# INDUSTRY STANDARD FOR INFORMATION DISCLOSURE IN LIFE SCIENCE CAPITAL RAISING

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The Swedish Life Science Industry Organization

# Foreword

The life science industry is capital-intensive – without substantial investments, few projects would reach patients. Many companies will fail, while a select few will create global blockbusters. As an industry, we therefore depend on investors who are willing to expose themselves to high risk, knowing that it can sometimes result in very high returns.

With around 200 publicly listed life science companies, the investor community in Sweden is a heterogeneous mix of specialists and retail investors. Since life science companies are often very complex, individual companies bear a particularly great responsibility to clearly report both the potential of development projects and their risks.

This industry standard has been created as a support for companies facing capital raising. By following the standard, you as a company ensure that investors can make well-informed decisions, which in turn creates conditions for a stable and long-term relationship. Significant uncertainties naturally exist in life science companies, and many questions often remain unanswered. However, this standard provides guidance for clarifying what is actually known and what assumptions have been made, creating a solid foundation for building trust both for individual companies and the industry as a whole.

An initial version of this industry standard was published in December 2020. This updated version includes a clearer division between pharmaceutical development companies and medical technology companies, as the conditions differ in a way that also affects what information is relevant to share with investors. The hope is that the industry standard is now so easy to follow that it becomes the obvious framework for how we jointly create transparency and clarity for life science companies in the capital market.

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## TARGET AUDIENCE

The target audience for the industry standard is all companies in the life science sector that are facing capital raising in Sweden, both private actors and companies operating in a listed environment.

## HOW TO READ THE INDUSTRY STANDARD

The industry standard provides an overview of the information areas that the company, according to SwedenBIO's assessment, should communicate in connection with capital raising to provide a clear and transparent description of the company's potential and risks. For all development companies in the life science industry, there are certain general areas that should always be reported. In addition to these, there is specific information that is relevant depending on whether the company conducts pharmaceutical development or develops medical technology products.

The industry standard is therefore structured in three parts:

- General information that all life science companies should disclose
- Specific information that pharmaceutical development companies should disclose
- Specific information that medical technology companies should provide

Note that the guidelines do not specify in which order the information should be presented to potential investors, but only what information should be included. The standard should also not be read as a recommendation on how to build an investment case; the purpose is solely to establish a common ground for what information should always be disclosed to achieve our common goal of strengthening confidence in the life science industry and enabling companies to realize their strategies through value building.

## A RECOMMENDATION THAT COMPLEMENTS THE REGULATIONS

The industry standard is applied on a voluntary basis and should be seen as a recommendation that complements the information that the company is obligated to provide in connection with capital raising according to applicable regulations. This includes, among other things, prospectus rules, the Market Abuse Regulation (MAR), and the information requirements imposed by the relevant marketplace. The industry standard also does not include the customary information that should be provided about the company and is relevant for companies in all industries, such as

information about the company's financial position and general risks associated with the business.

## FOCUS ON MATERIAL PROJECTS OR PRODUCTS

The information points focus on the company's most material projects or products, where materiality is defined based on the projects' potential impact on the company's market value and strategic position.

If the company conducts several strategically important development projects or has several significant products, the documentation should include detailed information about each of these.

# General information that all life science companies should disclose

## EXPERIENCE AND COMPETENCE

- **Background of management and board**
  Describe the experience and competence of management, board, and other key personnel in the development and/or commercialization of similar projects or products, or experiences and competence from other industries.

## BACKGROUND AND HISTORY

- **Founders**
  Describe the founders' background and the company's origin.
- **Project origin**
  Briefly describe the project or product origin. For example, specify whether it originated from an academic institution, pharmaceutical company, biotechnology company, or medical technology company.
- **Licensing**
  State whether the project or product is wholly owned or if any part of it is, or has previously been, licensed to a third party.
- **Commitments to third parties**
  Account for any existing commitments to third parties, such as obligations to pay royalties, milestone payments, or other financial obligations.

## PATENTS AND OTHER INTELLECTUAL PROPERTY RIGHTS

For the company's material projects or products, the following information should be disclosed:

- **FTO analysis (Freedom to Operate)**
  Describe if a patent landscape or FTO analysis has been conducted and account for its main conclusions, including any identified obstacles or limitations for commercialization.
- **Patent rights**
  Describe any patents and how they protect the relevant project or product (for example, "composition of matter," formulation, use patent, and in which markets) and what patent applications have been submitted.

- **Other intellectual property rights**
  Describe other material intellectual property rights that the company has or needs for the development and commercialization of the project or product, such as trademark protection or data exclusivity.
- **Patent term and duration of protection**
  State the validity period of the patent protection, including any possibilities for supplementary protection.

