HMA/EMA guidance document on the identification of personal data and commercially confidential information within the structure of the marketing authorisation application (MAA) dossier

	Line number(s) of the relevant text (e.g. 20-23)	Comment
1	General	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.
2	General	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).
3	General	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 This reference to Assessment Reports is not included in the draft guidance.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?
4	General	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.
5	Lines 89 - 93	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 redactions, propose the following

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		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.
6	Line 96	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"
7	Lines 120 - 122	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-european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use-version-14_en.pdf
8	Lines 160 - 164	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

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		respect to aspects of the MAA dossier (e.g., 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.
9	Lines 164 - 167	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, 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

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		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.
10	Lines 172 - 175	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.
11	Line 177	The text mentions “pseudo-anonymised” data and may be confusing. GDPR uses the term “pseudonymised.” Replace “pseudo-anonymised” with “pseudonymised.”
12	Lines 208	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. 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.
13	Lines 217 – 219	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.
14	Lines 283 - 285	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.

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		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.
15	Line 289	While the outcome of an inspection is publicly available, such outcome may be 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 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.
16	Lines 291 - 296	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.

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17	Lines 297 - 301	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 have not yet received regulatory approval (i.e. new indications, formulations, dosages, polymorphs, combinations, biomarkers etc.) should be protected and treated as CCI.
18	Lines 302 - 306	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.

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19	Lines 350+	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 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)

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		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 • 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)
20	1.4.1	There is a typo and this should be Module 1.3.4 and therefore the potential presence of PD should be re-evaluated.
21	1.4.2	There is a typo and this should be Module 1.3.5 and therefore the potential presence of PD should be re-evaluated.
22	1.4.3	There is a typo and this should be Module 1.3.6 and therefore the potential presence of PD should be re-evaluated.
23	1.8.2 and others	Propose adding the following PD categories to consider for redaction in each Section C: − Patient Dates − Patient Locations − Age − Gender − 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: 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.

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		– Patient Dates **– Patient Locations** – Age – Gender – Race **/ Ethnicity** **– Anthropometric Data (BMI, Height, Weight)** **– Visible or identifying physical features** **– Medical Information (to include genetic information)**
24	2.3.S.7	Proposed addition after "Partners/third parties such as suppliers, CMO, CROs, etc": "Information that may reveal strategic (contractual) agreements"
25	2.3.R	Proposed addition after "Partners/third parties such as suppliers, CMO, CROs, etc": "Information that may reveal strategic (contractual) agreements"
26	2.6.1	Proposed addition: "Information that may reveal strategic (contractual) agreements"
27	2.7.0	Proposed addition in "Information that may be considered CCI" column: "Reason for withdrawal and rebound"