European Medicines Agency

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# DECLARATION OF INTERESTS ASSESSMENT GROUP
# RULES OF PROCEDURE

## I MANDATE

The mandate of the Declaration of Interests Assessment Group (DIAG) is to assess the acceptability for involvement of Members/Experts in EMEA activities

When the outcome of assignment of the risk level is risk level "2" or "3", the Scientific Administrator should consult the DIAG in order to decide on the acceptability for involvement of the expert concerned in the specified EMEA activity / procedure.

## II COMPOSITION OF THE DIAG

DIAG is a "virtual" group, composed of 9 EMEA Staff Members, appointed by the Executive Director, for a period of three years.

Members of the DIAG group should ideally have a scientific experience in the field of human or veterinary medicines, and should be drawn from each of the three Scientific Units in the Agency – Pre Authorisation Human Unit, Post Authorisation Human Unit and Veterinary Unit and Inspections. Ideally, there should be an equal split in representation between the three Units.

There are 3 core members and 6 members providing back up.

The core membership rotates on an annual basis, such that each DIAG member is a core member for one year of the three-year mandate. (This rotation is determined at the start of the 3-year mandate). Where the DIAG membership allows, this rotation should be such that there is one core member from each of the Scientific Units.

## III RENEWAL OF MEMBERSHIP OF DIAG.

Three months before the end of the DIAG mandate, existing DIAG members will be invited to express an interest in continuing as back up members, for one additional year, in the new DIAG group. (The purpose of this is to ensure continuity and to share experiences with the new DIAG members). Three members (preferably one from each unit) will be sought from the current DIAG. Volunteers should have the agreement of their Head of Sector, before expressing such interest. In the absence of volunteers, the Heads of Units will be invited to nominate one person from each Unit to take on the role of back up members in the new DIAG group for the one-year period.

At the same time, Scientific Administrators in the three Scientific Units will be invited, to express an interest in becoming a member of the DIAG. Six new members are sought at the beginning of the new DIAG mandate (for a three year term) and an additional three members at the end of the first year (replacing the DIAG members from the previous Committee). These additional three members will participate in the current DIAG group for a period of 2 years and will then "cross over" to the next DIAG group, as back up members for a further year (three years in total).

Volunteers should have the agreement of their Head of Sector, before expressing such interest. Where, insufficient persons volunteer, the relevant Head of Unit can be asked to nominate



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members from within his /her Unit. Where a DIAG member leaves the group within the mandate, a replacement member should be appointed from the same Unit.

## IV BACK UP IN EVENT OF NON-AVAILABILITY OF CORE MEMBER.

There is a cascade list for each core member. It is the responsibility of the core member concerned, in the event that he /she is out of the office or unable to carry out an assessment due to other work commitments, to ensure that one of the assigned back ups is able to carry out the evaluation. It is the responsibility of the back up persons to inform the relevant core member (and follow up back up in cascade system) in the event that he/she will be unavailable for a defined period of time (holidays/missions/etc).

## V RESPONSIBILITIES OF DIAG CHAIRPERSON

A Chairperson of the DIAG is nominated (by DIAG members) from the DIAG membership – for the three-year mandate of the group. The responsibilities of the Chairperson are outlined below:

- Ensuring that replies are provided in timely manner
- Ensuring sufficient cover during holiday period – e.g. Christmas / summer break
- Overall responsibility for paper archiving and up to date Excel spreadsheet.
- Organisation of training on annual basis on DIAG procedures
- Involvement with DIAG members in review of need for revision of guidance documents
- Preparation of necessary DIAG reports – e.g. to Management Board.

## VI SUBMISSION OF REQUEST TO DIAG FOR EVALUATION

The Scientific Administrator should provide the DIAG with the following documents for the expert concerned:

1) Declaration of Interests and Confidentiality Undertaking (DI-CU) form,
2) Curriculum Vitae (CV),
3) Evaluation of Conflicts of Interests (ECI) form.

The Evaluation of Conflicts of Interest form must contain:

- **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;
- The source of the potential conflict – e.g. - 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. DIAG should only be consulted on such experts, when the search for alternative experts has already been carried out and the outcome of that search is negative.

