COMMERCIAL CONFIDENTIAL INFORMATION

Principles to be considered

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SOME PRELIMINARY REMARKS

- Openness approach
- Transparency ↔ Confidentiality
- Exception to refuse access to documents

  "*Commercial interests of a natural or legal person, including intellectual property*"

- Article 39(3) of the Trade-Related Aspects of IPRs Agreement (TRIPS)

  "*Members, when requiring, as a condition of approving the marketing of pharmaceutical … , the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use*"

TOOLS USED BY THE EMEA TO PROTECT CCI

- Deny access to documents whilst procedure is ongoing unless documents is already publicly available
- Third party consultation in case of doubt on the nature of the concerned information (i.e. CCI or not CCI)
- Redact document when access is granted whenever it contains CCI

HINTS TO DEFINE CCI

- No EU notion of CCI
- Information is not confidential when already in public domain
- Could it be of benefit for a competitor?
- Could it cause a disproportionate prejudice to and seriously harm the commercial interest of the applicant?

THE “PRISONER’S DILEMMA”

Inconsistent approach with regard to the interpretation of CCI could lead to a prisoner’s dilemma situation

If one MS reveals more information than the other ones, the effort of the MSs that deleted the CCI will have been a waste of resources and time.

The purpose of this workshop is to promote harmonisation.

WHAT CAN BE CONSIDERED CCI

- **Intellectual property**

Concerns the development and research (very costly in the pharma sector) prior to the filing of a patent or a design. The disclosure of the information prior to obtaining a patent can prevent the it from being registered. Therefore, high interest to put measure in place to keep it secret

WHAT CAN BE CONSIDERED CCI

- **Trade secrets**

Concern formulas, manufacturing and control processes which are or may be used in trade. They are generally not in the public domain and can draw a certain value from not being known. They are also subject to reasonable efforts of being kept secret

WHAT CAN BE CONSIDERED CCI

- **Commercial confidences**

Concern every piece of information which does not have a commercial value as such, but its disclosure might provoke damage to the party (e.g. structures and development plans of company, marketing strategies, etc.)

EXAMPLES OF CCI

- Detailed data concerning the synthesis or manufacturing of the active substance
- Names of manufacturers
- Detailed of studies regarding polymorphism and particles size
- Qualitative and quantitative information related to impurities and degradation products
- Details regarding facilities and equipments (Inspections)

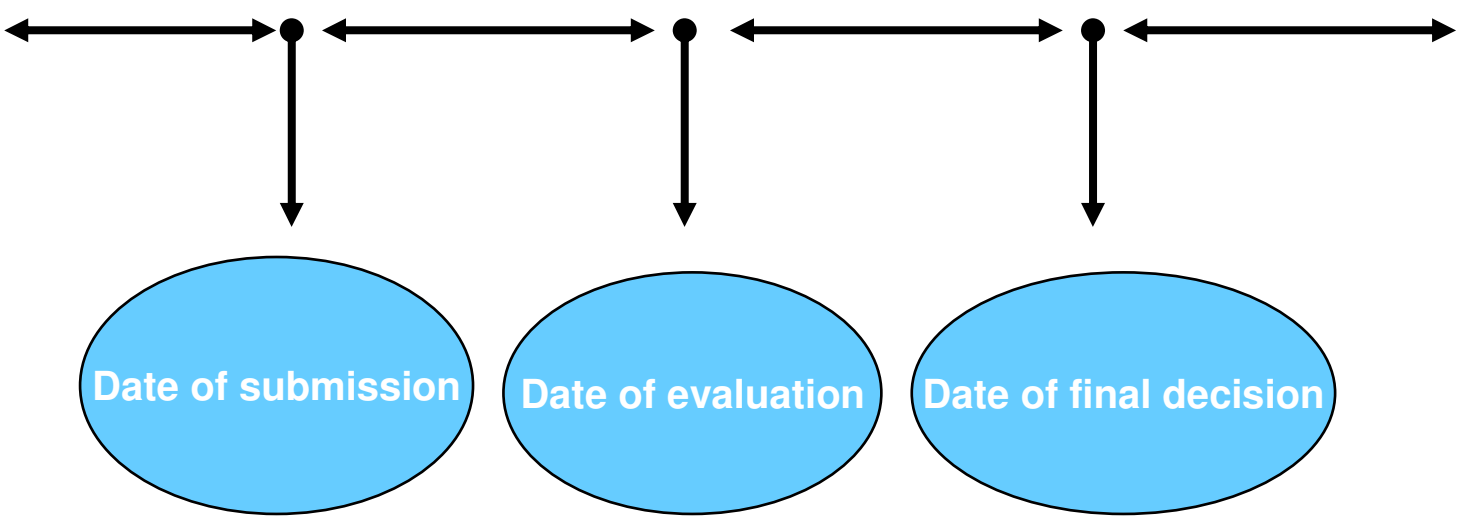
EXAMPLES OF NOT CCI

- Structure of the active substance (INN)
- Final qualitative formulation
- Outcome of stability studies
- Information related to non clinical and clinical development of concerned

  medicinal products once assessed by CHMP

COMMERCIAL CONDIFENTIALITY: A CONCEPT SUBJECT TO TIME

4 phases may in principle be identified:



A CONCEPT SUBJECT TO TIME

- The more we move left on the timeframe the more confidentially certain information must be treated (pending patent application, decision making process, independent scientific evaluation to be safeguarded)
- An independent factor which may affect the confidentiality of the information relates to the MSs rules governing the stock exchanges: e.g. most MSs require companies to disclose info that can influence the price of the shares, such as the filing of a MAA

TODAY'S MEETING EXPECTATIONS

- The applicant is in the best position to evaluate whether information are to be classified as CC
- The aim of this workshop is to trigger discussion on whether it is possible to agree on a shared notion of CCI between the EMEA and its stakeholders
- A positive outcome would increase the accountability of the medicines network and improve the efficiency of the system by minimising the need of third party consultation.

Thank you