Draft advice to the European Medicines Agency from the clinical trial advisory group on legal aspects

Meeting 1 and 2 Comments submitted

Date received	Name	Affiliation	Comments
30/01/2013	Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians UK	Healthcare professionals' organisation	CCI: EMA must conduct a case-by-case analysis noting Art. 4(2) Reg. 1049/2001 and the obligation to protect CTd pursuant to Art. 39.3 TRIPS (balance of the public interest test)
30/01/2013	Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians UK	Healthcare professionals' organisation	CCI: IPR - disclosure of CTd can affect the validity of filed patent rights (see T-0007/07 Bayer Pharma)
30/01/2013	Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians UK	Healthcare professionals' organisation	CCI: EMA should follow the conclusions of complaint EO 2560/2007/BEH - proportionate approach to ATD requests. Given that most of ATD requests are filed by competitors, info of a CC nature or where disclosure could prejudice the protection of IPR should not happen unless an overriding public interest is present
30/01/2013	Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians UK	Healthcare professionals' organisation	Copyright: EMA should adopt a licensing regime whereby a liited license is granted to use only the data for non-commercial purposes and only limited to assessing the benefit-risk balance of the authorised product; on the contrary, EMA could be breaching the copyrights of the appicant's documents, and even contributing to the copyright breach caused by the third party (contributory liability)
08/02/2013	Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians UK	Healthcare professionals' organisation	CCI: Specific claims to confidentiality on the basis of unfiled patent applications must be properly considered on a case-by-case basis. Information re inventions can be found in CTd and non-clinical study data and it's possible that these investions come up as a result of info analyses that take place after the MA submission. EMA's policy will prejudice later filings on subsequent inventions made on known products.

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08/02/2013	Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians UK	Healthcare professionals' organisation	CCI: The effect of the point above is that applicants will start to consider whether it's worth submitting MA applications in the EU or alternatively in other countries and subsequently in the EU only once it has accrued all the possible value from the CTd generated to back MA applications: this will as a result delay progress of meds into the EU market - a solution would be that EMA created templates to avoid MA being subject to applicant's copyright. But in general EMA should seek legal advice to ensure that copyright is not breached in any instance!
08/02/2013	Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians UK	Healthcare professionals' organisation	CCI: EMA's pro-active disclosure of CTd and non-clinical study data entails the risk that a host of sponsored further analyses and conflicting messages are published.
30/01/2013	Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians UK	Healthcare professionals' organisation	LR: EMA should introduce an in-house formal appeal hearing sytem to hear claims about commercial confidentiality.
08/02/2013	Prescrire	Healthcare professionals' organisation	General: EMA to publish in its website audio files and written contributions to the WG discussions.
08/02/2013	Prescrire	Healthcare professionals' organisation	CCI: No CCI in CTd - industry has failed to provide examples for exceptional circumstances where CCI can be claimed.
08/02/2013	Prescrire	Healthcare professionals' organisation	CCI: Helsinki Declaration 2008 supports the publication of CTd; EU Ombudsman has ruled that there are no pre-conditions for citizens to access these data, raw data included; it will also benefit competitiveness of the pharma industry.
08/02/2013	Prescrire	Healthcare professionals' organisation	CCI: CTd publication will allow independent analysis by researches, and avoid publication bias and the withholding of important info to avoid selective publication.
08/02/2013	Prescrire	Healthcare professionals' organisation	CCI: Sponsor should provide a detailed, well-substantiated explanation of why the publication of data would prejudice their commercial interests at the time of providing EMA with the data, and this would never apply to an entire document; the CCI protection should be temporary and never unlimited in time.
08/02/2013	A.R.C. Pharma	Consultant	Copyright: using a symbol or other system to anticipate future usage.
08/02/2013	A.R.C. Pharma	Consultant	CCI: how to prevent possible issues from a "Big Data"