Where any of these documents are not provided, or where the evaluation form does not contain all the necessary information, as outlined above, the requesting Scientific Administrator will be asked to provide the missing information /documents. The evaluation will not start until all documents and necessary information have been provided.

The relevant documents should be sent in electronic form to the DIAG e-mail address.

Archiving of DIAG requests and outcomes:

A DIAG folder in available under the Project folder in EDMS, with separate folders for each year. On receipt of a request, the first DIAG member to start the evaluation should create a new sub folder, with Expert name and activity involved, under the relevant year folder, and should save the original request in this folder. The individual replies of the DIAG members involved should be saved (by the individual DIAG member) in the newly created folder for the DIAG request.

*(Each new request should also be entered into the Excel spreadsheet in the DIAG folder. The final outcome of the DIAG evaluation should be entered into the Excel spreadsheet and a paper copy of the outcome printed, for inclusion in the Paper archive. (It will be the responsibility of the Chairperson to organise and allocate, as necessary, the responsibility for these tasks).*

## VII ASSESSMENT PROCEDURE

The advice of 3 DIAG members is required to reach a decision. In case the Scientific Administrator is both DIAG member and manager of the procedure to be assessed, he/she cannot participate in the assessment and should be replaced by a back-up person, using the agreed cascade system. (See section V)

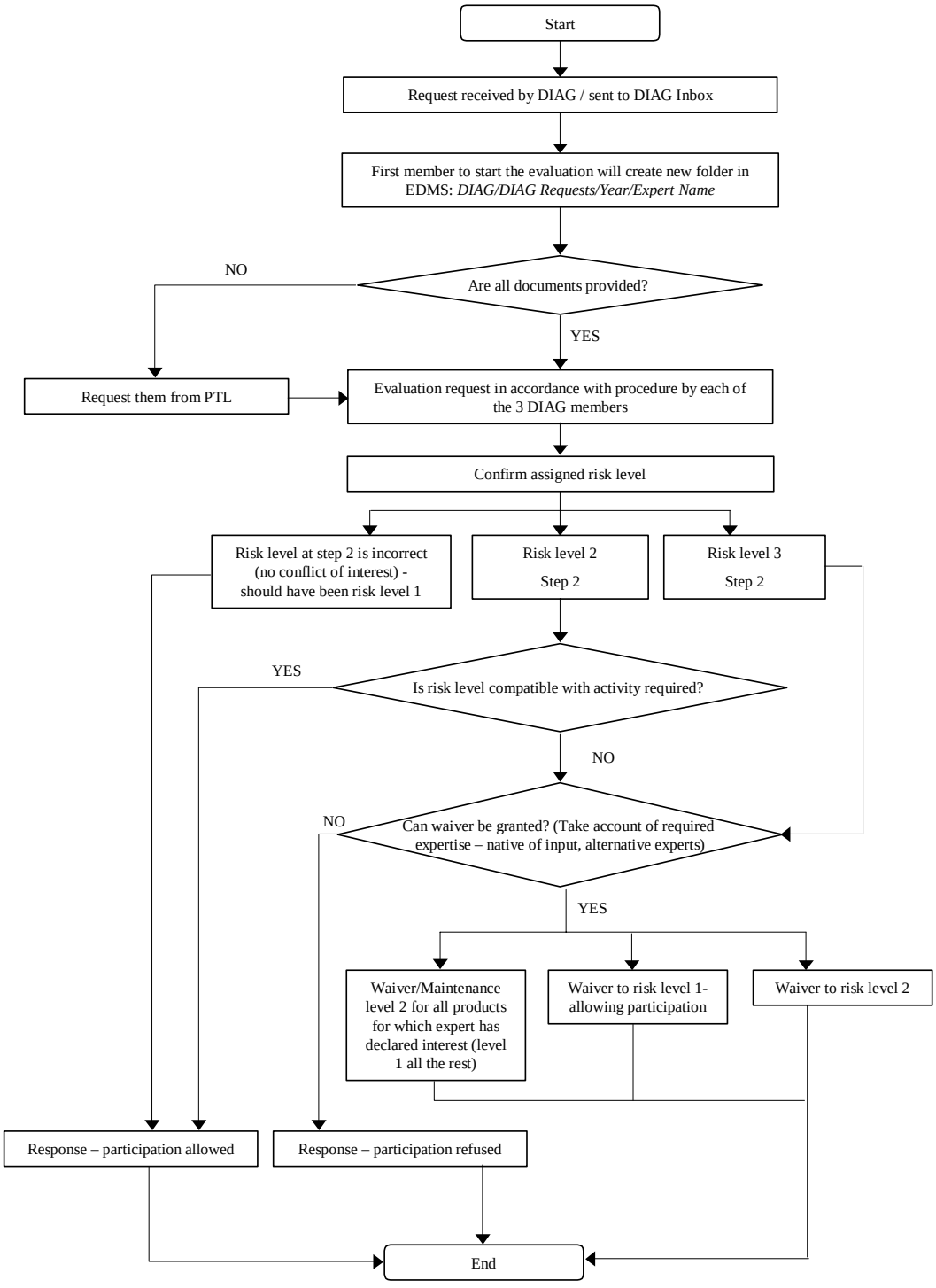
The assessment by the DIAG should be performed within 24 hours after receipt of the request, if possible.

