



European Medicines Agency

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**PRINCIPLES TO BE APPLIED FOR THE DELETION OF COMMERCIALY CONFIDENTIAL
INFORMATION FOR THE DISCLOSURE OF EMEA DOCUMENTS**

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I. INTRODUCTION

Community legislation¹ states that, in order to ensure the full application of the legislative provisions to all activities of the EU, all Agencies established by the EU Institutions should apply the principles laid down in the Community legislation regarding public access to documents. In this respect, the EMEA Management Board has adopted EMEA rules for the implementation of this legislation².

Nevertheless, prior to publishing or allowing access to any EMEA document, commercially confidential data should be deleted.

Since there is no unique and exhaustive legal interpretation of the concept of “commercially confidential information”, the present document defines the principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents.

II. LEGISLATIVE FRAMEWORK

The principles refer to 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. Article 4 (2) of this Regulation states that the Institutions shall refuse access to documents where disclosure would undermine the protection of commercial interest of a natural or legal person, including intellectual property, unless there is an overriding public interest in disclosure. Article 73 of Regulation (EC) No 726/2004 foresees that Regulation (EC) No 1049/2001 applies to the EMEA.

These principles also apply to EMEA publication, e.g. information as foreseen by Regulation (EC) No 726/2004, in particular Articles 13(3) and 38(3) related to EPARs, Articles 11 and 36 of Regulation (EC) No 726/2004 related to publication on withdrawals of applications, and Articles 12(3) and 37(3) related to refusals of applications. A list of relevant articles of the pharmaceutical legislation is appended to this document.

This document does not address issues of protection of personal data and of public interest nor any of the other exceptions listed in article 4 of Regulation (EC) No 1049/2001 that are not related to commercial interest. However, principles on deletion of commercially confidential information shall comply with rules on individual data protection.

The EMEA Principles on deletion of commercially confidential information have also been prepared in the light of Article 39(3) of the Trade-Related Aspects of Intellectual Property Rights ("TRIPS") Agreement.

III. GENERAL PRINCIPLES

The EMEA considers openness and transparency to be important measures in the promotion of public health. However, unless there is an overriding public interest in disclosure, the EMEA will refrain from disclosing commercially confidential information when it might hurt the interest or, in other words, prejudice to an unreasonable degree the commercial interests, of individuals or companies concerned.

¹ Regulation (EC) No. 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding access to European Parliament, Council and Commission documents; recital (8).

² Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents (EMEA/MB/203359/2006 Rev 1).

Guidance on the concept of “commercially confidential information” can be identified on the basis of European legislation and case law dealing mainly with competition, environmental and access to documents related issues.

“Commercially confidential information” is generally considered to fall broadly into two categories:

- confidential intellectual property, “know-how” and trade secrets (including e.g. formulas, programs, process or information contained or embodied in a product, unpublished aspects of trade marks, patents etc.);
- commercial confidences (e.g. structures and development plans of a company).

These principles will, apply to EMEA documents for deletion of commercially confidential information prior to publication or disclosure.

The application of the principles to the preparation of CHMP and CVMP assessment reports is provided as Annex 1. The Agency will progressively develop further guidance on the application of the above principles in other fields.

IV. PROCEDURAL CONSIDERATION

The EMEA shall apply these principles in accordance with the above-referred rules on access to EMEA documents (EMEA/MB/203359/2006 Rev 1), in particular the EMEA shall refrain from disclosing information when it could undermine the decision making process.

Consultation of third parties for deletion of commercially confidential information will be described in specific procedural documents as appropriate (e.g. EMEA reflection paper on publication of withdrawal of MAA - EMEA/239350/2005).

ANNEX 1

RECOMMENDATIONS FOR THE APPLICATION OF THE PRINCIPLES OF DELETION OF COMMERCIALLY CONFIDENTIAL INFORMATION IN THE CONTEXT OF CHMP AND CVMP ASSESSMENT REPORTS

These recommendations apply to the publication of assessment reports as foreseen by the pharmaceutical legislation, and disclosure of any other assessment report related to the outcome of an EMEA Committee's assessment of a marketing authorisation application.

The objective of the publication of assessment reports is to make information concerning marketing authorisations as well as refusals and withdrawals of marketing authorisation applications for medicinal products accessible to the public. For this reason the information should be comprehensive and complete, whilst respecting that commercially confidential information should be deleted prior to publication.

