Section 3 (iii) "Legal Environment": transparency, commercially confidential information and conflict of interests

(Liesbeth Breeveld, Benito Boone)

Preliminary reflections

In an European Union of 25 Member States that each have their own cultural and legal heritage, it would be utopian to try and provide an exhaustive list of particular things that can or cannot be communicated to the stakeholders. *Transparency* as a principle is undefined, and our goal should be to make it more specific, to provide some guidance for the different NCA's, but to keep it abstract enough as a principle to reach a common agreement between all these different points of view on how to apply this principle in practice. This delicate balance, projected against a legal background, will be the point of discussion in this paper.

First we will take a look at the different provisions of the Directives 2001/83, 2001/82 and the Regulation 726/2004 concerning transparency. Secondly, we will try to define what should be understood by "commercially confidential information", as this is clearly the complement of transparency: all that is not commercially confidential, can be transparent. By positively defining the notion of confidentiality, we can as of a consequence define what should be transparent. And finally we will discuss the problem of conflict of interests.

Transparency

"Article 126b (2001/83/EC): (…)In addition, the Member States shall ensure that the competent authority ***makes publicly accessible*** *its rules of procedure and those of its committees,* ***agendas*** *for its meetings and* ***records*** *of its meetings, accompanied by* ***decisions taken****, details of votes and explanations of votes, including minority opinions."*

"Art. 21, 4°, 2nd paragraph (2001/83): The competent authorities shall make publicly accessible ***without delay*** *the assessment report, together with the reasons for their opinion, after* ***deletion of any information of a commercially confidential nature****. (…)"*

Making publicly available

There has already been a lot of discussion on this notion, where some Member States seem to assimilate it with "publishing". From a legal point of view it has to be stressed that whereas "publishing" implies an **active** transparency, "making publicly accessible/available" implies **passive** transparency, i.e. the authority can *passively* wait for a demand from outside. From a practical point of view (*"if asked, you have to provide it anyway"*) it does not seem to make so much of a difference, except if you consider the workload. In Belgium for instance, which has three official languages, "publishing" implies translating all the required documents in three different languages. Making available would only be necessary in the language of the inquiring person.

In the long run publishing seems to be the way to go, but in the meantime Member States should be given the opportunity to choose between both options. This gives them the time to put the necessary means into place.

Accessibility of agenda's

It should be stressed that the meetings themselves do not have to be public as such (although hearings etc… could be held), only the agendas and records of these meetings are to be made publicly available. Although it is not mentioned that commercially confidential information should be deleted (as it does expressly say in art. 21 of the Directive), this can be considered a general rule in EC Law. In fact, in many competition law cases, the right to access of a concerned party to the documents gathered by the European Commission during

her investigation is limited by the rules that govern the "fair competition". This means that all information that could unfairly harm a competitor, should be restricted from access (*cf. infra* under the topic "commercially confidential information")[1].

If we apply this principle on the accessibility of agenda's, you can reach the conclusion that sometimes the agendas can contain information that could harm a competitor and cause unfair competition. For instance the mere fact that a specific generic company wants to put a product on the market that is no longer patent protected, could cause the innovator to systematically take legal action. This could influence the serenity of what should be an open scientific debate.

A solution to this problem could be to make available agendas *after* the meeting (or *after* the evaluation/decision to grant) and to only provide "general agendas" before the meetings, that contain general information that could interest the public. For instance, the fact that a generic application is filed whilst mentioning only the active principle and the indication. This can be legally justified, seeing that contrary to the disposition concerning the evaluation report, the agendas and records are not to be made publicly available **without delay**.

Accessibility of records

The same reasoning goes *mutatis mutandis* for the records of the meeting. These should not be made publicly accessible immediately after the meeting unless they do not contain commercially confidential information. On top of that, if the records are accessible before a final decision has been taken, this could again influence the outcome of what should be a open scientific debate, due to pressure of external parties.

This implies however that records of meetings that concern a same case should be integrated in one record.

Logically only records of meetings that relate to marketing authorisations and pharmacovigilance should be accessible (exclusion of for example management meetings).

Accessibility of decisions

It goes without saying that positive decisions and the information that accompanies them have to be made publicly accessible. In the Regulation 726/2004 article 12.3 states that negative decisions (refusals) and their reasons should also be made publicly available. A similar corresponding article for the Member States is missing in the Directives, but it cannot be denied that a negative decisions is a decision nevertheless, and should therefore be accessible as well, although in some cases this could harm an undertaking's reputation.