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			perspective and future negative "data mining" among all available data
08/02/2013	A.R.C. Pharma	Consultant	Unspecified: To whom does the data published belong?
08/02/2013	Mr Trudo Lemmens (HeLEX Centre for Health, Law, and Emerging Technologies. University of Oxford)	Academia	CCI: CTd are a public good intended for the public interest and not to protect corporate interests. Human rights re data transparency must be a consideration. Meta-analysis and confirmation of claims about safety and efficacy serves an important public purpose.
08/02/2013	Mr Trudo Lemmens (HeLEX Centre for Health, Law, and Emerging Technologies. University of Oxford)	Academia	CCI: full transparency has shown to be necessary to ensure CTd reliability; it also serves purposes of public accountability of the regulatory system itself.
08/02/2013	Mr Trudo Lemmens (HeLEX Centre for Health, Law, and Emerging Technologies. University of Oxford)	Academia	CCI: Patent protection and data exclusivity already allow companies to recoup their investments.
08/02/2013	Mr Trudo Lemmens (HeLEX Centre for Health, Law, and Emerging Technologies. University of Oxford)	Academia	CCI: clear, specific examples of negative commercial impact of data disclosure must be given in order to allow an informed discussion on CCI. They're also needed in the case of how data sharing by EMA could affect data exclusivity claims in other countries.
08/02/2013	Mr Trudo Lemmens (HeLEX Centre for Health, Law, and Emerging Technologies. University of Oxford)	Academia	CCI: contractual obligations entered into by sponsors cannot prevent disclosure as regulatory requirements can override specific clauses in informed consent forms; moreover, invoking sponsors' and researchers' commitments to patients re limited use of data and non-disclosure is again problematic; the same can be said of invoking respect of patients and their privacy interests as a ground to limit disclosure.
08/02/2013	BIA	Industry	CCI: EU CT Register and EPAR are two among many provisions already in force providing for transparency and info to the public. A balanced view should be taken to ensure a fair approach to transparency which does not undermine Europe's international competitiveness. Partnerships among a broad number of stakeholders is underpinned by protection of know-how, whose loss would dramatically impact upon investment into the sector.

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08/02/2013	BIA	Industry	CCI: companies in the life sciences sector incur in huge and increasing costs to develop new products and research, and companies take care to avoid such info being available to competitors. Pharmaceutical, non-clinical and clinical development data are generated through those partnerships and are considered as valuable assets and ordinarily protected from disclosure or cross-referencing by third parties through a period of regulatory data protection. It is also expected that confidential nature of certain info (manufacturing and control of the product and detailed pre-clinical testing and clinical strategic plan) is respected by the authorities during the regulatory review.
08/02/2013	BIA	Industry	CCI: Unlike patents, enforcement of regulatory data protection is the responsibility of the regulatory authorities. Such info is submitted to the authorities as part of, and solely for, the granting of a MA. Such data protection is important particularly where strong patent protection for a particular product/indication is not available. Art 10(1) Dir 2001/83 and Art 14(11) Reg 726/2004 provide for such a regulatory data protection upon granting of a MA.
08/02/2013	BIA	Industry	CCI: even if the MAA has been withdrawn or refused, the research data can be useful to competitors in the same therapeutic area, and hence the originator will be put at a disadvantageous position is this info is made public.
08/02/2013	BIA	Industry	CCI: EMA must consult the data holders as to disclosure and what form of disclosure it intends to conduct.
08/02/2013	BIA	Industry	LR: a robust procedure should be put in place to seek legal remedies in the event of disagreement.
08/02/2013	EUCOPE	Industry	CCI: EUCFOPE is fully supportive of EMA's transparency policy but it must be borne in mind that at present a large amount of info is publicly available (EudraCT and EPAR)
08/02/2013	EUCOPE	Industry	CCI: However, EMA must ensure that the commercial interests of MAH are protected and it should accordingly establish safeguards, e.g.: a) EMA to recognise that CTd contain info which form the basis of IPR; b) the publication of info contained in a MA is not generally justified by an overriding public interest in disclosure; c) know-how and trade secrets re manufacturing

