European Medicines Agency

Annex 3

EVALUATION OF CONFLICTS OF INTERESTS FORM
(IN RELATION TO SPECIFIC EMEA ACTIVITY)

Please note that once the evaluation is completed, this form should be filed, together with all relevant supporting documentation (emails, copy of Public Declaration of Interests and Confidentiality Undertaking form, etc.) in the product or meeting folder, as appropriate.

Name of Expert: .....

Nominated by: .....

For (specify EMEA activity): .....

Give relevant details of interest declared (email or other document where interest was declared) and attach latest Public Declaration of Interests and Confidentiality Undertaking form.

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Where the evaluation is in relation to participation at meeting, feedback on the outcome of the expert's evaluation must be provided by the Scientific Administrator to the relevant Committee/Working Party and the relevant HoS, and must be recorded in the minutes of the meeting.

STEP 1: **Preliminary assignment of the risk level.**

Note that only the background of the expert (current affiliation) and the nature of the interest declared are taken into account to determine the risk level at this stage. Details on the type of product and temporal considerations are applied at the next step.

(Note: CIG (Human Units) and equivalent for the Veterinary and Inspections Unit assign an initial risk level, which is inserted into the EMEA Experts Database). The initial risk level for an expert already in the Expert Database may be found by consulting the database. Alternatively, the Scientific Administrator (or Secretary) in charge of the procedure can assign an initial risk level for newly nominated experts.

	Industry	Academia	Regulators
Personal interest	**3**	**2**	**2**
Institution interest		**2**	**1**
No interest declared		**1**	**1**

Indicate interest level at step 1: ……

Signature: ……..……..

Date: ……

STEP 2: **Further analysis is required if the risk level is 2 at step 1.** (This analysis is carried out by the Scientific Administrator in relation to the specific procedure for which the participation of the Expert is required).

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

If at step 1 the risk level is 3, the expert, in principle, should not participate to EMEA activities. If the expert is considered indispensable (extremely specialised area of expertise, no alternative expert found), go to step 3 of this evaluation form.

Not applicable (risk level at previous step is 1): ☐ or

The expert has declared *(tick all boxes that apply):*

A financial interest in the pharmaceutical company or a competitor pharmaceutical company of:	**Tick**	**Risk level**
• more than 50,000 Euro or equivalent (Investment funds are excluded, as the expert has no control on their management)		3
• less than 50,000 Euro or equivalent (Investment funds excluded)		2
To be (have been): • **Employee with primary responsibility for product or competitor product** • **Consultant on the development of the product or competitor product** • **Principal investigator,** for the development of **the product** or a **competitor** product • **Member of a steering committee, an advisory board or an equivalent body for a company producing the product or a competitor product**		☐ ☐ ☐ ☐
• currently or in the previous year		3
• more than a year ago but less than 5 years ago		2
• more than 5 years ago		1
To be (have been) an investigator (not principal) for the development of **the product** or a **competitor** product		
• currently or in the previous year		2
• more than a year ago		1
To own a patent on the product or a competitor product		3
That the organisation he/she is employed with receives a grant or other funding from a pharmaceutical company (the expert receives no personal gain)		1

None of the above boxes apply to the specific activity for which the involvement of the expert is required.		1

The conflict risk level is the **highest** risk category for which an answer has been ticked (3 highest, 1 lowest).

Interest level after step 2 is: …. Graded by ……. Date: …….

Comments .....…

.....……

<u>STEP 3</u>: **The Scientific Administrator should consult the DIAG** if an expert at risk level 2 or level 3 needs to be involved in EMEA activities, in case no alternative expert has been found. Please provide t the DIAG members with the following information:

- This form with steps 1 and 2 completed (where relevant);
- **Full details of the activity for which participation / involvement of expert is required, with relevant supporting documentation as necessary:;**
- Date when the expert is needed;
- Where the potential conflict of interest relates to a competitor product, the name of the product involved and the therapeutic area ;
- Results of the search for an alternative expert (Risk level 3 experts only);
- Brief statement on why the expert input is considered necessary for the EMEA activity in spite of the declared interest.

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Names of DIAG members consulted

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Consensus meeting needed (if the outcome of the initial DIAG assessment is not unanimous): Yes ☐ No ☐

<u>STEP 4:</u> **Consensus meeting of the DIAG**

Meeting held on: ……..

Participants names:

…….

…….

…….

…….

Notes: ……

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- No consensus reached by DIAG: Referral to the Executive Director, or responsible HoU is necessary (step 5) ☐

Outcome of DIAG evaluation (attach their email with answer):

Participation refused:	☐
Waiver to / maintenance of Level 2 participation for products for which expert has declared interest and competitors to those products, level 1 for all other products.	☐
Risk level (2) is compatible with activity. Participation allowed – no waiver required.	☐
Waiver granted: • To Risk level 2 • To Risk level 1	 ☐ ☐
Incorrectly classified as Risk level 2/3. Correct risk level at step 2 was Level 1:	☐
Consensus not reached (Referral to Executive Director / Head of Unit. **(Step 5)**	☐

Where DIAG consensus has not been reached:

STEP 5: Consultation of Executive Director (or HoU by delegation), in event that DIAG does not reach consensus regarding participation.

Attach all relevant emails and memos.

Decision by the Executive Director/HoU: Waiver ☐ Participation refused.☐

Notes: ……

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The Executive Director/HoU Signature:.....Date: .....

The Scientific Administrator subsequently informs the HoU/HoS concerned of the result of the assessment and asks for sign off by the HoS concerned (or in his her absence, by the Head of Unit).

Agreement of HoS /HoU with result of DIAG assessment:

Yes: ☐

No[1]: ☐

(Note, in the event that the HoS /HoU does not agree with the outcome of the DIAG assessment , the concerned Scientific Administrator should record the reason and should indicate the action taken below (Acceptance or refusal of involvement in EMEA activity), and inform the DIAG accordingly):

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.....……

Signature of HoU /HoS: ……..

Date: ……..

Signature of Scientific Administrator: ……..

Date: ……..

[1] DIAG decision overruled.