

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 ten 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. BACKGROUND3

- 2. EMERGING RISKS MANAGEMENT APPROACH3

- 2.1. Emerging risks identification3
- 2.2. Emerging risks assessment3
- 2.3. Emerging risks scenarios4
- 2.4. Emerging risks radar overview4

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 ten years. 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, and Medical Affairs.

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 emerging risk becomes an active one, to be included in Sanofi risk profile.

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).

In 2020, the risk radar was adapted to capture our perception of COVID- 19 impact on emerging risks in geopolitical, macroeconomical and societal fields.

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 2020, 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 emerging risks from the radar.

2.4. Emerging risks radar overview

Emerging risks identified in 2020 are in relation with the following topics:

- **Technology progresses acceleration**

Gene therapies and new technologies based on mRNA, beyond COVID 19 vaccines, as well as digital solutions or outsourcing of key value chain steps such as discovery research or clinical development may lead to Pharma business model disruption.

- **Healthcare systems sustainability**

Changing societal, environmental, demographic and technological patterns are putting healthcare systems sustainability at risk. As a consequence, new ways of managing populations health as well as new pricing models may emerge.

- **Climate change and health**

Climate change will lead to extreme weather phenomena, food and drinking water shortages, and increased air pollution, impacting human health. Pharma capability to meet patient needs developing new drugs against air pollution and vector borne diseases is at stake.

- **Geopolitical and societal evolutions**

Political and social instability caused by global recession, protectionism attempts, and tensions between US and China are uncertainties Pharma industry will need to deal with, while stakeholders requirements keep strengthening, for example on product components.

Trend description, impact for Sanofi, opportunities and threats, and early actions are presented below for two of these topics: healthcare systems sustainability and climate change.

For Healthcare systems sustainability:

-Time horizon: 3 to 5 years

-Trend description:

Changing societal, environmental, demographic and technological patterns are straining healthcare systems capacity. While non communicable diseases (e.g. cardiovascular or mental illnesses) had replaced infectious diseases as leading causes of death, SARS Cov-2 pandemic (COVID-19) evidenced hospital systems limitations, questioning healthcare systems robustness and states ability to fund them.

-Impact for Sanofi:

- Pricing : pricing & market access landscape may evolve due to changes in payers priorities and funding. Sanofi may be impacted on the reimbursed part of its sales.
- Product mix : in the context of SARS Cov-2 pandemic, and given economic consequences expected in the middle run, switches may be observed in prescriptions or customers buying habits such as switch to less expensive Customer Healthcare products, prescription of drugs without adverse effect on immunology, or decline of travelers vaccines demand.

-Opportunities and threats

Opportunities:

- Digital technologies allowing aggregation and analysis of patient data into a single actionable patient record, and design of cost effective treatments adapted to each patient
- Subscription based model for drug purchases through which a payer would subscribe to a Pharma company for its drugs on a renewable contract
- Growing populations expectations regarding Corporate Social Responsibility, including contribution of pharmaceutical companies to healthcare systems sustainability
- Importance of improving populations health underscored by SARS Cov- 2 epidemic

Threats:

- Price cuts on reimbursed products
- Economic difficulties caused by pandemic reducing populations access to healthcare
- Vaccine hesitancy undermining progress against pandemic and keeping healthcare systems under tension

-Sanofi early actions:

Sanofi is willing to contribute to healthcare systems sustainability through:

- Development of two vaccines against COVID- 19
- Experiment on subscription based model with Insulin Valyou Savings Program in the US offering insulin and pens each month at fixed price regardless of patient income
- CHC importance in Play to Win strategy : “Invest in brands and geographies of focus for best-in-market growth in 2024/2025” (Presentation Play to win strategy – February 2020)

For Climate change and impact on health:

-Time horizon: 5 to 7 years

-Trend description:

Climate change creates multiple challenges in the middle and long run:

- Influencing human lives and health in numerous ways as it can lead to weather phenomena, heatwaves and extreme cold, food shortages, difficulties in accessing drinking water and increased air pollution

- Inducing indirect effects by creating favorable conditions for the intensification and spread and vector borne diseases

-Impact for Sanofi:

Climate change may impact Sanofi at two levels:

- Operational: Sanofi sites and supply chain may be impacted by climate change consequences
- Societal: Among its commitments regarding Corporate Social Responsibility, Sanofi has to participate to fight against climate change reducing its carbon footprint and taking measures to limit climate change impact on environment and human health

-Opportunities and threats

Opportunities:

- Develop treatments against pollution-related allergies and vector borne diseases

Threats:

- Water shortages causing production disruptions
- Severe weather events damaging Sanofi sites and / or disrupting supply chain
- Energy prices rise

-Sanofi early actions:

- Contribution to global fight against climate change (partnering with COP, commitment to follow TCFD guidelines)
- Objective to reduce CO2 emissions from industrial and R&D sites by 50% between 2015 and 2025
- R&D effort on climate sensitive diseases (e.g. oral treatment against sleeping sickness, new vaccine against yellow fever for Latin America)
- Development of case studies as anticipation tools to figure out how the emerging risk “climate change and impact on health” may materialize

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

2020 Unified Reference Document :

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

2020 Form 20-F:

- *Item 3-D: Key information – Risk Factors*
- *Item 4-B9: Information on the Company – Business overview – Insurance and Risk coverage*