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			and technological approaches are of crucial value: if not duly protected, CT will tend to be conducted in 3rd countries in order to protect innovation and IPR which in turn would contradict the CT proposed Directive to improve the legal framework for CT in the EU; d) if made public, CT info could be used in 3rd countries where data exclusivity rights donot or hardly apply and hence the very nature of data exclusivity would be undermined.
08/02/2013	EFPIA	Industry	CCI: innovation, research and development of new meds will be supported if transparency is balanced with due protection of CCI.
08/02/2013	EFPIA	Industry	CCI: EMA should not *prima facie* assume that data is not CCI without considering the particular data; there is no overriding public health benefit in disclosing CCI info if it is going to be used by competitors.
08/02/2013	EFPIA	Industry	CCI: EMA should not disclose documents before the granting of a MA.
08/02/2013	EFPIA	Industry	CCI: both PPD and CCI considerations to be taken into account to adopt EMA's policy on transparency; also the terms of consent given by CT subjects as an ethical/medico legal issue; also IPR and database protection rights. Under the existing PPD legislation any use and disclosure of PD must have been expressly consented to by the individual CT subject.
08/02/2013	EFPIA	Industry	CCI: CCI is info that is a) confidential as a results of steps taken to maintain its confidentiality, and b) disclosure of which could undermine the economic interest orf competitive position on of the MAH - hence EMA to should disclose this info only where there is an overriding public interest for doing so and release only the precise information needed to serve that interest and under conditions which serve that interest: consultation with the MAH is therefore always necessary. Furthermore, Art. 4 of the Transparency Regulation No. 1049/2001 expressly provides that access to a document shall be refused where disclosure would undermine the protection of "the commercial interests of a natural or legal person, including IP".
08/02/2013	EFPIA	Industry	CCI: Any access to CTd should be provided within an appropriate framework which ensures that that overriding public interest is served and that the data are appropriately used and protected in

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			terms of data privacy, IP and CCI considerations. The terms on which such access to CCI are provided should therefore be based on the nature and purpose of the request for data and be accompanied by appropriate safeguards to prevent CCI and IP being undermined by preventing further disclosure and use of the data. Of course, there should be no disclosure of CTd which compromises PPD.
08/02/2013	EFPIA	Industry	CCI: the legally required protection of CCI requires a 3-tier approach: a) adequate procedural guarantees; b) proper review of what data are CCI (including MAH consultation), and c) no disclosure before granting of MA.
08/02/2013	EFPIA	Industry	CCI: there should be a presumption that MA dossiers may contain CCI and a detailed and case-by-case analysis is hence required. MAA dossiers and CT study reports may contain info re the status of ongoing or planned studies, rationales of study designs and protocols, info and conclusions re data sets, stats analyses and methods, etc. Depending on certain considerations, certain elements of a MAA dossier may constitute CCI. Hence, a MAH's views on these concerns should be respected by EMA. However, the presumption may be rebutted with convincing evidence after a case-by-case assessment. As a conclusion, transparency measures must not undermine the IP or regulatory data protection rights which exist to encourage and safeguard the innovative R&D of medicines.
08/02/2013	EFPIA	Industry	CCI: Art 39.3 TRIPS describes the EU's obligation to protect proprietary data from disclosure and unfair commercial use. Both non-clinical and CTd are undisclosed test data, the origination of which involves a considerable effort, falling within Art 39.3 and hence EMA must keep them confidential unless an overriding public interest is present or EMA takes steps to prevent its unfair commercial use. In this regard, Reg 1049/2001 must be interpreted in line with EU's int'l obligations.
08/02/2013	EFPIA	Industry	CCI: EMA must respect legitimate expectations of MA applicants, and any new policy should only apply to data collected after adoption of such policy, on a clear legal basis, and not retroactively to data submitted under a prior expectation of

