# PRESCRIPTION MEDICINE PRICING OUR PRINCIPLES AND PERSPECTIVES

We at Sanofi work passionately, every day, to understand and solve health care needs of people across the world. We are dedicated to therapeutic areas such as diabetes, cardiovascular disease, immunology, oncology, multiple sclerosis, rare disease, rare blood disorders, and vaccines. As a global health care leader, Sanofi has a long-standing commitment to promote health care systems that make our treatments accessible and affordable to patients in need.

Countries are increasingly seeking to achieve better value in health care spending. Sanofi understands and shares concerns about the affordability of medicines for patients, while also recognizing that we are one of many stakeholders in the health care system. In the U.S., medicines are a small share – about 15 percent<sup>1</sup> – of total health care spending. In order to maintain an ecosystem that will continue to bring new health care solutions to patients, we must encourage a transition to a value-driven health care system that provides incentives for the highest-quality care. This evolution will enable both affordable access to treatment and continued investment in medical innovation.

Sanofi is committed to helping address this challenge. While many factors, including decisions affecting patient out-of-pocket spending and insurance coverage, are controlled by other health care players, we recognize that there are actions we can take to help improve access for patients and affordability for the system as a whole. For our part, we recognize that we must price our medicines transparently and according to their value, while contributing to broader solutions that improve patient outcomes and the sustainability of the U.S. health care system.

# **OUR PRICING PRINCIPLES:** ADVANCING RESPONSIBLE LEADERSHIP

Pharmaceutical innovation brings value to our patients, our society, and our health care systems. Given the growing concerns over rising health care costs, our approach to pricing reflects our continued efforts to support patient access while minimizing our contribution to health care inflation. We therefore commit to continued transparency in how we price our medicines and to limit any increase in prices in the U.S. to no more than the projected National Health Expenditure (NHE) growth rate.

The Pricing Principles we put forth focus on three pillars:









## PRESCRIPTION MEDICINE PRICING: OUR PRINCIPLES AND PERSPECTIVES



# CLEAR RATIONALE FOR PRICING

When we set the price of a new medicine, we hold ourselves to a rigorous and structured process that includes consultation with external stakeholders and considers the following factors:

A holistic assessment of value, including 1) clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to a standard of care; 2) economic value, or how the medicine reduces the need – and therefore costs – of other health care interventions; and 3) social value, or how the medicine contributes to quality of life, and productivity. Our assessments rely on a range of internal and external methodologies, including health technology assessment (HTA), and other analyses that help define or quantify value and include patient perspectives and priorities.

Similar treatment options available or anticipated at the time of launch in order to understand the landscape within the disease areas in which the medicine may be used.

Affordability, including the steps we must take to promote access for patients and contribute to a more sustainable system for payors and health care systems.

Unique factors specific to the medicine at the time of launch. For example, we may need to support ongoing clinical trials to reinforce the value of the product (e.g., longer-term outcomes studies), implement important regulatory commitments, or develop sophisticated patient support tools that improve care management and help decrease the total cost of care.



# LIMITED U.S. PRICE INCREASES

We acknowledge our role in supporting the sustainability of our health care system and minimizing our contribution to U.S. health care spending growth. Should we take a list price increase on one of our medicines, our guiding principle is to limit the total annual increase during our fiscal year (Jan. 1 to Dec. 31) to a level at or below the projected growth rate for National Health Expenditures for said year.

Our benchmark, the projected U.S. National Health Expenditure growth rate, is estimated and published annually by the Centers for Medicare & Medicaid Services (CMS). The NHE projection provides a critical forward-looking view needed for business planning. NHE measures spending across all health care goods and services and reflects payments made by both public and private payors.

Once the NHE projection is updated each year, we will adjust any future planned pricing actions to reflect the updated projection. Given the need

for business planning, we adopt the updated standard by April 1 each year.<sup>2</sup> More information about the NHE growth rate can be found <u>here</u>.

Should we take a price increase above the NHE growth rate for a given medicine

that results in a list price increase greater than \$15 for a full course of treatment per year, we will provide our rationale, highlighting clinical value, real world evidence, regulatory change, new data, or other circumstances that support our decision.



## PRESCRIPTION MEDICINE PRICING: OUR PRINCIPLES AND PERSPECTIVES



# CONTINUED TRANSPARENCY IN THE U.S.

We recognize calls for continued transparency in our pricing practices. Our policy reflects a desire to help our stakeholders better understand our pricing decisions.

