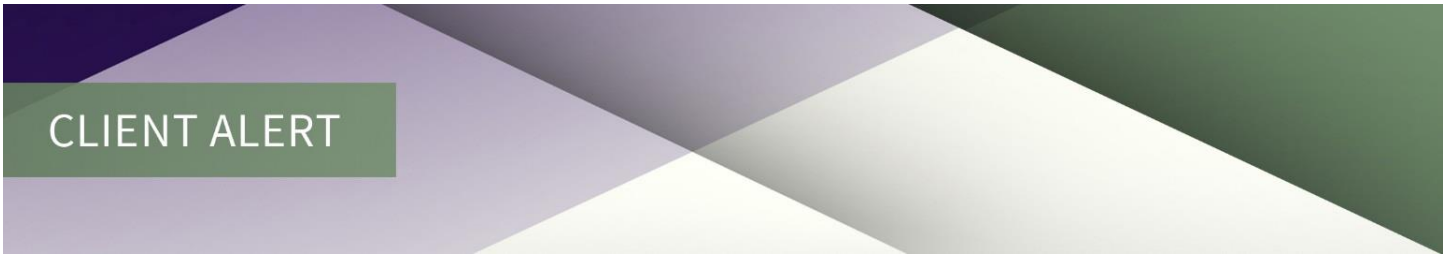

Inside Information Disclosure by Biotech Companies: the FSMA Has Published Good Practices Guidelines

January 22, 2021

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Introduction

Life sciences and biotechnologies have recently given rise to significant public attention. From a financial point of view, this has led to IPOs of various biotech companies (almost half of the IPOs on Euronext Brussels since 2015 relate to biotech companies) and, more generally, to strong interest from investors, private as well as institutional, to invest in such companies.

As the biotech sector grows and evolves, and to ensure efficient development of these sectors, it is crucial that investors and the public have confidence in the public information provided by listed biotech companies. In that respect, the Market Abuse Regulation (***MAR***)[1], which aims to increase market integrity and investor protection and to enhance the attractiveness of securities markets for capital-raising, plays a central role by prohibiting insider dealing, unlawful disclosure of inside information and market manipulation.

Given the specificity of biotech companies' activities (R&D process, development of products on the basis of clinical trial results, stepwise processes and complex, regular assessments on scientific and clinical results, as well as on future

[1] Regulation n° 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse.

perspectives), it might be difficult to circumscribe the notion of what constitutes inside information the disclosure of which is prohibited under the MAR. Deciding what to disclose requires significant judgment.

The recently published opinion by the Belgian Financial Services and Markets Authority (***FSMA***) on good practices with respect to inside information disclosures by listed biotech companies[2] provides useful and clear guidelines for listed biotech companies undertaking clinical trials, particularly those with a limited pipeline of product candidates and/or a limited number of commercial products.

Private companies are not subject to MAR requirements (in particular about what and when to disclose to the public). It remains the case that their communication must be clear and of a high standard. It must be correct when issued, not misleading, without omission and up to date[3]. It is also worthwhile for private companies to apply, to the extent possible and relevant, the guidelines provided by the FSMA with the view to keeping the confidence of shareholders, stakeholders, public and potential investors or partners (in particular, should a corporate transaction or IPO be envisaged).

General Principles

According to MAR, any issuer (whose financial instruments are admitted to trading on a regulated market or who have approved trading of their financial instruments on a multilateral trading facility (MTF) or another type of organized trading facility (OTF)) shall inform the public as soon as possible of inside information which directly concerns that issuer.

Inside information comprises "*information of a precise nature, which has not been made public, relating, directly or indirectly, to one or more issuers or to one or more financial instruments, and which, if it were made public, would be likely to have a significant effect on the prices of those financial instruments or on the price of related derivative financial instruments*." (***Inside Information***)[4]

The clinical development of products by biotech companies is usually a multi-step process and it might be complex to determine when "partial" or "intermediary" information becomes Inside Information to be disclosed. In that respect, the rule is that an intermediate step in a protracted process shall be deemed to be Inside Information if, by itself, it satisfies the criteria of Inside Information.