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			protection.
08/02/2013	EFPIA	Industry	Regulatory data protection (RDP): is a vital incentive for the conduct of R&D. Proactive broad disclosure of data will undermine data exclusivity and support competitor MA applications, potentially in the EU and especially elsewhere, by allowing third parties to circumvent existing RDP rules or take advantage of the absence of such rules. Hence EFPIA does not agree with HMA/EMA recent policy to generally consider non-clinical studies and CSRs as non-CCI and therefore disclosable. As such, the EMA should put into place a fair and robust process to disclose this info, involving the MAH and relying upon a case-by-case analysis, which takes into consideration the nature of the info, the proposed recipient and the purpose for disclosure.
08/02/2013	EFPIA	Industry	Patents: the filing of patents in various countries will be put at risk if CTd info is made public, hence prior consultation with the MAH is essential.
08/02/2013	EFPIA	Industry	Copyright: EMA must respect the copyrights of pharma companies and third parties, so the choice of access to docs should be the one which does not infringe these rights, for instance access on the spot rather than sending a hard or electronic copy of the documents. This also precludes proactive transparency of protected documents without consent of the right holders.
08/02/2013	EFPIA	Industry	LR: meaningful consultation between EMA and MAH and no release of EMA decision without giving the MAH the opportunity to seek legal relief/annulment.
08/02/2013	EFPIA	Industry	LR: given that CCI may be present in CTd, consultation with MAH always necessary unless the MAH in advance indicates that there is no confidentiality concerns.
08/02/2013	EFPIA	Industry	LR: in case of disagreement, the MAH must have the opportunity to take legal action in the ECJ, but the current 10-day policy is too short: it should be extended to the standard 2 months and 10 days to be in line with actions for annulment (justified by the general principle of effective legal remedies, Art 47 Charter of Fund Rights). Consideration should be given for an independent

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			review of the decision for disclosure conducted by a neutral third-party, as a means to reduce actions before the ECJ.
11/03/2013	CBG-MEB	Government Authority	Existence of a democratic right for openness and transparency.
11/03/2013	CBG-MEB	Government Authority	CCI: Directive and Regulation on medicines need a provision in which applicants for a marketing authorization have to file an application/dossier in twofold, one complete (confidential) version and a public version in which commercially and privately confidential information has been deleted (the same procedure as with novel foods).
11/03/2013	CBG-MEB	Government Authority	CCI: Clinical trails (and other documents) are wholly open to the public, unless it is motivated that some parts are confidential. No precise legal argumentation has been presented so far in this group that parts have to be treated as confidential.
13/03/2013	Covington & Burling LLP (Mr Peter Bogaert)	Law firm	CCI: EMA has historically recognised that preclinical and clinical data and information submitted in a MAA are confidential commercial information that may not be released under the Transparency Regulation. But following a non-binding decision of the Ombudsman in 2010, it released a final guidance document taking the unprecedented position that the clinical and non-clinical modules in MA dossiers are not presumptively confidential. for a number of reasons, explored below, the EMA should rescind the March 2012 guidance and consider alternatives to the proactive framework under discussion, such as private access conditioned on confidentiality agreements, in order to resolve the troubling consequences that may arise.
13/03/2013	Covington & Burling LLP (Mr Peter Bogaert)	Law firm	CCI: The clinical and non-clinical data submitted by innovator companies to the EMA for MA constitute presumptively confidential commercial information, as they do not only contain personal , private details about individual patients but also comprehensive information about the innovator's CT design and product development strategy, and his confidential strategies for managing its clinical development program. Furthermore, the documents contain the necessary information to obtain a MA and thus intrinsically are valuable.