Our policy reflects both a desire to help our stakeholders better understand our pricing decisions and to advance a more informed discussion of issues related to the pricing of medicines. To continue this dialogue and provide greater insights about this topic, we will disclose annually our aggregate U.S. gross and net price changes from the prior calendar year. These data may help illustrate how pricing changes accrue to manufacturers versus others in the value chain, highlighting our discrete roll in the broader U.S. health care environment.

While list prices often receive the most attention, they reflect only the initial prices set for our medicines and are not the prices typically paid by the insurers, employers, or pharmacy benefit managers who purchase our medicines on behalf of patients in their respective health plans. We negotiate significant discounts and rebates with these payors, which are designed to lead

to lower prices in exchange for greater access and affordability for patients.

This negotiated price is the net price. Net prices more accurately reflect the prices we are paid for the medicine and are the most accurate gauge to measure pharmaceutical prices and applicable increases.

However, the level of discounts and rebates vary and is often not visible to patients. While our efforts focus on access to care for patients and improved affordability, it is important to note that patient cost-sharing and coverage decisions are ultimately made by payors, not manufacturers of the medicines. Simply put, the out-of-pocket payments made by patients depend on how the plan is structured and the extent of the negotiated discounts passed on to patients.

These principles demonstrate Sanofi's commitment to patient access and affordability, a sustainable health care system, and greater transparency in our pricing actions. Moreover, our position supports an environment that will enable us to continue to advance scientific knowledge and bring innovative treatments to patients worldwide.





# SANOFI 2019 PRICING PRINCIPLES REPORT: ADVANCING RESPONSIBLE LEADERSHIP

# **SANOFI 2019 PRICING PRINCIPLES REPORT:**

# ADVANCING RESPONSIBLE **LEADERSHIP**

In May 2017, Sanofi committed to further addressing concerns over rising health care costs with the introduction of our Pricing Principles, which remain the most comprehensive assessment of corporate pricing decisions in the industry. Our approach to the prices of our medicines reflects a continued effort to support patient access while minimizing our contribution to health care spending growth. The following report outlines key 2018 pricing decisions.



# CLEAR RATIONALE FOR PRICING

Admelog® (insulin lispro injection) 100 Units/mL – Admelog was launched in April 2018 and our approach to pricing reflects our belief in the need to balance sustainability, affordability and the incentive to innovate. Admelog has the lowest list price of any mealtime insulin at \$90 per 3 mL pen and \$233 per 10 mL vial. In addition, Admelog is a part of our Insulins ValYOU Savings Program, and 100 percent of uninsured, cash-paying patients have access to the medicine at \$99 a vial or \$149 per pack of 5 pens.

Toujeo® (insulin glargine injection) 300 Units/mL Max SoloStar® – Sanofi introduced the Max SoloStar version of its Toujeo insulin in June 2018. Due to its higher capacity, Max SoloStar may lead to lower copays depending on the person's insurance coverage. One 3 mL pen has a list price of \$259.15, the same price per unit as the original, lower-capacity Toujeo SoloStar.

Libtayo® (cemiplimab-rwlc)³ – Libtayo was launched in September 2018 with a list price of \$9,100 per three-week treatment cycle, reflecting the clinical value it delivers as the only treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation. The price was established with input from physicians, hospital pharmacists, payors and other stakeholders.



## LIMITED U.S. PRICE INCREASES

In February 2017, the U.S. National Health Expenditure projected growth rate for 2018 was 5.9 percent.<sup>4</sup> That figure was updated to 5.3 percent in February 2018.<sup>5</sup>

In 2018, Sanofi increased the price of 35 of our 76 prescription medicines. All of these increases were within our Pricing Principles guidelines.

In addition, Sanofi announced in March 2018 that it will offer U.S. payors that agree to reduce burdensome access barriers for appropriate patients a further reduced net price for Praluent® (alirocumab) in alignment with a new value assessment. In May 2018, we lowered the net price of Praluent for Express Scripts in exchange for straightforward, more affordable patient access from the pharmacy benefit manager (PBM). The agreement significantly simplifies the documentation necessary to secure insurance coverage and was designed to help reduce outof-pocket costs for eligible patients.



<sup>&</sup>lt;sup>4</sup> Health Affairs, 2017.



