



Response to the HMA/EMA Guidance document on the identification of Commercially Confidential Information and Protection of Personal Data within the structure of the Marketing Authorisation (MA) Dossier – Release of information after granting of a Marketing Authorisation

31 August 2011

Summary

HAI Europe and MIEF welcome the initiative to comment on the HMA/EMA guidance document on the identification of Commercially Confidential Information and Protection of Personal Data within the structure of the Marketing Authorisation (MA) Dossier. We have, however, identified serious shortcomings in the guidance document.

Public accountability of regulatory decisions is only possible if the public has access to the evidence on which those decisions are based, and is provided with a rationale for decisions.

There is an inherent risk that vital information of public relevance, would remain inaccessible to the public, were such a draft guidance document to be approved. When medicines agencies fail to publicly disclose important safety information to potential users and the public at large, they also fail to fulfill their mandate to contribute to rational medicine use, safeguarding and upholding public health.

Lack of full public access to the body of available scientific evidence about the effects of medicines on human health leaves European citizens at greater risk for otherwise preventable harm. This is unacceptable. A broad definition of commercial confidentiality that puts commercial interests before human health is both inconsistent with EU regulations and almost certain to lead to otherwise preventable harm. Two steps are needed to prevent future harm: a precise and limited definition of commercial confidentiality and regulatory procedures that make transparency the norm and secrecy the exception.

Overall Comments

Legal obligations of the Medicines Authorities and the European Medicines Agency

The European Union Treaty Declaration Nr 17 on the right of access to information clearly states that the

'transparency of the decision making process strengthens the democratic nature of the institutions and the public's confidence in the administration.'

Both the European Medicines Agency and the Medicines' Authorities at national level have a clear duty to uphold transparency and to communicate with the public. Their obligations are specified clearly and repeatedly in several regulations:

- Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents
- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. (This regulation confirms that Regulation No 1049/2001 is applicable to the European Medicines Agency).
- Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community Institutions and bodies
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use.

Most notably, Article 12 of the regulation 1049/2001 recital reads that:

'All rules concerning access to documents of the institutions should be in conformity with this Regulation.'

Therefore, any guidance document being put forward by the EMA and/or national MA concerning the disclosure of information should abide to current regulations on access to documents.

Lack of compliance of the European Medicines Agency and the national Drug Regulatory Authorities with current regulations

A full 10 years after Regulation 1049/2001 EC came into force, the European Medicines Agency and national Drug Regulatory Authorities are still not complying with current legislation. The draft guidance document being proposed contradicts current regulations and existing case law.

In particular:

- A. Using article 4 of Regulation 1049/2001, which outlines exceptions to the law, as a stepping stone for this draft guidance document puts the onus on the non-disclosure of information, rather than on the public access to documents. It undermines the whole aim of the proposal.
- B. The concept of commercially confidential information being put forward is not compliant with official definitions.
- C. The notion of personal data, as presented in the draft document, constitutes a misinterpretation, and is, once again, not compliant with official recommendations.
- D. The reference to personal security of individuals involved in animal studies is pointless.

A. Undue application of article 4 of Regulation 1049/2001 outlining exceptions

In general, confidentiality is defined by way of exceptions:

*'In principle, all documents of the institutions should be accessible to the public. However, certain public and private interests should be protected **by way of exceptions.**'*

(Regulation 1049/2001, recital, article 11)

The exceptions that are applicable are further outlined under article 4 of the regulation, entitled 'Exceptions'. The following are of relevance to this draft guidance document:

1. The institutions shall refuse access to a document where disclosure would undermine the protection of:
(..)
(b) privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data.

*2. The institutions shall refuse access to a document where disclosure would undermine the protection of:
— commercial interests of a natural or legal person, including intellectual property (...)*

(Regulation 1049/2001, article 4)

The draft guidance document is unsound in that it misuses the above-mentioned exceptions. In light of the objectives pursued in Regulation No 1049/2001, the exceptions as laid down in Article 4 should be interpreted and applied strictly. Non-conforming cases should not be generalised, as stated in article 4.6 clearly that reads:

6. If only parts of the requested document are covered by any of the exceptions, the remaining parts of the document shall be released.

Therefore, exceptions are only applicable to the confidential elements of a document, not to its entirety. Refusing access to entire documents based on the sole presence of an allegedly confidential element in the *file name*, as proposed in the draft guidance document, is injudicious.

