COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME/AD/EC/17052017/049_Final/EN

On 17 May 2017, the CPME Executive Committee adopted the 'CPME response to the EMA public consultation on the revision of its policy on access to documents' (CPME 2017/049 FINAL)

CPME response to the EMA public consultation on the revision of its policy on access to documents

1. European Medicines Agency policy on access to documents (EMA/729522/2016)

The policy on access to documents (EMA/ 729522/2016) highlights the European Medicines Agency's (EMA) approach to embrace openness of operations as an important feature and the widest possible access to the documents that it produces or receives and has in its possession. The policy has been revised to take into account experience gained since the introduction of the policy in 2010.

Please use the table below to comment on the European Medicines Agency policy on access to documents (EMA/729522/2016).

Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted)*
L. 112-116 (page 4/11)	The EMA policy on access to documents states that "*EMA will ensure protection of commercial interest in accordance with the notion of commercial confidential information. In view of the lack of a legal definition and for the purpose of this policy 'commercial confidential*	

Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted)*
	information' shall mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information". While it is understood that commercially confidential information can be critical to pharmaceutical companies, CPME insists that public interest should always prevails over commercial interests. In particular all results of clinical trials, whether they are positive, negative or inconclusive, should be made publicly available in a systematic way. The legitimate economic interest of the pharmaceutical companies should therefore be defined in a restrictive way and should not take precedence over the public legitimate interest to gain knowledge and be informed in a timely manner about medicines that are on the EU market or that are being investigated. In line with the decision of the European Ombudsman on its own-initiative inquiry OI/3/2014/FOR concerning the partial refusal of the European Medicines Agency to give public access to studies related to the approval of a medicinal product (Humira), CPME considers that EMA should systematically investigate if "*there is a compelling overriding public interest for documents to be disclosed where the information they hold has clinical value to clinicians and researchers*	

Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted)*
	(as regards understanding the safety and efficacy of a product for uses to which it is put, including off-label use)".	

Please add more rows if needed.

2. Output of the European Medicines Agency policy on access to documents related to corporate documents (EMA/183710/2016)

This 'Output Table Corporate' relates to corporate documents, for example to conflicts of interest declarations, SOPs and WINs and corporate documents that are already publically available on the EMA's website.

Please use the table below to comment on the Output of the European Medicines Agency policy on access to documents related to corporate documents (EMA/183710/2016).

Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted)*
	NA	

Please add more rows if needed.

3. Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use (EMA/127362/2006, Rev. 1)

This "Output Table Scientific" lists the document types which may be subject to requests for access to documents related to medicinal products for human and veterinary use.

Please use the table below to comment on the Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use (EMA/127362/2006, Rev. 1).

Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted)*
Section 4 (page 49/58)	The second draft "output" document lists the various document types which may be subject to requests for access to documents related to medicinal products for human and veterinary use. However, no explicit reference is made to the clinical study reports (CSRs) which are the most exhaustive source of information on medicines and are essential to the good conduct of medical research, to the development of new medicines and medical treatments, and to expand scientific knowledge on those medicines and treatments. Since the research and medical community but also the general public may require access to this information, this should be reflected in the table.	Under section 4, add a reference to: '**clinical study reports (CSRs)'**.

Please add more rows if needed.