REVISION OF THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC. Concept Paper

Spanish Association of Pharmacists in Industry (AEFI)

Consultation item	Do you agree with this appraisal?	Other questions
no. 1: SINGLE SUBMISSION (WITH SEPARATE ASSESSMENT)	NO	*Please comment.* ***We better go for 1 submission+1 central assessment***
no. 2: SEPARATE ASSESSMENT	NO	*Please comment.* ***If local particularities cannot be avoided and differences are insurmountable, then go for 1 single submission+ separate assessment.***
no. 3 SINGLE SUBMISSION (WITH SUBSEQUENT CENTRAL ASSESSMENT)	YES	*Please comment.* ***A single submission would save time, efforts and money (more sustainable) Central Assessment would lead to more consistent methodology and criteria among countries.***
no. 4 SINGLE SUBMISSION WITH "COORDINATED ASSESSMENT PROCEDURE"	NO	*Is the above catalogue complete?* ***Only one topic (risk-benefit) could be fully centralized. This may cause 2 separated evaluations: CAP for risk-benefit and separated assessment for ethic and local.***
no. 5 Scope of the CAP: a) Risk-Benefit.	- YES	*Do you agree to include the aspects under a),and only these aspects, in the scope of the CAP?* ***Yes. That's the reason why we think CAP would not work.***
no. 6 DISAGREEMENT WITH THE ASSESSMENT REPORT	- Member State allowed to "opt out"	*Which of these approaches is preferable?* *Please give your reasons.* ***We do not see the CAP is a good option, and we foresee that actually there would be more requests for "opt out" than agreements reached due to the nature of local regulations. Only risk-befefit could be centralized, and this would duplicate procedures (central for risk-b and local for ethic and local)***
no. 7 MANDATORY/OPTIONAL USE OF CAP	- CAP Optional	*Which of these three approaches is preferable?* *Please give your reasons.* ***We better agree the CAP is not applicable. We think the most practical approach is "single submission, separate assessment", as CAP could only cover Risk-Benefit issues and the rest (ethical and local aspects)should be evaluated separately anyway.***

no. 8 PRE-ASSESSMENT OF "LOW RISK TRIAL" TO SUBJECTS	- NO	*Do you think such a pre-assessment is workable in practice?* *Please comment.* ***Direct assess of the trial itself will save time of pre-assessments and classifications. The need of written approval (no tacit approval for CAP) is also a pitfall in the process.***
no. 9 HARMONIZED REQUIREMENTS FOR *ALL* TRIALS, BETTER THAN A WIDER DEFINITION OF "NON-INTERVENTIONAL"	YES	*Please comment.* ***In our opinion this would allow a better knowledge of the procedure and would provide equal opportunities in different Member States.***
no. 10 HARMONIZED REQUIREMENTS FOR *ALL* TRIALS, INDEPENDENTLY OF THE NATURE OF THE SPONSOR	YES	*Please comment.* ***Again, this would allow better knowledge of the procedure and in this case would giv equal opportunities for different types of sponsors.***
no. 11 DETAILED RULES AND FORMS FOR APPLICATION AND SAFETY REPORTING	YES	*Please comment.* ***Clear and well organized forms in which all information required is requested are of great help.***
no. 12 OTHER KEY-AREAS WHICH MAY NEED UPDATED RULES/FORMS	-	*Are there other key aspects on which more detailed rules are needed?* - *Import Licenses and importation requirements gathered within the EU Directive* - *Consideration for "special medicines", such as radiopharmaceuticals* - *Clarify/harmonize procedure for communication of protocol deviations to the CA: what, when and how.*
no. 13 NARROWER DEFINITION OF IMP AND NOTION OF "AUXILLIARY MEDICINAL PRODUCTS"	YES	*Please comment.* ***This could help to simplify the use of medicinal products in the frame of clinical trials***
no. 14 FOR LOW-RISK TRIALS: REMOVING INSURANCE REQUIREMENTS or INDEMNIZATION BY MEMBER STATE	-- --	*Which policy option is favourable in view of legal and practical obstacles? What other options could be considered?* ***Both options should be acceptable: no insurance for Type-A labeled trials and according to local regulation for the remainder.***

no. 15 SINGLE SPONSOR (BETTER THAN ALLOWING CO-SPONSORSHIP)	YES	*Please comment.*
no. 16 ICF DURING OR AFTER THE STUDY IN CASE OF EMERGENCY	YES,, WITH THE TEMPORARY RESTRICTIONS EXPLAINED	*Please comment.* ***No deviations should be allowed in these procedures, and any deviation should be a major protocol violation(misconduct), in order to protect the subject's rights.***
no. 17 GCP COMPLIANCE IN THIRD COUNTRIES	YES	*Please comment.* ***This is absolutely necessary to protect human right, and to avoid discrimination.***
no. 18 comments on figures collected by DG SANCO	-	*Do you have any comments or additional quantifiable information apart from that set out in the annex to this document?* ***NO*** *If so, you are invited to submit them as part of this consultation exercise.* ----