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Continuity of Activities and Supplies

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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.

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1. Background

As a global healthcare leader, we are committed to organizing our supply chain so that it will deliver medicines and vaccines to the market without interruption, with the goal of protecting patients' health every day.

Global demand for medicines is rising, due to improved access to and development of healthcare in many regions of the world. While this is a good thing, it nevertheless raises issues about the capacity of manufacturing sites and their suppliers to adjust rapidly. Pressures on supplies of raw materials and active ingredients are intensifying, due in particular to more stringent environmental standards in China and other Asian countries. In the short term, this is causing the temporary shutdown of a number of manufacturing facilities, including some that supply active ingredients to the pharmaceutical industry. Tougher environmental regulations may temporarily reduce production capacity while manufacturing processes are upgraded. Finally, some of our products require long and complex production processes, and we may experience interruptions at any point in the chain.

We have for decades applied a regionalized production strategy in our network of in-house sites. Around two-thirds⁽¹⁾ of the active ingredients in our products are manufactured within our in-house network, and our dependence on India and China is approximately 15%.

Our global service level on prescription products (general medicines and specialty care) is approximately 98.7%.

2. Policies and action plan

Industrial Affairs at Sanofi have a governance structure that establishes the sourcing policy for our products; their core mission is to select and allocate the resources of our in-house and third-party manufacturing networks. The sourcing policy lays down rules for securing production of the principal active ingredients and currently marketed products, and on back-up sites for products in the launch phase (double or triple in-house/third-party sourcing).

We also have a supply chain continuity program in place that applies in priority to vital medicines, new and key products, and to pandemics and other major crises.

The program evaluates supply chain risks (from raw materials sourcing to active ingredient manufacture and product shipment) and includes fallback plans. It is integrated with our supply chain, and with our global risk management approach. We also have an ongoing multidisciplinary process in place to analyze risks relating to the raw materials included in our products, and to the suppliers we source those materials from. This process is built into the governance of our supply chain continuity program, facilitating a coordinated approach to the referencing of suppliers and back-up manufacturing sites. This helps secure supply chain continuity by reducing mono-source risks and critical regional dependency.

Our Industrial Affairs Risk Committee, which includes representatives from our technological platforms and support functions (such as Quality, HSE, Procurement, Biological Platform, and Dispensing Systems Development), is tasked with identifying and evaluating major risks relating to our industrial operations, and with ensuring that action plans are implemented.

We have also set up a global operational committee to address the risk of product shortages; the committee coordinates and activates fallback solutions to reduce the risks and supports the process of notifying health authorities.

For vital products (i.e., Sanofi medicines and vaccines for which there is no therapeutic equivalent or local alternative available), we make every effort to ensure that they are always available in sufficient quantities. Our Global Medical Department has for several years been working with our subsidiaries to identify vital products in each country where we do business.

¹ This calculation relates only to chemical active ingredients, which tend to be manufactured in Asia. It does not include biological active ingredients or vaccines.

This list can then be used to determine production priorities and emergency responses in the event of a pandemic, or of a major incident (such as fire or natural disaster) at one of our production sites.

2.1. ENSURING THE CONTINUITY OF THE SUPPLY CHAIN ON A DAILY BASIS

Sanofi has a range of instructions, tools and processes in place throughout the supply chain, which are subject to control and monitoring.

Sales & Operations Planning – Integrated Business Planning (S&OP – IBP) is the core tactical process operated within our organization. In this process, key players (marketing, sales, supply chain, industrial, finance, etc.) work together to identify, rank, decide, solve and plan actions to address the medium/long-term risks and opportunities around our portfolio.

It is based on sales forecasts (for up to 36 months) that are shared with all the stakeholders across the organization and includes an inventory policy that sets for each Sanofi subsidiary target inventory levels (of active ingredients, semi-finished and finished products) for all our products. The inventory policy is calibrated according to various criteria, such as product type (in particular, whether the product is identified as a vital medicine), the complexity of the manufacturing chain, or the number of sources of the various raw materials used. For example, a risk analysis conducted under the supply chain continuity program could lead us to constitute buffer stocks. The policy may also vary from one subsidiary to another, depending on specific circumstances in the country of operation.

At site level, sales forecasts are used to determine raw material and production needs for each product; careful resource planning is essential.

Once products have been manufactured and batch-released, they are shipped by our logistics organization, which combines in-house distribution centers and external service providers.

Our distribution centers deliver products through three main channels, depending on the country:

- directly to pharmacies;
- directly to hospitals; and
- to wholesalers.

To maintain a high level of customer service, we monitor a number of indicators throughout the supply chain that we can use to flag up potential risks or incidents with the various players.

In addition, we use long-term projections (from 36 months to five-ten years) to inform our investment decisions by giving us visibility on sales for a product, a region or a specific technology.

2.2. ENSURING GOOD DISTRIBUTION

In every country where we operate our own distribution centers, emergency plans are activated in the event of a supply chain interruption. All our distribution centers use the same information system, facilitating fallback solutions if one of our centers is temporarily out of action.

In countries where we outsource distribution, we apply rigorous selection procedures when referencing service providers, covering not only their financial health but also their service quality and compliance with HSE and CSR principles. If a potential risk is detected, we make sure we have alternative service providers. Over the last ten years, we have only had three major incidents (in Venezuela, the Netherlands and Korea), with no impact on patients.

The freight companies we use are subject to an audit before they can work with Sanofi and continue to be audited throughout their service term.

We use state-of-the-art techniques to track shipments and confirm delivery to the customer, including GPS tracking, real-time GPRS tracking and electronic signatures. Each center has a fallback plan, including a list of freight companies that can step in at any moment and be operational within 24 hours.

2.3. ENSURING THE CONTINUITY OF ACTIVITIES IN CASE OF A MAJOR CRISIS

We have continuity plans specific to our operations, so that in the event of a pandemic or major crisis (natural disaster, nuclear accident, humanitarian emergency, etc.) we can focus our efforts on simultaneously meeting all of the following objectives:

- guaranteeing and safeguarding continuity of our operations;
- ensuring that all our products meet the same quality standards;
- in the case of a pandemic, reacting as fast as possible to manufacture and distribute a pandemic vaccine in the affected regions;
- maintaining sufficient capacity in the development, production and distribution of medicines and vaccines to prevent or cure infections related to the pandemic in the shortest possible time frame;
- maintaining business continuity so that we can supply all our medicines and vaccines to patients; and
- continuing to provide assistance to patients and healthcare professionals, in particular through fallback solutions, such as 24/7 call centers, while also monitoring any side effects (pharmacovigilance).

Our experience of past natural disasters, such as Fukushima in Japan, floods and earthquakes in Italy and the volcanic ash cloud in Iceland, has shown that we are capable of activating solutions, such as fallback manufacturing capacity or alternative transportation methods, in real time.

The COVID-19 crisis put our pandemic plan to the test. The 20,000 people employed in our industrial operations were able to continue working in compliance with public health restrictions, and all of our industrial sites continued operating. We also implemented additional measures:

- using alternative sources of raw materials to ensure continuity of supply when a particular region was affected by the pandemic;
- immediate increase in output in response to recommendations in the treatment of COVID-19 and associated symptoms (injectable antibiotics, paracetamol, anti-thrombotics, hydroxychloroquine); and
- securing freight movements by activating a range of different modes of transport (air, sea, road).