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13/03/2013	Covington & Burling LLP (Mr Peter Bogaert)	Law firm	CCI: this information must remain confidential for several reasons, inter alia: a) in several cases, the Court of Justice has held that there exists a general presumption that documents submitted by a party to a specific administrative procedure that strikes a balance between transparency and confidentiality fall under Article 4(2) of Regulation 1049/2001 *(Case C-139/07 P, Commission v Technische Glaswerke Ilmenau GmbH [2010] ECR I-05885; Case C-404/10 P Commission v Éditions Odile Jacob, Judgment of 28 June 2012 (not yet published in ECR); Case C-477/10 P, Agrofert Holding v Commission, Judgment of 28 June 2012 (not yet)published in ECR);* this presumption is automatic, not optional, and does not require an examination of each individual document in order to be triggered; b) making available this information risks eliminating protections designed to incentivise the development of innovative products; making CTd available would facilitate the circumvention of existing data exclusivity provisions, rendering them ineffectual. For instance, in Australia legislation provides 5 years of data exclusivity to certain active components of new therapeutic goods, as long as the information is "not available to the public". The elimination of this protection would enable competitors to receive regulatory approval and to market the same medicines before the innovator company has a chance to recover its substantial investments in research and development, so in the long run innovators would be left with little inducement to undertake the immense expenditures necessary to develop new cures and treatment options for patients; c) proactive publication would allow competitors to reap the benefits of the innovator's expertise in the field and to improve the marketing position of their own products: this is supported by the fact that the vast majority of requests for access to documents received by the Agency, are from industry competitors; d) if EMA releases confidential non-clinical and clinical trial information, it would violate the EU's treaty obligations and potentially undermine European trade interests in the world. Article 39(3) TRIPS, as recognised by the European Commission in a report about Turkish trade practices,

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			prohibits disclosure of the precise confidential commercial information that the EMA now envisions releasing
13/03/2013	Covington & Burling LLP (Mr Peter Bogaert)	Law firm	Copyright: access on the spot rather than sending copies of documents should be favoured, in order to cause the least interference with copyright or data bse rights.
13/03/2013	Covington & Burling LLP (Mr Peter Bogaert)	Law firm	CCI: the release of CT reports and other CT data raises significant data privacy concerns. Even though the information submitted to the EMA does not contain personal identifying information in the conventional sense, i.e. legal names or birthdays, recent studies have found that the analysis of "anonymous" biological samples, such as a patient's DNA, can allow third parties to identify the patient's identity with the help of public databases. Because clinical studies can include biological information about a participant in an innovator's clinical trial, the disclosure of these data facilitates the exposure of patients' identities. This would violate their reasonable expectation of privacy in their medical information and would presumably extend far beyond the scope of any informed consent provided in the CT context.
13/03/2013	Covington & Burling LLP (Mr Peter Bogaert)	Law firm	CCI: Because the data and information in the non-clinical and clinical modules of MAA submitted to the EMA are presumptively confidential commercial information, the EMA may release them only if the requestor shows an overriding public interest in their release. This interest must be clear and actual, not speculative. It must also be a public interest, rather than a private commercial interest. The interest in transparency cannot itself be an overriding public interest outside of the legislative context, unless the circumstances of the particular case are "especially

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			pressing". Furthermore, the calculus of both public and private interests weighs strongly against implementing the EMA's guidance document. Although there is a relevant public interest in transparency, Regulation 726/2004 already provides a comprehensive set of transparency measures, making documents available to the public and healthcare professionals in the interest of public health. Specifically, the disclosures currently made through EPAR and product labeling advance the public interest by ensuring the availability of information regarding the essential aspects of medicines that are on the market
	Covington & Burling LLP (Mr Peter Bogaert)	Law firm	CCI: A proactive disclosure policy would require a clear legal basis and this is currently not the case under Regulation 726/2004 or under the Transparency Regulation
15/03/2013	European Ombudsman	Government Authority	CCI: Conditional access to documents could not be understood as an alternative to public access under Regulation 1049/2001, but rather as being complementary to it. A proactive disclosure policy based on need, and subject to a limitation of use, would only, however, be a useful complement to public access under Regulation 1049/2001 in those cases where that proactive policy would give broader access than is possible under Regulation 1049/2001 (such as where it could give rise to a release of documents which could not be released under Regulation 1049/2001 because of, for example, the application of the exception on the protection of commercial interests). However, there would be serious practical problems related to how such a system of broader privileged access would apply (for example, how would the conditions imposed on researchers be applied and who would enforce them).
15/03/2013	European Ombudsman	Government Authority	CCI: If the proactive disclosure policy were only to give more limited access than is possible under Regulation 1049/2001, it could be, legally, circumvented through making requests for public access under Regulation 1049/2001. Therefore, a proactive policy should be consistent with Regulation 1049/2001: documents should be released proactively if they would in any case be released subsequent to a request made

