

Eunethydis: a statement of the ethical principles governing the relationship between the European group for ADHD guidelines, and its members, with commercial for-profit organisations

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Eunethydis

A STATEMENT OF THE ETHICAL PRINCIPLES GOVERNING THE RELATIONSHIP BETWEEN THE EUROPEAN GROUP FOR ADHD GUIDELINES, AND ITS MEMBERS, WITH COMMERCIAL FOR PROFIT ORGANISATIONS

Saturday, 06 October 2007, Cagliari

Prof. Dr. J. A. Sergeant (Chairman)

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Preamble: The members of the Eunethydis ADHD Guidelines Group (referred to as *Group* below) are clinicians and researchers dedicated to the understanding of ADHD/Hyperkinetic Disorder and its effective treatment. Their role has been to prepare guidelines for the treatment of ADHD – three such guidelines have so far been published^{1,2,3}. This clearly raises potential conflicts of interest with the commercial companies who develop and market treatments for ADHD.

This document sets out the ethical principles governing the relations between the *Group*, and its members, and industry. This is important because many members of

the *Group* have at one time or another entered into financial relations with pharmaceutical companies for a range of different activities including consultancy, advice, presentations to meetings, as well as funding for trials and other studies. The goal of these collaborations varies across activities but the common element for the *Group* is that they are motivated by a desire to improve the understanding of ADHD and its treatment and to disseminate best practice in both research and therapy.

We are confident that these relations are conducted with both the highest ethical standards. The principles set out here are provided to ensure that this is both done and seen to be done. The impetus for these guidelines comes from within the *Group* and is linked to the recognition for the need for an open and transparent basis for *Group*-industry relations, especially in the light of the present concern that the pharmaceutical industry may be exerting a growing influence on the actions of researchers and clinicians in the ADHD field.

Transparency and register of potential conflicts of interest: The notion of transparency will be the core principle upon which this statement is built. A fully comprehensive register of any potential competing interests that arise out of work with commercial for-profit companies will be established and maintained by the chair of the *Group*. This will include a short detailed description of the activity involved as well as its time-frame. Examples of relevant activities include; advisory board membership, consultancy, presentations at company funded meetings, travel bursaries and conference attendance support. Both investigator initiated trials and pivotal phase 3 and phase 4 marketing trials should be declared.

Activities should be declared whether or not funds are paid directly to the individual or to an account within a university or other organisation. In time, these principles and procedures may be extended to not-for-profit organisations. At present it is not envisaged that these declarations will not include reference to the scale of financial involvement; but this will remain under review. Where confidentiality is required in these matters, register of competing interests should acknowledge the interaction in a general sense and note the company and product involved.

Independence of Group decision making: Members who have conducted trials on a particular product will be allowed to present data to the *Group* on those trials during the review process. However, these data will be evaluated by members of the *Group* that are independent of these involvements. In case of conflicting opinions about the merits of a study and the meaning of the results, members involved with a specific project will be excluded from making the final decision. If the situation arises (and it has not to date), when all members of the group are involved in a trial, then the chair will approach appropriately qualified experts to give their evaluation of the trial data. The value of independent statistical review of procedures and findings will be explored.

Protection of Group members' interests: In order to protect the interests of members of the group the following procedures will be established.

(i) A register of attempts at undue influence by companies on the opinions and activities of *Group* members will be established and occasions of such will be placed on public record.

(ii) An informal system of peer review will be established to ensure that documents written or talks prepared for companies and funded by them conform to these ethical guidelines.

(iii) A record will be made of the outcome of this review.

(iv) Before entering into financial arrangements with industrial interests *Group* members should make a disclosure that their conduct is regulated by the principles set out in this document.

5. Ethical conduct of Group members: In order to ensure that for-profit-related activities are conducted within an ethical framework the following principles are set down.

(i). Company funded drug trials should be undertaken by *Group* members only when there is an agreement that the full trial data will be made available to the investigators and there is no in principle veto on publication of data.

(ii) Involvement of *Group* member in ghost written papers prepared by professional medical writers for companies is prohibited. Furthermore members performing trials for companies are expected to be independent in their interpretation, able to review all material before it is published, and responsible for the whole of a paper of which they are an author. They should avoid inducements that could lead to bias in reporting.

(iii) When presenting data on company-funded trials the *Group* member must retain full editorial control and ensure that they operate in a completely unbiased and scientifically balanced way.

(iv) In relation to data reviewed by the *Group* for published guidelines, to ensure consistency and to protect their interests, a spirit of collective responsibility will be adopted in which *Group* members present the agreed guidelines position. However, this position needs to be reconciled with the need to maintain the individual academic freedom of *Group* members and to respond to developments in the field. Where these amendments to the published guideline position are made they will be reported to the *Group*.

(v) *Group* members conducting trials that are commercially funded (either investigator initiated or company sponsored) should avoid entering into personal financial relations with the trial sponsor (at least until after publication of the main outcomes).

References

1. Taylor E, et al., (1998). Clinical guidelines for hyperkinetic disorder. *Euro Child Adoles Psychiatry* 7: 184-200.

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3. Banaschewski, T. et al., (2006). Long-acting medications for the hyperkinetic disorders - A systematic review and European treatment guidelines. *Euro Child Adoles Psychiatry* 15: 476-495.