company and Product Name
I own a patent on a product	☒	☐	
The organisation I am employed by receives a grant or other funding from a pharmaceutical company (I receive no personal gain)[1]	☒	☐	

Further to the interests declared above, I do hereby declare on my honour that I do not have any other interests or facts that should be made known to the Agency and the public. In case of any other interests or facts, please specify:

Should there be any change to the above due to the fact that I acquire additional interests, I shall promptly notify the EMEA and complete a new Declaration of Interests detailing the changes. This declaration does not discharge me from my obligation to declare any potential conflicting interest(s) at the start of any EMEA Activity[2] in which I participate.

CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

"**EMEA Activities**" encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the EMEA's Management Board, Committees, its Working Parties, Expert Groups, or any other such meeting, work as an expert on assessments, and 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 EMEA 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 EMEA 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 EMEA 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[3] 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 EMEA 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 otherwise than as a result of a breach of any of the above undertakings.

SIGNATURE: [redacted]

DATE: 19 October 2009

[1] Excluding any fees paid by pharmaceutical industry for assessment work undertaken by National Competent Authorities.
[2] EMEA Activity encompasses any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the EMEA Management Board, Committees, its Working Parties, Expert Groups, or any other such meeting, work as an expert on assessments, and work as an expert on guidance development. Following the assessment of the declared interests, the EMEA may limit the input to EMEA activities.
[3] 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.