

## CONTINUITY OF ACTIVITIES AND SUPPLIES

**GRI Standards :**

416-1 : Customer Health and Safety

### EXECUTIVE SUMMARY

As a global healthcare leader Sanofi is committed to protecting our Patients Health every day. With this in mind we focus our Supply Chain efforts to deliver medicines and vaccines to the market without interruption.

In order to meet our “Zero out of stock” objective on a daily basis, Sanofi has implemented guidelines, tools and processes across the end to end supply chain.

Through these actions, Sanofi is committed to making sure that no link in the production and supply chain is missing or deficient, ensuring a good distribution, reacting as quickly as possible to safeguard the continuity of the company’s activities, as well as the medicines and vaccines production and creating the taskforce required in case of a pandemic or major crisis.

# TABLE OF CONTENTS

- 1. BACKGROUND .....3
- 2. POLICIES AND ACTION PLAN .....4
- 2.1. Ensuring the continuity of the supply chain on a daily basis .....4
- 2.2. Ensuring good distribution .....5
- 2.3. Ensuring the continuity of activities in case of a major crisis .....5

## 1. BACKGROUND

---

As a global healthcare leader Sanofi is committed to protecting our Patients Health every day. With this in mind we focus our Supply Chain efforts to deliver medicines and vaccines to the market without interruption.

Moreover, in the event of a pandemic or major crisis (natural disaster, nuclear accident, humanitarian emergency, health-related risks, etc.), Sanofi is committed to:

- Reacting as quickly as possible to bring to the market vaccines to prevent the outbreak of any pandemics.
- Taking all necessary measures to safeguard the continuity of the company's activities, ensuring that the production of medicines and vaccines is not interrupted.
- In the event of a supply crisis, creating a taskforce to manage the crisis. The principal taskforce members will include the appropriate specialists from across the company.

While our goal is meet a "Zero out of stock" objective, stock outs do occur. Stock outs can occur due to a disruption anywhere in the end to end Supply Chain: from our material Suppliers, through our manufacturing sites and through our distribution network to end customers.

Stockouts can have multifactorial origins.

- Increased Demand. The global demand for medicines is increasing due to the improvement and development of access to healthcare. This is a positive phenomenon, but given long lead times to bring on line additional capacities across the Supply Chain it can generate tight supply in the short term.
- Constrained supply of raw materials and active ingredients. An example of this is the risk of supply from Chinese or Indian Suppliers, who remain a key source across the industry. As Chinese authorities tighten environmental policy, in the short term this can lead to tight supply on some materials.

New regulatory requirements. An example of this is "Track and Trace" or Serialization policy. This has required significant investment in our sites, distribution centers and indeed in Hospitals and Pharmacies. In the short term this has reduced production throughput as we adapt our sites.

- Manufacturing issues. Given the long and complex production processes for some of our medicines, we can have interruptions along this chain. An example being our vaccines production, it can take up to 36 months to produce a complex vaccine. During this long biological process, made from living organisms, issues can arise which take time to address and can impact supply.
- Distribution issues. While these are rare, we can experience delays in supplying product to our customers in times of constrained air, sea or road shipments.

## 2. POLICIES AND ACTION PLAN

---

### 2.1. Ensuring the continuity of the supply chain on a daily basis

Sanofi's supply chain strategy aims to guarantee the continuous supply of drugs and vaccines to our patients, without any disruption. Our goal is to meet a "zero out-of-stock" objective. This means that no link in the chain should be missing or deficient, to protect patients and ensure that they will have access to our products at all times.

We have defined a set of guidelines, tools and processes to be used across the end to end supply chain. We monitor and control these in compliance with our continuous improvement policy.

In each affiliate, the supply chain and marketing functions work together to produce two kinds of sales forecasts:

- Short-term forecasts (up to 36 months) are for the most part operationally driven; when combined with appropriate inventory policies from each affiliate, these forecasts are the key to meeting the "zero out-of-stock" goal.
- Long-term forecasts (36 months to 5/10 years) provide the basis for investment decisions because they provide a view on long-term sales for a given product, geographical area, or for specific technologies.

At site level, sales forecasts are used to determine the manufacturing and raw material needs for each product. For this purpose, it is essential to carefully analyze and plan resource requirements.

After our products have been manufactured and released, they are shipped through the company's Distribution organization. This organization is made up of a mix of in house and third party distribution centers.

Once the products arrive in each domestic distribution center, they are delivered through our three main distribution channels:

- Direct to pharmacies.
- Direct to hospitals.
- Deliveries to wholesalers.

To maintain a high service level to our customers, several indicators are monitored across the end to end supply chain. Together they constitute an alert system to notify the different functions of any potential risks or incidents.

