21 May 2025
EMA/401681/2024
Stakeholders and Communication Division

Overview of comments received on the "HMA/EMA guidance document on the identification of personal data and commercially confidential information within the structure of the marketing authorisation application (MAA) dossier" – public consultation

List of interested parties (organisations) that commented on the draft guidance document as released for public consultation.

Stakeholder no.	Stakeholder, partner or group represented	Name of organisation
1	Pharmaceutical industry	Gilead Sciences International Ltd
2	Pharmaceutical industry	EUCOPE
3	Not-for-profit organisation	EFPIA
4	Pharmaceutical industry	Medicines for Europe
5	Independent, non-for-profit continuing education organisation committed to better patient care.	Prescrire
6	Contract Development and Manufacturing Organisation	Lonza AG
7	Not-for-profit organisation	ACRO

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Stakeholder no.	Stakeholder, partner or group represented	Name of organisation
8	Pharmaceutical industry	LEO Pharma A/S

Comments on the body of the guidance

Abbreviations section

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
4	2 abbreviations seem missing: EU, GCP	Agreed	
6	Consider expanding the CMO abbreviation to include CDMO	Agreed	

Definitions section

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
4	Nuance can be added to indicate distinction to be made between reviewers when comments are made in track change mode e.g. "Author - MAH" and "Author - HA". It will ease the review at receipt.	Not agreed with	The purpose of the guidance is to provide high-level principles on the protection of personal data.
2	Add the following methods "randomisation" and "generalisation" and remove words "masking" and "hiding" which are synonyms of "redaction". Proposed change (if any): Anonymisation: shall mean the operation performed on personal data (e.g. redaction, randomisation, generalisation…) in such a manner that the recipient can no longer attribute the resulting information to a data subject and make it identifiable.	Partially agreed	Agreed to include "randomisation" and "generalisation" and remove "hiding". "Masking" is a general term; "redaction" is one anonymisation technique of masking therefore, the term "masking" was not removed.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
2	Two responsibilities are mixed under the term "MAH": the actual MAH and the "IP right owner". It should be noted they might not be the same legal or natural person. Proposed change (if any): Applicant/Marketing Authorisation Holder (MAH): shall mean the natural or legal person(s) or organisation(s) that submitted documents to EMA/NCA in the context of applications in support of national, mutual recognition, decentralised or centralised marketing authorisations (MAs) and post-authorisation submissions for existing authorised medicinal products.	Not agreed with	The definition of the Applicant/marketing authorisation holder (MAH) is consistent with other publicly available documents such as the Policy - Publication and access to clinical data (2019 revision) (europa.eu).
1	Please clarify the interpretation of "undermine"	Not agreed with	The purpose of the guidance is to provide general principles that may be applied in the identification and protection of commercially confidential information (CCI) and personal data (PD) in different contexts (e.g. European Union (EU)/national context, requests for information/for access to documents). Accordingly, the provision of a more detailed definition is not considered appropriate in light of the above-referred purpose.
1	Please clarify the interpretation of "economic interest or competitive position"	Not agreed with	The purpose of the guidance is to provide general principles that may be applied in the identification and protection of CCI and PD in different contexts (e.g. EU/national context, requests for information/for access to documents). Accordingly, the provision of a more detailed definition is not considered appropriate in light of the above-referred purpose.
6	The definition of "Contract Manufacturing Organisation" should be edited: shall mean a manufacturing company that provides manufacturing services, based on a contractual agreement, to a pharmaceutical or	Not agreed with	The definition of "Contract Manufacturing Organisation" is consistent with other publicly available documents such as the Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/20041 and Article 57 of the Agreement on the European Economic Area.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	biopharmaceutical company to assist in the development and/or manufacture of a product.		
6	Add definition for CDMO/CMO (CDMO: Contract Development and Manufacturing Organisation).	Agreed	
2	Some of the documents in scope are assessment reports issued by authorities. This precision should be added in the definition. Proposed change (if any): Document: shall mean any content regardless of its medium (a written document stored electronically or on paper, or an audio, video or audio-visual recording) concerning a matter relating to the structure of the marketing authorisation application (MAA) dossier and documents containing data extracted from the MAA dossier for the purpose of this guidance and other documents related to finalised regulatory procedures (including documents issued by EMA and NCAs).	Agreed	The definition was expanded to cover European Medicines Agency (EMA) /National Competent Authority (NCA) documents.
6	Add definition of information as: "Information" refers to the communication of knowledge or facts about a specific subject, event or context which includes information in the form of data, written text, numbers, images, audio or video that is processed in a way that makes it meaningful or useful.	Not agreed with	Information is a commonly known term. The guidance does not aim at defining commonly used terms.
3	While we understand that the redaction categories listed in the guidance are not exhaustive, it would help the process to add a few categories of information that can be PD. In order to provide clarification around allowable PD	Not agreed with	The definition of "personal data" is consistent with other publicly available documents such as the General Data Protection Regulation (GDPR) and the Data Protection Regulation for the European Union institutions, bodies, offices and agencies (EUDPR). Some examples are included in the annex.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	redactions, propose the following text to be added to lines 89 - 93: 1. contact details 2. medical Proposed text for Lines 89 - 93: Personal data (PD): shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, contact details, an online identifier or to one or more factors specific to the physical, physiological, medical, genetic, mental, economic, cultural or social identity of that natural person.		
1	Please provide more explanation as to what is considered to be "an online identifier"	Not agreed with	The term "online identifiers" is defined in the General Data Protection Regulation (GDPR).
3	Proposed adding definition of pseudonymisation to definitions section: 'Pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person."	Agreed	

Introduction (box)

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
6	The title for the Introduction is missing, please add.	Not agreed with	
4	Summary of the Scientific advice may only be disclosed after the marketing authorisation has been granted. In this regard, Scientific advice differs from orphan designations and (PIPs)/waivers, which are published by EMA after the respective procedure is finalised. As Scientific advice is in vast majority finalised prior to Marketing Authorisation Application, the denoted sentence can be misleading as it is unclear to which type of scientific advice you are referring. A short clarification would be useful if this does not include a scientific advice for an MAA. In addition, disclosure rules for Scientific advice are described in Chapter 3.5. Proposed change: ''By extension, the principles laid down in this guidance can be considered for other types of finalised procedures such as orphan designations, Paediatric Investigation Plans (PIPs)/waivers.'' Alternative rewording proposed: "By extension, the principles laid down in this guidance can be considered for other types of procedures such as orphan designations,	Not agreed with	Scientific advice related documents may be disclosed after the finalisation of the related regulatory procedure. Please refer to section 3.5 of the guidance.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	Paediatric Investigation Plans (PIPs)/waivers or scientific advice related to finalized regulatory procedures."		
2	Scientific advice is not publicly disclosed. This type of data shall be removed from the list of examples. Other minor edits are also proposed. Proposed change (if any): By extension, the principles laid down in this guidance can be considered for other types of finalised procedures (which are publicly disclosed) such as European Commission decisions on orphan designations, PDCO decisions on Paediatric Investigation Plans (PIPs) / waivers.	Not agreed with	Scientific advice related documents may be disclosed after the finalisation of the related regulatory procedure. Please refer to section 3.5 of the guidance.

1. Scope and Purpose

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
6	"The objective remains to continue to facilitate a common and consistent approach across the European Economic Area (EEA) to provide guidance on the identification of PD that must be protected and CCI included in the MAA dossier." We would suggest to rephrase as:	Partially agreed	To ensure clarity, the paragraph was rephrased as follows: "*The objective remains to continue facilitating a common and consistent approach across the European Economic Area (EEA) by providing guidance on the identification of PD that must be protected and considerations on CCI included in the MAA dossier in the frame of transparency obligations*."