Case law decisions supporting the non-generalisation of exceptions

1 a) Exceptions cannot be applied to entire categories

Case law invalidates the approach chosen in the draft guidance paper to, *a priori*, distribute documents according to different levels of confidentiality.

Franchet and Byk v Commission

The Court of First Instance has rejected as insufficient an assessment of documents by reference to categories rather than on the basis of the actual information contained in those documents, since the examination required of an institution must enable it to assess specifically whether an exception invoked actually applies to all the information contained in those documents.

1 b) A document concerning an interest protected by an exception is not sufficient to justify an overall exception

T-2/03 Verein für Konsumenteninformation v Commission [2005] ECR II-1121
Joined Cases T-110/03, T-150/03 and T-405/03 Sison v Council [2005] ECR II-1429

The examination required for the purpose of processing a request for access to documents made under the procedure provided for by Regulation No 1049/2001 regarding public access to European Parliament, Council and Commission documents must be specific in nature. *The mere fact that a document concerns an interest protected by an exception is not sufficient to justify application of that exception.*

1c) Each document requires an individual and concrete examination

Case T-237/05 Éditions Odile Jacob SAS vs Commission [2010]

The General Court concluded that the European Commission's refusal to grant access to the documents under the exceptions in Regulation 1049/2001 could not be justified and was an error of law. It ordered the Commission to produce all the documents requested with the exception of an opinion from the Commission's legal service. The General Court stressed that in the case of a request for access, each document would need to be the subject of an individual and concrete examination.

1d) The institution is required to demonstrate specific and effective risks in disclosing the information

Joined cases C-39/05 P and C-52/05 P Sweden and Turco vs Council [2008] ECR I-4723

It is insufficient, in principle, for a document to fall within an activity mentioned in Article 4(2) of Regulation No 1049/2001. The institution concerned must also supply explanations as to how access to that document could specifically and effectively undermine the interest protected by an exception laid down in that article.

1e) The risk invoked must be reasonably foreseeable

***Sweden and Turco v Council* [2008] ECR I-4723**

The application of an exception may, as a rule, be justified only if the institution has previously assessed whether access to the document could specifically and effectively undermine the protected interest. In addition, the risk of a protected interest being undermined must be reasonably foreseeable and not purely hypothetical.

1g) The risk should be weighed against the public interest in disclosure

Case T-198/03 *Bank Austria Creditanstalt v Commission* [2006] ECR II-1429

Case T-474/04 *Pergan Hilfsstoffe für industrielle Prozesse v Commission* [2007] ECR II-4225

Accordingly, the assessment as to the confidentiality of an item of information requires, on the one hand, that the individual legitimate interests opposing disclosure of the information be weighed against, on the other, the public interest in ensuring that the activities of the Community institutions take place as openly as possible.

B. Definition of commercially confidential information

It is interesting to note that the notion of commercially confidential information (CCI) contained in this consultation goes beyond the definition established by the EMA five years ago; when the agency issued a policy paper on *Principles to be applied for the deletion of commercially confidential information for the disclosure of EMA documents* (EMA/45422/2006). This document justifies the withholding of commercial information only in those cases where the release of information could '*prejudice to an unreasonable degree the commercial interests*'.

The current proposal redefines CCI as: '*any information which is not in the public domain or publicly available and where disclosure **may undermine** the economic interest **or competitive position** of the **owner of the information***'.

This definition seems to rely solely on self-identification by the company of information that may undermine its economic interest or competitive position. Self-identification is not adequate. On the contrary, companies should be required to produce information showing how the release of information would harm their position. In general, the default position should be that information is not commercially confidential and companies should have to prove that it is.

A redefinition of the notion of commercially confidential information is essential to the improvement of transparency. The new EMEA policy should be based on the general principle of access to all documents, for complete transparency.

In particular, all information about efficacy and safety is of public interest, and should therefore be publicly available, following the removal of any information that might identify individuals. This is in alignment with the current regulations which specify that public health protection is paramount to commercial confidentiality.

The assessment of potential commercially confidential information on a case-by-case basis opens the door to subjective interpretation by the parties involved. When patient safety is at stake, it is essential to ensure objectivity.

C. Personal data protection

The Data Protection Working Party has been established by Article 29 of Directive 95/46/EC. It is the independent EU Advisory Body on Data Protection and Privacy. Its tasks are laid down in Article 30 of Directive 95/46/EC and in Article 15 of Directive 2002/58/ECⁱ.

This Working Party is responsible for making ‘recommendations to the public at large, and in particular to Community institutions on matters relating to the protection of persons with regard to the processing of personal data and privacy in the European Community.’

