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Continuous disclosure for life sciences companies

Continuous disclosure is a key challenge for boards of all ASX-Listed companies. The obligation of "immediate" disclosure of market-sensitive information requires Boards to make quick decisions, sometimes based on incomplete information.

For life sciences companies, there are added complexities such as:

- providing balanced and clear explanations of highly technical information;
- juggling disclosure obligations with embargo requirements for thought leadership journals and conferences; and
- keeping a reasonable flow of announcements over the long development timeline.

These challenges underpin the 'Code of Best Practice for Reporting by Life Science Companies' (the Code), written by ASX, AusBiotech and other key participants in the life science sector[1].

What are a listed company's legal obligations?

ASX Listing Rule 3.1 requires that entities immediately disclose market sensitive information that a reasonable person would expect to have a material effect on the price or value of the entity's securities. Breaking down this obligation:

Market Sensitive Information	Life science entities must objectively assess what information would likely influence an individual who commonly invests in securities to acquire or dispose their securities. The Code provides a number of relevant for life science companies.
Immediately (meaning "in a prompt manner without delay")	Be prepared by establishing a subcommittee of the board with delegated authority to release disclosures to the market. This is particularly important where speculation or inaccurate reports are published on social media or forums such as "Hot Copper" and the entity needs to correct the market. Life science entities can also use trading halts to respond to unexpected events, when faced with an evolving situation (such as a deal that is under negotiation and close to signing) or where there is a large volume of complex material to analyse (e.g clinical trial results).

The expectations of a reasonable person	Life science entities must contemplate what information an independent and prudent individual would expect to be disclosed. It is essential that entities do not "cherry pick" by over-emphasising positive information while downplaying or obscuring negative information. This is especially important when reporting on clinical trials. Entities must disclose the results of the trials regardless of their outcome, because that information will certainly have a material effect on the value of the securities.

What are the exceptions?

A life science entity does not need to disclose information for so long as all three of these requirements are fulfilled:

1. **At least one of these applies;**
   - it would be a breach of law to disclose the information;
   - the information concerns an incomplete proposal or negotiation;
   - the information comprises matters of supposition or is insufficiently definite to warrant disclosure;
   - the information is generated for the internal management purposes of the entity; or
   - the information is a trade secret;
2. **the information is confidential** and the ASX has not formed the view that the information has ceased to be confidential; and
3. **a reasonable person would not expect the information to be disclosed**.

As soon as one of these ceases to apply, the entity must disclose.

How does the Code assist?

The Code is a non-binding guideline for life science entities to use as a practical resource in applying the legal requirements of Listing Rule 3.1.

It promotes clear, timely and accurate market disclosures around key drivers of value for life science entities. Here is a summary of some of the guidelines:

Value Driver	Commentary
Clinical Trials	• Clearly state how the study is linked to the relevant regulatory pathway so investors understand the significance of the trial; • At the beginning, explain the endpoints, and other key aspects of the trial protocol; and • Report trial results by reference to the previously disclosed endpoints, structure and protocol. • The Code recognises the importance of peer review, through the process of publication in a journal or presentation at a scientific conference (which typically have embargo rules). Companies need to manage this process carefully, through ensuring that the information is shared in confidence with relevant reviewers. As the Code is a framework only, companies may reach a point where Listing Rule 3.1 requires disclosure regardless of a conference embargo.
Regulatory and Reimbursement Matters	• Disclose progress towards regulatory approvals and confirmation of reimbursement; • Explain how those milestones affect the potential future sale of products in the relevant jurisdictions
Intellectual Property and Regulatory Exclusivity Rights	• be clear on the extent of the rights and period of exclusivity conferred and its commercial significance. • Note that simply filing a patent is unlikely to be material[2]

Value Driver	Commentary
	• Entities need to balance commercial sensitivity of the key commercial terms with the needs of investors to properly assess the value of the transaction.
Licensing and other agreements of Commercial Significance	• Guidance Note 8 provides further direction: being subject to a confidentiality obligation does not excuse the entity from disclosing information if investors need to know it in order to assess the impact of the deal on the company's value. It is therefore essential that confidentiality clauses in contracts have a "carve out" for compliance with continuous disclosure obligations
Key Staff Appointments and Departures	• In addition to mandatory disclosures (changes in directors or company secretary), entities should disclose incoming and departing key managers or advisory board members, particularly where the organisation has a small team.

Applying the Code

Life science entities need to recognise that the investors (both retail and institutional) may struggle to understand how achieving (or missing) milestones in the commercialisation pathway affect the company's value. By applying relevant guidance from the Code, a listed life science entity can strengthen its continuous disclosure practices, and the clarity of disclosures. This will promote informed and engaged investors and assist the Board in managing risk of non-compliance.

[1] The Code, last updated in 2013, is currently being updated.

[2] Reiterated in **Listed@ASX Compliance Update no. 11/21**