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	"The objective remains to continue to facilitate a common and consistent approach across the European Economic Area (EEA) to provide guidance on the identification of PD and CCI included in the MAA dossier and that must be protected from public disclosure and or release to third parties".		
2	This paragraph is redundant with what is mentioned in the black box above on lines 98-102.	Not agreed with	The black box is an executive summary. As such, its content is likely to be redundant with other parts of the guidance.
4	Proposal: By extension, it is also intended to cover documents concerning the variation of the MA or documents containing information pertaining to the MAA dossier or Assessment reports linked to the aforementioned applications. Justification: It is not clear what would be considered "documents linked to the aforementioned applications". We interpret this to mean assessment reports but propose this to be clarified. Without clarification this statement could be interpreted too broadly.	Not agreed with	The interpretation is correct; the guidance is also applicable to assessment reports. Please refer to the definition of "Document" on page 5 of the guidance.
3	If applicant/MAH disagrees on redaction conclusions, may they file an application for annulment and related application for interim relief to the General Court of the European Union, as mentioned in "External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use", Sections 3.3.3.2. and 3.3.4.? https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/external-guidance-implementation-	Not agreed with	The purpose of the guidance is to provide general principles that may be applied in the identification and protection of CCI and PD in different contexts (e.g. EU/national context, requests for information/for access to documents). Accordingly, the establishment of the potential legal remedies that may be available in some of these contexts is not within the scope of the guidance.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	european-medicines-agency-policypublication-clinical-data-medicinal-products-human-use-version-14_en.pdf		
2	It should be noted that some of the listed regulatory applications are not following the CTD structure. Considering that the addition of the reference to the CTD structure is not relevant in the context of protection of CCI and PD, we propose to remove it. Proposed change (if any): This guidance addresses the shared approach to be taken as high-level principles when providing access to different information/documents in the MAA dossier.	Partially agreed	The fact that the common technical document (CTD) structure may not be applicable to all regulatory procedures within the scope of the guidance is acknowledged. However, as it covers most of the cases, it is considered of relevance. Reference to it was added for clarification.
6	"Any information identified as PD or CCI must be subject to a preliminary review by the EMA/NCA prior to the possible disclosure of the information / documents". We would suggest to rephrase as: "Any information identified as PD or CCI must be subject to a preliminary review by the EMA/NCA and agreement from the party disclosing the PD and or CCI must be obtained prior to the possible disclosure of the information / documents".	Not agreed with	The decision to release information/documents lies with the EMA/NCA in line with their respective legal frameworks.

2. Principles on the protection of personal data (PD)

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
2	For completeness, it should be explained that staff with no legally defined responsibilities can be staff of the MAH but also staff of other organisations such as CROs, CMOs, investigation sites, laboratories and any other service provider. Proposed change (if any): B. PD related to staff with no legally defined responsibilities (including but no limited to staff of the MAH, CROs, CMOs, investigation sites, laboratories and service providers).	Agreed	Examples have been included in section B of the guidance.
1	Please confirm and clarify in which legal texts the responsibilities and roles are defined.	Not agreed with	Such clarification is not considered necessary considering the purpose of the guidance and respective paragraph.
3	Propose limiting "legally responsible" investigators to "coordinating investigators" in order to align with other disclosure deliverables (i.e. EMA Policy 0070). Text proposed for removal: 1. investigator/principal Text proposed for addition: 1. Coordinating Proposed text for lines 160 - 167: In general, it is considered that names of experts or designated personnel with legally defined responsibilities and roles with respect to aspects of the MAA dossier (e.g.,	Partially agreed	The term "Coordinating investigator" was added but "Investigator/principal" was not removed as they have different roles and responsibilities.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	qualified person (QP), qualified person responsible for pharmacovigilance (QPPV), clinical expert, coordinating investigator, sponsor's signatory, etc.) are included in the MAA dossier because they have a legally defined role or responsibility and it is in the public interest to disclose this data. If a more practical solution may be considered, consideration should be given to the fact that it is technically challenging to anonymize documents with names of multiple roles having to be retained, while all other names have to be redacted. As the names of the individuals with the most relevant roles are public in CTIS structures data fields, would it be possible to allow the redaction of all names in clinical reports, which would decrease the effort and quality control of anonymization greatly, considering the useful names are already readily available to the public.		
2	The value of publicly disclosing the sponsor's signatory is very limited (considering that the details of the sponsoring organisation is already shared) so we would propose to remove this role from the list. Additionally, certain roles should be added for completeness. Proposed change (if any): In general, it is considered that names of experts or designated personnel with legally defined responsibilities and roles with respect to aspects of the MAA dossier (e.g., qualified person (QP), qualified person responsible for pharmacovigilance (QPPV), quality,	Not agreed with	The proposed additions were not added. The aim of the guidance is not to present an exhaustive list but the most frequently seen cases from regulatory authority's practice.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	nonclinical and clinical expert, investigator/principal investigator (PI), etc.) are included in the MAA dossier because they have a legally defined role or responsibility and it is in the public interest to disclose this data. (…)		
3	The practice of disclosing the names of the individuals referred in this section to has become established by the EMA and NCAs, although in some Member States, the name may be redacted. This practice of disclosure should now be reconsidered in the light of changes in the external environment, compounded by the impact of social media, especially the experiences of experts in the field of medicinal products and vaccines during and since the COVID-19 epidemic. The increased extent and degree of threatening communications and even behaviour, against those involved in the research, development and supply of medicines and vaccines has been marked. Therefore, the potential security risks to all experts or designated personnel with legally defined responsibilities should be taken into account, as a basis for withholding disclosure of these individual names (whether EMA/NCA experts or MAH representatives), not only those referred to as involved in animal studies. Text proposed for removal: 1. In addition Text to proposed for addition: 1. However,	Partially agreed	The proposed wording *per se* is not agreed. However, the context of the evolving environment is acknowledged and the text was modified accordingly.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	2. who may experience a security risk with the disclosure of the information due to the nature of the work they are involved in or the nature of the medicinal product in question (including but not limited to personnel involved in animal studies and the qualified person responsible pharmacovigilance) Proposed text for lines 164 - 167: However, the names of experts or designated personnel with legally defined responsibilities who may experience a security risk with the disclosure of the information due to the nature of the work they are involved in or the nature of the medicinal product in question (including but not limited to personnel involved in animal studies and the qualified person responsible pharmacovigilance) may be anonymised if it can be demonstrated that disclosure of such information may present a security risk to those individuals in the country concerned.		
2	This sentence should be removed as it creates confusion. Indeed, while the name of the non-clinical expert can be disclosed, names of non-clinical laboratory staff and of any other staff member who is not an expert shall be protected.	Partially agreed	The proposed wording *per se* is not agreed. However, the context of the evolving environment is acknowledged and the text was modified accordingly.
3	Recommend adding this sentence at the end of Lines 172 - 175: Staff names and any other PD should also be removed from metadata of documents.	Not agreed with	The processing of metadata is not within the scope of the guidance. However, please note that is a standard practice from regulatory authorities removing the metadata of documents before sharing them.
4	……clinical trials and clinical studies must be pseudo-anonymized when……	Not agreed with	Please refer to the definitions section on page 5 of the guidance where pseudo-anonymisation is listed.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	We propose to include meaning of pseudo-anonymized in brackets. Justification: There might be misunderstanding of the word hence providing the meaning with an example might help.		
2	There are multiple PD protection mechanisms, and the choice of a mechanism depends on multiple factors including re-identification risk level. Only a generic word should be used in this sentence. Proposed change (if any): Information on subjects involved in clinical trials and clinical studies must be anonymised when included in the MAA dossier submitted to competent authorities.	Not agreed with	Personal data on participants involved in clinical trials and clinical studies should be pseudonymised in the marketing authorisation application (MAA) when submitted to regulatory authorities. As per the guidance, this information should be anonymised prior to public disclosure. This is in accordance with Good Clinical Practices (GCP), including the respect of patient confidentiality [see: Principle 2.11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s)].
3	The text mentions "pseudo-anonymised" data and may be confusing. GDPR uses the term "pseudonymised." Replace "pseudo-anonymised" with "pseudonymised."	Agreed	
2	For completeness, it should be explained that subject data shall be shared with the EMA or NCAs for assessment purpose but will be anonymised before it is made public.	Not agreed with	Personal data on participants involved in clinical trials and clinical studies should be pseudonymised in the MAA when submitted to regulatory authorities. As per the guidance, this information should be anonymised prior to public disclosure.