In its *Opinion 4/2007 on the concept of personal data, article 29*, the Data Protection Working Party clarified its definition of personal data. This opinionⁱⁱ is particularly relevant to the draft guidance document, as it focuses specifically on pharmaceutical research data. It reads:

(...)Recital 26 of the Directive 95/46 EC pays particular attention to the term "identifiable" when it reads that "whereas to determine whether a person is identifiable account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the said person."

This means that a mere hypothetical possibility to single out the individual is not enough to consider the person as "identifiable". If, taking into account "all the means likely reasonably to be used by the controller or any other person", that possibility does not exist or is negligible, the person should not be considered as "identifiable", and the information would not be considered as "personal data". (...)

Example No. 13: pharmaceutical research data

Hospitals or individual physicians transfer data from medical records of their patients to a company for the purposes of medical research. No names of the patients are used but only serial numbers attributed randomly to each clinical case, in order to ensure coherence and to avoid confusion with information on different patients. The names of patients stay exclusively in possession of the respective doctors bound by medical secrecy. The data do not contain any additional information which make identification of the patients possible by combining it. In addition, all other measures have been taken to prevent the data subjects from being identified or becoming identifiable, be it legal, technical or organizational. Under these circumstances, a Data Protection Authority may consider that no means are present in the processing performed by the pharmaceutical company, which make it likely reasonably to be used to identify the data subjects.

Hence, the identification number attributed to an individual in the framework of a clinical trial or an adverse event report should not be considered personal data as it cannot be used to trace back the individual's identity. Similarly, the patient's nationality and age are not sufficient elements, even when combined with the identification number, to track an individual.

Therefore, the current consultation document's proposal to consider these three elements to be confidential personal data is in contradiction with the recommendations of the competent body, the Data Protection Working Party.

This proposal is all the more unacceptable as the three elements in question are of paramount importance in assessing the total number of adverse events and their frequency per country, and also for identifying pharmacovigilance patterns.

The recent cases of narcolepsy after pandemic influenza vaccination (Pandremix) illustrate the importance of two factors in assessing vaccine-induced harms: 'age' (only children were concerned) and 'nationality' (Scandinavians were at a higher risk). Had these elements been absent from the analysis, then the drug-induced harm would not have been detected.

In exceptional cases (patients suffering from a rare disease) should the combination of the three elements - date of birth, age and country - enable the direct or indirect identification of a natural person, then adequate measures should be implemented to prevent that occurrence. If the date of birth is to be unavailable, the age of the patient suffering the adverse reaction, or participating in the clinical trial, should be released.

As to the identification of EMA and DRA staff or scientific experts involved in the marketing authorisation process or related activities, such information should not be withheld. Without disclosing the identity of the individuals that have participated in the decision-making process, who sat at relevant committees, there is no possibility for the public to ascertain potential conflicts of interest.

D. Personal security of individuals involved in animal studies

The rationale brought forward to withhold documents is based on a subset application of personal data protection regulations. Yet, evidence from official sources casts a doubt on the likelihood of such a risk. EUROPOL's 2010 '*Terrorism Situation and Trends report*' identified but two attacks on individuals involved in animal studies, in the 27 European Member States. Both attacks targeted one company based in the United Kingdom. This low likelihood of events is not sufficient to warrant the non-disclosure of information relating to animal testing in medicines' research and development.

E. Encouraging transparency in medicines regulation across EU Member States

While harmonised procedures can greatly reduce the bureaucratic burden on regulatory agencies, the priority should always be to have the appropriate checks and balances to ensure the highest standards of medicines quality, efficacy and safety. Above all, the practical orientations laid down in the guidance document should be harmonised to the highest existing transparency standard. Therefore, if a given national regulatory agency discloses publicly more information than other counterparts in the EU, that same agency should be used as a point of reference.

The public should have access to a complete registry of all EMA documents, with a description of the aim of the document. Public accountability of regulatory decisions is only possible if the public has access to the evidence on which those decisions are based, and is provided with a rationale for decisions. Any decision and/or recommendation should be evidence-based and extensively referenced, in order to allow public scrutiny.

Access to data of public interest

Lack of full public access to the body of available scientific evidence about the effects of medicines on human health leaves European citizens at greater risk for otherwise preventable harm.

