

To communicate or not to communicate?

Some thoughts on the challenges of communicating R&D progress milestones for pipeline drugs to investors and the general public

The global COVID-19 pandemic has generated increased interest in the biotech sector, not only from investors but also from healthcare professionals (HCPs) and of course the general public. Biotech enterprises have responded to this interest with an avalanche of public information on the R&D progress of their COVID-19 product candidates (press releases, press articles, online communications, presentations at conferences, etc.) in all possible forms - from purely scientific publications in peer reviewed journals on the global clinical phase IIb results of an investigational vaccine to aspirational and unsubtle CEO interviews boasting about the massive success rate of a still preclinical candidate in flamboyant online magazines.

* * *

Pharmaceutical compliance

Our first reflex as an EU life sciences counsel would be to recommend said biotech players to exercise some care in the design and wording of such communications to avoid these being regarded as illegal promotion of pipeline vaccines or drugs under the pharmaceutical compliance standards generally applicable throughout the EU. This is definitely not the proper place to lecture you on the intricate ins-and-outs of pharmaceutical advertising within the EU (for those willing to take a deeper look at the subject, feel free to consult some global publications on the topic to which Quinz has contributed: <https://iclg.com/practice-areas/pharmaceutical-advertising-laws-and-regulations>; <https://www.legal500.com/guides/guide/pharmaceutical-advertising/>; <https://practiceguides.chambers.com/practice-guides/pharmaceutical-advertising-2021>). However, such standards can be very broadly simplified as follows:

- i. it is strictly forbidden throughout the EU for a pharma company to promote unregistered drugs to HCPs or the general public,¹
- ii. it is however fine to disclose scientific information on said pipeline drugs, provided that such disclosure is truthful, accurate, complete, and occurs without promotional intent.

Assessing the legitimacy of product pipeline communications under said pharmaceutical compliance standards is often seen as challenging, mainly due to the fact that the line between (i) and (ii) is difficult to draw, and as such leaves an ample grey area. It is sometimes even described as circular. This is also why compliance support for pipeline communications is generally regarded as a complex exercise in risk mitigation rather than an exact science (in part also due to the fact that such communications generally have a regional or global reach, while most compliance standards in the EU remain a national matter).

¹ Note that this prohibition does not apply to responses to an express request from a HCP or patient, as long as this response contains only information that is directly related to the relevant question (and hence does not provide additional information that is not strictly required to answer the relevant question).

Communications on the R&D status of unregistered vaccine or drug candidates will likely fall under scrutiny with regard to the above compliance standards *even if* such communications are specifically targeted at investors, since it seems impossible to completely shield such communications from HCPs or the relevant patient population. Overall, our advice to risk-neutral clients is that the risk of authorities taking offense to pipeline communications and trying to enforce applicable pharmaceutical compliance standards will be very low as long as such pipeline communications do not contain overly aspirational language or exaggerations, do not refer to a specific trademark, are scientifically and factually correct (i.e. are not misleading and are duly documented and supported, for example by peer reviewed publications or data on file), and contain adequate R&D disclaimers and/or forward-looking statements. By taking these steps, the biotech company can limit the chances of such communication being perceived as promotional (or create sound arguments for said communication lacking promotional *intent*). The *content* of the R&D communication is only one element of any compliance assessment, and particular care should also be taken to ensure that the most appropriate and reasonable platform is chosen to share a relevant communication with its intended *audience*. In this specific context, press releases or links to press releases on a corporate website should be appropriate; tweets and online shares by executive members or employees are more challenging as their intended audience is less predictable or controllable, and should in any event be accompanied by either no or a very neutral cover text. We notice that companies with more risk-averse compliance profiles remain very reluctant to publicly disclose R&D updates on their drug or vaccine candidates. Nevertheless, we feel that this reluctance is often unnecessary and might even deny investors (as well as HCPs and the general public) access to legitimate information. Life sciences counsel sometimes even overlook valid arguments to claim that biotech companies are in fact *obliged* to share certain updates on the R&D progress of their pipeline under applicable financial compliance standards, and that such standards should be balanced against the abovementioned principles on pharmaceutical advertising (and might even take precedence) - or at least that any communications in this respect would therefore lack *promotional intent*.

Financial compliance for listed biotech companies.

As mentioned above, share prices and investor confidence have been heavily influenced over the past 22 months by endless headlines on COVID-19 product candidates, vaccine timelines and success rates. This has not gone unnoticed by market authorities which, like supervising bodies for pharmaceutical advertising, are scrutinizing such headlines for potentially misleading information, this time towards investors. For instance, the U.S. Securities and Exchange Commission published an investors alert as early as February 2020 and at the beginning of the summer issued additional guidance on considerations for disclosure in light of the pandemic. Moreover, the SEC suspended trading in multiple biotech companies and brought enforcement actions against them for false or misleading statements and omissions regarding their COVID-19 product pipeline.