3. Principles to be applied for the redaction of commercially confidential information (CCI)

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
2	Definition is redundant. It is already provided on lines 75-77.	Not agreed with	Definition of CCI has not been removed for clarity purposes.
2	EMA and NCAs will be in contact with the MAH that may or may not be the owner of the information (MAH sometimes include registered or trademarked brands belonging to other companies for instance). For the purpose of simplification, only the MAH should be mentioned here. Proposed change (if any): Where the redaction of CCI is proposed by the MAH, an assessment of these proposed redactions should be performed by EMA/NCA, taking into account the justification provided by the MAH, in order to decide whether the definition of CCI applies.	Not agreed with	Other third parties can be the owners of the information. Please refer to the definitions section on page 5 of the guidance.
1	Please provide more guidance on what is considered to be economic or competitive interest.	Not agreed with	The purpose of the guidance is to provide general principles that may be applied in the identification and protection of CCI and personal data in different contexts (e.g. EU/national context, requests for information/for access to documents). Accordingly, the provision of a more detailed definition is not considered appropriate in light of the above-referred purpose.
3	Providing justifications that the risk to "should be foreseeable and not purely hypothetical" is an ambitious and potentially unrealistic standard. Creating a standard based on what competitors may, or may not do, is an unknown and unreliable standard that will likely have a negative impact on Sponsors.	Not agreed with	The purpose of the guidance is to provide general principles that may be applied in the identification and protection of CCI and personal data in different contexts (e.g. EU/national context, requests for information/for access to documents). Accordingly, the provision of a more detailed definition is not considered appropriate in light of the above-referred purpose.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	Propose removal of this sentence: In this respect, any reference(s) to the risk of that interest being undermined should be foreseeable and not purely hypothetical. If this sentence is not removed, additional guidance including examples of what the HMA/EMA would consider "foreseeable" and what is "purely hypothetical" would lessen the ambiguity.		Furthermore, as regards whether the concerned wording is "*ambitious and potentially unrealistic standard*", it bears noting that such standard is already routinely applied in certain areas, such as in the context of requests for access to documents to EU institutions, in accordance with the case-law of the EU Court of Justice (in this respect, see: judgment of 22 January 2020 in *PTC Therapeutics International v EMA*, C-175/18 P, EU:C:2020:24, paragraph 57 and the case-law cited).
4	It is difficult to show that a risk for undermining commercial interest is foreseeable and not theoretical. Any risk is hypothetical until it materializes. The owner of CCI should not have to identify actual Third Parties or scenarios that are likely to occur and lead to a undermining of commercial interest. It is suggested that the last sentence of this paragraph (lines 208, 209) is deleted.	Not agreed with	The concerned standard is already routinely applied in certain areas, such as in the context of requests for access to documents to EU institutions, in accordance with the case-law of the EU Court of Justice (in this respect, see: judgment of 22 January 2020 in *PTC Therapeutics International v EMA*, C-175/18 P, EU:C:2020:24, paragraph 57 and the case-law cited). Therefore, it is considered appropriate.
4	It is unclear if the information in writing has to be done: a) only if a request for redaction is started and the disclosure under breach of law has already happened or if it is meant that b) if an owner of CCI has already successfully redacted CCI in an EMA submission document, there is an obligation to monitor unauthorized disclosures and inform EMA about any? -> for the interpretation of b) there seems to be no reason or basis, so this should be clarified that a) is meant in this guidance.	Not agreed with	Defining the process of handling a disclosure under breach of law is not within the scope of the guidance.
2	This sentence should be re-phrased to highlight that Authorities and MAH should work together to reach an agreement on what information will eventually be publicly	Not agreed with	When it comes to the disclosure of information/documents, the decision lies with the EMA/NCA. Third parties shall be informed or consulted as

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	disclosed. Authorities should not take decision without consulting the MAH which may have contractual obligations with third parties.		needed depending on respective national and European legal frameworks.
1	Please provide guidance on what the authority will consider, at a minimum, for individual examination.	Not agreed with	The scope of the assessment may differ depending on the context and applicable legal framework. Therefore, such guidance is not considered appropriate.
3	The concept of overriding public interest seems to be vague and entirely at the discretion of the HMA/EMA. This creates legal uncertainty. Propose that the HMA/EMA clarify in which circumstances overriding public interest may apply. Propose that the HMA/EMA explain what the overriding public interest is in each case where overriding public interest is the reason for rejecting a redaction of CCI.	Not agreed with	The concerned concept is already routinely applied in certain areas, such as in the context of requests for access to documents to EU institutions (in this respect, see: Article 4(2), last paragraph, of Regulation (EC) No 1049/2001). Furthermore, there may be differences as regards the meaning of this concept due to the different applicable contexts (e.g. EU/national context, requests for information/for access to documents). Therefore, this concept is considered appropriate.
4	It would be helpful if the colloquial term "freedom of information request (FOI)" is also used in the document to make it easily traceable with search algorithms / Search engines. Also, a short procedural overview of how the EMA treats FOI requests to dossiers (explanation of administrative steps and responsible department) would be helpful in this section.	Not agreed with	References included in the guidance to requests for information are already considered appropriate. Procedural steps that are only applicable to EMA are not considered to fall within the scope of the guidance.
4	We propose to make the description more concrete and add that the use of overriding public interest is only possible in very exceptional cases, e.g. for public health needs in crisis situations. Generally, CCI should remain confident even if there is a public interest.	Not agreed with	The purpose of the guidance is to provide general principles that may be applied in the identification and protection of CCI and personal data in different contexts (e.g. EU/national context, requests for information/for access to documents). Accordingly, the provision of a

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			more detailed definition of overriding public interest is not considered appropriate in light of the above-referred purpose.
1	Please explain what the authority considers to be an "overriding public interest."	Not agreed with	The purpose of the guidance is to provide general principles that may be applied in the identification and protection of CCI and personal data in different contexts (e.g. EU/national context, requests for information/for access to documents). Accordingly, the provision of a more detailed definition of overriding public interest is not considered appropriate in light of the above-referred purpose.
4	3.1. Information on the Quality and Manufacturing of medicines A general principle regarding quality and manufacturing information is that detailed information could be considered commercially confidential but general information should be disclosed. Comment: it is important to be specific which sections can be disclosed.	Not agreed with	Please refer to the annex of the guidance for information that may be considered CCI in specific sections of the CTD, including sections on Quality and Manufacturing of Medicines.
4	We propose to also add specification (final specification but also development specifications).	Not agreed with	Please refer to the annex of the guidance for information that may be considered CCI in specific sections of the CTD including section related to specifications.
2	For clarification purposes, we are proposing to use the usual regulatory terminology. Proposed change (if any): The final qualitative formulation (composition) of the finished product is not commercially confidential.	Agreed	

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
2	For readability purposes, this sentence should be moved to the section dedicated to the active substance and excipients (3.1.2).	Agreed	
4	Here, it should be added that not only the manufacturer of the active substance or the excipients are CCI, but also manufacturers/ CMOs involved in the supply chain like intermediate product manufacturers, parties carrying out certain steps in the supply chain (for example, premixing, packaging, filling, purification steps, analysis steps or the like).	Agreed	
6	In general, and if not in the public domain, the names of the suppliers and manufacturers of the active substance…are considered commercially confidential". The name of the biological active substance manufacturer is currently publicly disclosed in the EMA assessment report and not considered commercially confidential information and it is also referred as an exception in this draft guidance annex. Please clarify this aspect in the wording of the final guidance.	Agreed	
2	For completeness, the scope should be specified and indicate this applies to the final registered process and previous development processes. Proposed change (if any): Information concerning the manufacturing of the active substance, including technical and industrial process parameters and in-process / intermediate specifications may be considered as CCI. This	Agreed	

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	applies to the final registered process and previous development processes.		
4	Include that Details of Container Closure System of active substance is CCI	Agreed	
4	Change … may be considered … to … are considered …	Not agreed with	Editorials in the guidance were reviewed by the HMA/EMA Transparency working group.
2	Information on raw materials should also be considered as commercially confidential. Proposed change (if any): Detailed information on the synthesis or manufacture of the active substance, including details on the raw materials, by-products and degradation products of active ingredients and validation of the manufacturing/synthesis process, is commercially confidential.	Agreed	
4	The statement that structure is not CCI is supported. However, for biologics, elucidation of structure is performed via an array of assays. That information is considered CCI. The document should be updated to clarify that the array of assays to elucidate of the structure for biologics is considered CCI. Alternatively introduce clear separation between chemical and biological APIs as from line 253 biological APIs are handled.	Not agreed with	Please refer to the annex of the guidance for information that may be considered CCI in specific sections of the CTD including sections related to assays.
2	The proposed wording is too broad and implies that the polymorphic form of the final API is not considered as CCI.	Agreed	

