Conflicts of Interests – striking the right balance

Example

CVMP must <u>appoint external experts</u> for a Scientific Advisory Group for a specific product. Experts are approached: asked for willingness to participate, then fill in all details on potential Col's, updated CV and lots of other paperwork.

In many small research fields, the number of active experts is very small.

Many will have had different contacts with or involvement of pharmaceutical companies in

their scientific work; giving expert advice on a development program or trial, participation in a clinical trial, support or funding of research projects in the topic, grants for ph.d.-students, etc.

The experts are told that if they have (had) any of these potential Cols, they are <u>RISK</u> LEVEL 2 or 3, and they may participate with restrictions ; they can <u>discuss but not vote/decide</u> in the group, or they may be called in as an Expert Witness to <u>answer specific questions</u> in front of the "cleared" group, but without any other involvement.

- What is the chance that a *leading expert in the field volunteers* to participate?
- Will the selection committee choose the less experienced, but "low-risk" experts to avoid problems?

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Background:

- <u>Impartiality and independence of the</u> involved persons are crucial elements of the trust in the decisions.
- Very <u>few experts</u> are available on specific (research) topics, in particular in the veterinary world.

Focus: the scientific experts and committee members:

- In decision making bodies, like CVMP, and for regular experts, assessors etc: necessary with full declarations and no Col in the decisions taken.
- In Scientific advisory groups/Ad-hoc expert groups: more <u>flexibility</u> is needed to attract the best external experts for specialised topics.

Changes needed in policy:

- Improved attitude (and gratitude) towards the specialised external experts, who volunteer to work for the Agency without payment and without any official recognition etc.
- The <u>wording</u> of the policy reflects the insinuation that a person is "a RISK" if he has any contact with the pharmaceutical industry. E.g.: change "risk level" to "Col-level" and so on.
- Flexibility in the Indirect interests
 assessment with regard to funding or
 grants, opening a possibility for <u>detailed</u>
 <u>assessment</u> of the expert's link to the
 fund given to the institution.
- The table related to the policy needs thorough improvement to facilitate understanding.