On the other side of the coin, various financial transparency regulations actually *require* - either directly or indirectly and with different levels of stringency - certain milestones in the R&D progress of biotech companies to be shared with investors (and the general public), notably to avoid information asymmetry and abuse of insider information. Examples of such transparency obligations can be found in US federal securities law (i.e. the Securities Act and the Securities Exchange Act), as interpreted and implemented through SEC rules (such as the Regulation Fair Disclosure) and SEC enforcement actions. The equivalent situation in the UK is well described in the 2018 UK BioIndustry Association's "Best practice for communicating R&D progress to investors and the public", which provides good (but general) guidance to listed biotech companies on their transparency obligations regarding pipeline drugs (including key clinical results).

The abovementioned friction in financial compliance rules between the *prohibition* for listed companies to share incomplete or misleading R&D progress information and the *obligation* to disclose key R&D milestones with the public requires heightened scrutiny on behalf of said companies. The Belgian Financial Services and Market Authority (FSMA) recently acknowledged the difficulty of this balancing act by publishing (in October 2020) an interesting set of considerations and best practices for sharing information on drug candidates from listed biotech companies (<https://www.fsma.be/en/opinion/considerations-and-good-practices-respect-inside-information-disclosures-listed-biotech>). This is based on the more general Belgian Market Abuse Regulation principle, which stipulates that inside information needs to be shared with the public as soon as possible and false or misleading signals must be avoided. What makes the FSMA's guidance particularly noteworthy is that it truly focuses on the *F* of listed companies to share R&D milestones on drug candidates with investors and contains clear and practical guidance on *how* and *when* such milestones must be shared.

The FSMA, for example, does not only provide a general definition of the type of R&D milestones that qualify as “to be disclosed” inside information (i.e., intermediate events or conclusions in the clinical development process of a product candidate with a significant revenue potential that significantly alter this revenue potential, the timing of a potential marketing authorization and/or a company's decision on whether or not move to the next phase of the clinical development program). It also identifies concrete milestones that would likely qualify as “to be disclosed” events (i.e., information regarding efficacy and safety results,² the recruitment progress, the decision to halt a clinical trial, marketing authorization decisions and the entering into or ending of a partnership). The FSMA also recommends that listed biotech companies disclose a calendar with the expected timings of clinical development milestones and to communicate any significant deviations from this timeline. Relevant inside information should in any event be disclosed as soon as possible unless immediate disclosure is likely to prejudice the legitimate interests of the company (e.g. need for additional analyses, an express request from the EMA) and the delay will not mislead the public. In such cases, the FSMA recommends requesting a temporary suspension of trade during the period of time between inside information arising and its disclosure. Finally, the FSMA stresses that any relevant information should be disclosed to the general public (notably through a press release) and should therefore not be revealed to a limited audience (e.g., presentations to scientists, scientific publications). Unfortunately, the FSMA does not specify to what extent it is possible to make further references to such general releases through other media, including tweets and shares by executives and employees. The latter will hence remain subject to scrutiny under applicable pharmaceutical compliance standards.

To communicate or not to communicate?

The abovementioned (concrete) financial transparency obligations (from the FSMA) might be perceived as onerous to certain listed biotech companies that have no organized communication strategy in place, but they provide comfort to (Belgian) biotech enterprises that have always been eager to share key R&D milestones with the world but were reluctant to do so for (pharmaceutical) compliance reasons.

Going back to our initial analysis of pharmaceutical compliance, we do not feel that biotech companies should be concerned that the public disclosure of R&D updates on drug or vaccine candidates through press releases still constitute a breach of the strict prohibition under pharmaceutical compliance standards to promote unregistered drug products, as long as (i) they have acted in conformity with applicable financial disclosure obligations;

² In this respect, the FSMA even clarifies that inside information regarding efficacy of a product candidate does not only arise from pivotal phase III results but may also be a consequence of intermediary phase IIB or proof-of-concept phase IIA results.

and (ii) the relevant communication does not contain aspirational language, exaggerations or references to trademarks, is scientifically and factually correct (i.e. not misleading and duly documented and supported, for example, by peer-reviewed publications or data on file)³, and is made through an adequate platform. Applied to the Belgian situation, in our view this would mean that supervising bodies for pharmaceutical compliance will not be able to argue that a general release concerning a certain pipeline communication has promotional intent if this communication is in line with relevant FSMA guidelines (subject of course to the above proviso under (ii)). As mentioned above, further references to such releases, including tweets and shares by executives and employees, present more of a challenge. In our view this should not be impossible as long as such references contain either no or a neutral cover text. . That said, we note that foreign authorities (such as the PMCPA in the United Kingdom) sometimes have stricter views in this respect.

Whether non-listed companies could invoke similar arguments to challenge the promotional intent of certain communications on R&D milestones is a more challenging question. Our feeling is that they should, subject to quite some caveats. But that's another story for another time.

³ Note that this second requirement is itself already embedded in the FSMA guidance note ("Communications should be clear, objective and balanced, provide a mix of technical and non-technical information and must not overstate the significance and novelty of any results").

Authors



Olivier Van Obberghen
Partner
Olivier.vanobberghen@quinz.be
+32 2 255 73 80



Pieter Wyckmans
Partner
Pieter.wyckmans@quinz.be
+32 2 255 73 80



Michiel D'herde
Associate
Michiel.dherde@quinz.be
+32 2 255 73 80



Amber Cockx
Associate
Amber.cockx@quinz.be
+32 2 255 73 80