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	Proposed change (if any): Detailed information concerning the particulars of polymorphism and particle size should be treated as CCI.		
5	In 2018, N-nitrosamines impurities, which are potent carcinogens have been found in some sartans and ranitidine. This proves that qualitative and quantitative information on impurities should not be considered as CCI.	Not agreed with	Such details cannot be generalised as each document is assessed on its own merit. In general, this information may be considered CCI. The guidance is about providing high level principles.
4	Propose adding clarity on type of test – e.g. potency, purity, visible particles. This detail is not considered CCI. However, details on the specific potency assay are considered CCI.	Not agreed with	Please refer to the annex of the guidance for information that may be considered CCI including sections related to assays.
2	Some exceptions should be made to this general rule. It is agreed that a general description can be given in most cases (i.e. assay and related impurities are determined by HPLC) but there are cases where even the test method provides indication on the route of synthesis and should be considered as CCI (i.e. specific test to control the presence of a catalyst used during synthesis). Proposed change (if any): Unless this discloses information on the route of synthesis, a general description of the type of test methods used and the appropriateness of the specification is not commercially confidential.	Not agreed with	In general, this type of information is not considered CCI. Each document is assessed on its own merit and elements may be considered CCI if properly justified.
2	For clarification purposes, several terms should be changed, and, for completeness, scope should be broadened.	Partially agreed	The term "Starting materials, intermediates" was added. "Reageant and solvent" has not been added. The guidance includes a non-exhaustive list based on the most frequent cases seen from regulatory authorities practice.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	Proposed change (if any): (…) However, detailed information on the test procedures used and the specification and quantitative acceptance criteria established for the active substance, starting materials, intermediates, reagents and solvents is commercially confidential, unless the active substance complies with the monographs in the European Pharmacopoeia or another national Pharmacopeia.		
4	It is hard to establish what the difference is between general description / general information (not considered CCI) and details (considered CCI) is. It would be good if the EMA could provide examples, or more explanation. Probably, the EMA seeks to maintain the status quo, i.e. that for example the information "produced in CHO-cells using genetic engineering techniques" is not CCI, whilst for example the exact type of CHO cells is CCI. But this section does not make it clear. Also, instead of qualifying "general information" as "not CCI", it would be more logical if that was CCI but there is a overriding public interest to receive this CCI.	Not agreed with	Please refer to the annex of the guidance for information that may be considered CCI including sections related to quality and manufacturing of medicines.
4	Precise that detailed information of host/clone cell line is CCI.	Agreed	
2	Use of terminology like "general statement" and "general information" is open to interpretation. We would propose to use "Principles of" in replacement. Furthermore, it should be added that any information on Master Virus Seed (MSV), Master Seed Lot (MSL) and Master Transgenic Bank (MTB) is considered as commercially confidential.	Agreed	

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	Proposed change (if any): ²Principles of the establishment of the Master Cell Bank (MCB) or Working Cell Bank (WCB) and on the stability of the cell banks is also not considered commercially confidential. Principles of the fermentation and purification process is not commercially confidential, although details including operating parameters and specific material requirements are commercially confidential. Information on Master Virus Seed (MSV), Master Seed Lot (MSL) and Master Transgenic Bank (MTB) is considered as commercially confidential.		
4	Propose to add … including number of validation batches	Not agreed with	In general, the number of batches is not considered CCI. Each document is assessed on its own merit and elements may be considered CCI if properly justified.
2	The case of stability data of the API should also be addressed in the guideline. Although a high-level information of the stability could be considered as not commercially confidential (storage temperature and duration), information on stability studies (including protocols) should be considered as confidential. Proposed change (if any): Storage conditions of the API are not considered commercially confidential. However stability studies (including protocols) are considered commercially confidential.	Partially agreed	A statement related to the storage conditions and shelf life of the active pharmaceutical ingredient (API) was included. In general, stability data of the API including studies and protocols is not CCI. Conditions of the stability testing are quite often derived from requirements and recommendations found in guidance documents published by regulatory authorities.
2	The case of stability data of the finished product should also be addressed in the guideline. Although a high-level information of the stability could be considered as not commercially confidential (storage temperature and	Partially agreed	A statement related to the storage conditions and shelf life of the finished product was included. In general, stability data of the finished product including studies and protocols is not CCI. Conditions of the stability testing are quite often

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	duration), information on stability studies (including protocols) should be considered as confidential. Proposed change (if any): Storage conditions of the finished product are not considered commercially confidential. However stability studies (including protocols) are considered commercially confidential.		derived from requirements and recommendations found in guidance documents published by regulatory authorities.
4	It is hard to establish what the difference is between general description / general information (not considered CCI) and details (considered CCI) is. It would be good if the EMA could provide examples, or more explanation.	Partially agreed	A few other examples considered "detailed information" were added. Please refer to the annex of the guidance for information that may be considered CCI.
2	For completeness, the scope should be precised and indicate this applies to the final registered process and previous development processes. Proposed change (if any): The detailed descriptions of the manufacturing and control processes for the product are commercially confidential. This applies to the final registered process and previous development processes.	Agreed	
4	It would be good to add that were CCI as defined in other sections of paragraph 3, such as the full qualitative AND quantitative composition, is included in clinical trial study reports, it may be redacted.	Not agreed with	In general, clinical and non-clinical information is not CCI. Please refer to the annex of the guidance for information that may be considered CCI.
5	This info is not per se commercially confidential. In general, data included in Clinical Study Reports can be disclosed once personal data has been anonymized.	Agreed	As a general principle, clinical and non-clinical information is not CCI.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	We fully support this principle. This part could be supported with detailed examples of past experience with errors/conflicted interpretations. The examples would contribute to a better understanding of how data help for and support the determination of the benefit-risk balance, including the risk of medication errors in certain patients. Pharmacovigilance data are crucial, and although their disclosure may affect the commercial results, they should not be considered as CCI and thus not be redacted. The guideline states that in exceptional and substantiated cases, particularly where innovative study designs or innovative analytical methods have been used, the need for redaction of specific elements will be considered. Regulators and companies highlight and promote the use of new innovative study designs. Based on our experience, these new study designs (single arm trials, umbrella trials, use of real-world data, etc;) include however higher uncertainty on evidence regarding benefits and risks of medicines. A high level of transparency on these designs and disclosure of information is needed including on the analysis methodologies. We invite the EMA/HMA to withdraw the reference to such exceptional cases to be protected. In addition, study protocols and data analysis methods should always be made public so that independent teams can provide nuanced comments. In parallel, references to these exceptions listed in the annex should be deleted as well.		

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
3	Text Proposed to be added: 1. CCI 2. Additionally, this section may contain HFE/Usability studies which contain information related to the development of drug-device combination that may be considered CCI. Proposed Lines 283 - 285: In the case of exceptional and substantiated cases, particularly where innovative study designs and/or innovative analytical methods have been used, consideration will be given to the need for redaction of specific CCI elements. Additionally, this section may contain HFE/Usability studies which contain information related to the development of drug-device combination that may be considered CCI. Additionally, it would be helpful to provide examples of these specific elements, and examples of previous cases when such redaction (of CCI) was allowed in order to provide further context.	Not agreed with	Reference to information related to the development of drug-device combination is too specific. The purpose of the guidance is to provide high-level principles on the identification of PD and CCI. Please refer to the annex of the guidance for information that may be considered CCI.
6	Information on inspections The revision only states the outcome of inspections is in the public domain and not the specific details. Please confirm if the details of inspections are considered commercially confidential information.	Partially agreed	The guidance states that inspection-related information/documentation could be considered commercially confidential on a case-by-case basis and in line with the principles laid out in the guidance.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
2	For clarification purposes, the case of inspections run by authorities from third countries should also be addressed. Proposed change (if any): Information on the outcome of inspections (e.g., conclusion on compliance/non-compliance/outstanding issues to be addressed) is already available in the public domain (e.g., EudraGMDP and EPAR) and therefore not considered commercially confidential. Information on the outcome of inspections run by authorities from third countries should be considered as commercially confidential.	Not agreed with	The principles laid down in the guidance apply regardless of the inspection authority.
3	While the outcome of an inspection is publicly available, such outcome maybe determined on the basis of a significant volume of information and documentation provided by a company, which should continue to be treated as confidential and should not be made publicly available alongside the inspection's conclusions. Where such information / documentation is referenced or quoted in inspection reports or other documents supporting. inspection conclusions/findings, the confidential information should be appropriately redacted. Suggested text: Information on inspections Information on the outcome of inspections (e.g., conclusion on compliance/non-compliance/outstanding issues to be addressed) is already available in the public domain (e.g., EudraGMDP and EPAR) and therefore not considered commercially confidential. Information and documentation	Agreed	