Our overall service level is around 98,3%. We have over the last year seen a slight increase in service level of around 0.3% points.

In addition, we are investing heavily in new process and tools across the end to end supply chain. The objective is to give greater visibility on demand and ability to adapt our supply chains to meet this demand. We have already launched these new processes and tools in some lead countries and have a program to roll out globally over the next three years.

These new processes and tools will increase our capability to predict supply issues and be better prepared to minimize their impact on customers and ultimately patients.

Our inventory policy for finished goods ranges from two to three months, depending on the product, country, market context, manufacturing process and distance between the manufacturing site and the targeted market. For products listed as lifesaving drugs, the minimum inventory level is set at 60

working days (three months minimum) to avoid stockouts. If a market estimates that a higher minimum level is needed, the parameter can be adjusted.

### **Managing supplies of lifesaving drugs**

For several years, the Global Medical Department has worked with affiliates to identify lifesaving drugs in each country where Sanofi operates. This concerns the company's medicines and vaccines that have no therapeutic equivalent or no local alternative available. The company's philosophy is that these medicines should always be available in adequate quantities.

On the basis of this list, it is possible to define production priorities in the event of a major accident at one of our production sites (fire, natural disaster, etc.) or of a pandemic outbreak. Contingency plans can then be drawn up based on these priorities.

## **2.2. Ensuring good distribution**

In countries where Sanofi has distribution centers, contingency plans are activated in the event of an interruption in the supply chain.

As an example, Sanofi has three distribution centers in France and manages domestic distribution to conventional channels (wholesale distributors, hospitals and pharmacies). All the company's distribution centers use the same information system and can easily provide back-up support to one another, if one of the centers is temporarily down.

In countries where outside service providers are in charge of distribution, these service providers are carefully selected for their quality of service as well as for their financial health and compliance with HSE/CSR principles. If a potential risk is detected, Sanofi enters into an agreement with another provider on the market that can act as a back-up, should difficulties arise with the main service provider. Over a 10-year period, only three significant events have occurred (in Venezuela, the Netherlands and Korea), without impact at the patient level. All materials, equipment and services (such as transport) that may have an impact on the product quality are purchased from approved sources according to predefined acceptance criteria, which include compliance with technical specifications and quality requirements.

Transporters undergo an audit process before they can start working with the company, and this audit process remains in force for their entire period of service. Transporters are subject to routine and careful monitoring for pharmaceutical quality, as well as for the quality of service.

The most sophisticated techniques are used during transport to trace shipments and confirm customer deliveries (GPS tracking, GPRS real-time tracking, electronic signatures, etc.). Each center has developed a back-up plan, including a list of transporters that can be activated at any time to be operational within 24 hours.

## **2.3. Ensuring the continuity of activities in case of a major crisis**

Sanofi has developed specific continuity plans for the company's activities in the event of a pandemic or a major crisis. In such a situation, the company's plans are designed to ensure that every effort is made to achieve the following goals simultaneously:

- Guarantee and safeguard the continuity of our business activities.

- Ensure that all company products meet the same quality standards.
- If a pandemic occurs, react as quickly as possible to manufacture and deliver a pandemic vaccine to the affected area(s).
- Maintain the capacity to continue the development, production and distribution of the medicines and vaccines needed to prevent or cure pandemic-related infections as quickly as possible.
- Safeguard the continuity of the company's activities to supply all company medicines and vaccines to all patients.
- Continue to provide assistance to patients and healthcare professionals, in particular by setting up alternative solutions such as call centers available 24 hours a day, seven days a week, and monitoring any adverse reactions (pharmacovigilance).

Notably, when a natural disaster has occurred, such as Fukushima (Japan), flooding or earthquakes in Italy, or the ash cloud in Iceland, Sanofi was able to activate real-time solutions (i.e., manufacturing back-up) or alternative transportation modes (i.e., sea shipment vs. air shipment).

### Implementing a supply continuity plan

In recent years, Sanofi has implemented a supply continuity plan focused on several categories of products, starting with global lifesaving drugs, new products and important products. This end-to-end supply continuity, from procurement of raw materials to the production, release, transport and distribution of finished products, is integrated within both the Global Supply Chain and the company risk management approach. It translates into a set of definitions, procedures, evaluation process, mitigation plan and monitoring. Multifunctional cross-committees ensure the detection, coordination, control and resolution of potential product supply hurdles.

This initiative also benefits from the implementation of an Industrial Affairs Risk Committee with representatives of all the technology platforms and the support functions, such as for example Quality, EHS, Procurement, Biological Platform, Devices Development Platform, etc.

Another important and transversal contribution is the Global Operational Shortage Risk Committee that was set up some years ago and enables the coordination and activation of alternative options in order to reduce the risk of supply shortages as well as supporting the process of notification to health authorities.