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			under Regulation 1049/2001.
15/03/2013	European Ombudsman	Government Authority	CCI: Regulation 1049/2001, correctly applied, allows for the redaction of commercial information if the disclosure of that information would undermine the protection of legitimate commercial interests (Article 4(2), first indent of Regulation 1049/2001). It is for EMA, with whom the burden of proof lies, to show that the exception applies. It should be recalled, in this regard, that the examination to be carried out in order to determine if an exception under Regulation 1049/2001 applies must be specific in nature. It must be reasonably foreseeable and not purely hypothetical that disclosure of the document would harm the protected interest.
15/03/2013	European Ombudsman	Government Authority	CCI: If a company is of the view that Article 4(2), first indent of Regulation 1049/2001 applies to all, or parts, of the documents it is submitting to EMA, it should explain to EMA why this is the case. It may also be asked by EMA to do so, if EMA consults the company under Article 4(4) of Regulation 1049/2001, following a request for public access. The company should indicate specifically what information would be of use to competitors to an extent which would meet the test described above. But even if EMA determines that disclosure of the documents in question would undermine the protection of commercial interests, the documents must be released if there is an overriding public interest in disclosure. Such a public interest could, for example, relate to the protection of public health.
15/03/2013	European Ombudsman	Government Authority	CCI: In terms of legitimate expectations, one should note that the rules on public access to documents apply to documents held by EMA and those rules have not changed since Regulation 1049/2001 became applicable to EMA. A company cannot rely on its lack of knowledge of the law to base a claim of legitimate expectations.
15/03/2013	European Ombudsman	Government Authority	LR: EMA is empowered under Regulation 1049/2001 to determine whether documents should be made public. Any decision to abdicate this role to a third party would be contrary to the Microsoft ruling of the General Court, in which the Court

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			said that the Commission's DG Competition could not transfer its powers to a third party (paras 1251-1279 of Case T-201/04 Microsoft v Commission)
15/03/2013	EUCOPE	Industry	CCI: Whereas EMA in the past has explicitly acknowledged that unrestricted and easy access to CTd might be a risk for patient confidentiality, the issue of commercial confidentiality has not been sufficiently addressed so far. The Agency has to ensure that not only information held on patients but also the commercial interests of sponsors and MAH are protected. Thus, it has to refuse access where disclosure would undermine the protection of commercial interests, including intellectual property rights. Consequently, it is crucial that the Agency establishes safeguards to protect these interests before it starts making documents publicly available.
15/03/2013	EUCOPE	Industry	CCI: EMA must acknowledge that cCTd has to be considered commercially confidential not only in exceptional circumstances: know-how and valuable intellectual property especially regarding the manufacturing, certain technological approaches and certain data in the development of an innovative medicinal product are often part of the data submitted by the applicant for a marketing authorisation. Therefore, EMA's view outlined in the HMA/EMA Guidance Document is not correct. EMA must also bear in mind the European Commission's recent view as expressed in atrade dispute with Turkey, where it stated that "keeping valuable information secret is often the only or the most effective way that companies have to protect their intellectual property". In this regard, the HMA/EMA guidance document the Agency itself has explicitly acknowledged that commercially confidential information has to be protected and stated that commercially confidential information is considered to be any information, including know how, trade secrets and information which is not in the public domain or publicly available and where disclosure could undermine or damage the economic interest or competitive position of the proprietor of such information.