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	provided by companies during inspections, for the purpose of complying with applicable obligations and to enable the conduct of such inspections, could be considered commercially confidential on a case-by-case basis, in line with the principles laid out in this guidance.		
7	THE CURRENT TEXT CONTAINS THE FOLLOWING LANGUAGE— Contractual agreements between companies are generally considered CCI, except contracts between companies and contract research organisations (CROs). With regard to information in modules 4 and 5 of the dossier, it is considered that contractual information with companies responsible for nonclinical and clinical studies, such as CROs, is not regarded as CCI as they may contribute to and be responsible for important information included in the dossier. The names of these CROs are therefore considered to be information which can be disclosed. ACRO HAS CONCERNS ABOUT THIS LANGUAGE— The wording of the first sentence of this section appears to indicate that the content of a contractual agreement between a company and a CRO may not be considered as CCI. This is significantly different to the final sentence of this section, which refers only to the disclosure of the names of the CROs involved in non-clinical and clinical studies. The extent of the disclosure expected is therefore not clear.	Agreed	The sentence was rephrased to reflect the proposal.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	ACRO MAKES THE FOLLOWING RECOMMENDATION— ACRO proposes supplementing the text to clarify that it is the names of the CRO that are considered appropriate for disclosure, if that is the intent of this section. Any other specific information that is relevant to the contracts between companies and CROs should also be described to avoid misinterpretation. A proposed amendment of the text is amendment of the text is included below. "Contractual agreements between companies are generally considered CCI, with the exception of certain information relevant to the contracts between companies and contract research organisations (CROs). With regard to information in modules 4 and 5 of the dossier, it is considered that contractual information with companies responsible for non-clinical and clinical studies, such as CROs, is not regarded as CCI as they may contribute to and be responsible for important information included in the dossier. The names of these CROs are therefore considered to be information which can be disclosed."		
4	Proposal to include clarity if contracts between companies and Contract Manufacturing Organizations, Device partners for drug device combinations are considered CCI.	Partially agreed	The sentence was clarified. Contract development and manufacturing organisations (CDMOs) have been added in the annex.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
2	Part of the contractual agreements between MAHs and CROs is confidential (such as the financial provisions). This should be explained. Proposed change (if any): Contractual agreements between companies are generally considered CCI, except contracts between companies and contract research organisations (CROs), with some exceptions such as the financial provisions.	Partially agreed	The sentence was clarified to reflect that in general, names of contract research organisations (CROs) or reference to an existing contract with companies responsible for non-clinical and clinical studies is not regarded as CCI. However, the details of the contract may be CCI, according to the principles in the guidance.
3	Text proposed for removal: 3.4. Contractual agreements 1. contractual information with companies 2. The names of these CROs are therefore considered to be information which can be disclosed. Text proposed to be added: 3.4. Contractual agreements 1. names of companies Proposed paragraph: 3.4 Contractual agreements Contractual agreements between companies are generally considered CCI, except contracts between companies and contract research organisations (CROs). With regard to information in modules 4 and 5 of the dossier, it is considered that names of companies responsible for non-clinical and clinical studies, such as CROs, is not regarded as CCI as they may contribute to and be responsible for important information included in the dossier.	Agreed	
4	The names of CROs can be disclosed on a case-by-case basis. When CRO is responsible only for the organization /	Not agreed with	This point has already been covered. Please refer to section 3.4 of the guidance.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	coordination of clinical studies, this information is not relevant for general public. The sponsor of the study is the one who carries all the responsibility that the clinical study is conducted in line with the latest guidelines and standards. Sponsor usually has a non-disclosure agreement with the CRO and the disclosure could lead to contractual infringement. Proposed change: Please add denoted text: ‘’The names of these CROs are therefore considered to be information which can in general be disclosed except when the role of CRO is only organization / coordination of the study.’’		Each document is assessed on its own merit and elements may be considered CCI if properly justified.
4	As scientific advice could include also other topics, not only topics on the clinical development, e.g. questions on non-clinical or quality development, this should be more clearly reflected in Chapter 3.5. Proposed change: Please add denoted text: The disclosure of information on an agreed therapeutical indication should not be regarded as CCI after the conclusion of the related regulatory procedure. However, all the information related to further developments and new formulations which have not yet received regulatory approval as well as other information considered PPD or CCI according to the principles of this guidance document should be protected.	Partially agreed	The text was re-worded. Information on an agreed indication is not CCI. Information on a new development may be considered CCI if properly justified.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	Alternatively, we suggest use of the term "is CCI" and not "should be protected." It should be added (like in line 345 in Annex) that substantiation for CCI only has to be given "if consulted" – not always (e.g. in clear cut cases, no lengthy substantiation will be required).		
3	Propose the word "finalised" in line 299 to remain consistent with line 101 of the guidance. All information which is directed to non-approved subject matter must be considered as CCI per se, because this information may become a trade secret, belongs to know how or even develop as an invention at a later stage and therefore must be kept non-public. Text to remove: 1. conclusion 2. and new formulations Text to add: 1. finalisation 2. (i.e. new indications, formulations, dosages, polymorphs, combinations, biomarkers etc.) Scientific advice The disclosure of information on an agreed therapeutical indication should not be regarded as CCI after the finalisation of the related regulatory procedure. However, all the information related to further developments which	Partially agreed	The text was re-worded to include "finalisation". Further details may be considered to be CCI upon assessment, when duly justified. The purpose of the guidance is to provide high-level principles on the identification of PD and CCI and not an exhaustive list of cases/examples. Further details of information that may be considered CCI have been included in the annex of the guidance.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	have not yet received regulatory approval (i.e. new indications, formulations, dosages, polymorphs, combinations, biomarkers etc.) should be protected and treated as CCI.		
3	Proposed additions to Lines 302 - 306: 1. Clinical Outcome Assessments may be subject to copyright of third parties. 2. Copyrighted material that is not contractually allowed to be shared will not be disclosed. Proposed text for Lines 302 - 306: 3.6. Handling of copyright information The list of references of the publications included in the dossier is not considered to be CCI and can thus be disclosed. However, if the actual manuscripts are included, these may be subject to copyright of third parties. Clinical Outcome Assessments may be subject to copyright of third parties. EMA/NCA expressly disclaims any liability with regard to possible infringements of third parties' copyrights. Copyrighted material that is not contractually allowed to be shared will not be disclosed.	Not agreed with	This point has already been covered in section 3.6 of the guidance. The purpose of the guidance is to provide the high-level principles on the protection of PD and CCI.
4	For some Marketing authorization applications important clinical data is sourced from bibliographic references, e.g. for Well-established use applications in accordance with Article 10a of Directive 2001/83/EC or Mixed dossiers with the combination of (non)clinical data from own studies and from bibliographic references in accordance with Article 8(3) or Article 10b applications of Directive 2001/83/EC. In	Not agreed with	The list of published bibliographic references is not considered CCI.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agreed / Partially agreed / Not agreed with)	Feedback (if applicable)
	such dossiers bibliographic references represent only/important clinical data to fully substantiate efficacy and safety of the respective product. Compilation and critical assessment of the searched and relevant bibliographic data represent company's know-how which is crucial for obtaining a Marketing authorization. The interpretation of mentioned literature references, which enables the MA, is combination of company's experts' special knowledge and experiences, which means companies also invested time and funds in them. Publication of these references would enable a simple replication of such dossier before expiry of regulatory protection (data exclusivity period) and in such way undermine the rights of the respective Marketing authorisation holder and competitive position of the company. Therefore, in our opinion, the list of references in case of WEU or mixed applications should be considered CCI. Proposed changes: Please add denoted sentence in Chapter 3.6 or elsewhere in the guidance document where deemed appropriate. The list of references of the publications included in the dossier is not considered to be CCI and can thus be disclosed except in case of bibliographic applications or mixed dossiers in which bibliographic references represent the only/important (non)clinical data on efficacy and safety of the respective product.''		

References section

Stakeholder no. *(See cover page)*	Line no.	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
6	307	Suggestion to add "25 April 2024 EMA/304162/2014 Rev.7 Stakeholders and communication Division Guide on access to unpublished documents".	Not agreed with	This reference is specific to the EMA Access to Documents process and has not been included in the "References" section.
2	316-318	Unless definitions and protection mechanisms of CCI and PD are fully aligned, there should be no reference to this guidance document.	Not agreed with	The principles are aligned and therefore this reference is considered relevant.

Comments on the annex of the guidance

Introduction

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
4	Here it is laid out that a third party should substantiate that the disclosure of CCI would concretely undermine commercial and economic interest. - Probably, it is meant that Applicants, not third parties, have to substantiate if they categorize something as CCI - Also, the addition "if consulted" is not present in the previous part of the guideline (section 3). It is preferable to applicants not having to substantiate every little piece of CCI, but only on question/ refusal/ request of the agency. This makes the procedure more efficient. But this "if consulted" should be added to the section 3 of the guidance as well - Why here it is requested that commercial AND economic interests are undermined? In the definition and earlier in the document, it was either or and that was sufficient. Suggest use of conjunction "or" instead of "and".	Partially agreed	The "owner of the information" is not limited to applicants; it may be any third party. Please refer to the definition of third parties on page 4 of the guidance. "If consulted" - this is covered under section 1 of the guidance ("Scope and purpose"). The text was updated to reflect the CCI definition.