Biotech Specificities

In order to determine which information must be disclosed by biotech companies, a first step is to consider whether the information related to a product candidate may likely have a significant effect on the price of the company shares (should

[2] FSMA opinion_2020_02 dated 28 October 2020.
See in that respect the document "Best Practice for Communicating R&D progress to investors and the public" published by the UK BioIndustry Association (http://bia.me/RDcommsguide).

[4] MAR, art. 7.1.

the information be made public). This depends on the “value” or the “materiality” of the product candidate, which in principle depends on the expectation of significant revenues for the company, assuming the granting of a marketing authorization.

With respect to a product candidate fulfilling this materiality test, any information modifying materially the evaluation of the expected revenues, the likelihood and timing of the marketing authorization and any decision of the company to start a new phase of the clinical development of the product candidate is in general considered Inside Information.

But the FSMA listed other examples of information which might be considered Inside Information (provided that the aforementioned materiality test is met).

Among those, it is worthy to underline the following elements, it being emphasized that each company must take responsibility for its own communications:

A.- In relation to efficacy and safety results:

(i) it is not only (confirmatory) pivotal phase III results that qualify in most cases as Inside Information, but usually also (controlled) intermediary phase IIB results, as well as (exploratory, non-controlled) proof-of-concept phase IIA results; indeed, Inside Information may arise earlier in the process, for example:

(1°) if there is no (effective) treatment of the disease that is the object of the study, (2°) if the results relate to a product candidate of a biotech company having no other products (or only a few) on the market or in the pipeline, or (3°) if the endpoints can be measured on objective criteria (and not on the basis of subjective evaluation by patients);

(ii) if any undesirable and serious unexpected results in terms of safety of the product candidate occur, then it must be noted that negative results or trends will qualify sooner as Inside Information than positive results; or

(iii) if any decision is made to halt the trials for safety or efficacy reasons.

When data collection is outsourced by a biotech company, data collected by Contract Research Organizations (CROs) or Data Monitoring Committees (DMCs) can also be considered as Inside Information, even before their transmission to the biotech company. These entities must respect the prohibition of disclosure of Inside Information and the biotech company having recourse to such entities shall draw up a list of all persons who have access to Inside Information and who are employed by it (insider list) and shall take all reasonable steps to ensure that any person on the insider list acknowledges in writing the legal and regulatory duties entailed and is aware of the sanctions applicable to insider dealing and the unlawful disclosure of Inside Information.

B.- In relation to the recruitment and treatment of patients: any significant divergence between the actual rate of patient recruitment and/or the number of trials and the forecasted rate of recruitment and number of trials.

C.- Any decision to halt clinical trials or to withdraw any demand for marketing authorization should also be deemed as Inside Information. It might also be the case for any suspension of clinical trials, depending on the circumstances.

D.- The granting of a marketing authorization is, in principle, Inside Information. But before such granting, the opinion given by the Committee for Medicinal Products for Human Use (CHMP) or by the Committee for Orphan Medicinal Products (COMP) might also be deemed as Inside Information. Some information received from the European Medicines Agency (EMA) or any other authority during the process of granting the marketing authorization might also be considered as Inside Information: for instance, additional requests from EMA affecting the likelihood or timing of the granting of marketing authorization or the positive-trending vote among members of a committee ready to recommend the marketing authorization.

E.- The conclusion of R&D, licensing, distribution or other agreements for the product candidate shall also, in principle, be considered as Inside Information. According to the FSMA, even a letter of intent might be considered, depending on the circumstances, Inside Information.

Once it is determined that information must be considered Inside Information, three additional questions arise: (i) when must the issuer disclose the information, (ii) what must be disclosed and (iii) how it must be disclosed.