The three DIAG core members (or nominated backups) will evaluate the request on the basis of the information provided. Additional information /clarification may be sought directly from the scientific administrator involved or by means of Internet searches, regarding named (competitor) products, companies, therapeutic indication etc.

Steps in the Assessment Procedure:

- The member will first of all confirm whether the assigned risk level (further to Step 2 of the procedure) is correct. In the event that this is considered to be incorrect, this should be reflected in the DIAG member's reply. (No further evaluation necessary).
- Where the assigned risk level is correct (level 2 or 3), the DIAG member will then consider whether the assigned risk level is compatible with the activity required. In this regard, reference should be made to the table in the procedure outlining the level of involvement, with respect to role of the member/expert or phase during which the person's involvement is required.
- Where the assigned risk level is not compatible with the activity required, the member will then consider whether a waiver can be granted. In this regard, consideration should be given to the specific expertise required, the availability (or not) of alternative experts with this specific expertise, the nature of the input required and the role of the member/expert or the phase during which the involvement is required.

## Diagram of Assessment Procedure



## VIII OUTCOME OF ASSESSMENT PROCEDURE

Each of the three members will circulate the conclusion of their assessment to the other DIA G members. Once three replies have been received:

- In the event of consensus, the last member to reply is responsible for summarising and communicating the outcome of the assessment to the Scientific Administrator concerned (by e-mail). The individual replies of the three members concerned should be included in the electronic reply. This member should then save the summary reply in the relevant DIAG folder.
- In the event of non-consensus, the concerned DIAG members request the Scientific Administrator concerned to organise a short meeting (30 minutes maximum), for further discussion and clarification, with a view to reaching consensus on the request. Once an outcome has been agreed (consensus /non consensus), the DIAG members concerned agree between themselves who will take the responsibility for providing the final reply. (In the event that no consensus can be found during such meeting, the Scientific Administrator should refer the issue to the Executive Director, or responsible Head of Unit (by delegation), for decision-making.

In view of their direct effect on third parties all decisions taken by the DIAG need to be signed off by the responsible Head of Sector or by the Head of Unit, in the absence of the Head of Sector. The responsibility for obtaining this sign off is the responsibility of the requesting Scientific Administrator. Such a sign off is by signature of the evaluation form.

All decisions (i.e. acceptance or exclusion of involvement, both in the case of product and non-product related issues) made by the DIAG, or the Executive Director or responsible Head of Unit (by delegation), as appropriate, are recorded in the relevant product master file and/or the minutes of the EMEA Scientific Committee, EMEA Scientific Committee Working Party, Scientific Advisory Group (SAG), ad-hoc expert group, drafting group, etc.

### Diagram of the outcome of Assessment Procedure