Module 1 – Administrative information and prescribing information

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
3	The Annex include examples for the different PPD types which are repeated multiple times throughout the same table. This makes the Annex lengthy and unique information are difficult to identify. Propose to provide the examples for the different types of PPD in a separate table of the Annex as follow: Within the Annex suggest to add a new Table to define the examples as follow: A. PD related to experts or designated personnel with legally defined responsibilities: • Direct contact details such as telephone number, fax number, email, postal address, IP address, etc. • Signature B. PD related to staff with no legally defined responsibilities: • Name of employee, consultant or contractor • Direct contact details such as telephone number, fax number, email, postal address, IP address, etc. • Function, position, organisational entity such as department, service, etc. • Signature Similarly for C. PD related to subjects involved in clinical trials and clinical studies and D. PD related to patients in the context of medicine safety	Not agreed with	The structure of the annex was agreed by the HMA/EMA Transparency working group.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	In the current table of the Annex, suggest to display only unique examples and refer to the newly added Table for the repeats, as follow: E.g. section 1.0 A. PD related to experts or designated personnel with legally defined responsibilities: Expected, examples are provided in Table 1 B. PD related to staff with no legally defined responsibilities: Expected, examples are provided in Table 1 (Similarly for the other categories and sections) E.g. section 1.8 B. PD related to staff with no legally defined responsibilities: Expected, in addition to examples provided in Table 1: • Name of Deputy QPPV • Name of employee, consultant or contractor • Name of healthcare professional (HCP) • Name of (vice-)chair, members and alternate members of Institutional Review Board (IRB) and Independent Ethics Committee (IEC) E.g. section 1.9: B. PD related to staff with no legally defined responsibilities: Expected, in addition to examples provided in Table 1: • Name of clinical study director		

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	• Name of investigators other than the principal investigator • Name of employee or consultant and contractor • Name of healthcare professional (HCP) • Name of members of CT Safety Monitoring Board or Independent/External Data Monitoring Committee • Names of (vice-) chair, members and alternate members of Institutional Review Board (IRB) and Independent Ethics Committee (IEC) (Similarly for the other categories and sections)		
2	If a reviewer's guide is appended to the cover letter, it could potentially contain commercially confidential information. Proposed change (if any): In the column "Information that may be considered CCI": Reviewer's guide	Partially agreed	Sections have been merged and a reference to potential CCI was included.
4	Proposal: The application form and its annexes may contain CCI. Some information contained therein reflects the various modules of the MA application. Therefore, please refer to the appropriate sub-modules hereafter for guidance, where applicable. Rationale: The application form and its annexes may contain information which is not a repetition of elsewhere in the dossier, such as invented name (s) (if not the final authorized product name), financial details, and organizational details reflecting commercial contractual arrangements between companies and/or consultants.	Partially agreed	The text was revised to reflect this proposal.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
2	Annexes to the application form should also be addressed in that section. These documents can include CCI or PD (names and signatures). Proposed change (if any): In the column "information that may be considered CCI": Annexes to the application form (including but not limited to proof of establishment, letter of authorisation, QP declaration, manufacturing flow charts…).	Partially agreed	The text was revised to reflect this proposal.
5	Listed information that might be considered CCI could be easily redacted so that the mock-up and specimen could be included with these redactions in the EPAR.	Not agreed with	EPAR publication is outside the scope of the guidance.
5	Listed information that might be considered CCI could be easily redacted so that the mock-up and specimen could be included with these redactions in the EPAR.	Not agreed with	EPAR publication is outside the scope of the guidance.
3	There is a typo and this should be Module 1.3.4 and therefore the potential presence of PD should be re-evaluated.	Agreed	The modules were updated.
4	The module parts are incorrectly numbered in the tabular annex. The 1.4.1, 1.4.2, 1.4.3 should be corrected to 1.3.4, 1.3.5, 1.3.6 respectively.	Agreed	The modules were updated.
4	Proposal: May contain CCI Rationale: readability testing and bridging reports may reveal commercial contractual arrangements between companies and/or consultants when prepared by someone other than the MAH.	Agreed	The relevant section was updated.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	Proposal: B. PD related to staff with no legally defined responsibilities: • Name of employee, consultant or contractor • Direct contact details such as telephone number, fax number, email, postal address, IP address, etc. • Function, position, organisational entity such as department, service, etc. • Signature Rationale: readability testing and bridging reports may contain personal details of the study/report author(s).		
3	There is a typo and this should be Module 1.3.5 and therefore the potential presence of PD should be re-evaluated.	Agreed	The modules were updated.
3	There is a typo and this should be Module 1.3.6 and therefore the potential presence of PD should be re-evaluated.	Agreed	The modules were updated.
4	Proposal: A. PD related to experts or designated personnel with legally defined responsibilities: • Direct contact details such as telephone number, fax number, email, postal address, IP address, etc. • Curriculum vitae • Signature Rationale: Experts' CVs should be included as PD	Not agreed with	The annex includes a non-exhaustive list of examples. If curriculum vitae (CV), or other details on experts other than those listed, are included in this section, they will be assessed on their own merit.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	Proposal: Not expected May contain CCI Rationale: Information of experts for sections 1.4.1 to 1.4.3 is CCI when not an employee of the MAH and this should be reflected in the guideline.		
4	Proposal: A. PD related to experts or designated personnel with legally defined responsibilities: • Direct contact details such as telephone number, fax number, email, postal address, IP address, etc. • Signature B. PD related to staff with no legally defined responsibilities: • Name of employee, consultant or contractor • Direct contact details such as telephone number, fax number, email, postal address, IP address, etc. • Function, position, organizational entity such as department, service, etc. • Signature Proposal: may contain CCI. Rationale: Additional data varies, but often includes administrative documentation containing personal data and commercially confidential information similar to the application form and its annexes. It may also include	Agreed	

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	documents reflecting commercially confidential information contained elsewhere in the dossier.		
4	CCI can apply sometimes when comparative physical characteristics are detailed with batch n°, specification parameters and limits in the document. This can be applicable to complex products or biological products. Would suggest adding a note on this in the column "Information that may be considered CCI "such as: This section includes quality data that may be considered CCI. Please refer to Module 3 hereafter for guidance".	Agreed	CCI may also be present in modules other than Module 3.
4	Proposal: This section may include quality data that may be considered CCI. Please refer to Module 3 hereafter for guidance. Rationale: Commercially confidential quality details such as but not limited to (quantitative) composition, comparative dissolution profiles, impurity profiles are frequently presented in module 1.5.1/1.5.2.	Agreed	CCI may also be present in modules other than Module 3.
2	Information on the properties of the API as well as information on key degradants may be considered CCI. This should be added to the guideline.	Agreed	
3	Propose adding the following PD categories to consider for redaction in each Section C: – Patient Dates – Patient Locations – Age – Gender	Not agreed with	It is acknowledged that other quasi-identifiers could be considered for listing. However, this annex includes a non-exhaustive list of information that may be considered protected personal data based on the most frequent cases seen from regulatory authorities practice.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	– Race / Ethnicity – Anthropometric Data (BMI, Height, Weight) – Visible or identifying physical features – Medical Information (to include genetic information) Propose that all Section Cs be updated as follows: C. PD related to subjects involved in clinical trials and clinical studies: Once the risk of re-identification has been defined, the following identifiers may be considered for anonymisation: – Identification number (ID) such as subject number, patient number, case number, etc. – Patient Dates – Patient Locations – Age – Gender – Race / Ethnicity – Anthropometric Data (BMI, Height, Weight) – Visible or identifying physical features – Medical Information (to include genetic information).		
2	The list of indirect identifiers should be completed with other criteria such as size, weight, other conditions and co-medications. Proposed change (if any): -	Not agreed with	It is acknowledged that other quasi-identifiers could be considered for listing. However, this annex includes a non-exhaustive list of information that may be considered protected personal data based on the most frequent cases seen from regulatory authorities practice.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
2	The list of indirect identifiers should be completed with other criteria such as size, weight, other conditions and co-medications.	Not agreed with	It is acknowledged that other quasi-identifiers could be considered for listing. However, this annex includes a non-exhaustive list of information that may be considered protected personal data based on the most frequent cases seen from regulatory authorities practice.
5	Innovative study designs and /or innovative analytical methods should not be considered CCI.	Agreed	
4	Same comment as for 278: It would be good to add that were CCI as defined in other sections of paragraph 3, such as the full qualitative AND quantitative composition, is included in clinical trial study reports, it may be redacted.	Not agreed with	This annex includes a non-exhaustive list of information that may be considered CCI based on frequent practice as seen in examples received from regulatory authorities. Should quality information be included in this section, the justification for redaction will need to be assessed in accordance with the principles laid down in the guidance.
2	The list of indirect identifiers should be completed with other criteria such as size, weight, other conditions and co-medications.	Not agreed with	It is acknowledged that other quasi-identifiers could be considered for listing. However, this annex includes a non-exhaustive list of information that may be considered protected personal data based on the most frequent cases seen from regulatory authorities practice.