When must Inside Information be disclosed

MAR is clear: any Inside Information must be disclosed as soon as possible and the company must not await the closing of the relevant market[5].

It is nevertheless possible to postpone the disclosure, provided that:

- the immediate disclosure is likely to prejudice the legitimate interests of the company;

- a delay of the disclosure is not likely to mislead the public; and

- the company is able to ensure the confidentiality of the information[6].

[5] MAR, art. 17.1.

[6] MAR, art. 17.4.

It could be the case that Inside Information need not be disclosed immediately when clinical trial results must be further implemented in order to give to the public an accurate view on such results.

The FSMA gives further examples of when disclosure may be delayed, such as when the EMA (or any other authority) prohibits any disclosure of the relevant information or when such disclosure would likely prevent the conclusion of an agreement (R&D, license or distribution agreement).

Pursuant to the Commission Implementing Regulation[7], the company shall, in case of such delay, which is determined by the company, on its own responsibility, use technical means that ensure the accessibility, readability, and maintenance in a durable medium of the following information:

(a) the dates and times when (i) the Inside Information first became known within the company, (ii) the decision to delay the disclosure of inside information was made and (iii) the issuer is likely to disclose the Inside Information;

(b) the identity of the persons within the company responsible for (i) making the decision to delay disclosure and deciding on the start of the delay, and its likely end, (ii) ensuring the ongoing monitoring of the conditions for the delay, (iii) making the decision to publicly disclose the Inside Information, and (iv) providing the requested information about the delay and the written explanation to the competent authority; and

(c) evidence of the initial fulfilment of the conditions referred to above, and of any change of this fulfilment during the delay period (including the information barriers which have been put in place internally and with regard to third parties to prevent access to Inside Information by persons other than those who require it for the normal exercise of their employment, profession or duties within the company, as well as the arrangements put in place to disclose the relevant Inside Information as soon as possible when the confidentiality is no longer ensured).

The company shall inform, by means of a written notification, the FSMA of a delay in the disclosure of Inside Information and provide any written explanation of such delay.

According to the FSMA, the circumstance that additional trials and tests are being implemented does not by itself justify a delay of disclosure of efficacy and safety results, in particular when it is likely that these additional trials or tests shall not materially modify the results of the initial trials and tests.

[7] Regulation 2016/1055 of 29 June 2016. Art. 4.

What must be disclosed

A.- General Principle.- If it is obvious that the assessment of what to disclose depends on the specific facts and circumstances of each case, with judgements to be made from a scientific and clinical point of view, issuers are required to make the necessary information available to the public in order to ensure the transparency, integrity and proper operation of the market. The information provided shall be true, accurate and genuine, and shall enable securities holders and the public to assess the effect of the information on the issuer's position, business and results[8].

In that respect, it is worth noting that disseminating information which gives, or is likely to give, false or misleading information as to the supply of, demand for, or price of a financial instrument or is likely to secure the price of one or several financial instruments at an abnormal or artificial level, including via the dissemination of rumors, where the person who made the dissemination knew, or ought to have known, that the information was false or misleading, is considered to be a market manipulation.

B.- Other General Guidelines.- In addition to this general rule, other general guidelines must be emphasized:

- Biotech companies must disclose general information but must also disclose scientific and clinical information (even if such information is difficult for financial investors with no expertise or experience in scientific and clinical sectors to understand): the information must be genuinely balanced between technical information and general information.

- The information must be objective and disclosed in a factual manner, avoiding any interpretation or subjective assessment. Should such interpretation be justified, then the disclosure shall include an explicit warning.

- Information related to future expected revenues is allowed only if these revenues can be reasonably expected and by providing the underlining hypothesis.

- Should a third party (such as an authority or a contractual partner) disclose material information, the company must cooperate with such third party (if possible) and in any case disclose similar information, avoiding any contradiction.

