



# Our position on Access and Benefit Sharing of Genetic Resources and Related Information

## What is the issue?

The Convention on Biological Diversity (CBD) is an international environmental treaty adopted by all countries in 1992 that governs the conservation of biological diversity. The CBD has three main goals:

1. Conservation of biological diversity of plants, animals and microorganisms
2. Sustainable use of biodiversity, such as soil, water and living organisms
3. Fair and equitable sharing of the benefits (e.g., financial value) arising from the use of GRs

Most CBD signatory countries also signed the Nagoya Protocol, which came into force in 2014. This is a supplementary agreement built upon the CBD, giving countries powers to exercise sovereign rights over the use of their genetic resources (GRs), the third pillar of the CBD. The Nagoya Protocol provides the framework for countries to implement access and benefit sharing (ABS) laws and regulations, which may require users to provide prior informed consent and to establish mutually agreed terms for sharing GRs, including physical specimens and pathogen strains.

In December 2022, CBD member countries adopted the post-2020 Kunming-Montreal Global Biodiversity Framework (GBF), including 23 targets and 4 overarching goals to preserve and protect nature and biodiversity by 2030. This includes a target to introduce a new “multilateral system for benefit sharing from the use of digital sequencing information” or “DSI”.<sup>i</sup>

GRs and related information are an important tool in researching and developing new medicines and vaccines that make a difference to patients’ lives. GRs may be used throughout the R&D process to help discover new medicines and vaccines and are obtained from different sources, including plant, animal, or microorganism specimens.

Stakeholders have recognised the potential for Nagoya-related laws and policies, and any additional ABS mechanisms (including the GBF), to have unintended consequences for public health, including potential delays in responses to seasonal and pandemic pathogens, and obstructing or delaying R&D into innovative medicines and vaccines. The Nagoya Protocol itself recognizes the need for ‘due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health’<sup>ii</sup>.

This paper sets out our position on the CBD, the Nagoya Protocol, and the GBF, with a particular focus on issues relating to public health and pandemic preparedness.

## What is GSK’s view?

- GSK is committed to a net zero, nature positive, healthier planet, with ambitious goals set for 2030 and 2045<sup>iii</sup>. Human health relies on the fundamentals of nature: clean air and fresh water. Our plan to contribute to a nature positive world is in line with the goal of the GBF to halt and reverse biodiversity loss by 2030, with full recovery by 2050. We support the GBF’s goal to protect 30% of the Earth’s land and ocean by 2030 and the requirement for large and transnational businesses and financial institutions to assess and disclose “their risks, dependencies and impacts on biodiversity” by 2030 at the latest.
- The objectives of the CBD, GBF and the Nagoya Protocol can be mutually supportive of broader public health interests. We support the equitable access and fairness principles of access and

benefit sharing (ABS) outlined in the CBD and the Nagoya Protocol. ABS and enforcement measures adopted by Nagoya Parties must be appropriate, clear, and proportional to promote the fair and equitable sharing of benefits resulting from the use of GRs.

- We make our medicines and vaccines available at responsible prices that are accessible for patients and sustainable for our business through strategic access programmes and partnerships that increase our global impact. For more information see our policy position on access and pricing.<sup>iv</sup>
- GSK supports special treatment for human and animal pathogen specimens, strains, and related information in ABS-related national legislation and regulation, consistent with the CBD's "due regard" directive for public health emergencies. Access to biospecimens and sequences for influenza and other pathogens are a critical first step to develop medicines and vaccines which can save lives. Regulation of access and benefit sharing must be unambiguous and specific, with special consideration given to pathogens with epidemic or pandemic potential.
- Any new mechanism incorporating DSI within the CBD framework (moving beyond 'physical' genetic material) must be designed to protect against negative implications for public health and advancement of science. Promoting the sharing of outbreak information, including the immediate access to pathogens and related information, is a critical step to help inform a coordinated global response to outbreaks and to trigger rapid R&D investment and action.

Access to and use of GRs can be vital to tackling diseases. Because access can be controlled by 'provider' and 'user' countries, it is important that government legislation helps facilitate health innovation and public health interests. This was confirmed by a 2016 study by the WHO Secretariat, which says: "The manner in which the Nagoya Protocol is implemented – both collectively through the Protocol's Meeting of the Parties, and by individual Parties through their domestic legislation – will be vital to ensuring that the Nagoya Protocol supports public health."