Access to the following data is essential:

- Clinical and non-clinical data (toxicology);
- Information about quality that has an impact on the benefit/harm balance;
- The qualitative and quantitative composition;
- Details of the dosage form;
- Primary and secondary packaging;
- Information on the production process (that can impact on the medicines' quality: excipient, impurities, and residues)
- The periodic safety update reports (PSURs) as well as its assessment reports
- Comprehensive register of clinical trials (completed, ongoing, stopped), including the protocols, detailed clinical data and results.

- Public register of risk management plans and post-marketing studies.

When information is not being disclosed by the EMA or national Medicines' Authorities, a list of the documents being withheld should be published, containing an abridged summary of their contents.

On a positive note, we welcome the release of information relating to modules 2.5 and 2.7, the Clinical Data and Clinical Summary, respectively. Furthermore, the disclosure of an up-to-date list of the marketing authorization documents is a positive development.

Granting access to documents

Dissemination is an important step, yet both the format and process through which the information is made available are equally important:

- Acknowledgement of request within a very short period of time (e.g., under a week).
- Expectation of a response to a request within 30 days – extensions only granted under very exceptional circumstances and requests for extensions can be appealed by the person requesting the documents. Current regulations foresee 15 days, with extension of another 15 days.
- Documents need to be provided in legible and easily up loadable/ downloadable format
- All information made available online should be on a searchable format, so that users can retrieve it easily using key words.

Lack of clarity about application to Variations

This draft guidance document does not specify whether these practical orientations are also to be applied to Variations procedures. If so, it should be clearly indicated. Access to information is particularly relevant in variations type II (related to new indications), or other variations related to pharmacovigilance aspects.

Specific comments

Specific comments to the draft document are outlined below.

Page 6

2.2 -The detailed description of a marketing authorisation holders' pharmacovigilance system should not be regarded as confidential.

It is unclear whether the outcomes of discussions at the level of Competent Authorities' scientific committees or other scientific groups are being regarded as confidential. That should not be the case.

3.1 -It is not clear why information about the reporting country needs to be deleted from Periodic Safety Update Reports in order to ensure individual autonomy. That should not be the case.

Page 22:

2.5.4 - Information about the study clinical centre and the study analytical centre should be publicly released as particular centres may have affiliations with industry that could create conflicts of interest.

2.6 – The full qualitative and quantitative composition of a medicine must be publicly available, on public health grounds.

Page 24:

4.1.1 - In general once an application is filed for a new drug in any Member State or with the EMA the names of the product and the Member State(s) should be publicly disclosed to allow for public participation/scrutiny in the approval process.

Page 25:

5 - The CV of the qualified person for pharmacovigilance should be publicly available so that the public and professionals can be assured that this person has the necessary training and independence to carry out the job.

Page 28:

14 – The Scientific advice given by the CHMP and/or Member States should always be publicly available to enable public scrutiny.

Page 30

1.3.4 - The justification for the failure to submit the tests results of the readability test should be accessible. There is no public health rationale in protecting commercial interests by withholding this information.

Page 31:

1.3.5 - Information about the experts – The CV of the experts should be publicly available so that the public and professionals can be assured that the experts have the necessary training and independence to carry out their tasks.

Page 32:

1.8.1 – Information on the Pharmacovigilance system should always be made available.

Page 33:

Sub-module 1.9 - There is no reason why the name of the API manufacturer should be hidden. It should be able to be disclosed as well as the rest of the information about clinical trials performed outside of the EC.

Page 35:

It is not clear why the summary of sub-module 2.1 is not to be fully accessible. That should not be the case.

Page 39 and 40:

The names and amounts (e.g., in parts per million) of any excipients should be released so that people who may be allergic to them will be aware of the contents of the medicines that they will be taking.

Page 43:

It is not clear why sub-module 5.3 which concerns clinical study reports, of relevance to public health, should not be fully accessible. That should not be the case.

Endorsing Organisations



HAI Europe. Health Action International (HAI) Europe is an independent European network of health, consumer and development organisations working to increase access to essential medicines and improve their rational use. More info: www.haieurope.org.
teresa@haieurope.org.



MiEF. Medicines in Europe Forum (MiEF), launched in March 2002, covers 12 European Member States. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the EU, and it certainly reflects the important stakes and expectations regarding European medicines policy. Admittedly, medicines are no simple consumer goods, and the Union represents an opportunity for European citizens when it comes to guarantees of efficacy, safety and pricing. Contact: pierrechirac@aol.com.

ⁱ Full document available at http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/tasks-art-29_en.pdf

ⁱⁱ Full document available at http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2007/wp136_en.pdf