

EMERGING RISKS MANAGEMENT

GRI Standards :

102-11: Precautionary Principle or approach

EXECUTIVE SUMMARY

Sanofi is operating in a volatile, uncertain, complex and ambiguous environment, and risk is inherent to its activity. Beyond management of risks facing the company in the short term (see factsheet “Risk Management”), it is critical to identify and assess risks arising from long term trends. Emerging risks take the form of a threat or opportunity, not yet impacting Sanofi and up to five years or more.

Through prospective surveys and collaborations with senior managers and expert’s functions from all departments within the company, Sanofi Risk Management team identifies trends, main threats and opportunities to be anticipated by pharma and biotech industry. Its survey, outcomes, map, deep-dive scenarios and analysis are presented in the Sanofi Risk Radar document updated each year.

TABLE OF CONTENTS

1. BACKGROUND	3
2. EMERGING RISKS MANAGEMENT APPROACH	3
2.1. Emerging risks identification	3
2.2. Emerging risks assessment	3
2.3. Emerging risks scenarios.....	3
3. EMERGING RISKS EXAMPLES	4
3.1. Increasing threats incurred by geopolitical factors.....	4
3.2. Rising regulatory expectations from Healthcare authorities.....	4

1. BACKGROUND

Sanofi is operating in a volatile, uncertain, complex and ambiguous environment, and risk is inherent to its activity. Beyond management of risks facing the company in the short term, it is critical to identify and assess risks arising from long term trends.

Emerging risk takes the form of a threat or opportunity, not yet impacting Sanofi and up to five years or more. The potential impact is still unknown, weakly understood and ambiguous due to a lack internal and external reference framework and data. The risk / benefit balance for Sanofi is uncertain and needs to be anticipated with scenario planning and early response implemented when relevant.

2. EMERGING RISKS MANAGEMENT APPROACH

Emerging risks management approach consists of a phase of environment observation and interviews with Sanofi senior managers to identify emerging risks, followed by an assessment phase to allow Sanofi to anticipate responses, and set up of scenarios to figure out how emerging risks may impact the company.

2.1. Emerging risks identification

Sanofi Risk management team performs a prospective survey regarding trends for the coming years and main threats and opportunities to be anticipated by pharma and biotech industry, in order to raise awareness over actual and emerging risks context. This prospective survey is updated each year in Q1.

In parallel, interviews are carried out to identify emerging risks specifically facing the company. They target Senior managers from expert functions requiring a long-term vision such as Strategy and Business Development, Research and Development, Market Access, Corporate Social Responsibility, Medical Affairs and Competitive intelligence.

2.2. Emerging risks assessment

Emerging risks are assessed based on the following criteria :

- > Likelihood ;
- > Anticipated impact on Sanofi activities ;
- > Velocity, i.e. time before the risk materializes.

Emerging risks are presented in a document called Sanofi risk radar, subject to the same governance rules as Sanofi risk profile (See Factsheet 2020 – Risk management).

2.3. Emerging risks scenarios

In order to support emerging risks assessment, deep-dive scenarios are developed for prioritized emerging risks, evidencing :

- Signals that emerging risks might become active ;

- Early response driven by operational teams to connect and share actions taken to anticipate risk impact ;
- Identification of proposed options for action.

In 2019, the Sanofi risk radar was presented to the Executive Committee and to the Audit Committee of the Board. Two sets of risk mapping and scenarios were presented to the Risk Committee in relation with two risks from the radar.

In 2020, a specific task force will assess to which extent risk radar shall be adapted to capture COVID 19 pandemics impacts, and potentially connected geopolitical, macroeconomic and societal consequences.

3. EMERGING RISKS EXAMPLES

As an illustration, we describe two emerging risks identified and assessed by the company in 2019, the potential consequences for patient, company reputation and business.

3.1. Increasing threats incurred by geopolitical factors

Due to its global footprint, Sanofi is might potentially exposed to the following geopolitical threats :

- Political and social instability :
 - > Political instability may trigger unexpected changes in Healthcare regulations in the countries where Sanofi operates.
 - > Social instability incurring protests or riots may lead to transportation disruptions or borders closing impacting our supply chain as well as the security of our employees.
- Populism and rise of protectionism might directly impact Sanofi business through increase of customs tariffs.
- State-on-state tensions or regional conflicts might as well cause supply disruptions.

In order to mitigate this risk, Sanofi monitors its exposure through an in-depth follow-up of country risk, and has procedures in place to protect company's assets, employees and contractors. On the top of this, in 2019, a deep dive was performed crossing geopolitical risk level of countries where Sanofi operates with Sanofi footprint in order to evidence geographies where Sanofi is most exposed.

The velocity of this risk is assessed as very rapid.

3.2. Rising regulatory expectations from Healthcare authorities

Due to the diversity of its product portfolio, Sanofi can be subject in the future to new regulatory requirements on some components of its products or raw materials, or on the manufacturing process and conditions.

For example,

- As part of the Registration Evaluation Authorization of Chemicals (REACH) European regulation, the use of some chemical substances may be restricted or banned.

- The use of Nanotechnologies in medicine is set to spread rapidly, e.g. for cancer therapy. Since the size of nanomaterials open new ways for drug delivery but also could raise toxicity issues, several agencies are in the process to issue regulatory frameworks covering this subject.
- The use of plastics and micro-plastics in Sanofi products.

In order to mitigate this emerging risk, Sanofi implements task forces involving representatives from relevant Global Business Units and Global Functions such as Quality, Medical affairs, Regulatory affairs, Health Safety and Environment and Risk management to assess the impact for Sanofi and define mitigation actions as necessary.

The velocity of this risk is assessed as rapid.

For more information, see our [Publications](#) :

2019 Universal Registration Document :

- Section 4.2 : Détail des enjeux et des risques (pages 321-366)

2019 Form 20-F :

- Item 3-D : Key information – Risk Factors (pages 3-14)
- Item 4-B9 : Information on the Company – Business overview – Insurance and Risk coverage (pages 41-42)