

CLASSIFICATION CHART OF THE RISKS ABOUT CONFLICTS OF INTERESTS

Two risk levels of conflicts of interests (high and low)

- Declared interests considered as important = high risk of conflict of interests
- Declared interests considered as minor = low risk of conflict of interests

Nota Bene : in the form for declaration of interests, details are required but won't have immediate consequences regarding the conflict of interests' level, enable to find out non defined risky situations or, on the contrary, enable to moderate the level of a potential conflict and justify the participation of a previously excluded expert on the base of the classification.

Criteria hold to elaborate this classification

- taking the present or past characteristic of interests into consideration ;
- the implication degree of the expert within the company concerned by the procedure (financial interests in a company ; salaried status or participation in a decision body ; other regular performances ; manager in an institution financially dependant on a pharmaceutical laboratory) ;
- works delivered in connection with specific products subject to assessment or processed matter and the nature of these links à (ex. Principal investigator/public presentation on a product for example).

Assessment of conflicts of interests: concrete, objective and balanced

- Declared interests must be considered **on a case-by-case basis in the concrete context of assessment** (ex. the study is carried out on various sites or on one site ; there are only one or over 3 competitor products) **as well as with regard to the nature of the files to assess** (ex. Sensitive matters or not, highly controversial or not) **and to the type of link** (ex. Link that is or that is not in connection with a specific product).
- Necessity to watch for intermediate situations that should be assessed with regard to quantitative elements (multiplication of occasional interventions could make believe that there is a usual relationship between the person and the concerned laboratory, for example) and qualitative elements (assessment of the implication and bias level of the person during a public presentation before evaluation, for example).
- Several definitions of the « competitor product » will have to be taken into account and assessed in a concrete manner to keep the most relevant definition depending on the evaluation context:
 1. product (on the market under evaluation or under development) from the same therapeutic class with similar indications,
 2. product (on the market under evaluation or under development) from the same therapeutic class with different indications from the indications of the product to assess,
 3. product (on the market under evaluation or under development) from another therapeutic class with similar indications to the indications of the product to assess.

IMPORTANT INTERESTS = High risk of conflict of interests	MINOR INTERESTS = Low Risk of conflict of interests
<p>1. FINANCIAL INTERESTS IN A COMPANY (FI)</p> <p><i>Currently :</i></p> <ul style="list-style-type: none"> ☛ Significant financial interests (more than 5000 euros or over 5% of the capital or equivalent) in a company manufacturing or marketing the product under evaluation <p>OR</p> <ul style="list-style-type: none"> ☛ Significant financial interests (more than 5000 euros or over 5% of the capital or equivalent) in a direct competitor company 	<p>1. FINANCIAL INTERESTS IN A COMPANY (FI)</p> <p><i>Currently :</i></p> <ul style="list-style-type: none"> ☛ Non-significant financial interests (less than 5000 euros or less than 5% of the capital) in a company manufacturing or marketing the product under evaluation
<p>2. PERSONAL ACTIVITIES</p> <p>2.1. Permanent links (PL)</p> <p>2.1.1. Owner, manager, partner, employee, participation in a company's decision body (PL-ODE)</p> <p><i>Currently or in the previous 3 years, or in negotiation :</i></p> <ul style="list-style-type: none"> ☛ in a company or institution manufacturing or marketing the product under evaluation or with direct competitor companies (including in subcontracting companies) <p>2.1.2. Other regular activities (PL-RA)</p> <p><i>Currently or in the previous 3 years:</i></p> <ul style="list-style-type: none"> ☛ for the company or institution manufacturing or marketing the product under evaluation 	<p>2. PERSONAL ACTIVITIES</p> <p>2.1. Permanent links (PL)</p> <p>2.1.1. Owner, manager, partner, employee, participation in a company's decision body</p> <p><i>More than 3 years ago but less than 5 years ago :</i></p> <ul style="list-style-type: none"> ☛ in the company or institution manufacturing or marketing the product under evaluation (including in subcontracting companies) <p>2.1.2. Other regular activities</p> <p><i>More than 3 years ago but less than 5 years ago :</i></p> <ul style="list-style-type: none"> ☛ for the company or institution manufacturing or marketing the product under evaluation
<p>2.2. Occasional interventions : clinical, preclinical trials and scientific works (OI-CT)</p> <p>2.2.1. As a principal investigator of a monocentric survey, coordinator investigator or principal experimenter</p> <p><i>Currently or in the previous 5 years :</i></p> <ul style="list-style-type: none"> ☛ for the product under evaluation <p>OR</p> <ul style="list-style-type: none"> ☛ for the direct competitor of the product under evaluation when there are only few competitor products (less than 3 for example) 	<p>2.2. Occasional interventions : clinical, preclinical trials and scientific works (OI-CT)</p> <p>2.2.2. As a co-investigator, non principal experimenter, contributor to studies</p> <p><i>Currently or in the previous 3 years :</i></p> <ul style="list-style-type: none"> ☛ for the product under evaluation
<p>2.3. Occasional interventions : expert-reports (OI-ER)</p> <p>2.3.1. Expert-reports carried out with a view to appear in a file subject to Afssaps assessment</p> <p><i>Currently or in the previous 5 years :</i></p> <ul style="list-style-type: none"> ☛ (for a company) on the product under evaluation <p>OU</p> <ul style="list-style-type: none"> ☛ on the direct competitor of the product under evaluation when there are only few competitor products (less than 3 for example) 	<p>2.3. Occasional interventions : expert-reports (OI-ER)</p> <p>2.3.2. Other expert-reports</p> <p>(Ex. specify)</p>
<p>2.3. Occasional interventions : expert-reports (OI-ER)</p> <p>2.3.2. Other expert-reports</p> <p><i>Currently or in the previous 3 years :</i></p> <ul style="list-style-type: none"> ☛ (for a company) on the product under evaluation <p>→ The level of conflict of interests is assessed on a case-by-case basis depending on the situation: date, nature of the performance, direct or indirect earnings...</p>	