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15/03/2013	EUCOPE	Industry	CCI: A MAA includes, inter alia, details of manufacturing and bioanalytical methods; details of specific formulation, and information and data relating to experimental design, methodologies, and patient disease diagnosis. Disclosure of such data which is, in general, not in the public domain, would doubtlessly undermine and damage the interests of the proprietor of such information. Competitors would benefit from access to this data by avoiding the investment in own experiments. In this regard, the European Court of Justice has underlined in its decision of 6 December 2012 that where applications for marketing authorisations in the abridged procedure are concerned, national authorities do not disclose clinical data to applicants (although they benefit from these data after the expiry of the data exclusivity period) and therefore do not prejudice its confidentiality (Case C-457/10 P, at no.152). The Court assumes that clinical data may contain commercially confidential information which should be protected from disclosure.
15/03/2013	EUCOPE	Industry	CCI: The EU is obliged to protect undisclosed test or other data under Article 39.3 (TRIPS which forms, according to the Court of Justice, an integral part of the Community legal order
15/03/2013	EUCOPE	Industry	CCI: In line with Article 4(4) of Regulation 1049/2001, the consultation of the MAH by EMA is an important step in assessing whether or not data submitted in the authorisation process contain commercially confidential information that was previously unpublished and would be valuable in the hands of competitors. Therefore, the consultation of the MAH before disclosure must remain mandatory not only where third parties' request access to this information but also where the information is proactively disclosed by the Agency.

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15/03/2013	EUCOPE	Industry	CCI: EMA has to take into consideration that the publication of commercially confidential information contained in the MA is not generally justified by an overriding public interest in disclosure. Publication as such does not necessarily lead to an improvement of public health. It is therefore vital that the Agency assesses whether or not information may be made publicly available. The use of such data by competitors of the MAH can never establish an overriding public interest in the publication of these data due to its pure commercial intent. Furthermore, know-how and trade secrets especially regarding the manufacturing and technological approaches in the development of an innovative medicinal product are of crucial value for the development of new medicinal products. Without any protection of this value innovation might be impeded significantly. Clinical trials would be conducted in third countries in order to safeguard the innovation and the intellectual property. This would contradict the main objective of the current Commission proposal on clinical trials (COM(2012) 369), namely to improve the legal framework for clinical trials within the EU in order to increase the number of trials performed within the Union and to support clinical research and development. The public interest in an improvement of the conditions for research and development of innovative medicinal products has to be taken into account when assessing whether or not clinical trials data may be disclosed.
15/03/2013	EUCOPE	Industry	CCI: Additionally, the use of disclosed CTd by competitors would grant them an unfair advantage of the substantial investments the MAH has made in the development of a new product. Competitors could avoid conducting their own clinical trials and instead use the data disclosed by the Agency for obtaining marketing authorisations either within the EU and/or in third countries.
15/03/2013	EUCOPE	Industry	CCI: The Agency has to assess on a case-by-case basis whether or not a disclosure of commercially confidential data is justified under exceptional circumstances, and cannot rely on the general and unsubstantiated assertion that publication of clinical trials

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			data is in any case justified by an overriding public interest.
15/03/2013	EUCOPE	Industry	CCI: Data contained in a pending marketing authorisation procedure should not be disclosed as this could undermine an independent decision making process. This general rule is included in Article 4(3) of Regulation No. 1049/2001. Any EMA policy should reflect the principles of the access-to-documents legislation of the European Union
24/03/2013	Ropes & Gray LLP	Law Firm	The patient privacy group appears not to be focusing on the issue of patient/research participant consent and notification regarding CTd transparency. This is a critical issue that must be addressed in any EMA guidance or rules. Issues relate both to prospective consenting of participants in ongoing and future trials, as well as retrospective – i.e., how can these data be made available when past participants were never advised of these uses of their data
24/03/2013	Ropes & Gray LLP	Law Firm	CCI: some countries, as a precondition of allowing researchers to undertake trials within their jurisdictions, have required that there be no secondary research uses of participant data without additional permissions from national authorities, and or unless their own native citizen-scientists are included as co-authors on additional publications that have re-used participant-level data. These issues are not related to copyright- they are instead related to national concerns about how participant-level data of their citizens may be re-used in ways that could reflect badly on the country and or its own researchers. Therefore, if the EMA were to bind pharma to make participant-level data available from completed CT used to support EMA applications, then this could effectively conflict with the conditions under which some trials were done in various non-EU jurisdictions. It is also possible that some IRBs or RECs or research institutions might place similar restrictions on trials done under their jurisdiction – in which case, the EMA might effectively be imposing data transparency requirements that could conflict the original terms of approval of the trials themselves.

