

Public Declaration of Interests /Confidentiality Undertaking /Consent to personal data processing for those collaborating with AIFA activities

The present document consists of four parts, Personal Data, Public Declaration of Interests, Confidentiality Undertaking and Consent to personal data processing. All parts must be duly filled, signed and dated.

Should the document be hand – filled, make sure that any information is readable. Also not applicable or not pertinent fields have to be crossed off in any case.

PERSONAL DATA

I, (Qualification) (First Name) (Surname)

Country :

Company / Institution:

Business address:

e-mail address:

Aware of the contents of the Italian criminal legislation in the event of false declarations and forgery of documents according to art.76 of the Presidential Decree n. 445 of 28/12/2000, I declare, under my own responsibility that I read the last section of this document called “Definition and Instructions for Filling” and I have not other direct or indirect interests in the pharmaceutical industry in addition to those listed below .

Table 1.Public Declaration of Interests ¹

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 previous years
<i>DIRECT INTERESTS:</i>				
1.1 Employment with a company: pharmaceutical company in an executive role	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.3 Employment with a company: other activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
2. Consultancy for a company	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
3. Strategic advisory role for a company	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
4. Financial interests	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
5. Ownership of a patent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
<i>INDIRECT INTERESTS:</i>				
6. Principal investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
7. Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
8. Grant or other funding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
9. Family members interests	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
The Experts who have a collaboration with the AIFA must declare the interests of first-line members of the family of the expert (i.e. a spouse or a partner, children and parents)				

Signature:

Date:

¹ Marking any grey box above (declared interests), you should provide further information in the following pages concerning the Company and the products. Should the form be filled in the grey part concerning the existence of any interests without providing further related information in the following pages, it shall be returned for completing it.

Table 2. DETAILS OF PUBLIC DECLARATION OF INTERESTS

(Fill this part if you have filled any grey box in table n. 1, otherwise cross off the following boxes anyway)

	Period of activity	Company or Institution	Products List all products for which you are responsible	Therapeutic Indication
1. Employment with a company				
	Period of activity	Company or Institution	Products List all products for which you have acted as consultant for developing them	Therapeutic Indication:
2. Consultancy for a company				
	Period of activity	Company or Institution	Area of activity/ Product	Therapeutic Indication:
3. Strategic advisory role for a company				
	Period of activity	Company or Institution	Type of financial interests	
4. Financial interests				
	Period of activity	Company or Institution	Area of activity/ Product	Therapeutic Indication:
5. Ownership of a patent				

Signature:

Date:

Table 2. DETAILS OF PUBLIC DECLARATION OF INTERESTS

(Fill this part if you have filled any grey box in table n. 1, otherwise cross off the following boxes anyway)

	Period of activity	Company or Institution	Area of activity/ Product	Therapeutic Indication:
6. Principal investigator				
	Period of activity	Company or Institution	Area of activity/ Product	Therapeutic Indication:
7. Investigator				
	Period of activity	Company or Institution	Type of interest	
8. Grant or other funding				
	Period of activity	Company or Institution	Type of interest	
Family Interests				

Signature:

Date:

In addition to the aforementioned interests, I, the undersigned, aware of the contents of the Italian criminal legislation in the event of false declarations and forgery of documents according to art.76 of the Presidential Decree n. 445 of 28/12/2000 and aware of sanctions provided for art. 15 of Regulation on the conflicts of interests of AIFA, declare that I DO NOT HOLD any other interest or to know any fact that should be brought to attention of AIFA or of public.

Should any of such interests or facts exist, please specify below:

Should any change to what declared above occur, I will forthwith report it to AIFA, filling a new declaration of interests.

Signature:

Date:

Section reserved to AIFA

The conflicts of interest are classified into 3 categories:

- a) Direct interests: Direct interests are assigned the highest risk level **(level 3)**;
- b) Indirect interests: Indirect interests are assigned an intermediate risk level **(level 2)**;
- c) No interest declared: the lowest risk level is assigned in case of no interest **(level 1)**.

Risk level assigned by evaluator:

- Level 3
- Level 2
- Level 1

NOTES or COMMENTS

The evaluator

Name Last name (block letters) _____

Signature _____

Date _____

Confidentiality Undertaking

Considering the following definitions:

“AIFA activity”: any meeting (including preliminary and follow-up meetings, talks or any other related activity) of Board Of Directors, Technical Scientific Commission and its sub-committees, of any groups of experts or any similar meeting working as a group of experts on scientific evaluations or on the development of guidelines.

“Confidential information”: all the information, facts, data and any other matter I know, directly or indirectly, as a consequence of my activities with AIFA.

“Confidential documents”: all drafts, preliminary information, documents as well as any other information to which I should have access, directly or indirectly as a consequence of my activities with AIFA, including documents, registrations and/or notes that I should write or register.

