

# Emerging Risk 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, 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.

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.

# TABLE OF CONTENTS

- 1. Background..... 3*
  
- 2. Emerging risk management approach..... 3*
  - 2.1. EMERGING RISK IDENTIFICATION ..... 3**
  - 2.2. EMERGING RISK ASSESSMENT ..... 3**
  - 2.3. EMERGING RISK SCENARIOS..... 3**
  - 2.4. EMERGING RISK RADAR OVERVIEW ..... 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 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 risk management approach

Emerging risk 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 RISK 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 RISK ASSESSMENT

Emerging risks are assessed based on the following criteria:

- likelihood;
- anticipated impact on Sanofi activities; and
- 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.

*For more information, see our [Document Center](#): Risk Management Factsheet.*

### 2.3. EMERGING RISK 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; and
- identification of proposed options for action.

The Sanofi risk radar is presented yearly to the Executive Committee and to the Audit Committee of the Board.

## 2.4. EMERGING RISK RADAR OVERVIEW

Emerging risks identified in 2021 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 patients' 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 the 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:*

Three to five 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, the 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; and
- product mix - in the context of the 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 (CSR), including contribution of pharmaceutical companies to healthcare systems sustainability; and
- importance of improving populations' health underscored by the SARS Cov-2 epidemic.

#### *Threats:*

- price cuts on reimbursed products;
- economic difficulties caused by pandemic reducing populations' access to healthcare; and
- vaccine hesitancy undermining progress against pandemic and keeping healthcare systems under tension.

#### *Sanofi early actions:*

Beyond launch of a vaccine against COVID-19, Sanofi is willing to contribute to healthcare systems sustainability through:

- 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; and
- 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:*

Five to seven 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; and
- inducing indirect effects by creating favorable conditions for the intensification and spread of vector-borne diseases.

#### *Impact for Sanofi:*

Climate change may impact Sanofi at two levels:

- operational - Sanofi sites and supply chain may be impacted by the consequences of climate change; and
- societal - among its commitments regarding CSR, Sanofi has to participate to fight against climate change reducing its carbon footprint and taking measures to limit the impact of climate change on the 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 the supply chain; and
- energy prices rise.

#### *Sanofi early actions:*

- contribution to global fight against climate change (partnering with COP, commitment to follow TCFD guidelines);
- objective to reduce CO<sub>2</sub> 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); and
- 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](#):*

- *Universal Registration Document:*

- > *Section 4.3: Détail des enjeux et des risques DPEF (in French – or see [English version](#))*

- *2021 Form 20-F:*

- > *Item 3-D: Key information – Risk Factors*

- > *Item 4-B: Information on the Company – Business overview – Insurance and Risk coverage*