During the last EMACOLEX meeting Member States did not agree upon this principle though. There only seemed to be a common understanding that refusals could be made public if it concerns public health reasons.

Withdrawals before reaching a decision

In the same way, Regulation 726/2004 contains an article concerning withdrawals that has not got a counterpart in the Directives. Article 11 states that "*if an applicant withdraws an application for a marketing authorisation submitted to the Agency before an opinion has been given on the application, the applicant shall communicate its reasons for doing so to the*

[1] Regulation (EC) n° 1049/2001 of the European Parliament and the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents provides an exception to rant access in its article 4.2: "*commercial interests of a natural or legal person, including intellectual property (…) unless there is an overriding public interest in disclosure.*"

Agency. The Agency shall make this information publicly accessible and shall publish the assessment report, if available, after deletion of all information of a commercially confidential nature." This would only go for the centralised procedure, but it is wishful that in the MRP and DP a harmonised approach is used (where possible on initiative of the RMS) in order to prevent confusion for the European public (nonetheless, for partial withdrawals there will a public decision in the end). Especially when it concerns public health reasons it is advised to make such information accessible. For national procedures it can be left to the discretion of the NCA's to make such information available.

Transparency in pharmacovigilance issues

Article 109.9 (Dir. 2001/83): *" The holder of a marketing authorisation may not communicate information relating to pharmacovigilance concerns to the general public in relation to its authorised medicinal product without giving prior or simultaneous notification to the competent authority.*

In any case, the marketing authorisation holder shall ensure that such information is presented objectively and is not misleading.

Member States shall take the necessary measures to ensure that a marketing authorisation holder who fails to discharge these obligations is subject to effective, proportionate and dissuasive penalties."

Article 125 (Dir. 2001/83): *"Decisions to grant or revoke a marketing authorisation shall be made publicly available.*

In the post-authorisation period, there can be a compelling public health reason to disclose information. In this regard the rules governing commercially confidential information set out below will be more difficult to apply for two reasons: a fast reaction is needed and when public health concerns are involved the interest of the MA holder is overridden by the interest of the pubic.

The transparency in these situations could often be considered as a "selective" or "phased" transparency, since in many cases the health care professionals would have to be informed before the public.

Commercially confidential information

Preliminary reflections

Although - as set out above - there are some textual discrepancies between the Directives and the Regulation with regard to confidentiality[2], the principle to keep information from being disclosed if it could effect the fair competition between persons, can be considered a general principle of EC Law. Transparency is the rule, confidentiality the exception. Determining the notion of "commercially confidential information", could be a start for a harmonised approach by Member States.

An important preliminary remark is that the exception of confidentiality cannot be invoked by one NCA against another. There is a principle of mutual confidence that the respective NCA's have a secrecy obligation. However, to exclude any legal issues and in order to stimulate this mutual trust, some sort of standard declaration/contract of secrecy could be accompanying confidential information that is being shared.

[2] For instance, the EMeA does not as such have the obligation to make records and agendas of meetings publicly accessible. They can still refuse to do so if it would undermine the serenity of an open scientific debate.

Determining the notion

In general "commercially confidential information" falls into three different categories, namely trade secrets, commercial confidences and intellectual property.

Trade secrets concern information such as formulas, production processes, composition, etc… that :

- are or may be used in trade,
- are generally not known in that particular commerce (not in the "public domain"),
- draw a certain value from not being generally known
- are subject of reasonable efforts to be kept secret.

Commercial confidences is a much broader and more abstract concept than trade secrets. It does not (necessarily) concern an industrial or commercial application, but it concerns every piece of information that :

- has a commercial value that strictly relates to the ability of the person that disposes of this information to maintain its secrecy (e.g. future projects, cost structures …); or
- does not have commercial value as such, but whose disclosure might disadvantage commercially and cause prejudice to the concerned person who tries to keep it a secret (e.g. marketing strategies, SOP's, …).

Intellectual property concerns mostly the research and development (that especially in the pharmaceutical sector are known to be very costly) prior to the filing of a patent or design. This information in particular has to be treated with the utmost precaution since the disclosure of this information prior to the obtaining of the patent/design could prevent it from being registered. It goes without saying that this would entail huge damage claims from the concerned party.

