EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public Declaration of Interests and Confidentiality Undertaking

INSTRUCTIONS

The document consists of three parts, your **Personal Details**, the **Public Declaration of Interests** and the **Confidentiality Undertaking**. All parts must be duly completed. **The form is designed to be completed electronically and the data entered stored electronically**. You are responsible for the accuracy and completeness of the submitted information. Please be aware that once you have submitted and signed the form, the Agency will publish your e-DoI on its website.

SECTION 1: PERSONAL DETAILS

First Name:	Elmer	
Last Name:	Schabel	
Organisation / Company:	Bundesinstitut für Arzneimittel und Medizinprodukte/Federal Institute for Drugs and M	
Country:	Germany	
Contact e-mail Address:	*elmer.schabel@bfarm.de*	*Note: Your e-mail address details will not be published*

SECTION 2: PUBLIC DECLARATION OF INTERESTS

If you have interests to declare, please click 'Yes' to the relevant questions and specify the interests. All questions in this section must be answered. Your declaration will not be accepted if any fields are left empty.

You may also 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 increased transparency regarding previous interests.

I do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests in the pharmaceutical industry I have currently (at the time of completion of the form) or have had within the past 5 years are those listed below:

2.1 Employment

No ☑ Yes ☐

Employment in a pharmaceutical company (includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product).

2.2 Consultancy

No ☑ Yes ☐

Provision of advice or services (including training on a one to one basis) to a pharmaceutical company (in a particular field such as the development of a product) regardless of contractual arrangements or any form of remuneration. Pharmaceutical company includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product.

Note i: Scientific advice provided by the NCA of a Member State is not considered a consultancy activity. Conference/Seminar attendance is not considered as a consultancy but should be mentioned under section 2.4 if subject to a fee/honoraria.
Note ii: If you are or have been an employee of a consultancy company (i.e. a professional business offering expert or professional advice to pharmaceutical companies), please declare this under Section 2.1.

2.3 Strategic Advisory Role

No ☑ Yes ☐

Participation (with a right to vote on/influence the outputs) in a (Scientific) Advisory Board/Steering Committee with the role of providing advice/expressing opinions on the (future) strategy, direction or development activities of a pharmaceutical company, either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration. Pharmaceutical company includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product.

Note: Involvement in Data Safety Monitoring Committees is not included in this category. Such involvement should be recorded under section 2.6 Principal Investigator. Involvement in clinical research should be listed under section 2.6 or 2.7 as appropriate.

2.4 Current Financial Interests

No ☑ Yes ☐

Financial interests relate to:

CURRENT Holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pension schemes that are not exclusively based on the pharmaceutical sector.
Compensation, fees, honoraria, salaries **CURRENTLY** being paid directly to you by a pharmaceutical company, other than payment for expenses incurred with research work or re-imbursement of reasonable expenses incurred in relation to conference/seminar attendance as a speaker, panellist or in a similar role (i.e. accommodation and travel costs).
Please note that, in the event of nomination to the Management Board, Scientific Committee, Working Party or Scientific Advisory Group for defined mandate, no financial interests are allowable within the term of the mandate.

(**CURRENT** is interpreted at time of completion of this form).

2.5 Patent

No ☑ Yes ☐

All process and product **patents** relating to **medicinal products** and/or patents with a link to a particular medicinal product (e.g. diagnostic tests, medical devices), **currently owned** by either you or your institution, to the extent that you are aware, and for which you are a **beneficiary**.

If you own a patent relating to a medicinal product, but you are not a beneficiary, for transparency purposes this should be included under "In case of any other interests or facts, please specify".

(**CURRENT** is interpreted at time of completion of this form)

2.6 Principal Investigator

No ☑ Yes ☐

Principal Investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre pharmaceutical industry instigated/sponsored trial or the leading investigator of a monocentre pharmaceutical industry instigated/sponsored trial, or the coordinating (principal) investigator signing the clinical study report. This definition does not include a national coordinating investigator in a multinational trial. Involvement in Data Safety Monitoring Committee should be included in this section.

Note: Academic trials and publicly funded research/development initiatives involving pharmaceutical products should be included under "In case of any other interests or facts, please specify".

2.7 Investigator

No ☑ Yes ☐

Investigator involved in a pharmaceutical industry instigated/sponsored trial at a specific trial site who can be the responsible lead investigator of the trial at that specific site or a member of the clinical trial team who performs critical trial related procedures and makes important trial related decisions.

Note: Academic trials and publicly funded research/development initiatives involving pharmaceutical products should be included under "In case of any other interests or facts, please specify"

2.8 Grant / Funding to Institution

No ☑ Yes ☐

Refers to a grant or other funding (other than compensation for services requested by National Competent Authorities) from a pharmaceutical company, received (as far as the individual is aware) by an institution (e.g. NCA or the department of an academic institution. Note: Department is defined as the immediate organisational entity in which the member/expert operates) or an organisation (e.g. patient organisation), irrespective of whether or not the individual is employed or is a volunteer, and the individual receives no personal gain.

Note: Management Board members should declare current grants and grants received without the previous 5 year period. Other experts need only to declare current grants.

Please list the name of the pharmaceutical company providing the grant and the subject matter of the grant. With respect to grants received within the previous 5 years, Management Board members should declare the end date of the grant as follows: Pharmaceutical company name (month/year). Where no date is provided, the grant will be considered as a current grant.

2.9 Household Member Interest

No ☑ Yes ◯

Interests to be declared include Employment, Consultancy, Strategic Advisory Role, Current Financial interests or current Patent Ownership.

CURRENT DIRECT interests held by household members (i.e. spouse, partner or child) living at the same address as the individual.

2.10 Any Other Interests or Facts

In case of any other interests or facts, please specify:

For Management Board Members, in addition to interests related to pharmaceutical industry, consideration should also be given to any possible interest with non-pharmaceutical companies that may have interaction with the Agency in other areas such as procurement procedures (e.g. in the area of information technology, office refurbishment, other services).

For transparency purposes, please also provide information on the following activities in this section:

- If you own a patent relating to a medicinal product, but you are not a beneficiary of this patent.
- Academic trials and publicly funded research/development initiatives involving pharmaceutical products.
- Membership of an Ethics Committee
- If you work in an organisation where your colleagues provide consultancy advice or services to pharmaceutical companies, but you are not directly involved in the provision of such advice or services.
- Participation in European Societies/Research Foundations/Strategy Boards/Treatment Groups/Focus groups, which may be funded in part from unrestricted grants from pharmaceutical companies (not from one single company), with or without involvement of industry participants and which may provide general advice (on development programmes, clinical study design, strategy etc.) to several pharmaceutical companies (not one particular company) in a specific therapeutic area.

Should there be any change to the above due to the fact that I acquire additional interests, I shall promptly notify the **European Medicines Agency** 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 EMA Activity in which I participate.

SECTION 3: 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[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.***

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:	Elmer Schabel 2012-06-20	Date:	20 Jun 2012

[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.

SUBMISSION AND VALIDATION

After completion of this form, please click on the '**Submit by E-mail**' button to send your information to the **European Medicines Agency** as an e-mail attachment using your local e-mail client. Please do not edit the e-mail address in the To field.

If your submission is successful, you will receive a notification with an attached completed copy of the form showing the information you supplied, together with a web link requesting you to validate the submission. For this validation (sign-off electronically), you must use your single sign-on credentials (user name and password) as provided to you by the EMA.

Once validated, your electronic declaration of interests form will be published automatically on the EMA website.

A guidance document on how to submit and validate the electronic declaration of interests form is available on the EMA website link.

http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2011/07/WC500109481.pdf