<p>2.4. Occasional interventions : council activities (OI-CA)</p> <p><i>Currently or in the previous 3 years :</i></p> <ul style="list-style-type: none"> ☛ occasional consultant (individual consulting or participation in a steering committee, working group, think tank or equivalent) on the product or in connection with the product under evaluation <p>➔ The level of conflict of interests is assessed on a case-by-case basis depending on the situation: date, nature of the performance, direct or indirect earnings...</p>	
<p>2.5.1. Invitations as a speaker</p> <p><i>Currently or in the previous 3 years :</i></p> <ul style="list-style-type: none"> ☛ specifically on the product under evaluation <p>OR</p> <ul style="list-style-type: none"> ☛ on the direct competitor of the product in evaluation when there are only few products (less than 3 for example) 	<p>2.5.1. Invitations as a speaker</p> <p><i>Currently or in the previous 3 years :</i></p> <ul style="list-style-type: none"> ☛ without connection with a specific product <p>2.5.2. Invitations as a member of the audience, whose travel and accomodation expenses are paid by a company</p> <p><i>Currently or in the previous year :</i></p> <ul style="list-style-type: none"> ☛ presentations supported or organised by the company or the institution manufacturing or marketing the product under evaluation
<p>2.6. Other</p> <p>Ex.</p> <ul style="list-style-type: none"> ☛ Current owner of a patent or inventor of a product, procedure, etc., under evaluation or its direct competitor ☛ Party or witness in a procedure relative to a product under evaluation 	<p>2.6. Other</p> <p>(Ex. specify)</p>
<p>➔ The level of conflict of interests is assessed on a case-by-case basis</p>	
<p>3. SIGNIFICANT FINANCIAL CONTRIBUTION TO THE BUDGET OF A COMPANY YOU ARE IN CHARGE OF (BC)</p> <p><i>Currently or in the previous year :</i></p> <ul style="list-style-type: none"> ☛ Manager of an institution that receives financial contributions from the company or institution manufacturing or marketing the product under evaluation (> 15% for example) 	
<p>4. SALARIED RELATIVES IN COMPANIES LISTED ABOVE</p> <p><i>Currently :</i></p> <ul style="list-style-type: none"> ☛ Close family relationship with an employee holding a manager position in the company manufacturing or marketing the product under evaluation or whose activity is in connection with the product under evaluation 	<p>4. SALARIED RELATIVES IN COMPANIES LISTED ABOVE</p> <p><i>Currently :</i></p> <ul style="list-style-type: none"> ☛ Close family relationship with an employee who does not hold a manager position in the company manufacturing or marketing the product under evaluation and whose activity is not in direct connection with the product under evaluation
<p>5. OTHER</p> <p>➔ The level of conflict of interests (or the incompatibility) is assessed on a case-by-case</p> <p>Ex. current subordination link (or cooperation link or convergence of interests) with a person¹ involved in the file (with the principal investigator (or experimenter) of the survey for the product under evaluation for example)²</p>	

¹ It can be payments in kind or in cash, equipments, training taxes, other... The substantiality of the contribution is assessed in a concrete manner (whose absence, regarding a specific company, could affect the stability of the beneficiary structure for example).

² This risk of conflict of interests will be communicated to experts so it can be spontaneously declared during the evaluation of a specific file.