1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Overall, the European Association of Hospital Pharmacists (EAHP) supports the direction of transparency indicated within this consultation document. However, we consider the period of consultation (4 weeks) to be well below best practice (12 weeks being a general standard by the Commission and many governments), especially in view of both the technical nature of the matters under consideration, and their high level of importance for the future medical and pharmaceutical research environment in Europe. Such short periods of consultation, especially without clear prior notice, can provide difficulties for resource-strained NGOs in coordinating expert submissions (e.g. contacting and eliciting responses from experts in the field), and is likely to consequently bias the levels of response the Agency will receive. In our own case, it has meant leaving some questions unanswered in our response as the time available has not permitted full reflection on the matters. In cases where the EMA consults in periods shorter than 12 weeks a reasoning provided for the shorter period would be helpful in promoting understanding of the Agency's perspective.	

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	Nevertheless, the importance of transparent reporting of clinical trial results appears well described and understood by the Agency in the early parts of the document, including: • Reinforcing public trust in clinical trial outcomes and the decisions taken by regulators based on those outcomes; and, • Acting as a knowledge management resource to foster innovation and stimulate and accelerate further research by building on accumulated knowledge and technical ability. From the strong levels of response received to past EMA consultations and consultative exercises by the EMA on this topic, as well as highly publicised court cases, we are sure the Agency appreciates the level of public interest that is at stake in relation to clinical trial transparency. The continuing growth of the AllTrials campaign, of which EAHP and many of its member associations are signatory supporters, also serves to underline the spotlight of public scrutiny in getting trial transparency in Europe right. EAHP supports suggestions that any deferrals to making information public must be justified and those justifications should be subject to periodic audit.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
Lines 299-301 *"The rules need to be applied in a fair and systematic way, in accordance with the established rules, and not based on repeated human judgement and intervention, which would be impossible to control and create a very large burden on authorities and or sponsors"*		Comment: EAHP supports this general approach to application of the regulation. Proposed change (if any):	
Lines 382-410 Question 1 – 4.3.2 – Please comment on whether these proposals **[on the publication of information about clinical trial investigators and their staff]** meet the requirements and objectives of the Regulation (EU) No 536/2014		Comment: EAHP support making the list of principal investigators and their sites public as part of marketing authorisation, including the CVs of the principal investigators, and their economic interests and institutional affiliations. All of this supports open scrutiny of a trial and secondary research and the general achievement of strong levels of transparency. Proposed change (if any):	
Lines 413-416 Question 2 – 4.3.3 – Please comment on whether this proposals **[to not include**		Comment: EAHP suggests there is value in transparent reporting of Member State experts in the database. The calls for greater transparency in the reporting of clinical trial results are based on a desire to improve confidence in the totality of the	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
Member State experts in the database] meet the requirements and objectives of the Regulation (EU) No 536/2014		clinical trial process, including the assessment arrangements. Proposed change (if any): To include Member State experts in the database.	
Lines 417-423 Question 3 – 4.3.4 – Please comment on whether this proposals **[to not include personal information identifying sponsor staff such as consultants, contractors etc]** meet the requirements and objectives of the Regulation (EU) No 536/2014		Comment: As above, EAHP suggest that identification of consultants and contractors involved in a clinical trial should also be available in the portal. We do not see the case for keeping this information hidden. Proposed change (if any): To include information on consultants and contractors to a trial.	
Lines 426-434 Question 4 – 4.3.5 – Please comment on whether this proposals **[to identify in the database MAH/applicant personnel who are identified in the clinical study report submitted to the database]** meet the requirements and objectives of the Regulation (EU) No 536/2014		Comment: EAHP identifies no good reason why this information should not be included in the database. Inclusion supports the principle of achieving strong levels of transparency in the reporting of clinical trials. The proposals are supported. Proposed change (if any):	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
Lines 437-444 Question 5 – 4.3.6 – Please comment on whether this proposals **[to not automatically provide contact details of clinical investigators]** meet the requirements and objectives of the Regulation (EU) No 536/2014		Comment: The database should allow for public access to a sponsor contact point to enable enquiries regarding the scientific aspects of the trial. It is also important that the database makes publically available the contact details of the investigator site. Trial participants, carers and healthcare professionals should be able to contact the investigator site to seek further information about the trial. Furthermore, this information can be used by portals of other organisations to promote trial opportunities to potential participants.	
Line 454-459 Definition of commercial confidentiality "Commercially confidential information can be considered as meaning "any information contained in the data or documents submitted to the database that is not in the public domain or publicly available **and where disclosure may undermine the legitimate economic interest of the sponsor."**		Comment: The final part of this definition appears to EAHP as very broad and conditional, and could provide large possibilities for information to be withheld that is actually in the public interest to disclose. EAHP suggest EMA consult specifically on this issue. It occurs to EAHP that the definition of what is considered by EMA as 'commercially confidential' is a critical matter to get correct from the beginning of the database's utility. The currently given definition appears to EAHP to offer wide possibilities for keeping information out of the public domain against the public interest. EAHP would like to see a more expansive document from the EMA describing the basis upon which it will make judgments about commercial confidentiality issues. As stated in an earlier part of the consultation document "*The rules need to be applied*	