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28/03/2013	European Ombudsman	Government Authority	CCI: If Article 4(2) first indent of Regulation 1049/2001 is to apply, it must be reasonably foreseeable, and not purely hypothetical, that disclosure of the document would undermine the protection of the legitimate commercial interests of the company that has submitted the CTD. It is reasonably foreseeable that a pharmaceutical company producing a competing molecule will seek public access to the CTD of a competitor to identify possible errors in that CTD and in the EMA analysis of the CTD. It is also reasonably foreseeable that a pharmaceutical company producing a competing molecule will seek public access to the CTD of a competitor to identify possible inconsistencies in the manner in which its competitor markets its product, or in the manner in which that product is analysed in scientific journals. finally, it is also reasonably foreseeable that the pharmaceutical company in question would seek to publicise any inconsistencies that they identify. Those very same points could be made as regards independent researchers, who are likely to request access to CTDs to identity such inconsistencies and to publicise them. Therefore, a pharmaceutical company cannot maintain that it has a legitimate commercial interest in ensuring that deficiencies in its CTD remain undiscovered, or that claims made in relation to its products cannot be cross checked with the CTD. Hence, it should be noted that when examining whether there is an overriding public interest in disclosure, it should be borne in mind that there is a public interest in ensuring that the public access that is given results in those parties that have both an interest in identifying deficiencies from CTDs, and the technical capacity to identify such deficiencies, having access to CTDs. Parties that are both capable of identifying deficiencies in CTDs, and are interested in doing so, are, potentially, independent researchers, but also competing pharmaceutical companies. Thus, if an inference can be drawn from the fact that competing pharmaceutical companies request public access to CTDs, it is that such access is likely to improve the protection of public health.

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28/03/2013	European Ombudsman	Government Authority	CCI: EMA constantly informs interested parties as regards how best to present requests for MA. It should do so because there is a public interest, in terms of improving public health, in ensuring that marketing authorisations are refused not on the basis of formal deficiencies in the manner in which a dossier is submitted, but rather on the basis of the substantive content of a dossier. The, it is unlikely that the structure of any particular dossier would be commercially sensitive as any information to be gleaned from it in terms of how it is presented could and should in any case be validly provided to the pharmaceutical industry by EMA. As a result, there is a public interest in ensuring that medicinal products used to treat illnesses in humans are not rejected on the basis of formal structural defiencencies.
28/03/2013	European Ombudsman	Government Authority	CCI: It is possible to envisage that the disclosure of a CTD before an MA has been granted could raise concerns; however, after an MA has been granted, it is difficult to imagine how the CTD, on which the MA is based, could be of strategic and operational use to a competing pharmaceutical company. All competing pharmaceutical companies will, through the MA, (which is made public by EMA) be able to estimate when a competing product might arrive on the market and what characteristics that product will have. In order for this argument to be sustained, it would have to be shown, on a case by case basis, that the CTD for a specific product would reveal details of what other products would be developed (in sum, such an arguement could never form the basis for a general presumption that the exception would apply to CTDs as a category of document).
28/03/2013	European Ombudsman	Government Authority	It has been argued that generic manufacturers will use a CTD to get an MA in those jurisdictions where there is no patent protection. It has not, however, been shown that the regulatory authorities in any such jurisdiction even require a detailed CTD to obtain MAs. If it were the case that they would currently demand a detailed CTD in order to grant an MA, this would surely imply that generic manufacturers would not be able to get MAs in those jurisdictions today. However, the reality would

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			appear to be that these generic manufacturers can obtain such MAs today, thus implying that they have no need for a CTD to obtain such MAs. This argument would thus appear to be entirely devoid of a factual basis.