Principles on
Responsible use of genetic resources

Purpose

This document defines and illustrates *Sanofi's commitment and rules for responsible use of genetic resources as they relate to biodiversity. It equips* Sanofi employees and anyone who works on behalf of Sanofi [such as contractors and business partners] with the knowledge to identify and mitigate biopiracy risks. The intention is to safeguard Sanofi's integrity and prevent the legal and financial consequences that arise from misuse of biodiversity.

Sanofi's commitments to preventing biopiracy and improper use of Genetic resources

Context

Biodiversity is generally understood in terms of the wide variety of plants, animals and microorganisms from various sources.

The Convention on Biological Diversity (CBD) is an international treaty which governs the conservation of biodiversity and the sustainable use of its components. The treaty entered into force in 1993, and has three main goals:

1. Conservation of biological diversity
2. Sustainable use of its components
3. Fair and equitable sharing of benefits arising from genetic resources.

According to the CBD, Genetic Resources are defined as "any material of plant, animal, microbial or other origin containing functional units of heredity, with actual or potential value". Human genetic resources are excluded from the definition of Genetic Resources (Confirmed by CBD COP Decision II/11 and CBD COP Decision X/1).

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization is a supplementary agreement to the CBD. It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising from the utilization of Genetic Resources, thereby contributing to the conservation and sustainable use of biodiversity. The Nagoya

Protocol on Access and Benefit sharing (ABS) was adopted on 29 October 2010, in Nagoya, Japan and entered into force on 12 October 2014. The Nagoya Protocol has 142 ratifications/accessions but notably not by USA as of end of October 2024.

Genetic Resources, which constitute the biodiversity and Traditional Knowledge associated with Genetic Resources, are commonly used in the development of new medicinal products, vaccines, and cosmetics. These materials may be obtained from sources ranging from cultivated commercially produced stocks to indigenous unique geographical locations. More specifically, the pharmaceutical industry utilizes Genetic Resources in Research and Development, for example, to provide chemical leads for progress towards new medicines and as the starting material for the manufacture of certain vaccines, e.g., seasonal influenza vaccines aiming to contain the predominant circulating influenza strains.

The Nagoya protocol refers to Genetic Resources, thereafter parties have their national legislation on ABS, and in many cases this legislation goes beyond GR, and includes ABS requirements on Digital Sequence Information (DSI). Multilateral instruments to manage ABS of DSI are under discussion through the CBD. These Sanofi principles will be updated to reflect the conclusions of those discussions.

Key Principles

- ✓ Sanofi stands firmly against improper use of genetic resources and Traditional Knowledge associated with genetic resources. *We are committed* to fully comply *with the provisions of the CBD and Nagoya Protocol* on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.

- ✓ *Sanofi, Sanofi Employees and Third Parties should* therefore fully comply with all local Access and Benefit- Sharing (ABS) regulations.
- ✓ This document also aims at *protecting Sanofi and Sanofi Employees' reputation and at avoiding potential civil and criminal fines.*

Preventive Measures

- ✓ Procedures: Sanofi established clear rules for bioprospecting, including for strains, for Genetic Resources obtained through third parties and for sharing Genetic Resources with, or transferring to, third parties e.g. during Research and Development (R&D) collaborations or R&D activities sponsored by Sanofi.

    - Sanofi must obtain the relevant authorization for accessing genetic resources, as required by the country of origin, to comply with the Nagoya Protocol and applicable local laws or regulations.

- Sanofi must keep appropriate documentation related to Genetic Resources used from Research and Development, up to Commercialization.
- Sanofi must regularly evaluate the Nagoya status of its products in development.

✓ Training Program: Regular training sessions are organized to ensure relevant employees are aware of their responsibilities and the legal implications of their actions.

Through these efforts, Sanofi maintains a proactive approach to managing risks associated with use of genetic resources in its R&D activities, ensuring that we remain a trusted and responsible partner in the healthcare industry.