Should I attend any meeting and/or activity with AIFA, I commit myself:

1. To treat all confidential information and documentation in a strictly confidential way.
2. Not to disclose (or authorize any person to disclose) in any way to third parties² any confidential information or documentation.
3. Not to use (or authorize any person to use) any confidential information or documentation except for what is strictly related to my activities with AIFA.
4. To delete or destroy any confidential documents when no longer needed.
5. Not to disclose, unless expressly authorized, any document or any information to my knowledge related to my activities with AIFA.

Compliance with the aforementioned obligations shall not terminate with the end of the work relationship with AIFA. Such obligations shall not apply to documents and information that the undersigned may demonstrate to have known before the signing of this form, or that should be publicly disclosed for any reason not related to the breach of confidential information by the undersigned.

I declare that the information herewith provided are, for what I know, accurate and reliable and I agree that such information be kept and published on the AIFA web site, should AIFA consider such disclosure appropriate.

Signature:

Date:

CONSENT to personal data treatment

I declare, under my own responsibility, that I have read the privacy Statement set out by par. 13, D. Lgs. N. 196/2003 (Italian Privacy Codice), available on AIFA website, section “Competitions”, AIFA Consultants and Experts’ List, on the following link:

http://www.agenziafarmaco.gov.it/sites/default/files/Mod350_03Rev.1_Informativa_privacy_consenso_trattamento_dati.pdf

and that I have found it complete.

I also declare to be aware that my name could not be inserted into AIFA Consultants’ Database and I could not participate into any AIFA activity in case I refuse to sign this declaration.

Signature:

Date:

² The Definition of “Third party” doesn’t include the employees of Competent National Authorities who have signed confidentiality agreements or are subject to confidentiality obligations as a consequence of national legislations or duty of secrecy.

DEFINITIONS AND INSTRUCTIONS FOR FILLING

“Employment with a company” is to be interpreted as any work activity – even free of charge – for a pharmaceutical Company:

1. Executive role within a pharmaceutical company (President/Vicepresident, Chief Executive Officer, Chief Scientific Officer, Executive Director/Director/Associate Director position).
2. Lead role in the development of a medicinal product (Clinical programme/project manager position, Product manager/specialist position, Programme leader/manager position, Project leader/manager position).
3. Any other activities that are not mentioned in the previous points 1 e 2.

It is assumed that the declared interest, not listed in categories 1 and 2, is considered over following a 3 year cooling-off period, on the contrary, the interests listed in categories 1 e 2, as provided in for Article 7 of the Conflict of interest’s policy of AIFA, must be always declared.

“Consultancy for a company” is to be interpreted as an activity where the concerned expert provides advice or services to a pharmaceutical company regardless of contractual arrangements or any form of remuneration. No conflict exists when an expert is appointed by AIFA (or other regulatory authority) for the release of a scientific advice.

Strategic advisory role for a company is to be interpreted as meaning that the expert is participating (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 and 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.

Note Well: The involvement of an expert in a research work for a pharmaceutical company, except for the activity on a specific product, is to be considered an indirect interest.

Financial interests are to be interpreted as:

- a) 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.
- b) Compensation, fees, honoraria, salaries paid directly by a pharmaceutical company to the individual, other than payment for expenses incurred with research work or re-imbusement of reasonable expenses incurred in relation to conference/seminar attendance (i.e. accommodation and travel costs). Any teaching activities, (CME courses included) directly or indirectly, partially or fully sponsored by pharmaceutical industry should be mentioned accurately.
- c) Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal product owned by the individual or of which the individual is directly a beneficiary

“Ownership of a patent”: a patent for a medicinal product/ competitor product owned by an individual or by the Institution in which such individual is employed. Intellectual property rights where the holder does not have any direct or indirect financial interest nor any development right on such patent are excluded.

“Principal investigator” Is the subject responsible for coordinating other investigators working in different centers taking part to the multicenter trial or the investigator responsible for a monocentre trial or the coordinating investigator (principal) signing the final report on the trial with the exception of the investigator that coordinates at the national level a multinational trial.

“Investigator”: is an investigator involved in a clinical trial at a specific trial site which can be the responsible lead investigator of the trial at that specific site or a member of the clinical trial team who performs clinical trial related procedures and makes important trial related decisions.

Grant or other funding to an organisation/institution shall mean: any funding received from a pharmaceutical company by an organisation/institution to which the expert belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the expert whether or not it is related to research work

Other definitions

“Expert Witness”: is to be interpreted as an expert whose role is limited to testify and give specialist advice on a specific issue by providing information and replying to any direct questions only. Such Expert Witness can be invited to participate at Scientific Board and Committee, Working Party, Ad-Hoc Expert Group meetings.

“pharmaceutical company”: also includes supply or service companies which contribute to the research, development, production and post - marketing surveillance of a medicinal product.

“Competitor product” is defined as a medicinal product that targets a similar patient population with the same clinical objective (i.e. to treat, prevent or diagnose a particular condition), hence constituting a potential commercial competition.

Family members shall mean: first-line members of the family of the expert (i.e. a spouse or a partner, children and parents)