## CAPITAL REQUIREMENTS AND FINANCING MODEL

- **Overall strategy to create shareholder value**
  Describe the company's primary strategy for creating shareholder value and estimate the approximate capital requirement to reach this point, for example, an estimate of the total capital requirement to reach commercialization, out-licensing, or exit.
- **Planned capital raising**
  Describe how the company plans to raise the needed capital – for example, through new share issues, debt, out-licensing, or public financing.
- **Next value-driving or risk-reducing milestone**
  Identify the next material milestone that is expected to drive value or reduce risk for the project or product. Estimate the approximate capital requirement to reach this milestone and describe the main assumptions underlying the calculation.
- **Previous capital raising and shareholder structure**
  Account for how much capital the company has raised so far, how this capital has been utilized within the business, and what the shareholder structure looks like.

## MARKET ASSESSMENTS

For the company's material projects or products, the following information should be disclosed:

- **Market size and potential**
  Describe the main assumptions regarding the possible market size, for example, number of relevant procedures, treatments, or tests per year, estimated annual sales value, and primary geographic markets.
- **Drivers and barriers**
  Identify the most important factors that can affect the project's success in the

market, such as regulatory changes, technological advances, and medical needs.

- **Competitive situation**
  If possible, indicate similar competing projects or products in the market and describe how the current project or product differentiates itself from these.
- **Subsidization and reimbursement systems**
  Assess whether the product can receive subsidies in the relevant markets and describe whether similar products are already subsidized and, if so, to what level.

# Specific information that pharmaceutical development companies should provide

## DEVELOPMENT STATUS

For the company's material projects or products, the following information should be clear:

- **Development phase**
  Indicate if the project is in the
  - Preclinical phase (identification, optimization, validation, safety/toxicity)
  - Clinical phase (phase 1, phase 2, or phase 3)
  - Registration or market approval
- **Available results**
  Report what results are already available and the timeline for when the remaining studies are planned to be conducted.
- **Planned clinical studies beyond regulatory requirements**
  Indicate if the company plans additional clinical studies beyond what is required by regulations, and the purpose of these, such as market differentiation and competitive advantages, follow-up studies for safety and efficacy, or health economic studies for subsidization.

## REGULATORY CLASSIFICATION AND STATUS

For the company's material projects and products, the following information should be clear:

- **Regulatory requirements**
  - What clinical study programs are required to obtain market approval.
  - If different clinical study programs are required for different markets.
- **Decisions and statements from authorities**
  - Account for material interactions with regulatory authorities, such as formal decisions and approvals, authority statements, or guidance.
  - Any regulatory obstacles or requirements that may affect the project's or product's market entry and planned measures to handle these.
- **Market approvals**
  - If the product is approved for sale, specify in which markets and for which indications.

# Specific information that medical technology companies should provide

## REGULATORY CLASSIFICATION AND STATUS

For the company's material projects or products, the following information should be disclosed:

- **Regulatory classification within the EU and USA**
  - What regulatory classification the product has according to EU regulations (MDR or IVDR) and regulatory status in the USA (510(k), PMA, De Novo, or Exempt Devices).
  - What clinical data and technical documentation are required for the current regulatory class to obtain certification via a Notified Body in the EU and FDA approval in the USA.
- **Regulatory requirements in other markets**
  - What regulatory requirements must be met in the identified markets.
  - Planned strategy for market entry and certification in these markets.
- **Status of regulatory process in the EU and USA**
  - Status of CE certification, FDA approval, and any ongoing applications in other markets.
- **Decisions and statements from authorities**
  - Account for material interactions with regulatory authorities, such as formal decisions and approvals, authority statements, or guidance.
  - Any regulatory obstacles or requirements that may affect the project's or product's market entry and planned measures to handle these.

## PRODUCT DEVELOPMENT STATUS AND CLINICAL DEVELOPMENT PLAN

For the company's material projects or products, the following information should be disclosed:

- **Planned clinical studies beyond regulatory requirements**
  Indicate if the company plans additional clinical studies beyond what is required by regulations, and the purpose of these, such as market differentiation and competitive advantages, follow-up studies for safety and efficacy, or health economic studies for subsidization.

## COMMERCIAL STATUS

For the company's material projects or products, the following information should be disclosed:

- **Sales force and market presence**
  Describe if there is an established sales force and if so, in which markets it is active and since when the sales force has been established.
- **Distribution and collaboration agreements**
  Account for any existing distributor or collaboration agreements, including in which markets the agreements apply and the scope and nature of the agreements (exclusive or non-exclusive).
- **Commercialization plan and expansion strategy**
  Describe how commercialization is planned in markets where establishment has not yet occurred, such as strategy for market entry (own sales, partnerships, licensing, etc.) and status of planned and ongoing activities.