Because there is considerable variation between Nagoya-related national laws and regulations, pathogen sharing is inconsistent and not always exempted from the scope of the framework. This could result in delays in pandemic and epidemic preparedness and response which would negatively impact global health.

We believe that if GRs with human pathogenic potential cannot be excluded from CBD, then access and use must be assured under reasonable and expeditious terms. The timely sharing of pathogens can contribute to the development of effective vaccines and medicines which can prevent significant loss of human life. It is estimated with SARS-CoV-2, a delay in one month of sharing the virus samples could have led to an additional loss of 400,000 lives.<sup>v</sup>

## **Seasonal flu and the Nagoya Protocol**

Timely access to seasonal flu strains is necessary in enabling rapid vaccine development and distribution. There is a well-established mechanism, based on the WHO's Global Influenza Surveillance and Response System (GISRS), to mitigate the threat to public health posed by seasonal flu. Every year, the WHO decides which flu virus strains to recommend for Northern and Southern hemisphere flu vaccines; the timelines for this decision and vaccine production are critical to the global response. Subsequent production of the vaccines tailored to these recommended virus strains does not require R&D on the genetic and/or biochemical composition of GRs as defined by the CBD and the Nagoya

Protocol. Only routine development and manufacturing processes are used, and clinical studies are conducted to confirm the safety and properties of the vaccine when one or more of the underlying GR components are introduced into an existing scaffold.

Since 2018, over 30 influenza virus strains have incurred delays from three weeks up to five months due to a lack of clarity<sup>vi</sup> over national Nagoya Protocol/ABS legislation. These delays resulted in a pause to research, manufacturing and development of a vaccine, hampering our ability to effectively respond to public health emergencies. While we respect countries' rights to regulate access to seasonal flu strains, access to the strains must be swift. Delays in this process could be detrimental to the communities and patients that are waiting to receive the vaccine.

### Digital Sequencing Information

There is a well-established international framework for submitting DSI and making it freely available. Open access to Digital Sequence Information (DSI) is a central tool in scientific research; it allows for timely R&D that supports the CBD objectives and can help combat global health crises. To create vaccines for SARS-COV-2, scientists all around the world used DSI which allowed certain vaccines to be developed and deployed in less than a year.<sup>vii</sup> In response to concerns from some countries that use of DSI could undermine the benefit-sharing objective of the Nagoya Protocol, member states to the CBD agreed to design and implement a new mechanism to regulate access and benefit sharing for DSI.

We look forward to contributing to the design of a practical and fair mechanism for timely access to DSI that promotes innovation as well as rapid response to pandemics and other public health emergencies. Any new mechanism incorporating DSI within the CBD framework (moving beyond 'physical' genetic material) must be designed to protect against negative implications for public health and advancement of science. Specifically, a new mechanism must, at minimum:

- preserve current access to the data available in public databanks, using an open, multilateral approach;
- minimize burdensome and time-consuming obligations, which would deter potential users; and
- avoid any incentives (direct or inadvertent) to move R&D to non-Nagoya countries, benefitting non-Nagoya signatory countries and undermining the CBD's benefit sharing objective.

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<sup>i</sup> [Recommendation Adopted by the Working Group on the Post-2020 Global Biodiversity Framework \(cbd.int\)](#)

<sup>ii</sup> [Text of the Nagoya Protocol \(cbd.int\)](#)

<sup>iii</sup> [Environment | GSK](#)

<sup>iv</sup> [Pricing and Access GSK Policy Position](#)

<sup>v</sup> Burci, Gian Luca, and Frederic Perron-Welch. 2021. "International Sharing of Human Pathogens to Promote Global Health Security—Still a Work in Progress." *Insights* 25 (13). [https://www.asil.org/sites/default/files/ASIL\\_Insights\\_2021\\_V25\\_I13.pdf](https://www.asil.org/sites/default/files/ASIL_Insights_2021_V25_I13.pdf).

<sup>vi</sup> The Bedrock of Global Health Security: Access to Pathogens and Their Genetic Codes. Case Studies: Executive Summary.

<sup>vii</sup> *ibid*