<sup>5</sup> Health Affairs, 2018



# CONTINUED TRANSPARENCY IN THE U.S.

U.S. Portfolio Annual Aggregate Price Changes\*

Year	Average Aggregate List Price	Average Aggregate Net Price
2016	4.0% INCREASE	2.1% DECREASE
2017	1.6% INCREASE	8.4% DECREASE
2018	4.6% INCREASE	8.0% DECREASE

<sup>\*</sup>Aggregate across Sanofi's prescription portfolio

In 2018, 55 percent of our gross sales were given back to payors as rebates, including \$4.5 billion in mandatory rebates to government payors and \$7.3 billion in discretionary rebates.



# SPOTLIGHT: PRIORITIZING PATIENT AFFORDABILITY

Our commitment extends beyond responsible launch pricing, limited price increases, and transparency. Sanofi recognizes that the U.S. health care system's safety net for underinsured and uninsured patients can fall short and fail to provide patient access to necessary medicines. Sanofi's Pricing Principles are also designed to facilitate patient affordability, and we must use all the resources at our disposal to make certain that every appropriate patient can receive – and access – the right medication. We have an innovative suite of programs to address a range of patient needs when it comes to accessing and affording Sanofi medicines prescribed to them.

Patients have access to support programs designed in part to assist them through numerous access-related services including benefit verifications, co-pay assistance, and patient assistance programs (free medicine) for eligible patients. In 2018, more than 400,000 patients were supported by Sanofi co-pay and other point-of-sale programs, while more than 93,000 Americans participated in Sanofi patient assistance programs.

We encourage anyone who is prescribed a Sanofi medicine, and who may be having financial challenges or trouble navigating their insurance, to call (800) 633-1610 where eligible patients can be connected to the resources they need at no cost.

**2018 PATIENT SUPPORT:** BY THE NUMBERS

334,818
# OF PATIENTS WHO USED A SANOFI
CO-PAY ASSISTANCE CARD ......

\$342 million
PATIENT SAVINGS FROM USE OF
CO-PAY ASSISTANCE PROGRAM

9,618 # OF INSULINS
PROGRAM CARDS USED
(LAUNCHED IN APRIL 2018) ---- 0 0 0 0

\$6.2 million PATIENT SAVINGS FROM USE OF INSULINS VALYOU SAVINGS PROGRAM

93,148 # OF PATIENTS
WHO RECEIVED
FREE PRODUCT THROUGH PATIENT
ASSISTANCE PROGRAMS

\$508 million VALUE OF MEDICINE PROVIDED VIA PATIENT ASSISTANCE PROGRAM



### **SPOTLIGHT: PRIORITIZING PATIENT AFFORDABILITY**

We feel a special obligation to address pressing issues around access and affordability of insulin. Sanofi has made a concerted effort to ensure both system sustainability and patient affordability in our approach to our portfolio of insulin products, which includes six different products to meet individualized patient needs.

In 2018, we raised the list price of Lantus by 5.3 percent, in line with our Pricing Principles of an increase no greater than the projected National Health Expenditure growth rate. Over the previous four years, we took one other price increase for Lantus – a 3 percent increase in 2017.

Lantus, however, is an excellent example of how list prices do not reflect the actual prices paid by insurance companies. Sanofi offers substantial discounts in the form of rebates to insurance companies, often through their pharmacy benefit managers, to help ensure that our products are available to patients without onerous copays.

The price of a medicine after taking these price concessions into account is known as the "net price," and the net price for Sanofi diabetes products has been falling, making our insulin less expensive, not more, for insurance companies.

# **INSULIN COST OVER TIME**



As detailed above, the aggregate net price across all Sanofi medicines has fallen during each of the past three years. For our entire insulin portfolio, the average net price is 25 percent lower today than it was in 2012.

However, Sanofi recognizes that too often patients struggle to afford the medicines they need, and patients' out-of-pocket costs continue to rise. To address such needs, Sanofi introduced the Insulins ValYOU Savings Program in early 2018, allowing all those who are uninsured or underinsured to have access to a Sanofi long-acting and mealtime insulin at more than half-off the list price. As we analyzed the use of the program, we listened to patient feedback and in November 2018 expanded the program to include all Sanofi insulins.

Taken together, our pricing and access efforts on our insulin products over the course of 2018 demonstrate Sanofi's commitment to address affordability for patients with diabetes.