[8] Art. 5 of the Royal Decree on the obligations of issuers of financial instruments admitted to trading on a regulated market dated 14 November 2007.

C.- Specific Guidelines.-

Depending on the characteristics of each case, the following actions are recommended:

In relation to efficacy and safety results,

- explain the main characteristics of the clinical essays (objectives, trial design, target, endpoints, etc.), with cross references to the company website or other references, and explain any deviation from previously announced timelines;

- indicate whether the endpoints (primary and secondary) have been met;

- provide a clear analysis of the results and conclusions with a balanced view of pros and cons, as well as information supporting the results without overestimating the significance of the results or their innovative character;

- mention the limits of the trials as well as any warnings, a comparison with other existing or expected treatment, the description of the target market and the existence of any interest; and

- indicate the timing of the next steps.

In relation to recruitment and treatment of patients,

- provide updated information describing the timing of further steps and any decisions in relation to any significant deviation from the expected rate of patient recruitment and/or number of trials.

In relation to any decision to stop clinical trials,

- provide the reasons for such decision as well as any possible consequences of such decision on other expected trials; and

- specify whether the trial might be resumed.

In relation to the granting of a marketing authorization,

- describe the scope of the marketing authorization (and thus its limits) and explain any possible further steps and timing.

In relation to R&D, licensing, distribution or other agreements,

- provide with sufficient information in order to enable investors to understand the advantages and disadvantages of the agreement (rights transferred, exclusivity duration, impact on the liquidity of the company, etc.); and

- in case of termination of such agreements, explain the causes of the termination and its financial consequences, as well as any possible prospects to replace the partner.

How to disclose

The information must always be disclosed in a way that ensures that all shareholders and investors, as well as the market in general, have the same access to the disclosed information at the same time.

There are four required disclosure channels for Inside Information: in the media, to the FSMA, to the regulated market or other trading facility on which the instruments are traded, and on the biotech company's own website.

Inside Information must be published in the media in a clear and safe way so as to (i) ensure quick, complete and non-discriminatory access as well as ensure a correct and quick assessment of the possible impact of the information, (ii) reach the widest possible public, and (iii) have the shortest possible time lapse between disclosure in Belgium and in other EU Member States.

Using the distribution channels such as press agencies and (international) newspapers is recommended. However, using media in each Member State separately is not required.

Practical recommendations

A company must be organized in such a way to ensure that any disclosure of Inside Information is made in an accurate way.

Since it might be difficult to determine when information must be considered Inside Information, when the Inside Information must be disclosed to the public and what must be disclosed, it is critical to implement internal arrangements and procedures within the company to detect any Inside Information and to escalate all information to a committee that might be put in place (a "disclosure committee") which would comprise members of the management board as well as any chief medical officer or chief regulatory officer. The idea is to put in place a multidisciplinary team (scientific, legal and public relation experts).

It is also worth drafting a "Communication Chart" that can be distributed within the company so that managers and employees are aware of and understand the regulation from a practical point of view. Such distribution is particularly important to ensure that no communication (including any communication containing Inside Information) is made during interviews with the press or speeches to investors or scientists/physicians or to other practitioners or in reviews unless the company has previously disclosed the Inside Information pursuant to the applicable rules. Since the confidentiality of any delayed disclosure of Inside Information must be ensured, the "Communication Chart" should also comprise NDA templates and emergency press release templates to be used in case of such delayed disclosure.

The FSMA also recommends establishing a calendar with the expected timing of milestones relating to the clinical trials, results on efficacy and safety, recruitment and treatment of patients' schedules, etc. and disclosing any material deviation from this calendar.

The aforementioned guidelines and recommendations must be understood as general guidelines and good practices but cannot capture the specificities of each biotech company nor each and every particular obligation under applicable regulations.

If you have any questions regarding this client alert, please contact the following attorneys or the Willkie attorney with whom you regularly work.

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