Information that is already in the public domain is not considered as commercially confidential. In case, information has been in the public domain through a breach of the law, it could still be considered confidential in accordance with the principles of this document. However, the owner of the information has to inform the EMEA in writing on the breach of law.

I. INFORMATION ON THE QUALITY AND MANUFACTURING OF MEDICINES

A general principle in the following section is that detailed information is commercially confidential but general information should be disclosed. However, it is acknowledged that in certain circumstances, even a general description of a specific aspect could be regarded as commercially confidential, if justified.

I.1 Composition and product development

In general, pharmaceutical development information is commercially confidential. This includes detailed data concerning active substance, formulation and manufacturing and test procedures and validation (see later).

The final qualitative formulation (composition) of the authorised product is not commercially confidential.

In general, the names of manufacturers or suppliers of the active substance or the excipients are accepted as commercially confidential, unless disclosure is necessary for public health reasons (e.g. for some biological products).

I.2 Active substance

Detailed information on the synthesis or manufacture of the active substance, including details on the by-products and degradation products of active ingredients and validation of the manufacturing / synthesis process, is commercially confidential.

Information on the structure of the active substance is not commercially confidential. This will be known and published at the time of allocating the INN.

Detailed information concerning the particulars of studies regarding polymorphism and particle size should be treated as confidential. However, a general statement on the results of these studies is not confidential.

Concerning impurities and degradation products, qualitative and quantitative information is regarded as confidential unless disclosure is necessary for public health reasons.

A general description of the types of test methods used and the appropriateness of the specification is not commercially confidential. However, detailed information on the test methods used and the specification and quantitative acceptance criteria established for the active substance is commercially confidential, unless the tests meet specific monographs in the European Pharmacopoeia.

In addition, for biotechnology products, a general description of the active ingredient including type of molecule and its general structural features (e.g. number of amino acids, general glycosylation details) or of the type of producer cell (e.g. E.Coli, S. Cerevisiae, Chinese Hamster Ovary cells, Madin Darby Kidney cells) is not considered commercially confidential. A general statement on 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. General information on the fermentation and purification process is not commercially confidential, although details including operating parameters and specific material requirements are commercially confidential. Details on the validation of the active substance manufacturing process are commercially confidential, although statements confirming that the manufacturing and control processes have been validated are not commercially confidential.

General information on the characterization of the active substance and statements confirming that the molecule is appropriately characterized are not considered commercially confidential. However, details of characterization methods are considered commercially confidential.

The above principles will also apply to novel excipients.

I.3 Finished product

The detailed descriptions of the manufacturing and control processes for the product are commercially confidential.

Details of the validation of the manufacturing process are also considered commercially confidential.

A general description of the types of test methods used and the appropriateness of the specification is not commercially confidential. Detailed information on the test methods included in the specification of the finished product and the quantitative acceptance criteria is commercially confidential, unless the tests are of Pharmacopoeial standard.

Concerning degradation products, qualitative and quantitative information is regarded as confidential unless disclosure is necessary for public health reasons.

Information on the outcome of stability studies (e.g. carried out in real time conditions or accelerated conditions) is not commercially confidential.

Any confidentiality issue regarding novel packaging or medical device aspects should be justified by the applicant, and will be assessed according to the above principles.

II. NON-CLINICAL AND CLINICAL INFORMATION

Any information encompassing non-clinical and clinical development of the medicinal product and the subsequent assessment by the Committee is not commercially confidential and therefore deletion cannot be accepted as a general rule.

An exception to this rule would be, for example, specific details on a method used in a study, which, upon justification from the company, could be regarded as trade secret.

Another example of commercially confidential information could be a development plan from the company, e.g. in a different indication, when it is neither requested by the Committee nor related to the safety of the product. However, when such studies, their results and their timelines are part of

conditions for marketing authorisations, specific obligations or follow up measures, they are not regarded as commercially confidential information.

Data generated by the applicant using another marketing authorisation holder's product, e.g. comparative studies against the reference medicinal product are not commercially confidential by virtue of this fact only. However the commercial confidentiality of such data shall be assessed in accordance with the principles set out in this document.

The same principles will apply for information related to environmental risk assessments and risk management plans.

III. INFORMATION ON INSPECTIONS

Information on the outcome of inspections (e.g. compliance/non-compliance/outstanding issues to be addressed) is not regarded as confidential, however specific details e.g information regarding facilities and equipment are considered commercially confidential.