Module 2 – Common Technical Document Summaries

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
4	Agreed to state manufacturer of API for biological products.	Not agreed with	This information is usually listed in the product information (PI).
2	Some information, even at high level (such as impurities or degradants) can be considered commercially	Not agreed with	The term "Information" is too broad. Therefore, the terms "general information" and "detailed information" were added.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	confidential. This is the reason why the wording "detailed information on…" should be replaced by "information on…" in the column "Information that may be considered CCI". Additionally, the term "controls" should be defined or changed as it is too vague. As previously mentioned, information on stability of the API (studies, for example) should be considered as CCI.		Defining all terminology is not the purpose of the guidance. In general, information on the stability of the API is not CCI.
4	DS storage conditions shall be considered CCI as this information is not available from the public domain and may provide some information on cost structure of the API.	Not agreed with	In general, information on the drug substance (DS) storage conditions is available in the public domain (e.g. EPAR of the product or ICH guidelines).
2	Information of post-approval change management protocols (PACMPs) applicable to the API should also be considered CCI.	Agreed	
4	Details on process validation and number of process validation batches. Provides information on the company specific validation concept.	Partially agreed	Details on process validation may be considered CCI. However, the number of batches is considered information that may be released except if justified otherwise.
3	Proposed addition after "Partners/third parties such as suppliers, CMO, CROs, etc": "Information that may reveal strategic (contractual) agreements".	Agreed	The sentence was re-worded to reflect the proposal.
4	Propose to specifically list specification and test method. Specification can still be provided as appearance, purity, visible particles, etc. However, without specific details on e.g. potency assay.	Not agreed with	In general, information on specifications for the active substance is not considered CCI except if justified otherwise. Further details are included in section 3.1.2. of the guidance.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
2	Acceptance criteria for starting materials should also be considered as CCI. Proposed change (if any): Quantitative acceptance criteria for starting materials, intermediates and active substances.	Agreed	
2	If commercial scale is mentioned, then we should also include development scale in the scope. Proposed change (if any): Batch size/production scale (commercial scale and development scale).	Agreed	
4	Details on number and type of stability batches. Provides information on the company specific development concept – e.g. use of technical batches for justification of commercial shelf-life.	Not agreed with	In general, details on the number and type of stability batches is not considered CCI except if justified otherwise.
3	Proposed addition after "Partners/third parties such as suppliers, CMO, CROs, etc": "Information that may reveal strategic (contractual) agreements"	Agreed	The sentence was re-worded to reflect the proposal.
2	Some information, even at high level can be considered commercially confidential. This is the reason why the wording "detailed information on…" should be replaced by "information on…" in the column "Information that may be considered CCI". Additionally, the term "controls" should be defined or changed as it is too vague. As previously mentioned, information on stability of the finished product (studies, for example) should be considered as CCI.	Not agreed with	The term "Information" is too broad. Therefore, the terms "general information" and "detailed information" were added. Defining all terminology is not the purpose of the guidance. In general, information on the stability of the API is not CCI.
4	Details on process validation and number of process validation batches.	Partially agreed	Details on process validation may be considered CCI. However, the number of batches is considered information that may be released.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	Provides information on the company specific validation concept.		
4	Propose to specifically list specification and test method. Specification can still be provided as appearance, purity, visible particles, etc. However, without specific details on e.g. potency assay.	Not agreed with	In general, information on specifications for the active substance is not considered CCI except if justified otherwise. Further details are included in section 3.1.2. of the guidance.
2	If commercial scale is mentioned, then we should also include development scale in the scope. Proposed change (if any): Batch size/production scale (commercial scale and development scale).	Agreed	
4	Details on number and type of stability batches. Provides information on the company specific development concept – e.g. use of technical batches for justification of commercial shelf-life.	Not agreed with	In general, details on the number and type of stability batches is not considered CCI except if justified otherwise.
4	For Information that may be considered CCI please add: -Any quality information that might be included here may be considered CCI. Please refer to Module 3 hereafter for guidance. - Details and results from nonclinical studies on product specific impurities.	Not agreed with	This annex includes a non-exhaustive list of information that may be considered CCI based on the most frequent cases seen from regulatory authorities practice.
5	Innovative study designs and /or innovative analytical methods should not be considered CCI.	Agreed	
4	For Information that may be considered CCI please add: 1.	Not agreed with	Quality data is not expected to be found in this module. This annex includes a non-exhaustive list of information that may be considered CCI based on the most frequent cases seen from regulatory authorities practice.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	-Any quality information that might be included here may be considered CCI. Please refer to Module 3 hereafter for guidance. 2. For some Marketing authorization applications important clinical data is sourced from bibliographic references, e.g. for Well-established use applications in accordance with Article 10a of Directive 2001/83/EC or Mixed dossiers with the combination of (non)clinical data from own studies and from bibliographic references in accordance with Article 8(3) or Article 10b applications of Directive 2001/83/EC. In such dossiers bibliographic references represent only/important clinical data to fully substantiate efficacy and safety of the respective product. Compilation and critical assessment of the searched and relevant bibliographic data represent company's know-how which is crucial for obtaining a Marketing authorization. The interpretation of mentioned literature references, which enables the MA, is combination of company's experts special knowledge and experiences, which means companies also invested time and funds in them. Publication of these references would enable a simple replication of such dossier before expiry of regulatory protection (data exclusivity period) and in such way undermine the rights of the respective Marketing authorization holder and competitive position of the company. Therefore, in our opinion, the list of references		The list of published bibliographic references is not considered CCI.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	in case of WEU or mixed applications should be considered CCI. Therefore, for Information that may be considered CCI please add: -List of references in case of bibliographic applications or mixed dossiers in which bibliographic references represent the only/important clinical data on efficacy and safety of the respective product.		
4	For Information that may be considered CCI please add: - Details and results from nonclinical studies on product specific impurities.	Not agreed with	The annex includes a non-exhaustive list of information that may be considered protected personal data based on the most frequent cases seen from regulatory authorities practice.
3	Proposed addition: "Information that may reveal strategic (contractual) agreements".	Agreed	The sentence was re-worded to reflect this proposal.
5	Innovative study designs and /or innovative analytical methods should not be considered CCI.	Agreed	
3	Proposed addition in "Information that may be considered CCI" column: "Reason for withdrawal and rebound"	Not agreed with	This information is usually not considered CCI.

Module 3 – Quality

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
4	Agreed to state manufacturer of API for biological products.	Not agreed with	This information is usually listed in the PI.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
2	All the comments made in section 2.3.S/P also apply to section 3.2.S/P.	Not applicable	Acknowledged.
4	DS storage conditions shall be considered CCI as this information is not available from the public domain and may provide some information on cost structure of the API.	Not agreed with	In general, information on the DS storage conditions is available in the public domain (e.g. EPAR of the product or ICH guidelines).
6	CCI information does not include validation of analytical methods	Not agreed with	The comment is acknowledged. The proposal can be found under "Validation of the manufacturing process".
4	Details on process validation and number of process validation batches. Provides information on the company specific validation concept.	Partially agreed	Details on process validation may be considered CCI however, the number of batches is considered information that may be released.
4	Propose to specifically list specification and test method. Specification can still be provided as appearance, purity, visible particles, etc. However, without specific details on e.g. potency assay.	Not agreed with	In general, information on specifications for the active substance is not considered CCI except if justified otherwise. Further details are included in section 3.1.2. of the guidance.
4	Details on number and type of stability batches. Provides information on the company specific development concept – e.g. use of technical batches for justification of commercial shelf-life.	Not agreed with	In general, details on the number and type of stability batches is not considered CCI except if justified otherwise.
4	3.2.S.4-3.2.S.7.: It should be described that specifications, analytical methods, analytical method validation, characterization of impurities, justification of specification, information about container closure system and stability data are CCI.	Partially agreed	In general, information on specifications, analytical methods and stability data is not considered CCI except if justified otherwise. Exceptions may be considered according to the principles laid down in the guidance. It should be noted that characterisation of impurities, justification of specification and information about the container closure system is already listed in the annex.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
6	CCI information does not include validation of analytical methods.	Not agreed with	The comment is acknowledged. The proposal can be found under "Validation of the manufacturing process".
2	All the comments made in section 2.3.S/P also apply to section.	Not applicable	Acknowledged.
4	Details on process validation and number of process validation batches. Provides information on the company specific validation concept.	Partially agreed	Details on process validation may be considered CCI, however, the number of batches is considered information that may be released.
4	Propose to specifically list specification and test method. Specification can still be provided as appearance, purity, visible particles, etc. However, without specific details on e.g. potency assay.	Not agreed with	Information on specifications for the active substance is not considered CCI except if justified otherwise. Further details are included in section 3.1.2. of the guidance.
4	Details on number and type of stability batches. Provides information on the company specific development concept – e.g. use of technical batches for justification of commercial shelf-life.	Not agreed with	In general, details on the number and type of stability batches are not considered CCI, except if justified otherwise.
4	Propose to separate 3.2.A from 3.2.P. Appendices with detailed facility information e.g. floor plans should be considered CCI.	Not agreed with	The same principles apply to both sections. Details on facilities are already listed in the annex.
4	Propose to separate 3.2.R from 3.2.P.	Not agreed with	The same principles apply to both sections.
4	Propose to specifically indicate that post approval change management protocols are considered CCI. Propose to specifically indicate that the CQA assessment is considered CCI.	Partially agreed	The annex includes a non-exhaustive list of information that may be considered CCI based on the on the most frequent cases seen from regulatory authorities practice. Post-Approval Change Management Protocols (PACMPs) are already listed in the annex.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	Propose to include specific guidance on similarity assessment – i.e. list only quality attributes, analytical methods and columns similarity assessment. Quantitative data, criticalities, etc. are considered CCI.		Critical quality attributes (CQA) assessment is covered by "Detailed information in-process controls" already listed in the annex.