How to go about

To determine whether certain information falls into the scope of "commercially confidential", you should ask yourself if this information:

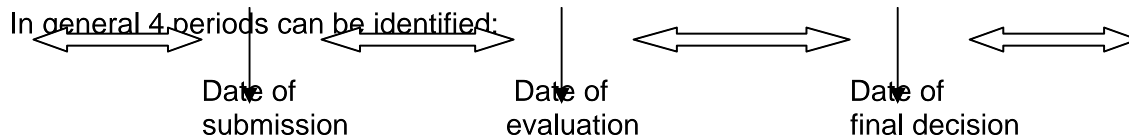
1) could be beneficiary for a competitor that would otherwise not get a hold of such information;
2) could disproportionately cause prejudice to the commercial interests of the – in most cases – applicant.

The person that is best placed to judge if certain information is commercially confidential would of course be the applicant himself. That's why prior to disclosure of this information, the applicant should be consulted - when possible - which part of the information he considers to be commercially confidential. To avoid the transparency principle to be undermined (if you rely solely on the opinion of the applicant, you could be left with an empty page to be made publicly accessible), you could ask the applicant to motivate substantially each part that is deemed commercially confidential. Afterwards the NCA can still make a balance between the company's commercial interest and the public (health) interest, and make certain parts publicly available nevertheless. Of course the NCA would have to motivate why he did not follow the instructions of the applicant.

The importance of timing

The element of timing is not often a negligible factor in order to determine whether or not information can be considered commercially confidential. If you take the example of the agendas (*cf. supra)*, timing is a major factor. Whether the agendas are disclosed before the meeting, after the evaluation or after the final decision, is of importance: after the decision, which is entirely public, certain elements that were considered to be commercially confidential (e.g. a generic application) at the moment of submission, can no longer be considered as such.

In general 4 periods can be identified:



The further we find ourselves on the left of the timeline, the more delicately certain information must be treated, because of multiple reasons (e.g. pending patent application, possibility of an independent scientific debate). After the final decision there will of course still be certain information that can be considered commercially confidential, .

Another aspect that can influence the fact if information can be considered commercially confidential is related to national legislation concerning the stock exchanges: most Member States - if not every - require companies to disclose quickly any information that could influence the price of its shares[3]. If such a disclosure happens e.g. before the date of evaluation, the disclosed information now belongs to the public domain and can no longer be considered confidential. It would be advisable if applicants or MA holders reveal information due to stock market legislation, that they inform the NCA at least at the same time.

A harmonised approach – "prisoner's dilemma"

The downside of a non-harmonised approach in the interpretation of "commercially confidential information" could lead to a "prisoner's dilemma"-situation[4]. If one Member State, for instance after a MRP procedure, reveals more information than the other ones, the efforts of the Member States that did delete the confidential information will have been a waste of resources and time. Only close cooperation and good communication between the NCA's can prevent such situations of legal insecurity.

The goal of this paper/discussion should be to further develop guidance on which information can and cannot be made publicly available, if necessary illustrated by practical examples (e.g. based on European Public Assessment Report SOP's, hypothetical situations, an old MA dossier, …).

Conflict of interests

Article 126b (Dir. 2001/83): "In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry which could affect their impartiality. These persons shall make an annual declaration of their financial interests."

A conflict of interests could lead to an assumption that the decision making process has not been conducted on objective grounds. In order to avoid these assumptions *post factum*, a declaration of interests by all the persons that have an direct influence in the decision making process would be advisable. After all, *justice does not only have to been done, it has to be seen to be done*.

---

[3] Belgian Royal Decree: "*the companies disclose without delay: any fact or decision of which they are aware and that, if made public, would be likely to influence in an appreciable way the share exchange quotation of the financial instruments*"

[4] A well known philosophical paradox where two prisoners that cannot communicate are offered the following options:
- either one confesses and the other does not: the first one goes free and the latter gets 5 years of prison
- either they both confess and get a milder sentence of 4 years
- either both deny and get a mild sentence of 2 years based on circumstantial evidence
In all options, cooperation leads to a better result.

Such a declaration, already applied by the EMeA and a number of NCA's, would make it clear to the public that a product is put on the market for the right (non commercial) reasons: namely that the standards of safety, efficacy and quality have been met. Once again, such a declaration would help make the whole MA-process become more transparent.