IV. OUTCOME OF THE SCIENTIFIC DISCUSSIONS

The outcome of discussions at the level of the CHMP and CVMP, including the benefit/risk assessment, as well as at the level of other scientific groups and bodies of the Agency (e.g. working parties, scientific advisory groups, etc) is not commercially confidential, but the considerations described in section I to III will apply in every case.

Committees' discussions on the data submitted for evaluation of a new application and related published information, ultimately reflected in the Product Information, are not of commercially confidential nature.

Divergent views within a Committee, as well as data related to the concerns raised are not commercially confidential.

Appendix:

**RELEVANT ARTICLES OF THE PHARMACEUTICAL LEGISLATION CONCERNING
EMEA PUBLICATION AND PUBLIC ACCESS OR AVAILABILITY TO EMEA
DOCUMENT**

REGULATION (EC) No 726/2004

Article 5 or 30 related to publication of Committee's Opinions.

Article 10(6) or 35(6) related to dissemination of SPC, labelling, package leaflet, conditions or restrictions on the supply or use, any recommended conditions or restrictions with regard to safe and effective use.

Article 11 or 36 related to public access to information on withdrawal of a marketing authorisation applications (after deletion of information of commercially confidential nature).

Article 12(3) or 37(3) related to public access to information on refusal of a marketing authorisation.

Article 13(3) or 38(3) related to publication of assessment report (after deletion of information of commercially confidential nature).

Article 14(7) related to Marketing Authorisation subject to specific obligations: the list of obligations shall be made publicly accessible.

Article 20(7) or 45(7) related to urgent provisional measures for which the final decision shall be made publicly accessible.

Article 22 or 47 related to adverse reactions where Committee opinions on measures necessary shall be made publicly accessible.

Article 26 or 51 related to alert related on faulty manufacture, serious adverse reactions and other pharmacovigilance data to be made publicly accessible if relevant, after evaluation.

Article 83 related to compassionate use: publication on the website of an updated list of Committee's opinions.

Tasks of the Agency

Article 57(1)(b): Assessment reports, SPCs, labels, package leaflets or inserts to be transmitted on request and made publicly available.

Article 57(1)(d): Dissemination of information on adverse reactions through appropriate levels of access to Eudravigilance.

Article 57(1)(f): Distribution of appropriate pharmacovigilance information to the general public.

Article 57(1)(l) and 57(2): Creation of a database of medicinal products including clinical trials data fields accessible to the public (Eudrapharm).

Article 59(4): Publication of joint document clarifying the scientific points of conflict between the Agency and a national body (*if conflict not resolved*).

General Provisions governing the Agency

Article 73: Setting up a register of documents that are publicly accessible pursuant to Regulation (EC) No 1049/2001.

Article 80: To ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products which is not of a confidential nature. To make available to the public at the Agency and on the Internet, the internal rules and procedures of the Agency, its committees and its working groups.

DIRECTIVE 2001/83/EC as amended

Article 21(3) related to public availability of marketing authorisation decision and SPC.

Article 21(4) related to public access to assessment report (after deletion of information of commercially confidential nature) and its update according to new information of importance.

Article 22 related to public access to the conditions, together with deadlines and dates of fulfilment, of marketing authorisation granted under exceptional circumstances.

Article 102 related to accessibility to the public to suitable information from the pharmacovigilance database (Eudravigilance).

Article 125 related to public access to decisions to grant or revoke a marketing authorisation.

Article 126b related to public access to Member States' Competent Authorities rules of procedure and those of its committees, agendas, records and decisions of its meetings, with details of votes.

DIRECTIVE 2001/82/EC as amended

Article 25(3) related to public availability of marketing authorisation decision and SPC.

Article 25(4) related to public access to assessment report (after deletion of information of commercially confidential nature) and its update according to new information of importance.

Article 73 related to accessibility to the public to suitable information from the pharmacovigilance database (Eudravigilance).

Article 94 related to public access to decisions to grant or revoke a marketing authorisation.

REGULATION (EC) No 1901/2006 as amended

Article 5(1) related to public access to Paediatric Committee's opinion.

Article 14 related to the public availability of a list of all waivers.

Article 25(7) related to publication of decisions of the Agency after deletion of any commercially confidential information.

Article 41 related to making public part of the information on paediatric clinical trials entered in the European database.