Module 4 – Nonclinical Study Reports

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
4	For Information that may be considered CCI please add: - Details and results from nonclinical studies on product specific impurities.	Not agreed with	The annex includes a non-exhaustive list of information that may be considered CCI based on the most frequent cases seen from regulatory authorities practice.

Module 5 – Clinical Study Reports

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
4	For Information that may be considered CCI please add: -Any quality information that might be included here may be considered CCI. Please refer to Module 3 hereafter for guidance.	Not agreed with	The annex includes a non-exhaustive list of information that may be considered CCI based on the most frequent cases seen from regulatory authorities practice.
4	For Information that may be considered CCI please add: -Any quality information that might be included here may be considered CCI. Please refer to Module 3 hereafter for guidance.	Not agreed with	The annex includes a non-exhaustive list of information that may be considered CCI based on the most frequent cases seen from regulatory authorities practice.
5	Innovative study designs and /or innovative analytical methods should not be considered CCI.	Agreed	
4	For some Marketing authorization applications important clinical data is sourced from bibliographic references, e.g. for Well-established use applications in accordance with Article 10a of Directive 2001/83/EC or Mixed dossiers with the combination of (non)clinical data from own studies and	Not agreed with	The list of published bibliographic references is not considered CCI. The purpose of the guidance is to provide high-level principles on the identification of PD and CCI, not an exhaustive list of cases/examples.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Agree / Partially agreed / Not agreed with)	Feedback (if applicable)
	from bibliographic references in accordance with Article 8(3) or Article 10b applications of Directive 2001/83/EC. In such dossiers bibliographic references represent only/important clinical data to fully substantiate efficacy and safety of the respective product. Compilation and critical assessment of the searched and relevant bibliographic data represent company's know-how which is crucial for obtaining a Marketing authorization. The interpretation of mentioned literature references, which enables the MA, is combination of company's experts special knowledge and experiences, which means companies also invested time and funds in them. Publication of these references would enable a simple replication of such dossier before expiry of regulatory protection (data exclusivity period) and in such way undermine the rights of the respective Marketing authorization holder and competitive position of the company. Therefore, in our opinion, the list of references in case of WEU or mixed applications should be considered CCI. For Information that may be considered CCI therefore please add: -List of references in case of bibliographic applications or mixed dossiers in which bibliographic references represent the only/important clinical data on efficacy and safety of the respective product.		

General comments

Stakeholder no. *(See cover page)*	Comments received	Outcome (Not applicable)	Feedback (if applicable)
2	For consistency with other CCI/PD guidance documents from EMA, there is no reference to signatures, which should be redacted, as this is personal information that may be copied. This information is listed in the Annex, but is not specified in the guidance document.	Not applicable	The body of the guidance provides high-level principles on the protection of personal data and consideration of commercially confidential information, whilst the annex provides some examples of information that may qualify as PPD and CCI, based on the most frequently seen examples from regulatory authorities practice.
3	While we understand that this guidance is intended to cover MAA dossier and dossier related disclosure deliverables across different regulations/policies, certain sections of the dossier warrant consideration for not being releasable because they meet the exceptions listed in Article 4 of Regulation (EC) No 1049/2001 given the proportion of CCI typically contained within these sections and are not in the public interest. Specifically, Modules 2.3, 2.4 and 2.6 and all of Module 3 should be considered as out of scope for access to documents or future publication policies. While we recognize that under specific policies such as the requirements under EMA Policy 0070 Clinical Data Publication these sections are out of scope for publication, we understand that in other policies such as EMA Policy 0043 these sections remain releasable. And while EMA Policy 0043 is not public disclosure per se, it poses similar disclosure risks to EMA Policy 0070 given the limited controls in place for the requestor once they receive the documents. Please consider Modules 2.3, 2.4 and 2.6 and all Module 3 as being out of scope for access to documents or future publication policies.	Not applicable	Regulation (EC) No 1049/2001 is applicable to any document held by the Agency. This includes all modules of the CTD. The annex of the guidance document was updated and includes a non-exhaustive list of information that may be considered CCI based on the most frequently seen examples from regulatory authorities practice. The guidance is also applicable to assessment reports. Please refer to the definition of "Document" on page 5 of the guidance. The terms "subjects" and "patients" have been replaced by "participants" in line with the WHO Declaration of Helsinki.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Not applicable)	Feedback (if applicable)
	The guideline provides very few specific examples on CCI. It is recommended to add some more cases for a better understanding (e.g. industry consider any information related to the manufacturing process, including analytical methods and the formulation, as CCI so any examples of where EMA deviate from this principle would be useful). In the current version of the guidance, it states that: "...The same principles for redaction of commercially confidential data and protection of personal data may therefore apply when disclosing the Assessment Reports...". This reference to Assessment Reports is not included in the draft guidance. Are Assessment Reports in-scope of this guidance? In keeping with recent proposed changes to the WHO Declaration of Helsinki, recommend using the word "participants" rather than "subjects" and "patients" to create a harmonised and neutral vocabulary.		
4	Innovative non-/clinical study design: studies that do not follow guidelines and/or require consultation with regulatory authorities (SciAdv) that have an innovative design. • The draft guidance will provide more clarity on PPD and CCI, which may lead to efficiencies and reducing timelines at the health authorities when processing information requests from stakeholders. For the generic industry it is	Not applicable	Acknowledged.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Not applicable)	Feedback (if applicable)
	especially important to get non-confidential information from the reference products in a timely manner to facilitate appropriate generic and biosimilar development and to increase affordable access to medicinal products.		
5	We welcome the provision that any request for the redaction of CCI has to be assessed by EMA/NCA. We also support that any request for redaction has to be properly justified with an explanation on how access to the information could undermine the economic or competitive interest. The redaction should only be accepted provided it is properly justified after an independent analysis by EMA. It would be helpful to include in the guideline lessons learnt from disclosure disputes on access to information /documents and the solutions applied. There is an increasing trend for the consideration of innovative study designs. This could disrupt the current regulatory process of the marketing authorisation process. New study designs are increasingly used for rare diseases, paediatric medicines, cell and gene therapies, personalized treatments, etc. The description of the design and the analytical method of a study, would they be innovative or not, is necessary for assessing the meaning of the results. Innovative study designs are linked with increased uncertainty on the evidence of benefits and risks. Information on these aspects is crucial for healthcare professionals, patients and the public health community. This is needed to have a full picture on	Not applicable	In relation to the proposal to include lessons learnt from disclosure disputes on access to information/documents and the solutions applied please note that, although not considered lessons learnt *per se*, the annex is based on EMA/NCA practice that has also stemmed from disclosure disputes on access to documents/information. In relation to innovative study designs, these are not considered CCI by default; they may be considered CCI upon assessment when duly justified by the third party.

Stakeholder no. *(See cover page)*	Comments received	Outcome (Not applicable)	Feedback (if applicable)
	evidence on benefits and risks of medicines, uncertainties on the evidence and trust in decision making. We therefore call on not to consider innovative study designs and /or innovative analytical methods as CCI.		
8	Thank you for the possibility to review the guidance. We have no comments to the guidance body or appendix but in general, a lot of the information listed for considerations as PPD/CCI is listed in documents / modules not intended for publication, and thus it would be helpful if it also is clarified which documents in the dossier are/will be made public. We find it very helpful that PPD/CCI is listed in e.g. module 3 so MAH might know what to look out for in other CTD modules.	Not applicable	Defining which documents shall be made public is not within the scope of the guidance. Regulation (EC) No 1049/2001 is applicable to any document held by the Agency. This includes all modules of the CTD.