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		in a fair and systematic way, in accordance with the established rules, and not based on repeated human judgement and intervention, which would be impossible to control and create a very large burden on authorities and or sponsors " At least from this consultation document, the procedures for applying commercial confidentiality test do not come across as abundantly clear and EAHP advise some work on explaining to the public precisely how determinations on CCI are/will be made by the Agency can valuably assist public confidence in the trial process.	
Line 480-490 Definition of "overriding public interest" "Overriding public interest can be considered, in this context, as meaning that the general public interest in having information made publically available may outweigh considerations that the same information should remain confidential. The public interest per se is multifactorial, but includes access to		Comment: The description of how the "overriding public interest" test will be applied in practice appears lacking in the document, which makes it difficult for EAHP to give strong comment on this aspect of the document and intentions for the development of the database. EAHP would welcome EMA giving further clarity on this topic in advance of the database being constructed and operational. This might helpfully include how external stakeholders could prompt use of the test, or question the results of its application.	

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information that supports the objectives for transparency set out in chapter 2 part 3 of this document…. Outside of the database a decision making process will need to be established in order to invoke use of the overriding public interest in such ad hoc cases."			
Line 517 "details of the potential risks and benefits of participation in the trial"		Comment: EAHP would expect information on the potential risks and benefits of participation in the trial to be made publicly available by default.	
Lines 584-605 Question 6 – 4.4.2 – Please comment on which of proposals 1.1. or 1.2. or 1.3. above best meets the requirements and objectives of the Regulation. Please provide a brief rationale for your choice of proposal and explain briefly disagreement with the other proposals.		Comment: EAHP supports proposal 1.2. the assesessment is more linked to the active ingredient and the dosing used in the indication, less to the formulation which could cause unintended consequences for adaptive licensing.	
Lines 635-642 Publication of study specific and product specific documents (see 4.4.1.2)		Comment: The same "public by default" position should apply to IMPD-Q sections. Deferrals may be allowable but, as with others, must be justified and open to audit.	

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Regardless of marketing authorisation status the IMPD-Q section on IMP quality and the related lists of questions, responses and assessment report sections **should be considered to be commercially confidential** and not be made public for any trial at any time, as this deals with the manufacturing and related pharmaceutical development information which continues to be CCI, indefinitely, post marketing authorisation. Question 7 – Please comment and give a brief rationale for your support or disagreement with this proposal regarding the IMPD-Q section.			
Line 643-651 "Clinical trials on products with a marketing authorisation: Taking into account the general considerations under 1, 2 and 3 the following should		Phase 4 trials should not have a deferral option as the product is on the market.	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
apply to trials of products with a marketing authorisation (the so called Phase IV trials and low-intervention trials) with respect to the publication of study specific and product specific documents. The study and product specific documentation should be made public at the time of the decision on the trial. However, the sponsor will be given the option to defer this publication until the time that the summary of trial results is loaded into the database and made public (i.e. 12 months after the end of the trial), in cases where protection of commercially confidential information would be required. The sponsor should indicate in the clinical trial application form if they are opting for this deferral. Question 8: Please comment and give a brief rationale for your support or disagreement with this proposal			

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
regarding clinical trials on products without a marketing authorisation			
Lines 655-708 Question 9: Please comment on proposals one, two, three or four regarding clinical trials on products with a marketing authorisation indicating which proposal best meets the requirements and objectives of the Regulation. Please provide a brief rationale for your choice of proposal and explain briefly disagreement with the other proposals.		EAHP supports Option 3, recognising that for medicines without authorisation publication of protocols before marketing authorisation could be detrimental for commercial sponsors and unhelpful to the European research environment.	
Question 10: Please comment on the proposed time points in paragraphs 6.5.1 and 6.5.2 and indicate whether they meet the requirements and objectives of the Regulation. Please provide a brief rationale for your support or disagreement.		Comment: EAHP has considered the suggested time points and believe the 10 year period described at 6.5.2 is too long. Such an elapse of time diminishes the value of the information to the scientific research community. In the intervening period it is likely that other studies in the same areas may have been conducted, unaided by information that otherwise could have been made available. This takes away from the research benefits of transparency and ultimately diminishes the value of the original trial, the assessment activity, and importantly, the patient's participation.	

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Question 17: Please comment on whether these proposals meet the requirements and objectives of the Regulation.		EAHP supports the proposals made	

Please add more rows if needed.